Protocol

PAROXETINE 29060/329

September 25 1996

Title: A Multi-Center, Double-Blind, Placebo Controlled Study of Paroxetine and Imipramine in Adolescents with Unipolar Major Depression

Item attached for approval: Protocol Amendment #2

Agreed By:

Coordinating Author: _____(signed)_____

_____ [redacted] Date

Biostatistician _____(signed)_____

_____ [redacted] Date

Clinical Project Director: _____(signed)_____

_____ [redacted] Date

Approved By:

[redacted] _____

_____ [redacted]

Date

Comments and questions can be directed to [redacted]

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STUDY DRUG : BRL 29060/PAROXETINE (PAXIL)

A MULTI-CENTER, DOUBLE-BLIND, PLACEBO CONTROLLED STUDY OF PAROXETINE AND IMIPRAMINE IN ADOLESCENTS WITH UNIPOLAR MAJOR DEPRESSION

PROTOCOL NUMBER 29060/329

PROTOCOL August 20, 1993	Date of approval: August 26, 1993
Amendment #1: March 24, 1994	Date Amendment Approved: April 17, 1994
Amendment #2: October 2, 1996	Date Amendment Approved: October 29, 1996

CONFIDENTIAL

STUDY DRUG: BRL 29060/PAROXETINE (PAXIL)

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PROTOCOL NUMBER 29060/329

Principal Investigators:

__ _____

Name

__ _____

Study Site Address

SB Responsible Physician: [redacted]

I, the undersigned, have reviewed the protocol, including Appendices and Amendment #1 and I will conduct the clinical study as described and will adhere to the Ethical and Regulatory Considerations stated.

_____ _____

Investigator's Signature Date Month Year

STUDY DRUG BRL 29060/*PAROXETINE* (PAXIL)

PROTOCOL NUMBER 29060/329
Approved: 26 August 1993

A MULTICENTER DOUBLE BLIND PLACEBO CONTROLLED STUDY OF PAROXETINE AND IMIPRAMINE IN ADOLESCENTS WITH UNIPOLAR MAJOR DEPRESSION

Amendment #1 Approved: April 17, 1994

Section 5.2.1 Screening Phase

Revised: 1) Diagnostic assessments will be done using the K-SADS-L in place of the K-SADS-P.

2) In subjects for whom a diagnosis of major depression may be equivocal, the case will be discussed with a principal investigator at a separate site (see Appendix H) who will have access to the interview tapes. If the external reviewer and investigator disagree on inclusion, the external reviewer's opinion shall take precedence.

Rationale: The K-SADS-L is an enhancement of the K-SADS-P in that it includes disorders omitted from the K-SADS-L (e.g. ADHD, antisocial personality disorder, social phobia). Additionally, the K-SADS-L provides for lifetime inquiry. The external review was added to assure uniformity of diagnosis.

Section 5.2.3 Treatment Phase Assessments

Added: In addition to the 12 lead EKG performed at weeks 4 and 8, a rhythm strip EKG will be carried out at all other visits.

Revised: The criterion for heart rate level requiring a dose adjustment has been changed. Patients whose heart rate exceeds 110 bpm on two consecutive visits or 130 bpm at any time will have their dosage decreased by one level if they are at dose level 5 or 6; if the patient is currently treated at dose level 4 or below, the patient will be removed from the study.

Added: Blood levels of imipramine and desipramine will be analyzed in real time following the week 4 and 8 visits. Patients whose combined serum levels of imipramine and desipramine exceed 500 mcg/ml will be withdrawn from the trial.

Rationale: The rhythm strips and the serum analysis have been added to provide additional safety monitoring for patients receiving tricyclic anti-depressants. The revised heart rate criterion agrees with FDA guidelines for studies in adolescents.

Section 7.5.2 Reporting Serious Adverse Events

Revised: The SB medical monitor has been changed from [redacted]

STUDY DRUG ; BRL 29060/*PAROXETINE* (PAXIL)

PROTOCOL NUMBER 29060/329
Approved: 26 August 1993
Amendment #1 Approved 17 April 1994

A MULTICENTER DOUBLE BLIND PLACEBO CONTROLLED STUDY OF PAROXETINE AND IMIPRAMINE IN ADOLESCENTS WITH UNIPOLAR MAJOR DEPRESSION

Amendment #2 Approved: October 28, 1996

Study Medication: Study medication supplies are limited necessitating change in target enrollment in both the acute and continuation phase.

Acute Phase: For the acute phase, the target enrollment will be reduced from 300 patients to approximately 275 patients. It is anticipated that this reduction in sample size will have no adverse effect on the estimated 80% power of this study to detect a four point difference between placebo and active groups. The initial sample size of 300 patients was based on an effect size of 0.4 in the HAMD. However, the actual variability in the HAMD measured for the initial 100 patients enrolled (standard deviation of 8) is smaller than estimated in the protocol at study start (standard deviation of 10). Thus, if the lower variability is maintained, 275 patients would provide greater than 80% power to detect the estimated difference of 4 points on the HAMD.

Continuation Phase The limited supply of blinded continuation medication may preclude up to 10 qualified patients from entering the extension phase. This amendment provides two options for responding patients who qualify for further treatment, but for whom blinded medication is unavailable.

Option #1) Provide same medication as used in acute phase of the trial. In this case, the patient will be withdrawn from the trial and continued treatment will be provided by a third party not associated with the trial. The third party will be provided the identity of the study medication.

Option #2) Initiate open label paroxetine. In this case, the patient is withdrawn from the trial but can elect to remain under

the care of the present study physician. If this option is deemed appropriate, the patient will be down titrated and after a one week wash out period, may begin open label paroxetine for up to six months.

There was no formal hypothesis established for the continuation phase. The primary objective is to provide long term safety data. Thus the small reduction in the number of patients entering this phase should not significantly impact the objective.

Regardless of which option is selected, the study medication identity will not be revealed to any personnel associated with the trial, unless required to treat an adverse event.

Information collected after the acute phase of the trial from patients selecting either of the two options will not be included in the formal study analysis. However, in so far as data are available, these will be summarized separately using descriptive statistics.

Section 7.5.2 : The address and phone number of the SB Medical Monitors has been changed to reflect new location.

SYNOPSIS

TITLE	A Multi-Center, Double-Blind, Placebo Controlled Study of Paroxetine and Imipramine in Adolescents with Unipolar Major Depression
DRUG UNDER STUDY	Imipramine (up to 300 mg) Paroxetine (up to 40 mg) Placebo
INTENDED INDICATION	Treatment of adolescents with unipolar major depression
OBJECTIVES OF STUDY	1. To compare the safety and efficacy of imipramine and Paroxetine to placebo in the treatment of adolescents with unipolar major depression. 2. To assess the rate of relapse among imipramine, Paroxetine and placebo responders who are maintained on treatment).
INVESTIGATORS	Multicenter, USA
STUDY DESIGN	Multicenter, double blind, placebo controlled, parallel group study
DURATION OF TREATMENT	8 Week acute phase with a 6 month extension.
NUMBER OF PATIENTS	300 patients with 100 randomized to each treatment group.

PRINCIPAL END POINTS

- Primary Efficacy Variables
  - Change in total HAMD score from beginning of treatment phase to the endpoint of the acute phase.
  - The proportion of responders at the end of the eight week acute treatment phase. Responders are defined as 50% or greater reduction in the HAM-D or a HAM-D score equal to or less than 8.
- Secondary Efficacy Variables
  - Change from baseline to endpoint (acute phase) in the depression items of the K-SADS-L, global impressions, autonomic function checklist, self perception profile and sickness impact scale.
  - The number of patients who relapse during the maintenance phase.
- Safety Variables
  - Safety evaluation will be based on adverse experience monitoring, laboratory evaluation, cardiovascular parameters, vital signs and physical examinations.

DURATION OF STUDY

- It is anticipated the study will start in November '93. Recruitment will be for three years, the 8-month study should complete 2Q97.

Protocol Table of Contents

Protocol List of Appendices

1.0 INTRODUCTION

Similarities between adolescent and adult depression in symptomotology, family history, and prospective course provide compelling rationale for investigating the efficacy of antidepressant drug therapy in young patients with depression. But unlike adults, the evidence from trials in adolescents does not support drug efficacy, although the existing studies have collectively evaluated fewer than 200 patients, a number hardly adequate for reliable clinical or statistical inferences.

This apparent difference in response between adults and younger patients has been the subject of much debate, and recent reviews (Conners, 1992; Strober, 1992; Jenson et al., 1992) have focused on three major areas of concern. These include: (1) deficiencies in study design, methodology and conduct; (2) the adequacy of diagnostic criteria and various nosological problems; and (3) developmental issues in that children and adolescents who suffer from adult-like depression may respond in a pharmacologically different manner due to quantitative and/or qualitative developmental differences in neurotransmitter/receptor systems.

The study outlined in this protocol proposes to re-examine antidepressant therapies in adolescents with unipolar major depression using a study plan designed to avoid the perceived flaws of previous studies. This will be a multi-center placebo controlled trial with a target enrollment that will provide sufficient power to detect clinical differences among treatment groups, if these differences exist. The study has rigorous inclusionary and exclusionary criteria so that the study population is more homogenous than reported in previous trials. Diagnostic interviews will be reviewed among the various sites to confirm criteria symptoms of depression and to promote uniformity in diagnosis. Responders will be prospectively defined.

One of the treatment arms will be paroxetine (Paxil), an orally administered antidepressant with a chemical structure unrelated to other selective serotonin reuptake inhibitors (SSRI), or heterocyclic or other antidepressant medications. It has recently been approved by the Food and Drug Administration for the treatment of depression based, in part, on clinical trial data in over 3000 adult patients with major depressive illness. Paroxetine has not been systematically studied in adolescent depression.

A second arm will be imipramine. This tricyclic has been the subject of two small open labeled clinical trials in adolescents, one of which has demonstrated a modest therapeutic response in patients with nondelusional depression.

Please refer to the Paxil (paroxetine) and Tofranil (imipramine) prescribing information for detailed information.

Adolescents from ages 12 years 0 months through 18 years 11 months inclusive who are currently in an episode of major depressive disorder (DSM-III-R) with a minimum duration of eight weeks and have a Hamilton severity score of 12 or greater will be included in this 8 week double-blind placebo controlled study. At the completion of the 8 week acute study, clinical responders will be blindly continued on the same medication in a 6 month extension study. Non-responders at the end of the 8 week acute period will be withdrawn and treated openly.

2.0 OBJECTIVES

2.1 Primary

- To compare the efficacy and safety of imipramine and paroxetine to placebo in the treatment of adolescents with unipolar major depression .

2.2 Secondary

- To identify predictors of treatment outcomes across clinical subtypes. The following indicators of differential response will be examined, but no directional hypotheses are formulated: endogenous subtype, age at onset, number of prior episodes, duration and severity of current episode, comorbidity with separation anxiety disorder, attention deficit disorder, and conduct disorder.

- To provide information on the safety profile of paroxetine and imipramine when these agents are given for an extended period of time.

- To estimate the rate of relapse among imipramine, paroxetine and placebo responders who are maintained on treatment.

3.0 STUDY PLAN

3.1 Study Design

This will be a multicenter double-blind placebo controlled trial. Adolescents from ages 12 years 0 months through 18 years 11 months inclusive who are currently in an episode of major depressive disorder (DSM-III-R) with a minimum duration of eight weeks and have a Hamilton severity score of 12 or greater will be included in this 8 week double-blind placebo controlled three cell study of the efficacy of paroxetine and the efficacy of imipramine versus placebo.

The treatment period will be of 8 weeks duration. During this time, patients will make weekly visits to the clinic and the effects of treatment on depression will be evaluated using standardized instruments and as well as global assessments. In addition, various safety assessments will be carried out at each visit. Section 5 below describes the study procedures in detail and Appendix D presents the study flow in schematic fashion.

At the completion of the 8 week acute study, clinical responders will be blindly continued on the same medication in a 6 month extension study. Non-responders at the end of the 8 week acute period will be withdrawn and treated openly. Throughout the study, at each site the number of subjects assigned will be approximately equal and each cell will be approximately group balanced for several potentially important covariates.

4.0 STUDY POPULATION

4.1 Number of patients

Three hundred patients will be entered in up to 6 centers and randomized to receive either imipramine (100 patients) paroxetine (100 patients) or placebo (100 patients). Each center will recruit approximately 12 -15 patients per year.

4.2 Inclusion criteria

1. Adolescents between the ages of 12 years 0 month and 18 years 11 months inclusive.

2. Currently in an episode of major depression (DSM-III-R) for at least 8 weeks. A diagnosis of major depression will be made on summary data aggregating parent and child report. In addition, both adolescent and parent(s) must agree that the adolescent has a disorder meriting treatment.

3. A severity score less than 60 on the Child Global Assessment Scale (C-GAS).

4. A score of 12 or greater on the 17-item Hamilton Depression Scale (HAM-D).

5. Medically healthy as determined by physical examination, medical history and laboratory screening.

6. IQ □ 80 by Peabody Picture Vocabulary Test.

4.3 Exclusion Criteria

1. Patients with current or lifetime DSM-III-R diagnosis of bipolar disorder, schizo-affective disorder, anorexia nervosa, bulimia, alcohol or drug abuse/dependence, obsessive/compulsive disorder, autism/pervasive mental disorder, or organic psychiatric disorder.

2. Patients with a current diagnosis (within 12 months) of post traumatic stress disorder (DSM-III-R).

3. Patients who have had an adequate trial of anti-depressants within 6-months prior to beginning this study. An adequate trial is defined as a treatment of at least four weeks or more with imipramine, desipramine, or amitriptyline at a dosage of 150 mg per day or greater, with nortriptyline at a dosage of 50 mg per day or greater, or with fluoxetine at a dosage of 20 mg per day or greater.

4. Patients who have suicidal ideation with a definite plan, or who have made a suicide attempt within the current episode, or who have ever made a suicide attempt by medication overdose.

5. Patients with medical illness which contraindicate the use of heterocyclic antidepressants (e.g. cardiovascular disease).

6. Patients using (1) psychotropic medications including anticonvulsants, anxiolytics, neuroleptics, lithium carbonate, or (2) illicit drugs as documented by a drug screen within two weeks of starting the study.

7. Patients with organic brain disease, epilepsy or mental retardation.

8. Patients who are pregnant or lactating.

9. Sexually active girls who are not using a reliable methods of contraception (oral contraception, surgical sterilization. I.U.D., diaphragm in conjunction with spermicidal foam and condom on partners).

10. Use of an investigational drug within 30 days of entry into the study or within five half lives of the investigation drug (the longer period will apply).

5.0 CONDUCT OF STUDY

The study will be conducted according to Good Clinical Practice, the Declaration of Helsinki (Appendix A) and US 21 CRF Part Protection of Human Subjects, and Part 56 - Institutional Review Board.

5.1 Ethical Considerations

5.1.1 Ethics Review Committee (ERC)/Institutional Review Board (IRB)

This protocol will be submitted to an appropriate Committee or Board and their written unconditional approval obtained and submitted to the sponsor before commencement of the study.

SB will supply relevant data for the investigator to submit to the hospital/university/independent ERC/IRB for the protocol's review and approval. Verification of the ERC/IRB's unconditional approval of the protocol and either the written informed consent statement or sample oral witnessed consent form with written information to be given to the subjects will be transmitted to the SB Study Monitor prior to shipment of drug supplies and CRFs to the site. This approval must refer to the study by exact protocol title and number, identify the documents reviewed and state the date of review.

The ERC/IRB must be informed by the investigator of all subsequent protocol amendments and of serious or unexpected adverse experiences occurring during the study which are likely to affect the safety of the subjects or the conduct of the study. Approval for such changes must be transmitted in writing to the SB Study Monitor via the investigator.

5.1.2 Informed Consent

The principals of informed consent in the current edition of the Declaration of Helsinki (Appendix A) should be implemented in each clinical study before protocol-specified procedures are carried out.

Informed consent will be obtained in accordance with 21 CFR 50.25.

Information should be given in both oral and written form whenever possible and deemed appropriate by the ERC/IRB. Subjects, their relatives, guardians or, if necessary, legal representatives must be given ample opportunity to inquire about details of the study.

The consent form generated by the investigator with the assistance of SB, must be approved (along with the protocol) by the ERC/IRB and be acceptable to SB. Consent forms must be in a language fully comprehensible to the prospective subject or the subject's legally authorized representative.

The written consent document will embody the elements of informed consent as described in the Declaration of Helsinki and will also comply with local regulations. This form may be read to the subject or the subject's legally authorized representative, but, in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.

Consent must be documented either by the subject's dated signature or by the signature of an independent witness who records the subject's assent. In either event the signature confirms the consent is based on information that has been understood. Each subject's signed informed consent form must be kept on file by the investigator for possible inspection by Regulatory Authorities and/or SB professional and Regulatory Compliance persons.

5.2 Study Method

A patient log will be kept of all patients considered for the study including those not entering the trial. The reasons for excluding patients from the study will be recorded.

The study will consist of three phases: 1) a screening phase of 7-10 days to assess the suitability of a patient for inclusion into the trial; 2) an acute treatment phase of 8 weeks duration in which eligible patients will be randomly assigned to receive either imipramine, paroxetine or placebo, and 3) an extension phase of 6 months duration during which clinical responders will be blindly continued

on their randomized medication. Non responders at the end of the 8-week acute period will be withdrawn and treated openly.

Appendix D provides a summary in tabular form of the study procedures and timings.

5.2.1 Screening Phase

Subjects will initially be screened by telephone. All sites will use the Screening for Youth Depression. This screen will review depressive syndrome criteria and major inclusion and exclusion criteria. Subjects who appear likely to meet the study criteria will be evaluated promptly thereafter.

Revised

24 March 1994

Diagnostic assessment will be done using the K-SADS-L with both the adolescent and parent(s). The K-SADS-L semi-structured clinical interview (revised to include present and past psychiatric disorders) will be administered in the fashion described in the instructions for that instrument and will be used to assess the presence or absence of each of the criteria symptoms for depression including a scale for atypical depression. The parent(s) and the adolescent are separately interviewed to assess each symptom. The clinician forms a summary rating based on best overall information combining all sources. For those symptoms where there is significant discrepancy between information provided by the adolescent and information provided by the parent(s), the clinician, adolescent and parent(s) all sit together and discuss the information provided by each source and reach a best conclusion.

Overall global functioning will be assessed at the initial interview using the Child Global Assessment Scale (C-GAS).

All K-SADS interview data will be directly confirmed by a senior clinician (psychiatrist or psychologist) who will interview both the adolescent and parent(s) and will confirm each of the positive criteria for depression by direct interview. The psychiatrist or psychologist will also review each of the items for the Hamilton Depression Rating Scale.

Diagnostic interviews will be audiotaped. If a prospective subject refuses to be audiotaped, this will not be a reason to deny entry. Cases will be reviewed by the Principal

investigator or Co-Principal Investigator at the local site who will confirm each patient meets the study entrance criteria.

Added
24 March 1994

If a subject meets 6 or fewer DSM III-R criteria for major depression disorder or the investigator reviewing the diagnosis is uncertain, the investigator must contact one of the principal investigator at a separate site (see Appendix H) to discuss the case. The external reviewer must review the audiotape and return a decision within 2 days. If investigator and external reviewer disagree on inclusion, the external reviewer's opinion shall take precedence.

Following the initial assessment of an adolescent who meets the inclusion criteria and signs the informed consent, the subsequent seven to ten days will be used to obtain medical or psychiatric records of prior treatment where indicated, and to document that the depressive symptomotology is stable after the initial psychiatric contact.

During this time a physical examination will also be conducted to assure the patient is in good medical health. The exam will include clinical laboratory studies (Appendix E) and a cardiovascular evaluation to include 12 lead EKG, heart rate and blood pressure measurements.

At the end of this interval, the adolescent will return to the clinic and will be re-evaluated. Only subjects continuing to meet inclusion criteria (DSM-III-R major depression and the Hamilton Rating Scale total score of 12 or greater) will be included.

Additional instruments to be administered at the end of the assessment period include the Autonomous Functioning Checklist, the Self Perception Profile for Adolescents and the Sickness Impact Scale.

During the assessment interval, a family history will be obtained on all first degree family members using the mother as informant (or other parent or parent surrogate if required). The mother will be interviewed about her lifetime history using the SADS-L and family history of all other first degree relatives using the Family History-Research Diagnostic Criteria (FH-RDC).

A brief description of the various scales and instruments is provided in Appendix F.

5.2.2 Randomization

Randomized Assignment of Subjects to Treatment

A computer generated randomization list will be used in which treatments are balanced within blocks of 6 consecutive patients. Patients will be allocated from 001 to 360. The master randomization list will be held by SmithKline Beecham. The treatment codes may be broken during the study for an individual patient in case of emergency. However, every effort should be made to contact SmithKline Beecham Medical Monitor prior to breaking the treatment code.

5.2.3 Treatment Phase

Assessments during study visits

During the eight week acute phase of the study, each patient will make weekly visits to the clinic. At each visit the following assessments will be carried out:

- HAM-D
- Depression section from the K-SADS-L (every other week)
- Clinical Global Improvement Scale
- Adverse Events
- Cardiovascular Functioning
- Clinical Laboratory Studies (Week 8)

Cardiovascular functioning will be assessed at baseline by obtaining a 12 lead EKG, heart rate, and blood pressure measurements. At each clinic visit, each subject will have a repeat blood pressure sitting and standing and heart rate assessment.

Revised 24 March 1994

A 12 Lead EKG will be performed at visits 4 and 8. Rythym strip EKG will be carried out at all other visits. Cardiovascular limits to titration (i.e. acceptable limits requiring no change in study medication) will be as follows, using criteria developed by [redacted] and [redacted]

resting heart rate < 130*.
resting systolic BP < 140; resting diastolic BP < 85
PR interval < 0.21
QRS interval < 0.12 and less than 150% of baseline
QTC < 0.48

* If the resting heart rate exceeds 110 bpm on two consecutive visits, a dose adjustment is required.

Cardiovascular parameters outside those described above will result in decreasing medication dosage by one tablet level. If a patient is at level 4 or below (see Section 6.0 - Study Drug Administration), he or she will be removed from the study.

Serum Levels

Revised

24 March 1994

Blood samples for analysis of paroxetine as well as imipramine and desipramine will be obtained on all subjects no matter to which treatment they are assigned. Blood will be collected at baseline and after 4 and 8 weeks of treatment and the samples shipped to the Clinical Trials Center of SmithKline Clinical Laboratories (SBCL) in VanNuys California. Written instructions for the collection, preparation and shipping of the samples will be provided to each investigator.

The paroxetine samples will be stored by SBCL until the completion of the study when the plasma will be analyzed for paroxetine concentration. The imipramine/desipramine sample will be analyzed when received by the SBCL. The concentration of imipramine and desipramine data will be retained by SBCL until the completion of the trial. However, if in a given patient, the combined levels of imipramine and desipramine exceed 500 mcg/ml of serum, the investigator will be immediately notified and that patient will be withdrawn from the study. Any further treatment will be as deemed appropriate.

Medical Management -- Psychotherapy

Experience in protocols in depressed adolescents suggest that patients and families expect psychotherapy and are reluctant to consider a course of medication treatment alone, especially

where the medication may be solely placebo. On the other hand, a provision of treatment with a psychotherapy which, in retrospect, turned out to be extraordinarily efficacious might well preclude the demonstration of a real, significant, and clinically meaningful medication effect. There are currently several research groups beginning the process of examining different specific psychotherapies (e.g. cognitive behavioral and interpersonal) for adolescent depression. As of yet, however, there are no completed controlled studies which would suggest a "reference" psychotherapy treatment. The present study will include supportive psychotherapy,

Modified

similar to the management as described by Fawcett in Appendix G.

24 March 1994

Please note, however, that the procedures in this appendix are meant to serve as a guideline. Where differences exists between the appendix and the protocol (e.g. dosing criteria), the protocol takes precedence.

Weekly visits will consist of a 45 minute visit with the therapist. In unusual circumstances, emergency contact of greater duration is permitted. Duration of all contact including phone calls will be systematically documented.

Definition of "responders" and "non-responders" at the end of eight-week acute treatment

To be classified as a "responder" and continue to the continuation phase, a subject must have a HAM-D score ≤ 8 or a decrease in baseline HAM-D total score □ 50%:

Termination at end of acute study for non-responders

At the end of the acute phase subjects who are "non-responders", as defined above, will be terminated from the study. Medication/placebo will be tapered off over a 7-17 day period at which time their care will be transferred to clinical personnel who are not part of this study. The patient and family, all clinical personnel, and all research personnel will remain blind to medication assignment of all subjects even after termination of the acute phase.

In some subjects, for safety reasons, it may be necessary for the clinical personnel to be informed which medication the subject was on. The decision to unblind the clinical personnel will be made jointly with clinical personnel at the site and clinical personnel at SmithKline Beecham.

5.2.4 Extension study

Subjects who are "responders" at the end of the double-blind acute study will be blindly continued on the current (final) dose of imipramine/paroxetine/placebo for an additional six months. For the purposes of this study, it is estimated that 65% of subjects in both active treatment will be "responders" and 40% of subjects on placebo will be a "responder".

The aims of the continuation phase are: 1) to provide an estimate of the benefits of extended treatment with anti-depressant medications and 2) to provide a safety profile of antidepressants given for an extended period of time.

Procedures for 6-month follow-up:

1. Maintain last medication/placebo dose blindly.

Revised
24 March 1994

2. Monthly psychiatric and safety assessments:

    a) Affective section of K-SADS-L interview
    b) Hamilton depression rating scale
    c) Adverse Events
    d) Clinical Global Assessment Scales
    e) EKG rhythm strip, blood pressure, and heart rate assessment
    f) Clinical Laboratory Studies (Week 20)
    g) Serum Drug Levels (Week 20)

3. Assessment at termination of the 6-month extension:

    a) Full K-SADS-L
    b) Hamilton Depression rating scale
    c) Adverse Events
    d) Clinical Global Assessment Scales
    e) 12 lead EKG strip, blood pressure, and heart rate assessment
    f) Clinical Laboratory Studies
    g) Serum Drug Levels

6.0 DRUG SUPPLIES AND PACKAGING

6.1 Formulations

Medication will be administered in the form of green capsules. Paroxetine will be provided as 10 mg over encapsulated tablets, imipramine will be 50 mg over encapsulated tablets while placebo will be provided in a tablet dosage form identical in appearance to paroxetine, over encapsulated.

6.2 Study Drug Administration

Dose of study medication

There will be six dosing levels. All patients will be titrated to level 4 regardless of response. Levels 5 and 6 are optional for those who do not respond after reaching level 4. The timings and dosage at each level are as follows:

	DAY	IMIPRAMINE	PAROXETINE
Level 1	1 - 7	50 mg	20 mg
Level 2	8 - 14	100 mg	20 mg
Level 3	15 - 21	150 mg	20 mg
Level 4	22 - 28	200 mg	20 mg
Level 5	*	250 mg	30 mg
Level 6	*	300 mg	40 mg

6.3 Blinding

The study will use 10 and 20 mg paroxetine tablets and the corresponding placebos. Also to be used will be the 50 mg imipramine tablets and corresponding placebo tablets. The "paroxetine placebos" will be identical in size, color and shape to the 10 and 20 mg paroxetine un-monogrammed tablets. Likewise, the imipramine placebo tablet will be the same size, shape and color as the active imipramine.

6.4 Concomitant Medication

All concomitant medication taken during the study must be recorded in the case report form with indication, daily dose, and dates of administration.

Subjects will not be allowed to take other psychotropic medications. Subjects will be permitted to take medications without CNS effects for medical illnesses or conditions as necessary. Medications which are not psychotropic, but which may have CNS effects (e.g. prednisone, antihistamines) should be avoided or used for the minimum length of time consistent with good medical care.

6.5 Packaging

The capsules will be packaged using blister cards. One card will hold sufficient supplies for a one week treatment period (10 days). Patients will be instructed to take medication twice daily, one dose in the morning and one at night. The number of capsules for each dose will depend on the dosing level achieved; the minimum number of capsules to be taken daily is two, the maximum is six.

6.6 Labeling and Preparation

For all phases, the tear off portion of the label must be affixed to the CRF when medication is dispensed to the patient. All unused cards must be returned to the sponsor at the end of the study.

6.7 Storage

Study medications must be kept in a locked area and dispensed according to the protocol. Records of dispensed supplies must be kept current on forms which the sponsor will also supply. All unused supplies must be returned to the sponsor at the end of the study.

6.8 Drug Accountability

The investigator will sign that he or she has received the clinical supplies for this study and that the study supplies will be handled and stored safety and properly.

6.9 Assessment of Compliance

A record of the amount of drug dispensed, taken, and returned will be recorded in the CRF for each patient, to assess compliance. The patient will be instructed to return the previous intervals drug container, including any unused medication at each visit.

If a patient takes less than 80% or more than 120% of study drug at each of two consecutive visits, the patient will be considered non-compliant and withdrawn from the study. A patient who misses two consecutive visits will also be withdrawn from the study.

6.10 Overdosage

The following information on overdosage is provided in the prescribing information for Paxil and Tofranil.

For paroxetine, treatment should be consistent with those general measures employed in the management of overdosage with any antidepressant. There are no specific antidotes for paroxetine. Establish and maintain an airway, ensure adequate oxygenation and ventilation. Gastric evacuation either by the induction of emesis or lavage or both should be performed. In most cases, following evacuation, 20 to 30 grams of activated charcoal may be administered every 4-6 hours during the first 24-36 hours after ingestion. An ECG should be taken and monitoring of cardiac function instituted if there is any evidence of abnormality. Supportive care with frequent monitoring of vital signs and careful observation is indicated. Due to the large volume of distribution of paroxetine, forced diuresis, dialysis, hemoperfusion, and exchange transfusion are unlikely to be of benefit.

A specific caution involves patients taking paroxetine or recently having taken paroxetine who might ingest by accident or intent excessive quantities of a tricyclic antidepressant or a MAO inhibitor. In such a case, accumulation of the parent tricyclic and its active metabolite may increase the possibility of clinically significant sequalae and extend the time needed for close observation.

In managing overdosage, consider the possibility of multiple drug involvement. The physician should consider contacting a poison control center for additional information on the treatment of overdosage.

For imipramine:

Children have been reported to be more sensitive than adults to an acute overdosage of imipramine hydrochloride. An acute overdose of any amount in infants or young children, especially, must be considered serious and potentially fatal.

Signs and Symptoms:

These may vary in severity depending upon factors such as the amount of drug absorbed, the age of the patient, and the interval between drug ingestion and the start of treatment. Blood and urine levels of imipramine may not reflect the severity of poisoning; they have chiefly a qualitative rather than quantitative value, and are unreliable indicators in the clinical management of the patient. CNS abnormalities may include drowsiness, stupor, coma, ataxia, restlessness, agitation, hyperactive reflexes, muscle rigidity, athetoid and choreiform movements, and convulsions.

Cardiac abnormalities may include arrhythmia, tachycardia, ECG evidence of impaired condition, and signs of congestive failure.

Respiratory depression, cyanosis, and diaphoresis may also be present.

Treatment:

The recommended treatment for overdosage with tricyclic antidepressants may change periodically. Therefore, it is recommended that the physician contact a poison control center for current information on treatment. Because CNS involvement, respiratory depression and cardiac arrhythmia can occur suddenly, hospitalization and close observation may be necessary, even when the amount ingested is thought to be small or the initial degree of intoxication appears slight or moderate. All patients with ECG abnormalities should have continuous cardiac monitoring and be closely observed until well after cardiac status has returned to normal; relapses may occur after apparent recovery.

In the alert patient, empty the stomach promptly by lavage. In the obtunded patient, secure the airway with a cuffed endotracheal tube before beginning lavage (do not induce emesis). Instillation of activated charcoal slurry may help reduce absorption of imipramine.

Minimize external stimulation to reduce the tendency to convulsions. If anticonvulsants are necessary, diazepam, and phenytoin may be useful.

Maintain adequate respiratory exchange. Do not use respiratory stimulants.

Shock should be treated with supportive measures, such as appropriate position, intravenous fluids, and if necessary, a vasopressor agent. The use of corticosteroids in shock is controversial and may be contraindicated in cases of overdosage with tricyclic antidepressants. Digitalis may increase conduction abnormalities and further irritate an already sensitized myocardium. If congestive heart failure necessitates rapid digitalization, particular care must be exercised.

Hyperpyrexia should be controlled by whatever external means are available, including ice packs and cooling sponge baths, if necessary.

Hemodialysis, peritoneal dialysis, exchange transfusions and forced diuresis have been generally reported as ineffective because of the rapid fixation of imipramine in tissues. Blood and urine levels of imipramine may not correlate with the degree of intoxication, and are unreliable indicators in the clinical management of the patient.

The slow intravenous administration of physostigmine salicylate has been used as a last resort to reverse CNS anticholinergic manifestations of overdosage with tricyclic antidepressants; however, it should not be used routinely, since it may induce seizures and cholinergic crises.

7.0 ADVERSE EXPERIENCES

The recording of adverse experiences is an important aspect of study documentation. Detailed guidelines are set out below.

7.1 Eliciting and Documenting Adverse Experiences

It is the responsibility of the investigator to document all adverse experiences which occur during the investigation. An adverse experience includes any noxious, pathologic or unintended change in anatomical, physiologic or metabolic functions as indicated by physical signs, symptoms and/or laboratory changes occurring in any phase of the clinical trial whether associated with drug or placebo and whether or not considered drug related.

This includes an exacerbation of pre-existing conditions or events, intercurrent illnesses, drug interaction or the significant worsening of the disease under investigation that is not recorded elsewhere in the case report form under specific efficacy assessments. Anticipated day-to-day fluctuations of the disease under study that do not represent a clinically significant exacerbation or worsening need not be considered an adverse event.

All adverse experiences occurring after the start of the study must be reported. Subject entry into the study is defined as the time at which informed consent is obtained. (This must be before any protocol-specific diagnostic procedures or interventions.) All subsequent adverse experiences, whether no drug (ie. during reference 'run-in' or 'wash-out' period) or when active drug or placebo is being administered, must be reported REGARDLESS OF WHETHER OR NOT THEY ARE CONSIDERED DRUG RELATED.

At each visit/assessment, adverse experiences will be evaluated by the investigator. Adverse experiences not previously documented in the study will be recorded in the adverse experience section of the subject's case record form. The nature of each experience, data and time (where appropriate) of onset, duration, severity and relationship to treatment should be established. Details of changes to the dosage schedule or any corrective treatment should be recorded on the appropriate pages of the case record form.

Adverse experiences already documented in the CRF ie. at a previous assessment and designated as 'continuing' should be

reviewed. If these have resolved, the documentation in the CRF should be completed. NB. If an adverse experience changes in frequency or severity during a study period, a new record of the experience will be started.

Ask the subject a non-leading question such as: "Do you feel different in any way since starting the new treatment/the last assessment."

7.2 Assessment of Severity

Maximum intensity should be assigned to one of the following categories:

Mild: For example, an adverse experience which is easily tolerated by the patient, causing minimal discomfort and not interfering with everyday activities.

Moderate: For example, an adverse experience which is sufficiently discomforting to interfere with normal everyday activities.

Severe: For example, an adverse experience which is incapacitating and prevents normal everyday activities.

7.3 Assessment of Causality

Every effort should be made by the investigator to explain each adverse experience and assess its relationship, if any, to study drug treatment. Causality should be assessed using the following categories: unrelated, probably unrelated, possibly related, related.

The degree of certainty with which an adverse experience is attributed to drug treatment (or alternative causes, e.g. natural history of the underlying diseases, concomitant therapy, etc.) will be determined by how well the experience can be understood in terms of the following:

- Known pharmacology of the drug

- Reaction of similar nature being previously observed with this drug or class of drug

- The experience having often been reported in literature for similar drugs as drugs related, e.g. skin rashes, blood dyscrasia

- The experience being related by time to drug ingestion terminating with drug withdrawal (dechallenge) or reproduced on rechallenge.

7.4 Following-up of Adverse Experiences

Investigators should follow-up subjects with adverse experiences until the event has subsided (disappeared) or until the condition has stabilized. Reports relative to the subject's subsequent course must be submitted to the clinical study monitor.

7.5 Serious Adverse Experiences

7.5.1 Definition of Serious Adverse Experiences:

A serious adverse experience is any event which is fatal, life threatening, disabling or incapacitating or results in hospitalization, prolongs a hospital stay or is associated with congenital abnormality, cancer or overdose (either accidental or intentional). In addition any experience which the investigator regards as serious or which would suggest any significant hazard, contraindication, side effect or precaution that may be associated with the use of the drug should be reported as a serious event.

Life threatening - definition:

An adverse experience is life threatening if the subject was at immediate risk of death from the event as it occurred; i.e. it does not include a reaction that if it had occurred in a more serious form might have caused death. For example, drug induced hepatitis that resolved without evidence of hepatic failure would not be considered life threatening even though drug induced hepatitis can be fatal.

Disability/incapacitating definition:

An adverse experience is incapacitating or disabling if the experience results in a substantial and/or permanent disruption of the subject's ability to carry out normal life functions.

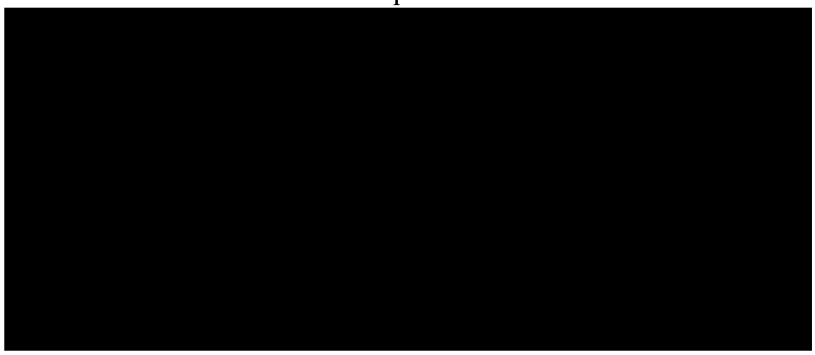
7.5.2 Reporting Serious Adverse Experiences

Any serious adverse experiences which occur during the clinical study or within 30 days (or five half lives whichever is the longer) of receiving the last dose of study medication, whether or not related to the study drug, must be reported by the investigator to the study monitor (by telephone within 24 hours).

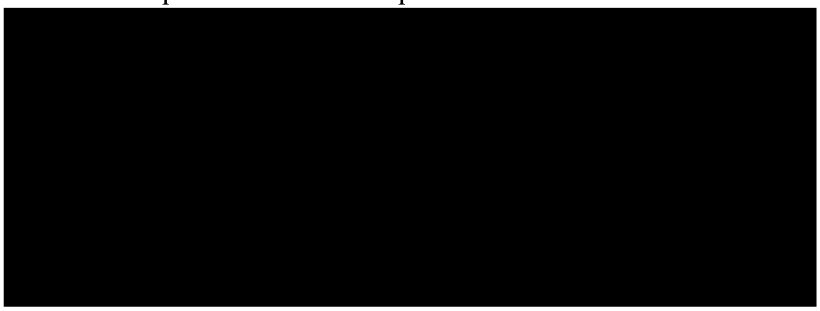
All serious adverse experiences must be reported by telephone within 24 hours to the study monitor:

Revised
24 March 1994

The Medical Monitor for this protocol is:



The Back-up Monitor for this protocol is:



The telephone report should be followed by a full written summary detailing relevant aspects of the adverse experiences in question. Where applicable, information from relevant hospital case records and autopsy reports should be obtained.

Instances of death, cancer or congenital abnormality if brought to the attention of the investigator AT ANY TIME after cessation of study medication and linked by the investigator to a previous clinical trial, should be reported to the study monitor.

7.6 Overdosage

Any instance of overdosage (suspected or confirmed) must be communicated to SmithKline Beecham within 24 hours and be fully documented as a serious adverse experience. Details of any signs or symptoms and their management should be recorded including details of any antidote(s) administered.

7.7 Pregnancy

Subjects who become pregnant during the study should discontinue the study immediately, unless the protocol states otherwise.

Patients should be instructed to notify the investigator if it is determined after completion of the study that they become pregnant either during the treatment phase of the study or within 30 days or five half-lives after the treatment period, whichever is longer.

Whenever possible a pregnancy should be followed to term, any premature termination reported, and the status of the mother and child should be reported to SmithKline Beecham after delivery.

7.8 Breaking the Study Blind

Only in the event of a serious adverse experience which the investigator feels cannot be adequately treated without knowing the identity of the study medication, may the medication code be broken for a particular subject. Every effort must be made to contact an SB Medical Monitor prior to breaking the code. If this is not possible and the situation is an emergency the investigator may break the code and contact the Medical Monitor as soon as possible thereafter.

8.0 SUBJECT COMPLETION AND WITHDRAWAL

8.1 Definitions

For the purpose of this protocol, a patient will be considered to be a "completed subject if they complete the 8 week acute phase". A withdrawal will be any subject who enters the study i.e. gives informed consent, and does not complete the 8 week study period (whether or not subject received study medication).

Because the extension phase is addressing maintenance therapy, it is anticipated that some patients will relapse. Accordingly, the definition of a "completed subject will be modified to be any patient who completes the full six months of therapy or any patient who withdrawals from therapy because of a relapse".

8.2 Procedures for Handling Withdrawals

It is anticipated that in a few subjects the study will be terminated early because of medication side effects. potential reasons for early termination include cardiovascular side effects beyond those permitted (see above), allergic reaction to medications, etc. Decisions for early study termination for medical or other reasons should be the responsibility of the principal investigator at each site. In all cases, subjects terminated early for any reason including medical reasons will be included in data analysis. Decision to terminate or not will be made blind to actual medication/placebo status--the blind will be broken only after termination is decided.

Should a patient decide to terminate the study early, a discontinuation taper is strongly recommended. If this accepted by the family, the medication will be tapered off in a linear fashion over a 7 to 17 day period.

8.3 Reason for withdrawal

A patient may withdraw from the study prior to completion for one of six possible reasons:

1. Adverse experiences including intercurrent illness
2. Insufficient therapeutic effect
3. Deviation from protocol including non-compliance

4. Lost to follow-up
5. Termination by SB
6. Other (specify).

The investigator should determine the primary reason for withdrawal and cite the one reason.

9.0 DATA EVALUATION

9.1 Criteria for Efficacy

9.1.1 Primary efficacy variables

a) The change in total HAMD score from beginning of the treatment phase to the endpoint of the acute phase.

b) The proportion of responders at the end of the eight week acute treatment phase.

9.1.2 Secondary efficacy variables

a) Changes from baseline to endpoint in the following parameters:

- Depression items in K-SAD-L
- Global Impressions
- Autonomic Function Checklist
- Self Perception Profile
- Sickness Impact Scale.

b) Predictors of response (endogenous subtypes, age, prior episodes, duration and severity of present episode, comorbidity with separate anxiety, attention deficit, and conduct disorder).

c) The number of patients who relapse during the maintenance phase.

9.2 Statistical Methods

9.2.1 Comparisons of interest

The comparison of primary interest is active treatment versus placebo. Hypotheses concerning these comparison will be tested at the alpha level of 0.05

9.2.2 Sample size determination

This study is designed to have adequate power to detect a clinically meaningful difference in both active-placebo comparisons at a two tailed alpha level of 0.05 and power 0.80. The sample size estimates are further based on an effect size of 0.40. The rationale for this effect size is as follows:

- A difference of 4 in the HAMD Total change from baseline scores at endpoint. This is a smaller difference than that seen in previous studies with antidepressants in adults, yet it is large enough to be clinically meaningful, and

- A standard deviation of 10. This is 20% larger than observed in studies with anti-depressants in adults and should reflect the greater variability in response expected in adolescent depression.

These parameter estimates result in 100 patients per treatment group.

9.3 Efficacy Analysis

9.3.1 Intent to Treat Analysis

All patients who receive double-blind medication will be considered as part of the ITT population. This patient population will be considered the primary population.

9.3.2 Patients Valid For The Efficacy Analysis

All patients randomized to study treatment and for whom at least one valid post-treatment efficacy evaluation is available will be valid for inclusion in an 'intent-to-treat' analysis. Patients who meet the following criteria will be eligible for the efficacy analysis:

a) No major protocol violation exists with regard to inclusion or exclusion criteria.

b) No other major protocol violation during the first 8 weeks of active treatment has occurred.

Only primary efficacy variables will be analyzed using this population. Patients to be excluded from the efficacy analysis will be identified before the randomization code is broken.

9.3.3 Statistical Methodology

Psychometric scales using at least an ordinal measurement scale will be analyzed using parametric analysis of variance, effects in the model will include treatment, investigator and treatment by investigator interaction. If the treatment by investigator interaction is not significant ($p > 0.1$) the interaction term will be dropped from the model. This analysis will be performed using the General Linear Models procedure of the SAS system. The ordinal scales which have very few levels (such as the CGI Severity of Illness) will also be analyzed using nonparametric methodology to ensure that the results are consistent across modes of analysis.

Dichotomous variables such as response (based on HAMD criteria) will be analyzed using Logistic Regression methodology. Effects in the model will include treatment, investigator, and treatment by investigator interaction; if the interaction is not significant then it will be dropped from the model. These analyses will be performed using the LOGISTIC procedure of the SAS system.

Summary statistics will be presented for demography, disease history, and baseline measures of efficacy.

An analysis of covariance will be performed to evaluate the effect of possibly important prognostic variables on the HAMD total score at endpoint. These include endogenous subtype, age at onset, gender, number of prior episodes, duration and severity of current episode, comorbidity with separate anxiety disorder, attention deficit disorder and conduct disorder.

9.3.4 Test of Significance

Tests of hypothesis regarding model assumptions such as the significance of treatment by investigator interactions will be made at the 10% level.

All other statistical tests will be two-tailed and performed at the 5% significance level.

9.3.5 Patient Characteristics At Baseline

Demographic and diagnostic variables at baseline will be checked for homogeneity between the treatment groups. If major differences exist for variables predictive of treatment response, their impact on the trial results will be investigated.

9.4 Safety Analysis

9.4.1 Patients Valid for Clinical Safety & Tolerability

All patients who receive coded medication will be assessed for clinical safety and tolerability.

9.4.2 Adverse Experiences

Adverse experiences will be coded for each subject with reference to body system and preferred terms. The treatment groups will be compared regarding the incidence of the reported adverse experiences with reference to both preferred term and body system. The comparison between treatments with regard to incidence of adverse experiences will be performed primarily by using descriptive statistics.

9.4.3 Other Clinical Safety Variables

Information regarding demographic data, vital signs, physical examination, adverse experiences and abnormal laboratory values will be presented as listings and tables. All deviations from the study protocol and study withdrawals will be documented.

10.0 ADMINISTRATIVE MATTERS

To comply with Good Clinical Practice, important administrative obligations relating to investigator responsibilities, monitoring, archiving data, confidentiality and publications must be fulfilled as given in Appendix B.

BIBLIOGRAPHY

Adams PB, Hoven C, Bird H: Family Psychiatric History Screen.

Bergner L, et al: Public Health, 75:1321-1323, 1985.

Bergner M, et al: Int. J. Health Serv., 6:393-415, 1986.

Bielski RJ, Friedel RD: Prediction of tricyclic antidepressant responses. Arch Gen Psychiatry, 33:1479-1489, 1976.

Boulos C, et al: Response to desipramine treatment in adolescent major depression. Psychopharm Bulletin, 27:59-65.

Brent DA, et al: Suicidality in affectively disordered adolescent inpatients. J Am Acad Ch Adol Psychiatry, 29:586-593, 1990.

Fleming JE, et al: Epidemiology of childhood depressive disorders: A critical review. J Am Acad Ch Adol Psychiatry, 29:571-580, 1990.

Garber J, et al: Recurrent depression in adolescents: A follow-up study. J Am Acad Ch Adol Psychiatry, 27:49-54, 1988.

Geller B, et al: Baseline and 2- to 3-year follow-up characteristics of placebo-washout responders from the nortriptyline study of depressed 6- to 12 year olds. J Am Acad Ch Adol Psychiatry, 31:622-628, 1992.

Geller B, et al: Double-blind controlled study of nortriptyline in depressed adolescents using a "fixed plasma level" design. Psychopharm Bulletin, 26:85-90, 1990.

Halpern JK, Glassman AH: Adequate tricyclic treatment: Defining the tricyclic nonresponder. In: Treatment Strategies for Refratory Depression. Edited by Roose SP, Glassman AH. Washington, DC, American Psychiatry Press, 1990, pp 11-32.

Harrington RD, et al: Adult outcomes of childhood and adolescent depression: I. Psychiatric status. Arch Gen Psychiatry, 47:465-473, 1990.

Himmelhoch JM, et al: Tranylcypromine versus imipramine in anergic bipolar depression. Am J Psychiatry, 148:910-916, 1991.

Joyce PR, Paykel ES: Predictors of drug response in depression. Arch Gen Psychiatry, 46:88-99, 1989.

Klein DR, Gittelman-Klein R: Progress in Psychiatric Drug Treatment, Volume 2, New York, New York, Brunner/Mazel, 1976.

Kovacs M, et al: Depressive disorders in childhood. I. A longitudinal prospective study of characteristics and recovery. Arch Gen Psychiatry, 41:229-237, 1984.

Kramer A, Feguine B: Clinical effects of amitriptyline in adolescent depression. J Am Acad Ch Adol Psychiatry, 20:636-644, 1983.

Kupfer DJ, et al: Family history in recurrent depression. J Affective Disorders, 17:113-119, 1989.

Lavori PW, et al: Clinical trials in psychiatry: Should protocol deviation censor patient data? Neuropsychopharm, 6:39-48, 1992.

Liebowitz MR, et al: Phenylzine versus imipramine in a typical depression. Arch Gen Psychiatry, 41:669-677, 19840.

Lish JD, Weissman MM, Adams PB, Hoven C, Bird H: Family Psychiatric History Screen for Epidermiologic Studies (FHE): Pilot Testing and Validation.

Nelson JC, Charney DS: Symptoms of major depressive illness. Am J Psychiatry, 138:1-13. 1981.

Rao U, et al: Childhood depression and risk of suicide: A preliminary report of a longitudinal study. J Am Acad Ch Adol Psychiatry. (in press)

Raskin A, Crook TH: The endogenous-neurotic distinction as response to antidepressant drugs. Psycho Medicine, 6:59-70, 1976.

Raskin JG, et al: Follow-up of patients who improve during placebo washout. J Clin Psychopharm, 6:274-278, 1986.

Reimherr FW, et al: The introductory placebo washout. A retrospective evaluation. Psychiatr Res, 30:191-199, 1989.

Ryan ND, et al: A placebo controlled study of amtriptyline in adolescent major depression. (in preparation, 1992).

Ryan ND, et al: Imipramine in adolescent major depression: Plasma level and clinical response. Acta Psychiatr Scand, 73:275-288, 1986.

Simeon JG, et al: Adolescent depression: A placebo controlled fluoxetine treatment study and follow-up. Prog Neuro-Psychopharm Biol Psychiatry, 14:791-795, 1990.

Stewart JW, et al: Relevance of DSM-III depressive subtype and chronicity on antidepressant efficacy ion a typical depression: Differential response to phenylzine, imipramine, and placebo. Arch Gen Psychiatry, 46:1080-1087, 1989.

Strober M, et al: The course of major depressive disorder in adolescents. I. Recovery and manic switching in a 24-month prospective, naturalistic follow-up. J Am Acad Ch Adol Psychiatry. (in press)

Strober M, et al: The pharmacotherapy of depressive illness in adolescence. I. An open label trial of imipramine. Psychopharm Bulletin, 26:80-84, 1990.

Strober M, et al: The pharmacotherapy of depressive illness in adolescents: II. Effects of lithium augmentation in nonresponders to imipramine. J Am Acad Ch Adol Psychiatry. 31:16-20, 1992.

Thase ME, Kupfer DJ: Characteristics of treatment resistant depression. In: Treating Resistant Depression. Edited by Zohar J, Belmaker RH. new York, PMA Publishing Corp., 1987, pp 23-45.

Weissman MM, et al: Onset of major depression in early adulthood: Increased familial loading and specificity. Arch Gen Psychiatry, 41:1136-1143, 1984.

Young JG, et al: Neurotransmitter ontogeny as a perspective for studies of child development and pathology. In: The Psychobiology of Childhood. Edited by L. Greenhill, B. Shopsin. New York, Spectrum Publishers, 1984, pp 51-84.

Appendices

APPENDIX A

DECLARATION OF HELSINKI

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI

Recommendations guiding physicians in
biomedical research involving human subjects

Adopted by the 18th World Medical Assembly,
Helsinki, Finland, June 1964,
Amended by the 29th World Medical Assembly,
Tokyo, Japan, October 1975,
35th World Medical Assembly,
Venice, Italy, October 1983
and the
41st World Medical Assembly
Hong Kong, September 1989

INTRODUCTION

It is the mission of the physician to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfillment of this mission.

The Declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration", and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."

The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially to biomedical research.

Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

In the field of biomedical research a fundamental distinction must be recognized between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely

scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings for further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every physician in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Physicians are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

I. BASIC PRINCIPLES

1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.

2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.

3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.

4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

5. Every biomedical research project involving human subjects should be preceded with careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the

interests of the subject must always prevail over the interests of science and society.

6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

7. Physicians should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Physicians should cease any investigation if the hazards are found to outweigh the potential benefits.

8. In publication of the results of his or her research, the physician is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject's freely-given informed consent, preferably in writing.

10. When obtaining informed consent for the research project, the physician should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a physician who is not engaged in the investigation and who is completely independent of this official relationship.

11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation. Whenever the minor child is in fact able to give a consent, the minor's consent must be obtained in addition to the consent of the minor's legal guardian.

12. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

II. MEDICAL RESEARCH COMBINED WITH PROFESSIONAL CARE
(Clinical Research)

1. In the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if in his or her judgment it offers hope of saving life, re-establishing health or alleviating suffering.

2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.

3. In any medical study, every patient including those of a control group, if any, should be assured of the best proven diagnostic and therapeutic method.

4. The refusal of the patient to participate in a study must never interfere with the physician-patient relationship.

5. If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee (I,2).

6. The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

III. NON-THERAPEUTIC BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS
(Non-clinical biomedical research)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the physician to remain the protector of the life and health of that person on whom biomedical research is being carried out.

2. The subjects should be volunteers -- either healthy persons or patients for whom the experimental design is not related to the patient's illness.

3. The investigator or the investigating team should discontinue the research if in his/her or their judgment it may, if continued, be harmful to the individual.

4. In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject.

APPENDIX B

ADMINISTRATIVE MATTERS

I. RESPONSIBILITIES OF THE INVESTIGATOR

- To ensure that he/she has sufficient time to conduct and complete the study and has adequate staff and appropriate facilities which are available for the duration of the study and to ensure that other studies do not divert essential subjects or facilities away from the study at hand.

- To submit an up-to-date curriculum vitae and other credentials (e.g. medical license number in the United States) to the sponsor and - where required - to relevant authorities.

- To acquire the normal ranges for laboratory tests performed locally and, if required by local regulations, obtain the Laboratory License or Certification.

- To prepare and maintain adequate case histories designed to record observations and other data pertinent to the study.

II. PROTOCOL AMENDMENTS

No changes to the study protocol will be allowed unless discussed in detail with the SmithKline Beecham (SB) Medical Monitor and filed as an amendment/modification to this protocol.

Any amendment/modification to the protocol will be adhered to by the participating centre (or all participating centres) and will apply to tall subjects following approval as appropriate by the Ethical Review Committee or Institutional Review Board.

III. SPONSOR'S TERMINATION OF STUDY

SB reserves the right to discontinue the clinical study at any time for medical or administrative reasons. When feasible, a 30-day written notification will be tendered.

IV. CASE REPORT FORM INSTRUCTIONS

Prior to screening the first potential participant, the investigator will provide a list showing the signature and handwritten initials of all individuals authorized to make or change entries and case report forms (CRFs). If the authorized individuals should change during the study, the investigator is to inform SB.

CRFs (and subject diary cards, if applicable), will be supplied by SB for recording all data. It is the responsibility of the investigator or co-investigator to ensure that CRFs (and subject diary cards) are legible and completely filled in with a black ink ballpoint pen. Include the subject's identification (2-3 alphabetic letters representing initials or first letter of subject's name) on the front page of the CRF, the allocation number (if not pre-printed) and the visit date.

Errors must be corrected by drawing a single line through the incorrect entry and writing in the new value/data positioned as close to the original as possible. The correction must then be initialed, dated and justified by the authorized individual making the change. Do not obliterate, write over, or erase the original entry when making a correction.

When a subject completes a visit, it is anticipated that relevant sections of the CRF will be completed by the investigator (or designated staff) within 24 hours of the last data becoming available, but in no case later than 5 days. Similarly, when a subject completes a study, it is anticipated that all relevant CRF pages will be completed with in 24 hours of the last data becoming available, but in no case later than 5 days. This also applies to forms for potential study participants who were not randomized to a treatment group.

As soon as the subject has completed/withdrawn from the study and the CRF is completed the principal investigator or designated physician(s) under his/her supervision will sign the adverse experience page(s) as well as study conclusion page of t he CRF to confirm that they have reviewed the data and that the data are completed and accurate. If sections of a CRF are to be brought into SB prior to study conclusion, a section conclusion signature is required.

An original (top copy) CRF must be submitted for all subjects who have undergone protocol specific procedures, whether or not the subject completed the study.

While completed CRFs will be reviewed by an SB professional monitor at the study side, error detected by subsequent in-house CRF review may necessitate

clarification or correction of errors and documentation and approval by the investigator.

Any questions or comments related to the CRF should be directed to the assigned study monitor.

V. MONITORING BY SMITHKLINE BEECHAM (i.e. the Sponsor)

Monitoring visits by a professional representative of the sponsor will be scheduled to take place before entry of the first subject, during the study at appropriate intervals and after the last subject is completed.

These visits are for the purpose of verifying adherence to the protocol and the completeness and exactness of data entered on the CRF and Drug Inventory Forms. The monitor will verify CRF entries by comparing them with the hospital/clinic/office records which will be made available for this purpose. The monitor will retrieve completed CRF sections at each visit. Adequate time and space for these visits should be made available by the investigator.

Investigator must ensure provision of reasonable space and adequate qualified personnel for monitoring visits.

VI. ARCHIVING OF DATA

The investigator must retain subject records and CRFs as well as drug disposition records in an easily retrievable form until disposal has been agreed in writing with SB. The investigator must have a 'key' linking the subject's study identification number (i.e., treatment number) to the subject's clinical file. If the investigator moves or retires, he/she should nominate someone in writing to be responsible for record keeping. Archived data may be held on microfiche or electronic record, provided that a back-up exists and a hard copy can be obtained from it if required.

SB agrees to retain a copy of the protocol, documentation, approvals and all other documents related to the study, including certificates that satisfactory audit and inspection procedures have been carried out.

VII. AUDITS

For the purpose of compliance with Good Clinical Practice and Regulatory Agency Guidelines it may be necessary for SB or a Drug Regulatory Agency to conduct a site audit. This may occur at any time from start to after conclusion of the study.

When an investigator signs the protocol, he agrees to allow Drug Regulatory Agency and SB auditors to inspect his/her study records. Furthermore, if an investigator refuses an inspection, his/her data will not be accepted in support of a New Drug Registration and/or Application.

SB has a substantial investment in clinical studies. Having the highest quality data and studies are essential aspects of drug development. SB has a Regulatory Compliance staff who audit investigational sites. Regulatory Compliance assesses the quality of data with regard to accuracy, adequacy and consistency. In addition, Regulatory Compliance assures that SB sponsored studies are in accordance with the relevant Good Clinical Practices regulation/guidelines are being followed.

To accomplish these functions, Regulatory Compliance selects investigational sites to audit. These audits usually take 1 to 2 days. The SB audits entail review of source documents supporting the adequacy and accuracy of CRFs, review of documentation required to be maintained, and checks on drug accountability. The SB audit therefore helps prepare an investigator for a possible regulatory agency inspection as well as assuring SB of the validity of the database across investigational sites.

The Inspector will be especially interested in the following items:

- Log of visits from the sponsor's representatives
- ERC/IRB approval
- Test article accountability
- Approved study protocol and amendments
- Informed consent of the subjects (written or witnessed oral consent)
- Medical records supportive of CRF data
- Reports to the ERC/IRB and the sponsor
- Record retention.

SB will gladly help investigators prepare for an inspection

VIII. CONFIDENTIALITY AND PUBLICATION

You agree that all information communicated to you by SB is the exclusive property of SB and you will ensure that the same shall be kept strictly confidential by you or any other person connected with the work and shall not be disclosed by you or such person to any third party.

We agree that you shall have the right to publish or permit the publication of any information or material relating to or arising out of the work after prior submission to us provided that if we shall so request you will delay publication for a maximum of six months to enable us to protect our rights

in such information or material. Any proposed publication or presentation (e.g. manuscript, abstract or poster) for submission to a journal or scientific meeting, should be sent to the study monitor prior to submission. SB will undertake to comment on such documents within four weeks.

All rights and interest worldwide in any inventions, know-how or other intellectual or industrial property rights which arise during the course of and/or as a result of the clinical study which is the subject of this protocol or which otherwise arise from the information or materials supplied under this Agreement, shall be assigned to, vest in and remain the property of SmithKline Beecham plc.

In drafting this section, additional stipulations can be included in accordance with local custom and practice but the above aspects.

APPENDIX C

SAMPLE INFORMED CONSENT

Study Title: A Multicenter, Double-blind Placebo Controlled Study of Paroxetine and Imipramine in Adolescents with Unipolar Major Depression.

Protocol Number: 29060/329

1. Nature and Purpose of the Project

I authorize Dr. _____ to include me in the research study "Multicenter, Double-blind Placebo Controlled Study of Paroxetine and Imipramine in Adolescents with Unipolar Major Depression." I have been asked to participate in a research project which is designed to learn if paroxetine and/or imipramine has any benefit in the long-term treatment of unipolar depression in adolescents. It has been explained to me that I have been asked to participate in this research study because I have a diagnosis of unipolar depression. Both paroxetine and imipramine have been shown to be effective in treating unipolar depression in adults; however, it is not known if either paroxetine or imipramine has similar effects in adolescents with this illness. I understand that the study proposes to examine the clinical benefits of both paroxetine and imipramine in this disorder.

Procedures

I understand that if I participate in this research study, I will be interviewed by the research team to determine my history of emotional or psychiatric disturbance, and I will be asked questions about the psychiatric status of other members of my family. I also understand that I may be asked permission for research staff to contact these members of my family for further history of their emotional disturbance, and that I may deny this request.

I will also undergo various standard medical tests, including a complete physical exam, blood and urine tests, and a test of heart function to make sure that I am free of any physical or medical problems that would advise against use of the medications to be used in this study. I understand that at intake my urine will be screened for any drugs in my system.

It has been explained to me that I will be eligible to enter the study after the research staff has determined that I meet the criteria for depression and am in generally good medical health. At this point, I will be assigned randomly to receive paroxetine, imipramine, or a placebo sugar substitute. I will not find out what kind of mediation I am taking until completion of the study, which could run for as long as five years. In order to learn the benefits of anti-depressant medication, it is essential that neither I nor my doctors know to which treatment I have been assigned.

During the study, I will be interviewed by members of the research team every week for eight consecutive weeks. If my condition improves I may elect to continue treatment for additional 6 months. During this time I will be interviewed by the research team on a monthly basis. At the interviews, I will be asked questions about my behavior and mood and whether I have been taking the prescribed number of pills on a regular basis. I understand that no costs will be incurred for my participating in this phase of the research. Payment for lengthy sessions (two or more hours) with the adolescent and family for initial evaluation will be $ per subject. Participants will be reimbursed for the weekly and subsequently monthly evaluation sessions including blood drawing at $ per visit. No visit in connection with my participation in this phase of the study will be billed to me or my insurance carrier.

2. Discomforts and Risks

It is possible that paroxetine or imipramine will relieve depression in some adolescents as in adults. If so, assignment to placebo treatment might result in a lesser degree of treatment.

I understand that I may experience some discomfort as a result of the medication I receive. Treatment with paroxetine could produce side effects, the most common side effects are:

> General fatigue and muscular pain, sweating, nausea, itching, rashes, decreased appetite, sleepiness, dizziness, insomnia, nervousness, coughs, running nose, muscular tremors, changes in weight, and changes in heart rate.

Treatment with imipramine could produce side effects. The most common are:

> Dry mouth, blurred vision, rashes, nausea, and stomach upset, changes in heart rate, fainting, restlessness and agitation.

I understand that I am not more likely to experience side effects as a result of my participation in this study than if I were being treated with paroxetine or

imipramine in the usual manner. If I experience side effects, the doctors will attempt to adjust the dose.

If I cannot continue to take the medication because of side effects, I will not continue in the study and will receive the best alternative treatment. I understand that if I am a female I will be counseled by the research staff as to the risks involved in becoming pregnant while participating in the study. I am also aware that I may experience discomfort when having blood drawn; this may be a source of mild pain, and some mild swelling may occur at the site of the blood draw. Although it is uncommon, this may also cause me to feel faint, to bleed slightly, or to develop an infection at the site of the blood draw.

The interviews that I will receive during the course of the study involve no specific risks or discomforts beyond those of a standard clinical interview situation such as feeling upset at a review of my psychiatric status, boredom, or fatigue.

3. Benefits

I understand that the possible benefits to society include furthering our knowledge of the treatment of depression in teenagers. I also understand that of the treatment, medication, and testing will be free of charge.

4. Appropriate Alternative Procedures Beneficial to the Subject

The findings of this study will contribute to the understanding of a possible role for antidepressant medication in adolescent patients with depression. The researchers also expect to learn more about the longer term effects of both paroxetine and imipramine in the teenage population. I understand that I may choose not to participate in this study. If I do not participate, I will receive the best available treatment as prescribed by my doctor.

5. Confidentiality

All records relating to this project will be handled and safeguarded according to standard University policy for medical records. Any information obtained in connection with this study that can be identified with the subject will remain confidential, and will be disclosed only with my permission. Information of a sensitive personal nature will not be part of the medical record, but will be stored in the investigators' research file and identified only by a code number. The code key connecting name to numbers will be kept in a separate secure location. If the data are used for publication in the medical literature or for teaching purposes, no names will be used, and other identifiers, such as audiotapes, will be used only with special written permission. I understand that I may hear the audiotape before

giving this permission. Should the research staff discover use of other drugs by me such information will be kept confidential to the extent allowed by law. No information about me will be released without my consent except as required by law.

6. Risk of Injury

The investigators do not expect any (further) unusual risks as a direct result of participation in this project. However, should any unforeseen physical injury occur, appropriate medical care will be provided, but no financial compensation will be given.

7. Contact

I understand that if I have any questions, comments, or concerns about this study or the informed consent process I may call Dr. _____ at _____, or write to him at _____. If I have any questions about my rights as a subject, I may call _____.

If I become ill or injured as a result of participation in this clinical study, medical treatment will be provided, and the reasonable cost of such treatment will be paid by SmithKline Beecham. If I have any questions concerning the availability of compensation/medial care or if I thing I have experienced a drug-related illness or injury I will contact _____ at _____.

I will be given a copy of this form to keep.

8. Refusal/Withdrawal

I understand that participation in this study is voluntary and that refusal to participate at any time will involve no penalty of loss of benefits to which I am otherwise entitled. I know that I can refuse to answer any question that I may not wish to answer and that I may refuse to participate or withdraw from the study at any time without negative consequences or effect on medical care being provided. Since abrupt discontinuation of medication can result in unwanted side-effects, if I wish to withdraw, I agree to permit the slow tapering of my medication over two week period.

*****

I ACKNOWLEDGE THAT I HAVE READ AND FULLY UNDERSTAND THE ABOVE EXPLANATION OF THE PROJECT, THAT ALL MY QUESTIONS HAVE BEEN SATISFACTORILY ANSWERED. I AGREE TO PARTICIPATE IN THIS RESEARCH PROJECT.

_____ _____

Signature of Participant Date

*****

I CERTIFY THAT I HAVE EXPLAINED FULLY TO THE ABOVE PATIENT THE NATURE AND PURPOSE, PROCEDURES, POSSIBLE RISKS AND POTENTIAL BENEFITS OF THIS RESEARCH PROJECT.

_____ _____

Signature of Investigator Date

APPENDIX D

SUMMARY OF STUDY PROCEDURES

Assessment Continuation Phase	Baseline		Acute Phase								Continuation Phase					
Time (Weeks)	-1	0	1	2	3	4	5	6	7	8	12	16	20	24	28	32
Informed Consent	X															
Medical History and Physical Exam	X															
Clinical Laboratory Studies	X									X			X			X
Serum Pregnancy	X						X*							X*		
ECG-12 Lead	X					X				X			X			X
ECG Rhythm Strip			X	X	X		X	X	X		X	X		X	X	
Hamilton Depression Scale	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Full K-SADS-L	X															X
Affect Section of K-SADS-L		X		X		X		X		X	X	X	X	X	X	X
C-GAS		X														
CGI		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
SADS-L		X														
FH-RDC		X														
Autonomous Functioning Checklist	X									X						
Self Perception Profile	X									X						
Sickness Impact Scale	X									X						
Randomization		X														
Adverse Events		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Supportive Psychotherapy		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Plasma Sampling for Drug Analysis		X				X				X			X			X
Study Medication Record			X	X	X	X	X	X	X	X	X	X	X	X	X	X
Concomitant Medication	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

* On suspicion of pregnancy

APPENDIX E

CLINICAL LABORATORY PARAMETERS

- Blood

Hematology:	RBC WBC (total and differential) Platelets
Biochemistry:	Liver function: Bilirubin, alkaline phosphatase SGOT, SGPT Renal function: Urea, creatinine, uric acid Other biochemistry Glucose, serum proteins

- Urine

Blood, protein, glucose. If blood or protein noted in urine, microscopy will be performed. In addition a drug abuse screen will be performed at baseline.

- Prenancy Test - at baseline and on suspicion

- Plasma and Serum Drug Concentrtion

APPENDIX F

INSTRUMENTS

Family History Screen (FHE), Subject Version: The Family History Screen is a brief computer-scorable instrument which collects a pedigree and screens for DSM-III-R diagnoses in family members. The instrument has been shown to have good levels of sensitivity and specificity for adults reporting on themselves. (Lish et at)

Self Perception Profile for Adolescents: This scale (Harter, 1987) is an upward extension of the Self Perception Profile for Children which in turn is based on the Perceived Competence Scale (Harter, 1985). It is a measure of "self" as a dimension of competence in the proposed research. it consists of 45 item self report questionnaire, assessing perceived competence in 9 domains: Scholastic, social, athletic, physical appearance, job, romantic, conduct/morality, close friendship, and global self-worth. Psychometric information regarding this scale is available for a parochial school population. Subscale reliability is generally very high. Validity of the perceive competence scale has been supported by a number of recent studies (Cauce 1987; Nottelman 1987). Scores do not correlate with age.

Autonomous Functioning Checklist: The AFC is a parent-completed checklist designed to measure behavioral autonomous functioning in adolescents between the ages of twelve and eighteen. It contains seventy-eight items and is subdivided into four conceptually distinct subscales: Self-and Family Care, Management, Recreational Activity, and Social and Vocational Activity. Each item in the first three subscales is a short description of a behavior. The parent rates the adolescent in relation to each item on a five-point scale ranging from 0 (does not do) to 4 (does every time three is an opportunity). The items on the fourth subscale, Social and Vocational Activity, are rated by the parent on a dichotomous, yes/no scale. For each scale, high scores indicate that the adolescent routinely performs many of the activities listed.

Revised 24 March 1994

The K-SADS-L was initially developed by [redacted] M.D. and [redacted] M.D. The authors took as point of departure the audit SADS (developed by [redacted] M.D. and [redacted] Ph.D. with the assistance of other participants in the NIMH clinical Research Branch Collaborative Project on the Psychobiology of Depression), from which many items and scales remain. Guidelines for the unstructured interview were modified from [redacted] and [redacted] interview with the child (Isle of Wight Study). A fourth version was written by [redacted] M.D. and [redacted] M.D. and present and past

members of the Child and Adolescent Depression Program contributed their experience and expertise and commented on prior versions of this draft. [redacted] Ph.D. in 1993 for lifetime inquiry (thus the designation K-SADS-L) and to provide diagnoses of ADHD, oppositional disorder, antisocial personality disorder, social phobia, tic disorders, and to expand the anxiety disorders.

These sections have made use of items from other interview schedules, especially the CHAMPS by [redacted] Ph.D. and [redacted], Ph.D. Investigators wishing to use this instrument should contact Dr. [redacted] Western Psychiatric Institute and Clinic, University of Pittsburgh School of Medicine, 3811 O'Hara Street, Pittsburgh, PA 15213.

The Sickness Impact Profile (SIP) is a behaviorally based measure of health-related dysfunction that was developed to provide a measure of health status useful in the assessment of individuals or populations with both chronic and acute illnesses. It may be either interviewer or self administered and is scored as a total SIP score or as two dimensions, physical and psychological. It has undergone extensive field testing and has demonstrated good reliability (internal consistency, Cronbach's alpha, ranges from 0.94 to 0.97; overall reproducibility score ranges from 0.88 to 0.92) and validity (SIP to self assessment of sickness ranges from 0.54 to 0.69 and dysfunction ranges from 0.52 to 0.69; SIP to NHIS ranges from 0.55 to 0.61). It is easily understood by patients and the version used in this study has been modified for an adolescent population and has been piloted in an adolescent outpatient affective disorders clinic where it has demonstrated good utility. (Bergner et al., 1976; ibid. 1985).

APPENDIX G

CLINICAL MANAGEMENT FOR ADOLESCENT DEPRESSION

Adolescent Depression Collaborative Research Group

A Modification of [redacted] Clinical Management - Imipramine/Placebo Administration Manual. Psychopharmacology Bulletin 23:309-324, 1987.

INTRODUCTION

The intent of The Clinical Management for Adolescent Depression (CMAD) Manual is to define a psychosocial interaction between clinicians and adolescent patients which will maximize the chance of observing a pharmacotherapeutic effect in a study of antidepressant medication, assure the careful and safe monitoring of patients, and maintain consistency of approach among clinicians. It attempts to encompass elements of care used by clinicians who have experience with psychiatrically-ill adolescents, and it intentionally includes the "nonspecific" effects associated with other psychosocial therapies, such as warmth, empathy, genuine interest in the patient's welfare, and optimism about the outcome of treatment. These aims are shared by the approach defined in the Clinical Management - Imipramine/- Placebo Condition (CMIPC), developed for the NIMH Treatment of Depression Collaborative Research Program (Fawcett, et. al., 1987), of which CMAD is a modification. We are indebted to Drs. [redacted], who developed the CMIPC and consented to this modification of their manual.

The CMIPC had a secondary aim of minimizing overlap with two psychotherapy conditions which were being compared in that study, Interpersonal Psychotherapy and Cognitive Therapy. This study does not contrast psychosocial therapies, so this is not a principal aim. Consistency across pharmacotherapeutic conditions is the first priority in this study. Nevertheless, the current study intends that observed clinical change will reflect effects of the medication under study rather than of active psychotherapies. Thus, while there is slightly greater overlap with interpersonal and cognitive therapies than with CMIPC, this clinical management condition intentionally maintains clear distinctions from those therapies. An additional rationale for maintaining these distinctions is the possibility of using this clinical management manual in future studies of active psychotherapies with adolescents.

A further intent of this approach is to maximize compliance with the treatment under study. Attrition from treatment trials and clinical studies can be high with adolescents.

The investigators share the impression that maintaining rapport with the adolescent patients and their families requires the addition, to the CMIPC, of defined contract with parents, a more specific educational component about the illness and its treatment, and a modest increase in the time spent in contract with the patients. For these reasons, the length of sessions was increased and four psychoeducational conjoint sessions, with the adolescent and at least one parent, were added. Additional adjustments to treatment with adolescents include an emphasis on flexibility and active concern about the adolescent's social, school and family life.

Because of the central importance of maintaining consistent adherence of therapists to the psychosocial approach - particularly in a multicenter study - a means of rating tapes of therapy sessions is needed. Considerable work went into the development of the Collaborative Study Psychotherapy Rating Scale (CSPRS-6) and an accompanying Raters Manual. Review of these instruments indicates that they can be used without modification to rate tapes of sessions with adolescents.

Modifications of the CMIPC manual are intentionally minimal. They consist essentially of setting aside discussions of the adult psychotherapy study, rephrasing references to medications to fit the current study medications and their administration, lengthening of sessions, and modifying references to family contact.

Adaptation of the clinical management approach to the context of adolescence is provided by added descriptions of the initial session, a subsequent session, and illustrations of approaches to three potential problem situations - a depressed adolescent's refusal to attend school because of conflicts with peers, a dispute between an adolescent and parents, and an increase in an adolescent patient's suicidal ideation.

I. Purpose of Study

The major aim of the study for which this manual has been generated is to evaluate the effectiveness of two antidepressant medications, paroxetine and imipramine, for treating nonbipolar nonpsychotic outpatient depressive illness in adolescents. The medications will be compared to treatment with a placebo, and all three conditions will be accompanied by a program of education and support, defined in this manual. The clinical management approach (CMAD) which this program follows and augments has been observed to be effective with many depressed adults (Elkin, et. al., 1989). Thus, it is intentionally not therapeutically neutral but rather a presumably effective supportive therapy which will be constant across the three treatment groups.

II. Aims of the CMAD

A. General Aims

In order to provide valid data with which to compare the effectiveness of the treatment and with which to address other major questions posed by this study, each of the study treatment conditions must be provided in an optimal fashion allowing for maximal therapeutic effectiveness. The purpose of this manual is to describe the Clinical Management Condition and to outline the procedures involved in the optimal delivery of this condition. The CMAD has been designed to resemble as closely as possible the manner in which medications would be most effectively adolescent administered in the clinical management of depressed adolescent outpatients.

B. Specific Aims

One of the main goals of the CMAD is to foster and maintain the kind of therapeutic relationship between patient and pharmacotherapist that will promote compliance with the treatment regimen in general and, in particular, compliance with medication. A second major goal of the CMAD is to promote the patient's continuation in the study throughout the entire 8-week study period. This will be most difficult to achieve both early and late in treatment: early if the patient is not receiving obvious benefit; later if the patient has a partial or complete therapeutic response and does not appreciate the need to continue therapy. Maintaining a very low attrition rate is crucial in producing reliable data.

III. Protocol for the CMAD

A. General Organization and Focus of the Psychopharmacotherapy Sessions

The pharmacotherapist must be responsive to the adolescent's complaints and needs while also maintaining control in the interview. This can best be accomplished through a rational and organized structuring of sessions. The pharmacotherapist's ability to focus and appropriately sequence the inquiry and discussion is of great importance for an effective psychopharmacotherapy session. In considering the issue of initial focusing, it is important to remember that the patient is finally entering a treatment situation after several weeks of preliminary screening and data gathering. The patient's clinical needs and treatment expectations are of the highest priority and deserve the utmost respect and attention as the pharmacotherapist proceeds with organizing the interview. The initial sessions should ideally be developed as therapist-patient collaborative efforts to characterize general and specific features of the depressive episode. A therapeutic agenda can thus be established on which to base treatment expectations consistent with the psychopharmacotherapy approach.

The appropriate organization and structuring of the CMAD sessions together with the inclusion of the appropriate content should sufficiently distinguish the sessions from psychotherapy and help prevent the pharmacotherapist from straying into "psychotherapeutic territory." We do not wish to encourage an interview structure or process so rigidly structured as to preclude opportunities from empathy, support, and those naturally spontaneous and more casual exchanges that permit treatment to be carried out in a warm and truly human way. However, open-ended inquiry into or discussion of interpersonal relationships is to be especially avoided.

The appropriate sequencing of clinical inquiry and therapeutic discussion is also an important factor influencing the effectiveness of the session. Generally, sessions should begin with a general review of the previous week's events and activities, with therapist eliciting information about domains not specifically covered, including school, home, friends, family, and specific inquiry about previously-identified important situations, activities, or relationships. Specific target symptoms should be asked about if not brought up spontaneously. Potential or past side effects should then be reviewed. Among the more frequent examples of inappropriate sequencing are the discussion of medication effects prior to the elicitation of target symptoms and the premature discussion of side effects prior to a thorough discussion of therapeutic benefits of the medication.

B. Initial Session

The initial patient visit will consist of a 1-hour session, divided approximately into 30 minutes with the adolescent and parent(s) and 30 minutes with the patient alone. During this session the pharmacotherapist will attempt to establish a positive relationship with the adolescent and parents in the content of a thorough discussion of the course of the present as well as previous episodes of depressive illness. The elucidation of the past history, family history, and relevant medical history will focus on elaborating information about clinical symptoms of major depression.

Considerable attention will be devoted to the establishment of the target symptoms* as a basis for ongoing clinical assessment and management within CMAD. The content of subsequent sessions will depend on the accurate and comprehensive establishment of target symptoms in the initial sessions. In addition to providing material for future sessions, discussion of target symptoms will help structure sessions so that active psychotherapeutic interventions can be avoided, thus keeping the pharmacotherapy sessions as free from "psychotherapeutic contamination" as possible. The initial comprehensive determination of target and accessory symptoms will also be necessary for later detection of study medication side effects. **The Symptom, Sign, Side-Effect Checklist will provide a basic inventory and format for obtaining the baseline and subsequent medication side-effect assessments. Also, in the process of assessing the patient's symptoms and experience of depressive illness, the pharmacotherapist should routinely and completely assess suicidal ideation and impulses. This will be particularly crucial in patients with a previous history of depressive illness involving suicidal ideation or behavior.

* Target the symptoms include sleep disturbance, appetite disturbance, diurnal mood variations, anhedonia, feelings of hopelessness, suicidal ideation, etc. Symptoms such as anxiety, irritability, and hypochondriacal preoccupation's should also be explored.

** The Term "study medication" will be used throughout the CMAD as a generic term for the active drugs or placebo.

A basic and easily understandable explanatory model of how and why antidepressant medication is effective should be provided. Theoretical and practical aspects of the treatment rationale should be presented in the patient's own language, and discussion of the patient's concerns and questions should be actively facilitated.

The rationale for the use of medication in the treatment of depression should be explained and any resistance to the idea of medication therapy should be addressed. The patient should be allowed and even encouraged to express his or her concerns, fears, and attitudes regarding medication in general and psychotropic drugs in particular. Common concerns of adolescents and parents should be addressed, such as the risk of becoming dependent on the medication, how long one needs to take medication, and potential side effects. The interpersonal ambience should provide the patient an opportunity to air prejudices, distortions, and fantasies regarding either the positive or negative effects of the medication. These distortions should be corrected by responding to the patient's questions with further clarification and support.

It is critically important to obtain a comprehensive history of previous experiences with and responses to pharmacotherapy (including specific medication dosages and the duration of treatment) prior to explanation and discussion of the current treatment. Educating the patient about the individual variability of responses often encountered with different antidepressants, coupled with assurances that medication response will be closely monitored, will help the patient and parents overcome possible negative attitudes based on previous experiences and/or ignorance or misinformation about antidepressant pharmacotherapy.

The adolescent and the parents should be instructed about the importance of taking the prescribed dosage of study medication and apprised of the fact that adjustment of the dosage may be necessary to achieve the desired effect. The patient should also be instructed that it may be 2 to 6 weeks before a therapeutic response is achieved and should be informed about which symptoms (e.g., sleep disturbance, appetite disturbance) are likely to respond to treatment initially. The concept of gradual response or progressive improvement should be discussed so that patients do not unrealistically expect an early "all or none" response.

The possibility of the occurrence of side effects during treatment should be discussed. Pharmacotherapists should mention the side effects which most frequently occurred during treatment (dry mouth, dizziness or lightheadedness, especially on changing positions, blurred vision, nonspecific sedative effects, and delayed micturition). The patient should be instructed that these side effects are not dangerous if reported to the pharmacotherapist and managed correctly. If mild side effects do occur, the patient will be instructed to continue the medication at the prescribed dose, if possible, until the physician can be reached. If more severe side effects occur and the patient is not able to reach the

pharmacotherapist immediately, the medication should be temporarily discontinued until the therapist is contacted.

The patient should be instructed that future visits will be 20 to 45 minutes in length, generally with patient alone. Up to 15 minutes of a session may be spent with the adolescent and parents(s) if the clinician, patient, or parents feel this is necessary. The session will be devoted to reviewing the patient's general progress, the current status of depressive signs and symptoms, and possible side effects, as well as to discussing his or her questions and concerns. It should be made clear that this time limit is relatively inflexible and will not be modified unless there is some pressing need. The patient should be instructed that these sessions will be conducted on a weekly basis but that in case of severe side effects or worsening symptoms of the illness, it will be possible to reach the pharmacotherapist or an associate by telephone.

Especially during the initial session, the pharmacotherapist should attempt to develop an accepting, understanding, and supportive relationship with the patient and to convey hope and optimism regarding the outcome of treatment. The pharmacotherapist should also clearly communicate any expectation that the patient will improve and should explicitly link this expectation of improvement or mitigation of target symptoms with the idea of positive therapeutic outcome as a result of antidepressant pharmacotherapy. By assisting the patient in developing a positive set of hopeful expectations linking the relief of core symptoms with medication effects, the pharmacotherapist creates opportunities for ongoing therapeutic discussions focused on those aspects of the medical treatment of depressive illness that are personally important to the patient.

Here we would like to present a brief sketch of an ideal first session. In such an idealized version of the initial psychopharmacotherapy session, we see the pharmacotherapist warmly greeting and welcoming the adolescent and his/her parent(s), and providing an explicit introduction that unambiguously establishes his/her role as the doctor who will be in charge of the patient's clinical care for the duration of the study. This introduction should distinguish the pharmacotherapist's role as primary managing clinician from the research roles of various study personnel the patient has previously seen. It is during the initial exchange that the pharmacotherapist clearly establishes the overall importance of the patient's clinical care and well-being in the study context. The psychiatrist should also demonstrate knowledge about the study in general.

After acknowledging review of the patient's diagnostic summary, the psychiatrist should begin an independent evaluation with the primary objective of establishing a set of core or target symptoms, manifestations of the underlying disease process which will serve as indicators of potential response to the treatment that will be prescribed. The therapist should inquire about all domains of the adolescent's life, e.g., school, home, friends, family, favorite activities, and how the symptoms have affected these. Accessory signs and symptoms can be simultaneously elicited. Screening for the presence of possible medication side effects at baseline can also be done as an associate component of this phase of the session; however, the use of the Symptom, Sign, Side-Effect Checklist as a primary device or method to maintain structure is definitely not recommended. At appropriate junctures, clinical attention and questions should be directed towards life problems with the objective of information gathering, learning about the patient as a person, and conveying empathic concern. The pharmacotherapist should not, however, engage in psychodynamic incursions and digressions.

We recommend that time be allowed for the psychiatrist to establish and convey a sense of warmth, concern, and authoritative responsibility and knowledgeability about the pharmacotherapy, to appropriately educate the patient about how and why the medication can help, and to allow for questions from the patient and further discussion.

C. Second and Subsequent Sessions

At the second and subsequent sessions, the pharmacotherapist will meet with the patient for approximately 20 to 30 minutes, extending to 45 minutes if necessary because of clinical concerns. Parents may be included for up to 15 minutes of this time, as described above. A systematic inquiry into the presence, intensity, and features of the already established target symptoms that characterize the patient's depression should provide the basis for the assessment of response to treatment, following the general sequence described in A. This systematic inquiry should also provide a framework for ongoing assessment during subsequent sessions. Similarly, a systematic evaluation for side effects will be made during the second and all subsequent sessions.

The Symptoms, Sign, Side-Effect Checklist will serve as a standard format for evaluating the above. Regarding technique when administering the Symptom, Sign, Side-Effect Checklist, we suggest that the pharmacotherapist inquire about the presence of items by presenting them in groups of related items, e.g., "Have you ever had weakness, faintness, dizziness, lightheadedness, headaches, visual disturbances?" This allows the screening for symptoms and signs to be done efficiently, leaving more time for other therapeutic tasks. Sitting and standing blood pressures should be routinely taken during the first, second, fourth and sixth sessions to assess for postural hypertension. If at any other time the patient presents with signs or symptoms suggestive of postural hypotension (i.e.,

dizziness or lightheadedness upon arising from a sitting or recumbent position), then the sitting and standing blood pressure should be taken, recorded, and appropriate clinical management initiated.

During the second session the patient will be asked about reactions to the medication, possible side effects, and possible early therapeutic effects. Patients who are unusually sensitive to the medication or who have idiosyncratic reactions (palpitations, etc.) will be identified at this time.

Since it is highly possible that no therapeutic response will have occurred by the second session, special effort will usually be necessary to reinforce the patient's continued hope and optimism regarding improvement. The patient should be encourage to continue the medication and should also be instructed that higher doses usually produce symptomatic improvement. Although it is unlikely that the patient will have any appreciable side effects to the medication at this point, there may be minor side effects, especially in patients who are apprehensive about taking medication. Further education efforts regarding the "hows" and "whys" of antidepressant medication may be helpful and perhaps necessary to avoid dropouts and/or noncompliance during the early stages of the pharmacotherapeutic treatment.

Here, we would like to emphasize the importance of flexibility in determining the duration of pharmacotherapy sessions. Time should be allowed to indicate general interest in the adolescent's life and to maintain a positive relationship. For some patients whose clinical course has demonstrated significant improvement, a 20-minute visit may be quite adequate and appropriate. On the other hand, we do not recommend visits under 15 minutes or over 45 minutes, except in extraordinary circumstances when the clinical management definitely requires an extended period of time.

D. Prescription of Study Medication

Study medication will be prescribed each week and will consist of identical containers of identical capsules for all three conditions. A sufficient number of capsules should be provided to cover the possibility of a missed appointment by the patient or pharmacotherapist, i.e., an additional 2 to 3 days of study medication may be prescribed. However, medication may only be prescribed for a maximum period of 10 days. If there is risk of an overdose, the pharmacotherapist may choose to have the patient return for an additional appointment that week in order to limit the total amount of medication the patient has in his/her possession at any one time. Patients are instructed to return all unused medication to the therapist at each session. The physician must maintain an accurate record of all unused study medication. The number of capsules prescribed and the number of unused capsules should be recorded at each session.

The CMAD dosage schedule is designed to optimize the possibility of a full response to the study medication by approximating usual clinical practice. To accomplish this, an attempt should be made to systematically expose each patient to a full dose of medication by the third week of the study a
nd to maintain this dosage of study medication for a period of at least 4 weeks. If, at any dosage, the patient manifests severe side effects which appear to be dose related (e.g., anticholinergic effects, drowsiness), this may signify that a lower dose is the maximum tolerated dose at that time. If the patient dose not appear to be responding optimally to the study medication at a given dosage level, the dosage may be increased up to the ceiling dose. This potential range of dosage combined with flexibility in the dosage schedule should assure an adequate trial of medication for each patient (see Appendix).

The very first dosages taken by the patient should constitute a test for hypersensitivity. If overwhelmingly severe side effects (e.g., extreme dysphoria or anxiety, massive sedation, headache) emerge in response to the initial dosage of the medication, the dose may be dropped. However, if the patient is not able to achieve a dosage of (x) without significant or severe side effects, he/she should then be considered hypersensitive to the medication and withdrawn according to the study guidelines.

If moderately severe side effects emerge as the dose is being increased, the patient should attempt to contact the pharmacotherapist. Several alternatives are then available. For example, the dosage may be redistributed over the course of the day in an attempt to increase patient tolerance, or the dosage may be temporarily reduced in order to allow the patient to accommodate. If dosage has been decreased because of side effects, the pharmacotherapist should later attempt to increase the dosage more gradually until a therapeutic level has been achieved unless there is a resurgence of severe side effects, the appearance of new and serious side effects, or clinical deterioration. Over the ensuing weeks, the pharmacotherapist may increase the medication up to the maximum dosage based on the patient's response to treatment.

Not all patients may be able to tolerate maximal levels of study medication. If only lower doses are tolerated, therapist should note the reason for this and use direct patient quotations when possible. Under no circumstances should patients be prescribed less than (x) per day of study medication. In the rare case where a patient cannot tolerate at least (x) of study medication, the patient should be withdrawn from the study and an appropriate referral should be made. If a patient misses a dose of medication, it should be recorded and the patient advised not to make up the missed dose, but to continue with the prescribed dosage schedule.

We would like to emphasize the importance of dosage flexibility. The schedule guidelines recommended here are not meant to be absolute, although there is, indeed, an upper limit of (x) of study medication which is not to be exceeded.

Some patients, because of unusual sensitivity to the medication, may need to be advanced more slowly than suggested. In these cases, the pharmacotherapist may adopt a scheduling strategy of alternating doses every other day to achieve a more gradual dosage increase.

Dosage changes and titration's are also recommended to manage side effects, although the therapist should, if possible, attempt to deliver the maximal therapeutic dose. In addition, dosage flexibility is also recommended during the latter weeks of treatment as patients may experience relapse when a decrease in dosage occurs. In such circumstances we recommend that the patient continue on sufficient medication to maintain the therapeutic response.

E. Pharmacotherapy Management Issues

Drug interaction with other medication. Patients should be instructed to avoid all other medications, including over-the-counter compounds, if possible, during the study treatment. The use of proprietary (nonprescription) medication that the patient may take under ordinary circumstance such as aspirin or acetaminophen for headache or laxatives for constipation is acceptable, but the use of prescription medication is not allowed. If the patient is using other medication (e.g., laxatives), he/she should be advised to allow at least a 2-hour interval between the time of ingesting study medication and the time of ingesting the laxative to avoid possible interference with absorption of the study medication. If the ingestion of a prescription medication is unavoidable (e.g., antibiotic for an acute febrile bacterial illness), the medication, dose, and reason for prescribing should be recorded. Patients should also be told that if they require dental work while on study medication, their dentist should be advised that they might be on a tricyclic medication that could interact adversely with the epinephrine-like medication often used in local anesthetic preparations.

Adolescents should be advised to refrain from the use of alcohol, marijuana, or other drugs. Substance use should be discussed frankly as something which may prolong their depression and make treatment ineffective. One should not, however, attempt to deter substance used by exaggerating the risks of concomitant use with study medication. Adolescents have often been given inaccurate information about effects of substance abuse and this approach is likely to impair the credibility of the therapist.

Laboratory work. At any time during the course of treatment, the CMAD psychiatrist may request laboratory tests (e.g., liver function tests) or an evaluation of the patient by a pediatrician.

Side-effects management. The thorough discussion and successful management of disconcerting or troublesome side effects early on in the course of treatment is often of critical significance with regard to pharmacotherapy compliance in

general. Detecting anxiety associated with an increase in dosage or disturbing side effects resulting from such an increase is necessary for the successful management of further dosage adjustments. Mild side effects may often be adequately managed by explaining to patients that the severity of side effects usually decreases over time. This is most effectively accomplished through discussion carried out in the context of a concerned, reassuring, and supportive attitude on the part of the pharmacotherapist. Moderately severe side effects are usually best managed by a temporary lowering of the dose. Advice may be given regarding physiological management of side effects (e.g., laxative diet for the mitigation of constipation). Managing more severe side effects may require a permanent lowering of the dosage. Other than the ordinary use of proprietary medication, adjunctive medication for the management of side effects (e.g., urecholine for the management of urinary retention) is not permitted.

F. General Management Issues

Avoiding dropouts. The avoidance of dropouts from the clinical management condition will depend to a great extent on the nature of the relationship established between the pharmacotherapist, the adolescent patient, and the parents. In order to avoid dropouts, it is important that the pharmacotherapist not only be supportive and encouraging, but remind the patient of the delayed effect of the medication and reiterate the possibility that the dosage may need to be increased. Without such attention and reassurance there is a danger that the patient who experiences an absence of therapeutic benefit particularly in the presence of side effects may discontinue treatment within the first 2 to 4 weeks.

Phone calls. Especially during the early weeks of treatment, the physician must be available to the patient and the parents for telephone calls between appointments for questions about side effects which may occur as medication dosage is increased. Phone calls allow the pharmacotherapist to receive clinical information from the patient about symptoms or medication side effects, make a determination about their significance, and provide an opportunity for immediate management of problems. In addition, they provide the patient with the reassuring knowledge that a concerned and available physician is managing the psychopharmacotherapy. The reassurance provided by such brief calls in everyday clinical practice often makes the difference between a successful outcome and early treatment dropout of a patient who might have responded to the medication. These phone calls can often provide the support necessary to assist the patient in continuing medication despite depressive feelings of hopelessness and discouragement or fears and anxieties stimulated by the occurrence of side effects. It is often reassuring to a patient to know that the physician will be available at a particular time of day to respond to phone calls if necessary. The patient should also be instructed that in the event the pharmacotherapist is not immediately available, there is an emergency number at which to contact a psychiatrist 24 hours a day. In addition, at the outset of the

study, each patient is provided with emergency numbers for contacting the Principal Investigator and Project Coordinator at that site. Phone calls are not to constitute supplementary or adjunctive therapy. The CMAD physician should keep an accurate record of every phone call received from the patient and his/her family. This information should be noted and should include date, time, length of call, content of call, specific and general concerns, and the therapist's response (e.g., advice, instructions, education, and medication adjustments).

Family accessory visits. The clinician will clearly indicate that sessions are primarily for the adolescent, but that input from parents is valued and that parents' concerns will be addressed. Parents will be included in up to 15 minutes of a session at least monthly, up to weekly in the case of urgent concerns on the part of the parent. Parents should be helped to share their observations or concerns in the presence of the adolescent, rather than meeting with the clinician alone, in order to minimize distrust by the adolescent.

These contacts should emphasize open airing of concerns, provide information about affective disorder and pharmacotherapy, and reassure parents that the safety of their son or daughter is being protected. Such intervention may result in increased family support, but active family therapy intervention is not to be conducted during the eight week study.

The parents will also be involved in the four psychoeducational sessions described below.

Clinical deterioration. A clinical management issue of major significance is the referral of unimproved or deteriorating patients for a clinical evaluation. If the patient has shown no improvement or begins to show clinical deterioration after a reasonable therapeutic trial of study medication and further continuation under such circumstance would be detrimental to the patient, a referral should be made for a clinical evaluation to determine whether the patient should be withdrawn from the study. Such clinical evaluations can be done by the PI or a psychiatrist designated by the PI. If the patient is withdrawn from the study, appropriate referral arrangements will be made by research staff. The pharmacotherapist has full responsibility and authority to refer the patient for clinical evaluation at any time regarding the patient's suitability for remaining in the study.

Crisis Management. Treatment of adolescents often requires the therapist to respond to crises which may involve risk of self-destructive or assaultive behavior, intensification of conflict in the family, or disruption of the relationship with the therapist. These possibilities should be anticipated in the initial session and in the four Psychoeducational sessions. Certain general principles should guide the management of such crises. The first priority must be to assess the degree of potential harm to the patient or others and to assure safety. The therapist should take an actively empathic, supportive role rather than being

neutral or distant. One may offer assistance with problem-solving, such as by asking the patient to talk about alternative options and their probable consequences. Simple advice or suggestions may be given. Sustained focus on interpersonal difficulties, e.g. role transitions or disputes other than the crisis itself, on cognitive distortions, or psychodydnamic interpretations are not part of CMAD. A general hierarchy of response, then, beginning with the most universal elements, is:

1. Evaluate risk of harm to self or others. Assure safety.
2. Empathic listening.
3. Assistance with problem-solving.
4. Advice or suggestions.

Options for response to crisis include extra sessions, more involvement of parents in sessions, consultation to school, and full or partial hospitalization. None of these interventions requires withdrawal of the subject from the study, as long as the medication protocol can be continued. Such additional interventions should be kept as brief as possible, with the patient returning to the study treatment schedule as soon as possible.

G. Termination

Even though active psychotherapy as such is not provided in the CMAD, a significant doctor-patient relationship will likely develop during the 8 weeks of the study. In light of this, discussion of termination should occur and will likely be an important issue in the last few sessions. A sensitively directed inquiry and guided discussion that permits the patient to express inquiry and guided discussion that permits the patient to express feelings and ideas about having participated in the study, attitude towards the therapist, fears about discontinuing medication, future plans, and possible future therapy needs is essential. Deficiencies in dealing with termination issues can led to instances of "acting out" (e.g., patients abruptly and unilaterally stopping their medications or not returning for tapering sessions). If previously unrecognized or currently unresolved termination issues still remain, an additional session during the tapering phase may be necessary to discuss such issues. However, this is not encouraged as termination issues should be adequately addressed during the final session.

If, at any time during the course of treatment, the patient inquires about continuing treatment beyond the 8-week study period, he/she should be reassured that the appropriate referral will be made if it appears that the patient needs further treatment at the conclusion of the study period.

IV. Maintenance and Continuation Phases

A. Medication and Evaluation Schedule

In most cases, patients who demonstrate a "medication response" will do so between the second and eighth week of treatment. The period after the demonstrated therapeutic response should be considered the maintenance phase.

It is crucial that the patient who is showing a medication response as evidenced by clinical improvement be educated regarding the need to continue medication throughout the entire study period. This should be emphasized especially at the point when the patient begins to show improvement as patients are at high risk for discontinuing treatment shortly after an initial improvement.

In the event that a patient shows a dramatic improvement and develops a state of euphoria or hypomania, it may be necessary to lower the dosage. If this occurs, the therapist should attempt to maintain at least the minimum medication dosage of "x" mg. If the episode progresses to definite mania, it may be necessary to discontinue medication and to withdraw this patient from the study.

The schedule and nature of evaluations in the Continuation Phase should be reviewed prior to the end of the acute treatment study.

B. Evaluation of Response to Treatment

The Symptom, Sign, Side-Effect Checklist will serve as a standard format for assessing symptoms as well as evaluating side effects, and will be completed after every session. Change in the number and intensity of target symptoms of depression and the presence and severity of side effects should be the primary referents for making decisions concerning changes in medication dosage. It is important that increases in the medication dosage be continued as long as any target symptoms of depression remain, since patients who achieve only partial improvement frequently relapse on medication several weeks later.

In the case of patients who fail to improve, the pharmacotherapist and/or the patient may assume that the patient has been receiving a placebo. However, it is important not to make this assumption as some patients may respond slowly, not showing a clinical response until exposed to an adequate blood level for several weeks (blood levels will be determined throughout the study, but will not be available to the clinicians for dosage adjustment). For this reason, it is essential to continue to increase the medication dosage if possible even though improvement has not been achieved. Since and adequate dose may make the difference in

response, it is entirely reasonable and honest to encourage a patient to continue treatment with the expectation of a possible future therapeutic response. In summary, pharmacotherapists should manage medication "as if" every patient were receiving active medication.

V. The Interpersonal Context

A. Therapist Factors

It is essential that pharmacotherapists have sufficient experience with the use of antidepressants to have an appreciation for the importance of adequate dosage as a condition for maximal therapeutic response. The should also be aware of the concept of delayed therapeutic response and its relationship to adequate dosage. Pharmacotherapists should also be familiar with the relative medical importance of side effects and methods for their management. A background of knowledge about, and clinical experience in, the use of antidepressants coupled with confidence in their therapeutic value will help foster a therapeutic relationship that can facilitate patient compliance, prevent premature discontinuation of medication, and contribute to a beneficial outcome.

The importance of this knowledge is highlighted by studies of the treatment-resistant depressions. In examining the reasons for patients' failure to respond to pharmacotherapy combined with supportive psychotherapy, researchers found that at least 50 percent of the patients did not receive an adequate trial of any antidepressant medication because the physician did not prescribe adequate doses of the medication or stopped the medication prematurely due to patient noncompliance or the emergence of side effects of little medical consequences. Furthermore, noncompliance was often a result of lack of an adequate relationship with the physician. For some patients, failure to comply with the treatment regimen was attributed to insufficient information about side effects or about the course of therapeutic effect.

B. Role of Therapist

Of critical importance is the pharmacotherapist's role as physician with primary clinical responsibility for the patient. The pharmacotherapist should function as the patient's physician just as physician would in a nonresearch clinical setting. Pharmacotherapists should not permit the study design, research procedures, or their role as members of a research team to interfere with their role of primary responsibility for the care of the patient. Pharmacotherapists should actively assure the patient and parents of their primary and unwavering commitment to the patient's care. The supportive ad therapeutic engagement of the patient is an integral component of the CMAD. In order to engage the patient rapidly in a positive relationship and inspire confidence in the treatment condition, pharmacotherapists should create an ambiance of warmth and trust and convey a positive and optimistic attitude about the patient's clinical treatment. Ideally pharmacotherapists should be able to communicate relevant clinical information

to the patient in understandable terms, if possible in the patient's own words, and convey their knowledge and experience in the pharmacotherapy of depressive disorders.

Any tendency to administer the pharmacotherapy condition mechanically, to maintain inappropriate distance, or to relate in a perfunctory way is antitherapeutic and must be avoided. The rationalization of antitherapeutic behavior such as distancing by conceptualizing it as consistent with the role of "research therapist" should be considered a breach of doctor-patient responsibility. Neither remoteness nor aloofness in the name of therapeutic neutrality has a place in the CMAD. It is hoped that the pharmacotherapy condition in this study will approximate the best and most effective treatment that could be provided by an eclectic psychiatrist, given the study constraints on active psychotherapeutic intervention.

C. Interpersonal Processes

Although pharmacotherapists should concentrate on target symptoms and side effects, certain interpersonal processes are both permitted and suggested in the CMAD conditions. Clinical management requires the basic keen observational skills, interpersonal sensitivities, and technical interventions that are ideally characteristic of any competent psychiatrist. As described above, flexibility, empathy with both the adolescent and the parents, and active interest are encouraged.

The pharmacotherapist should engage in the types of interpersonal interventions which foster a good doctor-patient relationship, while at the same time avoiding specific interpersonal interactions that would be characterized as formal psychotherapeutic interventions. For example, inquiry into the cognitive, affective, and behavioral-interpersonal realm for the purpose of clarifying the patient's current state or situation is permitted and can be successfully accomplished without utilizing a dynamic, cognitive, behavioral, or other specific organized, systematized psychotherapeutic approach. The separation of these two levels of inquiry and intervention is somewhat arbitrary and may be experienced by the pharmacotherapist as a constraint.

However, it is important that the prohibition on active psychotherapeutic intervention not result in the patient's receiving limited emotional support. The general injunction against "active psychotherapy" should not lead to self-consciousness or rigidity that diminishes the therapist's responsiveness to the patient's immediate need for supportive interaction. In summary, clinically indicated and appropriate supportive psychotherapeutic measures and interventions are sanctioned, whereas interventions related to specific organized systems of psychotherapy are not permitted. See the sample clinical vignettes.

The following sections define several areas of interpersonal process and types of intervention that are permitted within the context of the Clinical Management Condition and several that are not.

1. Interpersonal context factors. Depression is an illness in which the patient is frequently anxious and may have negative expectations regarding the treatment intervention and outcome. Because of this, it is critically important to elicit the patient's confidence in the treatment. This can be accomplished through attention to the interpersonal context of the treatment. Research has shown that the medication is more efficacious when it is administered within a supportive interpersonal context. Frequently, the patient will need reassurance to continue to take medication in spite of mild and medically insignificant but anxiety-provoking side effects such as dry mouth and blurred vision. The patient may also need support in the face of criticism by family, friends, or peers who communicate negative attitudes about the medication. The patient's positive and meaningful relationship with the physician is crucial in sustaining medication compliance under adverse or unsupportive psychosocial circumstances. If the patient has trust in the physician, believes in his/her knowledge and competence, and maintains a conviction that the medication will be helpful, the patient will persist in the course of therapy even in the absence of initial improvement.

2. Psychological support. Psychological support should be provided by the pharmacotherapist throughout the course of treatment. Conveying a sense of hope and optimism is especially necessary in the earlier phase of treatment when the patient is likely to develop doubts that the treatment will help in the face of an initial lack of improvement. Reassurance may be particularly important if the patient is having medication side effects or physical symptoms of depressive illness. Furthermore, the patient may need special reassurance in the face of criticism of medication use by relatives or friends.

3. Instruction, education, and information giving. It is particularly important that, in the first session, the patient be instructed about the characteristics of the medication and the reason that it is given for depression. In addition, there should be some discussion of the notion that depression may be related to a change in brain biochemistry which the medication may help correct. This explanation must be general enough to allow for the possibility that psychotherapeutic treatment can also be effective and the possibility that the type of medication used in the study may not be effective for each individual patient. Physical symptoms of depression and the side effects of the medication should also be discussed.

4. Advice. Frequently, patients will ask what they can do to help themselves out of their depression. The pharmacotherapist might give simple suggestions to the patient such as advising increased physical activity (e.g.,

age-appropriate exercise). Patients may also request advice concerning whether to make decisions or to attempt to engage in certain activities during a depressive episode. Simple advice is permitted within the context of the CMAD. For instance, a patient under certain circumstances might be advised to avoid a particular stressful situation or advised to socialize more, depending on the situation. Pharmacotherapists should keep notes on any such direct advise that is given.

5. Ventilation and abreaction. Patients will usually need to describe their depressive feelings at length and share their fears and doubts. Within the limited time frame of the CMAD sessions, patients should be permitted to do this to the extent that it is thought to be of help in sustaining a positive therapeutic relationship.

The following list defines several areas of interpersonal processes and types of intervention which are not permitted within the context of the CMAD:

1. Focusing on specific psychological themes, especially interpersonal relationships and cognitive distortions.

2. The interpretation of interpersonal events, styles of interpersonal relating, suppressed feelings, or distorted cognition's.

3. Interpretations relating to recent losses, secondary gain, and other psychological mechanisms.

4. Clarification of the patient's feelings toward others and toward the therapist.

5. Specific behavioral instructions or routines other than simple advice about activity such as instructions that the patient should be going out more as he/she shows improvement.

6. Explanations of the psychodynamics of depressive conditions (e.g., suppressed anger, shame, and helplessness).

7. Any involved interpersonal interactions.

DO'S and DON'T of CMAD

DO'S:

1. Speak about current experiences.
2. Inquire about feelings.
3. Acknowledge understanding of feelings.
4. Inquire about events not spontaneously reported.
5. Inquire about the patient's thoughts about solving problems
6. Express sympathy if misfortunes occur.
7. Communicate shared pleasure at positive events.
8. Congratulate patient for success.
9. Give the patient hope of the likelihood of his/her getting better.

DON'Ts:

1. Relate current conflict or attitudes to earlier experiences.
2. Draw analogies between behavior toward some people and other, such toward parent and toward friends, siblings, teachers, etc.
3. Challenge patient's view of self or others.
4. Give specific suggestions for resolving conflict.
5. Bring up childhood experiences.
6. Bring to the patient's attention that his/her behavior appears to represent specific difficulties, such as fear of failure, fear of rejection, etc.
7. Bring to the patient's attention that his/her behavior has intents that he/she is not acknowledging (i.e., punishing parents, getting revenge on friends, trying to prove is generous, etc.).

VI. Psychoeducational Program

All patients and at least one parent - both if possible - will participate in a psychoeducational program consisting of an initial two-session course on Weeks 1 and 2 and review session in Weeks 4 and 6. These will be up to 50 minutes in length.

The program will use the manual Living with Depression: A Survival Manual for Families, developed by Kim Poling, M.S.W., Western Psychiatric Institute and Clinic (1989). The eight sections will be covered in order in the two initial sessions, with the clinician presenting material variably, in the terms understandable to the patient and family, and responding to questions. The manual will be given to the family to read but it is expected that comprehension of the written material will vary. The clinician may answer questions about how the information fits a particular family, but the emphasis will be on sharing information rather than exploring family interactions. Consistent with the CMAD, simple advice can be given (see V. The Interpersonal Context, C.4).

In each of the two review sessions, the clinician will briefly review the outline of the manual and review areas of particular interest and respond to questions. The family and patient are likely to focus on the last three sections: The Family and Depression, Helping The Depressed Person, and Coping with Depression. When family conflicts are presented, the clinician's responses should communicate empathy for the stress of living with a depressed or irritable adolescent, and identification of problematic behaviors or interactions which may be the results of the depression. The family should be helped to be supportive and to avoid critical or pejorative comments, or punitive behavior which results from their frustration.

VII. Pharmacotherapist Training and Adherence Monitoring

Pharmacotherapists will be psychiatrists who have experience with adolescents and with the pharmacotherapy of affective disorders. All will review three videotaped sessions of CMAD and then conduct at least six session, with three different patient, using the model. Audiotapes of three tapes - one per patient - will be rated using the Collaborative Study Psychotherapy Rating Scale (CSPRS-6), an instrument developed by the NIMH Treatment of Depression Collaborative Research Program to assess adherence to the models used in that study, i.e. Cognitive Therapy, Interpersonal Psychotherapy, and Clinical Management.

After agreement by a committee of investigators ( ), a pharmacotherapist will be accepted for the study.

Continuing adherence will be assessed by reviewing 3 audiotapes from each pharmacotherapist every 6 months, using the CSPRS-6.

The CSPRS-6 is a 96 item instrument developed for rating audiotapes of therapy sessions with depressed adult outpatients. A review of the instrument indicates that it can be used without modification to rate sessions with adolescents. The instrument has scaled to assess Cognitive, Interpersonal and Clinical Management models, Facilitative Conditions (e.g. supportiveness, warmth), Explicit Directiveness, "Tangential" Cognitive and Interpersonal Therapy, and nonspecific strategies (e.g.), the entire instrument will be used to allow a full characterization of the Clinical Management sessions, including the degree of overlap with other models and the extent of the use of nonspecific therapeutic characteristics.

The use of the CSPRS-6 is described in the Raters Manual for the 96-item CSPRS-6. Performance of the instrument and its scale V are reviewed and selection and training of raters for the CSPRS-6 in the Final Report: System for Rating Psychotherapy Audiotapes.

APPENDIX H

EXTERNAL REVIEWERS

Blank Case Report Form (CRF)

Tracking Number

Project	Protocol	Center	Patient Number
29060	329	0	

SmithKline Beecham
Pharmaceuticals

CONFIDENTIAL

CASE REPORT FORM

PROTOCOL 29060/329

SCREENING/ELIGIBILITY - BINDER 1

A Multi-Center, Double-Blind, Placebo Controlled Study of Paroxetine and Imipramine in Adolescents with Unipolar Major Depression

Patient Initials ____ Country _____

SMITHKLINE BEECHAM PROTOCOL 29060/329 - SCHEDULE OF PROCEDURES

Assessments	Baseline		Acute Phase								Continuation Phase					
Time (weeks)	-1	0	1	2	3	4	5	6	7	8	12	16	20	24	28	32
Informed Consent	●															
Medical History and Physical Exam	●															
Clinical Laboratory Studies	● [1]									●			●			●
Serum Pregnancy	●		● [2]	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....
ECG	●			●		●		●		●			●			●
Vital Signs	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Hamilton Depression Scale	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Full K-SADS-L	●															●
Affect Section of K-SADS-L		●		●		●		●		●	●	●	●	●	●	
C-GAS	●															
CGI		●	●	●	●	●	●	●	●	●	●	●	●		●	●
SADS-L	●															
FH-FHE	●															
Autonomous Functioning Checklist	●									●						●
Self Perception Profile	●									●						●
Sickness Impact Scale	●									●						●
Randomization		●														
Adverse Experiences		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Supportive Psychotherapy		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Plasma Sampling for Drug Analysis	●					●				●				●		●
Study Medication Record			●	●	●	●	●	●	●	●	●	●	●	●	●	●
Concomitant Medication	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●

[1] - Clinical laboratory studies should include a Urine Drug Screen
[2] - On suspicion of pregnancy

GENERAL INSTRUCTIONS

Print clearly in CAPITAL LETTERS using a black ball-point pen and press firmly so that all copies are legible. DO NOT print in shaded areas. Answer all questions on every page.

The plastic writing board in the back of the binder should be used to divide each set of pages before writing on them with a ball-point pen.

Important: Errors should be crossed with a single line and the alteration made as close to the original as possible. All alterations must be printed, initialled and dated.

DATE

Use the following three-letter abbreviations for month:

January	=	JAN
February	=	FEB
March	=	MAR
April	=	APR
May	=	MAY
June	=	JUN
July	=	JUL
August	=	AUG
September	=	SEP
October	=	OCT
November	=	NOV
December	=	DEC

Example: | 0 | 1 | J | A | N | 9 | 4 | = 1st January 1994

day month year

TIME

Unless specified otherwise, use the 24 hour clock: 00:00 - 23:59.

Example: | 1 | 5 | 3 | 0 | = 3:30 p.m.

24 hr. clock

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MODULE PARAMETERS - SCREENING/ELIGIBILITY

For SmithKline Beecham Use	Project	*29060*
	Protocol	*329*
	Center	
	Tracking Number	
	Module Pages	*V0117*

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DEMOGRAPHY

Date of Birth ____ ____ ____ (day month year)

Sex ☐ Male ☐ Female

Race
☐ White
☐ Black
☐ Oriental
☐ Other - specify: _____

VITAL SIGNS

Weight ☐ lbs ☐ kg	Height ☐ in ☐ cm	Sitting		Standing	
		Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)
___.___	___	___ / ___	___	___ / ___	___

ELECTROCARDIOGRAM

Were there any clinically significant abnormalities?

☐ Yes ☐ No

Record in the Significant Medical/Surgical History and Physical Examination section, page 3.

Date Performed (day month year) ____ ____ ____

Patient Initials ____ Country _____

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PERSONAL HISTORY

Record the highest level of education for mother and father.

Father	Mother	
☐	☐	Graduated JHS
☐	☐	Graduated HS (do not count G.E.D.)
☐	☐	Graduated Junior College (A.A.)
☐	☐	Graduated Senior College (B.A., B.S., B.F.A., etc)
☐	☐	Completed Masters Degree (M.A., M.S., M.S.W., etc.)
☐	☐	Completed Doctoral, Medical, Law or Comparable Degree
☐	☐	Dropped out of JHS
☐	☐	Dropped out of HS
☐	☐	Dropped out of College
☐	☐	Received G.E.D.

Record the occupation for mother and father. If retired or deceased, record prior to retirement or death.

Father	Mother	
☐	☐	Higher executive, proprietors of large concerns, major professionals
☐	☐	Business managers in large concerns, proprietors of medium-sized businesses, minor professionals
☐	☐	Administrative personnel, owners of small independent businesses, minor professionals
☐	☐	Clerical and sales workers, technicians, owners of little businesses
☐	☐	Skilled manual employees
☐	☐	Machine operators, semi-skilled employees
☐	☐	Unskilled employees
☐	☐	Not relevant (e.g., was never employed)

Family Composition

☐ 2 parents home
☐ Single parent alone
☐ Parent + 1 step-parent
☐ 1 parent + 1 common-law parent
☐ Other relative(s) is (are) caretaker
☐ Parent + other relative(s) are caretaker

Number of People in Household ___

Adopted/Natural Offspring

☐ Adopted ☐ Natural

School Placement

☐ Regular Ed
☐ Special ED - specify: _____

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SIGNIFICANT MEDICAL/SURGICAL HISTORY AND PHYSICAL EXAMINATION

Is the patient presently suffering from or has he/she ever suffered from any SIGNIFICANT medical or surgical condition?

☐ No

☐ Yes ⟶ **Provide diagnosis below, listing no more than one diagnosis per line**

Diagnosis	Year of First Diagnosis	Past	Current/ Active
		☐	☐
For SB			
		☐	☐
For SB			
		☐	☐
For SB			
		☐	☐
For SB			
		☐	☐
For SB			
		☐	☐
For SB			
		☐	☐
For SB			
		☐	☐
For SB			
		☐	☐
For SB			
		☐	☐
For SB			
		☐	☐
For SB			
		☐	☐
For SB			

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PRIOR MEDICATION

Has the patient taken any medication in the past month?

☐ No
☐ Yes ⟶ Record details below

➧ Where appropriate, medical conditions recorded here must correlate with conditions listed in the Significant Medical History section, utilizing the same terminology.

Drug Name (Trade Name Preferred)	Total Daily Dose (e.g., 500 mg)	Route	Medical Condition	Start Date *	End Date *	★
				day month year	day month year	
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						

* State dates as precisely as possible
★ If medication continues, mark box.

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LABORATORY TESTS

For SB Lab Number Code

Sample Date ___ ___ ___ ___ ___ ___
day month year

➧ Attach SBCL laboratory report behind this page.

➧ Was a urine sample taken and sent to SBCL for drug abuse analysis?

☐ No
☐ Yes

➧ Are there CLINICALLY SIGNIFICANT ABNORMAL laboratory values?

☐ No
☐ Yes ⟶ Record the findings and/or diagnosis in the Significant Medical/Surgical History and Physical Examination section, page 3.

PLASMA SAMPLE - DRUG CONCENTRATION

Was a plasma sample obtained for drug concentration?

☐ No
☐ Yes

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
   - ☐ 1 = These feeling states indicated only on questioning
   - ☐ 2 = These feeling states spontaneously reported verbally
   - ☐ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
   - ☐ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication

2. Feelings of Guilt
   - ☐ 0 = Absent
   - ☐ 1 = Self reproach, feels he/she has let people down
   - ☐ 2 = Ideas of guilt or rumination over past errors or sinful deeds
   - ☐ 3 = Present illness is a punishment. Delusions of guilt
   - ☐ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide
   - ☐ 0 = Absent
   - ☐ 1 = Feels life is not worth living
   - ☐ 2 = Wishes he/she were dead or any thoughts of possible death to self
   - ☐ 3 = Suicide ideas or gesture
   - ☐ 4 = Attempts at suicide (any serious attempt rates 4)

4. Insomnia Early
   - ☐ 0 = No difficulty falling asleep
   - ☐ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
   - ☐ 2 = Complains of nightly difficulty falling asleep

5. Insomnia Middle
   - ☐ 0 = No difficulty
   - ☐ 1 = Patient complains of being restless and disturbed during the night
   - ☐ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia Late
   - ☐ 0 = No difficulty
   - ☐ 1 = Waking in early hours of the morning but goes back to sleep
   - ☐ 2 = Unable to fall asleep again if he/she gets out of bed

7. Work and Activities
   - ☐ 0 = No difficulty
   - ☐ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
   - ☐ 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
   - ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
   - ☐ 4 = Stopped working because of present illness.

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
- ☐ 0 = Normal speech and thought
- ☐ 1 = Slight retardation at interview
- ☐ 2 = Obvious retardation at interview
- ☐ 3 = Interview difficult
- ☐ 4 = Complete stupor

9. Agitation
- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = "Playing with" hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety Psychic
- ☐ 0 = No difficulty
- ☐ 1 = Subjective tension and irritability
- ☐ 2 = Worrying about minor matters
- ☐ 3 = Apprehensive attitude apparent in face or speech
- ☐ 4 = Fears expressed without questioning

11. Anxiety Somatic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal
- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating. Heavy feelings in abdomen
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. Somatic Symptoms General
- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
- ☐ 2 = Any clear-cut symptoms rates 2

14. Genital Symptoms (such as loss of libido and menstrual disturbances)
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis

- ☐ 0 = Not present
- ☐ 1 = Self-absorption (bodily)
- ☐ 2 = Preoccupation with health
- ☐ 3 = Frequent complaints, requests for help, etc.
- ☐ 4 = Hypochondriacal delusions

16. Loss of Weight

- ☐ 0 = No weight loss
- ☐ 1 = Slight or doubtful loss of weight
- ☐ 2 = Obvious or severe loss of weight

17. Insight

- ☐ 0 = Acknowledges being depressed and ill
- ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
- ☐ 2 = Denies being ill at all

➧ ☐☐ HAMD Score (Items 1-17)

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AUTONOMOUS FUNCTIONING CHECKLIST

Grade in School ____

Informant (mother, father, guardian, other) _____

Instructions

The purpose of this checklist is to learn about what your teenager does every day. There are no "right" or "wrong" things for your teenager to do, since teenagers of different ages do many different things. These questions are simply for the purpose of getting an idea of your teenager's daily activity.

When you answer these questions, first, read the question and think about whether or not it describes what you see or have seen your teenager do. You should answer the questions according to what you know your teenager does or does not do rather than what you ***believe*** or ***think*** he or she ***could*** do or ***could not*** do.

Second, tell us how the question describes what you teenager does by choosing one of the alternatives "0", "1", "2", "3", or "4" from the scale and circling that number in the space to the right of the item. Here is how to use the rating scale with a sample question.

0	1	2	3	4
Does Not Do	**Does Only Rarely**	**Does About Half the Time There is an Opportunity**	**Does Most of the Time There is an Opportunity**	**Does Every Time There is an Opportunity**

Sample Item. Pick up trash in the yard. 0 1 2 3 4

0 - Circle "0" if you have never seen your teenager do this, even if he or she may never have had an opportunity. (For example mark "0" if your teenager has never done it, even if you live in an apartment and do not have a yard.)

1 - Circle "1" if you have seen your teenager do this when there has been a chance, but if there have been many more times that he or she has not done it.

2 - Circle "2" if your teenager does this about half the time there is a chance, but if he or she does not do it readily or comfortably.

3 - Circle "3" if there are more times that your teenager does this than does not do it, given the chance, and if he or she does it readily.

4 - Circle "4" if your teenager does this whenever there is a chance and if he or she does it readily.

Your teenager will not have had the chance to participate in some of the activities the questions described. These items should be answered as "does not do," even though you may feel that your teenager would do it if given the chance. Please circle "0" for questions that describe activities your teenager has ***never had the chance*** to do.

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AUTONOMOUS FUNCTIONING CHECKLIST

Some questions describe things that your teenager may do with help from others. Answer these questions after you think about who has the most responsibility for completing the activity. For example, your teenager may cook the family meals and may be helped by other family members who set the table or chop vegetables. If your teenager is the family member with the most responsibility for cooking every meal that the family eats together, your answer would be "4", which stands for "does every time there is an opporunity." On the other hand, if your teenager helps other family members by doing jobs that they tell him or her to do, and never has the most responsibility for fixing dinner, your answer would be "0", for "does not do."

0	1	2	3	4
Does Not Do	**Does Only Rarely**	**Does About Half the Time There is an Opportunity**	**Does Most of the Time There is an Opportunity**	**Does Every Time There is an Opportunity**

My teenager:

1.	Keeps own personal items and belongings in order (for example makes bed, puts away own clothing and belongings).	0	1	2	3	4
2.	Prepares food that does not require cooking for himself/ herself (for example, cereal, sandwich).	0	1	2	3	4
3.	Care for his/her own clothing (for example, laundry, simple repair, shoe cleaning)	0	1	2	3	4
4.	Travels to and from daily activities (for example, rides bike or walks, takes bus, arranges for transportation, drives car).	0	1	2	3	4
5.	Prepares food that requires cooking for himself/herself (for example, hamburger, soup).	0	1	2	3	4
6.	Performs simple first aid or medical care for himself/ herself (for example, bandages, takes own temperature).	0	1	2	3	4
7.	Purchases his/her own clothing and personal items that are used on a daily basis (for example, underwear, toiletries).	0	1	2	3	4
8.	Performs minor repair and maintance in his/her owm environment (for example, changes light bulbs, hangs pitcure).	0	1	2	3	4
9.	Shops for and purchases his/her own groceries.	0	1	2	3	4
10.	Responds to his/her own medical emergency by calling parent.	0	1	2	3	4
11.	Responds to his/her own medical emergency by calling doctor or hospital.	0	1	2	3	4
12.	Does designated household maintenance chores involving family living areas (for example, cleans, takes out trash, does simple yard work).	0	1	2	3	4

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AUTONOMOUS FUNCTIONING CHECKLIST

	0 Does Not Do	1 Does Only Rarely	2 Does About Half the Time There is an Opportunity	3 Does Most of the Time There is an Opportunity	4 Does Every Time There is an Opportunity
13.	Performs routine daily personal care for another family member. (for example, dresses, feeds).	0	1	2	3	4
14.	Keeps personal items and belongings of another family member in order (for example, makes bed, puts away clothing and belongings).	0	1	2	3	4
15.	Prepares meals for other family member(s).	0	1	2	3	4
16.	Transports (or arranges for transport of) another family member to and from daily activities.	0	1	2	3	4
17.	Purchases clothing and personal items (that are used on a daily basis) for other family members.	0	1	2	3	4
18.	Shops for and purchases family groceries.	0	1	2	3	4
19.	Performs minor repairs and maintenance in family living areas (for example, changes light bulbs, hangs picture).	0	1	2	3	4
20.	Repairs and maintains (or makes arrangement for repair and maintenance of) major household needs (for example, plumbing, yard work, electrical wiring).	0	1	2	3	4
21.	Responds to household emergency (for example, stove fire, plumbing problem) by calling parent or neighbor.	0	1	2	3	4
22.	Reponds to household emergency (for example, stove fire, plumbing problem) by calling fire department, using fire extinguisher, or calling repair service or shuting off water.	0	1	2	3	4
My teenager:						
23.	Uses the telphone and telephone directories.	0	1	2	3	4
24.	Carries out transactions with sales people (for example, listens to information, asks questions, gives payment, receives change).	0	1	2	3	4
25.	Uses postal services (for example, uses postage, mails letters. packages).	0	1	2	3	4
26.	Uses bank (for example, fills out deposit or withdrawal slips, uses passbook).	0	1	2	3	4

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AUTONOMOUS FUNCTIONING CHECKLIST

	0 Does Not Do	1 Does Only Rarely	2 Does About Half the Time There is an Opportunity	3 Does Most of the Time There is an Opportunity	4 Does Every Time There is an Opportunity

27.	Uses travel-related services for short trips (for example, taxi, bus subway).	0	1	2	3	4
28.	Uses travel-related services for long trips (for example, airline, train, bus).	0	1	2	3	4
29.	Uses library services (for example, checks out books or uses Xerox machine).	0	1	2	3	4
30.	Maintains and uses his/her own savings account.	0	1	2	3	4
31.	Maintains and uses his/her own checking or charge account.	0	1	2	3	4
32.	Maintains adequate personal care and grooming (for example, bathes, trims fingernails and toenails when needed)	0	1	2	3	4
33.	Maintains his/her routine general health and fitness (for example, has adequate eating, sleeping and exercise habits).	0	1	2	3	4
34.	Selects clothing that is suited to weather (for example, raincoat if raining, warm clothes in winter).	0	1	2	3	4
35.	Plans and initiates activity for himself/herself in everday unscheduled free time (for example, chooses to watch television or work on a hobby if bored).	0	1	2	3	4
36.	Plans activity for his/her long-term free time (for example, makes plans for summer vacation, mid-semester vacation).	0	1	2	3	4
37.	Initiates friendships with peers (for example, plans or attends parties, outings, games, club meetings).	0	1	2	3	4
38.	Meets nonacademic social obligations or commitments (for example, keeps appointments for family and peer related social events arranged by self or others).	0	1	2	3	4
39.	Meets academic obligations amd commitments (for example, completes homework assignments on time, brings necessary supplies to class).	0	1	2	3	4
40.	Plan transportation to and from special activities (for example arranges for rides with friends or family or plans care or bus route and schedule).	0	1	2	3	4

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AUTONOMOUS FUNCTIONING CHECKLIST

0	1	2	3	4
Does Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Does Every Time There is an Opportunity

41.	Manage his/her own budget from allowance or income (for example, saves money for large purchases, pays for routine expenses throughout week without running out of money).	0	1	2	3	4
42.	Make long-term educational and/or career plans (for example, selects courses, investigates colleges or technical schools).	0	1	2	3	4

When my teenager is free to choose how he/she will spend his/her unscheduled free time. He/she chooses to:

43.	Listen to music (for example, radio or stereo).	0	1	2	3	4
44.	Read for relaxation (for example, books, newspapers)	0	1	2	3	4
45.	Play games or puzzles (for example, cards, crossword puzzles, jigsaw puzzles, computer games).	0	1	2	3	4
46.	Write letters to friends, relatives, aquaintances.	0	1	2	3	4
47.	Work on or take lessons in crafts or hobbies (for example cooking, collections, pet care, sewing, model building, car repair).	0	1	2	3	4
48.	Practice or take lessons that involve a trained artistic or academic skill (for example, piano or other musical instrument, ballet, singing, creative writing, foreign languages).	0	1	2	3	4
49.	Go to the movies, rock concerts, dances.					
50.	Go to plays, theater, lectures.	0	1	2	3	4
51.	Pursue activities that are related to his or her career interest(s) (for example, runs a business, works on a computer, practices piano for professional preparation).	0	1	2	3	4
52.	Go for walks.	0	1	2	3	4
53.	Go shopping, or spend time at shopping centers or in shopping areas.	0	1	2	3	4
54.	Attend club meetings or other organized social group meetings.	0	1	2	3	4
55.	Work for pay (for example, babysit, play in a band, do yard work, walk dogs, work at part-time job, deliver papers).	0	1	2	3	4

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AUTONOMOUS FUNCTIONING CHECKLIST

0	1	2	3	4
Does Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Does Every Time There is an Opportunity

56.	Clean and/or maintan living environment or belongings (for example, clean house, wash or repair clothes, wash car, make household repairs).	0	1	2	3	4
57.	Work on schoolwork (for example, spend extra time on homework, make special preparations for class projects, spend time in library).	0	1	2	3	4
58.	Spend time with family (for example, work on family projects, have discussions or casual conversations, attend family gatherings such as picnics or parties).	0	1	2	3	4

On these final items, please check "Yes" or "No" in response to each description. Check "Yes" if the description fits your teenager. Check "No" if it does not.

My teenager:	Yes	No
59. Has casual friendships with teenagers of opposite sex.	☐	☐
60. Has close friendships with teenagers of opposite sex.	☐	☐
61. Has casual friendships with adults outside the family (for example, teachers, neighbors, coaches, scout leaders)	☐	☐
62. Has close friendships with adults outside the family (for example, teachers, neighbors, coaches, scout leaders).	☐	☐
63. Has casual friendships with younger children.	☐	☐
64. Has close friendships with younger children.	☐	☐
65. Is active in casual/recreational groups of teenage friends.	☐	☐
66. Has many friendships.	☐	☐
67. Is active in one or more organized extracurricular group (for example, French club, student council, sports team).	☐	☐
68. Has leadership position in one or more organized extracurricular group (for example, president of the student council, captain of the sports team).	☐	☐
69. Has close friendship with adult member of the extended family (for example, an uncle, aunt, grandparent).	☐	☐
70. Works or has worked either for pay or volunteer in an area of particular career interest.	☐	☐

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AUTONOMOUS FUNCTIONING CHECKLIST

		Yes	No
71.	Works or has worked to earn money by providing a service on a regular scheduled basis (for example, contracts for yard work, dog walking, baby sitting)	☐	☐
72.	Works or has worked to earn money by using a special skill (for example, musical performance, typing, tutoring).	☐	☐
73.	Works or has worked to earn money in a self-or-peer-run organization or business.	☐	☐
74.	Works or has worked to earn money fundraising for an organization or charity (for example, scouts, church groups, political organizations).	☐	☐
75.	Does or has done volunteer work without pay for a service, a school or political organization, a social agency, a club, a church, or a hospital.	☐	☐
76.	Participates or has participated in prevocational (career) or vocational (career) classes or training (for example, any technical training or career development class).	☐	☐
77.	Has explored career interest by visiting work sites or interviewing people in that job or career.	☐	☐
78.	Has spent time reading, researching, or "finding out" about a career that particularly interests him/her.	☐	☐

Comments:

If you have any additional information about your teenager's everyday independent or self-sufficient behavior, use the space below to write your comments. Thank you.

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SELF-PERCEPTION PROFILE FOR ADOLESCENTS

WHAT AM I LIKE

	Really True for Me	Sort of True for Me	Sample Sentence			Sort of True for Me	Really True for Me
a.	☐	☐	Some teenagers like to go to movies in their spare time	BUT	Other teenagers would rather go to sport events.	☐	☐
1.	☐	☐	Some teenagers feel that they are just as smart as others their age	BUT	Other teenagers aren't so sure and wonder if they are as smart.	☐	☐
2.	☐	☐	Some teenagers find it hard to make friends	BUT	For other teenagers it's pretty easy.	☐	☐
3.	☐	☐	Some teenagers do very well at all kinds of sports	BUT	Other teenagers don't feel that they are very good when it comes to sports.	☐	☐
4.	☐	☐	Some teenagers are not happy with the way they look	BUT	Other teenagers are happy with the way they look.	☐	☐
5.	☐	☐	Some teenagers feel that they are ready to do well at a part-time job	BUT	Other teenagers feel that they are not quite ready to handle a part-time job.	☐	☐
6.	☐	☐	Some teenagers feel that if they are romantically interested in someone, that person will like them back	BUT	Other teenagers worry that when they like someone romantically that person won't like them back.	☐	☐
7.	☐	☐	Some teenagers usually do the right thing	BUT	Other teenagers often don't do what they know is right.	☐	☐
8.	☐	☐	Some teenagers are able to make really close friends.	BUT	Other teenagers find it hard to make really close friends.	☐	☐
9.	☐	☐	Some teenagers are often disappointed with themselves	BUT	Other teenagers are pretty pleased with themselves.	☐	☐
10.	☐	☐	Some teenagers are pretty slow in finishing their school work	BUT	Other teenagers can do their school work more quickly	☐	☐

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SELF-PERCEPTION PROFILE FOR ADOLESCENTS

	Really True for Me	Sort of True for Me				Sort of True for Me	Really True for Me
11.	☐	☐	Some teenagers have a lot of friends	BUT	Other teenagers don't have very many friends.	☐	☐
12.	☐	☐	Some teenagers think they could do well at just about any new athletic activity	BUT	Other teenagers are afraid they might not do well at a new athletic activity.	☐	☐
13.	☐	☐	Some teenagers wish their body was different	BUT	Other teenagers like their body the way it is.	☐	☐
14.	☐	☐	Some teenagers feel that they don't have enough skills to do well at a job	BUT	Other teenagers feel that they do have enough skills to do a job well.	☐	☐
15.	☐	☐	Some teenagers are not dating the people they are really attracted to	BUT	Other teenagers are dating those people they are attracted to	☐	☐
16.	☐	☐	Some teenagers often feel guilty about certain things they do	BUT	Other teenagers hardly ever feel guilty about what they do.	☐	☐
17.	☐	☐	Some teenagers can be trusted to keep secrets that their friends tell them	BUT	Other teenagers have a hard time keeping secrets that their friends tell them.	☐	☐
18.	☐	☐	Some teenagers don't like the way they are leading their life	BUT	Other teenagers do like the way they are leading their life.	☐	☐
19.	☐	☐	Some teenagers do very well at their classwork	BUT	Other teenagers don't do very well at their class-work.	☐	☐
20.	☐	☐	Some teenagers are very hard to like	BUT	Other teenagers are really easy to like.	☐	☐
21.	☐	☐	Some teenagers feel that they are better than others their age at sports	BUT	Other teenagers don't feel they can play as well.	☐	☐
22.	☐	☐	Some teenagers wish their physical appearance was different	BUT	Other teenagers like their physical appearance the way it is.	☐	☐

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SELF-PERCEPTION PROFILE FOR ADOLESCENTS

	Really True for Me	Sort of True for Me				Sort of True for Me	Really True for Me
23.	☐	☐	Some teenagers are proud of the work they do on jobs they get paid for	BUT	For other teenagers, getting paid is more important than feeling proud of what they do.	☐	☐
24.	☐	☐	Some teenagers feel that people their age will be romantically attracted to them	BUT	Other teenagers worry about whether people their age will be attacted to them.	☐	☐
25.	☐	☐	Some teenagers are usually pleased with the way they act	BUT	Other teenagers are often ashamed of the way they act.	☐	☐
26.	☐	☐	Some teenagers don't really have a close friend to share things with.	BUT	Other teenagers do have a close friend to share things with.	☐	☐
27.	☐	☐	Some teenagers are happy with themselves most of the time	BUT	Other teenagers are often not happy with themselves.	☐	☐
28.	☐	☐	Some teenagers have trouble figuring out the answers in school	BUT	Other teenagers almost always can figure out the answers.	☐	☐
29.	☐	☐	Some teenagers are popular with others their age	BUT	Other teenagers are not very popular.	☐	☐
30.	☐	☐	Some teenagers don't do well at new outdoor games	BUT	Other teenagers are good at new outdoor games right away.	☐	☐
31.	☐	☐	Some teenagers think that they are good looking	BUT	Other teenagers think that they are not very good looking.	☐	☐
32.	☐	☐	Some teenagers feel like they could do better at work they do pay for	BUT	Other teenagers feel that they are doing really well at work they do pay for.	☐	☐
33.	☐	☐	Some teenagers feel that they are fun and interesting on a date	BUT	Other teenagers wonder about how fun and interesting they are on a date.	☐	☐
34.	☐	☐	Some teenagers do things they know they shouldn't do	BUT	Other teenagers hardly ever do things they know they shouldn't do.	☐	☐

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SELF-PERCEPTION PROFILE FOR ADOLESCENTS

	Really True for Me	Sort of True for Me				Sort of True for Me	Really True for Me
35.	☐	☐	Some teenagers find it hard to make friends they can really trust	BUT	Other teenagers are able to make close friends they can really trust.	☐	☐
36.	☐	☐	Some teenagers like the kind of person they are	BUT	Other teenagers often wish they were someone else.	☐	☐
37.	☐	☐	Some teenagers feel that they are pretty intelligent	BUT	Other teenagers question whether they are intelligent.	☐	☐
38.	☐	☐	Some teenagers feel that they are socially acceptable	BUT	Other teenagers wished that more people their age accepted them.	☐	☐
39.	☐	☐	Some teenagers do not feel that they are very athletic	BUT	Other teenagers feel that they are very athletic.	☐	☐
40.	☐	☐	Some teenagers really like their looks	BUT	Other teenagers wished they looked different.	☐	☐
41.	☐	☐	Some teenagers feel that it's really important to do the best you can on paying jobs	BUT	Other teenagers feel that getting the job done is what really counts.	☐	☐
42.	☐	☐	Some teenagers usually don't get asked out by people they would like to date	BUT	Other teenagers do get asked out by people they really want to date.	☐	☐
43.	☐	☐	Some teenagers usually act the way they know the are supposed to	BUT	Other teenagers often don't act the way they are supposed to.	☐	☐
44.	☐	☐	Some teenagers don't have a friend that is close enough to share really personal thoughts with	BUT	Other teenagers do have a close friend that they can share personal thoughts and feelings with.	☐	☐
45.	☐	☐	Some teenagers are very happy being the way they are	BUT	Other teenagers wish they were different.	☐	☐

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SICKNESS IMPACT PROFILE: ADOLESCENT VERSION

Introduction

On the next few pages are statements which describe things people often do when they are not well.

As you read them, think of yourself today:

- If a statement describes you TODAY, mark the box under "Yes" (Yes, this statement describes me today).
- However, if a statement does not describe you TODAY, or does not apply you, mark the box under "No". (No, this statement does not describe me today or does not apply to me).

For Example:

"I am not doing any of the shopping that I would usually do."

- If you have not been doing any shopping for some time, and still are not doing any shopping today, check "YES". (Yes, this statement describes me today).
- If you are doing your shopping as usual, check "NO" (No this statement does not describe me today or does not apply to me).

Read and respond to the statements in the order listed. Some of the statements will differ only in a few words, so please read each one carefully. While you may wish to go back to change a response, your first answer is usually best. Please do not read ahead in the questionnaire.

Please do not discuss the statements with anyone, including family members, while doing the questionnaire.

Please mark your answers by placing an "X" in the appropriate box like this. ☒

Thank you for your time and help.

How would you describe your present health

☐ very good ☐ good ☐ fair ☐ poor ☐ very poor

How would you describe you present quality of life (how things are going for you generally)?

☐ very good ☐ good ☐ fair ☐ poor ☐ very poor

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SICKNESS IMPACT PROFILE: ADOLESCENT VERSION

		Yes	No
A.	**These statements describe your sleep and rest this week.**		
1.	I spend much of the day lying down in order to rest.	☐	☐
2.	I sit for much of the day.	☐	☐
3.	I am sleeping or dozing much of the time - day and night.	☐	☐
4.	I lie down more often than my friends during the day in order to rest.	☐	☐
5.	I sit around half asleep.	☐	☐
6.	I sleep less at night, for example, I wake up easily, I do not fall asleep for a long time, I keep waking up.	☐	☐
7.	I sleep or doze more during the day.	☐	☐
B.	**These statements describe your daily work around the house.**		
1.	I only do work that I need to do around the house for short periods of time or I rest often.	☐	☐
2.	I am doing less of the daily household chores that I would usually do.	☐	☐
3.	I am not doing any of the daily household chores that I would usually do.	☐	☐
4.	I am not doing any of the shopping that I would usually do.	☐	☐
5.	I am not doing any of the cleaning that I would usually do.	☐	☐
6.	I am not doing any of the clothes washing that I would usually do.	☐	☐
C.	**These statements describe your contact with your family and friends today.**		
1.	I am going out less to visit people.	☐	☐
2.	I am not going out to visit people at all.	☐	☐
3.	I show less interest in other people's problems, for example, I do not listen when they tell me about their problems. I do not offer to help.	☐	☐
4.	I am often irritable with those around me, for example, I snap at people or criticize easily.	☐	☐
5.	I show less affection.	☐	☐
6.	I take part in fewer social activities than I used to, for example, I go to fewer parties or social events.	☐	☐

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SICKNESS IMPACT PROFILE: ADOLESCENT VERSION

		Yes	No
7.	I am cutting down the length of visits to friends.	☐	☐
8.	I avoid having visitors.	☐	☐
9.	My sexual activity is decreased.	☐	☐
10.	I talk less with those around me.	☐	☐
11.	I make demands on other people that they find irritating, for example, I insist that they do things for me, or tell them how to do things.	☐	☐
12.	I stay alone much of the time.	☐	☐
13.	I am disagreeable with my family, for example, I act spitefully or stubbornly.	☐	☐
14.	I frequently get angry with my family, for example, I hit them, scream or throw things at them.	☐	☐
15.	I isolate myself as much as I can from the rest of my family.	☐	☐
16.	I refuse contact with my family, for example, I turn away from them.	☐	☐
17.	I am not joking with my family members as I usually do.	☐	☐

D.	**These statements describe your feelings.**	Yes	No
1.	I am confused and start to do more than one thing at a time.	☐	☐
2.	I have more minor accidents, for example, I drop things, I trip and fall or bump into things.	☐	☐
3.	I react slowly to things that are said or done.	☐	☐
4.	I do not finish things I start.	☐	☐
5.	I have difficulty reasoning and solving problems, for example, making plans, making decisions, learning new things.	☐	☐
6.	I sometimes get confused, for example, I do not know where I am, who is around, or what day it is.	☐	☐
7.	I forget a lot, for example, things that happened recently, where I put things, or to keep appointments.	☐	☐
8.	I do not keep my attention on any activity for long.	☐	☐
9.	I make more mistakes than usual.	☐	☐
10.	I have difficulty doing things which involve thought and concentration, for example, paying attention in school or at my job.	☐	☐

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SICKNESS IMPACT PROFILE: ADOLESCENT VERSION

E. These statements are about how you talk to other people and write.	Yes	No
1. I am having trouble writing or typing.	☐	☐
2. I am having trouble talking to people.	☐	☐
3. I am not comfortable in most social situations like parties.	☐	☐
4. I speak with difficulty, for example, I get stuck for words, I stutter, I stammer, I slur my words.	☐	☐
5. I do not speak clearly when I am under stress.	☐	☐

F. The following statements decribe the activities you usually do in your spare time for relaxation, entertainment or just to pass the time.	Yes	No
1. I spend shorter periods of time on my hobbies and recreation.	☐	☐
2. I am going out and enjoying myself less often.	☐	☐
3. I am cutting down on some of my usual inactive pastimes, for example, I watch less TV, play cards less, or read less.	☐	☐
4. I am not doing any of my usual inactive pastimes, for example, I watch less TV, play cards less, or read less.	☐	☐
5. I am doing more inactive pastimes in place of my other usual activities.	☐	☐
6. I am taking part in fewer activities with my friends.	☐	☐
7. I am cutting down on some of my usual physical recreation or more active pastimes.	☐	☐
8. I am not doing any of my usual physical recreation or more active pastimes.	☐	☐

Now please look through this questionnaire and make sure that you have read every question.

Thank you once again for your help.

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FAMILY HISTORY - EPIDEMIOLOGIC (FHE) BIOLOGICAL PARENTS, SIBLINGS, AND CHILDREN

Subject Version

1. ***Family Members***

Please tell me the first names and ages of your biological mother and father.

Now tell me the names, ages and sexes of all the children born to (Mother's first name) and (Father's first name). Please start with the first born (the oldest) and include yourself in the list.

Now please tell me the names of your children, if any. Please start with the first born (the oldest).

	Name	*Member ID#*	*Age (or age at death) 00=<1*	*Sex*	*Deceased*	*Correct Birth Order?*
Biologic Mother:		1	___ ___	☐ Female ☐ Male ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know	
Biologic Father:		2	___ ___	☐ Female ☐ Male ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know	
Sibling #1:		3	___ ___	☐ Female ☐ Male ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know
Sibling #2:		4	___ ___	☐ Female ☐ Male ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know
Sibling #3:		5	___ ___	☐ Female ☐ Male ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know
Sibling #4:		6	___ ___	☐ Female ☐ Male ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know
Sibling #5:		7	___ ___	☐ Female ☐ Male ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know
Child #1:		8	___ ___	☐ Female ☐ Male ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know
Child #2:		9	___ ___	☐ Female ☐ Male ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know	☐ No ☐ Yes ☐ Don't Know

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FAMILY HISTORY - EPIDEMIOLOGIC (FHE) BIOLOGICAL PARENTS, SIBLINGS, AND CHILDREN

0 = NO; 1 = YES; 9 = DON'T KNOW

Now I'd like you to take a pencil or pen and a piece of paper and write down the names as I read them off. ***(Do so.)*** Could you read the list back to me? ***(Check to make sure the list matches yours.)*** Now I'm going to ask you questions about these people. Looking at the list, can you tell me...

2. Has anyone on the list ever had a serious mental illness, emotional problem, or nervous breakdown? 0 1 9

If no or don't know, go to Q.3

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

3. Has anyone on the list ever seen a psychiatrist, psychologist, social worker, doctor or other health professional for a psychological or emotional problem? 0 1 9

If no or don't know, go to Q.4

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

4. Has anyone on the list ever stayed overnight or longer in a hospital or treatment facility because of any mental or emotional problem? 0 1 9

If no or don't know, go to Q.5

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

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FAMILY HISTORY - EPIDEMIOLOGIC (FHE) BIOLOGICAL PARENTS, SIBLINGS, AND CHILDREN

0 = NO; 1 = YES; 9 = DON'T KNOW

5. Has anyone on the list ever stayed overnight or longer in a hospital or treatment facility because of a drug or alcohol problem? 0 1 9

If no or don't know, go to Q.6

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

6. Has a doctor ever given anyone on the list any medicine for a psychological or emotional problem? 0 1 9

If no or don't know, go to Q.7

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

7. Has anyone on the list ever had difficulty carrying out their usual responsibilities, such as working, going to school, or taking care of the family or household? 0 1 9

If no or don't know, go to Q.8

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

B. I don't mean because (you/NAME) were physically ill. Other than that, was anyone UNABLE to carry out their usual responsibilities for a WEEK OR MORE? 0 1 9

If no or don't know, go to Q.8

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

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FAMILY HISTORY - EPIDEMIOLOGIC (FHE) BIOLOGICAL PARENTS, SIBLINGS, AND CHILDREN

0 = NO; 1 = YES; 9 = DON'T KNOW

8. Did anyone on the list ever feel sad, blue, or depressed for most of the time for two days or more? 0 1 9

If no or don't know, go to Q.9

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

B. Without including times of physical illness, or mourning after a death, did anyone have a period during which they felt sad, blue or depressed that lasted TWO WEEKS OR MORE? 0 1 9

If no or don't know, go to Q.9

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

9. Did anyone on the list ever have a period of feeling quite tired, having less energy, or not caring about their usual activities? 0 1 9

If no or don't know, go to Note 1

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

B. Do not include times of physical illness, or mourning after a death. Other than that, did anyone feel VERY tired MOST of the time, have no energy, or not care about their usual activities, for at least TWO WEEKS? 0 1 9

If no or don't know, go to Note 1

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

Note 1: ***Say:*** "I know you know this, but I'm supposed to remind you that ALL of these questions are about whether ANY of these people listed on the page have had any these problems; that is; (names on template)."

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FAMILY HISTORY - EPIDEMIOLOGIC (FHE) BIOLOGICAL PARENTS, SIBLINGS, AND CHILDREN

0 = NO; 1 = YES; 9 = DON'T KNOW

10. Did anyone on the list ever have sleep problems, like trouble falling asleep, or waking up too early, or sleeping too much? 0 1 9

If no or don't know, go to Q.11

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

B. Was it as much as an hour a night for TWO WEEKS OR MORE, and not because of a physical illness? 0 1 9

If no or don't know, go to Q.11

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

11. Has anyone on the list ever had a period of feeling extremely happy or high? 0 1 9

If no or don't know, go to Q.12

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

B. I mean "high as a kite," so that other people worried about them, or so that it interfered with carrying out normal responsibilities. Has anyone been unusually happy or high, not because of drugs or alcohol, for TWO DAYS OR MORE? 0 1 9

If no or don't know, go to Q.12

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

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FAMILY HISTORY - EPIDEMIOLOGIC (FHE) BIOLOGICAL PARENTS, SIBLINGS, AND CHILDREN

0 = NO; 1 = YES; 9 = DON'T KNOW

12. Has anyone on the list ever had a period in which they were more active or talkative than normal? 0 1 9

If no or don't know, go to Q.13

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child#1***	***Child#2***

B. I mean EXTREMELY over-active or talkative, so that people WORRIED about them, or so that it interfered with carrying out their usual responsibilities. Has anyone been like that, without being under the influence of drugs or alcohol, for at least TWO DAYS? 0 1 9

If no or don't know, go to Q.13

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child#1***	***Child#2***

13. Has anyone on the list ever had a sudden spell or attack in which they felt frightened or panicked? 0 1 9

If no or don't know, go to Q.14

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child#1***	***Child#2***

B. Has anyone had SEVERAL attacks of EXTREME fear or panic, even though there was nothing to be afraid of? 0 1 9

If no or don't know, go to Q.14

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child#1***	***Child#2***

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FAMILY HISTORY - EPIDEMIOLOGIC (FHE) BIOLOGICAL PARENTS, SIBLINGS, AND CHILDREN

0 = NO; 1 = YES; 9 = DON'T KNOW

14. Has anyone on the list ever had a sudden spell or attack of difficulty breathing or of a rapid heartbeat? 0 1 9

If no or don't know, go to Q.15

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child#1***	***Child#2***

B. Did the person have SEVERAL such attacks, NOT caused by heart problems, exercise, or something that would have terrified most people? 0 1 9

If no or don't know, go to Q.15

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child#1***	***Child#2***

15. Has anyone on the list ever had a period of at least one month when they were very tense or nervous and worried? 0 1 9

If no or don't know, go to Q.16

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child#1***	***Child#2***

B. Did anyone worry ALMOST EVERY DAY FOR SIX MONTHS OR MORE, about things that other people wouldn't have worried about that much? 0 1 9

If no or don't know, go to Q.16

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child#1***	***Child#2***

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0 = NO; 1 = YES; 9 = DON'T KNOW

16. Has anyone on the list ever been frightened of going out of the house alone, being in a crowd, standing in lines, going over bridges, or travelling by bus, train or car? 0 1 9

If no or don't know, go to Q.17

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child#1***	***Child#2***

B. Do not include children who were too young to do these things. Other than that was anyone so frightened that they either COULDN'T do something, or really had to force themselves to do it? 0 1 9

If no or don't know, go to Q.17

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child#1***	***Child#2***

17. Has anyone on the list ever been very frightened of heights, animals, insects, or blood? 0 1 9

If no or don't know, go to Q.18

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child#1***	***Child#2***

B. Was anyone more frightened than others at their age -- so frightened of something that they tried very hard to AVOID IT? 0 1 9

If no or don't know, go to Q.18

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child#1***	***Child#2***

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FAMILY HISTORY - EPIDEMIOLOGIC (FHE) BIOLOGICAL PARENTS, SIBLINGS, AND CHILDREN

0 = NO; 1 = YES; 9 = DON'T KNOW

18. Has anyone on the list ever gotten very embarrassed when they had to do something that involved other people, such as attend parties or social gatherings, or speak or eat in public? 0 1 9

If no or don't know, go to Note 2

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

B. Was anyone so EXTREMELY embarrassed that they COULDN'T DO the things that bothered them, for at least TWO MONTHS? 0 1 9

If no or don't know, go to Note 2

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

Note 2: ***Say:*** "I want to remind you that all of these questions are about all of the people on the list; that is; (names on template)."

19. Did anyone on the list ever have a habit of checking, counting or cleaning things? 0 1 9

If no or don't know, go to Q.20

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

B. Did the person do this over and over again, so much that it interfered with their usual activities? 0 1 9

If no or don't know, go to Q.20

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

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FAMILY HISTORY - EPIDEMIOLOGIC (FHE) BIOLOGICAL PARENTS, SIBLINGS, AND CHILDREN

0 = NO; 1 = YES; 9 = DON'T KNOW

20. Has anyone on the list ever had unpleasant, nagging thoughts, such as that they hadn't locked the door, when they really had, or that things were dirty, when they were really clean? 0 1 9

If no or don't know, go to Q.21

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child#1***	***Child#2***

B. Did these thoughts keep coming back, no matter how hard the person tried to get rid of them? 0 1 9

If no or don't know, go to Q.21

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child#1***	***Child#2***

21. Has anyone on the list ever heard voices, or seen visions, that other people could not see or hear? 0 1 9

If no or don't know, go to Q.22

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child#1***	***Child#2***

B. Don't include experiences caused by alcohol or drugs, or religious experiences that are common in their religion, or a younger child who had an imaginary playmate. Other than that, did the person clearly and frequently hear voices or see visions? 0 1 9

If no or don't know, go to Q.22

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child#1***	***Child#2***

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FAMILY HISTORY - EPIDEMIOLOGIC (FHE) BIOLOGICAL PARENTS, SIBLINGS, AND CHILDREN

0 = NO; 1 = YES; 9 = DON'T KNOW

22. Has anyone on the list ever believed in things that were very unusual and not true, for example, that people were plotting against them, or that TV programs were sending special messages just to them? 0 1 9

If no or don't know, go to Q.23

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

B. Don't include beliefs caused by alcohol or drugs, or shared religious beliefs. Other than that, did the person believe things that were very unusual and not true? 0 1 9

If no or don't know, go to Q.23

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

23. Did anyone on the list ever have a period in his or her life when they drank a lot? 0 1 9

If no or don't know, go to Q.24

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

B. Did the person have a drinking problem, or did people think they had a drinking problem? 0 1 9

If no or don't know, go to Q.24

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

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FAMILY HISTORY - EPIDEMIOLOGIC (FHE) BIOLOGICAL PARENTS, SIBLINGS, AND CHILDREN

0 = NO; 1 = YES; 9 = DON'T KNOW

24. Did anyone on the list ever have a period in his or her life when they used illegal drugs regularly? 0 1 9

If no or don't know, go to Q.25

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

B. Did the person have a drug problem, or did people think they had a drug problem? 0 1 9

If no or don't know, go to Q.25

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

25. Has anyone on the list ever been fired from a job, or laid off? 0 1 9

If no or don't know, go to Q.26

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

B. Was it because their supervisor was not happy with their work, behavior, or attitude? 0 1 9

If no or don't know, go to Q.26

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

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0 = NO; 1 = YES; 9 = DON'T KNOW

26. Has anyone on the list ever been put in jail, or arrested or convicted of a crime, other than drunk driving? 0 1 9

If no or don't know, go to Note 3

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child#1***	***Child#2***

Note 3: ***Say:*** "The next few questions are about problems children and teenagers sometimes have. Since we want to know whether anyone on the list ever had the problem in their whole life, please remember to think about whether the adults had the problems when they were young, as well as thinking about whether the youngsters have had it."

27. When they were young, did anyone on the list get upset or frightened when they had to go to school, sleep away from home, or be away from their parents? 0 1 9

If no or don't know, go to Q.28

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child#1***	***Child#2***

B. Was it much more than most children their age? 0 1 9

If no or don't know, go to Q.28

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child#1***	***Child#2***

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28. When they were children, did anyone on the list steal property, skip school, run away from home, or break rules? 0 1 9

If no or don't know, go to Q.29

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

B. Did the person steal <u>valuable</u> property, skip school <u>a lot</u>, or break <u>a lot</u> of rules, more than other children their age? 0 1 9

If no or don't know, go to Q.29

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

29. In grade school, did anyone on the list fidget, leave their seats when they weren't supposed to, not finish their schoolwork, or not pay attention to the teacher? 0 1 9

If no or don't know, go to Q.30

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

B. Was the person really doing those things all the time, more than other (boys/girls) (his/her) age? 0 1 9

If no or don't know, go to Q.30

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

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FAMILY HISTORY - EPIDEMIOLOGIC (FHE) BIOLOGICAL PARENTS, SIBLINGS, AND CHILDREN

0 = NO; 1 = YES; 9 = DON'T KNOW

30. Has anyone on the list EVER been suspended or expelled from school? 0 1 9

If no or don't know, go to Q.31

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

31. Has anyone on the list EVER tried to kill him or herself, or made a suicide attempt? 0 1 9

If no or don't know, go to Note 4

If yes ask: A. Who was that? Anyone else? ***(until no more names are given)***

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

B. This may be a painful question, but did the person actually kill him or herself? 0 1 9

If no or don't know, go to Note 4

If yes ask: C. Who was that? Anyone else? ***(until no more names are given)***
I'm sorry. That must be hard to think about.

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	***Father***	***Sib.#1***	***Sib.#2***	***Sib.#3***	***Sib.#4***	***Sib.#5***	***Child #1***	***Child #2***

Note 4: Say: "Thank you very much for giving me so much information about your relatives."

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SADS-L

Using the scale below, mark the appropriate box for each term listed below. Complete Onset and Offset dates as applicable.

1 = Not present (screen denied)
2 = Possible (screen and 1 symptom)
3 = Probable (1 criterion short)
4 = Definite (meets DSM III criteria)
5 = Unknown (no information available)
6 = Not Applicable

	Current							Past							
	1	2	3	4	5	6	Onset Date (day/mth/yr)	1	2	3	4	5	6	Onset Date (day/mth/yr)	Offset Date (day/mth/yr)
Schizophrenia	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Schizo-affective-manic	☐	☐	☐	☐	☐	☐									
Schizo-affective-depressed	☐	☐	☐	☐	☐	☐									
Other functional psychosis	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Major depression	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
W psychotic features	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Dysthymia	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Mania	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
W psychotic features	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Hypomania	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Cyclothymia	☐	☐	☐	☐	☐	☐									
Recurrent Unipolar	☐	☐	☐	☐	☐	☐									
Bipolar I	☐	☐	☐	☐	☐	☐									
Bipolar II	☐	☐	☐	☐	☐	☐									
Other affective disorder	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Simple phobia	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Social phobia	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Agoraphobia	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Generalized anxiety	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		

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SADS-L

Using the scale below, mark the appropriate box for each term listed below. Complete Onset and Offset dates as applicable.

1 = Not present (screen denied)
2 = Possible (screen and 1 symptom)
3 = Probable (1 criterion short)
4 = Definite (meets DSM III criteria)
5 = Unknown (no information available)
6 = Not Applicable

	Current							Past							
	1	2	3	4	5	6	Onset Date (day/mth/yr)	1	2	3	4	5	6	Onset Date (day/mth/yr)	Offset Date (day/mth/yr)
Panic disorder	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Obsessive-compulsive	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Alcohol abuse	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Drug abuse	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Conduct disorder	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Antisocial personality disorder	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Attention deficit disorder	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Anorexia nervosa	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Bulimia	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Separation anxiety	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Post traumatic stress disorder	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Mental retardation	☐	☐	☐	☐	☐	☐									
Learning disability	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Organic brain disorder	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		
Other psychiatric disorder - specify: _____	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	☐		

Current Psychiatric Disorder		Past Psychiatric Disorder		Direct Interview		Number of Informants
Yes	No	Yes	No	Yes	No	
☐	☐	☐	☐	☐	☐	

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SADS-L

	None (1)	Threat (2)	Assault (3)	Homicide (4)	No information (5)	Age of earliest behavior	Age of earliest assault	Number of assaultive acts
Assaultive Behavior	☐	☐	☐	☐	☐			

	Never hospitalized (1)	Less than 5 days (2)	Less than 3 months (3)	Less than 6 months (4)	6 months or more (5)	No information (6)	Age of 1st hospital-ization	Number of hospital-izations
Total Psychiatric Hospitalizations	☐	☐	☐	☐	☐	☐		

	No contact (1)	Consultation or brief period of treatment (2)	6 months to 2 years (3)	2 years or more (4)	No information (5)	Age of 1st outpatient contact
Total Outpatient Treatment	☐	☐	☐	☐	☐	

	None (1)	Ideation (2)	Threat (3)	Gesture (4)	Attempt (5)	Com-pletion (6)	No infor-mation (7)	Age of earliest behavior	Age of earliest attempt	Number of attempts
Suicidal Behavior	☐	☐	☐	☐	☐	☐	☐			

	Not applicable (living) (1)	Natural death (2)	Accidental death (3)	Possible suicide (4)	Definite suicide (5)	No information (6)
Circumstances of Death	☐	☐	☐	☐	☐	☐

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29060	329	0 0		Screening (Week -1)	01	42

KIDDIE-SADS-LIFETIME - SCORING FORM

DEPRESSED MOOD

1. Worst Severity of Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Duration of Current Episode: [ ] # of weeks

2. Worst Severity of Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Frequency: [ ] Days/week

Average % time of the day: [ ] %

DEPRESSED APPEARANCE

3. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

4. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

IRRITABILITY AND ANGER

5. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Duration: [ ] # of weeks

6. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Frequency: [ ] Days/week

Average % time of the day: [ ] %

SEPARATION-DEPENDENT-DYSPHORIA

7. Current Episode: [0] NI [1] NO [2] OCC [3] USL [4] ALW

8. Last Two Weeks: [0] NI [1] NO [2] OCC [3] USL [4] ALW

SmithKline Beecham Pharmaceuticals

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29060	329	0 0		Screening (Week -1)		43

KIDDIE-SADS-LIFETIME - SCORING FORM

QUALITY OF DYPSHORIC MOOD

9. Current Episode: [0] NI [1] ND [2] QUE [3] DDF [4] VDF

10. Last Two Weeks: [0] NI [1] ND [2] QUE [3] DDF [4] VDF

DEGREE OF ASSOCIATION OF DEPRESSED OR IRRITABLE MOOD WITH SPECIFIC EVENTS OR PREOCCUPATIONS

11. Current Episode: [0] NI [1] NAL [2] MOT [3] UN [4] PN

12. Last Two Weeks: [0] NI [1] NAL [2] MOT [3] UN [4] PN

REACTIVITY OF DEPRESSED OR IRRITABLE MOOD

13. Current Episode: [0] NI [1] VR [2] FUL [3] RES [4] MLD [5] SLT [6] UNR

[ ] % Usual % of Normal

14. Last Two Weeks: [0] NI [1] VR [2] FUL [3] RES [4] MLD [5] SLT [6] UNR

[ ] % Usual % of Normal

[ ] % Maximum % of Normal

[ ] Number of hours good feeling last

DIURNAL MOOD VARIATION

Worse in Morning

15. Current Episode: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

16. Last Two Weeks: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

Worse in Afternoon and/or Evening

17. Current Episode: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

18. Last Two Weeks: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

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29060	329	0 0		Screening (Week -1)	01	44

KIDDIE-SADS-LIFETIME - SCORING FORM

EXCESSIVE INAPPROPRIATE GUILT

19. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

20. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

Frequency: Days/Week [ ]

NEGATIVE SELF IMAGE

21. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

22. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

FEELING UNLOVED/FORLORN

23. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

24. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

Frequency: Days/Week [ ]

HOPELESSNESS, HELPLESSNESS, DISCOURAGEMENT, PESSIMISM

25. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

26. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

SELF-PITY

27. Current Episode: [0] NI [1] NO [2] OCC [3] MLD [4] CON

28. Last Two Weeks: [0] NI [1] NO [2] OCC [3] MLD [4] CON

ACHES AND PAINS

29. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

30. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

SmithKline Beecham Pharmaceuticals

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29060	329	0 0		Screening (Week -1)	01	45

KIDDIE-SADS-LIFETIME - SCORING FORM

HYPOCHONDRIASIS

31. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

32. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

ANHEDONIA, LACK OF INTEREST, APATHY, LOW MOTIVATION, BOREDOM

Combined Overall Rating

33. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Duration: [ ] # of weeks

34. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/week

Average % time of the day: [ ] %

Differentiating Lack of Interest from Anhedonia

Lack of Interest

35. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

36. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Anhedonia

37. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

38. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

FATIGUE, LACK OF ENERGY AND TIREDNESS

39. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

40. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/Week

SmithKline Beecham Pharmaceuticals

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KIDDIE-SADS-LIFETIME - SCORING FORM

DIFFICULTY CONCENTRATING, INATTENTION, OR SLOWED THINKING

41. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

42. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

PSYCHOMOTOR AGITATION

43. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

44. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Unable to sit still

45. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

46. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Pacing

47. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

48. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

Hand wringing

49. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

50. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

Pulling or rubbing on hair, clothing, skin

51. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

52. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

Can't stop talking, talks on and on

53. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

54. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

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29060	329	0 0		Screening (Week -1)	01	47

KIDDIE-SADS-LIFETIME - SCORING FORM

PSYCHOMOTOR RETARDATION

55. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

56. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Slowed Speech

57. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

58. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Increased pauses before answering

59. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

60. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Low or monotonous speech

61. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

62. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Mute or markedly decreased amount of speech

63. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

64. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Slowed body movements

65. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

66. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Depressive stupor

67. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

68. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

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KIDDIE-SADS-LIFETIME - SCORING FORM

SOCIAL WITHDRAWAL

69.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
70.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

REJECTION SENSITIVITY

71.	Last Year:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
72.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
73.	Last Year:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
74.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

SLEEP PROBLEMS

75. ___ Hours slept before onset of depression

76. ___ Hours slept during the current episode

77. ___ Hours slept during the last two weeks

HYPERSOMNIA

78. ___ Hours slept in daytime of current episode

79. ___ Hours slept in daytime in the last two weeks

80. ___ Hours lying down in current episode

81. ___ Hours lying down in last two weeks

82.	Current Episode:	(0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)
83.	Last Two Weeks:	(0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)

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KIDDIE-SADS-LIFETIME - SCORING FORM

INSOMNIA

84. Current Episode: [0] NI [1] NO [2] [3] [4] [5] [6]

85. Last Two Weeks: [0] NI [1] NO [2] [3] [4] [5] [6]

Frequency: ___ Nights/Week

TYPES OF INSOMNIA

Initial Insomnia

86. Current Episode: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

87. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

Middle Insomnia

88. Current Episode: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

89. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

Terminal Insomnia

90. Current Episode: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

91. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

Circadian Reversal

92. Current Episode: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

93. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

Non-restorative sleep

94. Current Episode: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

95. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

Daytime sleepiness

96. Current Episode: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

97. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

SmithKline Beecham Pharmaceuticals

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29060	329	0 0		Screening (Week -1)	01		50

KIDDIE-SADS-LIFETIME - SCORING FORM

ANOREXIA

98. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) RAR] [(6) NVR]

99. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) RAR] [(6) NVR]

WEIGHT LOSS

100. Current Episode:

Pounds lost: [ ] lbs.

Number of Weeks: [ ]

101. Last Two Weeks:

Pounds lost: [ ] lbs.

INCREASED APPETITE

102. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EX]

103. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EX]

Frequency: [ ] Days/Week

STRONG CRAVING FOR SWEETS

104. Current Episode: [(0) NI] [(1) ABS] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

105. Last Two Weeks: [(0) NI] [(1) ABS] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

WEIGHT GAIN

106. Current Episode:

Pounds gained: [ ] lbs.

Number of Weeks: [ ]

107. Last Two Weeks:

Pounds gained: [ ] lbs.

SmithKline Beecham Pharmaceuticals

Tracking Number

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29060	329	0 0		Screening (Week -1)	01		51

KIDDIE-SADS-LIFETIME - SCORING FORM

SUICIDAL IDEATION

108. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

109. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Suicidal Acts - Number

110. Current Episode: [ ]

111. Last Two Weeks: [ ]

Suicidal Acts - Seriousness

112. Current Episode: [0] NI [1] NO [2] MIN [3] DEF [4] SER [5] VS [6] EXT

113. Last Two Weeks: [0] NI [1] NO [2] MIN [3] DEF [4] SER [5] VS [6] EXT

Medical Lethality

114. Current Episode [0] NI [1] NO [2] MIN [3] MLD [4] MO [5] SVR [6] EXT

115. Last Two Weeks: [0] NI [1] NO [2] MIN [3] MLD [4] MO [5] SVR [6] EXT

Non-Suicidal Physical Self-Demaging Acts

116. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] ACT

117. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] ACT

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KIDDIE-SADS-LIFETIME - SCORING FORM

DIAGNOSTIC CRITERIA - MAJOR DEPRESSIVE EPISODE

Onset and Course

118. Number of Episodes ⌊_ _⌋

Ages of onset and offset of each episode

119. Onset ⌊_ _⌋
Offset ⌊_ _⌋
Weeks ⌊_ _ _⌋

120. Onset ⌊_ _⌋
Offset ⌊_ _⌋
Weeks ⌊_ _ _⌋

121. Onset ⌊_ _⌋
Offset ⌊_ _⌋
Weeks ⌊_ _ _⌋

122. Onset ⌊_ _⌋
Offset ⌊_ _⌋
Weeks ⌊_ _ _⌋

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KIDDIE-SADS-LIFETIME - SCORING FORM

MANIC SYNDROME

ELATION, EXPANSIVE MOOD

1. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX
2. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX

DECREASED NEED FOR SLEEP

3. Current Episode:	[0] NI	[1] NO	[2] -1	[3] -2	[4] -3	[5] -4	[6] -4+
4. Last Two Weeks:	[0] NI	[1] NO	[2] -1	[3] -2	[4] -3	[5] -4	[6] -4+

UNUSUALLY ENERGETIC

5. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] LCH	[4] MOR	[5] MM	[6] UA
6. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] LCH	[4] MOR	[5] MM	[6] UA

INCREASE IN GOAL DIRECTED ACTIVITY

7. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX
8. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX

GRANDIOSITY

9. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX
10. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX

ACCELERATED, PRESSURED OR INCREASED AMOUNT OF SPEECH

11. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX
12. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX

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KIDDIE-SADS-LIFETIME - SCORING FORM

RACING THOUGHTS

13. Current Episode: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

14. Last Two Weeks: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

FLIGHT OF IDEAS

15. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

16. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

POOR JUDGEMENT

17. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) VS]

18. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) VS]

DISTRACTABILITY

19. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR]

20. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR]

MOTOR HYPERACTIVITY

21. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) MKD] [(6) EX]

22. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) MKD] [(6) EX]

Inappropriate laughing, joking or punning

23. Current Episode: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

24. Last Two Weeks: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

Uninhibited people seeking, gregarious

25. Current Episode: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

26. Last Two Weeks: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

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KIDDIE-SADS-LIFETIME - SCORING FORM

Increased Productivity

27. Current Episode: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

28. Last Two Weeks: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

Sharpened and unusually creative thinking

29. Current Episode: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

30. Last Two Weeks: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

Hypersexuality

31. Current Episode: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

32. Last Two Weeks: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

INFLUENCE OF ILLICIT DRUGS OR ALCOHOL

33. Current Episode: [0] NA [1] NVR [2] SMT [3] ONL

34. Last Two Weeks: [0] NA [1] NVR [2] SMT [3] ONL

NUMBER OF MANIC PERIODS

35. [ ]

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KIDDIE-SADS-LIFETIME - SCORING FORM

DIAGNOSTIC CRITERIA - HYPOMANIC EPISODE

Onset and Course

36. Number of Episodes [ ]

Ages of onset and offset of each episode

37. Onset [ ] Offset [ ] Weeks [ ]

38. Onset [ ] Offset [ ] Weeks [ ]

DIAGNOSTIC CRITERIA - MANIC EPISODE

39. Onset and Course

Number of Episodes [ ]

Ages of onset and offset of each episode

40. Onset [ ] Offset [ ] Weeks [ ]

41. Onset [ ] Offset [ ] Weeks [ ]

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KIDDIE-SADS-LIFETIME - SCORING FORM

EATING DISORDERS

REFUSAL TO MAINTAIN BODY WEIGHT

1. Lifetime: [(0) NI] [(1) NP] [(2)] [(3)] [(4)] [(5)] [(6)]

METHODS OF WEIGHT LOSS

2. ***Restriction*** Lifetime: [(0) NI] [(1) NVR] [(2) SMT] [(3) OFT] [(4) ROU]
3. ***Only Liquids*** Lifetime: [(0) NI] [(1) NVR] [(2) SMT] [(3) OFT] [(4) ROU]
4. ***Vomiting*** Lifetime: [(0) NI] [(1) NVR] [(2) SMT] [(3) OFT] [(4) ROU]
5. ***Supressants*** Lifetime: [(0) NI] [(1) NVR] [(2) SMT] [(3) OFT] [(4) ROU]
6. ***Laxatives*** Lifetime: [(0) NI] [(1) NVR] [(2) SMT] [(3) OFT] [(4) ROU]
7. ***Diurectics*** Lifetime: [(0) NI] [(1) NVR] [(2) SMT] [(3) OFT] [(4) ROU]

BODY IMAGE DISTURBANCE

8. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

INTENSE AND PERSISTENT FEAR OF GAINING WEIGHT

9. Lifetime: [(0) NI] [(1) NO] [(2)] [(3)] [(4)] [(5)] [(6)]

INTENSE PREOCCUPATION WITH FOOD AND EATING

10. Lifetime: [(0) NI] [(1) NO] [(2)] [(3)] [(4)] [(5)] [(6)]

AMENORRHEA

11. Age of Menarche: [ ]
12. [(0) NI] [(1) NO] [(2) YES]
13. [(0) NI] [(1) NO] [(2) YES]

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KIDDIE-SADS-LIFETIME - SCORING FORM

14. Weeks: ___

15. Weeks: ___

16. [0] NI [1] NO [2] YES

BULIMIA

17. Lifetime: [0] NI [1] NO [2] [3] [4] [5] [6]

18. ***Eats faster*** Lifetime: [0] NI [1] NVR [2] SMT [3] OFT [4] AS

19. ***Uncontrollable*** Lifetime: [0] NI [1] NVR [2] SMT [3] OFT [4] AS

20. ***Eats alone*** Lifetime: [0] NI [1] NVR [2] SMT [3] OFT [4] AS

21. ***Abdominal Pain*** Lifetime: [0] NI [1] NVR [2] SMT [3] OFT [4] AS

22. ***Vomiting*** Lifetime: [0] NI [1] NVR [2] SMT [3] OFT [4] AS

23. ***Sleep*** Lifetime: [0] NI [1] NVR [2] SMT [3] OFT [4] AS

24. ***Interruption*** Lifetime: [0] NI [1] NVR [2] SMT [3] OFT [4] AS

25. ***Depression*** Lifetime: [0] NI [1] NVR [2] SMT [3] OFT [4] AS

26. Binges: ___ hours

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KIDDIE-SADS-LIFETIME - SCORING FORM

DIAGNOSTIC CRITERIA - ANOREXIA NERVOSA

Onset and Course

27. Number of Episodes

Ages of onset and offset of each episode

28. Onset
Offset
Weeks

29. Onset
Offset
Weeks

DIAGNOSTIC CRITERIA - BULIMIA NERVOSA

Onset and Course

30. Number of Episodes

Ages of onset and offset of each episode

31. Onset
Offset
Weeks

32. Onset
Offset
Weeks

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KIDDIE-SADS-LIFETIME - SCORING FORM

ANXIETY DISORDERS

SPECIFIC PHOBIAS

1.	***Overall*** Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
2.	***Flying*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
3.	***Elevators*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
4.	***Small Spaces*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
5.	***Heights*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
6.	***Dark*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
7.	***Swimming*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
8.	***Dogs/animals*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
9.	***Insects*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
10.	***Thunderstorms*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
11.	***Cars/Buses/Trains*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
12.	***Dentist/Doctors*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
13.	***Other*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	

DIAGNOSTIC CRITERIA - SPECIFIC PHOBIA

Onset and Course

14. Number of Episodes ____

Ages of onset and offset of each episode

15. Onset ____ Offset ____ Weeks ____

16. Onset ____ Offset ____ Weeks ____

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KIDDIE-SADS-LIFETIME - SCORING FORM

SEPARATION ANXIETY

PREOCCUPATION WITH THOUGHTS OF HARM TO PARENTS

1. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

PREOCCUPATION WITH HARM BEFALLING SELF

2. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

FEAR OF BEING HOME ALONE

3. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

EXCESSIVE REACTION TO SEPARATION

4. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

DIFFICULTY BEING AWAY FROM HOME

5. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

HOMESICKNESS

6. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

FEAR OF SLEEPING AWAY FROM HOME

7. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

NIGHTMARES

8. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

SCHOOL REFUSAL/RELUCTANCE

9. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

PHYSICAL SYMPTOMS DURING SEPARATION

10. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

DIAGNOSTIC CRITERIA - SEPARATION ANXIETY DISORDER

Onset and Course

11. Number of Episodes [ ]

Ages of onset and offset of each episode

12. Onset [ ]
Offset [ ]
Weeks [ ]

13. Onset [ ]
Offset [ ]
Weeks [ ]

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KIDDIE-SADS-LIFETIME - SCORING FORM

PANIC DISORDER AND AGORAPHOBIA

1. Lifetime: [(0) NI] [(1) NP] [(2) DBT] [(3) DPR] [(4) 6] [(5) 3X] [(6) DLY]

SPONTANEOUS ATTACKS

2. Lifetime: [(0) NI] [(1) NO] [(2) 1] [(3) 2-3] [(4) 4] [(5) 4+]

DURATION OF SPONTANEOUS ATTACKS

3. Lifetime: [(0) NI] [(1) 20] [(2) 10] [(3) SOM] [(4) MST] [(5) ALL]

SITUATIONALLY PREDISPOSED ATTACKS

4. Lifetime: [(0) NI] [(1) NO] [(2) -4] [(3)] [(4)] [(5) 4+]

PHOBIA RELATED ATTACKS

5. Lifetime: [(0) NI] [(1) NO] [(2)] [(3)]

6. ***Shortness of Breath*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

7. ***Palpitations*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

8. ***Chest Pains*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

9. ***Choking*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

10. ***Dizziness*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

11. ***Numbness*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

12. ***Sweating*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

13. ***Trembling*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

14. ***Dying*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

15. ***Losing Control*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

16. ***Nausea*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

17. ***Depersonalization*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

18. ***Flashes/Chills*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

19. Most Number of Attacks: [ ] in a 4 week period

20. Lifetime: [(0) NI] [(1) NP] [(2) VM] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

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KIDDIE-SADS-LIFETIME - SCORING FORM

AGORAPHOBIA WITH PANIC DISORDER

21. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

AGORAPHOBIA WITHOUT PANIC DISORDER

22. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

DIAGNOSTIC CRITERIA - PANIC DISORDER WITHOUT AGORAPHOBIA

Onset and Course

23. Number of Episodes ____

Ages of onset and offset of each episode

24. Onset ____ Offset ____ Weeks ____

25. Onset ____ Offset ____ Weeks ____

DIAGNOSTIC CRITERIA - PANIC DISORDER WITH AGORAPHOBIA

26. Onset and Course

Number of Episodes ____

Ages of onset and offset of each episode

27. Onset ____ Offset ____ Weeks ____

28. Onset ____ Offset ____ Weeks ____

DIAGNOSTIC CRITERIA - AGORAPHOBIA WITHOUT HISTORY OF PANIC DISORDER

29. Onset and Course

Number of Episodes ____

Ages of onset and offset of each episode

30. Onset ____ Offset ____ Weeks ____

31. Onset ____ Offset ____ Weeks ____

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KIDDIE-SADS-LIFETIME - SCORING FORM

SOCIAL PHOBIA

1. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

DIAGNOSTIC CRITERIA - SOCIAL PHOBIA

2. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

3. Onset ___ Offset ___ Weeks ___

4. Onset ___ Offset ___ Weeks ___

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KIDDIE-SADS-LIFETIME - SCORING FORM

OBSESSIONS OR COMPULSIONS

OBSESSIONS

1. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

COMPULSIONS

2. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

3. ***Touching*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

4. ***Counting*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

5. ***Washing*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

6. ***Checking*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

7. ***Collecting*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

8. ***Arranging*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

9. ***Other*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

DEPERSONALIZATION OR DEREALIZATION

10. Lifetime: [(0) NI] [(1) NO] [(2) FLT] [(3) OCC] [(4) SVL] [(5) MRK] [(6) FQT]

DIAGNOSTIC CRITERIA - OBSESSIVE-COMPULSIVE DISORDER

11. Onset and Course

Number of Episodes [ ]

Ages of onset and offset of each episode

12. Onset [ ] Offset [ ] Weeks [ ]

13. Onset [ ] Offset [ ] Weeks [ ]

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KIDDIE-SADS-LIFETIME - SCORING FORM

GENERALIZED ANXIETY DISORDER

WORRY

1. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

2. Lifetime: [0] NI [1] NO [2] DBT [3] MLD [4] MOD

DIFFICULTY CONTROLLING WORRIES

3. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

SYMPTOMS ASSOCIATED WITH WORRY

4. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

DIAGNOSTIC CRITERIA - GENERALIZED ANXIETY DISORDER

5. Onset and Course

Number of Episodes [ ]

Ages of onset and offset of each episode

6. Onset [ ]
Offset [ ]
Weeks [ ]

7. Onset [ ]
Offset [ ]
Weeks [ ]

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KIDDIE-SADS-LIFETIME - SCORING FORM

POST-TRAUMATIC STRESS DISORDER

TRAUMA TO OTHERS

1. Lifetime: [(0) NI] [(1) NO] [(2)] [(3)] [(4)] [(5)] [(6)]

TRAUMATIC TO SELF

2. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR]

INTRUSIVE RECOLLECTIONS OF TRAUMA

3. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

RECURRENT DISTRESSING DREAMS

4. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

SENSE OF RELIVING TRAUMA AND INTENSE DISTRESS AT RE-EXPERIENCE

5. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

PHYSIOLOGICAL REACTION UPON EXPOSURE

6. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

THOUGHTS, FEELINGS, CONVERSATIONS, ACTIVITIES, PLACES OF PEOPLE

7. Lifetime: [(0) NI] [(1) NO] [(2) YES]

NO RECALL OF IMPORTANT ASPECTS OF TRAUMA

8. Lifetime: [(0) NI] [(1) NO] [(2) YES]

MARKEDLY REDUCED ACTIVITIES/INTEREST

9. Lifetime: [(0) NI] [(1) NO] [(2) YES]

DETACHMENT, ENSTRANGEMENT, RESTRICTED AFFECT

10. Lifetime: [(0) NI] [(1) NO] [(2) YES]

SENSE OF FORESHORTENED FUTURE

11. Lifetime: [(0) NI] [(1) NO] [(2) YES]

SLEEP PROBLEMS

12. Lifetime: [(0) NI] [(1) NO] [(2) YES]

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KIDDIE-SADS-LIFETIME - SCORING FORM

IRRITABILITY

13. Lifetime: [(0) NI] [(1) NO] [(2) YES]

DIFFICULTY CONCENTRATING

14. Lifetime: [(0) NI] [(1) NO] [(2) YES]

HYPERVIGILENCE

15. Lifetime: [(0) NI] [(1) NO] [(2) YES]

EXAGGERATED STARTLED RESPONSE

16. Lifetime: [(0) NI] [(1) NO] [(2) YES]

OVERALL SEVERITY OF POST-TRAUMATIC STRESS DISORDER

17. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

DIAGNOSTIC CRITERIA - POST-TRAUMATIC STRESS DISORDER

18. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

19.		20.	
Onset	___	Onset	___
Offset	___	Offset	___
Weeks	___	Weeks	___

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KIDDIE-SADS-LIFETIME - SCORING FORM

ATTENTION-DEFICIT/HYPERACTIVITY DISORDER

INATTENTION

1. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

HYPERACTIVITY

2. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

IMPULSIVITY

3. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

DIAGNOSTIC CRITERIA - ATTENTION-DEFICIT/HYPERACTIVITY DISORDER

4. Onset and Course

Number of Episodes [ ]

Ages of onset and offset of each episode

5. Onset [ ]
Offset [ ]
Weeks [ ]

6. Onset [ ]
Offset [ ]
Weeks [ ]

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KIDDIE-SADS-LIFETIME - SCORING FORM

CONDUCT DISORDER/ANTISOCIAL PERSONALITY

CHRONIC VIOLATION OF RULES AT HOME AND/OR SCHOOL

1. Lifetime: [(0) NI] [(1) NO] [(2)] [(3)] [(4)]

SCHOOL SUSPENSION/EXPULSION

2. Lifetime: [(0) NI] [(1) NO] [(2) -1] [(3) 1+] [(4) EXP]

TRUANCY

3. Lifetime: [(0) NI] [(1) NO] [(2) OCC] [(3) FQT] [(4) 50%]

PATHOLOGICAL LYING

4. Lifetime: [(0) NI] [(1) NO] [(2)] [(3)] [(4)]

STAYING OUT AT NIGHT

5. Lifetime: [(0) NI] [(1) NO] [(2)] [(3)] [(4)]

RUNAWAY OVERNIGHT

6. Lifetime: [(0) NI] [(1) NO] [(2) 1] [(3) 1+] [(4) FQT]

NONAGGRESIVE STEALING

7. Lifetime: [(0) NI] [(1) NO] [(2)] [(3) $10] [(4) $50]

BULLYING

8. Lifetime: [(0) NI] [(1) NO] [(2)] [(3) FQT] [(4) DLY]

PERSISTENT PHYSICAL FIGHTING

9. Lifetime: [(0) NI] [(1) NO] [(2)] [(3) FQT] [(4)]

USE OF A WEAPON

10. Lifetime: [(0) NI] [(1) NVR] [(2) CON] [(3) 1] [(4) 1+]

VANDALISM

11. Lifetime: [(0) NI] [(1) NO] [(2)] [(3)] [(4)]

FIRESETTING

12. Lifetime: [(0) NI] [(1) NO] [(2)] [(3)] [(4)]

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KIDDIE-SADS-LIFETIME - SCORING FORM

BREAKING AND ENTERING

13. Lifetime: [(0) NI] [(1) NO] [(2) -1] [(3) 2] [(4) 2+]

AGGRESSIVE STEALING

14. Lifetime: [(0) NI] [(1) NO] [(2) -1] [(3) 2] [(4) 2+]

CRUELTY TO ANIMALS

15. Lifetime: [(0) NI] [(1) NO] [(2) OCC] [(3)] [(4)]

PHYSICAL CRUELTY TO PERSONS

16. Lifetime: [(0) NI] [(1) NO] [(2) -1] [(3) 2] [(4) 2+]

HOMICIDAL ACTS

17. Lifetime: [(0) NI] [(1) NO] [(2) GTR] [(3) ATT] [(4) COM]

FORCED SEX

18. Lifetime: [(0) NI] [(1) NO] [(2)] [(3)] [(4)] [(5) RAP]

GANG ACTIVITIES

19. Lifetime: [(0) NI] [(1) NO] [(2) PER] [(3) MEM] [(4) LDR]

DELINQUENCY

20. Lifetime: [(0) NI] [(1) NO] [(2) ARR] [(3) CHA] [(4) CON]

INCARCERATION

21. Lifetime: [(0) NI] [(1) NO] [(2) HLD] [(3) REF] [(4) JAL]

SUMMARY RATING

22. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

DIAGNOSTIC CRITERIA - CONDUCT DISORDER

23. Onset and Course

Number of Episodes [ ]

Ages of onset and offset of each episode

24. Onset [ ] Offset [ ] Weeks [ ]

25. Onset [ ] Offset [ ] Weeks [ ]

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KIDDIE-SADS-LIFETIME - SCORING FORM

ANTISOCIAL PERSONALITY DISORDER

WORK

1. Lifetime: [(0) NI] [(1) NO] [(2) MLD] [(3) MOD] [(4) SVR] [(5) EX]

FINANCIAL RESPONSIBILITY

2. Lifetime: [(0) NI] [(1) NO] [(2) MLD] [(3) MOD] [(4) SVR] [(5) EX]

CONNING

3. Lifetime: [(0) NI] [(1) MLD] [(2) MOD] [(3) SVR] [(4) EX]

DISREGARD FOR SAFETY OF SELF/OTHERS

4. Lifetime: [(0) NI] [(1) MLD] [(2) MOD] [(3) EX]

LACK OF REMORSE

5. Lifetime: [(0) NI] [(1) MLD] [(2) MOD] [(3) EX]

DIAGNOSTIC CRITERIA - ANTISOCIAL PERSONALITY DISORDER

6. Onset and Course

Number of Episodes [ ]

Ages of onset and offset of each episode

7. Onset [ ] Offset [ ] Weeks [ ]

8. Onset [ ] Offset [ ] Weeks [ ]

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KIDDIE-SADS-LIFETIME - SCORING FORM

OPPOSITIONAL DEFIANT DISORDER

1. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

DIAGNOSTIC CRITERIA - OPPOSITIONAL DEFIANT DISORDER

2. Onset and Course

Number of Episodes [ ]

Ages of onset and offset of each episode

3. Onset [ ]
Offset [ ]
Weeks [ ]

4. Onset [ ]
Offset [ ]
Weeks [ ]

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KIDDIE-SADS-LIFETIME - SCORING FORM

ALCOHOL

ALCOHOL ABUSE

1. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

ALCOHOL DEPENDENCE

2. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

DIAGNOSTIC CRITERIA - ALCOHOL DEPENDENCE

3. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

4. Onset ___ Offset ___ Weeks ___

5. Onset ___ Offset ___ Weeks ___

DIAGNOSTIC CRITERIA - ALCOHOL ABUSE

6. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

7. Onset ___ Offset ___ Weeks ___

8. Onset ___ Offset ___ Weeks ___

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KIDDIE-SADS-LIFETIME - SCORING FORM

DRUGS

DRUG ABUSE

1. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

DRUG DEPENDENCE

2. Lifetime: [0] NI [1] NO [2] MLD [3] MOD [4] SVR [5] EX

DIAGNOSTIC CRITERIA - SUBSTANCE DEPENDENCE

3. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

4. Onset ___ Offset ___ Weeks ___

5. Onset ___ Offset ___ Weeks ___

DIAGNOSTIC CRITERIA - SUBSTANCE ABUSE

6. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

7. Onset ___ Offset ___ Weeks ___

8. Onset ___ Offset ___ Weeks ___

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KIDDIE-SADS-LIFETIME - SCORING FORM

TIC DISORDERS

MOTOR TICS

1. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

VOCAL TICS

2. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

DIAGNOSTIC CRITERIA - TIC DISORDERS

3. Onset and Course

Number of Episodes [ ]

Ages of onset and offset of each episode

4. Onset [ ] Offset [ ] Weeks [ ]

5. Onset [ ] Offset [ ] Weeks [ ]

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KIDDIE-SADS-LIFETIME - SCORING FORM

PSYCHOTIC SYMPTOMOLOGY

COMMAND HALLUCINATIONS

1. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

CONVERSING VOICES

2. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

PERSECUTORY HALLUCINATIONS

3. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

COMMENTING VOICE

4. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

RELIGIOUS HALLUCINATIONS

5. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

THOUGHTS ALOUD

6. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

OTHER VERBAL HALLUCINATIONS

7. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

LOCATION OF AUDITORY HALLUCINATIONS

8. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

9. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

10. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

VISUAL HALLUCINATIONS

11. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

TACTILE HALLUCINATIONS

12. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

OLFACTORY HALLUCINATIONS

13. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

14. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

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KIDDIE-SADS-LIFETIME - SCORING FORM

OTHER PERCEPTUAL CHILDHOOD PHENOMENA

HYPNAGOGIC OR HYPNAPOMPIC HALLUCINATIONS

1. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]
2. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]
3. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

ILLUSIONS

4. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

EIDETIC IMAGERY

5. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

ELABORATED FANTASIES

6. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

IMAGINARY COMPANIONS

7. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

CHARACTERISTICS OF PSYCHOPATHOLOGICALLY MEANINGFUL HALLUCINATIONS

FREQUENCY

8. Lifetime: [(0) NI] [(1) NO] [(2) SUS] [(3) -5] [(4) SOM] [(5) LOT] [(6) DLY]

SEVERITY

9. Lifetime: [(0) NI] [(1) NO] [(2) SUS] [(3) DEF] [(4) GEN] [(5) CNV] [(6) ACT]

THEMATIC CONSISTENCY WITH MOOD DISORDER

DEPRESSION

10. Lifetime: [(0) NI] [(1) NO] [(2) POS] [(3) COM]

MANIA

11. Lifetime: [(0) NI] [(1) NO] [(2) POS] [(3) COM]

TEMPORAL CONSISTENCY WITH MOOD DISORDER

DEPRESSION

12. Lifetime: [(0) NI] [(1) NO] [(2) SUS] [(3) POS]

MANIA

13. Lifetime: [(0) NI] [(1) NO] [(2) SUS] [(3) POS]

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KIDDIE-SADS-LIFETIME - SCORING FORM

DELUSIONS

DELUSIONS OF REFERENCE

1. Lifetime: [0] NI [1] ABS [2] NON [3] SUS [4] DEF

DELUSIONS OF BEING CONTROLLED OR INFLUENCED

2. Lifetime: [0] NI [1] ABS [2] NON [3] SUS [4] DEF

DELUSIONS THAT PEOPLE CAN READ HIS MIND

3. Lifetime: [0] NI [1] ABS [2] NON [3] SUS [4] DEF

THOUGHT BROADCASTING

4. Lifetime: [0] NI [1] ABS [2] NON [3] SUS [4] DEF

THOUGHT INSERTION

5. Lifetime: [0] NI [1] ABS [2] NON [3] SUS [4] DEF

THOUGHT WITHDRAWAL

6. Lifetime: [0] NI [1] ABS [2] NON [3] SUS [4] DEF

DELUSIONS OF GUILT OR SIN

7. Lifetime: [0] NI [1] ABS [2] NON [3] SUS [4] DEF

DELUSIONS OF INFLUENCE

8. Lifetime: [0] NI [1] ABS [2] NON [3] SUS [4] DEF

PERSECUTORY DELUSIONS

9. Lifetime: [0] NI [1] ABS [2] NON [3] SUS [4] DEF

GUILT RELATED PERSECUTORY DELUSIONS

10. Lifetime: [0] NI [1] ABS [2] NON [3] SUS [4] DEF

SOMATIC DELUSIONS

11. Lifetime: [0] NI [1] ABS [2] NON [3] SUS [4] DEF

GUILT RELATED SOMATIC DELUSIONS

12. Lifetime: [0] NI [1] ABS [2] NON [3] SUS [4] DEF

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KIDDIE-SADS-LIFETIME - SCORING FORM

NIHILISTIC DELUSIONS

13. Lifetime: [(0) NI] [(1) ABS] [(2) NON] [(3) SUS] [(4) DEF]

GUILT RELATED NIHILISTIC DELUSIONS

14. Lifetime: [(0) NI] [(1) ABS] [(2) NON] [(3) SUS] [(4) DEF]

GRANDIOSE DELUSIONS

15. Lifetime: [(0) NI] [(1) ABS] [(2) NON] [(3) SUS] [(4) DEF]

SUBCULTURAL OR FAMILY DELUSIONS

16. Lifetime: [(0) NI] [(1) DEF] [(2) LIK] [(3) ALL]

SEVERITY OF DELUSIONS OF ANY TYPE

17. Lifetime: [(0) NI] [(1) NO] [(2) SUS] [(3) PST] [(4) GEN] [(5) SIG] [(6) ACT]

SENSORIUM WHILE DELUDED

18. Lifetime: [(0) NI] [(1) DEL] [(2) PLX] [(3) ALW]

THEMATIC CONSISTENCY WITH MOOD DISORDER

DEPRESSION

19. Lifetime: [(0) NI] [(1) NO] [(2) POSS] [(3) COM]

MANIA

20. Lifetime: [(0) NI] [(1) NO] [(2) POSS] [(3) COM]

TEMPORAL CONSISTENCY WITH MOOD DISORDER

DEPRESSION

21. Lifetime: [(0) NI] [(1) NO] [(2) SUS] [(3) POS]

MANIA

22. Lifetime: [(0) NI] [(1) NO] [(2) SUS] [(3) POS]

BIZARRENESS OF DELUSIONAL CONTENT

23. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EX]

MULTIPLE DELUSIONS

24. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

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KIDDIE-SADS-LIFETIME - SCORING FORM

FORMAL THOUGHT DISORDER

SENTENCE INCOHERENCE

1.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
2.	Observed:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

DERAILMENT

3.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
4.	Observed:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

ILLOGICAL THINKING

5.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
6.	Observed:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

POVERTY OF CONTENT OF SPEECH

7.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
8.	Observed:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

NEOLOGISMS

9.	Lifetime:	(0) NI	(1) ABS	(2) SLT	(3) MLD	(4) MOD	(5) 20%	(6) JAR
10.	Observed:	(0) NI	(1) ABS	(2) SLT	(3) MLD	(4) MOD	(5) 20%	(6) JAR

PRESSURE OF SPEECH

11.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
12.	Observed:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

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KIDDIE-SADS-LIFETIME - SCORING FORM

OBSERVATIONAL ITEMS

INAPPROPRIATE AFFECT

1. Observed: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EX]

BLUNTED AFFECT

2. Observed: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EX]

CATATONIC MOTOR BEHAVIOR

3. Observed: [(0) NI] [(1) ABS] [(2) DBT] [(3) MM] [(4) SVR]
4. Observed: [(0) NI] [(1) ABS] [(2) DBT] [(3) MM] [(4) SVR]
5. Observed: [(0) NI] [(1) ABS] [(2) DBT] [(3) MM] [(4) SVR]
6. Observed: [(0) NI] [(1) ABS] [(2) DBT] [(3) MM] [(4) SVR]
7. Observed: [(0) NI] [(1) ABS] [(2) DBT] [(3) MM] [(4) SVR]

BIZARRENESS

8. Observed: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EX]
9. Observed: [(0) NI] [(1) ABS] [(2) DBT] [(3) PST] [(4) SVR]
10. Observed: [(0) NI] [(1) ABS] [(2) DBT] [(3) PST] [(4) SVR]
11. Observed: [(0) NI] [(1) ABS] [(2) DBT] [(3) PST] [(4) SVR]
12. Observed: [(0) VG] [(1) G] [(2) OF] [(3) P] [(4) VP]

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KIDDIE-SADS-LIFETIME - SCORING FORM

DIAGNOSTIC CRITERIA - SCHIZOPHRENIA

1. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

2. Onset ___ Offset ___ Weeks ___

3. Onset ___ Offset ___ Weeks ___

DIAGNOSTIC CRITERIA - SCHIZOAFFECTIVE DISORDER

4. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

5. Onset ___ Offset ___ Weeks ___

6. Onset ___ Offset ___ Weeks ___

DIAGNOSTIC CRITERIA - BRIEF PSYCHOTIC DISORDER

7. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

8. Onset ___ Offset ___ Weeks ___

9. Onset ___ Offset ___ Weeks ___

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KIDDIE-SADS-LIFETIME - SCORING FORM

DIAGNOSTIC CRITERIA - DELUSIONAL DISORDER

10. Onset and Course

Number of Episodes ⌊_ _⌋

Ages of onset and offset of each episode

11. Onset ⌊_ _⌋ **12.** Onset ⌊_ _⌋

Offset ⌊_ _⌋ Offset ⌊_ _⌋

Weeks ⌊_ _ _⌋ Weeks ⌊_ _ _⌋

KIDDY-GAS (C-GAS)

1. Current Episode:	100-91	90-81	80-71	70-61	60-51	50-41	40-31	30-21	20-11	10-1
2. Last Two Weeks:	100-91	90-81	80-71	70-61	60-51	50-41	40-31	30-21	20-11	10-1

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VITAL SIGNS

Weight ☐ lbs ☐ kg	Sitting		Standing	
	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)
.	/		/	

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

☐ Yes ☐ No

Record in the Adverse Experience section, page

Has there been any change in concomitant medication since the last visit?

☐ Yes ☐ No

Record in the Concomitant Medication section, page

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
   - ☐ 1 = These feeling states indicated only on questioning
   - ☐ 2 = These feeling states spontaneously reported verbally
   - ☐ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
   - ☐ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication

2. Feelings of Guilt
   - ☐ 0 = Absent
   - ☐ 1 = Self reproach, feels he/she has let people down
   - ☐ 2 = Ideas of guilt or rumination over past errors or sinful deeds
   - ☐ 3 = Present illness is a punishment. Delusions of guilt
   - ☐ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide
   - ☐ 0 = Absent
   - ☐ 1 = Feels life is not worth living
   - ☐ 2 = Wishes he/she were dead or any thoughts of possible death to self
   - ☐ 3 = Suicide ideas or gesture
   - ☐ 4 = Attempts at suicide (any serious attempt rates 4)

4. Insomnia Early
   - ☐ 0 = No difficulty falling asleep
   - ☐ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
   - ☐ 2 = Complains of nightly difficulty falling asleep

5. Insomnia Middle
   - ☐ 0 = No difficulty
   - ☐ 1 = Patient complains of being restless and disturbed during the night
   - ☐ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia Late
   - ☐ 0 = No difficulty
   - ☐ 1 = Waking in early hours of the morning but goes back to sleep
   - ☐ 2 = Unable to fall asleep again if he/she gets out of bed

7. Work and Activities
   - ☐ 0 = No difficulty
   - ☐ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
   - ☐ 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
   - ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
   - ☐ 4 = Stopped working because of present illness.

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
- ☐ 0 = Normal speech and thought
- ☐ 1 = Slight retardation at interview
- ☐ 2 = Obvious retardation at interview
- ☐ 3 = Interview difficult
- ☐ 4 = Complete stupor

9. Agitation
- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = "Playing with" hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety Psychic
- ☐ 0 = No difficulty
- ☐ 1 = Subjective tension and irritability
- ☐ 2 = Worrying about minor matters
- ☐ 3 = Apprehensive attitude apparent in face or speech
- ☐ 4 = Fears expressed without questioning

11. Anxiety Somatic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal
- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating. Heavy feelings in abdomen
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. Somatic Symptoms General
- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
- ☐ 2 = Any clear-cut symptoms rates 2

14. Genital Symptoms (such as loss of libido and menstrual disturbances)
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis
- ☐ 0 = Not present
- ☐ 1 = Self-absorption (bodily)
- ☐ 2 = Preoccupation with health
- ☐ 3 = Frequent complaints, requests for help, etc.
- ☐ 4 = Hypochondriacal delusions

16. Loss of Weight
- ☐ 0 = No weight loss
- ☐ 1 = Slight or doubtful loss of weight
- ☐ 2 = Obvious or severe loss of weight

17. Insight
- ☐ 0 = Acknowledges being depressed and ill
- ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
- ☐ 2 = Denies being ill at all

➧ ⌊_⌋ HAMD Score (Items 1-17)

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DEPRESSED MOOD

1. Worst Severity of Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Duration of Current Episode: [ ] # of weeks

2. Worst Severity of Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Frequency: [ ] Days/week

Average % time of the day: [ ] %

DEPRESSED APPEARANCE

3. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

4. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

IRRITABILITY AND ANGER

5. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Duration: [ ] # of weeks

6. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Frequency: [ ] Days/week

Average % time of the day: [ ] %

SEPARATION-DEPENDENT-DYSPHORIA

7. Current Episode: [0] NI [1] NO [2] OCC [3] USL [4] ALW

8. Last Two Weeks: [0] NI [1] NO [2] OCC [3] USL [4] ALW

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

QUALITY OF DYPSHORIC MOOD

9. Current Episode: [0] NI [1] ND [2] QUE [3] DDF [4] VDF

10. Last Two Weeks: [0] NI [1] ND [2] QUE [3] DDF [4] VDF

DEGREE OF ASSOCIATION OF DEPRESSED OR IRRITABLE MOOD WITH SPECIFIC EVENTS OR PREOCCUPATIONS

11. Current Episode: [0] NI [1] NAL [2] MOT [3] UN [4] PN

12. Last Two Weeks: [0] NI [1] NAL [2] MOT [3] UN [4] PN

REACTIVITY OF DEPRESSED OR IRRITABLE MOOD

13. Current Episode: [0] NI [1] VR [2] FUL [3] RES [4] MLD [5] SLT [6] UNR

[ ] % Usual % of Normal

14. Last Two Weeks: [0] NI [1] VR [2] FUL [3] RES [4] MLD [5] SLT [6] UNR

[ ] % Usual % of Normal

[ ] % Maximum % of Normal

[ ] Number of hours good feeling last

DIURNAL MOOD VARIATION

Worse in Morning

15. Current Episode: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

16. Last Two Weeks: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

Worse in Afternoon and/or Evening

17. Current Episode: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

18. Last Two Weeks: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

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29060	329	0 0		Eligibility Determination	02	91

KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

EXCESSIVE INAPPROPRIATE GUILT

19. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

20. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

Frequency: Days/Week [ ]

NEGATIVE SELF IMAGE

21. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

22. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

FEELING UNLOVED/FORLORN

23. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

24. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

Frequency: Days/Week [ ]

HOPELESSNESS, HELPLESSNESS, DISCOURAGEMENT, PESSIMISM

25. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

26. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

SELF-PITY

27. Current Episode: [0] NI [1] NO [2] OCC [3] MLD [4] CON

28. Last Two Weeks: [0] NI [1] NO [2] OCC [3] MLD [4] CON

ACHES AND PAINS

29. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

30. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

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29060	329	0 0		Eligibility Determination	92	92

KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

HYPOCHONDRIASIS

31. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

32. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

ANHEDONIA, LACK OF INTEREST, APATHY, LOW MOTIVATION, BOREDOM

Combined Overall Rating

33. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Duration: [ ] # of weeks

34. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/week

Average % time of the day: [ ] %

Differentiating Lack of Interest from Anhedonia

Lack of Interest

35. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

36. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Anhedonia

37. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

38. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

FATIGUE, LACK OF ENERGY AND TIREDNESS

39. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

40. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/Week

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DIFFICULTY CONCENTRATING, INATTENTION, OR SLOWED THINKING

41. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

42. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

PSYCHOMOTOR AGITATION

43. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

44. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Unable to sit still

45. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) PR] [(4) MOD] [(5) SVR]

46. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) PR] [(4) MOD] [(5) SVR]

Pacing

47. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) PR] [(4) SVR] [(5) SVR]

48. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) PR] [(4) SVR] [(5) SVR]

Hand wringing

49. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) PR] [(4) SVR] [(5) SVR]

50. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) PR] [(4) SVR] [(5) SVR]

Pulling or rubbing on hair, clothing, skin

51. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) PR] [(4) SVR] [(5) SVR]

52. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) PR] [(4) SVR] [(5) SVR]

Can't stop talking, talks on and on

53. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) PR] [(4) SVR] [(5) SVR]

54. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) PR] [(4) SVR] [(5) SVR]

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29060	329	0 0		Eligibility Determination	01	94

KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

PSYCHOMOTOR RETARDATION

55. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

56. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Slowed Speech

57. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

58. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Increased pauses before answering

59. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

60. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Low or monotonous speech

61. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

62. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Mute or markedly decreased amount of speech

63. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

64. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Slowed body movements

65. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

66. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Depressive stupor

67. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

68. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SOCIAL WITHDRAWAL

69.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
70.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

REJECTION SENSITIVITY

71.	Last Year:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
72.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
73.	Last Year:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
74.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

SLEEP PROBLEMS

75. ⌊__⌋ Hours slept before onset of depression

76. ⌊__⌋ Hours slept during the current episode

77. ⌊__⌋ Hours slept during the last two weeks

HYPERSOMNIA

78. ⌊__⌋ Hours slept in daytime of current episode

79. ⌊__⌋ Hours slept in daytime in the last two weeks

80. ⌊__⌋ Hours lying down in current episode

81. ⌊__⌋ Hours lying down in last two weeks

82.	Current Episode:	(0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)
83.	Last Two Weeks:	(0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

INSOMNIA

84. Current Episode: [(0) NI] [(1) NO] [(2)] [(3)] [(4)] [(5)] [(6)]

85. Last Two Weeks: [(0) NI] [(1) NO] [(2)] [(3)] [(4)] [(5)] [(6)]

Frequency: [ ] Nights/Week

TYPES OF INSOMNIA

Initial Insomnia

86. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

87. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Middle Insomnia

88. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

89. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Terminal Insomnia

90. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

91. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Circadian Reversal

92. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

93. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Non-restorative sleep

94. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

95. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Daytime sleepiness

96. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

97. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

ANOREXIA

98. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] RAR [6] NVR

99. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] RAR [6] NVR

WEIGHT LOSS

100. Current Episode:

Pounds lost: ___ lbs.

Number of Weeks: ___

101. Last Two Weeks:

Pounds lost: ___ lbs.

INCREASED APPETITE

102. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

103. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

Frequency: ___ Days/Week

STRONG CRAVING FOR SWEETS

104. Current Episode: [0] NI [1] ABS [2] DBT [3] MLD [4] MOD [5] SVR

105. Last Two Weeks: [0] NI [1] ABS [2] DBT [3] MLD [4] MOD [5] SVR

WEIGHT GAIN

106. Current Episode:

Pounds gained: ___ lbs.

Number of Weeks: ___

107. Last Two Weeks:

Pounds gained: ___ lbs.

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SUICIDAL IDEATION

108. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

109. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Suicidal Acts - Number

110. Current Episode: [ ]

111. Last Two Weeks: [ ]

Suicidal Acts - Seriousness

112. Current Episode: [0] NI [1] NO [2] MIN [3] DEF [4] SER [5] VS [6] EXT

113. Last Two Weeks: [0] NI [1] NO [2] MIN [3] DEF [4] SER [5] VS [6] EXT

Medical Lethality

114. Current Episode [0] NI [1] NO [2] MIN [3] MLD [4] MO [5] SVR [6] EXT

115. Last Two Weeks: [0] NI [1] NO [2] MIN [3] MLD [4] MO [5] SVR [6] EXT

Non-Suicidal Physical Self-Demaging Acts

116. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] ACT

117. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] ACT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DIAGNOSTIC CRITERIA - MAJOR DEPRESSIVE EPISODE

Onset and Course

118. Number of Episodes [ ]

Ages of onset and offset of each episode

119. Onset [ ]
Offset [ ]
Weeks [ ]

120. Onset [ ]
Offset [ ]
Weeks [ ]

121. Onset [ ]
Offset [ ]
Weeks [ ]

122. Onset [ ]
Offset [ ]
Weeks [ ]

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

MANIC SYNDROME

ELATION, EXPANSIVE MOOD

1.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
2.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

DECREASED NEED FOR SLEEP

3.	Current Episode:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+
4.	Last Two Weeks:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+

UNUSUALLY ENERGETIC

5.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA
6.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA

INCREASE IN GOAL DIRECTED ACTIVITY

7.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
8.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

GRANDIOSITY

9.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
10.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

ACCELERATED, PRESSURED OR INCREASED AMOUNT OF SPEECH

11.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
12.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

RACING THOUGHTS

13. Current Episode: [0] NI [1] NO [2] DBT [3] MLD [4] MO [5] SVR [6] EX

14. Last Two Weeks: [0] NI [1] NO [2] DBT [3] MLD [4] MO [5] SVR [6] EX

FLIGHT OF IDEAS

15. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

16. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

POOR JUDGEMENT

17. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] VS

18. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] VS

DISTRACTABILITY

19. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR

20. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR

MOTOR HYPERACTIVITY

21. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] MKD [6] EX

22. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] MKD [6] EX

Inappropriate laughing, joking or punning

23. Current Episode: [0] NI [1] NO [2] DBT [3] MLD [4] MOD

24. Last Two Weeks: [0] NI [1] NO [2] DBT [3] MLD [4] MOD

Uninhibited people seeking, gregarious

25. Current Episode: [0] NI [1] NO [2] DBT [3] MLD [4] MOD

26. Last Two Weeks: [0] NI [1] NO [2] DBT [3] MLD [4] MOD

SmithKline Beecham Pharmaceuticals

Tracking Number

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Eligibility Determination	02	102

KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

Increased Productivity

27. Current Episode: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

28. Last Two Weeks: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

Sharpened and unusually creative thinking

29. Current Episode: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

30. Last Two Weeks: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

Hypersexuality

31. Current Episode: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

32. Last Two Weeks: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

INFLUENCE OF ILLICIT DRUGS OR ALCOHOL

33. Current Episode: [0] NA [1] NVR [2] SMT [3] ONL

34. Last Two Weeks: [0] NA [1] NVR [2] SMT [3] ONL

NUMBER OF MANIC PERIODS

35. [ ]

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Tracking Number

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DIAGNOSTIC CRITERIA - HYPOMANIC EPISODE

Onset and Course

36. Number of Episodes [ ]

Ages of onset and offset of each episode

37. Onset [ ] Offset [ ] Weeks [ ]

38. Onset [ ] Offset [ ] Weeks [ ]

DIAGNOSTIC CRITERIA - MANIC EPISODE

39. Onset and Course

Number of Episodes [ ]

Ages of onset and offset of each episode

40. Onset [ ] Offset [ ] Weeks [ ]

41. Onset [ ] Offset [ ] Weeks [ ]

SmithKline Beecham Pharmaceuticals

Tracking Number

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29060	329	0 0		Eligibility Determination	12	104

ELIGIBILITY CHECKLIST

Answer the following statements by marking the appropriate box.

Inclusion criteria

If any of the following statements are answered 'No', the patient is not eligible for the study.

		Yes	No
1.	Has the patient and legal guardian signed an informed consent?	☐	☐
2.	Is the patient an adolescent between the ages of 12 years 0 month and 18 years 11 months inclusive?	☐	☐
3.	Is the patient currently in an episode of major depression (DSM-III-R) for at least 8 weeks?	☐	☐
4.	Does the patient have a score of ≥ 12 on the 17-item Hamilton Depression Scale (Screening visit ***and*** Eligibility Determination visit, pages 8 and 88)?	☐	☐
5.	Is the patient medically healthy as determined by physical examination, medical history and laboratory screening (pages 3 and 5)?	☐	☐
6.	Does the patient have an IQ ≥ 80 by Peabody Picture Vocabulary Test?	☐	☐
7.	Is the patient male, or if female and sexually active, is the patient using a reliable method of contraception (oral contraception, surgical sterilization, I.U.D., diaphragm in conjunction with spermicidal foam amd condom on partners)?	☐	☐

Exclusion criteria

If any of the following statements are answered 'Yes', the patient is not eligible for the study.

		Yes	No
1.	Does the patient have or have had a DSM-III-R diagnosis of bipolar disorder, schizo-affective disorder, anorexia, bulimia, alcohol or drug abuse/dependence, obsessive/compulsive disorder, autism/pervasive mental disorder, or organic psychiatric disorder?	☐	☐
2.	Does the patient have a current diagnosis (within 12 months) of post traumatic stress disorder (DSM-III-R)?	☐	☐
3.	Has the patient been adequately treated with anti-depressants within 6 months prior to beginning this study (page 4)?	☐	☐
4.	Has the patient ever had suicidal ideation with a definite plan, or made a suicide attempt within the current episode, or ever made a suicide attempt by medication overdose?	☐	☐
5.	Has the patient any medical illness which would contraindicate the use of heterocyclic antidepressants (e.g., cardiovascular disease)?	☐	☐
6.	Is the patient currently using (1) psychotropic medications including anticonvulsants, anxiolytics, neuroleptics, lithium carbonate, (2) illicit drugs as documented by a drug screen with two weeks of starting the study (page 4)?	☐	☐
7.	Does the patient have evidence of organic brain disease, epilepsy or mental retardation?	☐	☐
8.	Is the patient pregnant or lactating?	☐	☐
9.	Has the patient been treated with any investigational drug within 30 days of entry into the study or within 5 half lives of the investigation drug (the longer period will apply)(page 4)?	☐	☐

SmithKline Beecham Pharmaceuticals

Tracking Number

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29060	329	0 0		Eligibility Determination	02	105

QUALIFICATION FOR ENTRY TO DOUBLE-BLIND PHASE

Does the patient qualify to enter the double-blind phase of the study, i.e., are the inclusion and exclusion criteria listed on page 104 satisfied?

☐ No - the patient does not qualify for entry

1. Complete page 106 (concomitant medication) and page 107 (adverse experience) if the patient has taken any medication or reported an adverse experience during the screening phase.

   Note: These pages are to be completed only for patients who ***will not*** enter the double-blind phase.

☐ Yes - the patient does qualify for entry

1. Dispense the Week 1 study medication card.
2. Detach the tear off label from the Week 1 card and affix the label to the Week 1 Label page (page 113) in Binder 2. Also record the start date in the Study Medication Record on page 112 in Binder 2.

   Important: The drug code on the randomization label ***must be identical*** to the Patient Number preprinted in the Patient Number box atop of pages 108-232 in Binder 2.
   To ensure that this Patient Number is properly referenced to the Tracking Number of the Screening/Eligibility pages of this case report form record the pre-printed Patient Number from the top of page 108 (Binder 2) in the space below and again on page 1 (Binder 1-in the page header) of the case report form.

   Patient Number

3. If the patient is entering the double-blind phase and had an adverse experience during the screening procedures, the experience must be recorded in the adverse experience section (pages 226-231). Additionally, if the patient has taken any medication, either over the counter or prescription, during the screening procedures, these must be recorded in the concomitant medication section (pages 224-225).

I certify that I have reviewed the screening/eligiblity data in the case report form (pages 1-107) and that all information is complete and accurate.

Investigator's Signature _____ _____

Date

SmithKline Beecham Pharmaceuticals

Tracking Number

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Eligibility Determination	02	106

CONCOMITANT MEDICATION → SCREENING FAILURES ONLY

- Record all concomitant medication taken as corrective therapy for Baseline Adverse Experience.
- Where appropriate, medical conditions should be recorded on the Adverse Experiences form utilizing the same terminology.

Drug Name (Trade name preferred)	Total Daily Dose (e.g., 500 mg)	Route	Medical Condition	Start Date ★ day month year	End Date ★ or Continuation (mark box) day month year	
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
For SB						

★ State dates as precisely as possible.

SmithKline Beecham Pharmaceuticals

Tracking Number

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Eligibility Determination	02	107

ADVERSE EXPERIENCE → SCREENING FAILURES ONLY

➧ Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).

Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
Duration if less than 24 hours		hours minutes	hours minutes	hours minutes
Experience continuing		☐	☐	☐
Experience continuing at end of study		☐	☐	☐
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -	☐ Yes ☐ No -	☐ Yes ☐ No -
Intensity	1 Mild	☐	☐	☐
	2 Moderate	☐	☐	☐
	3 Severe	☐	☐	☐
Action Taken on Study Medication	1 None	☐	☐	☐
	2 Dose decreased	☐	☐	☐
	3 Dose increased	☐	☐	☐
	4 Drug stopped	☐	☐	☐
Suspected Relationship To Study Medication	1 Related	☐	☐	☐
	2 Possibly related	☐	☐	☐
	3 Probably unrelated	☐	☐	☐
	4 Unrelated	☐	☐	☐
Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Do you consider this a serious adverse experience by the definitions on previous page?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
➧ If yes, report experience to SB by telephone within 24 hours		AE Number	AE Number	AE Number
Investigator's Signature				➧ If patient died, complete Form D

Table of Contents

Tab 1

Tab 2

Tab 3

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Table of Contents

ELIGIBILITY DETERMINATION

QUALIFICATION FOR
ENTRY INTO
DOUBLE-BLIND-PHASE

Project	Protocol	Center	Patient Number
29060	329	0	

SmithKline Beecham
Pharmaceuticals

CONFIDENTIAL

CASE REPORT FORM

PROTOCOL 29060/329

ACUTE PHASE - BINDER 2

A Multi-Center, Double-Blind, Placebo Controlled Study of Paroxetine and Imipramine in Adolescents with Unipolar Major Depression

Patient Initials ____ Country _____

GENERAL INSTRUCTIONS

Print clearly in CAPITAL LETTERS using a black ball-point pen and press firmly so that all copies are legible. DO NOT print in shaded areas. Answer all questions on every page.

The plastic writing board in the back of the binder should be used to divide each set of pages before writing on them with a ball-point pen.

Important: Errors should be crossed with a single line and the alteration made as close to the original as possible. All alterations must be printed, initialled and dated.

DATE

Use the following three-letter abbreviations for month:

January	=	JAN
February	=	FEB
March	=	MAR
April	=	APR
May	=	MAY
June	=	JUN
July	=	JUL
August	=	AUG
September	=	SEP
October	=	OCT
November	=	NOV
December	=	DEC

Example: | 0 | 1 | J | A | N | 9 | 4 | = 1st January 1994

day month year

TIME

Unless specified otherwise, use the 24 hour clock: 00:00 - 23:59.

Example: | 1 | 5 | 3 | 0 | = 3:30 p.m.

24 hr. clock

SMITHKLINE BEECHAM PROTOCOL 29060/329 - SCHEDULE OF PROCEDURES

Assessments	Baseline		Acute Phase								Continuation Phase					
Time (weeks)	-1	0	1	2	3	4	5	6	7	8	12	16	20	24	28	32
Informed Consent	●															
Medical History and Physical Exam	●															
Clinical Laboratory Studies	● [1]									●			●			●
Serum Pregnancy	●		● [2]	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....
ECG	●			●		●		●		●			●			●
Vital Signs	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Hamilton Depression Scale	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Full K-SADS-L	●															●
Affect Section of K-SADS-L		●		●		●		●		●	●	●	●	●	●	
C-GAS	●															
CGI		●	●	●	●	●	●	●	●	●	●	●	●		●	●
SADS-L	●															
FH-FHE	●															
Autonomous Functioning Checklist	●									●						●
Self Perception Profile	●									●						●
Sickness Impact Scale	●									●						●
Randomization		●														
Adverse Experiences		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Supportive Psychotherapy		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Plasma Sampling for Drug Analysis	●					●				●				●		●
Study Medication Record			●	●	●	●	●	●	●	●	●	●	●	●	●	●
Concomitant Medication	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●

[1] - Clinical laboratory studies should include a Urine Drug Screen
[2] - On suspicion of pregnancy

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	
29060	329	0 0		Acute Phase	

MODULE PARAMETERS - SCREENING/ELIGIBILITY

For SmithKline Beecham Use	Project	*29060*
	Protocol	*329*
	Center	
	Patient Number	
	Module Pages	*V0117*

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	
29060	329	0 0		Acute Phase	

MODULE PARAMETERS - WEEK 1

For SmithKline Beecham Use	Project	*29060*
	Protocol	*329*
	Center	
	Patient Number	
	Module Pages	*V0217*

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	Visit Date	Page
29060	329	0 0		Acute Phase Week 1	day month year	108

TRACKING NUMBER

Enter the Tracking Number from the top of page 107. Tracking Number

VITAL SIGNS

Weight ☐ lbs ☐ kg	Sitting		Standing	
	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)
.	/		/	

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

☐ Yes ☐ No

Record in the Adverse Experience section

Has there been any change in concomitant medication since the last visit?

☐ Yes ☐ No

Record in the Concomitant Medication section

CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

Rate the total improvement whether or not, in your judgment, it is due entirely to drug treatment. Compared to his/her condition at admission to the study, how much has the patient changed?

- ☐ 1 = Very much improved
- ☐ 2 = Much improved
- ☐ 3 = Minimally improved
- ☐ 4 = No change
- ☐ 5 = Minimally worse
- ☐ 6 = Much worse
- ☐ 7 = Very much worse

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 1	1	109

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
   - ☐ 1 = These feeling states indicated only on questioning
   - ☐ 2 = These feeling states spontaneously reported verbally
   - ☐ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
   - ☐ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication

2. Feelings of Guilt
   - ☐ 0 = Absent
   - ☐ 1 = Self reproach, feels he/she has let people down
   - ☐ 2 = Ideas of guilt or rumination over past errors or sinful deeds
   - ☐ 3 = Present illness is a punishment. Delusions of guilt
   - ☐ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide
   - ☐ 0 = Absent
   - ☐ 1 = Feels life is not worth living
   - ☐ 2 = Wishes he/she were dead or any thoughts of possible death to self
   - ☐ 3 = Suicide ideas or gesture
   - ☐ 4 = Attempts at suicide (any serious attempt rates 4)

4. Insomnia Early
   - ☐ 0 = No difficulty falling asleep
   - ☐ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
   - ☐ 2 = Complains of nightly difficulty falling asleep

5. Insomnia Middle
   - ☐ 0 = No difficulty
   - ☐ 1 = Patient complains of being restless and disturbed during the night
   - ☐ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia Late
   - ☐ 0 = No difficulty
   - ☐ 1 = Waking in early hours of the morning but goes back to sleep
   - ☐ 2 = Unable to fall asleep again if he/she gets out of bed

7. Work and Activities
   - ☐ 0 = No difficulty
   - ☐ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
   - ☐ 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
   - ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
   - ☐ 4 = Stopped working because of present illness.

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)

- ☐ 0 = Normal speech and thought
- ☐ 1 = Slight retardation at interview
- ☐ 2 = Obvious retardation at interview
- ☐ 3 = Interview difficult
- ☐ 4 = Complete stupor

9. Agitation

- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = "Playing with" hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety Psychic

- ☐ 0 = No difficulty
- ☐ 1 = Subjective tension and irritability
- ☐ 2 = Worrying about minor matters
- ☐ 3 = Apprehensive attitude apparent in face or speech
- ☐ 4 = Fears expressed without questioning

11. Anxiety Somatic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.

- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal

- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating. Heavy feelings in abdomen
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. Somatic Symptoms General

- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
- ☐ 2 = Any clear-cut symptoms rates 2

14. Genital Symptoms (such as loss of libido and menstrual disturbances)

- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 1	04	111

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis
- ☐ 0 = Not present
- ☐ 1 = Self-absorption (bodily)
- ☐ 2 = Preoccupation with health
- ☐ 3 = Frequent complaints, requests for help, etc.
- ☐ 4 = Hypochondriacal delusions

16. Loss of Weight
- ☐ 0 = No weight loss
- ☐ 1 = Slight or doubtful loss of weight
- ☐ 2 = Obvious or severe loss of weight

17. Insight
- ☐ 0 = Acknowledges being depressed and ill
- ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
- ☐ 2 = Denies being ill at all

➧ ☐☐ HAMD Score (Items 1-17)

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 1		112

STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily
		1	2

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No

☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance
20				

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(2 \times \text{days since last visit})} \times 100$$

➧ Compliance must be $\geq$ 80% and $\leq$ 120%.

Has the patient been ***non-compliant***?

☐ Yes ☐ No

SmithKline Beecham
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Project	Protocol	Center	Patient Number	Visit		Page
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STUDY MEDICATION LABEL

Attach label here

➧ Enter patient number (drug code as listed on clinical supplies) ⌊_____⌋

Important: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

STUDY MEDICATION DISPENSING

Record study medication information for Week 2 in the Study Medication Record, page 131. Attach label to page 132. Record number of capsules dispensed on page 131.

Reminder: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	
29060	329	0 0		Acute Phase	

MODULE PARAMETERS - WEEK 2

For SmithKline Beecham Use	Project	* 2 9 0 6 0 *
	Protocol	* 3 2 9 *
	Center	
	Patient Number	
	Module Pages	* V 0 3 1 7 *

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	Visit Date	Page
29060	329	0 0		Acute Phase Week 2 04	day month year	114

VITAL SIGNS

Weight ☐ lbs ☐ kg	Sitting		Standing	
	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)
.	/		/	

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

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Record in the Adverse Experience section

Has there been any change in concomitant medication since the last visit?

☐ Yes ☐ No

Record in the Concomitant Medication section

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Rate the total improvement whether or not, in your judgment, it is due entirely to drug treatment. Compared to his/her condition at admission to the study, how much has the patient changed?

☐ 1 = Very much improved
☐ 2 = Much improved
☐ 3 = Minimally improved
☐ 4 = No change
☐ 5 = Minimally worse
☐ 6 = Much worse
☐ 7 = Very much worse

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 2	04	115

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
   - ☐ 1 = These feeling states indicated only on questioning
   - ☐ 2 = These feeling states spontaneously reported verbally
   - ☐ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
   - ☐ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication

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   - ☐ 0 = Absent
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   - ☐ 2 = Ideas of guilt or rumination over past errors or sinful deeds
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   - ☐ 2 = Wishes he/she were dead or any thoughts of possible death to self
   - ☐ 3 = Suicide ideas or gesture
   - ☐ 4 = Attempts at suicide (any serious attempt rates 4)

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   - ☐ 0 = No difficulty falling asleep
   - ☐ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
   - ☐ 2 = Complains of nightly difficulty falling asleep

5. Insomnia Middle
   - ☐ 0 = No difficulty
   - ☐ 1 = Patient complains of being restless and disturbed during the night
   - ☐ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia Late
   - ☐ 0 = No difficulty
   - ☐ 1 = Waking in early hours of the morning but goes back to sleep
   - ☐ 2 = Unable to fall asleep again if he/she gets out of bed

7. Work and Activities
   - ☐ 0 = No difficulty
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   - ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
   - ☐ 4 = Stopped working because of present illness.

SmithKline Beecham
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Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 2	04	116

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
- ☐ 0 = Normal speech and thought
- ☐ 1 = Slight retardation at interview
- ☐ 2 = Obvious retardation at interview
- ☐ 3 = Interview difficult
- ☐ 4 = Complete stupor

9. Agitation
- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = "Playing with" hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
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- ☐ 4 = Fears expressed without questioning

11. Anxiety Somatic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
- ☐ 0 = Absent
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- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal
- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating. Heavy feelings in abdomen
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. Somatic Symptoms General
- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
- ☐ 2 = Any clear-cut symptoms rates 2

14. Genital Symptoms (such as loss of libido and menstrual disturbances)
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis
- ☐ 0 = Not present
- ☐ 1 = Self-absorption (bodily)
- ☐ 2 = Preoccupation with health
- ☐ 3 = Frequent complaints, requests for help, etc.
- ☐ 4 = Hypochondriacal delusions

16. Loss of Weight
- ☐ 0 = No weight loss
- ☐ 1 = Slight or doubtful loss of weight
- ☐ 2 = Obvious or severe loss of weight

17. Insight
- ☐ 0 = Acknowledges being depressed and ill
- ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
- ☐ 2 = Denies being ill at all

➧ ☐☐ HAMD Score (Items 1-17)

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DEPRESSED MOOD

1. Worst Severity of Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Duration of Current Episode: [ ] # of weeks

2. Worst Severity of Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Frequency: [ ] Days/week

Average % time of the day: [ ] %

DEPRESSED APPEARANCE

3. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

4. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

IRRITABILITY AND ANGER

5. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Duration: [ ] # of weeks

6. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Frequency: [ ] Days/week

Average % time of the day: [ ] %

SEPARATION-DEPENDENT-DYSPHORIA

7. Current Episode: [0] NI [1] NO [2] OCC [3] USL [4] ALW

8. Last Two Weeks: [0] NI [1] NO [2] OCC [3] USL [4] ALW

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

QUALITY OF DYPSHORIC MOOD

9. Current Episode: [0] NI [1] ND [2] QUE [3] DDF [4] VDF

10. Last Two Weeks: [0] NI [1] ND [2] QUE [3] DDF [4] VDF

DEGREE OF ASSOCIATION OF DEPRESSED OR IRRITABLE MOOD WITH SPECIFIC EVENTS OR PREOCCUPATIONS

11. Current Episode: [0] NI [1] NAL [2] MOT [3] UN [4] PN

12. Last Two Weeks: [0] NI [1] NAL [2] MOT [3] UN [4] PN

REACTIVITY OF DEPRESSED OR IRRITABLE MOOD

13. Current Episode: [0] NI [1] VR [2] FUL [3] RES [4] MLD [5] SLT [6] UNR

[ ] % Usual % of Normal

14. Last Two Weeks: [0] NI [1] VR [2] FUL [3] RES [4] MLD [5] SLT [6] UNR

[ ] % Usual % of Normal

[ ] % Maximum % of Normal

[ ] Number of hours good feeling last

DIURNAL MOOD VARIATION

Worse in Morning

15. Current Episode: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

16. Last Two Weeks: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

Worse in Afternoon and/or Evening

17. Current Episode: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

18. Last Two Weeks: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

EXCESSIVE INAPPROPRIATE GUILT

19. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

20. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

Frequency: Days/Week [ ]

NEGATIVE SELF IMAGE

21. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

22. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

FEELING UNLOVED/FORLORN

23. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

24. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

Frequency: Days/Week [ ]

HOPELESSNESS, HELPLESSNESS, DISCOURAGEMENT, PESSIMISM

25. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

26. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

SELF-PITY

27. Current Episode: [(0) NI] [(1) NO] [(2) OCC] [(3) MLD] [(4) CON]

28. Last Two Weeks: [(0) NI] [(1) NO] [(2) OCC] [(3) MLD] [(4) CON]

ACHES AND PAINS

29. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

30. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

HYPOCHONDRIASIS

31. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

32. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

ANHEDONIA, LACK OF INTEREST, APATHY, LOW MOTIVATION, BOREDOM

Combined Overall Rating

33. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Duration: [ ] # of weeks

34. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/week

Average % time of the day: [ ] %

Differentiating Lack of Interest from Anhedonia

Lack of Interest

35. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

36. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Anhedonia

37. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

38. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

FATIGUE, LACK OF ENERGY AND TIREDNESS

39. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

40. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/Week

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DIFFICULTY CONCENTRATING, INATTENTION, OR SLOWED THINKING

41. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

42. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

PSYCHOMOTOR AGITATION

43. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

44. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Unable to sit still

45. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

46. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Pacing

47. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

48. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

Hand wringing

49. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

50. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

Pulling or rubbing on hair, clothing, skin

51. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

52. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

Can't stop talking, talks on and on

53. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

54. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

PSYCHOMOTOR RETARDATION

55. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

56. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Slowed Speech

57. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

58. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Increased pauses before answering

59. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

60. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Low or monotonous speech

61. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

62. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Mute or markedly decreased amount of speech

63. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

64. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Slowed body movements

65. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

66. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Depressive stupor

67. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

68. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SOCIAL WITHDRAWAL

69.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX
70.	Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX

REJECTION SENSITIVITY

71.	Last Year:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MOD	[5] SVR	[6] EX
72.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MOD	[5] SVR	[6] EX
73.	Last Year:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MOD	[5] SVR	[6] EX
74.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MOD	[5] SVR	[6] EX

SLEEP PROBLEMS

75. ⌊_⌋ Hours slept before onset of depression

76. ⌊_⌋ Hours slept during the current episode

77. ⌊_⌋ Hours slept during the last two weeks

HYPERSOMNIA

78. ⌊_⌋ Hours slept in daytime of current episode

79. ⌊_⌋ Hours slept in daytime in the last two weeks

80. ⌊_⌋ Hours lying down in current episode

81. ⌊_⌋ Hours lying down in last two weeks

82.	Current Episode:	[0] NI	[1] NO	[2]	[3]	[4]	[5]	[6]
83.	Last Two Weeks:	[0] NI	[1] NO	[2]	[3]	[4]	[5]	[6]

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

INSOMNIA

84. Current Episode: [(0) NI] [(1) NO] [(2)] [(3)] [(4)] [(5)] [(6)]

85. Last Two Weeks: [(0) NI] [(1) NO] [(2)] [(3)] [(4)] [(5)] [(6)]

Frequency: [__] Nights/Week

TYPES OF INSOMNIA

Initial Insomnia

86. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

87. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Middle Insomnia

88. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

89. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Terminal Insomnia

90. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

91. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Circadian Reversal

92. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

93. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Non-restorative sleep

94. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

95. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Daytime sleepiness

96. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

97. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

ANOREXIA

98. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] RAR [6] NVR

99. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] RAR [6] NVR

WEIGHT LOSS

100. Current Episode:

Pounds lost: ___ lbs.

Number of Weeks: ___

101. Last Two Weeks:

Pounds lost: ___ lbs.

INCREASED APPETITE

102. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

103. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

Frequency: ___ Days/Week

STRONG CRAVING FOR SWEETS

104. Current Episode: [0] NI [1] ABS [2] DBT [3] MLD [4] MOD [5] SVR

105. Last Two Weeks: [0] NI [1] ABS [2] DBT [3] MLD [4] MOD [5] SVR

WEIGHT GAIN

106. Current Episode:

Pounds gained: ___ lbs.

Number of Weeks: ___

107. Last Two Weeks:

Pounds gained: ___ lbs.

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SUICIDAL IDEATION

108. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

109. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Suicidal Acts - Number

110. Current Episode: [ ]

111. Last Two Weeks: [ ]

Suicidal Acts - Seriousness

112. Current Episode: [0] NI [1] NO [2] MIN [3] DEF [4] SER [5] VS [6] EXT

113. Last Two Weeks: [0] NI [1] NO [2] MIN [3] DEF [4] SER [5] VS [6] EXT

Medical Lethality

114. Current Episode [0] NI [1] NO [2] MIN [3] MLD [4] MO [5] SVR [6] EXT

115. Last Two Weeks: [0] NI [1] NO [2] MIN [3] MLD [4] MO [5] SVR [6] EXT

Non-Suicidal Physical Self-Demaging Acts

116. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] ACT

117. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] ACT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

MANIC SYNDROME

ELATION, EXPANSIVE MOOD

1.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX
2.	Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX

DECREASED NEED FOR SLEEP

3.	Current Episode:	[0] NI	[1] NO	[2] -1	[3] -2	[4] -3	[5] -4	[6] -4+
4.	Last Two Weeks:	[0] NI	[1] NO	[2] -1	[3] -2	[4] -3	[5] -4	[6] -4+

UNUSUALLY ENERGETIC

5.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] LCH	[4] MOR	[5] MM	[6] UA
6.	Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] LCH	[4] MOR	[5] MM	[6] UA

INCREASE IN GOAL DIRECTED ACTIVITY

7.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX
8.	Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX

GRANDIOSITY

9.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX
10.	Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX

ACCELERATED, PRESSURED OR INCREASED AMOUNT OF SPEECH

11.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX
12.	Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

RACING THOUGHTS

13. Current Episode:	[0] NI	[1] NO	[2] DBT	[3] MLD	[4] MO	[5] SVR	[6] EX
14. Last Two Weeks:	[0] NI	[1] NO	[2] DBT	[3] MLD	[4] MO	[5] SVR	[6] EX

FLIGHT OF IDEAS

15. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX
16. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX

POOR JUDGEMENT

17. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] VS
18. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] VS

DISTRACTABILITY

19. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR
20. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR

MOTOR HYPERACTIVITY

21. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX
22. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX

Inappropriate laughing, joking or punning

23. Current Episode:	[0] NI	[1] NO	[2] DBT	[3] MLD	[4] MOD
24. Last Two Weeks:	[0] NI	[1] NO	[2] DBT	[3] MLD	[4] MOD

Uninhibited people seeking, gregarious

25. Current Episode:	[0] NI	[1] NO	[2] DBT	[3] MLD	[4] MOD
26. Last Two Weeks:	[0] NI	[1] NO	[2] DBT	[3] MLD	[4] MOD

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

Increased Productivity

27. Current Episode: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

28. Last Two Weeks: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

Sharpened and unusually creative thinking

29. Current Episode: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

30. Last Two Weeks: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

Hypersexuality

31. Current Episode: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

32. Last Two Weeks: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

INFLUENCE OF ILLICIT DRUGS OR ALCOHOL

33. Current Episode: [0] NA [1] NVR [2] SMT [3] ONL

34. Last Two Weeks: [0] NA [1] NVR [2] SMT [3] ONL

NUMBER OF MANIC PERIODS

35. [ ]

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STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily
		2	

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No
☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance
20				

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(2 \times \text{days since last visit})} \times 100$$

➧ Compliance must be $\geq$ 80% and $\leq$ 120%.

Has the patient been ***non-compliant***?

☐ Yes ☐ No

Withdraw patient from study. Complete Acute Phase Conclusion section.

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 2	04	132

STUDY MEDICATION LABEL

Attach label here

Enter patient number (drug code as listed on clinical supplies) _____

Important: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

ELECTROCARDIOGRAM

Was electrocardiogram performed and sent to a central reader for interpretation?

☐ Yes ☐ No

Date Performed (day month year) _____

STUDY MEDICATION DISPENSING

Record study medication information for Week 3 in the Study Medication Record, page 137. Attach label to page 138. Record number of capsules dispensed on page 137.

Reminder: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	
29060	329	0 0		Acute Phase	

MODULE PARAMETERS - WEEK 3

For SmithKline Beecham Use	Project	*29060*
	Protocol	*329*
	Center	
	Patient Number	
	Module Pages	*V0417*

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	Visit Date	Page
29060	329	0 0		Acute Phase Week 3	day month year	133

VITAL SIGNS

Weight ☐ lbs ☐ kg	Sitting		Standing	
	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)
.	/		/	

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

☐ Yes ☐ No

Record in the Adverse Experience section

Has there been any change in concomitant medication since the last visit?

☐ Yes ☐ No

Record in the Concomitant Medication section

CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

Rate the total improvement whether or not, in your judgment, it is due entirely to drug treatment. Compared to his/her condition at admission to the study, how much has the patient changed?

☐ 1 = Very much improved
☐ 2 = Much improved
☐ 3 = Minimally improved
☐ 4 = No change
☐ 5 = Minimally worse
☐ 6 = Much worse
☐ 7 = Very much worse

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 3	03	134

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
   - ☐ 1 = These feeling states indicated only on questioning
   - ☐ 2 = These feeling states spontaneously reported verbally
   - ☐ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
   - ☐ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication

2. Feelings of Guilt
   - ☐ 0 = Absent
   - ☐ 1 = Self reproach, feels he/she has let people down
   - ☐ 2 = Ideas of guilt or rumination over past errors or sinful deeds
   - ☐ 3 = Present illness is a punishment. Delusions of guilt
   - ☐ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide
   - ☐ 0 = Absent
   - ☐ 1 = Feels life is not worth living
   - ☐ 2 = Wishes he/she were dead or any thoughts of possible death to self
   - ☐ 3 = Suicide ideas or gesture
   - ☐ 4 = Attempts at suicide (any serious attempt rates 4)

4. Insomnia Early
   - ☐ 0 = No difficulty falling asleep
   - ☐ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
   - ☐ 2 = Complains of nightly difficulty falling asleep

5. Insomnia Middle
   - ☐ 0 = No difficulty
   - ☐ 1 = Patient complains of being restless and disturbed during the night
   - ☐ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia Late
   - ☐ 0 = No difficulty
   - ☐ 1 = Waking in early hours of the morning but goes back to sleep
   - ☐ 2 = Unable to fall asleep again if he/she gets out of bed

7. Work and Activities
   - ☐ 0 = No difficulty
   - ☐ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
   - ☐ 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
   - ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
   - ☐ 4 = Stopped working because of present illness.

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 3		135

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
- ☐ 0 = Normal speech and thought
- ☐ 1 = Slight retardation at interview
- ☐ 2 = Obvious retardation at interview
- ☐ 3 = Interview difficult
- ☐ 4 = Complete stupor

9. Agitation
- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = "Playing with" hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety Psychic
- ☐ 0 = No difficulty
- ☐ 1 = Subjective tension and irritability
- ☐ 2 = Worrying about minor matters
- ☐ 3 = Apprehensive attitude apparent in face or speech
- ☐ 4 = Fears expressed without questioning

11. Anxiety Somatic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal
- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating. Heavy feelings in abdomen
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. Somatic Symptoms General
- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
- ☐ 2 = Any clear-cut symptoms rates 2

14. Genital Symptoms (such as loss of libido and menstrual disturbances)
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 3		136

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis
- ☐ 0 = Not present
- ☐ 1 = Self-absorption (bodily)
- ☐ 2 = Preoccupation with health
- ☐ 3 = Frequent complaints, requests for help, etc.
- ☐ 4 = Hypochondriacal delusions

16. Loss of Weight
- ☐ 0 = No weight loss
- ☐ 1 = Slight or doubtful loss of weight
- ☐ 2 = Obvious or severe loss of weight

17. Insight
- ☐ 0 = Acknowledges being depressed and ill
- ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
- ☐ 2 = Denies being ill at all

➧ ☐☐ HAMD Score (Items 1-17)

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 3	05	137

STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily
		3	

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No
☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance
30				

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(3 \times \text{days since last visit})} \times 100$$

➧ Compliance must be $\geq$ 80% and $\leq$ 120%.

Has the patient been ***non-compliant***?

☐ Yes ☐ No

Withdraw patient from study. Complete Acute Phase Conclusion section.

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 3	15	138

STUDY MEDICATION LABEL

Attach label here

➧ Enter patient number (drug code as listed on clinical supplies) ____

Important: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

STUDY MEDICATION DISPENSING

Record study medication information for Week 4 in the Study Medication Record, page 156. Attach label to page 157. Record number of capsules dispensed on page 156.

Reminder: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	
29060	329	0 0		Acute Phase	

MODULE PARAMETERS - WEEK 4

For SmithKline Beecham Use	Project	* 2 9 0 6 0 *
	Protocol	* 3 2 9 *
	Center	
	Patient Number	
	Module Pages	* V 0 5 1 7 *

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	Visit Date	Page
29060	329	0 0		Acute Phase Week 4	day month year	139

VITAL SIGNS

Weight ☐ lbs ☐ kg	Sitting		Standing	
	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)
.	/		/	

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

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- ☐ 4 = No change
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- ☐ 6 = Much worse
- ☐ 7 = Very much worse

PLASMA SAMPLE - DRUG CONCENTRATION

Was a plasma sample obtained for drug concentration?

☐ Yes ☐ No

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 4		140

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
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SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit			Page
29060	329	0 0		Acute Phase Week 4	08		141

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
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SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 4		142

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis
- ☐ 0 = Not present
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- ☐ 3 = Frequent complaints, requests for help, etc.
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- ☐ 0 = No weight loss
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- ☐ 0 = Acknowledges being depressed and ill
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- ☐ 2 = Denies being ill at all

➧ ☐☐ HAMD Score (Items 1-17)

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 4		143

KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DEPRESSED MOOD

1. Worst Severity of Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Duration of Current Episode: ___ # of weeks

2. Worst Severity of Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Frequency: __ Days/week

Average % time of the day: ___ %

DEPRESSED APPEARANCE

3. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

4. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

IRRITABILITY AND ANGER

5. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Duration: ___ # of weeks

6. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Frequency: __ Days/week

Average % time of the day: ___ %

SEPARATION-DEPENDENT-DYSPHORIA

7. Current Episode: [0] NI [1] NO [2] OCC [3] USL [4] ALW

8. Last Two Weeks: [0] NI [1] NO [2] OCC [3] USL [4] ALW

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 4		144

KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

QUALITY OF DYPSHORIC MOOD

9. Current Episode: [(0) NI] [(1) ND] [(2) QUE] [(3) DDF] [(4) VDF]

10. Last Two Weeks: [(0) NI] [(1) ND] [(2) QUE] [(3) DDF] [(4) VDF]

DEGREE OF ASSOCIATION OF DEPRESSED OR IRRITABLE MOOD WITH SPECIFIC EVENTS OR PREOCCUPATIONS

11. Current Episode: [(0) NI] [(1) NAL] [(2) MOT] [(3) UN] [(4) PN]

12. Last Two Weeks: [(0) NI] [(1) NAL] [(2) MOT] [(3) UN] [(4) PN]

REACTIVITY OF DEPRESSED OR IRRITABLE MOOD

13. Current Episode: [(0) NI] [(1) VR] [(2) FUL] [(3) RES] [(4) MLD] [(5) SLT] [(6) UNR]

[ ] % Usual % of Normal

14. Last Two Weeks: [(0) NI] [(1) VR] [(2) FUL] [(3) RES] [(4) MLD] [(5) SLT] [(6) UNR]

[ ] % Usual % of Normal

[ ] % Maximum % of Normal

[ ] Number of hours good feeling last

DIURNAL MOOD VARIATION

Worse in Morning

15. Current Episode: [(0) NI] [(1) NW] [(2) MIN] [(3) MLD] [(4) CW] [(5) EXT]

16. Last Two Weeks: [(0) NI] [(1) NW] [(2) MIN] [(3) MLD] [(4) CW] [(5) EXT]

Worse in Afternoon and/or Evening

17. Current Episode: [(0) NI] [(1) NW] [(2) MIN] [(3) MLD] [(4) CW] [(5) EXT]

18. Last Two Weeks: [(0) NI] [(1) NW] [(2) MIN] [(3) MLD] [(4) CW] [(5) EXT]

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 4	00	145

KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

EXCESSIVE INAPPROPRIATE GUILT

19. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

20. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

Frequency: Days/Week [ ]

NEGATIVE SELF IMAGE

21. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

22. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

FEELING UNLOVED/FORLORN

23. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

24. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

Frequency: Days/Week [ ]

HOPELESSNESS, HELPLESSNESS, DISCOURAGEMENT, PESSIMISM

25. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

26. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

SELF-PITY

27. Current Episode: [0] NI [1] NO [2] OCC [3] MLD [4] CON

28. Last Two Weeks: [0] NI [1] NO [2] OCC [3] MLD [4] CON

ACHES AND PAINS

29. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

30. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 4	06	146

KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

HYPOCHONDRIASIS

31. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

32. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

ANHEDONIA, LACK OF INTEREST, APATHY, LOW MOTIVATION, BOREDOM

Combined Overall Rating

33. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Duration: [ ] # of weeks

34. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/week

Average % time of the day: [ ] %

Differentiating Lack of Interest from Anhedonia

Lack of Interest

35. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

36. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Anhedonia

37. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

38. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

FATIGUE, LACK OF ENERGY AND TIREDNESS

39. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

40. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/Week

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 4	06	147

KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DIFFICULTY CONCENTRATING, INATTENTION, OR SLOWED THINKING

41. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

42. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

PSYCHOMOTOR AGITATION

43. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

44. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Unable to sit still

45. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) PR] [(4) MOD] [(5) SVR]

46. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) PR] [(4) MOD] [(5) SVR]

Pacing

47. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) PR] [(4) SVR] [(5) SVR]

48. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) PR] [(4) SVR] [(5) SVR]

Hand wringing

49. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) PR] [(4) SVR] [(5) SVR]

50. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) PR] [(4) SVR] [(5) SVR]

Pulling or rubbing on hair, clothing, skin

51. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) PR] [(4) SVR] [(5) SVR]

52. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) PR] [(4) SVR] [(5) SVR]

Can't stop talking, talks on and on

53. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) PR] [(4) SVR] [(5) SVR]

54. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) PR] [(4) SVR] [(5) SVR]

SmithKline Beecham Pharmaceuticals

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

PSYCHOMOTOR RETARDATION

55. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

56. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Slowed Speech

57. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

58. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Increased pauses before answering

59. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

60. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Low or monotonous speech

61. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

62. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Mute or markedly decreased amount of speech

63. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

64. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Slowed body movements

65. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

66. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Depressive stupor

67. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

68. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SOCIAL WITHDRAWAL

69. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

70. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

REJECTION SENSITIVITY

71. Last Year: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

72. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

73. Last Year: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

74. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

SLEEP PROBLEMS

75. [ ][ ] Hours slept before onset of depression

76. [ ][ ] Hours slept during the current episode

77. [ ][ ] Hours slept during the last two weeks

HYPERSOMNIA

78. [ ][ ] Hours slept in daytime of current episode

79. [ ][ ] Hours slept in daytime in the last two weeks

80. [ ][ ] Hours lying down in current episode

81. [ ][ ] Hours lying down in last two weeks

82. Current Episode: [0] NI [1] NO [2] [3] [4] [5] [6]

83. Last Two Weeks: [0] NI [1] NO [2] [3] [4] [5] [6]

SmithKline Beecham Pharmaceuticals

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

INSOMNIA

84. Current Episode: [0] NI [1] NO [2] [3] [4] [5] [6]

85. Last Two Weeks: [0] NI [1] NO [2] [3] [4] [5] [6]

Frequency: [ ] Nights/Week

TYPES OF INSOMNIA

Initial Insomnia

86. Current Episode: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

87. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

Middle Insomnia

88. Current Episode: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

89. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

Terminal Insomnia

90. Current Episode: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

91. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

Circadian Reversal

92. Current Episode: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

93. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

Non-restorative sleep

94. Current Episode: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

95. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

Daytime sleepiness

96. Current Episode: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

97. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

ANOREXIA

98. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) RAR] [(6) NVR]

99. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) RAR] [(6) NVR]

WEIGHT LOSS

100. Current Episode:

Pounds lost: [ ] lbs.

Number of Weeks: [ ]

101. Last Two Weeks:

Pounds lost: [ ] lbs.

INCREASED APPETITE

102. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EX]

103. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EX]

Frequency: [ ] Days/Week

STRONG CRAVING FOR SWEETS

104. Current Episode: [(0) NI] [(1) ABS] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

105. Last Two Weeks: [(0) NI] [(1) ABS] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

WEIGHT GAIN

106. Current Episode:

Pounds gained: [ ] lbs.

Number of Weeks: [ ]

107. Last Two Weeks:

Pounds gained: [ ] lbs.

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SUICIDAL IDEATION

108. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX] [(7) VEX]

109. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX] [(7) VEX]

Suicidal Acts - Number

110. Current Episode: [ ]

111. Last Two Weeks: [ ]

Suicidal Acts - Seriousness

112. Current Episode: [(0) NI] [(1) NO] [(2) MIN] [(3) DEF] [(4) SER] [(5) VS] [(6) EXT]

113. Last Two Weeks: [(0) NI] [(1) NO] [(2) MIN] [(3) DEF] [(4) SER] [(5) VS] [(6) EXT]

Medical Lethality

114. Current Episode [(0) NI] [(1) NO] [(2) MIN] [(3) MLD] [(4) MO] [(5) SVR] [(6) EXT]

115. Last Two Weeks: [(0) NI] [(1) NO] [(2) MIN] [(3) MLD] [(4) MO] [(5) SVR] [(6) EXT]

Non-Suicidal Physical Self-Demaging Acts

116. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) ACT]

117. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) ACT]

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

MANIC SYNDROME

ELATION, EXPANSIVE MOOD

1. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX
2. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX

DECREASED NEED FOR SLEEP

3. Current Episode:	[0] NI	[1] NO	[2] -1	[3] -2	[4] -3	[5] -4	[6] -4+
4. Last Two Weeks:	[0] NI	[1] NO	[2] -1	[3] -2	[4] -3	[5] -4	[6] -4+

UNUSUALLY ENERGETIC

5. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] LCH	[4] MOR	[5] MM	[6] UA
6. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] LCH	[4] MOR	[5] MM	[6] UA

INCREASE IN GOAL DIRECTED ACTIVITY

7. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX
8. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX

GRANDIOSITY

9. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX
10. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX

ACCELERATED, PRESSURED OR INCREASED AMOUNT OF SPEECH

11. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX
12. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX

SmithKline Beecham Pharmaceuticals

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

RACING THOUGHTS

13. Current Episode: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

14. Last Two Weeks: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

FLIGHT OF IDEAS

15. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

16. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

POOR JUDGEMENT

17. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) VS]

18. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) VS]

DISTRACTABILITY

19. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR]

20. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR]

MOTOR HYPERACTIVITY

21. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) MKD] [(6) EX]

22. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) MKD] [(6) EX]

Inappropriate laughing, joking or punning

23. Current Episode: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

24. Last Two Weeks: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

Uninhibited people seeking, gregarious

25. Current Episode: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

26. Last Two Weeks: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

Increased Productivity

27. Current Episode: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

28. Last Two Weeks: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

Sharpened and unusually creative thinking

29. Current Episode: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

30. Last Two Weeks: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

Hypersexuality

31. Current Episode: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

32. Last Two Weeks: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

INFLUENCE OF ILLICIT DRUGS OR ALCOHOL

33. Current Episode: [0] NA [1] NVR [2] SMT [3] ONL

34. Last Two Weeks: [0] NA [1] NVR [2] SMT [3] ONL

NUMBER OF MANIC PERIODS

35. [ ]

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Project	Protocol	Center	Patient Number	Visit			Page
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STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily
		4	

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No
☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance
40				

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(4 \times \text{days since last visit})} \times 100$$

➧ Compliance must be $\geq$ 80% and $\leq$ 120%.

Has the patient been ***non-compliant***?

☐ Yes ☐ No

Withdraw patient from study. Complete Acute Phase Conclusion section.

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Project	Protocol	Center	Patient Number	Visit		Page
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STUDY MEDICATION LABEL

Attach label here

➧ Enter patient number (drug code as listed on clinical supplies) ____

Important: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

ELECTROCARDIOGRAM

Was electrocardiogram performed and sent to a central reader for interpretation?

☐ Yes ☐ No

Date Performed (day month year) ____

STUDY MEDICATION DISPENSING

Record study medication information for Week 5 in the Study Medication Record, page 162. Attach label to page 163. Record number of capsules dispensed on page 162.

Reminder: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	
29060	329	0 0		Acute Phase	

MODULE PARAMETERS - WEEK 5

For SmithKline Beecham Use	Project	*29060*
	Protocol	*329*
	Center	
	Patient Number	
	Module Pages	*V0617*

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	Visit Date	Page
29060	329	0 0		Acute Phase Week 5	day month year	158

VITAL SIGNS

Weight ☐ lbs ☐ kg	Sitting		Standing	
	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)
.	/		/	

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

☐ Yes ☐ No

Record in the Adverse Experience section

Has there been any change in concomitant medication since the last visit?

☐ Yes ☐ No

Record in the Concomitant Medication section

CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

Rate the total improvement whether or not, in your judgment, it is due entirely to drug treatment. Compared to his/her condition at admission to the study, how much has the patient changed?

☐ 1 = Very much improved
☐ 2 = Much improved
☐ 3 = Minimally improved
☐ 4 = No change
☐ 5 = Minimally worse
☐ 6 = Much worse
☐ 7 = Very much worse

SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 5	07	159

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
   - ☐ 1 = These feeling states indicated only on questioning
   - ☐ 2 = These feeling states spontaneously reported verbally
   - ☐ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
   - ☐ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication

2. Feelings of Guilt
   - ☐ 0 = Absent
   - ☐ 1 = Self reproach, feels he/she has let people down
   - ☐ 2 = Ideas of guilt or rumination over past errors or sinful deeds
   - ☐ 3 = Present illness is a punishment. Delusions of guilt
   - ☐ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide
   - ☐ 0 = Absent
   - ☐ 1 = Feels life is not worth living
   - ☐ 2 = Wishes he/she were dead or any thoughts of possible death to self
   - ☐ 3 = Suicide ideas or gesture
   - ☐ 4 = Attempts at suicide (any serious attempt rates 4)

4. Insomnia Early
   - ☐ 0 = No difficulty falling asleep
   - ☐ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
   - ☐ 2 = Complains of nightly difficulty falling asleep

5. Insomnia Middle
   - ☐ 0 = No difficulty
   - ☐ 1 = Patient complains of being restless and disturbed during the night
   - ☐ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia Late
   - ☐ 0 = No difficulty
   - ☐ 1 = Waking in early hours of the morning but goes back to sleep
   - ☐ 2 = Unable to fall asleep again if he/she gets out of bed

7. Work and Activities
   - ☐ 0 = No difficulty
   - ☐ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
   - ☐ 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
   - ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
   - ☐ 4 = Stopped working because of present illness.

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Project	Protocol	Center	Patient Number	Visit		Page
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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
- ☐ 0 = Normal speech and thought
- ☐ 1 = Slight retardation at interview
- ☐ 2 = Obvious retardation at interview
- ☐ 3 = Interview difficult
- ☐ 4 = Complete stupor

9. Agitation
- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = "Playing with" hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety Psychic
- ☐ 0 = No difficulty
- ☐ 1 = Subjective tension and irritability
- ☐ 2 = Worrying about minor matters
- ☐ 3 = Apprehensive attitude apparent in face or speech
- ☐ 4 = Fears expressed without questioning

11. Anxiety Somatic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal
- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating. Heavy feelings in abdomen
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. Somatic Symptoms General
- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
- ☐ 2 = Any clear-cut symptoms rates 2

14. Genital Symptoms (such as loss of libido and menstrual disturbances)
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 5	07	161

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis
- ☐ 0 = Not present
- ☐ 1 = Self-absorption (bodily)
- ☐ 2 = Preoccupation with health
- ☐ 3 = Frequent complaints, requests for help, etc.
- ☐ 4 = Hypochondriacal delusions

16. Loss of Weight
- ☐ 0 = No weight loss
- ☐ 1 = Slight or doubtful loss of weight
- ☐ 2 = Obvious or severe loss of weight

17. Insight
- ☐ 0 = Acknowledges being depressed and ill
- ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
- ☐ 2 = Denies being ill at all

➧ ☐☐ HAMD Score (Items 1-17)

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 5	07	162

STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No
☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(N^{\bigstar} \times \text{days since last visit})} \times 100$$

★N = number of capsules daily (see above)

➧ Compliance must be ≥ 80% and ≤ 120%.

Has the patient been ***non-compliant?***

☐ Yes ☐ No

Withdraw patient from study. Complete Acute Phase Conclusion section.

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Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit			Page
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STUDY MEDICATION LABEL

Attach label here

➧ Enter patient number (drug code as listed on clinical supplies) ____

Important: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

STUDY MEDICATION DISPENSING

Record study medication information for Week 6 in the Study Medication Record, page 181. Attach label to page 182. Record number of capsules dispensed on page 181.

Reminder: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	
29060	329	0		Acute Phase	

MODULE PARAMETERS - WEEK 6

For SmithKline Beecham Use	Project	*29060*
	Protocol	*329*
	Center	
	Patient Number	
	Module Pages	*V0717*

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	Visit Date	Page
29060	329	0 0		Acute Phase Week 6	day month year	164

VITAL SIGNS

Weight ☐ lbs ☐ kg	Sitting		Standing	
	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)
.	/		/	

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

☐ Yes ☐ No

Record in the Adverse Experience section

Has there been any change in concomitant medication since the last visit?

☐ Yes ☐ No

Record in the Concomitant Medication section

CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

Rate the total improvement whether or not, in your judgment, it is due entirely to drug treatment. Compared to his/her condition at admission to the study, how much has the patient changed?

☐ 1 = Very much improved
☐ 2 = Much improved
☐ 3 = Minimally improved
☐ 4 = No change
☐ 5 = Minimally worse
☐ 6 = Much worse
☐ 7 = Very much worse

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
   - ☐ 1 = These feeling states indicated only on questioning
   - ☐ 2 = These feeling states spontaneously reported verbally
   - ☐ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
   - ☐ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication

2. Feelings of Guilt
   - ☐ 0 = Absent
   - ☐ 1 = Self reproach, feels he/she has let people down
   - ☐ 2 = Ideas of guilt or rumination over past errors or sinful deeds
   - ☐ 3 = Present illness is a punishment. Delusions of guilt
   - ☐ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide
   - ☐ 0 = Absent
   - ☐ 1 = Feels life is not worth living
   - ☐ 2 = Wishes he/she were dead or any thoughts of possible death to self
   - ☐ 3 = Suicide ideas or gesture
   - ☐ 4 = Attempts at suicide (any serious attempt rates 4)

4. Insomnia Early
   - ☐ 0 = No difficulty falling asleep
   - ☐ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
   - ☐ 2 = Complains of nightly difficulty falling asleep

5. Insomnia Middle
   - ☐ 0 = No difficulty
   - ☐ 1 = Patient complains of being restless and disturbed during the night
   - ☐ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia Late
   - ☐ 0 = No difficulty
   - ☐ 1 = Waking in early hours of the morning but goes back to sleep
   - ☐ 2 = Unable to fall asleep again if he/she gets out of bed

7. Work and Activities
   - ☐ 0 = No difficulty
   - ☐ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
   - ☐ 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
   - ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
   - ☐ 4 = Stopped working because of present illness.

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
- ☐ 0 = Normal speech and thought
- ☐ 1 = Slight retardation at interview
- ☐ 2 = Obvious retardation at interview
- ☐ 3 = Interview difficult
- ☐ 4 = Complete stupor

9. Agitation
- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = "Playing with" hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety Psychic
- ☐ 0 = No difficulty
- ☐ 1 = Subjective tension and irritability
- ☐ 2 = Worrying about minor matters
- ☐ 3 = Apprehensive attitude apparent in face or speech
- ☐ 4 = Fears expressed without questioning

11. Anxiety Somatic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal
- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating. Heavy feelings in abdomen
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. Somatic Symptoms General
- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
- ☐ 2 = Any clear-cut symptoms rates 2

14. Genital Symptoms (such as loss of libido and menstrual disturbances)
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis
- ☐ 0 = Not present
- ☐ 1 = Self-absorption (bodily)
- ☐ 2 = Preoccupation with health
- ☐ 3 = Frequent complaints, requests for help, etc.
- ☐ 4 = Hypochondriacal delusions

16. Loss of Weight
- ☐ 0 = No weight loss
- ☐ 1 = Slight or doubtful loss of weight
- ☐ 2 = Obvious or severe loss of weight

17. Insight
- ☐ 0 = Acknowledges being depressed and ill
- ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
- ☐ 2 = Denies being ill at all

➧ ☐☐ HAMD Score (Items 1-17)

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DEPRESSED MOOD

1. Worst Severity of Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Duration of Current Episode: ___ # of weeks

2. Worst Severity of Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Frequency: ___ Days/week

Average % time of the day: ___ %

DEPRESSED APPEARANCE

3. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

4. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

IRRITABILITY AND ANGER

5. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Duration: ___ # of weeks

6. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Frequency: ___ Days/week

Average % time of the day: ___ %

SEPARATION-DEPENDENT-DYSPHORIA

7. Current Episode: [0] NI [1] NO [2] OCC [3] USL [4] ALW

8. Last Two Weeks: [0] NI [1] NO [2] OCC [3] USL [4] ALW

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

QUALITY OF DYPSHORIC MOOD

9. Current Episode: [0] NI [1] ND [2] QUE [3] DDF [4] VDF

10. Last Two Weeks: [0] NI [1] ND [2] QUE [3] DDF [4] VDF

DEGREE OF ASSOCIATION OF DEPRESSED OR IRRITABLE MOOD WITH SPECIFIC EVENTS OR PREOCCUPATIONS

11. Current Episode: [0] NI [1] NAL [2] MOT [3] UN [4] PN

12. Last Two Weeks: [0] NI [1] NAL [2] MOT [3] UN [4] PN

REACTIVITY OF DEPRESSED OR IRRITABLE MOOD

13. Current Episode: [0] NI [1] VR [2] FUL [3] RES [4] MLD [5] SLT [6] UNR

[ ] % Usual % of Normal

14. Last Two Weeks: [0] NI [1] VR [2] FUL [3] RES [4] MLD [5] SLT [6] UNR

[ ] % Usual % of Normal

[ ] % Maximum % of Normal

[ ] Number of hours good feeling last

DIURNAL MOOD VARIATION

Worse in Morning

15. Current Episode: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

16. Last Two Weeks: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

Worse in Afternoon and/or Evening

17. Current Episode: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

18. Last Two Weeks: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

EXCESSIVE INAPPROPRIATE GUILT

19. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
20. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

Frequency: Days/Week ☐

NEGATIVE SELF IMAGE

21. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
22. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

FEELING UNLOVED/FORLORN

23. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
24. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

Frequency: Days/Week ☐

HOPELESSNESS, HELPLESSNESS, DISCOURAGEMENT, PESSIMISM

25. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
26. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

SELF-PITY

27. Current Episode:	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON
28. Last Two Weeks:	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON

ACHES AND PAINS

29. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
30. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

HYPOCHONDRIASIS

31. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

32. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

ANHEDONIA, LACK OF INTEREST, APATHY, LOW MOTIVATION, BOREDOM

Combined Overall Rating

33. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Duration: [ ] # of weeks

34. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/week

Average % time of the day: [ ] %

Differentiating Lack of Interest from Anhedonia

Lack of Interest

35. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

36. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Anhedonia

37. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

38. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

FATIGUE, LACK OF ENERGY AND TIREDNESS

39. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

40. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/Week

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DIFFICULTY CONCENTRATING, INATTENTION, OR SLOWED THINKING

41. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

42. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

PSYCHOMOTOR AGITATION

43. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

44. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Unable to sit still

45. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

46. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Pacing

47. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

48. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

Hand wringing

49. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

50. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

Pulling or rubbing on hair, clothing, skin

51. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

52. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

Can't stop talking, talks on and on

53. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

54. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

PSYCHOMOTOR RETARDATION

55.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
56.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

Frequency: ___ Days/Week

MANIFESTATIONS INCLUDED:

Slowed Speech

57.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
58.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Increased pauses before answering

59.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
60.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Low or monotonous speech

61.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
62.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Mute or markedly decreased amount of speech

63.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
64.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Slowed body movements

65.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
66.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Depressive stupor

67.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
68.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SOCIAL WITHDRAWAL

69.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX
70.	Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX

REJECTION SENSITIVITY

71.	Last Year:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MOD	[5] SVR	[6] EX
72.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MOD	[5] SVR	[6] EX
73.	Last Year:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MOD	[5] SVR	[6] EX
74.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MOD	[5] SVR	[6] EX

SLEEP PROBLEMS

75. [ ] Hours slept before onset of depression

76. [ ] Hours slept during the current episode

77. [ ] Hours slept during the last two weeks

HYPERSOMNIA

78. [ ] Hours slept in daytime of current episode

79. [ ] Hours slept in daytime in the last two weeks

80. [ ] Hours lying down in current episode

81. [ ] Hours lying down in last two weeks

82.	Current Episode:	[0] NI	[1] NO	[2]	[3]	[4]	[5]	[6]
83.	Last Two Weeks:	[0] NI	[1] NO	[2]	[3]	[4]	[5]	[6]

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

INSOMNIA

84. Current Episode: [0] NI [1] NO [2] [3] [4] [5] [6]

85. Last Two Weeks: [0] NI [1] NO [2] [3] [4] [5] [6]

Frequency: [ ] Nights/Week

TYPES OF INSOMNIA

Initial Insomnia

86. Current Episode: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

87. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

Middle Insomnia

88. Current Episode: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

89. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

Terminal Insomnia

90. Current Episode: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

91. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

Circadian Reversal

92. Current Episode: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

93. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

Non-restorative sleep

94. Current Episode: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

95. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

Daytime sleepiness

96. Current Episode: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

97. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] MLD [4] MOD [5] SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

ANOREXIA

98. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) RAR] [(6) NVR]

99. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) RAR] [(6) NVR]

WEIGHT LOSS

100. Current Episode:

Pounds lost: [ ] lbs.

Number of Weeks: [ ]

101. Last Two Weeks:

Pounds lost: [ ] lbs.

INCREASED APPETITE

102. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EX]

103. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EX]

Frequency: [ ] Days/Week

STRONG CRAVING FOR SWEETS

104. Current Episode: [(0) NI] [(1) ABS] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

105. Last Two Weeks: [(0) NI] [(1) ABS] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

WEIGHT GAIN

106. Current Episode:

Pounds gained: [ ] lbs.

Number of Weeks: [ ]

107. Last Two Weeks:

Pounds gained: [ ] lbs.

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SUICIDAL IDEATION

108. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

109. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Suicidal Acts - Number

110. Current Episode: [ ]

111. Last Two Weeks: [ ]

Suicidal Acts - Seriousness

112. Current Episode: [0] NI [1] NO [2] MIN [3] DEF [4] SER [5] VS [6] EXT

113. Last Two Weeks: [0] NI [1] NO [2] MIN [3] DEF [4] SER [5] VS [6] EXT

Medical Lethality

114. Current Episode [0] NI [1] NO [2] MIN [3] MLD [4] MO [5] SVR [6] EXT

115. Last Two Weeks: [0] NI [1] NO [2] MIN [3] MLD [4] MO [5] SVR [6] EXT

Non-Suicidal Physical Self-Demaging Acts

116. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] ACT

117. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] ACT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

MANIC SYNDROME

ELATION, EXPANSIVE MOOD

1. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX
2. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX

DECREASED NEED FOR SLEEP

3. Current Episode:	[0] NI	[1] NO	[2] -1	[3] -2	[4] -3	[5] -4	[6] -4+
4. Last Two Weeks:	[0] NI	[1] NO	[2] -1	[3] -2	[4] -3	[5] -4	[6] -4+

UNUSUALLY ENERGETIC

5. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] LCH	[4] MOR	[5] MM	[6] UA
6. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] LCH	[4] MOR	[5] MM	[6] UA

INCREASE IN GOAL DIRECTED ACTIVITY

7. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX
8. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX

GRANDIOSITY

9. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX
10. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX

ACCELERATED, PRESSURED OR INCREASED AMOUNT OF SPEECH

11. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX
12. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

RACING THOUGHTS

13. Current Episode: [0] NI [1] NO [2] DBT [3] MLD [4] MO [5] SVR [6] EX

14. Last Two Weeks: [0] NI [1] NO [2] DBT [3] MLD [4] MO [5] SVR [6] EX

FLIGHT OF IDEAS

15. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

16. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

POOR JUDGEMENT

17. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] VS

18. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] VS

DISTRACTABILITY

19. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR

20. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR

MOTOR HYPERACTIVITY

21. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] MKD [6] EX

22. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] MKD [6] EX

Inappropriate laughing, joking or punning

23. Current Episode: [0] NI [1] NO [2] DBT [3] MLD [4] MOD

24. Last Two Weeks: [0] NI [1] NO [2] DBT [3] MLD [4] MOD

Uninhibited people seeking, gregarious

25. Current Episode: [0] NI [1] NO [2] DBT [3] MLD [4] MOD

26. Last Two Weeks: [0] NI [1] NO [2] DBT [3] MLD [4] MOD

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

Increased Productivity

27. Current Episode: [(0) NI] [(1) NO] [(2) DBT] [(3) PRS] [(4) SVR]

28. Last Two Weeks: [(0) NI] [(1) NO] [(2) DBT] [(3) PRS] [(4) SVR]

Sharpened and unusually creative thinking

29. Current Episode: [(0) NI] [(1) NO] [(2) DBT] [(3) PRS] [(4) SVR]

30. Last Two Weeks: [(0) NI] [(1) NO] [(2) DBT] [(3) PRS] [(4) SVR]

Hypersexuality

31. Current Episode: [(0) NI] [(1) NO] [(2) DBT] [(3) PRS] [(4) SVR]

32. Last Two Weeks: [(0) NI] [(1) NO] [(2) DBT] [(3) PRS] [(4) SVR]

INFLUENCE OF ILLICIT DRUGS OR ALCOHOL

33. Current Episode: [(0) NA] [(1) NVR] [(2) SMT] [(3) ONL]

34. Last Two Weeks: [(0) NA] [(1) NVR] [(2) SMT] [(3) ONL]

NUMBER OF MANIC PERIODS

35. [ ]

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STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No
☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(N^{\bigstar} \times \text{days since last visit})} \times 100$$

★N = number of capsules daily (see above)

➧ Compliance must be ≥ 80% and ≤ 120%.

Has the patient been ***non-compliant***?

☐ Yes ☐ No

Withdraw patient from study. Complete Acute Phase Conclusion section.

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Project	Protocol	Center	Patient Number	Visit		Page
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STUDY MEDICATION LABEL

Attach label here

Enter patient number (drug code as listed on clinical supplies) _____

Important: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

ELECTROCARDIOGRAM

Was electrocardiogram performed and sent to a central reader for interpretation?

☐ Yes ☐ No

Date Performed (day month year) _____

STUDY MEDICATION DISPENSING

Record study medication information for Week 7 in the Study Medication Record, page 187. Attach label to page 188. Record number of capsules dispensed on page 187.

Reminder: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

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MODULE PARAMETERS - WEEK 7

For SmithKline Beecham Use	Project	*29060*
	Protocol	*329*
	Center	
	Patient Number	
	Module Pages	*V0817*

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Project	Protocol	Center	Patient Number	Visit	Visit Date	Page
29060	329	0 0		Acute Phase Week 7	day month year	183

VITAL SIGNS

Weight ☐ lbs ☐ kg	Sitting		Standing	
	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)
.	/		/	

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

☐ Yes ☐ No

Record in the Adverse Experience section

Has there been any change in concomitant medication since the last visit?

☐ Yes ☐ No

Record in the Concomitant Medication section

CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

Rate the total improvement whether or not, in your judgment, it is due entirely to drug treatment. Compared to his/her condition at admission to the study, how much has the patient changed?

☐ 1 = Very much improved
☐ 2 = Much improved
☐ 3 = Minimally improved
☐ 4 = No change
☐ 5 = Minimally worse
☐ 6 = Much worse
☐ 7 = Very much worse

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 7	00	184

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
   - ☐ 1 = These feeling states indicated only on questioning
   - ☐ 2 = These feeling states spontaneously reported verbally
   - ☐ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
   - ☐ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication

2. Feelings of Guilt
   - ☐ 0 = Absent
   - ☐ 1 = Self reproach, feels he/she has let people down
   - ☐ 2 = Ideas of guilt or rumination over past errors or sinful deeds
   - ☐ 3 = Present illness is a punishment. Delusions of guilt
   - ☐ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide
   - ☐ 0 = Absent
   - ☐ 1 = Feels life is not worth living
   - ☐ 2 = Wishes he/she were dead or any thoughts of possible death to self
   - ☐ 3 = Suicide ideas or gesture
   - ☐ 4 = Attempts at suicide (any serious attempt rates 4)

4. Insomnia Early
   - ☐ 0 = No difficulty falling asleep
   - ☐ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
   - ☐ 2 = Complains of nightly difficulty falling asleep

5. Insomnia Middle
   - ☐ 0 = No difficulty
   - ☐ 1 = Patient complains of being restless and disturbed during the night
   - ☐ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia Late
   - ☐ 0 = No difficulty
   - ☐ 1 = Waking in early hours of the morning but goes back to sleep
   - ☐ 2 = Unable to fall asleep again if he/she gets out of bed

7. Work and Activities
   - ☐ 0 = No difficulty
   - ☐ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
   - ☐ 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
   - ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
   - ☐ 4 = Stopped working because of present illness.

SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 7	00	185

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)

- ☐ 0 = Normal speech and thought
- ☐ 1 = Slight retardation at interview
- ☐ 2 = Obvious retardation at interview
- ☐ 3 = Interview difficult
- ☐ 4 = Complete stupor

9. Agitation

- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = "Playing with" hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety Psychic

- ☐ 0 = No difficulty
- ☐ 1 = Subjective tension and irritability
- ☐ 2 = Worrying about minor matters
- ☐ 3 = Apprehensive attitude apparent in face or speech
- ☐ 4 = Fears expressed without questioning

11. Anxiety Somatic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.

- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal

- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating. Heavy feelings in abdomen
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. Somatic Symptoms General

- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
- ☐ 2 = Any clear-cut symptoms rates 2

14. Genital Symptoms (such as loss of libido and menstrual disturbances)

- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 7	07	186

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis

- ☐ 0 = Not present
- ☐ 1 = Self-absorption (bodily)
- ☐ 2 = Preoccupation with health
- ☐ 3 = Frequent complaints, requests for help, etc.
- ☐ 4 = Hypochondriacal delusions

16. Loss of Weight

- ☐ 0 = No weight loss
- ☐ 1 = Slight or doubtful loss of weight
- ☐ 2 = Obvious or severe loss of weight

17. Insight

- ☐ 0 = Acknowledges being depressed and ill
- ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
- ☐ 2 = Denies being ill at all

➧ ☐☐ HAMD Score (Items 1-17)

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 7	09	187

STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No

☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(N^{\bigstar} \times \text{days since last visit})} \times 100$$

★N = number of capsules daily (see above)

➧ Compliance must be ≥ 80% and ≤ 120%.

Has the patient been ***non-compliant***?

☐ Yes ☐ No

Withdraw patient from study. Complete Acute Phase Conclusion section.

SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 7	00	188

STUDY MEDICATION LABEL

Attach label here

Enter patient number (drug code as listed on clinical supplies) ⌊_____⌋

Important: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

STUDY MEDICATION DISPENSING

Record study medication information for Week 8 in the Study Medication Record, page 222. Attach label to page 223. Record number of capsules dispensed on page 222.

Reminder: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

SmithKline Beecham Pharmaceuticals

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29060	329	0 0		Acute Phase	

MODULE PARAMETERS - WEEK 8

For SmithKline Beecham Use	Project	*29060*
	Protocol	*329*
	Center	
	Patient Number	
	Module Pages	*V0917*

SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	Visit Date	Page
29060	329	0 0		Acute Phase Week 8	day month year	189

VITAL SIGNS

Weight ☐ lbs ☐ kg	Sitting		Standing	
	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)
.	/		/	

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

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- ☐ 4 = No change
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- ☐ 6 = Much worse
- ☐ 7 = Very much worse

PLASMA SAMPLE - DRUG CONCENTRATION

Was a plasma sample obtained for drug concentration?

☐ Yes ☐ No

SmithKline Beecham Pharmaceuticals

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
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   - ☐ 2 = These feeling states spontaneously reported verbally
   - ☐ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
- ☐ 0 = Normal speech and thought
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- ☐ 2 = Obvious retardation at interview
- ☐ 3 = Interview difficult
- ☐ 4 = Complete stupor

9. Agitation
- ☐ 0 = None
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- ☐ 2 = "Playing with" hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
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10. Anxiety Psychic
- ☐ 0 = No difficulty
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- ☐ 2 = Worrying about minor matters
- ☐ 3 = Apprehensive attitude apparent in face or speech
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11. Anxiety Somatic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal
- ☐ 0 = None
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13. Somatic Symptoms General
- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
- ☐ 2 = Any clear-cut symptoms rates 2

14. Genital Symptoms (such as loss of libido and menstrual disturbances)
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

SmithKline Beecham Pharmaceuticals

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis
- ☐ 0 = Not present
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- ☐ 2 = Preoccupation with health
- ☐ 3 = Frequent complaints, requests for help, etc.
- ☐ 4 = Hypochondriacal delusions

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- ☐ 0 = No weight loss
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- ☐ 2 = Obvious or severe loss of weight

17. Insight
- ☐ 0 = Acknowledges being depressed and ill
- ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
- ☐ 2 = Denies being ill at all

➧ ⌊__⌋ HAMD Score (Items 1-17)

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AUTONOMOUS FUNCTIONING CHECKLIST

Grade in School ____

Informant (mother, father, guardian, other) _____

Instructions

The purpose of this checklist is to learn about what your teenager does every day. There are no "right" or "wrong" things for your teenager to do, since teenagers of different ages do many different things. These questions are simply for the purpose of getting an idea of your teenager's daily activity.

When you answer these questions, first, read the question and think about whether or not it describes what you see or have seen your teenager do. You should answer the questions according to what you know your teenager does or does not do rather than what you ***believe*** or ***think*** he or she ***could*** do or ***could not*** do.

Second, tell us how the question describes what you teenager does by choosing one of the alternatives "0", "1", "2", "3", or "4" from the scale and circling that number in the space to the right of the item. Here is how to use the rating scale with a sample question.

0	1	2	3	4
Does Not Do	**Does Only Rarely**	**Does About Half the Time There is an Opportunity**	**Does Most of the Time There is an Opportunity**	**Does Every Time There is an Opportunity**

Sample Item. Pick up trash in the yard. **0 1 2 3 4**

0 - Circle "0" if you have never seen your teenager do this, even if he or she may never have had an opportunity. (For example mark "0" if your teenager has never done it, even if you live in an apartment and do not have a yard.)

1 - Circle "1" if you have seen your teenager do this when there has been a chance, but if there have been many more times that he or she has not done it.

2 - Circle "2" if your teenager does this about half the time there is a chance, but if he or she does not do it readily or comfortably.

3 - Circle "3" if there are more times that your teenager does this than does not do it, given the chance, and if he or she does it readily.

4 - Circle "4" if your teenager does this whenever there is a chance and if he or she does it readily.

Your teenager will not have had the chance to participate in some of the activities the questions described. These items should be answered as "does not do," even though you may feel that your teenager would do it if given the chance. Please circle "0" for questions that describe activities your teenager has ***never had the chance*** to do.

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AUTONOMOUS FUNCTIONING CHECKLIST

Some questions describe things that your teenager may do with help from others. Answer these questions after you think about who has the most responsibility for completing the activity. For example, your teenager may cook the family meals and may be helped by other family members who set the table or chop vegetables. If your teenager is the family member with the most responsibility for cooking every meal that the family eats together, your answer would be "4", which stands for "does every time there is an opporunity." On the other hand, if your teenager helps other family members by doing jobs that they tell him or her to do, and never has the most responsibility for fixing dinner, your answer would be "0", for "does not do."

0	1	2	3	4
Does Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Does Every Time There is an Opportunity

My teenager:

1.	Keeps own personal items and belongings in order (for example makes bed, puts away own clothing and belongings).	0	1	2	3	4
2.	Prepares food that does not require cooking for himself/ herself (for example, cereal, sandwich).	0	1	2	3	4
3.	Care for his/her own clothing (for example, laundry, simple repair, shoe cleaning)	0	1	2	3	4
4.	Travels to and from daily activities (for example, rides bike or walks, takes bus, arranges for transportation, drives car).	0	1	2	3	4
5.	Prepares food that requires cooking for himself/herself (for example, hamburger, soup).	0	1	2	3	4
6.	Performs simple first aid or medical care for himself/ herself (for example, bandages, takes own temperature).	0	1	2	3	4
7.	Purchases his/her own clothing and personal items that are used on a daily basis (for example, underwear, toiletries).	0	1	2	3	4
8.	Performs minor repair and maintance in his/her owm environment (for example, changes light bulbs, hangs pitcure).	0	1	2	3	4
9.	Shops for and purchases his/her own groceries.	0	1	2	3	4
10.	Responds to his/her own medical emergency by calling parent.	0	1	2	3	4
11.	Responds to his/her own medical emergency by calling doctor or hospital.	0	1	2	3	4
12.	Does designated household maintenance chores involving family living areas (for example, cleans, takes out trash, does simple yard work).	0	1	2	3	4

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Project	Protocol	Center	Patient Number	Visit		Page
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AUTONOMOUS FUNCTIONING CHECKLIST

0	1	2	3	4
Does Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Does Every Time There is an Opportunity

13.	Performs routine daily personal care for another family member. (for example, dresses, feeds).	0	1	2	3	4
14.	Keeps personal items and belongings of another family member in order (for example, makes bed, puts away clothing and belongings).	0	1	2	3	4
15.	Prepares meals for other family member(s).	0	1	2	3	4
16.	Transports (or arranges for transport of) another family member to and from daily activities.	0	1	2	3	4
17.	Purchases clothing and personal items (that are used on a daily basis) for other family members.	0	1	2	3	4
18.	Shops for and purchases family groceries.	0	1	2	3	4
19.	Performs minor repairs and maintenance in family living areas (for example, changes light bulbs, hangs picture).	0	1	2	3	4
20.	Repairs and maintains (or makes arrangement for repair and maintenance of) major household needs (for example, plumbing, yard work, electrical wiring).	0	1	2	3	4
21.	Responds to household emergency (for example, stove fire, plumbing problem) by calling parent or neighbor.	0	1	2	3	4
22.	Reponds to household emergency (for example, stove fire, plumbing problem) by calling fire department, using fire extinguisher, or calling repair service or shuting off water.	0	1	2	3	4

My teenager:

23.	Uses the telphone and telephone directories.	0	1	2	3	4
24.	Carries out transactions with sales people (for example, listens to information, asks questions, gives payment, receives change).	0	1	2	3	4
25.	Uses postal services (for example, uses postage, mails letters. packages).	0	1	2	3	4
26.	Uses bank (for example, fills out deposit or withdrawal slips, uses passbook).	0	1	2	3	4

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AUTONOMOUS FUNCTIONING CHECKLIST

	0 Does Not Do	1 Does Only Rarely	2 Does About Half the Time There is an Opportunity	3 Does Most of the Time There is an Opportunity	4 Does Every Time There is an Opportunity

27.	Uses travel-related services for short trips (for example, taxi, bus subway).	0	1	2	3	4
28.	Uses travel-related services for long trips (for example, airline, train, bus).	0	1	2	3	4
29.	Uses library services (for example, checks out books or uses Xerox machine).	0	1	2	3	4
30.	Maintains and uses his/her own savings account.	0	1	2	3	4
31.	Maintains and uses his/her own checking or charge account.	0	1	2	3	4
32.	Maintains adequate personal care and grooming (for example, bathes, trims fingernails and toenails when needed)	0	1	2	3	4
33.	Maintains his/her routine general health and fitness (for example, has adequate eating, sleeping and exercise habits).	0	1	2	3	4
34.	Selects clothing that is suited to weather (for example, raincoat if raining, warm clothes in winter).	0	1	2	3	4
35.	Plans and initiates activity for himself/herself in everday unscheduled free time (for example, chooses to watch television or work on a hobby if bored).	0	1	2	3	4
36.	Plans activity for his/her long-term free time (for example, makes plans for summer vacation, mid-semester vacation).	0	1	2	3	4
37.	Initiates friendships with peers (for example, plans or attends parties, outings, games, club meetings).	0	1	2	3	4
38.	Meets nonacademic social obligations or commitments (for example, keeps appointments for family and peer related social events arranged by self or others).	0	1	2	3	4
39.	Meets academic obligations amd commitments (for example, completes homework assignments on time, brings necessary supplies to class).	0	1	2	3	4
40.	Plan transportation to and from special activities (for example arranges for rides with friends or family or plans care or bus route and schedule).	0	1	2	3	4

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AUTONOMOUS FUNCTIONING CHECKLIST

0	1	2	3	4
Does Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Does Every Time There is an Opportunity

41.	Manage his/her own budget from allowance or income (for example, saves money for large purchases, pays for routine expenses throughout week without running out of money).	0	1	2	3	4
42.	Make long-term educational and/or career plans (for example, selects courses, investigates colleges or technical schools).	0	1	2	3	4

When my teenager is free to choose how he/she will spend his/her unscheduled free time. He/she chooses to:

43.	Listen to music (for example, radio or stereo).	0	1	2	3	4
44.	Read for relaxation (for example, books, newspapers)	0	1	2	3	4
45.	Play games or puzzles (for example, cards, crossword puzzles, jigsaw puzzles, computer games).	0	1	2	3	4
46.	Write letters to friends, relatives, aquaintances.	0	1	2	3	4
47.	Work on or take lessons in crafts or hobbies (for example cooking, collections, pet care, sewing, model building, car repair).	0	1	2	3	4
48.	Practice or take lessons that involve a trained artistic or academic skill (for example, piano or other musical instrument, ballet, singing, creative writing, foreign languages).	0	1	2	3	4
49.	Go to the movies, rock concerts, dances.					
50.	Go to plays, theater, lectures.	0	1	2	3	4
51.	Pursue activities that are related to his or her career interest(s) (for example, runs a business, works on a computer, practices piano for professional preparation).	0	1	2	3	4
52.	Go for walks.	0	1	2	3	4
53.	Go shopping, or spend time at shopping centers or in shopping areas.	0	1	2	3	4
54.	Attend club meetings or other organized social group meetings.	0	1	2	3	4
55.	Work for pay (for example, babysit, play in a band, do yard work, walk dogs, work at part-time job, deliver papers).	0	1	2	3	4

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AUTONOMOUS FUNCTIONING CHECKLIST

0	1	2	3	4
Does Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Does Every Time There is an Opportunity

56.	Clean and/or maintan living environment or belongings (for example, clean house, wash or repair clothes, wash car, make household repairs).	0	1	2	3	4
57.	Work on schoolwork (for example, spend extra time on homework, make special preparations for class projects, spend time in library).	0	1	2	3	4
58.	Spend time with family (for example, work on family projects, have discussions or casual conversations, attend family gatherings such as picnics or parties).	0	1	2	3	4

On these final items, please check "Yes" or "No" in response to each description. Check "Yes" if the description fits your teenager. Check "No" if it does not.

My teenager:		Yes	No
59.	Has casual friendships with teenagers of opposite sex.	☐	☐
60.	Has close friendships with teenagers of opposite sex.	☐	☐
61.	Has casual friendships with adults outside the family (for example, teachers, neighbors, coaches, scout leaders)	☐	☐
62.	Has close friendships with adults outside the family (for example, teachers, neighbors, coaches, scout leaders).	☐	☐
63.	Has casual friendships with younger children.	☐	☐
64.	Has close friendships with younger children.	☐	☐
65.	Is active in casual/recreational groups of teenage friends.	☐	☐
66.	Has many friendships.	☐	☐
67.	Is active in one or more organized extracurricular group (for example, French club, student council, sports team).	☐	☐
68.	Has leadership position in one or more organized extracurricular group (for example, president of the student council, captain of the sports team).	☐	☐
69.	Has close friendship with adult member of the extended family (for example, an uncle, aunt, grandparent).	☐	☐
70.	Works or has worked either for pay or volunteer in an area of particular career interest.	☐	☐

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AUTONOMOUS FUNCTIONING CHECKLIST

		Yes	No
71.	Works or has worked to earn money by providing a service on a regular scheduled basis (for example, contracts for yard work, dog walking, baby sitting)	☐	☐
72.	Works or has worked to earn money by using a special skill (for example, musical performance, typing, tutoring).	☐	☐
73.	Works or has worked to earn money in a self-or-peer-run organization or business.	☐	☐
74.	Works or has worked to earn money fundraising for an organization or charity (for example, scouts, church groups, political organizations).	☐	☐
75.	Does or has done volunteer work without pay for a service, a school or political organization, a social agency, a club, a church, or a hospital.	☐	☐
76.	Participates or has participated in prevocational (career) or vocational (career) classes or training (for example, any technical training or career development class).	☐	☐
77.	Has explored career interest by visiting work sites or interviewing people in that job or career.	☐	☐
78.	Has spent time reading, researching, or "finding out" about a career that particularly interests him/her.	☐	☐

Comments:

If you have any additional information about your teenager's everyday independent or self-sufficient behavior, use the space below to write your comments. Thank you.

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SELF-PERCEPTION PROFILE FOR ADOLESCENTS

WHAT AM I LIKE

	Really True for Me	Sort of True for Me	Sample Sentence			Sort of True for Me	Really True for Me
a.	☐	☐	Some teenagers like to go to movies in their spare time	BUT	Other teenagers would rather go to sport events.	☐	☐
1.	☐	☐	Some teenagers feel that they are just as smart as others their age	BUT	Other teenagers aren't so sure and wonder if they are as smart.	☐	☐
2.	☐	☐	Some teenagers find it hard to make friends	BUT	For other teenagers it's pretty easy.	☐	☐
3.	☐	☐	Some teenagers do very well at all kinds of sports	BUT	Other teenagers don't feel that they are very good when it comes to sports.	☐	☐
4.	☐	☐	Some teenagers are not happy with the way they look	BUT	Other teenagers are happy with the way they look.	☐	☐
5.	☐	☐	Some teenagers feel that they are ready to do well at a part-time job	BUT	Other teenagers feel that they are not quite ready to handle a part-time job.	☐	☐
6.	☐	☐	Some teenagers feel that if they are romantically interested in someone, that person will like them back	BUT	Other teenagers worry that when they like someone romantically that person won't like them back.	☐	☐
7.	☐	☐	Some teenagers usually do the right thing	BUT	Other teenagers often don't do what they know is right.	☐	☐
8.	☐	☐	Some teenagers are able to make really close friends.	BUT	Other teenagers find it hard to make really close friends.	☐	☐
9.	☐	☐	Some teenagers are often disappointed with themselves	BUT	Other teenagers are pretty pleased with themselves.	☐	☐
10.	☐	☐	Some teenagers are pretty slow in finishing their school work	BUT	Other teenagers can do their school work more quickly	☐	☐

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SELF-PERCEPTION PROFILE FOR ADOLESCENTS

	Really True for Me	Sort of True for Me				Sort of True for Me	Really True for Me
11.	☐	☐	Some teenagers have a lot of friends	BUT	Other teenagers don't have very many friends.	☐	☐
12.	☐	☐	Some teenagers think they could do well at just about any new athletic activity	BUT	Other teenagers are afraid they might not do well at a new athletic activity.	☐	☐
13.	☐	☐	Some teenagers wish their body was different	BUT	Other teenagers like their body the way it is.	☐	☐
14.	☐	☐	Some teenagers feel that they don't have enough skills to do well at a job	BUT	Other teenagers feel that they do have enough skills to do a job well.	☐	☐
15.	☐	☐	Some teenagers are not dating the people they are really attracted to	BUT	Other teenagers are dating those people they are attracted to	☐	☐
16.	☐	☐	Some teenagers often feel guilty about certain things they do	BUT	Other teenagers hardly ever feel guilty about what they do.	☐	☐
17.	☐	☐	Some teenagers can be trusted to keep secrets that their friends tell them	BUT	Other teenagers have a hard time keeping secrets that their friends tell them.	☐	☐
18.	☐	☐	Some teenagers don't like the way they are leading their life	BUT	Other teenagers do like the way they are leading their life.	☐	☐
19.	☐	☐	Some teenagers do very well at their classwork	BUT	Other teenagers don't do very well at their class-work.	☐	☐
20.	☐	☐	Some teenagers are very hard to like	BUT	Other teenagers are really easy to like.	☐	☐
21.	☐	☐	Some teenagers feel that they are better than others their age at sports	BUT	Other teenagers don't feel they can play as well.	☐	☐
22.	☐	☐	Some teenagers wish their physical appearance was different	BUT	Other teenagers like their physical appearance the way it is.	☐	☐

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SELF-PERCEPTION PROFILE FOR ADOLESCENTS

	Really True for Me	Sort of True for Me				Sort of True for Me	Really True for Me
23.	☐	☐	Some teenagers are proud of the work they do on jobs they get paid for	BUT	For other teenagers, getting paid is more important than feeling proud of what they do.	☐	☐
24.	☐	☐	Some teenagers feel that people their age will be romantically attracted to them	BUT	Other teenagers worry about whether people their age will be attacted to them.	☐	☐
25.	☐	☐	Some teenagers are usually pleased with the way they act	BUT	Other teenagers are often ashamed of the way they act.	☐	☐
26.	☐	☐	Some teenagers don't really have a close friend to share things with.	BUT	Other teenagers do have a close friend to share things with.	☐	☐
27.	☐	☐	Some teenagers are happy with themselves most of the time	BUT	Other teenagers are often not happy with themselves.	☐	☐
28.	☐	☐	Some teenagers have trouble figuring out the answers in school	BUT	Other teenagers almost always can figure out the answers.	☐	☐
29.	☐	☐	Some teenagers are popular with others their age	BUT	Other teenagers are not very popular.	☐	☐
30.	☐	☐	Some teenagers don't do well at new outdoor games	BUT	Other teenagers are good at new outdoor games right away.	☐	☐
31.	☐	☐	Some teenagers think that they are good looking	BUT	Other teenagers think that they are not very good looking.	☐	☐
32.	☐	☐	Some teenagers feel like they could do better at work they do pay for	BUT	Other teenagers feel that they are doing really well at work they do pay for.	☐	☐
33.	☐	☐	Some teenagers feel that they are fun and interesting on a date	BUT	Other teenagers wonder about how fun and interesting they are on a date.	☐	☐
34.	☐	☐	Some teenagers do things they know they shouldn't do	BUT	Other teenagers hardly ever do things they know they shouldn't do.	☐	☐

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SELF-PERCEPTION PROFILE FOR ADOLESCENTS

	Really True for Me	Sort of True for Me				Sort of True for Me	Really True for Me
35.	☐	☐	Some teenagers find it hard to make friends they can really trust	BUT	Other teenagers are able to make close friends they can really trust.	☐	☐
36.	☐	☐	Some teenagers like the kind of person they are	BUT	Other teenagers often wish they were someone else.	☐	☐
37.	☐	☐	Some teenagers feel that they are pretty intelligent	BUT	Other teenagers question whether they are intelligent.	☐	☐
38.	☐	☐	Some teenagers feel that they are socially acceptable	BUT	Other teenagers wished that more people their age accepted them.	☐	☐
39.	☐	☐	Some teenagers do not feel that they are very athletic	BUT	Other teenagers feel that they are very athletic.	☐	☐
40.	☐	☐	Some teenagers really like their looks	BUT	Other teenagers wished they looked different.	☐	☐
41.	☐	☐	Some teenagers feel that it's really important to do the best you can on paying jobs	BUT	Other teenagers feel that getting the job done is what really counts.	☐	☐
42.	☐	☐	Some teenagers usually don't get asked out by people they would like to date	BUT	Other teenagers do get asked out by people they really want to date.	☐	☐
43.	☐	☐	Some teenagers usually act the way they know the are supposed to	BUT	Other teenagers often don't act the way they are supposed to.	☐	☐
44.	☐	☐	Some teenagers don't have a friend that is close enough to share really personal thoughts with	BUT	Other teenagers do have a close friend that they can share personal thoughts and feelings with.	☐	☐
45.	☐	☐	Some teenagers are very happy being the way they are	BUT	Other teenagers wish they were different.	☐	☐

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SICKNESS IMPACT PROFILE: ADOLESCENT VERSION

Introduction

On the next few pages are statements which describe things people often do when they are not well.

As you read them, think of yourself today:

- If a statement describes you TODAY, mark the box under "Yes" (Yes, this statement describes me today).
- However, if a statement does not describe you TODAY, or does not apply you, mark the box under "No". (No, this statement does not describe me today or does not apply to me).

For Example:

"I am not doing any of the shopping that I would usually do."

- If you have not been doing any shopping for some time, and still are not doing any shopping today, check "YES". (Yes, this statement describes me today).
- If you are doing your shopping as usual, check "NO" (No this statement does not describe me today or does not apply to me).

Read and respond to the statements in the order listed. Some of the statements will differ only in a few words, so please read each one carefully. While you may wish to go back to change a response, your first answer is usually best. Please do not read ahead in the questionnaire.

Please do not discuss the statements with anyone, including family members, while doing the questionnaire.

Please mark your answers by placing an "X" in the appropriate box like this. ☒

Thank you for your time and help.

How would you describe your present health

☐ very good ☐ good ☐ fair ☐ poor ☐ very poor

How would you describe you present quality of life (how things are going for you generally)?

☐ very good ☐ good ☐ fair ☐ poor ☐ very poor

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SICKNESS IMPACT PROFILE: ADOLESCENT VERSION

		Yes	No
A.	**These statements describe your sleep and rest this week.**		
1.	I spend much of the day lying down in order to rest.	☐	☐
2.	I sit for much of the day.	☐	☐
3.	I am sleeping or dozing much of the time - day and night.	☐	☐
4.	I lie down more often than my friends during the day in order to rest.	☐	☐
5.	I sit around half asleep.	☐	☐
6.	I sleep less at night, for example, I wake up easily, I do not fall asleep for a long time, I keep waking up.	☐	☐
7.	I sleep or doze more during the day.	☐	☐
B.	**These statements describe your daily work around the house.**	**Yes**	**No**
1.	I only do work that I need to do around the house for short periods of time or I rest often.	☐	☐
2.	I am doing less of the daily household chores that I would usually do.	☐	☐
3.	I am not doing any of the daily household chores that I would usually do.	☐	☐
4.	I am not doing any of the shopping that I would usually do.	☐	☐
5.	I am not doing any of the cleaning that I would usually do.	☐	☐
6.	I am not doing any of the clothes washing that I would usually do.	☐	☐
C.	**These statements describe your contact with your family and friends today.**	**Yes**	**No**
1.	I am going out less to visit people.	☐	☐
2.	I am not going out to visit people at all.	☐	☐
3.	I show less interest in other people's problems, for example, I do not listen when they tell me about their problems. I do not offer to help.	☐	☐
4.	I am often irritable with those around me, for example, I snap at people or criticize easily.	☐	☐
5.	I show less affection.	☐	☐
6.	I take part in fewer social activities than I used to, for example, I go to fewer parties or social events.	☐	☐

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SICKNESS IMPACT PROFILE: ADOLESCENT VERSION

		Yes	No
7.	I am cutting down the length of visits to friends.	☐	☐
8.	I avoid having visitors.	☐	☐
9.	My sexual activity is decreased.	☐	☐
10.	I talk less with those around me.	☐	☐
11.	I make demands on other people that they find irritating, for example, I insist that they do things for me, or tell them how to do things.	☐	☐
12.	I stay alone much of the time.	☐	☐
13.	I am disagreeable with my family, for example, I act spitefully or stubbornly.	☐	☐
14.	I frequently get angry with my family, for example, I hit them, scream or throw things at them.	☐	☐
15.	I isolate myself as much as I can from the rest of my family.	☐	☐
16.	I refuse contact with my family, for example, I turn away from them.	☐	☐
17.	I am not joking with my family members as I usually do.	☐	☐

D. These statements describe your feelings.

		Yes	No
1.	I am confused and start to do more than one thing at a time.	☐	☐
2.	I have more minor accidents, for example, I drop things, I trip and fall or bump into things.	☐	☐
3.	I react slowly to things that are said or done.	☐	☐
4.	I do not finish things I start.	☐	☐
5.	I have difficulty reasoning and solving problems, for example, making plans, making decisions, learning new things.	☐	☐
6.	I sometimes get confused, for example, I do not know where I am, who is around, or what day it is.	☐	☐
7.	I forget a lot, for example, things that happened recently, where I put things, or to keep appointments.	☐	☐
8.	I do not keep my attention on any activity for long.	☐	☐
9.	I make more mistakes than usual.	☐	☐
10.	I have difficulty doing things which involve thought and concentration, for example, paying attention in school or at my job.	☐	☐

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SICKNESS IMPACT PROFILE: ADOLESCENT VERSION

E. These statements are about how you talk to other people and write.	Yes	No
1. I am having trouble writing or typing.	☐	☐
2. I am having trouble talking to people.	☐	☐
3. I am not comfortable in most social situations like parties.	☐	☐
4. I speak with difficulty, for example, I get stuck for words, I stutter, I stammer, I slur my words.	☐	☐
5. I do not speak clearly when I am under stress.	☐	☐

F. The following statements decribe the activities you usually do in your spare time for relaxation, entertainment or just to pass the time.	Yes	No
1. I spend shorter periods of time on my hobbies and recreation.	☐	☐
2. I am going out and enjoying myself less often.	☐	☐
3. I am cutting down on some of my usual inactive pastimes, for example, I watch less TV, play cards less, or read less.	☐	☐
4. I am not doing any of my usual inactive pastimes, for example, I watch less TV, play cards less, or read less.	☐	☐
5. I am doing more inactive pastimes in place of my other usual activities.	☐	☐
6. I am taking part in fewer activities with my friends.	☐	☐
7. I am cutting down on some of my usual physical recreation or more active pastimes.	☐	☐
8. I am not doing any of my usual physical recreation or more active pastimes.	☐	☐

Now please look through this questionnaire and make sure that you have read every question.

Thank you once again for your help.

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DEPRESSED MOOD

1. Worst Severity of Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Duration of Current Episode: [ ] # of weeks

2. Worst Severity of Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Frequency: [ ] Days/week

Average % time of the day: [ ] %

DEPRESSED APPEARANCE

3. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

4. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

IRRITABILITY AND ANGER

5. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Duration: [ ] # of weeks

6. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Frequency: [ ] Days/week

Average % time of the day: [ ] %

SEPARATION-DEPENDENT-DYSPHORIA

7. Current Episode: [0] NI [1] NO [2] OCC [3] USL [4] ALW

8. Last Two Weeks: [0] NI [1] NO [2] OCC [3] USL [4] ALW

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

QUALITY OF DYPSHORIC MOOD

9. Current Episode: [0] NI [1] ND [2] QUE [3] DDF [4] VDF

10. Last Two Weeks: [0] NI [1] ND [2] QUE [3] DDF [4] VDF

DEGREE OF ASSOCIATION OF DEPRESSED OR IRRITABLE MOOD WITH SPECIFIC EVENTS OR PREOCCUPATIONS

11. Current Episode: [0] NI [1] NAL [2] MOT [3] UN [4] PN

12. Last Two Weeks: [0] NI [1] NAL [2] MOT [3] UN [4] PN

REACTIVITY OF DEPRESSED OR IRRITABLE MOOD

13. Current Episode: [0] NI [1] VR [2] FUL [3] RES [4] MLD [5] SLT [6] UNR

[ ] % Usual % of Normal

14. Last Two Weeks: [0] NI [1] VR [2] FUL [3] RES [4] MLD [5] SLT [6] UNR

[ ] % Usual % of Normal

[ ] % Maximum % of Normal

[ ] Number of hours good feeling last

DIURNAL MOOD VARIATION

Worse in Morning

15. Current Episode: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

16. Last Two Weeks: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

Worse in Afternoon and/or Evening

17. Current Episode: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

18. Last Two Weeks: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

EXCESSIVE INAPPROPRIATE GUILT

19. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

20. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

Frequency: Days/Week [ ]

NEGATIVE SELF IMAGE

21. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

22. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

FEELING UNLOVED/FORLORN

23. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

24. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

Frequency: Days/Week [ ]

HOPELESSNESS, HELPLESSNESS, DISCOURAGEMENT, PESSIMISM

25. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

26. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

SELF-PITY

27. Current Episode: [(0) NI] [(1) NO] [(2) OCC] [(3) MLD] [(4) CON]

28. Last Two Weeks: [(0) NI] [(1) NO] [(2) OCC] [(3) MLD] [(4) CON]

ACHES AND PAINS

29. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

30. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

HYPOCHONDRIASIS

31. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EX]

32. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EX]

ANHEDONIA, LACK OF INTEREST, APATHY, LOW MOTIVATION, BOREDOM

Combined Overall Rating

33. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

Duration: [ ] # of weeks

34. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

Frequency: [ ] Days/week

Average % time of the day: [ ] %

Differentiating Lack of Interest from Anhedonia

Lack of Interest

35. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

36. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

Anhedonia

37. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

38. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

FATIGUE, LACK OF ENERGY AND TIREDNESS

39. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

40. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

Frequency: [ ] Days/Week

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DIFFICULTY CONCENTRATING, INATTENTION, OR SLOWED THINKING

41. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

42. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

PSYCHOMOTOR AGITATION

43. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

44. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Unable to sit still

45. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

46. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Pacing

47. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

48. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

Hand wringing

49. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

50. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

Pulling or rubbing on hair, clothing, skin

51. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

52. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

Can't stop talking, talks on and on

53. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

54. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

PSYCHOMOTOR RETARDATION

55. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

56. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Slowed Speech

57. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

58. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Increased pauses before answering

59. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

60. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Low or monotonous speech

61. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

62. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Mute or markedly decreased amount of speech

63. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

64. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Slowed body movements

65. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

66. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Depressive stupor

67. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

68. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SOCIAL WITHDRAWAL

69. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

70. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

REJECTION SENSITIVITY

71. Last Year: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

72. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

73. Last Year: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

74. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

SLEEP PROBLEMS

75. [ ][ ] Hours slept before onset of depression

76. [ ][ ] Hours slept during the current episode

77. [ ][ ] Hours slept during the last two weeks

HYPERSOMNIA

78. [ ][ ] Hours slept in daytime of current episode

79. [ ][ ] Hours slept in daytime in the last two weeks

80. [ ][ ] Hours lying down in current episode

81. [ ][ ] Hours lying down in last two weeks

82. Current Episode: [0] NI [1] NO [2] [3] [4] [5] [6]

83. Last Two Weeks: [0] NI [1] NO [2] [3] [4] [5] [6]

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

INSOMNIA

84. Current Episode: [(0) NI] [(1) NO] [(2)] [(3)] [(4)] [(5)] [(6)]

85. Last Two Weeks: [(0) NI] [(1) NO] [(2)] [(3)] [(4)] [(5)] [(6)]

Frequency: ___ Nights/Week

TYPES OF INSOMNIA

Initial Insomnia

86. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

87. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Middle Insomnia

88. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

89. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Terminal Insomnia

90. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

91. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Circadian Reversal

92. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

93. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Non-restorative sleep

94. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

95. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Daytime sleepiness

96. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

97. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

ANOREXIA

98. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] RAR [6] NVR

99. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] RAR [6] NVR

WEIGHT LOSS

100. Current Episode:

Pounds lost: ___ lbs.

Number of Weeks: ___

101. Last Two Weeks:

Pounds lost: ___ lbs.

INCREASED APPETITE

102. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

103. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

Frequency: ___ Days/Week

STRONG CRAVING FOR SWEETS

104. Current Episode: [0] NI [1] ABS [2] DBT [3] MLD [4] MOD [5] SVR

105. Last Two Weeks: [0] NI [1] ABS [2] DBT [3] MLD [4] MOD [5] SVR

WEIGHT GAIN

106. Current Episode:

Pounds gained: ___ lbs.

Number of Weeks: ___

107. Last Two Weeks:

Pounds gained: ___ lbs.

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SUICIDAL IDEATION

108. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

109. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Suicidal Acts - Number

110. Current Episode: [ ]

111. Last Two Weeks: [ ]

Suicidal Acts - Seriousness

112. Current Episode: [0] NI [1] NO [2] MIN [3] DEF [4] SER [5] VS [6] EXT

113. Last Two Weeks: [0] NI [1] NO [2] MIN [3] DEF [4] SER [5] VS [6] EXT

Medical Lethality

114. Current Episode [0] NI [1] NO [2] MIN [3] MLD [4] MO [5] SVR [6] EXT

115. Last Two Weeks: [0] NI [1] NO [2] MIN [3] MLD [4] MO [5] SVR [6] EXT

Non-Suicidal Physical Self-Demaging Acts

116. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] ACT

117. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] ACT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

MANIC SYNDROME

ELATION, EXPANSIVE MOOD

1.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX
2.	Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX

DECREASED NEED FOR SLEEP

3.	Current Episode:	[0] NI	[1] NO	[2] -1	[3] -2	[4] -3	[5] -4	[6] -4+
4.	Last Two Weeks:	[0] NI	[1] NO	[2] -1	[3] -2	[4] -3	[5] -4	[6] -4+

UNUSUALLY ENERGETIC

5.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] LCH	[4] MOR	[5] MM	[6] UA
6.	Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] LCH	[4] MOR	[5] MM	[6] UA

INCREASE IN GOAL DIRECTED ACTIVITY

7.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX
8.	Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX

GRANDIOSITY

9.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX
10.	Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX

ACCELERATED, PRESSURED OR INCREASED AMOUNT OF SPEECH

11.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX
12.	Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

RACING THOUGHTS

13. Current Episode:	[0] NI	[1] NO	[2] DBT	[3] MLD	[4] MO	[5] SVR	[6] EX
14. Last Two Weeks:	[0] NI	[1] NO	[2] DBT	[3] MLD	[4] MO	[5] SVR	[6] EX

FLIGHT OF IDEAS

15. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX
16. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX

POOR JUDGEMENT

17. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] VS
18. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] VS

DISTRACTABILITY

19. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR
20. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR

MOTOR HYPERACTIVITY

21. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX
22. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX

Inappropriate laughing, joking or punning

23. Current Episode:	[0] NI	[1] NO	[2] DBT	[3] MLD	[4] MOD
24. Last Two Weeks:	[0] NI	[1] NO	[2] DBT	[3] MLD	[4] MOD

Uninhibited people seeking, gregarious

25. Current Episode:	[0] NI	[1] NO	[2] DBT	[3] MLD	[4] MOD
26. Last Two Weeks:	[0] NI	[1] NO	[2] DBT	[3] MLD	[4] MOD

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

Increased Productivity

27. Current Episode: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

28. Last Two Weeks: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

Sharpened and unusually creative thinking

29. Current Episode: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

30. Last Two Weeks: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

Hypersexuality

31. Current Episode: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

32. Last Two Weeks: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

INFLUENCE OF ILLICIT DRUGS OR ALCOHOL

33. Current Episode: [0] NA [1] NVR [2] SMT [3] ONL

34. Last Two Weeks: [0] NA [1] NVR [2] SMT [3] ONL

NUMBER OF MANIC PERIODS

35. [ ]

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LABORATORY TESTS

For SB	Lab Number Code

Sample Date ___ ___ ___
day month year

➧ Attach SBCL laboratory report behind this page.

➧ Are there CLINICALLY SIGNIFICANT ABNORMAL laboratory values?

☐ No
☐ Yes ⟶ Record the findings and/or diagnosis in the Adverse Experiences.

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STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No

☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(N^{\bigstar} \times \text{days since last visit})} \times 100$$

$^{\bigstar}N$ = number of capsules daily (see above)

➧ Compliance must be ≥ 80% and ≤ 120%.

Has the patient been ***non-compliant***?

☐ Yes ☐ No

Withdraw patient from study. Complete Acute Phase Conclusion section.

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STUDY MEDICATION LABEL

Attach label here

➧ Enter patient number (drug code as listed on clinical supplies) ____

Important: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

ELECTROCARDIOGRAM

Was electrocardiogram performed and sent to a central reader for interpretation?

☐ Yes ☐ No

Date Performed (day month year) ____

STUDY MEDICATION DISPENSING

Record study medication information for Weeks 9-12 in the Study Medication Record, page 250 in Binder 3. Attach label to page 251. Record number of capsules dispensed on page 250.

Reminder: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

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MODULE PARAMETERS - CONCOMITANT MEDICATION

For SmithKline Beecham Use	Project	*29060*
	Protocol	*329*
	Center	
	Patient Number	
	Module Pages	*V1017*

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CONCOMITANT MEDICATION

- Record all concomitant medication taken since the Eligibility Determination visit (Week 0).
- Where appropriate, medical conditions should be recorded on the Adverse Experiences form utilizing the same terminology.

Drug Name (Trade name preferred)	Total Daily Dose (e.g., 500 mg)	Route	Medical Condition	Start Date ★ day month year	End Date ★ or Continuation (mark box) day month year	
						☐
For SB						
						☐
For SB						
						☐
For SB						
						☐
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For SB						

★ State dates as precisely as possible.

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CONCOMITANT MEDICATION (CONTINUED)

Drug Name (Trade name preferred)	Total Daily Dose (e.g., 500 mg)	Route	Medical Condition	Start Date ★ day month year	End Date ★ or Continuation (mark box) day month year	
						☐
For SB						
						☐
For SB						
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						☐
For SB						

★ State dates as precisely as possible.

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MODULE PARAMETERS - ADVERSE EXPERIENCES/CONCLUSION

For SmithKline Beecham Use	Project	* 2 9 0 6 0 *
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ADVERSE EXPERIENCE

➧ Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).

Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
Duration if less than 24 hours		hours minutes	hours minutes	hours minutes
Experience continuing		☐	☐	☐
Experience continuing at end of study		☐	☐	☐
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -	☐ Yes ☐ No -	☐ Yes ☐ No -
Intensity	1 Mild	☐	☐	☐
	2 Moderate	☐	☐	☐
	3 Severe	☐	☐	☐
Action Taken on Study Medication	1 None	☐	☐	☐
	2 Dose decreased	☐	☐	☐
	3 Dose increased	☐	☐	☐
	4 Drug stopped	☐	☐	☐
Suspected Relationship To Study Medication	1 Related	☐	☐	☐
	2 Possibly related	☐	☐	☐
	3 Probably unrelated	☐	☐	☐
	4 Unrelated	☐	☐	☐
Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Do you consider this a serious adverse experience by the definitions on previous page?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
➧ If yes, report experience to SB by telephone within 24 hours		AE Number	AE Number	AE Number
Investigator's Signature				➧ If patient died, complete Form D

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number		Page
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ADVERSE EXPERIENCE

➧ Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).

Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
Duration if less than 24 hours		hours minutes	hours minutes	hours minutes
Experience continuing		☐	☐	☐
Experience continuing at end of study		☐	☐	☐
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -	☐ Yes ☐ No -	☐ Yes ☐ No -
Intensity	1 Mild	☐	☐	☐
	2 Moderate	☐	☐	☐
	3 Severe	☐	☐	☐
Action Taken on Study Medication	1 None	☐	☐	☐
	2 Dose decreased	☐	☐	☐
	3 Dose increased	☐	☐	☐
	4 Drug stopped	☐	☐	☐
Suspected Relationship To Study Medication	1 Related	☐	☐	☐
	2 Possibly related	☐	☐	☐
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	4 Unrelated	☐	☐	☐
Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Do you consider this a serious adverse experience by the definitions on previous page?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
➧ If yes, report experience to SB by telephone within 24 hours		AE Number	AE Number	AE Number
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SmithKline Beecham Pharmaceuticals

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ADVERSE EXPERIENCE

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Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
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Duration if less than 24 hours		hours minutes	hours minutes	hours minutes
Experience continuing		☐	☐	☐
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SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number		Page
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ADVERSE EXPERIENCE

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Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
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SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number		Page
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ADVERSE EXPERIENCE

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Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
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Do you consider this a serious adverse experience by the definitions on previous page?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
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SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number		Page
29060	329	0 0			231

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Experience				
For SmithKline Beecham				
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Date Stopped		day month year	day month year	day month year
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Experience continuing		☐	☐	☐
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Investigator's Signature				➧ If patient died, complete Form D

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number		Page
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ACUTE PHASE CONCLUSION

Will the patient enter the continuation phase of this study?

☐ Yes - Go to Binder 3 - Ensure the preprinted Patient Number is identical to the Patient Number assigned in this phase.

☐ No

➧ If 'No', mark the ONE most appropriate category

1 ☐ Adverse experience (complete Adverse Experience section)
2 ☐ Lack of efficacy
3 ☐ Deviation from protocol (including non-compliance)
4 ☐ Lost to follow-up
6 ☐ Termination by sponsor
7 ☐ Other

Comments on reason for withdrawal:

Date of Last Visit ____ ____ ____ (day month year)

Date of Last Dose ____ ____ ____ (day month year)

I certify that I have reviewed the data on this case report form (pages 108-232) and that all information is complete and accurate.

Investigator's Signature _____ _____ Date

Project	Protocol	Center	Patient Number
29060	329	0	

← Ensure Patient Number is identical for Binder 2 and Binder 3

SmithKline Beecham
Pharmaceuticals

CONFIDENTIAL

CASE REPORT FORM

PROTOCOL 29060/329

CONTINUATION PHASE - BINDER 3

A Multi-Center, Double-Blind, Placebo Controlled Study of Paroxetine and Imipramine in Adolescents with Unipolar Major Depression

Patient Initials ____ Country _____

GENERAL INSTRUCTIONS

Print clearly in CAPITAL LETTERS using a black ball-point pen and press firmly so that all copies are legible. DO NOT print in shaded areas. Answer all questions on every page.

The plastic writing board in the back of the binder should be used to divide each set of pages before writing on them with a ball-point pen.

Important: Errors should be crossed with a single line and the alteration made as close to the original as possible. All alterations must be printed, initialled and dated.

DATE

Use the following three-letter abbreviations for month:

January	=	JAN
February	=	FEB
March	=	MAR
April	=	APR
May	=	MAY
June	=	JUN
July	=	JUL
August	=	AUG
September	=	SEP
October	=	OCT
November	=	NOV
December	=	DEC

Example: | 0 | 1 | J | A | N | 9 | 3 | = 1st January 1993

day month year

TIME

Unless specified otherwise, use the 24 hour clock: 00:00 - 23:59.

Example: | 1 | 5 | 3 | 0 | = 3:30 p.m.

24 hr. clock

ADVERSE EXPERIENCE DEFINITIONS

INTENSITY

Mild	Adverse experience which is easily tolerated.
Moderate	Adverse experience sufficiently discomforting to interfere with daily activity.
Severe	Adverse experience which prevents normal everyday activities.

SUSPECTED RELATIONSHIP TO STUDY MEDICATION

Related	There is a direct cause and effect relationship between the adverse experience and the study drug.
Possibly Related	A direct cause and effect relationship between the drug and the adverse experience has not been demonstrated but is possible or likely.
Probably Unrelated	Cause and effect relationship between the drug and the adverse experience has not been demonstrated, is improbable but not impossible.
Unrelated	The adverse experience is definitely not related to the test drug.

SERIOUS ADVERSE EXPERIENCE

A serious adverse experience is any experience which:

- Is fatal
- Is life threatening
- Is permanently or temporarily disabling
- Is incapacitating
- Results in hospitalization
- Prolongs a hospital stay
- Is associated with congenital abnormality, carcinoma or overdose

In addition, any experience which the investigator regards as serious or which would suggest any significant hazard, contraindication, side effect or precaution that may be associated with the use of the drug should be reported as a serious experience.

- Use each form for a maximum of three experiences.
- All questions on the Adverse Experience form should be completed.

SMITHKLINE BEECHAM PROTOCOL 29060/329 - SCHEDULE OF PROCEDURES

Assessments	Baseline		Acute Phase								Continuation Phase					
Time (weeks)	-1	0	1	2	3	4	5	6	7	8	12	16	20	24	28	32
Informed Consent	●															
Medical History and Physical Exam	●															
Clinical Laboratory Studies	● [1]									●			●			●
Serum Pregnancy	●		● [2]	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....
ECG	●			●		●		●		●			●			●
Vital Signs	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Hamilton Depression Scale	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Full K-SADS-L	●															●
Affect Section of K-SADS-L		●		●		●		●		●	●	●	●	●	●	
C-GAS	●															
CGI		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
SADS-L	●															
FH-FHE	●															
Autonomous Functioning Checklist	●									●						●
Self Perception Profile	●									●						●
Sickness Impact Scale	●									●						●
Randomization		●														
Adverse Experiences		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Supportive Psychotherapy		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Plasma Sampling for Drug Analysis	●					●				●				●		●
Study Medication Record			●	●	●	●	●	●	●	●	●	●	●	●	●	●
Concomitant Medication	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●

[1] - Clinical laboratory studies should include a Urine Drug Screen
[2] - On suspicion of pregnancy

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	
29060	329	0 0		Continuation Phase	

MODULE PARAMETERS - WEEK 12

For SmithKline Beecham Use	Project	* 2 9 0 6 0 *
	Protocol	* 3 2 9 *
	Center	
	Patient Number	
	Module Pages	* V 1 3 1 7 *

SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	Visit Date	Page
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VITAL SIGNS

Weight	Sitting		Standing	
	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)
☐ lbs ☐ kg				
.	/		/	

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

☐ Yes ☐ No

Record in the Adverse Experience section

Has there been any change in concomitant medication since the last visit?

☐ Yes ☐ No

Record in the Concomitant Medication section

CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

Rate the total improvement whether or not, in your judgment, it is due entirely to drug treatment. Compared to his/her condition at admission to the study, how much has the patient changed?

☐ 1 = Very much improved
☐ 2 = Much improved
☐ 3 = Minimally improved
☐ 4 = No change
☐ 5 = Minimally worse
☐ 6 = Much worse
☐ 7 = Very much worse

SmithKline Beecham Pharmaceuticals

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
   - ☐ 1 = These feeling states indicated only on questioning
   - ☐ 2 = These feeling states spontaneously reported verbally
   - ☐ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
   - ☐ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication

2. Feelings of Guilt
   - ☐ 0 = Absent
   - ☐ 1 = Self reproach, feels he/she has let people down
   - ☐ 2 = Ideas of guilt or rumination over past errors or sinful deeds
   - ☐ 3 = Present illness is a punishment. Delusions of guilt
   - ☐ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide
   - ☐ 0 = Absent
   - ☐ 1 = Feels life is not worth living
   - ☐ 2 = Wishes he/she were dead or any thoughts of possible death to self
   - ☐ 3 = Suicide ideas or gesture
   - ☐ 4 = Attempts at suicide (any serious attempt rates 4)

4. Insomnia Early
   - ☐ 0 = No difficulty falling asleep
   - ☐ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
   - ☐ 2 = Complains of nightly difficulty falling asleep

5. Insomnia Middle
   - ☐ 0 = No difficulty
   - ☐ 1 = Patient complains of being restless and disturbed during the night
   - ☐ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia Late
   - ☐ 0 = No difficulty
   - ☐ 1 = Waking in early hours of the morning but goes back to sleep
   - ☐ 2 = Unable to fall asleep again if he/she gets out of bed

7. Work and Activities
   - ☐ 0 = No difficulty
   - ☐ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
   - ☐ 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
   - ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
   - ☐ 4 = Stopped working because of present illness.

SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Continuation Phase Week 12		235

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
- ☐ 0 = Normal speech and thought
- ☐ 1 = Slight retardation at interview
- ☐ 2 = Obvious retardation at interview
- ☐ 3 = Interview difficult
- ☐ 4 = Complete stupor

9. Agitation
- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = "Playing with" hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety Psychic
- ☐ 0 = No difficulty
- ☐ 1 = Subjective tension and irritability
- ☐ 2 = Worrying about minor matters
- ☐ 3 = Apprehensive attitude apparent in face or speech
- ☐ 4 = Fears expressed without questioning

11. Anxiety Somatic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal
- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating. Heavy feelings in abdomen
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. Somatic Symptoms General
- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
- ☐ 2 = Any clear-cut symptoms rates 2

14. Genital Symptoms (such as loss of libido and menstrual disturbances)
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

SmithKline Beecham Pharmaceuticals

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis
- ☐ 0 = Not present
- ☐ 1 = Self-absorption (bodily)
- ☐ 2 = Preoccupation with health
- ☐ 3 = Frequent complaints, requests for help, etc.
- ☐ 4 = Hypochondriacal delusions

16. Loss of Weight
- ☐ 0 = No weight loss
- ☐ 1 = Slight or doubtful loss of weight
- ☐ 2 = Obvious or severe loss of weight

17. Insight
- ☐ 0 = Acknowledges being depressed and ill
- ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
- ☐ 2 = Denies being ill at all

➧ ☐☐ HAMD Score (Items 1-17)

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DEPRESSED MOOD

1. Worst Severity of Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Duration of Current Episode: ___ # of weeks

2. Worst Severity of Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Frequency: ___ Days/week

Average % time of the day: ___ %

DEPRESSED APPEARANCE

3. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

4. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

IRRITABILITY AND ANGER

5. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Duration: ___ # of weeks

6. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Frequency: ___ Days/week

Average % time of the day: ___ %

SEPARATION-DEPENDENT-DYSPHORIA

7. Current Episode: [0] NI [1] NO [2] OCC [3] USL [4] ALW

8. Last Two Weeks: [0] NI [1] NO [2] OCC [3] USL [4] ALW

SmithKline Beecham Pharmaceuticals

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

QUALITY OF DYPSHORIC MOOD

9. Current Episode: [(0) NI] [(1) ND] [(2) QUE] [(3) DDF] [(4) VDF]

10. Last Two Weeks: [(0) NI] [(1) ND] [(2) QUE] [(3) DDF] [(4) VDF]

DEGREE OF ASSOCIATION OF DEPRESSED OR IRRITABLE MOOD WITH SPECIFIC EVENTS OR PREOCCUPATIONS

11. Current Episode: [(0) NI] [(1) NAL] [(2) MOT] [(3) UN] [(4) PN]

12. Last Two Weeks: [(0) NI] [(1) NAL] [(2) MOT] [(3) UN] [(4) PN]

REACTIVITY OF DEPRESSED OR IRRITABLE MOOD

13. Current Episode: [(0) NI] [(1) VR] [(2) FUL] [(3) RES] [(4) MLD] [(5) SLT] [(6) UNR]

[ ] % Usual % of Normal

14. Last Two Weeks: [(0) NI] [(1) VR] [(2) FUL] [(3) RES] [(4) MLD] [(5) SLT] [(6) UNR]

[ ] % Usual % of Normal

[ ] % Maximum % of Normal

[ ] Number of hours good feeling last

DIURNAL MOOD VARIATION

Worse in Morning

15. Current Episode: [(0) NI] [(1) NW] [(2) MIN] [(3) MLD] [(4) CW] [(5) EXT]

16. Last Two Weeks: [(0) NI] [(1) NW] [(2) MIN] [(3) MLD] [(4) CW] [(5) EXT]

Worse in Afternoon and/or Evening

17. Current Episode: [(0) NI] [(1) NW] [(2) MIN] [(3) MLD] [(4) CW] [(5) EXT]

18. Last Two Weeks: [(0) NI] [(1) NW] [(2) MIN] [(3) MLD] [(4) CW] [(5) EXT]

SmithKline Beecham Pharmaceuticals

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

EXCESSIVE INAPPROPRIATE GUILT

19. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

20. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

Frequency: Days/Week [ ]

NEGATIVE SELF IMAGE

21. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

22. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

FEELING UNLOVED/FORLORN

23. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

24. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

Frequency: Days/Week [ ]

HOPELESSNESS, HELPLESSNESS, DISCOURAGEMENT, PESSIMISM

25. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

26. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

SELF-PITY

27. Current Episode: [0] NI [1] NO [2] OCC [3] MLD [4] CON

28. Last Two Weeks: [0] NI [1] NO [2] OCC [3] MLD [4] CON

ACHES AND PAINS

29. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

30. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

HYPOCHONDRIASIS

31. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

32. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

ANHEDONIA, LACK OF INTEREST, APATHY, LOW MOTIVATION, BOREDOM

Combined Overall Rating

33. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Duration: [ ] # of weeks

34. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/week

Average % time of the day: [ ] %

Differentiating Lack of Interest from Anhedonia

Lack of Interest

35. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

36. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Anhedonia

37. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

38. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

FATIGUE, LACK OF ENERGY AND TIREDNESS

39. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

40. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/Week

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DIFFICULTY CONCENTRATING, INATTENTION, OR SLOWED THINKING

41. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

42. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

PSYCHOMOTOR AGITATION

43. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

44. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Unable to sit still

45. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

46. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Pacing

47. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

48. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

Hand wringing

49. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

50. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

Pulling or rubbing on hair, clothing, skin

51. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

52. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

Can't stop talking, talks on and on

53. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

54. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

PSYCHOMOTOR RETARDATION

55. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

56. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Slowed Speech

57. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

58. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Increased pauses before answering

59. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

60. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Low or monotonous speech

61. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

62. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Mute or markedly decreased amount of speech

63. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

64. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Slowed body movements

65. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

66. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Depressive stupor

67. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

68. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SOCIAL WITHDRAWAL

69.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
70.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

REJECTION SENSITIVITY

71.	Last Year:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
72.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
73.	Last Year:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
74.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

SLEEP PROBLEMS

75. ⌊_⌋ Hours slept before onset of depression

76. ⌊_⌋ Hours slept during the current episode

77. ⌊_⌋ Hours slept during the last two weeks

HYPERSOMNIA

78. ⌊_⌋ Hours slept in daytime of current episode

79. ⌊_⌋ Hours slept in daytime in the last two weeks

80. ⌊_⌋ Hours lying down in current episode

81. ⌊_⌋ Hours lying down in last two weeks

82.	Current Episode:	(0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)
83.	Last Two Weeks:	(0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

INSOMNIA

84. Current Episode: [(0) NI] [(1) NO] [(2)] [(3)] [(4)] [(5)] [(6)]

85. Last Two Weeks: [(0) NI] [(1) NO] [(2)] [(3)] [(4)] [(5)] [(6)]

Frequency: ☐☐ Nights/Week

TYPES OF INSOMNIA

Initial Insomnia

86. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

87. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Middle Insomnia

88. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

89. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Terminal Insomnia

90. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

91. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Circadian Reversal

92. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

93. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Non-restorative sleep

94. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

95. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Daytime sleepiness

96. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

97. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

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ANOREXIA

98. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] RAR [6] NVR

99. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] RAR [6] NVR

WEIGHT LOSS

100. Current Episode:

Pounds lost: ___ lbs.

Number of Weeks: ___

101. Last Two Weeks:

Pounds lost: ___ lbs.

INCREASED APPETITE

102. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

103. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

Frequency: ___ Days/Week

STRONG CRAVING FOR SWEETS

104. Current Episode: [0] NI [1] ABS [2] DBT [3] MLD [4] MOD [5] SVR

105. Last Two Weeks: [0] NI [1] ABS [2] DBT [3] MLD [4] MOD [5] SVR

WEIGHT GAIN

106. Current Episode:

Pounds gained: ___ lbs.

Number of Weeks: ___

107. Last Two Weeks:

Pounds gained: ___ lbs.

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SUICIDAL IDEATION

108. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

109. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Suicidal Acts - Number

110. Current Episode: [ ]

111. Last Two Weeks: [ ]

Suicidal Acts - Seriousness

112. Current Episode: [0] NI [1] NO [2] MIN [3] DEF [4] SER [5] VS [6] EXT

113. Last Two Weeks: [0] NI [1] NO [2] MIN [3] DEF [4] SER [5] VS [6] EXT

Medical Lethality

114. Current Episode [0] NI [1] NO [2] MIN [3] MLD [4] MO [5] SVR [6] EXT

115. Last Two Weeks: [0] NI [1] NO [2] MIN [3] MLD [4] MO [5] SVR [6] EXT

Non-Suicidal Physical Self-Demaging Acts

116. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] ACT

117. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] ACT

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MANIC SYNDROME

ELATION, EXPANSIVE MOOD

1. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX
2. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX

DECREASED NEED FOR SLEEP

3. Current Episode:	[0] NI	[1] NO	[2] -1	[3] -2	[4] -3	[5] -4	[6] -4+
4. Last Two Weeks:	[0] NI	[1] NO	[2] -1	[3] -2	[4] -3	[5] -4	[6] -4+

UNUSUALLY ENERGETIC

5. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] LCH	[4] MOR	[5] MM	[6] UA
6. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] LCH	[4] MOR	[5] MM	[6] UA

INCREASE IN GOAL DIRECTED ACTIVITY

7. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX
8. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX

GRANDIOSITY

9. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX
10. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX

ACCELERATED, PRESSURED OR INCREASED AMOUNT OF SPEECH

11. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX
12. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

RACING THOUGHTS

13. Current Episode:	[0] NI	[1] NO	[2] DBT	[3] MLD	[4] MO	[5] SVR	[6] EX
14. Last Two Weeks:	[0] NI	[1] NO	[2] DBT	[3] MLD	[4] MO	[5] SVR	[6] EX

FLIGHT OF IDEAS

15. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX
16. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX

POOR JUDGEMENT

17. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] VS
18. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] VS

DISTRACTABILITY

19. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	
20. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	

MOTOR HYPERACTIVITY

21. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX
22. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX

Inappropriate laughing, joking or punning

23. Current Episode:	[0] NI	[1] NO	[2] DBT	[3] MLD	[4] MOD	
24. Last Two Weeks:	[0] NI	[1] NO	[2] DBT	[3] MLD	[4] MOD	

Uninhibited people seeking, gregarious

25. Current Episode:	[0] NI	[1] NO	[2] DBT	[3] MLD	[4] MOD	
26. Last Two Weeks:	[0] NI	[1] NO	[2] DBT	[3] MLD	[4] MOD	

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

Increased Productivity

27. Current Episode: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

28. Last Two Weeks: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

Sharpened and unusually creative thinking

29. Current Episode: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

30. Last Two Weeks: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

Hypersexuality

31. Current Episode: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

32. Last Two Weeks: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

INFLUENCE OF ILLICIT DRUGS OR ALCOHOL

33. Current Episode: [0] NA [1] NVR [2] SMT [3] ONL

34. Last Two Weeks: [0] NA [1] NVR [2] SMT [3] ONL

NUMBER OF MANIC PERIODS

35. [ ]

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STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No
☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(N^{\bigstar} \times \text{days since last visit})} \times 100$$

$^{\bigstar}N$ = number of capsules daily (see above)

➧ Compliance must be $\geq$ 80% and $\leq$ 120%.

Has the patient been ***non-compliant*** for two consecutive visits?

☐ Yes ☐ No

Withdraw patient from study. Complete Study Conclusion section.

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STUDY MEDICATION LABEL

Attach label here

Attach label here

Attach label here

Attach label here

➧ Enter patient number (drug code as listed on clinical supplies) _____

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STUDY MEDICATION DISPENSING

Record study medication information for Weeks 13-16 in the Study Medication Record, page 270. Attach label(s) to page 271. Record number of capsules dispensed on page 270.

Reminder: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

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MODULE PARAMETERS - WEEK 16

For SmithKline Beecham Use	Project	*29060*
	Protocol	*329*
	Center	
	Patient Number	
	Module Pages	*V1417*

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VITAL SIGNS

Weight ☐ lbs ☐ kg	Sitting		Standing	
	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)
.	/		/	

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

☐ Yes ☐ No

Record in the Adverse Experience section

Has there been any change in concomitant medication since the last visit?

☐ Yes ☐ No

Record in the Concomitant Medication section

CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

Rate the total improvement whether or not, in your judgment, it is due entirely to drug treatment. Compared to his/her condition at admission to the study, how much has the patient changed?

- ☐ 1 = Very much improved
- ☐ 2 = Much improved
- ☐ 3 = Minimally improved
- ☐ 4 = No change
- ☐ 5 = Minimally worse
- ☐ 6 = Much worse
- ☐ 7 = Very much worse

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
   - ☐ 1 = These feeling states indicated only on questioning
   - ☐ 2 = These feeling states spontaneously reported verbally
   - ☐ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
   - ☐ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication

2. Feelings of Guilt
   - ☐ 0 = Absent
   - ☐ 1 = Self reproach, feels he/she has let people down
   - ☐ 2 = Ideas of guilt or rumination over past errors or sinful deeds
   - ☐ 3 = Present illness is a punishment. Delusions of guilt
   - ☐ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide
   - ☐ 0 = Absent
   - ☐ 1 = Feels life is not worth living
   - ☐ 2 = Wishes he/she were dead or any thoughts of possible death to self
   - ☐ 3 = Suicide ideas or gesture
   - ☐ 4 = Attempts at suicide (any serious attempt rates 4)

4. Insomnia Early
   - ☐ 0 = No difficulty falling asleep
   - ☐ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
   - ☐ 2 = Complains of nightly difficulty falling asleep

5. Insomnia Middle
   - ☐ 0 = No difficulty
   - ☐ 1 = Patient complains of being restless and disturbed during the night
   - ☐ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia Late
   - ☐ 0 = No difficulty
   - ☐ 1 = Waking in early hours of the morning but goes back to sleep
   - ☐ 2 = Unable to fall asleep again if he/she gets out of bed

7. Work and Activities
   - ☐ 0 = No difficulty
   - ☐ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
   - ☐ 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
   - ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
   - ☐ 4 = Stopped working because of present illness.

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
- ☐ 0 = Normal speech and thought
- ☐ 1 = Slight retardation at interview
- ☐ 2 = Obvious retardation at interview
- ☐ 3 = Interview difficult
- ☐ 4 = Complete stupor

9. Agitation
- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = "Playing with" hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety Psychic
- ☐ 0 = No difficulty
- ☐ 1 = Subjective tension and irritability
- ☐ 2 = Worrying about minor matters
- ☐ 3 = Apprehensive attitude apparent in face or speech
- ☐ 4 = Fears expressed without questioning

11. Anxiety Somatic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal
- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating. Heavy feelings in abdomen
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. Somatic Symptoms General
- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
- ☐ 2 = Any clear-cut symptoms rates 2

14. Genital Symptoms (such as loss of libido and menstrual disturbances)
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis
- ☐ 0 = Not present
- ☐ 1 = Self-absorption (bodily)
- ☐ 2 = Preoccupation with health
- ☐ 3 = Frequent complaints, requests for help, etc.
- ☐ 4 = Hypochondriacal delusions

16. Loss of Weight
- ☐ 0 = No weight loss
- ☐ 1 = Slight or doubtful loss of weight
- ☐ 2 = Obvious or severe loss of weight

17. Insight
- ☐ 0 = Acknowledges being depressed and ill
- ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
- ☐ 2 = Denies being ill at all

➧ ⌊__⌋ HAMD Score (Items 1-17)

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DEPRESSED MOOD

1. Worst Severity of Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

   Duration of Current Episode: ___ # of weeks

2. Worst Severity of Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

   Frequency: ___ Days/week

   Average % time of the day: ___ %

DEPRESSED APPEARANCE

3. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

4. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

IRRITABILITY AND ANGER

5. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

   Duration: ___ # of weeks

6. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

   Frequency: ___ Days/week

   Average % time of the day: ___ %

SEPARATION-DEPENDENT-DYSPHORIA

7. Current Episode: [0] NI [1] NO [2] OCC [3] USL [4] ALW

8. Last Two Weeks: [0] NI [1] NO [2] OCC [3] USL [4] ALW

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

QUALITY OF DYPSHORIC MOOD

9. Current Episode: [0] NI [1] ND [2] QUE [3] DDF [4] VDF

10. Last Two Weeks: [0] NI [1] ND [2] QUE [3] DDF [4] VDF

DEGREE OF ASSOCIATION OF DEPRESSED OR IRRITABLE MOOD WITH SPECIFIC EVENTS OR PREOCCUPATIONS

11. Current Episode: [0] NI [1] NAL [2] MOT [3] UN [4] PN

12. Last Two Weeks: [0] NI [1] NAL [2] MOT [3] UN [4] PN

REACTIVITY OF DEPRESSED OR IRRITABLE MOOD

13. Current Episode: [0] NI [1] VR [2] FUL [3] RES [4] MLD [5] SLT [6] UNR

[ ] % Usual % of Normal

14. Last Two Weeks: [0] NI [1] VR [2] FUL [3] RES [4] MLD [5] SLT [6] UNR

[ ] % Usual % of Normal

[ ] % Maximum % of Normal

[ ] Number of hours good feeling last

DIURNAL MOOD VARIATION

Worse in Morning

15. Current Episode: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

16. Last Two Weeks: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

Worse in Afternoon and/or Evening

17. Current Episode: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

18. Last Two Weeks: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

EXCESSIVE INAPPROPRIATE GUILT

19. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

20. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

Frequency: Days/Week [ ]

NEGATIVE SELF IMAGE

21. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

22. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

FEELING UNLOVED/FORLORN

23. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

24. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

Frequency: Days/Week [ ]

HOPELESSNESS, HELPLESSNESS, DISCOURAGEMENT, PESSIMISM

25. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

26. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

SELF-PITY

27. Current Episode: [0] NI [1] NO [2] OCC [3] MLD [4] CON

28. Last Two Weeks: [0] NI [1] NO [2] OCC [3] MLD [4] CON

ACHES AND PAINS

29. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

30. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

HYPOCHONDRIASIS

31. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

32. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

ANHEDONIA, LACK OF INTEREST, APATHY, LOW MOTIVATION, BOREDOM

Combined Overall Rating

33. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Duration: [ ] # of weeks

34. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/week

Average % time of the day: [ ] %

Differentiating Lack of Interest from Anhedonia

Lack of Interest

35. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

36. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Anhedonia

37. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

38. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

FATIGUE, LACK OF ENERGY AND TIREDNESS

39. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

40. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/Week

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DIFFICULTY CONCENTRATING, INATTENTION, OR SLOWED THINKING

41. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

42. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

PSYCHOMOTOR AGITATION

43. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

44. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Unable to sit still

45. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

46. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Pacing

47. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

48. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

Hand wringing

49. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

50. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

Pulling or rubbing on hair, clothing, skin

51. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

52. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

Can't stop talking, talks on and on

53. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

54. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

PSYCHOMOTOR RETARDATION

55.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
56.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Slowed Speech

57.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
58.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Increased pauses before answering

59.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
60.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Low or monotonous speech

61.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
62.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Mute or markedly decreased amount of speech

63.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
64.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Slowed body movements

65.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
66.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Depressive stupor

67.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
68.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SOCIAL WITHDRAWAL

69.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
70.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

REJECTION SENSITIVITY

71.	Last Year:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
72.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
73.	Last Year:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
74.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

SLEEP PROBLEMS

75. ⌊__⌋ Hours slept before onset of depression

76. ⌊__⌋ Hours slept during the current episode

77. ⌊__⌋ Hours slept during the last two weeks

HYPERSOMNIA

78. ⌊__⌋ Hours slept in daytime of current episode

79. ⌊__⌋ Hours slept in daytime in the last two weeks

80. ⌊__⌋ Hours lying down in current episode

81. ⌊__⌋ Hours lying down in last two weeks

82.	Current Episode:	(0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)
83.	Last Two Weeks:	(0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

INSOMNIA

84. Current Episode: [(0) NI] [(1) NO] [(2)] [(3)] [(4)] [(5)] [(6)]

85. Last Two Weeks: [(0) NI] [(1) NO] [(2)] [(3)] [(4)] [(5)] [(6)]

Frequency: ☐☐ Nights/Week

TYPES OF INSOMNIA

Initial Insomnia

86. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

87. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Middle Insomnia

88. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

89. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Terminal Insomnia

90. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

91. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Circadian Reversal

92. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

93. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Non-restorative sleep

94. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

95. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Daytime sleepiness

96. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

97. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

ANOREXIA

98. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) RAR] [(6) NVR]

99. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) RAR] [(6) NVR]

WEIGHT LOSS

100. Current Episode:

Pounds lost: ___ lbs.

Number of Weeks: ___

101. Last Two Weeks:

Pounds lost: ___ lbs.

INCREASED APPETITE

102. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EX]

103. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EX]

Frequency: ___ Days/Week

STRONG CRAVING FOR SWEETS

104. Current Episode: [(0) NI] [(1) ABS] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

105. Last Two Weeks: [(0) NI] [(1) ABS] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

WEIGHT GAIN

106. Current Episode:

Pounds gained: ___ lbs.

Number of Weeks: ___

107. Last Two Weeks:

Pounds gained: ___ lbs.

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SUICIDAL IDEATION

108. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

109. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Suicidal Acts - Number

110. Current Episode: ___

111. Last Two Weeks: ___

Suicidal Acts - Seriousness

112. Current Episode: [0] NI [1] NO [2] MIN [3] DEF [4] SER [5] VS [6] EXT

113. Last Two Weeks: [0] NI [1] NO [2] MIN [3] DEF [4] SER [5] VS [6] EXT

Medical Lethality

114. Current Episode [0] NI [1] NO [2] MIN [3] MLD [4] MO [5] SVR [6] EXT

115. Last Two Weeks: [0] NI [1] NO [2] MIN [3] MLD [4] MO [5] SVR [6] EXT

Non-Suicidal Physical Self-Demaging Acts

116. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] ACT

117. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] ACT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

MANIC SYNDROME

ELATION, EXPANSIVE MOOD

1. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX
2. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX

DECREASED NEED FOR SLEEP

3. Current Episode:	[0] NI	[1] NO	[2] -1	[3] -2	[4] -3	[5] -4	[6] -4+
4. Last Two Weeks:	[0] NI	[1] NO	[2] -1	[3] -2	[4] -3	[5] -4	[6] -4+

UNUSUALLY ENERGETIC

5. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] LCH	[4] MOR	[5] MM	[6] UA
6. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] LCH	[4] MOR	[5] MM	[6] UA

INCREASE IN GOAL DIRECTED ACTIVITY

7. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX
8. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX

GRANDIOSITY

9. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX
10. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX

ACCELERATED, PRESSURED OR INCREASED AMOUNT OF SPEECH

11. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX
12. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

RACING THOUGHTS

13. Current Episode: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

14. Last Two Weeks: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

FLIGHT OF IDEAS

15. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

16. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

POOR JUDGEMENT

17. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) VS]

18. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) VS]

DISTRACTABILITY

19. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR]

20. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR]

MOTOR HYPERACTIVITY

21. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) MKD] [(6) EX]

22. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) MKD] [(6) EX]

Inappropriate laughing, joking or punning

23. Current Episode: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

24. Last Two Weeks: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

Uninhibited people seeking, gregarious

25. Current Episode: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

26. Last Two Weeks: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

Increased Productivity

27. Current Episode: [(0) NI] [(1) NO] [(2) DBT] [(3) PRS] [(4) SVR]

28. Last Two Weeks: [(0) NI] [(1) NO] [(2) DBT] [(3) PRS] [(4) SVR]

Sharpened and unusually creative thinking

29. Current Episode: [(0) NI] [(1) NO] [(2) DBT] [(3) PRS] [(4) SVR]

30. Last Two Weeks: [(0) NI] [(1) NO] [(2) DBT] [(3) PRS] [(4) SVR]

Hypersexuality

31. Current Episode: [(0) NI] [(1) NO] [(2) DBT] [(3) PRS] [(4) SVR]

32. Last Two Weeks: [(0) NI] [(1) NO] [(2) DBT] [(3) PRS] [(4) SVR]

INFLUENCE OF ILLICIT DRUGS OR ALCOHOL

33. Current Episode: [(0) NA] [(1) NVR] [(2) SMT] [(3) ONL]

34. Last Two Weeks: [(0) NA] [(1) NVR] [(2) SMT] [(3) ONL]

NUMBER OF MANIC PERIODS

35. [ ]

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STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No
☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(N^{\star} \times \text{days since last visit})} \times 100$$

★N = number of capsules daily (see above)

➧ Compliance must be ≥ 80% and ≤ 120%.

Has the patient been ***non-compliant*** for two consecutive visits?

☐ Yes ☐ No

Withdraw patient from study. Complete Study Conclusion section.

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STUDY MEDICATION LABEL

Attach label here

Attach label here

Attach label here

Attach label here

➧ Enter patient number (drug code as listed on clinical supplies) _____

Important: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

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STUDY MEDICATION DISPENSING

Record study medication information for Weeks 17-20 in the Study Medication Record, page 291. Attach label(s) to page 292. Record number of capsules dispensed on page 291.

Reminder: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

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MODULE PARAMETERS - WEEK 20

For SmithKline Beecham Use	Project	*29060*
	Protocol	*329*
	Center	
	Patient Number	
	Module Pages	*V1517*

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VITAL SIGNS

Weight ☐ lbs ☐ kg	Sitting		Standing	
	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)
.	/		/	

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

☐ Yes ☐ No

Record in the Adverse Experience section

Has there been any change in concomitant medication since the last visit?

☐ Yes ☐ No

Record in the Concomitant Medication section

CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

Rate the total improvement whether or not, in your judgment, it is due entirely to drug treatment. Compared to his/her condition at admission to the study, how much has the patient changed?

☐ 1 = Very much improved
☐ 2 = Much improved
☐ 3 = Minimally improved
☐ 4 = No change
☐ 5 = Minimally worse
☐ 6 = Much worse
☐ 7 = Very much worse

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
   - ☐ 1 = These feeling states indicated only on questioning
   - ☐ 2 = These feeling states spontaneously reported verbally
   - ☐ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
   - ☐ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication

2. Feelings of Guilt
   - ☐ 0 = Absent
   - ☐ 1 = Self reproach, feels he/she has let people down
   - ☐ 2 = Ideas of guilt or rumination over past errors or sinful deeds
   - ☐ 3 = Present illness is a punishment. Delusions of guilt
   - ☐ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide
   - ☐ 0 = Absent
   - ☐ 1 = Feels life is not worth living
   - ☐ 2 = Wishes he/she were dead or any thoughts of possible death to self
   - ☐ 3 = Suicide ideas or gesture
   - ☐ 4 = Attempts at suicide (any serious attempt rates 4)

4. Insomnia Early
   - ☐ 0 = No difficulty falling asleep
   - ☐ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
   - ☐ 2 = Complains of nightly difficulty falling asleep

5. Insomnia Middle
   - ☐ 0 = No difficulty
   - ☐ 1 = Patient complains of being restless and disturbed during the night
   - ☐ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia Late
   - ☐ 0 = No difficulty
   - ☐ 1 = Waking in early hours of the morning but goes back to sleep
   - ☐ 2 = Unable to fall asleep again if he/she gets out of bed

7. Work and Activities
   - ☐ 0 = No difficulty
   - ☐ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
   - ☐ 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
   - ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
   - ☐ 4 = Stopped working because of present illness.

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
- ☐ 0 = Normal speech and thought
- ☐ 1 = Slight retardation at interview
- ☐ 2 = Obvious retardation at interview
- ☐ 3 = Interview difficult
- ☐ 4 = Complete stupor

9. Agitation
- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = "Playing with" hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety Psychic
- ☐ 0 = No difficulty
- ☐ 1 = Subjective tension and irritability
- ☐ 2 = Worrying about minor matters
- ☐ 3 = Apprehensive attitude apparent in face or speech
- ☐ 4 = Fears expressed without questioning

11. Anxiety Somatic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal
- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating. Heavy feelings in abdomen
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. Somatic Symptoms General
- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
- ☐ 2 = Any clear-cut symptoms rates 2

14. Genital Symptoms (such as loss of libido and menstrual disturbances)
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis
- ☐ 0 = Not present
- ☐ 1 = Self-absorption (bodily)
- ☐ 2 = Preoccupation with health
- ☐ 3 = Frequent complaints, requests for help, etc.
- ☐ 4 = Hypochondriacal delusions

16. Loss of Weight
- ☐ 0 = No weight loss
- ☐ 1 = Slight or doubtful loss of weight
- ☐ 2 = Obvious or severe loss of weight

17. Insight
- ☐ 0 = Acknowledges being depressed and ill
- ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
- ☐ 2 = Denies being ill at all

➧ ☐☐ HAMD Score (Items 1-17)

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DEPRESSED MOOD

1. Worst Severity of Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX] [(7) VEX]

Duration of Current Episode: [ ] # of weeks

2. Worst Severity of Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX] [(7) VEX]

Frequency: [ ] Days/week

Average % time of the day: [ ] %

DEPRESSED APPEARANCE

3. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

4. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

IRRITABILITY AND ANGER

5. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX] [(7) VEX]

Duration: [ ] # of weeks

6. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX] [(7) VEX]

Frequency: [ ] Days/week

Average % time of the day: [ ] %

SEPARATION-DEPENDENT-DYSPHORIA

7. Current Episode: [(0) NI] [(1) NO] [(2) OCC] [(3) USL] [(4) ALW]

8. Last Two Weeks: [(0) NI] [(1) NO] [(2) OCC] [(3) USL] [(4) ALW]

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

QUALITY OF DYPSHORIC MOOD

9. Current Episode: [0] NI [1] ND [2] QUE [3] DDF [4] VDF

10. Last Two Weeks: [0] NI [1] ND [2] QUE [3] DDF [4] VDF

DEGREE OF ASSOCIATION OF DEPRESSED OR IRRITABLE MOOD WITH SPECIFIC EVENTS OR PREOCCUPATIONS

11. Current Episode: [0] NI [1] NAL [2] MOT [3] UN [4] PN

12. Last Two Weeks: [0] NI [1] NAL [2] MOT [3] UN [4] PN

REACTIVITY OF DEPRESSED OR IRRITABLE MOOD

13. Current Episode: [0] NI [1] VR [2] FUL [3] RES [4] MLD [5] SLT [6] UNR

[ ] % Usual % of Normal

14. Last Two Weeks: [0] NI [1] VR [2] FUL [3] RES [4] MLD [5] SLT [6] UNR

[ ] % Usual % of Normal

[ ] % Maximum % of Normal

[ ] Number of hours good feeling last

DIURNAL MOOD VARIATION

Worse in Morning

15. Current Episode: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

16. Last Two Weeks: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

Worse in Afternoon and/or Evening

17. Current Episode: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

18. Last Two Weeks: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

EXCESSIVE INAPPROPRIATE GUILT

19. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

20. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

Frequency: Days/Week ⌊_⌋

NEGATIVE SELF IMAGE

21. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

22. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

FEELING UNLOVED/FORLORN

23. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

24. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

Frequency: Days/Week ⌊_⌋

HOPELESSNESS, HELPLESSNESS, DISCOURAGEMENT, PESSIMISM

25. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

26. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

SELF-PITY

27. Current Episode: [0] NI [1] NO [2] OCC [3] MLD [4] CON

28. Last Two Weeks: [0] NI [1] NO [2] OCC [3] MLD [4] CON

ACHES AND PAINS

29. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

30. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

HYPOCHONDRIASIS

31. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

32. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

ANHEDONIA, LACK OF INTEREST, APATHY, LOW MOTIVATION, BOREDOM

Combined Overall Rating

33. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Duration: [ ] # of weeks

34. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/week

Average % time of the day: [ ] %

Differentiating Lack of Interest from Anhedonia

Lack of Interest

35. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

36. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Anhedonia

37. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

38. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

FATIGUE, LACK OF ENERGY AND TIREDNESS

39. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

40. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/Week

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DIFFICULTY CONCENTRATING, INATTENTION, OR SLOWED THINKING

41.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
42.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

PSYCHOMOTOR AGITATION

43.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
44.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

Frequency: ___ Days/Week

MANIFESTATIONS INCLUDED:

Unable to sit still

45.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
46.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Pacing

47.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR
48.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR

Hand wringing

49.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR
50.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR

Pulling or rubbing on hair, clothing, skin

51.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR
52.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR

Can't stop talking, talks on and on

53.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR
54.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

PSYCHOMOTOR RETARDATION

55.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
56.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

Frequency: ___ Days/Week

MANIFESTATIONS INCLUDED:

Slowed Speech

57.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
58.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Increased pauses before answering

59.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
60.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Low or monotonous speech

61.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
62.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Mute or markedly decreased amount of speech

63.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
64.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Slowed body movements

65.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
66.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Depressive stupor

67.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
68.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SOCIAL WITHDRAWAL

69.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX
70.	Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX

REJECTION SENSITIVITY

71.	Last Year:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MOD	[5] SVR	[6] EX
72.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MOD	[5] SVR	[6] EX
73.	Last Year:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MOD	[5] SVR	[6] EX
74.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MOD	[5] SVR	[6] EX

SLEEP PROBLEMS

75. [ ][ ] Hours slept before onset of depression

76. [ ][ ] Hours slept during the current episode

77. [ ][ ] Hours slept during the last two weeks

HYPERSOMNIA

78. [ ][ ] Hours slept in daytime of current episode

79. [ ][ ] Hours slept in daytime in the last two weeks

80. [ ][ ] Hours lying down in current episode

81. [ ][ ] Hours lying down in last two weeks

82.	Current Episode:	[0] NI	[1] NO	[2]	[3]	[4]	[5]	[6]
83.	Last Two Weeks:	[0] NI	[1] NO	[2]	[3]	[4]	[5]	[6]

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

INSOMNIA

84. Current Episode: [(0) NI] [(1) NO] [(2)] [(3)] [(4)] [(5)] [(6)]

85. Last Two Weeks: [(0) NI] [(1) NO] [(2)] [(3)] [(4)] [(5)] [(6)]

Frequency: [ ] Nights/Week

TYPES OF INSOMNIA

Initial Insomnia

86. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

87. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Middle Insomnia

88. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

89. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Terminal Insomnia

90. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

91. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Circadian Reversal

92. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

93. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Non-restorative sleep

94. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

95. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Daytime sleepiness

96. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

97. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

ANOREXIA

98. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) RAR] [(6) NVR]

99. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) RAR] [(6) NVR]

WEIGHT LOSS

100. Current Episode:

Pounds lost: [ ] lbs.

Number of Weeks: [ ]

101. Last Two Weeks:

Pounds lost: [ ] lbs.

INCREASED APPETITE

102. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EX]

103. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EX]

Frequency: [ ] Days/Week

STRONG CRAVING FOR SWEETS

104. Current Episode: [(0) NI] [(1) ABS] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

105. Last Two Weeks: [(0) NI] [(1) ABS] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

WEIGHT GAIN

106. Current Episode:

Pounds gained: [ ] lbs.

Number of Weeks: [ ]

107. Last Two Weeks:

Pounds gained: [ ] lbs.

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SUICIDAL IDEATION

108. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX	[7] VEX
109. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX	[7] VEX

Suicidal Acts – Number

110. Current Episode: [ ]

111. Last Two Weeks: [ ]

Suicidal Acts – Seriousness

112. Current Episode:	[0] NI	[1] NO	[2] MIN	[3] DEF	[4] SER	[5] VS	[6] EXT
113. Last Two Weeks:	[0] NI	[1] NO	[2] MIN	[3] DEF	[4] SER	[5] VS	[6] EXT

Medical Lethality

114. Current Episode	[0] NI	[1] NO	[2] MIN	[3] MLD	[4] MO	[5] SVR	[6] EXT
115. Last Two Weeks:	[0] NI	[1] NO	[2] MIN	[3] MLD	[4] MO	[5] SVR	[6] EXT

Non-Suicidal Physical Self-Demaging Acts

116. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] ACT
117. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] ACT

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MANIC SYNDROME

ELATION, EXPANSIVE MOOD

1.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX
2.	Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX

DECREASED NEED FOR SLEEP

3.	Current Episode:	[0] NI	[1] NO	[2] -1	[3] -2	[4] -3	[5] -4	[6] -4+
4.	Last Two Weeks:	[0] NI	[1] NO	[2] -1	[3] -2	[4] -3	[5] -4	[6] -4+

UNUSUALLY ENERGETIC

5.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] LCH	[4] MOR	[5] MM	[6] UA
6.	Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] LCH	[4] MOR	[5] MM	[6] UA

INCREASE IN GOAL DIRECTED ACTIVITY

7.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX
8.	Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX

GRANDIOSITY

9.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX
10.	Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX

ACCELERATED, PRESSURED OR INCREASED AMOUNT OF SPEECH

11.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX
12.	Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX

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RACING THOUGHTS

13. Current Episode: [0] NI [1] NO [2] DBT [3] MLD [4] MO [5] SVR [6] EX

14. Last Two Weeks: [0] NI [1] NO [2] DBT [3] MLD [4] MO [5] SVR [6] EX

FLIGHT OF IDEAS

15. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

16. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

POOR JUDGEMENT

17. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] VS

18. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] VS

DISTRACTABILITY

19. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR

20. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR

MOTOR HYPERACTIVITY

21. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] MKD [6] EX

22. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] MKD [6] EX

Inappropriate laughing, joking or punning

23. Current Episode: [0] NI [1] NO [2] DBT [3] MLD [4] MOD

24. Last Two Weeks: [0] NI [1] NO [2] DBT [3] MLD [4] MOD

Uninhibited people seeking, gregarious

25. Current Episode: [0] NI [1] NO [2] DBT [3] MLD [4] MOD

26. Last Two Weeks: [0] NI [1] NO [2] DBT [3] MLD [4] MOD

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

Increased Productivity

27. Current Episode: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

28. Last Two Weeks: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

Sharpened and unusually creative thinking

29. Current Episode: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

30. Last Two Weeks: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

Hypersexuality

31. Current Episode: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

32. Last Two Weeks: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

INFLUENCE OF ILLICIT DRUGS OR ALCOHOL

33. Current Episode: [0] NA [1] NVR [2] SMT [3] ONL

34. Last Two Weeks: [0] NA [1] NVR [2] SMT [3] ONL

NUMBER OF MANIC PERIODS

35. [ ]

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LABORATORY TESTS

For SB	Lab Number Code

Sample Date ___ ___ ___
day month year

➧ Attach SBCL laboratory report behind this page.

➧ Are there CLINICALLY SIGNIFICANT ABNORMAL laboratory values?

☐ No
☐ Yes ⟶ Record the findings and/or diagnosis in the Adverse Experiences.

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STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No

☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(N^{\bigstar} \times \text{days since last visit})} \times 100$$

★N = number of capsules daily (see above)

➧ Compliance must be ≥ 80% and ≤ 120%.

Has the patient been ***non-compliant*** for two consecutive visits?

☐ Yes ☐ No

Withdraw patient from study. Complete Study Conclusion section.

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STUDY MEDICATION LABEL

Attach label here

Attach label here

Attach label here

Attach label here

➧ Enter patient number (drug code as listed on clinical supplies) _____

Important: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

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ELECTROCARDIOGRAM

Was electrocardiogram performed and sent to a central reader for interpretation?

☐ Yes ☐ No

Date Performed (day month year)

STUDY MEDICATION DISPENSING

Record study medication information for Weeks 21-24 in the Study Medication Record, page 311. Attach label(s) to page 312. Record number of capsules dispensed on page 311.

Reminder: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

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MODULE PARAMETERS - WEEK 24

For SmithKline Beecham Use	Project	*29060*
	Protocol	*329*
	Center	
	Patient Number	
	Module Pages	*V1617*

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VITAL SIGNS

Weight ☐ lbs ☐ kg	Sitting		Standing	
	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)
.	/		/	

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

☐ Yes ☐ No

Record in the Adverse Experience section

Has there been any change in concomitant medication since the last visit?

☐ Yes ☐ No

Record in the Concomitant Medication section

CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

Rate the total improvement whether or not, in your judgment, it is due entirely to drug treatment. Compared to his/her condition at admission to the study, how much has the patient changed?

☐ 1 = Very much improved
☐ 2 = Much improved
☐ 3 = Minimally improved
☐ 4 = No change
☐ 5 = Minimally worse
☐ 6 = Much worse
☐ 7 = Very much worse

PLASMA SAMPLE - DRUG CONCENTRATION

Was a plasma sample obtained for drug concentration?

☐ Yes ☐ No

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD)
PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
   - ☐ 1 = These feeling states indicated only on questioning
   - ☐ 2 = These feeling states spontaneously reported verbally
   - ☐ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
   - ☐ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication

2. Feelings of Guilt
   - ☐ 0 = Absent
   - ☐ 1 = Self reproach, feels he/she has let people down
   - ☐ 2 = Ideas of guilt or rumination over past errors or sinful deeds
   - ☐ 3 = Present illness is a punishment. Delusions of guilt
   - ☐ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide
   - ☐ 0 = Absent
   - ☐ 1 = Feels life is not worth living
   - ☐ 2 = Wishes he/she were dead or any thoughts of possible death to self
   - ☐ 3 = Suicide ideas or gesture
   - ☐ 4 = Attempts at suicide (any serious attempt rates 4)

4. Insomnia Early
   - ☐ 0 = No difficulty falling asleep
   - ☐ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
   - ☐ 2 = Complains of nightly difficulty falling asleep

5. Insomnia Middle
   - ☐ 0 = No difficulty
   - ☐ 1 = Patient complains of being restless and disturbed during the night
   - ☐ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia Late
   - ☐ 0 = No difficulty
   - ☐ 1 = Waking in early hours of the morning but goes back to sleep
   - ☐ 2 = Unable to fall asleep again if he/she gets out of bed

7. Work and Activities
   - ☐ 0 = No difficulty
   - ☐ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
   - ☐ 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
   - ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
   - ☐ 4 = Stopped working because of present illness.

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
- ☐ 0 = Normal speech and thought
- ☐ 1 = Slight retardation at interview
- ☐ 2 = Obvious retardation at interview
- ☐ 3 = Interview difficult
- ☐ 4 = Complete stupor

9. Agitation
- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = "Playing with" hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety Psychic
- ☐ 0 = No difficulty
- ☐ 1 = Subjective tension and irritability
- ☐ 2 = Worrying about minor matters
- ☐ 3 = Apprehensive attitude apparent in face or speech
- ☐ 4 = Fears expressed without questioning

11. Anxiety Somatic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal
- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating. Heavy feelings in abdomen
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. Somatic Symptoms General
- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
- ☐ 2 = Any clear-cut symptoms rates 2

14. Genital Symptoms (such as loss of libido and menstrual disturbances)
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis
- ☐ 0 = Not present
- ☐ 1 = Self-absorption (bodily)
- ☐ 2 = Preoccupation with health
- ☐ 3 = Frequent complaints, requests for help, etc.
- ☐ 4 = Hypochondriacal delusions

16. Loss of Weight
- ☐ 0 = No weight loss
- ☐ 1 = Slight or doubtful loss of weight
- ☐ 2 = Obvious or severe loss of weight

17. Insight
- ☐ 0 = Acknowledges being depressed and ill
- ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
- ☐ 2 = Denies being ill at all

➧ ☐☐ HAMD Score (Items 1-17)

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DEPRESSED MOOD

1. Worst Severity of Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Duration of Current Episode: ___ # of weeks

2. Worst Severity of Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Frequency: ___ Days/week

Average % time of the day: ___ %

DEPRESSED APPEARANCE

3. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

4. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

IRRITABILITY AND ANGER

5. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Duration: ___ # of weeks

6. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Frequency: ___ Days/week

Average % time of the day: ___ %

SEPARATION-DEPENDENT-DYSPHORIA

7. Current Episode: [0] NI [1] NO [2] OCC [3] USL [4] ALW

8. Last Two Weeks: [0] NI [1] NO [2] OCC [3] USL [4] ALW

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

QUALITY OF DYPSHORIC MOOD

9. Current Episode: [0] NI [1] ND [2] QUE [3] DDF [4] VDF

10. Last Two Weeks: [0] NI [1] ND [2] QUE [3] DDF [4] VDF

DEGREE OF ASSOCIATION OF DEPRESSED OR IRRITABLE MOOD WITH SPECIFIC EVENTS OR PREOCCUPATIONS

11. Current Episode: [0] NI [1] NAL [2] MOT [3] UN [4] PN

12. Last Two Weeks: [0] NI [1] NAL [2] MOT [3] UN [4] PN

REACTIVITY OF DEPRESSED OR IRRITABLE MOOD

13. Current Episode: [0] NI [1] VR [2] FUL [3] RES [4] MLD [5] SLT [6] UNR

[ ] % Usual % of Normal

14. Last Two Weeks: [0] NI [1] VR [2] FUL [3] RES [4] MLD [5] SLT [6] UNR

[ ] % Usual % of Normal

[ ] % Maximum % of Normal

[ ] Number of hours good feeling last

DIURNAL MOOD VARIATION

Worse in Morning

15. Current Episode: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

16. Last Two Weeks: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

Worse in Afternoon and/or Evening

17. Current Episode: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

18. Last Two Weeks: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

EXCESSIVE INAPPROPRIATE GUILT

19. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

20. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

Frequency: Days/Week [ ]

NEGATIVE SELF IMAGE

21. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

22. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

FEELING UNLOVED/FORLORN

23. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

24. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

Frequency: Days/Week [ ]

HOPELESSNESS, HELPLESSNESS, DISCOURAGEMENT, PESSIMISM

25. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

26. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

SELF-PITY

27. Current Episode: [0] NI [1] NO [2] OCC [3] MLD [4] CON

28. Last Two Weeks: [0] NI [1] NO [2] OCC [3] MLD [4] CON

ACHES AND PAINS

29. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

30. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

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HYPOCHONDRIASIS

31. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

32. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

ANHEDONIA, LACK OF INTEREST, APATHY, LOW MOTIVATION, BOREDOM

Combined Overall Rating

33. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Duration: [ ] # of weeks

34. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/week

Average % time of the day: [ ] %

Differentiating Lack of Interest from Anhedonia

Lack of Interest

35. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

36. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Anhedonia

37. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

38. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

FATIGUE, LACK OF ENERGY AND TIREDNESS

39. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

40. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/Week

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DIFFICULTY CONCENTRATING, INATTENTION, OR SLOWED THINKING

41.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
42.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

PSYCHOMOTOR AGITATION

43.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
44.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Unable to sit still

45.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
46.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Pacing

47.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR
48.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR

Hand wringing

49.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR
50.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR

Pulling or rubbing on hair, clothing, skin

51.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR
52.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR

Can't stop talking, talks on and on

53.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR
54.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

PSYCHOMOTOR RETARDATION

55.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
56.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

Frequency: ___ Days/Week

MANIFESTATIONS INCLUDED:

Slowed Speech

57.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
58.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Increased pauses before answering

59.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
60.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Low or monotonous speech

61.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
62.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Mute or markedly decreased amount of speech

63.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
64.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Slowed body movements

65.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
66.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

Depressive stupor

67.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR
68.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SOCIAL WITHDRAWAL

69.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX
70.	Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX

REJECTION SENSITIVITY

71.	Last Year:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MOD	[5] SVR	[6] EX
72.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MOD	[5] SVR	[6] EX
73.	Last Year:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MOD	[5] SVR	[6] EX
74.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MOD	[5] SVR	[6] EX

SLEEP PROBLEMS

75. ⌊_⌋ Hours slept before onset of depression

76. ⌊_⌋ Hours slept during the current episode

77. ⌊_⌋ Hours slept during the last two weeks

HYPERSOMNIA

78. ⌊_⌋ Hours slept in daytime of current episode

79. ⌊_⌋ Hours slept in daytime in the last two weeks

80. ⌊_⌋ Hours lying down in current episode

81. ⌊_⌋ Hours lying down in last two weeks

82.	Current Episode:	[0] NI	[1] NO	[2]	[3]	[4]	[5]	[6]
83.	Last Two Weeks:	[0] NI	[1] NO	[2]	[3]	[4]	[5]	[6]

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

INSOMNIA

84. Current Episode: [(0) NI] [(1) NO] [(2)] [(3)] [(4)] [(5)] [(6)]

85. Last Two Weeks: [(0) NI] [(1) NO] [(2)] [(3)] [(4)] [(5)] [(6)]

Frequency: [ ] Nights/Week

TYPES OF INSOMNIA

Initial Insomnia

86. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

87. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Middle Insomnia

88. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

89. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Terminal Insomnia

90. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

91. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Circadian Reversal

92. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

93. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Non-restorative sleep

94. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

95. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Daytime sleepiness

96. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

97. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

ANOREXIA

98. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] NVR

99. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] NVR

WEIGHT LOSS

100. Current Episode:

Pounds lost: ___ lbs.

Number of Weeks: ___

101. Last Two Weeks:

Pounds lost: ___ lbs.

INCREASED APPETITE

102. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

103. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

Frequency: ___ Days/Week

STRONG CRAVING FOR SWEETS

104. Current Episode: [0] NI [1] ABS [2] DBT [3] MLD [4] MOD [5] SVR

105. Last Two Weeks: [0] NI [1] ABS [2] DBT [3] MLD [4] MOD [5] SVR

WEIGHT GAIN

106. Current Episode:

Pounds gained: ___ lbs.

Number of Weeks: ___

107. Last Two Weeks:

Pounds gained: ___ lbs.

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SUICIDAL IDEATION

108. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

109. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Suicidal Acts - Number

110. Current Episode: [ ]

111. Last Two Weeks: [ ]

Suicidal Acts - Seriousness

112. Current Episode: [0] NI [1] NO [2] MIN [3] DEF [4] SER [5] VS [6] EXT

113. Last Two Weeks: [0] NI [1] NO [2] MIN [3] DEF [4] SER [5] VS [6] EXT

Medical Lethality

114. Current Episode [0] NI [1] NO [2] MIN [3] MLD [4] MO [5] SVR [6] EXT

115. Last Two Weeks: [0] NI [1] NO [2] MIN [3] MLD [4] MO [5] SVR [6] EXT

Non-Suicidal Physical Self-Demaging Acts

116. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] ACT

117. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] ACT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

MANIC SYNDROME

ELATION, EXPANSIVE MOOD

1.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX
2.	Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX

DECREASED NEED FOR SLEEP

3.	Current Episode:	[0] NI	[1] NO	[2] -1	[3] -2	[4] -3	[5] -4	[6] -4+
4.	Last Two Weeks:	[0] NI	[1] NO	[2] -1	[3] -2	[4] -3	[5] -4	[6] -4+

UNUSUALLY ENERGETIC

5.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] LCH	[4] MOR	[5] MM	[6] UA
6.	Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] LCH	[4] MOR	[5] MM	[6] UA

INCREASE IN GOAL DIRECTED ACTIVITY

7.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX
8.	Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX

GRANDIOSITY

9.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX
10.	Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX

ACCELERATED, PRESSURED OR INCREASED AMOUNT OF SPEECH

11.	Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX
12.	Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

RACING THOUGHTS

13. Current Episode: [0] NI [1] NO [2] DBT [3] MLD [4] MO [5] SVR [6] EX

14. Last Two Weeks: [0] NI [1] NO [2] DBT [3] MLD [4] MO [5] SVR [6] EX

FLIGHT OF IDEAS

15. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

16. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

POOR JUDGEMENT

17. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] VS

18. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] VS

DISTRACTABILITY

19. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR

20. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR

MOTOR HYPERACTIVITY

21. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] MKD [6] EX

22. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] MKD [6] EX

Inappropriate laughing, joking or punning

23. Current Episode: [0] NI [1] NO [2] DBT [3] MLD [4] MOD

24. Last Two Weeks: [0] NI [1] NO [2] DBT [3] MLD [4] MOD

Uninhibited people seeking, gregarious

25. Current Episode: [0] NI [1] NO [2] DBT [3] MLD [4] MOD

26. Last Two Weeks: [0] NI [1] NO [2] DBT [3] MLD [4] MOD

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

Increased Productivity

27. Current Episode: [(0) NI] [(1) NO] [(2) DBT] [(3) PRS] [(4) SVR]

28. Last Two Weeks: [(0) NI] [(1) NO] [(2) DBT] [(3) PRS] [(4) SVR]

Sharpened and unusually creative thinking

29. Current Episode: [(0) NI] [(1) NO] [(2) DBT] [(3) PRS] [(4) SVR]

30. Last Two Weeks: [(0) NI] [(1) NO] [(2) DBT] [(3) PRS] [(4) SVR]

Hypersexuality

31. Current Episode: [(0) NI] [(1) NO] [(2) DBT] [(3) PRS] [(4) SVR]

32. Last Two Weeks: [(0) NI] [(1) NO] [(2) DBT] [(3) PRS] [(4) SVR]

INFLUENCE OF ILLICIT DRUGS OR ALCOHOL

33. Current Episode: [(0) NA] [(1) NVR] [(2) SMT] [(3) ONL]

34. Last Two Weeks: [(0) NA] [(1) NVR] [(2) SMT] [(3) ONL]

NUMBER OF MANIC PERIODS

35. [ ]

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STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No
☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(N^{\bigstar} \times \text{days since last visit})} \times 100$$

$^{\bigstar}N$ = number of capsules daily (see above)

➧ Compliance must be ≥ 80% and ≤ 120%.

Has the patient been ***non-compliant*** for two consecutive visits?

☐ Yes ☐ No

Withdraw patient from study. Complete Study Conclusion section.

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STUDY MEDICATION LABEL

Attach label here

Attach label here

Attach label here

Attach label here

➧ Enter patient number (drug code as listed on clinical supplies) ⌊_____⌋

Important: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

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STUDY MEDICATION DISPENSING

Record study medication information for Weeks 25-28 in the Study Medication Record, page 331. Attach label(s) to page 332. Record number of capsules dispensed on page 331.

Reminder: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

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MODULE PARAMETERS - WEEK 28

For SmithKline Beecham Use	Project	*29060*
	Protocol	*329*
	Center	
	Patient Number	
	Module Pages	*V1717*

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VITAL SIGNS

Weight ☐ lbs ☐ kg	Sitting		Standing	
	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)
.	/		/	

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

☐ Yes ☐ No

Record in the Adverse Experience section

Has there been any change in concomitant medication since the last visit?

☐ Yes ☐ No

Record in the Concomitant Medication section

CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

Rate the total improvement whether or not, in your judgment, it is due entirely to drug treatment. Compared to his/her condition at admission to the study, how much has the patient changed?

- ☐ 1 = Very much improved
- ☐ 2 = Much improved
- ☐ 3 = Minimally improved
- ☐ 4 = No change
- ☐ 5 = Minimally worse
- ☐ 6 = Much worse
- ☐ 7 = Very much worse

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD)
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1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
   - ☐ 1 = These feeling states indicated only on questioning
   - ☐ 2 = These feeling states spontaneously reported verbally
   - ☐ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
   - ☐ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication

2. Feelings of Guilt
   - ☐ 0 = Absent
   - ☐ 1 = Self reproach, feels he/she has let people down
   - ☐ 2 = Ideas of guilt or rumination over past errors or sinful deeds
   - ☐ 3 = Present illness is a punishment. Delusions of guilt
   - ☐ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide
   - ☐ 0 = Absent
   - ☐ 1 = Feels life is not worth living
   - ☐ 2 = Wishes he/she were dead or any thoughts of possible death to self
   - ☐ 3 = Suicide ideas or gesture
   - ☐ 4 = Attempts at suicide (any serious attempt rates 4)

4. Insomnia Early
   - ☐ 0 = No difficulty falling asleep
   - ☐ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
   - ☐ 2 = Complains of nightly difficulty falling asleep

5. Insomnia Middle
   - ☐ 0 = No difficulty
   - ☐ 1 = Patient complains of being restless and disturbed during the night
   - ☐ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia Late
   - ☐ 0 = No difficulty
   - ☐ 1 = Waking in early hours of the morning but goes back to sleep
   - ☐ 2 = Unable to fall asleep again if he/she gets out of bed

7. Work and Activities
   - ☐ 0 = No difficulty
   - ☐ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
   - ☐ 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
   - ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
   - ☐ 4 = Stopped working because of present illness.

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
- ☐ 0 = Normal speech and thought
- ☐ 1 = Slight retardation at interview
- ☐ 2 = Obvious retardation at interview
- ☐ 3 = Interview difficult
- ☐ 4 = Complete stupor

9. Agitation
- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = "Playing with" hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety Psychic
- ☐ 0 = No difficulty
- ☐ 1 = Subjective tension and irritability
- ☐ 2 = Worrying about minor matters
- ☐ 3 = Apprehensive attitude apparent in face or speech
- ☐ 4 = Fears expressed without questioning

11. Anxiety Somatic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal
- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating. Heavy feelings in abdomen
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. Somatic Symptoms General
- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
- ☐ 2 = Any clear-cut symptoms rates 2

14. Genital Symptoms (such as loss of libido and menstrual disturbances)
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD)
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15. Hypochondriasis
- ☐ 0 = Not present
- ☐ 1 = Self-absorption (bodily)
- ☐ 2 = Preoccupation with health
- ☐ 3 = Frequent complaints, requests for help, etc.
- ☐ 4 = Hypochondriacal delusions

16. Loss of Weight
- ☐ 0 = No weight loss
- ☐ 1 = Slight or doubtful loss of weight
- ☐ 2 = Obvious or severe loss of weight

17. Insight
- ☐ 0 = Acknowledges being depressed and ill
- ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
- ☐ 2 = Denies being ill at all

➧ ☐☐ HAMD Score (Items 1-17)

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DEPRESSED MOOD

1. Worst Severity of Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX] [(7) VEX]

Duration of Current Episode: ___ # of weeks

2. Worst Severity of Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX] [(7) VEX]

Frequency: ___ Days/week

Average % time of the day: ___ %

DEPRESSED APPEARANCE

3. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

4. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

IRRITABILITY AND ANGER

5. Current Episode: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX] [(7) VEX]

Duration: ___ # of weeks

6. Last Two Weeks: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX] [(7) VEX]

Frequency: ___ Days/week

Average % time of the day: ___ %

SEPARATION-DEPENDENT-DYSPHORIA

7. Current Episode: [(0) NI] [(1) NO] [(2) OCC] [(3) USL] [(4) ALW]

8. Last Two Weeks: [(0) NI] [(1) NO] [(2) OCC] [(3) USL] [(4) ALW]

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

QUALITY OF DYPSHORIC MOOD

9. Current Episode: [(0) NI] [(1) ND] [(2) QUE] [(3) DDF] [(4) VDF]

10. Last Two Weeks: [(0) NI] [(1) ND] [(2) QUE] [(3) DDF] [(4) VDF]

DEGREE OF ASSOCIATION OF DEPRESSED OR IRRITABLE MOOD WITH SPECIFIC EVENTS OR PREOCCUPATIONS

11. Current Episode: [(0) NI] [(1) NAL] [(2) MOT] [(3) UN] [(4) PN]

12. Last Two Weeks: [(0) NI] [(1) NAL] [(2) MOT] [(3) UN] [(4) PN]

REACTIVITY OF DEPRESSED OR IRRITABLE MOOD

13. Current Episode: [(0) NI] [(1) VR] [(2) FUL] [(3) RES] [(4) MLD] [(5) SLT] [(6) UNR]

[ ] % Usual % of Normal

14. Last Two Weeks: [(0) NI] [(1) VR] [(2) FUL] [(3) RES] [(4) MLD] [(5) SLT] [(6) UNR]

[ ] % Usual % of Normal

[ ] % Maximum % of Normal

[ ] Number of hours good feeling last

DIURNAL MOOD VARIATION

Worse in Morning

15. Current Episode: [(0) NI] [(1) NW] [(2) MIN] [(3) MLD] [(4) CW] [(5) EXT]

16. Last Two Weeks: [(0) NI] [(1) NW] [(2) MIN] [(3) MLD] [(4) CW] [(5) EXT]

Worse in Afternoon and/or Evening

17. Current Episode: [(0) NI] [(1) NW] [(2) MIN] [(3) MLD] [(4) CW] [(5) EXT]

18. Last Two Weeks: [(0) NI] [(1) NW] [(2) MIN] [(3) MLD] [(4) CW] [(5) EXT]

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

EXCESSIVE INAPPROPRIATE GUILT

19. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

20. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

Frequency: Days/Week [ ]

NEGATIVE SELF IMAGE

21. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

22. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

FEELING UNLOVED/FORLORN

23. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

24. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

Frequency: Days/Week [ ]

HOPELESSNESS, HELPLESSNESS, DISCOURAGEMENT, PESSIMISM

25. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

26. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

SELF-PITY

27. Current Episode: [0] NI [1] NO [2] OCC [3] MLD [4] CON

28. Last Two Weeks: [0] NI [1] NO [2] OCC [3] MLD [4] CON

ACHES AND PAINS

29. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

30. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

HYPOCHONDRIASIS

31. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

32. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

ANHEDONIA, LACK OF INTEREST, APATHY, LOW MOTIVATION, BOREDOM

Combined Overall Rating

33. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Duration: ___ # of weeks

34. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: ___ Days/week

Average % time of the day: ___ %

Differentiating Lack of Interest from Anhedonia

Lack of Interest

35. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

36. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Anhedonia

37. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

38. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

FATIGUE, LACK OF ENERGY AND TIREDNESS

39. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

40. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: ___ Days/Week

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

DIFFICULTY CONCENTRATING, INATTENTION, OR SLOWED THINKING

41. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

42. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

PSYCHOMOTOR AGITATION

43. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

44. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Unable to sit still

45. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

46. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Pacing

47. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

48. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

Hand wringing

49. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

50. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

Pulling or rubbing on hair, clothing, skin

51. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

52. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

Can't stop talking, talks on and on

53. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

54. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

PSYCHOMOTOR RETARDATION

55. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

56. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Slowed Speech

57. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

58. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Increased pauses before answering

59. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

60. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Low or monotonous speech

61. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

62. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Mute or markedly decreased amount of speech

63. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

64. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Slowed body movements

65. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

66. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Depressive stupor

67. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

68. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SOCIAL WITHDRAWAL

69. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

70. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

REJECTION SENSITIVITY

71. Last Year: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

72. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

73. Last Year: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

74. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

SLEEP PROBLEMS

75. ⌊__⌋ Hours slept before onset of depression

76. ⌊__⌋ Hours slept during the current episode

77. ⌊__⌋ Hours slept during the last two weeks

HYPERSOMNIA

78. ⌊__⌋ Hours slept in daytime of current episode

79. ⌊__⌋ Hours slept in daytime in the last two weeks

80. ⌊__⌋ Hours lying down in current episode

81. ⌊__⌋ Hours lying down in last two weeks

82. Current Episode: [0] NI [1] NO [2] [3] [4] [5] [6]

83. Last Two Weeks: [0] NI [1] NO [2] [3] [4] [5] [6]

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

INSOMNIA

84. Current Episode: [(0) NI] [(1) NO] [(2)] [(3)] [(4)] [(5)] [(6)]

85. Last Two Weeks: [(0) NI] [(1) NO] [(2)] [(3)] [(4)] [(5)] [(6)]

Frequency: ___ Nights/Week

TYPES OF INSOMNIA

Initial Insomnia

86. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

87. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Middle Insomnia

88. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

89. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Terminal Insomnia

90. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

91. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Circadian Reversal

92. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

93. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Non-restorative sleep

94. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

95. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Daytime sleepiness

96. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

97. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

ANOREXIA

98. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] NVR

99. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] NVR

WEIGHT LOSS

100. Current Episode:

Pounds lost: ___ lbs.

Number of Weeks: ___

101. Last Two Weeks:

Pounds lost: ___ lbs.

INCREASED APPETITE

102. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

103. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

Frequency: ___ Days/Week

STRONG CRAVING FOR SWEETS

104. Current Episode: [0] NI [1] ABS [2] DBT [3] MLD [4] MOD [5] SVR

105. Last Two Weeks: [0] NI [1] ABS [2] DBT [3] MLD [4] MOD [5] SVR

WEIGHT GAIN

106. Current Episode:

Pounds gained: ___ lbs.

Number of Weeks: ___

107. Last Two Weeks:

Pounds gained: ___ lbs.

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

SUICIDAL IDEATION

108. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

109. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Suicidal Acts - Number

110. Current Episode: [ ]

111. Last Two Weeks: [ ]

Suicidal Acts - Seriousness

112. Current Episode: [0] NI [1] NO [2] MIN [3] DEF [4] SER [5] VS [6] EXT

113. Last Two Weeks: [0] NI [1] NO [2] MIN [3] DEF [4] SER [5] VS [6] EXT

Medical Lethality

114. Current Episode [0] NI [1] NO [2] MIN [3] MLD [4] MO [5] SVR [6] EXT

115. Last Two Weeks: [0] NI [1] NO [2] MIN [3] MLD [4] MO [5] SVR [6] EXT

Non-Suicidal Physical Self-Demaging Acts

116. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] ACT

117. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] ACT

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

MANIC SYNDROME

ELATION, EXPANSIVE MOOD

1. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX
2. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX

DECREASED NEED FOR SLEEP

3. Current Episode:	[0] NI	[1] NO	[2] -1	[3] -2	[4] -3	[5] -4	[6] -4+
4. Last Two Weeks:	[0] NI	[1] NO	[2] -1	[3] -2	[4] -3	[5] -4	[6] -4+

UNUSUALLY ENERGETIC

5. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] LCH	[4] MOR	[5] MM	[6] UA
6. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] LCH	[4] MOR	[5] MM	[6] UA

INCREASE IN GOAL DIRECTED ACTIVITY

7. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX
8. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX

GRANDIOSITY

9. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX
10. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX

ACCELERATED, PRESSURED OR INCREASED AMOUNT OF SPEECH

11. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX
12. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

RACING THOUGHTS

13. Current Episode: [0] NI [1] NO [2] DBT [3] MLD [4] MO [5] SVR [6] EX

14. Last Two Weeks: [0] NI [1] NO [2] DBT [3] MLD [4] MO [5] SVR [6] EX

FLIGHT OF IDEAS

15. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

16. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

POOR JUDGEMENT

17. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] VS

18. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] VS

DISTRACTABILITY

19. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR

20. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR

MOTOR HYPERACTIVITY

21. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] MKD [6] EX

22. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] MKD [6] EX

Inappropriate laughing, joking or punning

23. Current Episode: [0] NI [1] NO [2] DBT [3] MLD [4] MOD

24. Last Two Weeks: [0] NI [1] NO [2] DBT [3] MLD [4] MOD

Uninhibited people seeking, gregarious

25. Current Episode: [0] NI [1] NO [2] DBT [3] MLD [4] MOD

26. Last Two Weeks: [0] NI [1] NO [2] DBT [3] MLD [4] MOD

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KIDDIE-SADS-LIFETIME AFFECTIVE EVALUATION - SCORING FORM

Increased Productivity

27. Current Episode: [(0) NI] [(1) NO] [(2) DBT] [(3) PRS] [(4) SVR]

28. Last Two Weeks: [(0) NI] [(1) NO] [(2) DBT] [(3) PRS] [(4) SVR]

Sharpened and unusually creative thinking

29. Current Episode: [(0) NI] [(1) NO] [(2) DBT] [(3) PRS] [(4) SVR]

30. Last Two Weeks: [(0) NI] [(1) NO] [(2) DBT] [(3) PRS] [(4) SVR]

Hypersexuality

31. Current Episode: [(0) NI] [(1) NO] [(2) DBT] [(3) PRS] [(4) SVR]

32. Last Two Weeks: [(0) NI] [(1) NO] [(2) DBT] [(3) PRS] [(4) SVR]

INFLUENCE OF ILLICIT DRUGS OR ALCOHOL

33. Current Episode: [(0) NA] [(1) NVR] [(2) SMT] [(3) ONL]

34. Last Two Weeks: [(0) NA] [(1) NVR] [(2) SMT] [(3) ONL]

NUMBER OF MANIC PERIODS

35. [ ]

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STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No

☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(N^{\star} \times \text{days since last visit})} \times 100$$

★N = number of capsules daily (see above)

◗ Compliance must be ≥ 80% and ≤ 120%.

Has the patient been ***non-compliant*** for two consecutive visits?

☐ Yes ☐ No

Withdraw patient from study. Complete Study Conclusion section.

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STUDY MEDICATION LABEL

Attach label here

Attach label here

Attach label here

Attach label here

Enter patient number (drug code as listed on clinical supplies) _____

Important: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

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STUDY MEDICATION DISPENSING

Record study medication information for Weeks 29-32 in the Study Medication Record, page 397. Attach label(s) to page 398. Record number of capsules dispensed on page 397.

Reminder: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

Project	Protocol	Center	Patient Number
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← **Ensure Patient Number is identical for Binder 3 and Binder 4**

SmithKline Beecham
Pharmaceuticals

CONFIDENTIAL

CASE REPORT FORM

PROTOCOL 29060/329

CONTINUATION PHASE - BINDER 4

A Multi-Center, Double-Blind, Placebo Controlled Study of Paroxetine and Imipramine in Adolescents with Unipolar Major Depression

Patient Initials ____ **Country** _____

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MODULE PARAMETERS - WEEK 32

For SmithKline Beecham Use	Project	*29060*
	Protocol	*329*
	Center	
	Patient Number	
	Module Pages	*V1817*

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VITAL SIGNS

Weight ☐ lbs ☐ kg	Sitting		Standing	
	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic / diastolic	Pulse (beats/ min)
.	/		/	

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

☐ Yes ☐ No

Record in the Adverse Experience section

Has there been any change in concomitant medication since the last visit?

☐ Yes ☐ No

Record in the Concomitant Medication section

CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

Rate the total improvement whether or not, in your judgment, it is due entirely to drug treatment. Compared to his/her condition at admission to the study, how much has the patient changed?

☐ 1 = Very much improved
☐ 2 = Much improved
☐ 3 = Minimally improved
☐ 4 = No change
☐ 5 = Minimally worse
☐ 6 = Much worse
☐ 7 = Very much worse

PLASMA SAMPLE - DRUG CONCENTRATION

Was a plasma sample obtained for drug concentration?

☐ Yes ☐ No

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1. Depressed Mood (sadness, hopelessness, helpless, worthless)
   - ☐ 0 = Absent
   - ☐ 1 = These feeling states indicated only on questioning
   - ☐ 2 = These feeling states spontaneously reported verbally
   - ☐ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
   - ☐ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication

2. Feelings of Guilt
   - ☐ 0 = Absent
   - ☐ 1 = Self reproach, feels he/she has let people down
   - ☐ 2 = Ideas of guilt or rumination over past errors or sinful deeds
   - ☐ 3 = Present illness is a punishment. Delusions of guilt
   - ☐ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide
   - ☐ 0 = Absent
   - ☐ 1 = Feels life is not worth living
   - ☐ 2 = Wishes he/she were dead or any thoughts of possible death to self
   - ☐ 3 = Suicide ideas or gesture
   - ☐ 4 = Attempts at suicide (any serious attempt rates 4)

4. Insomnia Early
   - ☐ 0 = No difficulty falling asleep
   - ☐ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
   - ☐ 2 = Complains of nightly difficulty falling asleep

5. Insomnia Middle
   - ☐ 0 = No difficulty
   - ☐ 1 = Patient complains of being restless and disturbed during the night
   - ☐ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)

6. Insomnia Late
   - ☐ 0 = No difficulty
   - ☐ 1 = Waking in early hours of the morning but goes back to sleep
   - ☐ 2 = Unable to fall asleep again if he/she gets out of bed

7. Work and Activities
   - ☐ 0 = No difficulty
   - ☐ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
   - ☐ 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
   - ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
   - ☐ 4 = Stopped working because of present illness.

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation
(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
- ☐ 0 = Normal speech and thought
- ☐ 1 = Slight retardation at interview
- ☐ 2 = Obvious retardation at interview
- ☐ 3 = Interview difficult
- ☐ 4 = Complete stupor

9. Agitation
- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = "Playing with" hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety Psychic
- ☐ 0 = No difficulty
- ☐ 1 = Subjective tension and irritability
- ☐ 2 = Worrying about minor matters
- ☐ 3 = Apprehensive attitude apparent in face or speech
- ☐ 4 = Fears expressed without questioning

11. Anxiety Somatic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal
- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating. Heavy feelings in abdomen
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. Somatic Symptoms General
- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
- ☐ 2 = Any clear-cut symptoms rates 2

14. Genital Symptoms (such as loss of libido and menstrual disturbances)
- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis
- ☐ 0 = Not present
- ☐ 1 = Self-absorption (bodily)
- ☐ 2 = Preoccupation with health
- ☐ 3 = Frequent complaints, requests for help, etc.
- ☐ 4 = Hypochondriacal delusions

16. Loss of Weight
- ☐ 0 = No weight loss
- ☐ 1 = Slight or doubtful loss of weight
- ☐ 2 = Obvious or severe loss of weight

17. Insight
- ☐ 0 = Acknowledges being depressed and ill
- ☐ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
- ☐ 2 = Denies being ill at all

➧ ☐☐ HAMD Score (Items 1-17)

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AUTONOMOUS FUNCTIONING CHECKLIST

Grade in School ____

Informant _____
(mother, father, guardian, other)

Instructions

The purpose of this checklist is to learn about what your teenager does every day. There are no "right" or "wrong" things for your teenager to do, since teenagers of different ages do many different things. These questions are simply for the purpose of getting an idea of your teenager's daily activity.

When you answer these questions, first, read the question and think about whether or not it describes what you see or have seen your teenager do. You should answer the questions according to what you know your teenager does or does not do rather than what you ***believe*** or ***think*** he or she ***could*** do or ***could not*** do.

Second, tell us how the question describes what you teenager does by choosing one of the alternatives "0", "1", "2", "3", or "4" from the scale and circling that number in the space to the right of the item. Here is how to use the rating scale with a sample question.

0	1	2	3	4
Does Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Does Every Time There is an Opportunity

Sample Item. Pick up trash in the yard. **0 1 2 3 4**

0 - Circle "0" if you have never seen your teenager do this, even if he or she may never have had an opportunity. (For example mark "0" if your teenager has never done it, even if you live in an apartment and do not have a yard.)

1 - Circle "1" if you have seen your teenager do this when there has been a chance, but if there have been many more times that he or she has not done it.

2 - Circle "2" if your teenager does this about half the time there is a chance, but if he or she does not do it readily or comfortably.

3 - Circle "3" if there are more times that your teenager does this than does not do it, given the chance, and if he or she does it readily.

4 - Circle "4" if your teenager does this whenever there is a chance and if he or she does it readily.

Your teenager will not have had the chance to participate in some of the activities the questions described. These items should be answered as "does not do," even though you may feel that your teenager would do it if given the chance. Please circle "0" for questions that describe activities your teenager has ***never had the chance*** to do.

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Some questions describe things that your teenager may do with help from others. Answer these questions after you think about who has the most responsibility for completing the activity. For example, your teenager may cook the family meals and may be helped by other family members who set the table or chop vegetables. If your teenager is the family member with the most responsibility for cooking every meal that the family eats together, your answer would be "4", which stands for "does every time there is an opporunity." On the other hand, if your teenager helps other family members by doing jobs that they tell him or her to do, and never has the most responsibility for fixing dinner, your answer would be "0", for "does not do."

0	1	2	3	4
Does Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Does Every Time There is an Opportunity

My teenager:

1.	Keeps own personal items and belongings in order (for example makes bed, puts away own clothing and belongings).	0	1	2	3	4
2.	Prepares food that does not require cooking for himself/ herself (for example, cereal, sandwich).	0	1	2	3	4
3.	Care for his/her own clothing (for example, laundry, simple repair, shoe cleaning)	0	1	2	3	4
4.	Travels to and from daily activities (for example, rides bike or walks, takes bus, arranges for transportation, drives car).	0	1	2	3	4
5.	Prepares food that requires cooking for himself/herself (for example, hamburger, soup).	0	1	2	3	4
6.	Performs simple first aid or medical care for himself/ herself (for example, bandages, takes own temperature).	0	1	2	3	4
7.	Purchases his/her own clothing and personal items that are used on a daily basis (for example, underwear, toiletries).	0	1	2	3	4
8.	Performs minor repair and maintance in his/her owm environment (for example, changes light bulbs, hangs pitcure).	0	1	2	3	4
9.	Shops for and purchases his/her own groceries.	0	1	2	3	4
10.	Responds to his/her own medical emergency by calling parent.	0	1	2	3	4
11.	Responds to his/her own medical emergency by calling doctor or hospital.	0	1	2	3	4
12.	Does designated household maintenance chores involving family living areas (for example, cleans, takes out trash, does simple yard work).	0	1	2	3	4

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AUTONOMOUS FUNCTIONING CHECKLIST

0	1	2	3	4
Does Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Does Every Time There is an Opportunity

13.	Performs routine daily personal care for another family member. (for example, dresses, feeds).	0	1	2	3	4
14.	Keeps personal items and belongings of another family member in order (for example, makes bed, puts away clothing and belongings).	0	1	2	3	4
15.	Prepares meals for other family member(s).	0	1	2	3	4
16.	Transports (or arranges for transport of) another family member to and from daily activities.	0	1	2	3	4
17.	Purchases clothing and personal items (that are used on a daily basis) for other family members.	0	1	2	3	4
18.	Shops for and purchases family groceries.	0	1	2	3	4
19.	Performs minor repairs and maintenance in family living areas (for example, changes light bulbs, hangs picture).	0	1	2	3	4
20.	Repairs and maintains (or makes arrangement for repair and maintenance of) major household needs (for example, plumbing, yard work, electrical wiring).	0	1	2	3	4
21.	Responds to household emergency (for example, stove fire, plumbing problem) by calling parent or neighbor.	0	1	2	3	4
22.	Reponds to household emergency (for example, stove fire, plumbing problem) by calling fire department, using fire extinguisher, or calling repair service or shuting off water.	0	1	2	3	4
My teenager:						
23.	Uses the telphone and telephone directories.	0	1	2	3	4
24.	Carries out transactions with sales people (for example, listens to information, asks questions, gives payment, receives change).	0	1	2	3	4
25.	Uses postal services (for example, uses postage, mails letters. packages).	0	1	2	3	4
26.	Uses bank (for example, fills out deposit or withdrawal slips, uses passbook).	0	1	2	3	4

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AUTONOMOUS FUNCTIONING CHECKLIST

0	1	2	3	4
Does Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Does Every Time There is an Opportunity

27.	Uses travel-related services for short trips (for example, taxi, bus subway).	0	1	2	3	4
28.	Uses travel-related services for long trips (for example, airline, train, bus).	0	1	2	3	4
29.	Uses library services (for example, checks out books or uses Xerox machine).	0	1	2	3	4
30.	Maintains and uses his/her own savings account.	0	1	2	3	4
31.	Maintains and uses his/her own checking or charge account.	0	1	2	3	4
32.	Maintains adequate personal care and grooming (for example, bathes, trims fingernails and toenails when needed)	0	1	2	3	4
33.	Maintains his/her routine general health and fitness (for example, has adequate eating, sleeping and exercise habits).	0	1	2	3	4
34.	Selects clothing that is suited to weather (for example, raincoat if raining, warm clothes in winter).	0	1	2	3	4
35.	Plans and initiates activity for himself/herself in everday unscheduled free time (for example, chooses to watch television or work on a hobby if bored).	0	1	2	3	4
36.	Plans activity for his/her long-term free time (for example, makes plans for summer vacation, mid-semester vacation).	0	1	2	3	4
37.	Initiates friendships with peers (for example, plans or attends parties, outings, games, club meetings).	0	1	2	3	4
38.	Meets nonacademic social obligations or commitments (for example, keeps appointments for family and peer related social events arranged by self or others).	0	1	2	3	4
39.	Meets academic obligations amd commitments (for example, completes homework assignments on time, brings necessary supplies to class).	0	1	2	3	4
40.	Plan transportation to and from special activities (for example arranges for rides with friends or family or plans care or bus route and schedule).	0	1	2	3	4

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AUTONOMOUS FUNCTIONING CHECKLIST

0	1	2	3	4
Does Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Does Every Time There is an Opportunity

41.	Manage his/her own budget from allowance or income (for example, saves money for large purchases, pays for routine expenses throughout week without running out of money).	0	1	2	3	4
42.	Make long-term educational and/or career plans (for example, selects courses, investigates colleges or technical schools).	0	1	2	3	4

When my teenager is free to choose how he/she will spend his/her unscheduled free time. He/she chooses to:

43.	Listen to music (for example, radio or stereo).	0	1	2	3	4
44.	Read for relaxation (for example, books, newspapers)	0	1	2	3	4
45.	Play games or puzzles (for example, cards, crossword puzzles, jigsaw puzzles, computer games).	0	1	2	3	4
46.	Write letters to friends, relatives, aquaintances.	0	1	2	3	4
47.	Work on or take lessons in crafts or hobbies (for example cooking, collections, pet care, sewing, model building, car repair).	0	1	2	3	4
48.	Practice or take lessons that involve a trained artistic or academic skill (for example, piano or other musical instrument, ballet, singing, creative writing, foreign languages).	0	1	2	3	4
49.	Go to the movies, rock concerts, dances.					
50.	Go to plays, theater, lectures.	0	1	2	3	4
51.	Pursue activities that are related to his or her career interest(s) (for example, runs a business, works on a computer, practices piano for professional preparation).	0	1	2	3	4
52.	Go for walks.	0	1	2	3	4
53.	Go shopping, or spend time at shopping centers or in shopping areas.	0	1	2	3	4
54.	Attend club meetings or other organized social group meetings.	0	1	2	3	4
55.	Work for pay (for example, babysit, play in a band, do yard work, walk dogs, work at part-time job, deliver papers).	0	1	2	3	4

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AUTONOMOUS FUNCTIONING CHECKLIST

0	1	2	3	4
Does Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Does Every Time There is an Opportunity

56.	Clean and/or maintan living environment or belongings (for example, clean house, wash or repair clothes, wash car, make household repairs).	0	1	2	3	4
57.	Work on schoolwork (for example, spend extra time on homework, make special preparations for class projects, spend time in library).	0	1	2	3	4
58.	Spend time with family (for example, work on family projects, have discussions or casual conversations, attend family gatherings such as picnics or parties).	0	1	2	3	4

On these final items, please check "Yes" or "No" in response to each description. Check "Yes" if the description fits your teenager. Check "No" if it does not.

My teenager:		Yes	No
59.	Has casual friendships with teenagers of opposite sex.	☐	☐
60.	Has close friendships with teenagers of opposite sex.	☐	☐
61.	Has casual friendships with adults outside the family (for example, teachers, neighbors, coaches, scout leaders)	☐	☐
62.	Has close friendships with adults outside the family (for example, teachers, neighbors, coaches, scout leaders).	☐	☐
63.	Has casual friendships with younger children.	☐	☐
64.	Has close friendships with younger children.	☐	☐
65.	Is active in casual/recreational groups of teenage friends.	☐	☐
66.	Has many friendships.	☐	☐
67.	Is active in one or more organized extracurricular group (for example, French club, student council, sports team).	☐	☐
68.	Has leadership position in one or more organized extracurricular group (for example, president of the student council, captain of the sports team).	☐	☐
69.	Has close friendship with adult member of the extended family (for example, an uncle, aunt, grandparent).	☐	☐
70.	Works or has worked either for pay or volunteer in an area of particular career interest.	☐	☐

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AUTONOMOUS FUNCTIONING CHECKLIST

		Yes	No
71.	Works or has worked to earn money by providing a service on a regular scheduled basis (for example, contracts for yard work, dog walking, baby sitting)	☐	☐
72.	Works or has worked to earn money by using a special skill (for example, musical performance, typing, tutoring).	☐	☐
73.	Works or has worked to earn money in a self-or-peer-run organization or business.	☐	☐
74.	Works or has worked to earn money fundraising for an organization or charity (for example, scouts, church groups, political organizations).	☐	☐
75.	Does or has done volunteer work without pay for a service, a school or political organization, a social agency, a club, a church, or a hospital.	☐	☐
76.	Participates or has participated in prevocational (career) or vocational (career) classes or training (for example, any technical training or career development class).	☐	☐
77.	Has explored career interest by visiting work sites or interviewing people in that job or career.	☐	☐
78.	Has spent time reading, researching, or "finding out" about a career that particularly interests him/her.	☐	☐

Comments:

If you have any additional information about your teenager's everyday independent or self-sufficient behavior, use the space below to write your comments. Thank you.

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SELF-PERCEPTION PROFILE FOR ADOLESCENTS

WHAT AM I LIKE

Sample Sentence

	Really True for Me	Sort of True for Me				Sort of True for Me	Really True for Me
a.	☐	☐	Some teenagers like to go to movies in their spare time	BUT	Other teenagers would rather go to sport events.	☐	☐
1.	☐	☐	Some teenagers feel that they are just as smart as others their age	BUT	Other teenagers aren't so sure and wonder if they are as smart.	☐	☐
2.	☐	☐	Some teenagers find it hard to make friends	BUT	For other teenagers it's pretty easy.	☐	☐
3.	☐	☐	Some teenagers do very well at all kinds of sports	BUT	Other teenagers don't feel that they are very good when it comes to sports.	☐	☐
4.	☐	☐	Some teenagers are not happy with the way they look	BUT	Other teenagers are happy with the way they look.	☐	☐
5.	☐	☐	Some teenagers feel that they are ready to do well at a part-time job	BUT	Other teenagers feel that they are not quite ready to handle a part-time job.	☐	☐
6.	☐	☐	Some teenagers feel that if they are romantically interested in someone, that person will like them back	BUT	Other teenagers worry that when they like someone romantically that person won't like them back.	☐	☐
7.	☐	☐	Some teenagers usually do the right thing	BUT	Other teenagers often don't do what they know is right.	☐	☐
8.	☐	☐	Some teenagers are able to make really close friends.	BUT	Other teenagers find it hard to make really close friends.	☐	☐
9.	☐	☐	Some teenagers are often disappointed with themselves	BUT	Other teenagers are pretty pleased with themselves.	☐	☐
10.	☐	☐	Some teenagers are pretty slow in finishing their school work	BUT	Other teenagers can do their school work more quickly	☐	☐

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SELF-PERCEPTION PROFILE FOR ADOLESCENTS

	Really True for Me	Sort of True for Me				Sort of True for Me	Really True for Me
11.	☐	☐	Some teenagers have a lot of friends	BUT	Other teenagers don't have very many friends.	☐	☐
12.	☐	☐	Some teenagers think they could do well at just about any new athletic activity	BUT	Other teenagers are afraid they might not do well at a new athletic activity.	☐	☐
13.	☐	☐	Some teenagers wish their body was different	BUT	Other teenagers like their body the way it is.	☐	☐
14.	☐	☐	Some teenagers feel that they don't have enough skills to do well at a job	BUT	Other teenagers feel that they do have enough skills to do a job well.	☐	☐
15.	☐	☐	Some teenagers are not dating the people they are really attracted to	BUT	Other teenagers are dating those people they are attracted to	☐	☐
16.	☐	☐	Some teenagers often feel guilty about certain things they do	BUT	Other teenagers hardly ever feel guilty about what they do.	☐	☐
17.	☐	☐	Some teenagers can be trusted to keep secrets that their friends tell them	BUT	Other teenagers have a hard time keeping secrets that their friends tell them.	☐	☐
18.	☐	☐	Some teenagers don't like the way they are leading their life	BUT	Other teenagers do like the way they are leading their life.	☐	☐
19.	☐	☐	Some teenagers do very well at their classwork	BUT	Other teenagers don't do very well at their class-work.	☐	☐
20.	☐	☐	Some teenagers are very hard to like	BUT	Other teenagers are really easy to like.	☐	☐
21.	☐	☐	Some teenagers feel that they are better than others their age at sports	BUT	Other teenagers don't feel they can play as well.	☐	☐
22.	☐	☐	Some teenagers wish their physical appearance was different	BUT	Other teenagers like their physical appearance the way it is.	☐	☐

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SELF-PERCEPTION PROFILE FOR ADOLESCENTS

	Really True for Me	Sort of True for Me				Sort of True for Me	Really True for Me
23.	☐	☐	Some teenagers are proud of the work they do on jobs they get paid for	BUT	For other teenagers, getting paid is more important than feeling proud of what they do.	☐	☐
24.	☐	☐	Some teenagers feel that people their age will be romantically attracted to them	BUT	Other teenagers worry about whether people their age will be attacted to them.	☐	☐
25.	☐	☐	Some teenagers are usually pleased with the way they act	BUT	Other teenagers are often ashamed of the way they act.	☐	☐
26.	☐	☐	Some teenagers don't really have a close friend to share things with.	BUT	Other teenagers do have a close friend to share things with.	☐	☐
27.	☐	☐	Some teenagers are happy with themselves most of the time	BUT	Other teenagers are often not happy with themselves.	☐	☐
28.	☐	☐	Some teenagers have trouble figuring out the answers in school	BUT	Other teenagers almost always can figure out the answers.	☐	☐
29.	☐	☐	Some teenagers are popular with others their age	BUT	Other teenagers are not very popular.	☐	☐
30.	☐	☐	Some teenagers don't do well at new outdoor games	BUT	Other teenagers are good at new outdoor games right away.	☐	☐
31.	☐	☐	Some teenagers think that they are good looking	BUT	Other teenagers think that they are not very good looking.	☐	☐
32.	☐	☐	Some teenagers feel like they could do better at work they do pay for	BUT	Other teenagers feel that they are doing really well at work they do pay for.	☐	☐
33.	☐	☐	Some teenagers feel that they are fun and interesting on a date	BUT	Other teenagers wonder about how fun and interesting they are on a date.	☐	☐
34.	☐	☐	Some teenagers do things they know they shouldn't do	BUT	Other teenagers hardly ever do things they know they shouldn't do.	☐	☐

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SELF-PERCEPTION PROFILE FOR ADOLESCENTS

	Really True for Me	Sort of True for Me				Sort of True for Me	Really True for Me
35.	☐	☐	Some teenagers find it hard to make friends they can really trust	BUT	Other teenagers are able to make close friends they can really trust.	☐	☐
36.	☐	☐	Some teenagers like the kind of person they are	BUT	Other teenagers often wish they were someone else.	☐	☐
37.	☐	☐	Some teenagers feel that they are pretty intelligent	BUT	Other teenagers question whether they are intelligent.	☐	☐
38.	☐	☐	Some teenagers feel that they are socially acceptable	BUT	Other teenagers wished that more people their age accepted them.	☐	☐
39.	☐	☐	Some teenagers do not feel that they are very athletic	BUT	Other teenagers feel that they are very athletic.	☐	☐
40.	☐	☐	Some teenagers really like their looks	BUT	Other teenagers wished they looked different.	☐	☐
41.	☐	☐	Some teenagers feel that it's really important to do the best you can on paying jobs	BUT	Other teenagers feel that getting the job done is what really counts.	☐	☐
42.	☐	☐	Some teenagers usually don't get asked out by people they would like to date	BUT	Other teenagers do get asked out by people they really want to date.	☐	☐
43.	☐	☐	Some teenagers usually act the way they know the are supposed to	BUT	Other teenagers often don't act the way they are supposed to.	☐	☐
44.	☐	☐	Some teenagers don't have a friend that is close enough to share really personal thoughts with	BUT	Other teenagers do have a close friend that they can share personal thoughts and feelings with.	☐	☐
45.	☐	☐	Some teenagers are very happy being the way they are	BUT	Other teenagers wish they were different.	☐	☐

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SICKNESS IMPACT PROFILE: ADOLESCENT VERSION

Introduction

On the next few pages are statements which describe things people often do when they are not well.

As you read them, think of yourself today:

- If a statement describes you TODAY, mark the box under "Yes" (Yes, this statement describes me today).
- However, if a statement does not describe you TODAY, or does not apply you, mark the box under "No". (No, this statement does not describe me today or does not apply to me).

For Example:

"I am not doing any of the shopping that I would usually do."

- If you have not been doing any shopping for some time, and still are not doing any shopping today, check "YES". (Yes, this statement describes me today).
- If you are doing your shopping as usual, check "NO" (No this statement does not describe me today or does not apply to me).

Read and respond to the statements in the order listed. Some of the statements will differ only in a few words, so please read each one carefully. While you may wish to go back to change a response, your first answer is usually best. Please do not read ahead in the questionnaire.

Please do not discuss the statements with anyone, including family members, while doing the questionnaire.

Please mark your answers by placing an "X" in the appropriate box like this. ☒

Thank you for your time and help.

How would you describe your present health

☐ very good ☐ good ☐ fair ☐ poor ☐ very poor

How would you describe you present quality of life (how things are going for you generally)?

☐ very good ☐ good ☐ fair ☐ poor ☐ very poor

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PATIENT LOG - CONTINUATION PHASE

Investigator _____

Directions: Enter ALL patients who have been considered for the study and who have been interviewed. For patients not entering the Continuation Phase, note the reason for exclusion in the designated column.

Patient Initials	Initial Interview (day month year)	Reason for Exclusion

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PATIENT ASSIGNMENT SHEET - CONTINUATION PHASE

Investigator _____ For SB Date ___ day ___ month ___ year

Directions: Do not enter the patient on the patient assignment sheet until he/she starts continuation phase medication.

Final Dose Status: C = Completed all treatment visits
W = Withdrawn prior to completing all treatment visits

	Patient Initials	Patient Number	Date of First Dose of Continuation Phase (day month year)	Date of Last Dose (day month year)	Status (C/W)
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					

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SICKNESS IMPACT PROFILE: ADOLESCENT VERSION

		Yes	No
A.	**These statements describe your sleep and rest this week.**		
1.	I spend much of the day lying down in order to rest.	☐	☐
2.	I sit for much of the day.	☐	☐
3.	I am sleeping or dozing much of the time - day and night.	☐	☐
4.	I lie down more often than my friends during the day in order to rest.	☐	☐
5.	I sit around half asleep.	☐	☐
6.	I sleep less at night, for example, I wake up easily, I do not fall asleep for a long time, I keep waking up.	☐	☐
7.	I sleep or doze more during the day.	☐	☐
B.	**These statements describe your daily work around the house.**	**Yes**	**No**
1.	I only do work that I need to do around the house for short periods of time or I rest often.	☐	☐
2.	I am doing less of the daily household chores that I would usually do.	☐	☐
3.	I am not doing any of the daily household chores that I would usually do.	☐	☐
4.	I am not doing any of the shopping that I would usually do.	☐	☐
5.	I am not doing any of the cleaning that I would usually do.	☐	☐
6.	I am not doing any of the clothes washing that I would usually do.	☐	☐
C.	**These statements describe your contact with your family and friends today.**	**Yes**	**No**
1.	I am going out less to visit people.	☐	☐
2.	I am not going out to visit people at all.	☐	☐
3.	I show less interest in other people's problems, for example, I do not listen when they tell me about their problems. I do not offer to help.	☐	☐
4.	I am often irritable with those around me, for example, I snap at people or criticize easily.	☐	☐
5.	I show less affection.	☐	☐
6.	I take part in fewer social activities than I used to, for example, I go to fewer parties or social events.	☐	☐

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SICKNESS IMPACT PROFILE: ADOLESCENT VERSION

		Yes	No
7.	I am cutting down the length of visits to friends.	☐	☐
8.	I avoid having visitors.	☐	☐
9.	My sexual activity is decreased.	☐	☐
10.	I talk less with those around me.	☐	☐
11.	I make demands on other people that they find irritating, for example, I insist that they do things for me, or tell them how to do things.	☐	☐
12.	I stay alone much of the time.	☐	☐
13.	I am disagreeable with my family, for example, I act spitefully or stubbornly.	☐	☐
14.	I frequently get angry with my family, for example, I hit them, scream or throw things at them.	☐	☐
15.	I isolate myself as much as I can from the rest of my family.	☐	☐
16.	I refuse contact with my family, for example, I turn away from them.	☐	☐
17.	I am not joking with my family members as I usually do.	☐	☐

D. These statements describe your feelings.

		Yes	No
1.	I am confused and start to do more than one thing at a time.	☐	☐
2.	I have more minor accidents, for example, I drop things, I trip and fall or bump into things.	☐	☐
3.	I react slowly to things that are said or done.	☐	☐
4.	I do not finish things I start.	☐	☐
5.	I have difficulty reasoning and solving problems, for example, making plans, making decisions, learning new things.	☐	☐
6.	I sometimes get confused, for example, I do not know where I am, who is around, or what day it is.	☐	☐
7.	I forget a lot, for example, things that happened recently, where I put things, or to keep appointments.	☐	☐
8.	I do not keep my attention on any activity for long.	☐	☐
9.	I make more mistakes than usual.	☐	☐
10.	I have difficulty doing things which involve thought and concentration, for example, paying attention in school or at my job.	☐	☐

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SICKNESS IMPACT PROFILE: ADOLESCENT VERSION

E. These statements are about how you talk to other people and write.	Yes	No
1. I am having trouble writing or typing.	☐	☐
2. I am having trouble talking to people.	☐	☐
3. I am not comfortable in most social situations like parties.	☐	☐
4. I speak with difficulty, for example, I get stuck for words, I stutter, I stammer, I slur my words.	☐	☐
5. I do not speak clearly when I am under stress.	☐	☐

F. The following statements decribe the activities you usually do in your spare time for relaxation, entertainment or just to pass the time.	Yes	No
1. I spend shorter periods of time on my hobbies and recreation.	☐	☐
2. I am going out and enjoying myself less often.	☐	☐
3. I am cutting down on some of my usual inactive pastimes, for example, I watch less TV, play cards less, or read less.	☐	☐
4. I am not doing any of my usual inactive pastimes, for example, I watch less TV, play cards less, or read less.	☐	☐
5. I am doing more inactive pastimes in place of my other usual activities.	☐	☐
6. I am taking part in fewer activities with my friends.	☐	☐
7. I am cutting down on some of my usual physical recreation or more active pastimes.	☐	☐
8. I am not doing any of my usual physical recreation or more active pastimes.	☐	☐

Now please look through this questionnaire and make sure that you have read every question.

Thank you once again for your help.

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KIDDIE-SADS-LIFETIME - SCORING FORM

DEPRESSED MOOD

1. Worst Severity of Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Duration of Current Episode: [ ] # of weeks

2. Worst Severity of Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Frequency: [ ] Days/week

Average % time of the day: [ ] %

DEPRESSED APPEARANCE

3. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

4. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

IRRITABILITY AND ANGER

5. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Duration: [ ] # of weeks

6. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Frequency: [ ] Days/week

Average % time of the day: [ ] %

SEPARATION-DEPENDENT-DYSPHORIA

7. Current Episode: [0] NI [1] NO [2] OCC [3] USL [4] ALW

8. Last Two Weeks: [0] NI [1] NO [2] OCC [3] USL [4] ALW

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KIDDIE-SADS-LIFETIME - SCORING FORM

QUALITY OF DYPSHORIC MOOD

9. Current Episode: [0] NI [1] ND [2] QUE [3] DDF [4] VDF

10. Last Two Weeks: [0] NI [1] ND [2] QUE [3] DDF [4] VDF

DEGREE OF ASSOCIATION OF DEPRESSED OR IRRITABLE MOOD WITH SPECIFIC EVENTS OR PREOCCUPATIONS

11. Current Episode: [0] NI [1] NAL [2] MOT [3] UN [4] PN

12. Last Two Weeks: [0] NI [1] NAL [2] MOT [3] UN [4] PN

REACTIVITY OF DEPRESSED OR IRRITABLE MOOD

13. Current Episode: [0] NI [1] VR [2] FUL [3] RES [4] MLD [5] SLT [6] UNR

[ ][ ][ ] % Usual % of Normal

14. Last Two Weeks: [0] NI [1] VR [2] FUL [3] RES [4] MLD [5] SLT [6] UNR

[ ][ ][ ] % Usual % of Normal

[ ][ ][ ] % Maximum % of Normal

[ ][ ] Number of hours good feeling last

DIURNAL MOOD VARIATION

Worse in Morning

15. Current Episode: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

16. Last Two Weeks: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

Worse in Afternoon and/or Evening

17. Current Episode: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

18. Last Two Weeks: [0] NI [1] NW [2] MIN [3] MLD [4] CW [5] EXT

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KIDDIE-SADS-LIFETIME - SCORING FORM

EXCESSIVE INAPPROPRIATE GUILT

19. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

20. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

Frequency: Days/Week [ ]

NEGATIVE SELF IMAGE

21. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

22. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

FEELING UNLOVED/FORLORN

23. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

24. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

Frequency: Days/Week [ ]

HOPELESSNESS, HELPLESSNESS, DISCOURAGEMENT, PESSIMISM

25. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

26. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

SELF-PITY

27. Current Episode: [0] NI [1] NO [2] OCC [3] MLD [4] CON

28. Last Two Weeks: [0] NI [1] NO [2] OCC [3] MLD [4] CON

ACHES AND PAINS

29. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

30. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EXT

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KIDDIE-SADS-LIFETIME - SCORING FORM

HYPOCHONDRIASIS

31. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

32. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

ANHEDONIA, LACK OF INTEREST, APATHY, LOW MOTIVATION, BOREDOM

Combined Overall Rating

33. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Duration: ___ # of weeks

34. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: ___ Days/week

Average % time of the day: ___ %

Differentiating Lack of Interest from Anhedonia

Lack of Interest

35. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

36. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Anhedonia

37. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

38. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

FATIGUE, LACK OF ENERGY AND TIREDNESS

39. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

40. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: ___ Days/Week

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KIDDIE-SADS-LIFETIME - SCORING FORM

DIFFICULTY CONCENTRATING, INATTENTION, OR SLOWED THINKING

41. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

42. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

PSYCHOMOTOR AGITATION

43. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

44. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Unable to sit still

45. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

46. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Pacing

47. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

48. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

Hand wringing

49. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

50. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

Pulling or rubbing on hair, clothing, skin

51. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

52. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

Can't stop talking, talks on and on

53. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

54. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] SVR [5] SVR

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KIDDIE-SADS-LIFETIME - SCORING FORM

PSYCHOMOTOR RETARDATION

55. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

56. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

Frequency: [ ] Days/Week

MANIFESTATIONS INCLUDED:

Slowed Speech

57. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

58. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Increased pauses before answering

59. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

60. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Low or monotonous speech

61. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

62. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Mute or markedly decreased amount of speech

63. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

64. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Slowed body movements

65. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

66. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

Depressive stupor

67. Current Episode: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

68. Last Two Weeks: [0] NI [1] NPR [2] DBT [3] PR [4] MOD [5] SVR

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KIDDIE-SADS-LIFETIME - SCORING FORM

SOCIAL WITHDRAWAL

69.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
70.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

REJECTION SENSITIVITY

71.	Last Year:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
72.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
73.	Last Year:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
74.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

SLEEP PROBLEMS

75. ⌊_⌋ Hours slept before onset of depression

76. ⌊_⌋ Hours slept during the current episode

77. ⌊_⌋ Hours slept during the last two weeks

HYPERSOMNIA

78. ⌊_⌋ Hours slept in daytime of current episode

79. ⌊_⌋ Hours slept in daytime in the last two weeks

80. ⌊_⌋ Hours lying down in current episode

81. ⌊_⌋ Hours lying down in last two weeks

82.	Current Episode:	(0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)
83.	Last Two Weeks:	(0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)

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KIDDIE-SADS-LIFETIME - SCORING FORM

INSOMNIA

84. Current Episode: [(0) NI] [(1) NO] [(2)] [(3)] [(4)] [(5)] [(6)]

85. Last Two Weeks: [(0) NI] [(1) NO] [(2)] [(3)] [(4)] [(5)] [(6)]

Frequency: [ ] Nights/Week

TYPES OF INSOMNIA

Initial Insomnia

86. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

87. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Middle Insomnia

88. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

89. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Terminal Insomnia

90. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

91. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Circadian Reversal

92. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

93. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Non-restorative sleep

94. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

95. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

Daytime sleepiness

96. Current Episode: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

97. Last Two Weeks: [(0) NI] [(1) NPR] [(2) DBT] [(3) MLD] [(4) MOD] [(5) SVR]

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KIDDIE-SADS-LIFETIME - SCORING FORM

ANOREXIA

98. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

99. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

WEIGHT LOSS

100. Current Episode:

Pounds lost: ___ lbs.

Number of Weeks: ___

101. Last Two Weeks:

Pounds lost: ___ lbs.

INCREASED APPETITE

102. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

103. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MOD [5] SVR [6] EX

Frequency: ___ Days/Week

STRONG CRAVING FOR SWEETS

104. Current Episode: [0] NI [1] ABS [2] DBT [3] MLD [4] MOD [5] SVR

105. Last Two Weeks: [0] NI [1] ABS [2] DBT [3] MLD [4] MOD [5] SVR

WEIGHT GAIN

106. Current Episode:

Pounds gained: ___ lbs.

Number of Weeks: ___

107. Last Two Weeks:

Pounds gained: ___ lbs.

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KIDDIE-SADS-LIFETIME - SCORING FORM

SUICIDAL IDEATION

108. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

109. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX [7] VEX

Suicidal Acts - Number

110. Current Episode: ___

111. Last Two Weeks: ___

Suicidal Acts - Seriousness

112. Current Episode: [0] NI [1] NO [2] MIN [3] DEF [4] SER [5] VS [6] EXT

113. Last Two Weeks: [0] NI [1] NO [2] MIN [3] DEF [4] SER [5] VS [6] EXT

Medical Lethality

114. Current Episode [0] NI [1] NO [2] MIN [3] MLD [4] MO [5] SVR [6] EXT

115. Last Two Weeks: [0] NI [1] NO [2] MIN [3] MLD [4] MO [5] SVR [6] EXT

Non-Suicidal Physical Self-Demaging Acts

116. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] ACT

117. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] ACT

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KIDDIE-SADS-LIFETIME - SCORING FORM

DIAGNOSTIC CRITERIA - MAJOR DEPRESSIVE EPISODE

Onset and Course

118. Number of Episodes [ ]

Ages of onset and offset of each episode

119. Onset [ ]
Offset [ ]
Weeks [ ]

120. Onset [ ]
Offset [ ]
Weeks [ ]

121. Onset [ ]
Offset [ ]
Weeks [ ]

122. Onset [ ]
Offset [ ]
Weeks [ ]

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KIDDIE-SADS-LIFETIME - SCORING FORM

MANIC SYNDROME

ELATION, EXPANSIVE MOOD

1. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX
2. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX

DECREASED NEED FOR SLEEP

3. Current Episode:	[0] NI	[1] NO	[2] -1	[3] -2	[4] -3	[5] -4	[6] -4+
4. Last Two Weeks:	[0] NI	[1] NO	[2] -1	[3] -2	[4] -3	[5] -4	[6] -4+

UNUSUALLY ENERGETIC

5. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] LCH	[4] MOR	[5] MM	[6] UA
6. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] LCH	[4] MOR	[5] MM	[6] UA

INCREASE IN GOAL DIRECTED ACTIVITY

7. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX
8. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX

GRANDIOSITY

9. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX
10. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] SVR	[6] EX

ACCELERATED, PRESSURED OR INCREASED AMOUNT OF SPEECH

11. Current Episode:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX
12. Last Two Weeks:	[0] NI	[1] NO	[2] SLT	[3] MLD	[4] MO	[5] MKD	[6] EX

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KIDDIE-SADS-LIFETIME - SCORING FORM

RACING THOUGHTS

13. Current Episode: [0] NI [1] NO [2] DBT [3] MLD [4] MO [5] SVR [6] EX

14. Last Two Weeks: [0] NI [1] NO [2] DBT [3] MLD [4] MO [5] SVR [6] EX

FLIGHT OF IDEAS

15. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

16. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

POOR JUDGEMENT

17. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] VS

18. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] VS

DISTRACTABILITY

19. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR

20. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR

MOTOR HYPERACTIVITY

21. Current Episode: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] MKD [6] EX

22. Last Two Weeks: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] MKD [6] EX

Inappropriate laughing, joking or punning

23. Current Episode: [0] NI [1] NO [2] DBT [3] MLD [4] MOD

24. Last Two Weeks: [0] NI [1] NO [2] DBT [3] MLD [4] MOD

Uninhibited people seeking, gregarious

25. Current Episode: [0] NI [1] NO [2] DBT [3] MLD [4] MOD

26. Last Two Weeks: [0] NI [1] NO [2] DBT [3] MLD [4] MOD

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KIDDIE-SADS-LIFETIME - SCORING FORM

Increased Productivity

27. Current Episode: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

28. Last Two Weeks: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

Sharpened and unusually creative thinking

29. Current Episode: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

30. Last Two Weeks: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

Hypersexuality

31. Current Episode: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

32. Last Two Weeks: [0] NI [1] NO [2] DBT [3] PRS [4] SVR

INFLUENCE OF ILLICIT DRUGS OR ALCOHOL

33. Current Episode: [0] NA [1] NVR [2] SMT [3] ONL

34. Last Two Weeks: [0] NA [1] NVR [2] SMT [3] ONL

NUMBER OF MANIC PERIODS

35. [ ]

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KIDDIE-SADS-LIFETIME - SCORING FORM

DIAGNOSTIC CRITERIA - HYPOMANIC EPISODE

Onset and Course

36. Number of Episodes [ ]

Ages of onset and offset of each episode

37. Onset [ ] Offset [ ] Weeks [ ]

38. Onset [ ] Offset [ ] Weeks [ ]

DIAGNOSTIC CRITERIA - MANIC EPISODE

39. Onset and Course

Number of Episodes [ ]

Ages of onset and offset of each episode

40. Onset [ ] Offset [ ] Weeks [ ]

41. Onset [ ] Offset [ ] Weeks [ ]

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KIDDIE-SADS-LIFETIME - SCORING FORM

EATING DISORDERS

REFUSAL TO MAINTAIN BODY WEIGHT

1. Lifetime: [(0) NI] [(1) NP] [(2)] [(3)] [(4)] [(5)] [(6)]

METHODS OF WEIGHT LOSS

2. ***Restriction*** Lifetime: [(0) NI] [(1) NVR] [(2) SMT] [(3) OFT] [(4) ROU]
3. ***Only Liquids*** Lifetime: [(0) NI] [(1) NVR] [(2) SMT] [(3) OFT] [(4) ROU]
4. ***Vomiting*** Lifetime: [(0) NI] [(1) NVR] [(2) SMT] [(3) OFT] [(4) ROU]
5. ***Supressants*** Lifetime: [(0) NI] [(1) NVR] [(2) SMT] [(3) OFT] [(4) ROU]
6. ***Laxatives*** Lifetime: [(0) NI] [(1) NVR] [(2) SMT] [(3) OFT] [(4) ROU]
7. ***Diurectics*** Lifetime: [(0) NI] [(1) NVR] [(2) SMT] [(3) OFT] [(4) ROU]

BODY IMAGE DISTURBANCE

8. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

INTENSE AND PERSISTENT FEAR OF GAINING WEIGHT

9. Lifetime: [(0) NI] [(1) NO] [(2)] [(3)] [(4)] [(5)] [(6)]

INTENSE PREOCCUPATION WITH FOOD AND EATING

10. Lifetime: [(0) NI] [(1) NO] [(2)] [(3)] [(4)] [(5)] [(6)]

AMENORRHEA

11. Age of Menarche: [ ]
12. [(0) NI] [(1) NO] [(2) YES]
13. [(0) NI] [(1) NO] [(2) YES]

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KIDDIE-SADS-LIFETIME - SCORING FORM

14. Weeks: [ ]

15. Weeks: [ ]

16. [(0) NI] [(1) NO] [(2) YES]

BULIMIA

17. Lifetime: [(0) NI] [(1) NO] [(2)] [(3)] [(4)] [(5)] [(6)]

18. ***Eats faster*** Lifetime: [(0) NI] [(1) NVR] [(2) SMT] [(3) OFT] [(4) AS]

19. ***Uncontrollable*** Lifetime: [(0) NI] [(1) NVR] [(2) SMT] [(3) OFT] [(4) AS]

20. ***Eats alone*** Lifetime: [(0) NI] [(1) NVR] [(2) SMT] [(3) OFT] [(4) AS]

21. ***Abdominal Pain*** Lifetime: [(0) NI] [(1) NVR] [(2) SMT] [(3) OFT] [(4) AS]

22. ***Vomiting*** Lifetime: [(0) NI] [(1) NVR] [(2) SMT] [(3) OFT] [(4) AS]

23. ***Sleep*** Lifetime: [(0) NI] [(1) NVR] [(2) SMT] [(3) OFT] [(4) AS]

24. ***Interruption*** Lifetime: [(0) NI] [(1) NVR] [(2) SMT] [(3) OFT] [(4) AS]

25. ***Depression*** Lifetime: [(0) NI] [(1) NVR] [(2) SMT] [(3) OFT] [(4) AS]

26. Binges: [ ] hours

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KIDDIE-SADS-LIFETIME - SCORING FORM

DIAGNOSTIC CRITERIA - ANOREXIA NERVOSA

Onset and Course

27. Number of Episodes [ ]

Ages of onset and offset of each episode

28. Onset [ ] Offset [ ] Weeks [ ]

29. Onset [ ] Offset [ ] Weeks [ ]

DIAGNOSTIC CRITERIA - BULIMIA NERVOSA

Onset and Course

30. Number of Episodes [ ]

Ages of onset and offset of each episode

31. Onset [ ] Offset [ ] Weeks [ ]

32. Onset [ ] Offset [ ] Weeks [ ]

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KIDDIE-SADS-LIFETIME - SCORING FORM

ANXIETY DISORDERS

SPECIFIC PHOBIAS

1.	***Overall*** Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
2.	***Flying*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
3.	***Elevators*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
4.	***Small Spaces*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
5.	***Heights*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
6.	***Dark*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
7.	***Swimming*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
8.	***Dogs/animals*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
9.	***Insects*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
10.	***Thunderstorms*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
11.	***Cars/Buses/Trains*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
12.	***Dentist/Doctors*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	
13.	***Other*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	

DIAGNOSTIC CRITERIA - SPECIFIC PHOBIA

Onset and Course

14. Number of Episodes [ ]

Ages of onset and offset of each episode

15. Onset [ ] Offset [ ] Weeks [ ]

16. Onset [ ] Offset [ ] Weeks [ ]

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KIDDIE-SADS-LIFETIME - SCORING FORM

SEPARATION ANXIETY

PREOCCUPATION WITH THOUGHTS OF HARM TO PARENTS

1. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

PREOCCUPATION WITH HARM BEFALLING SELF

2. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

FEAR OF BEING HOME ALONE

3. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

EXCESSIVE REACTION TO SEPARATION

4. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

DIFFICULTY BEING AWAY FROM HOME

5. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

HOMESICKNESS

6. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

FEAR OF SLEEPING AWAY FROM HOME

7. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

NIGHTMARES

8. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

SCHOOL REFUSAL/RELUCTANCE

9. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

PHYSICAL SYMPTOMS DURING SEPARATION

10. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

DIAGNOSTIC CRITERIA - SEPARATION ANXIETY DISORDER

Onset and Course

11. Number of Episodes [ ]

Ages of onset and offset of each episode

12. Onset [ ]
Offset [ ]
Weeks [ ]

13. Onset [ ]
Offset [ ]
Weeks [ ]

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KIDDIE-SADS-LIFETIME - SCORING FORM

PANIC DISORDER AND AGORAPHOBIA

1. Lifetime: [(0) NI] [(1) NP] [(2) DBT] [(3) DPR] [(4) 6] [(5) 3X] [(6) DLY]

SPONTANEOUS ATTACKS

2. Lifetime: [(0) NI] [(1) NO] [(2) 1] [(3) 2-3] [(4) 4] [(5) 4+]

DURATION OF SPONTANEOUS ATTACKS

3. Lifetime: [(0) NI] [(1) 20] [(2) 10] [(3) SOM] [(4) MST] [(5) ALL]

SITUATIONALLY PREDISPOSED ATTACKS

4. Lifetime: [(0) NI] [(1) NO] [(2) -4] [(3)] [(4)] [(5) 4+]

PHOBIA RELATED ATTACKS

5. Lifetime: [(0) NI] [(1) NO] [(2)] [(3)]

6. ***Shortness of Breath*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

7. ***Palpitations*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

8. ***Chest Pains*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

9. ***Choking*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

10. ***Dizziness*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

11. ***Numbness*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

12. ***Sweating*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

13. ***Trembling*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

14. ***Dying*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

15. ***Losing Control*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

16. ***Nausea*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

17. ***Depersonalization*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

18. ***Flashes/Chills*** Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

19. Most Number of Attacks: [ ] in a 4 week period

20. Lifetime: [(0) NI] [(1) NP] [(2) VM] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

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KIDDIE-SADS-LIFETIME - SCORING FORM

AGORAPHOBIA WITH PANIC DISORDER

21. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

AGORAPHOBIA WITHOUT PANIC DISORDER

22. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

DIAGNOSTIC CRITERIA - PANIC DISORDER WITHOUT AGORAPHOBIA

Onset and Course

23. Number of Episodes ___

Ages of onset and offset of each episode

	24.	25.
Onset	___	___
Offset	___	___
Weeks	___	___

DIAGNOSTIC CRITERIA - PANIC DISORDER WITH AGORAPHOBIA

26. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

	27.	28.
Onset	___	___
Offset	___	___
Weeks	___	___

DIAGNOSTIC CRITERIA - AGORAPHOBIA WITHOUT HISTORY OF PANIC DISORDER

29. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

	30.	31.
Onset	___	___
Offset	___	___
Weeks	___	___

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KIDDIE-SADS-LIFETIME - SCORING FORM

SOCIAL PHOBIA

1. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

DIAGNOSTIC CRITERIA - SOCIAL PHOBIA

2. Onset and Course

Number of Episodes [ ]

Ages of onset and offset of each episode

3. Onset [ ]
Offset [ ]
Weeks [ ]

4. Onset [ ]
Offset [ ]
Weeks [ ]

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KIDDIE-SADS-LIFETIME - SCORING FORM

OBSESSIONS OR COMPULSIONS

OBSESSIONS

1.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX

COMPULSIONS

2.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
3.	***Touching*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD		
4.	***Counting*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD		
5.	***Washing*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD		
6.	***Checking*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD		
7.	***Collecting*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD		
8.	***Arranging*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD		
9.	***Other*** Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD		

DEPERSONALIZATION OR DEREALIZATION

10.	Lifetime:	(0) NI	(1) NO	(2) FLT	(3) OCC	(4) SVL	(5) MRK	(6) PQT

DIAGNOSTIC CRITERIA - OBSESSIVE-COMPULSIVE DISORDER

11. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

12.	Onset ___	13.	Onset ___
	Offset ___		Offset ___
	Weeks ___		Weeks ___

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KIDDIE-SADS-LIFETIME - SCORING FORM

GENERALIZED ANXIETY DISORDER

WORRY

1. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

2. Lifetime: [(0) NI] [(1) NO] [(2) DBT] [(3) MLD] [(4) MOD]

DIFFICULTY CONTROLLING WORRIES

3. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

SYMPTOMS ASSOCIATED WITH WORRY

4. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

DIAGNOSTIC CRITERIA - GENERALIZED ANXIETY DISORDER

5. Onset and Course

Number of Episodes [ ]

Ages of onset and offset of each episode

6. Onset [ ]
Offset [ ]
Weeks [ ]

7. Onset [ ]
Offset [ ]
Weeks [ ]

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KIDDIE-SADS-LIFETIME - SCORING FORM

POST-TRAUMATIC STRESS DISORDER

TRAUMA TO OTHERS

1. Lifetime: [(0) NI] [(1) NO] [(2)] [(3)] [(4)] [(5)] [(6)]

TRAUMATIC TO SELF

2. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR]

INTRUSIVE RECOLLECTIONS OF TRAUMA

3. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

RECURRENT DISTRESSING DREAMS

4. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

SENSE OF RELIVING TRAUMA AND INTENSE DISTRESS AT RE-EXPERIENCE

5. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

PHYSIOLOGICAL REACTION UPON EXPOSURE

6. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

THOUGHTS, FEELINGS, CONVERSATIONS, ACTIVITIES, PLACES OF PEOPLE

7. Lifetime: [(0) NI] [(1) NO] [(2) YES]

NO RECALL OF IMPORTANT ASPECTS OF TRAUMA

8. Lifetime: [(0) NI] [(1) NO] [(2) YES]

MARKEDLY REDUCED ACTIVITIES/INTEREST

9. Lifetime: [(0) NI] [(1) NO] [(2) YES]

DETACHMENT, ENSTRANGEMENT, RESTRICTED AFFECT

10. Lifetime: [(0) NI] [(1) NO] [(2) YES]

SENSE OF FORESHORTENED FUTURE

11. Lifetime: [(0) NI] [(1) NO] [(2) YES]

SLEEP PROBLEMS

12. Lifetime: [(0) NI] [(1) NO] [(2) YES]

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KIDDIE-SADS-LIFETIME - SCORING FORM

IRRITABILITY

13. Lifetime: [(0) NI] [(1) NO] [(2) YES]

DIFFICULTY CONCENTRATING

14. Lifetime: [(0) NI] [(1) NO] [(2) YES]

HYPERVIGILENCE

15. Lifetime: [(0) NI] [(1) NO] [(2) YES]

EXAGGERATED STARTLED RESPONSE

16. Lifetime: [(0) NI] [(1) NO] [(2) YES]

OVERALL SEVERITY OF POST-TRAUMATIC STRESS DISORDER

17. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EXT]

DIAGNOSTIC CRITERIA - POST-TRAUMATIC STRESS DISORDER

18. Onset and Course

Number of Episodes [ ]

Ages of onset and offset of each episode

19. Onset [ ] Offset [ ] Weeks [ ]

20. Onset [ ] Offset [ ] Weeks [ ]

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KIDDIE-SADS-LIFETIME - SCORING FORM

ATTENTION-DEFICIT/HYPERACTIVITY DISORDER

INATTENTION

1. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

HYPERACTIVITY

2. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

IMPULSIVITY

3. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

DIAGNOSTIC CRITERIA - ATTENTION-DEFICIT/HYPERACTIVITY DISORDER

4. Onset and Course

Number of Episodes [ ]

Ages of onset and offset of each episode

5. Onset [ ] Offset [ ] Weeks [ ]

6. Onset [ ] Offset [ ] Weeks [ ]

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KIDDIE-SADS-LIFETIME - SCORING FORM

CONDUCT DISORDER/ANTISOCIAL PERSONALITY

CHRONIC VIOLATION OF RULES AT HOME AND/OR SCHOOL

1. Lifetime: [(0) NI] [(1) NO] [(2)] [(3)] [(4)]

SCHOOL SUSPENSION/EXPULSION

2. Lifetime: [(0) NI] [(1) NO] [(2) -1] [(3) 1+] [(4) EXP]

TRUANCY

3. Lifetime: [(0) NI] [(1) NO] [(2) OCC] [(3) FQT] [(4) 50%]

PATHOLOGICAL LYING

4. Lifetime: [(0) NI] [(1) NO] [(2)] [(3)] [(4)]

STAYING OUT AT NIGHT

5. Lifetime: [(0) NI] [(1) NO] [(2)] [(3)] [(4)]

RUNAWAY OVERNIGHT

6. Lifetime: [(0) NI] [(1) NO] [(2) 1] [(3) 1+] [(4) FQT]

NONAGGRESIVE STEALING

7. Lifetime: [(0) NI] [(1) NO] [(2)] [(3) $10] [(4) $50]

BULLYING

8. Lifetime: [(0) NI] [(1) NO] [(2)] [(3) FQT] [(4) DLY]

PERSISTENT PHYSICAL FIGHTING

9. Lifetime: [(0) NI] [(1) NO] [(2)] [(3) FQT] [(4)]

USE OF A WEAPON

10. Lifetime: [(0) NI] [(1) NVR] [(2) CON] [(3) 1] [(4) 1+]

VANDALISM

11. Lifetime: [(0) NI] [(1) NO] [(2)] [(3)] [(4)]

FIRESETTING

12. Lifetime: [(0) NI] [(1) NO] [(2)] [(3)] [(4)]

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KIDDIE-SADS-LIFETIME - SCORING FORM

BREAKING AND ENTERING

13. Lifetime: [(0) NI] [(1) NO] [(2) -1] [(3) 2] [(4) 2+]

AGGRESSIVE STEALING

14. Lifetime: [(0) NI] [(1) NO] [(2) -1] [(3) 2] [(4) 2+]

CRUELTY TO ANIMALS

15. Lifetime: [(0) NI] [(1) NO] [(2) OCC] [(3)] [(4)]

PHYSICAL CRUELTY TO PERSONS

16. Lifetime: [(0) NI] [(1) NO] [(2) -1] [(3) 2] [(4) 2+]

HOMICIDAL ACTS

17. Lifetime: [(0) NI] [(1) NO] [(2) GTR] [(3) ATT] [(4) COM]

FORCED SEX

18. Lifetime: [(0) NI] [(1) NO] [(2)] [(3)] [(4)] [(5) RAP]

GANG ACTIVITIES

19. Lifetime: [(0) NI] [(1) NO] [(2) PER] [(3) MEM] [(4) LDR]

DELINQUENCY

20. Lifetime: [(0) NI] [(1) NO] [(2) ARR] [(3) CHA] [(4) CON]

INCARCERATION

21. Lifetime: [(0) NI] [(1) NO] [(2) HLD] [(3) REF] [(4) JAL]

SUMMARY RATING

22. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

DIAGNOSTIC CRITERIA - CONDUCT DISORDER

23. Onset and Course

Number of Episodes [ ]

Ages of onset and offset of each episode

24. Onset [ ]
Offset [ ]
Weeks [ ]

25. Onset [ ]
Offset [ ]
Weeks [ ]

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KIDDIE-SADS-LIFETIME - SCORING FORM

ANTISOCIAL PERSONALITY DISORDER

WORK

1. Lifetime: [0] NI [1] NO [2] MLD [3] MOD [4] SVR [5] EX

FINANCIAL RESPONSIBILITY

2. Lifetime: [0] NI [1] NO [2] MLD [3] MOD [4] SVR [5] EX

CONNING

3. Lifetime: [0] NI [1] MLD [2] MOD [3] SVR [4] EX

DISREGARD FOR SAFETY OF SELF/OTHERS

4. Lifetime: [0] NI [1] MLD [2] MOD [3] EX

LACK OF REMORSE

5. Lifetime: [0] NI [1] MLD [2] MOD [3] EX

DIAGNOSTIC CRITERIA - ANTISOCIAL PERSONALITY DISORDER

6. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

7. Onset ___ Offset ___ Weeks ___

8. Onset ___ Offset ___ Weeks ___

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KIDDIE-SADS-LIFETIME - SCORING FORM

OPPOSITIONAL DEFIANT DISORDER

1. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

DIAGNOSTIC CRITERIA - OPPOSITIONAL DEFIANT DISORDER

2. Onset and Course

Number of Episodes [ ]

Ages of onset and offset of each episode

3. Onset [ ]
   Offset [ ]
   Weeks [ ]

4. Onset [ ]
   Offset [ ]
   Weeks [ ]

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KIDDIE-SADS-LIFETIME - SCORING FORM

ALCOHOL

ALCOHOL ABUSE

1. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

ALCOHOL DEPENDENCE

2. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MO] [(5) SVR] [(6) EX]

DIAGNOSTIC CRITERIA - ALCOHOL DEPENDENCE

3. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

4. Onset ___ Offset ___ Weeks ___

5. Onset ___ Offset ___ Weeks ___

DIAGNOSTIC CRITERIA - ALCOHOL ABUSE

6. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

7. Onset ___ Offset ___ Weeks ___

8. Onset ___ Offset ___ Weeks ___

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KIDDIE-SADS-LIFETIME - SCORING FORM

DRUGS

DRUG ABUSE

1. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

DRUG DEPENDENCE

2. Lifetime: [0] NI [1] NO [2] MLD [3] MOD [4] SVR [5] EX

DIAGNOSTIC CRITERIA - SUBSTANCE DEPENDENCE

3. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

4. Onset ___ Offset ___ Weeks ___

5. Onset ___ Offset ___ Weeks ___

DIAGNOSTIC CRITERIA - SUBSTANCE ABUSE

6. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

7. Onset ___ Offset ___ Weeks ___

8. Onset ___ Offset ___ Weeks ___

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KIDDIE-SADS-LIFETIME - SCORING FORM

TIC DISORDERS

MOTOR TICS

1. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

VOCAL TICS

2. Lifetime: [0] NI [1] NO [2] SLT [3] MLD [4] MO [5] SVR [6] EX

DIAGNOSTIC CRITERIA - TIC DISORDERS

3. Onset and Course

Number of Episodes ___

Ages of onset and offset of each episode

4. Onset ___ Offset ___ Weeks ___

5. Onset ___ Offset ___ Weeks ___

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KIDDIE-SADS-LIFETIME - SCORING FORM

PSYCHOTIC SYMPTOMOLOGY

COMMAND HALLUCINATIONS

1. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

CONVERSING VOICES

2. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

PERSECUTORY HALLUCINATIONS

3. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

COMMENTING VOICE

4. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

RELIGIOUS HALLUCINATIONS

5. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

THOUGHTS ALOUD

6. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

OTHER VERBAL HALLUCINATIONS

7. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

LOCATION OF AUDITORY HALLUCINATIONS

8. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

9. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

10. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

VISUAL HALLUCINATIONS

11. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

TACTILE HALLUCINATIONS

12. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

OLFACTORY HALLUCINATIONS

13. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

14. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

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KIDDIE-SADS-LIFETIME - SCORING FORM

OTHER PERCEPTUAL CHILDHOOD PHENOMENA

HYPNAGOGIC OR HYPNAPOMPIC HALLUCINATIONS

1. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]
2. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]
3. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

ILLUSIONS

4. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

EIDETIC IMAGERY

5. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

ELABORATED FANTASIES

6. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

IMAGINARY COMPANIONS

7. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

CHARACTERISTICS OF PSYCHOPATHOLOGICALLY MEANINGFUL HALLUCINATIONS

FREQUENCY

8. Lifetime: [(0) NI] [(1) NO] [(2) SUS] [(3) -5] [(4) SOM] [(5) LOT] [(6) DLY]

SEVERITY

9. Lifetime: [(0) NI] [(1) NO] [(2) SUS] [(3) DEF] [(4) GEN] [(5) CNV] [(6) ACT]

THEMATIC CONSISTENCY WITH MOOD DISORDER

DEPRESSION

10. Lifetime: [(0) NI] [(1) NO] [(2) POS] [(3) COM]

MANIA

11. Lifetime: [(0) NI] [(1) NO] [(2) POS] [(3) COM]

TEMPORAL CONSISTENCY WITH MOOD DISORDER

DEPRESSION

12. Lifetime: [(0) NI] [(1) NO] [(2) SUS] [(3) POS]

MANIA

13. Lifetime: [(0) NI] [(1) NO] [(2) SUS] [(3) POS]

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KIDDIE-SADS-LIFETIME - SCORING FORM

DELUSIONS

DELUSIONS OF REFERENCE

1. Lifetime: [0] NI [1] ABS [2] NON [3] SUS [4] DEF

DELUSIONS OF BEING CONTROLLED OR INFLUENCED

2. Lifetime: [0] NI [1] ABS [2] NON [3] SUS [4] DEF

DELUSIONS THAT PEOPLE CAN READ HIS MIND

3. Lifetime: [0] NI [1] ABS [2] NON [3] SUS [4] DEF

THOUGHT BROADCASTING

4. Lifetime: [0] NI [1] ABS [2] NON [3] SUS [4] DEF

THOUGHT INSERTION

5. Lifetime: [0] NI [1] ABS [2] NON [3] SUS [4] DEF

THOUGHT WITHDRAWAL

6. Lifetime: [0] NI [1] ABS [2] NON [3] SUS [4] DEF

DELUSIONS OF GUILT OR SIN

7. Lifetime: [0] NI [1] ABS [2] NON [3] SUS [4] DEF

DELUSIONS OF INFLUENCE

8. Lifetime: [0] NI [1] ABS [2] NON [3] SUS [4] DEF

PERSECUTORY DELUSIONS

9. Lifetime: [0] NI [1] ABS [2] NON [3] SUS [4] DEF

GUILT RELATED PERSECUTORY DELUSIONS

10. Lifetime: [0] NI [1] ABS [2] NON [3] SUS [4] DEF

SOMATIC DELUSIONS

11. Lifetime: [0] NI [1] ABS [2] NON [3] SUS [4] DEF

GUILT RELATED SOMATIC DELUSIONS

12. Lifetime: [0] NI [1] ABS [2] NON [3] SUS [4] DEF

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KIDDIE-SADS-LIFETIME - SCORING FORM

NIHILISTIC DELUSIONS

13. Lifetime: [(0) NI] [(1) ABS] [(2) NON] [(3) SUS] [(4) DEF]

GUILT RELATED NIHILISTIC DELUSIONS

14. Lifetime: [(0) NI] [(1) ABS] [(2) NON] [(3) SUS] [(4) DEF]

GRANDIOSE DELUSIONS

15. Lifetime: [(0) NI] [(1) ABS] [(2) NON] [(3) SUS] [(4) DEF]

SUBCULTURAL OR FAMILY DELUSIONS

16. Lifetime: [(0) NI] [(1) DEF] [(2) LIK] [(3) ALL]

SEVERITY OF DELUSIONS OF ANY TYPE

17. Lifetime: [(0) NI] [(1) NO] [(2) SUS] [(3) PST] [(4) GEN] [(5) SIG] [(6) ACT]

SENSORIUM WHILE DELUDED

18. Lifetime: [(0) NI] [(1) DEL] [(2) PLX] [(3) ALW]

THEMATIC CONSISTENCY WITH MOOD DISORDER

DEPRESSION

19. Lifetime: [(0) NI] [(1) NO] [(2) POSS] [(3) COM]

MANIA

20. Lifetime: [(0) NI] [(1) NO] [(2) POSS] [(3) COM]

TEMPORAL CONSISTENCY WITH MOOD DISORDER

DEPRESSION

21. Lifetime: [(0) NI] [(1) NO] [(2) SUS] [(3) POS]

MANIA

22. Lifetime: [(0) NI] [(1) NO] [(2) SUS] [(3) POS]

BIZARRENESS OF DELUSIONAL CONTENT

23. Lifetime: [(0) NI] [(1) NO] [(2) SLT] [(3) MLD] [(4) MOD] [(5) SVR] [(6) EX]

MULTIPLE DELUSIONS

24. Lifetime: [(0) NI] [(1) ABS] [(2) SUS] [(3) DEF]

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KIDDIE-SADS-LIFETIME - SCORING FORM

FORMAL THOUGHT DISORDER

SENTENCE INCOHERENCE

1.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
2.	Observed:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

DERAILMENT

3.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
4.	Observed:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

ILLOGICAL THINKING

5.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
6.	Observed:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

POVERTY OF CONTENT OF SPEECH

7.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
8.	Observed:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

NEOLOGISMS

9.	Lifetime:	(0) NI	(1) ABS	(2) SLT	(3) MLD	(4) MOD	(5) 20%	(6) JAR
10.	Observed:	(0) NI	(1) ABS	(2) SLT	(3) MLD	(4) MOD	(5) 20%	(6) JAR

PRESSURE OF SPEECH

11.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
12.	Observed:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

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KIDDIE-SADS-LIFETIME - SCORING FORM

OBSERVATIONAL ITEMS

INAPPROPRIATE AFFECT

1.	Observed:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

BLUNTED AFFECT

2.	Observed:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX

CATATONIC MOTOR BEHAVIOR

3.	Observed:	(0) NI	(1) ABS	(2) DBT	(3) MM	(4) SVR		
4.	Observed:	(0) NI	(1) ABS	(2) DBT	(3) MM	(4) SVR		
5.	Observed:	(0) NI	(1) ABS	(2) DBT	(3) MM	(4) SVR		
6.	Observed:	(0) NI	(1) ABS	(2) DBT	(3) MM	(4) SVR		
7.	Observed:	(0) NI	(1) ABS	(2) DBT	(3) MM	(4) SVR		

BIZARRENESS

8.	Observed:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
9.	Observed:	(0) NI	(1) ABS	(2) DBT	(3) PST	(4) SVR		
10.	Observed:	(0) NI	(1) ABS	(2) DBT	(3) PST	(4) SVR		
11.	Observed:	(0) NI	(1) ABS	(2) DBT	(3) PST	(4) SVR		
12.	Observed:	(0) VG	(1) G	(2) OF	(3) P	(4) VP		

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KIDDIE-SADS-LIFETIME - SCORING FORM

DIAGNOSTIC CRITERIA - SCHIZOPHRENIA

1. Onset and Course

   Number of Episodes ___

   Ages of onset and offset of each episode

2. Onset ___ Offset ___ Weeks ___

3. Onset ___ Offset ___ Weeks ___

DIAGNOSTIC CRITERIA - SCHIZOAFFECTIVE DISORDER

4. Onset and Course

   Number of Episodes ___

   Ages of onset and offset of each episode

5. Onset ___ Offset ___ Weeks ___

6. Onset ___ Offset ___ Weeks ___

DIAGNOSTIC CRITERIA - BRIEF PSYCHOTIC DISORDER

7. Onset and Course

   Number of Episodes ___

   Ages of onset and offset of each episode

8. Onset ___ Offset ___ Weeks ___

9. Onset ___ Offset ___ Weeks ___

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KIDDIE-SADS-LIFETIME - SCORING FORM

DIAGNOSTIC CRITERIA - DELUSIONAL DISORDER

10. Onset and Course

Number of Episodes ⌊_ _⌋

Ages of onset and offset of each episode

11.		12.	
Onset	⌊_ _⌋	Onset	⌊_ _⌋
Offset	⌊_ _⌋	Offset	⌊_ _⌋
Weeks	⌊_ _ _⌋	Weeks	⌊_ _ _⌋

KIDDY-GAS (C-GAS)

1. Current Episode:	100-91	90-81	80-71	70-61	60-51	50-41	40-31	30-21	20-11	10-1
2. Last Two Weeks:	100-91	90-81	80-71	70-61	60-51	50-41	40-31	30-21	20-11	10-1

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LABORATORY TESTS

For SB	Lab Number Code

Sample Date ___ ___ ___ (day month year)

➧ Attach SBCL laboratory report behind this page.

➧ Are there CLINICALLY SIGNIFICANT ABNORMAL laboratory values?

☐ No
☐ Yes ⟶ Record the findings and/or diagnosis in the Adverse Experiences.

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STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No
☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(N^{\bigstar} \times \text{days since last visit})} \times 100$$

$^{\bigstar}N$ = number of capsules daily (see above)

➧ Compliance must be $\geq$ 80% and $\leq$ 120%.

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STUDY MEDICATION LABEL

Attach label here

Attach label here

Attach label here

Attach label here

➧ Enter patient number (drug code as listed on clinical supplies) _____

Important: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

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ELECTROCARDIOGRAM

Was electrocardiogram performed and sent to a central reader for interpretation?

☐ Yes ☐ No

Date Performed (day month year)

STUDY MEDICATION DISPENSING

Record study medication information for Down Titration in the Study Medication Record, page 401. Attach label to page 400. Record number of capsules dispensed on page 401.

Reminder: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

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MODULE PARAMETERS - DOWN TITRATION

For SmithKline Beecham Use	Project	*29060*
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ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?

☐ Yes ☐ No

Record in the Adverse Experience section

Has there been any change in concomitant medication since the last visit?

☐ Yes ☐ No

Record in the Concomitant Medication section

STUDY MEDICATION LABEL

Attach label here

➧ Enter patient number (drug code as listed on clinical supplies)

Important: The drug code on the study medication label ***must be identical*** to the preprinted Patient Number above.

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Down Titration		401

STUDY MEDICATION RECORD

Record the start and end date of each dose level as the patient is down titrated.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily

STUDY MEDICATION DOSING CHANGES

Have there been any investigator prescribed changes in study medication since the last visit?

☐ No

☐ Yes ⟶ Indicate change(s) below

Reminder: Changes in dose constitute deviation from the protocol.

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance

$$\text{Compliance} = \frac{\text{Number of capsules taken}}{(N^{\bigstar} \times \text{days since last visit})} \times 100$$

$^{\bigstar}N$ = number of capsules daily (see above)

➧ Compliance must be $\geq$ 80% and $\leq$ 120%.

SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	
29060	329	0 0		Continuation Phase	

MODULE PARAMETERS - CONCOMITANT MEDICATION

For SmithKline Beecham Use	Project	*29060*
	Protocol	*329*
	Center	
	Patient Number	
	Module Pages	*V2017*

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number		Page
29060	329	0 0			402

CONCOMITANT MEDICATION

- Record all concomitant medication taken since the Week 8 visit.
- Where appropriate, medical conditions should be recorded on the Adverse Experiences form utilizing the same terminology.

Drug Name (Trade name preferred)	Total Daily Dose (e.g., 500 mg)	Route	Medical Condition	Start Date ★ day month year	End Date ★ or Continuation (mark box) day month year	
						☐
For SB						
						☐
For SB						
						☐
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For SB						
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For SB						
						☐
For SB						
						☐
For SB						

★ State dates as precisely as possible.

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number		Page
29060	329	0 0			403

CONCOMITANT MEDICATION (CONTINUED)

Drug Name (Trade name preferred)	Total Daily Dose (e.g., 500 mg)	Route	Medical Condition	Start Date ★ day month year	End Date ★ or Continuation (mark box) day month year	
						☐
For SB						
						☐
For SB						
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For SB						
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For SB						

★ State dates as precisely as possible.

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number		Page
29060	329	0 0			404

CONCOMITANT MEDICATION (CONTINUED)

Drug Name (Trade name preferred)	Total Daily Dose (e.g., 500 mg)	Route	Medical Condition	Start Date ★ day month year	End Date ★ or Continuation (mark box) day month year	
						☐
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For SB						

★ State dates as precisely as possible.

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number		Page
29060	329	0 0			405

CONCOMITANT MEDICATION (CONTINUED)

Drug Name (Trade name preferred)	Total Daily Dose (e.g., 500 mg)	Route	Medical Condition	Start Date ★ day month year	End Date ★ or Continuation (mark box) day month year	
						☐
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For SB						

★ State dates as precisely as possible.

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number		Page
29060	329	0 0			406

CONCOMITANT MEDICATION (CONTINUED)

Drug Name (Trade name preferred)	Total Daily Dose (e.g., 500 mg)	Route	Medical Condition	Start Date ★ day month year	End Date ★ or Continuation (mark box) day month year	
						☐
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For SB						

★ State dates as precisely as possible.

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number		Page
29060	329	0 0			407

CONCOMITANT MEDICATION (CONTINUED)

Drug Name (Trade name preferred)	Total Daily Dose (e.g., 500 mg)	Route	Medical Condition	Start Date ★ day month year	End Date ★ or Continuation (mark box) day month year	
						☐
For SB						
						☐
For SB						
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For SB						
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For SB						
						☐
For SB						

★ State dates as precisely as possible.

SmithKline Beecham
Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	
29060	329	0 0		Continuation Phase	

MODULE PARAMETERS-ADVERSE EXPERIENCE

For SmithKline Beecham Use	Project	*29060*
	Protocol	*329*
	Center	
	Patient Number	
	Module Pages	*V2117*

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number		Page
29060	329	0 0			408

ADVERSE EXPERIENCE

▶ Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).

Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
Duration if less than 24 hours		hours minutes	hours minutes	hours minutes
Experience continuing		☐	☐	☐
Experience continuing at end of study		☐	☐	☐
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -	☐ Yes ☐ No -	☐ Yes ☐ No -
Intensity	1 Mild	☐	☐	☐
	2 Moderate	☐	☐	☐
	3 Severe	☐	☐	☐
Action Taken on Study Medication	1 None	☐	☐	☐
	2 Dose decreased	☐	☐	☐
	3 Dose increased	☐	☐	☐
	4 Drug stopped	☐	☐	☐
Suspected Relationship To Study Medication	1 Related	☐	☐	☐
	2 Possibly related	☐	☐	☐
	3 Probably unrelated	☐	☐	☐
	4 Unrelated	☐	☐	☐
Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Do you consider this a serious adverse experience by the definitions on previous page?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
▶ If yes, report experience to SB by telephone within 24 hours		AE Number	AE Number	AE Number
Investigator's Signature				▶ If patient died, complete Form D

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number		Page
29060	329	0 0			409

ADVERSE EXPERIENCE

▶ Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).

Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
Duration if less than 24 hours		hours minutes	hours minutes	hours minutes
Experience continuing		☐	☐	☐
Experience continuing at end of study		☐	☐	☐
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -	☐ Yes ☐ No -	☐ Yes ☐ No -
Intensity	1 Mild	☐	☐	☐
	2 Moderate	☐	☐	☐
	3 Severe	☐	☐	☐
Action Taken on Study Medication	1 None	☐	☐	☐
	2 Dose decreased	☐	☐	☐
	3 Dose increased	☐	☐	☐
	4 Drug stopped	☐	☐	☐
Suspected Relationship To Study Medication	1 Related	☐	☐	☐
	2 Possibly related	☐	☐	☐
	3 Probably unrelated	☐	☐	☐
	4 Unrelated	☐	☐	☐
Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Do you consider this a serious adverse experience by the definitions on previous page?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
▶ If yes, report experience to SB by telephone within 24 hours		AE Number	AE Number	AE Number
Investigator's Signature				▶ If patient died, complete Form D

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number		Page
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ADVERSE EXPERIENCE

▶ Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).

Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
Duration if less than 24 hours		hours minutes	hours minutes	hours minutes
Experience continuing		☐	☐	☐
Experience continuing at end of study		☐	☐	☐
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -	☐ Yes ☐ No -	☐ Yes ☐ No -
Intensity	1 Mild	☐	☐	☐
	2 Moderate	☐	☐	☐
	3 Severe	☐	☐	☐
Action Taken on Study Medication	1 None	☐	☐	☐
	2 Dose decreased	☐	☐	☐
	3 Dose increased	☐	☐	☐
	4 Drug stopped	☐	☐	☐
Suspected Relationship To Study Medication	1 Related	☐	☐	☐
	2 Possibly related	☐	☐	☐
	3 Probably unrelated	☐	☐	☐
	4 Unrelated	☐	☐	☐
Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Do you consider this a serious adverse experience by the definitions on previous page?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
▶ If yes, report experience to SB by telephone within 24 hours		AE Number	AE Number	AE Number
Investigator's Signature				▶ If patient died, complete Form D

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number		Page
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ADVERSE EXPERIENCE

▶ Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).

Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
Duration if less than 24 hours		hours minutes	hours minutes	hours minutes
Experience continuing		☐	☐	☐
Experience continuing at end of study		☐	☐	☐
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -	☐ Yes ☐ No -	☐ Yes ☐ No -
Intensity	1 Mild	☐	☐	☐
	2 Moderate	☐	☐	☐
	3 Severe	☐	☐	☐
Action Taken on Study Medication	1 None	☐	☐	☐
	2 Dose decreased	☐	☐	☐
	3 Dose increased	☐	☐	☐
	4 Drug stopped	☐	☐	☐
Suspected Relationship To Study Medication	1 Related	☐	☐	☐
	2 Possibly related	☐	☐	☐
	3 Probably unrelated	☐	☐	☐
	4 Unrelated	☐	☐	☐
Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Do you consider this a serious adverse experience by the definitions on previous page? ▶ If yes, report experience to SB by telephone within 24 hours		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
		AE Number	AE Number	AE Number
Investigator's Signature				▶ If patient died, complete Form D

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ADVERSE EXPERIENCE

▶ Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).

Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
Duration if less than 24 hours		hours minutes	hours minutes	hours minutes
Experience continuing		☐	☐	☐
Experience continuing at end of study		☐	☐	☐
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -	☐ Yes ☐ No -	☐ Yes ☐ No -
Intensity	1 Mild	☐	☐	☐
	2 Moderate	☐	☐	☐
	3 Severe	☐	☐	☐
Action Taken on Study Medication	1 None	☐	☐	☐
	2 Dose decreased	☐	☐	☐
	3 Dose increased	☐	☐	☐
	4 Drug stopped	☐	☐	☐
Suspected Relationship To Study Medication	1 Related	☐	☐	☐
	2 Possibly related	☐	☐	☐
	3 Probably unrelated	☐	☐	☐
	4 Unrelated	☐	☐	☐
Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Do you consider this a serious adverse experience by the definitions on previous page?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
▶ If yes, report experience to SB by telephone within 24 hours		AE Number	AE Number	AE Number
Investigator's Signature				▶ If patient died, complete Form D

SmithKline Beecham Pharmaceuticals

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ADVERSE EXPERIENCE

▶ Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).

Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
Duration if less than 24 hours		hours minutes	hours minutes	hours minutes
Experience continuing		☐	☐	☐
Experience continuing at end of study		☐	☐	☐
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -	☐ Yes ☐ No -	☐ Yes ☐ No -
Intensity	1 Mild	☐	☐	☐
	2 Moderate	☐	☐	☐
	3 Severe	☐	☐	☐
Action Taken on Study Medication	1 None	☐	☐	☐
	2 Dose decreased	☐	☐	☐
	3 Dose increased	☐	☐	☐
	4 Drug stopped	☐	☐	☐
Suspected Relationship To Study Medication	1 Related	☐	☐	☐
	2 Possibly related	☐	☐	☐
	3 Probably unrelated	☐	☐	☐
	4 Unrelated	☐	☐	☐
Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Do you consider this a serious adverse experience by the definitions on previous page?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
▶ If yes, report experience to SB by telephone within 24 hours		AE Number	AE Number	AE Number
Investigator's Signature				▶ If patient died, complete Form D

SmithKline Beecham Pharmaceuticals

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ADVERSE EXPERIENCE

➧ Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).

Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
Duration if less than 24 hours		hours minutes	hours minutes	hours minutes
Experience continuing		☐	☐	☐
Experience continuing at end of study		☐	☐	☐
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No - ☐☐	☐ Yes ☐ No - ☐☐	☐ Yes ☐ No - ☐☐
Intensity	1 Mild	☐	☐	☐
	2 Moderate	☐	☐	☐
	3 Severe	☐	☐	☐
Action Taken on Study Medication	1 None	☐	☐	☐
	2 Dose decreased	☐	☐	☐
	3 Dose increased	☐	☐	☐
	4 Drug stopped	☐	☐	☐
Suspected Relationship To Study Medication	1 Related	☐	☐	☐
	2 Possibly related	☐	☐	☐
	3 Probably unrelated	☐	☐	☐
	4 Unrelated	☐	☐	☐
Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Do you consider this a serious adverse experience by the definitions on previous page?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
➧ If yes, report experience to SB by telephone within 24 hours		AE Number	AE Number	AE Number
Investigator's Signature				➧ If patient died, complete Form D

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ADVERSE EXPERIENCE

Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).

Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
Duration if less than 24 hours		hours minutes	hours minutes	hours minutes
Experience continuing		☐	☐	☐
Experience continuing at end of study		☐	☐	☐
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -	☐ Yes ☐ No -	☐ Yes ☐ No -
Intensity	1 Mild	☐	☐	☐
	2 Moderate	☐	☐	☐
	3 Severe	☐	☐	☐
Action Taken on Study Medication	1 None	☐	☐	☐
	2 Dose decreased	☐	☐	☐
	3 Dose increased	☐	☐	☐
	4 Drug stopped	☐	☐	☐
Suspected Relationship To Study Medication	1 Related	☐	☐	☐
	2 Possibly related	☐	☐	☐
	3 Probably unrelated	☐	☐	☐
	4 Unrelated	☐	☐	☐
Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Do you consider this a serious adverse experience by the definitions on previous page?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
If yes, report experience to SB by telephone within 24 hours		AE Number	AE Number	AE Number
Investigator's Signature				If patient died, complete Form D

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number		Page
29060	329	0 0			416

ADVERSE EXPERIENCE

➧ Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).

Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
Duration if less than 24 hours		hours minutes	hours minutes	hours minutes
Experience continuing		☐	☐	☐
Experience continuing at end of study		☐	☐	☐
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -	☐ Yes ☐ No -	☐ Yes ☐ No -
Intensity	1 Mild	☐	☐	☐
	2 Moderate	☐	☐	☐
	3 Severe	☐	☐	☐
Action Taken on Study Medication	1 None	☐	☐	☐
	2 Dose decreased	☐	☐	☐
	3 Dose increased	☐	☐	☐
	4 Drug stopped	☐	☐	☐
Suspected Relationship To Study Medication	1 Related	☐	☐	☐
	2 Possibly related	☐	☐	☐
	3 Probably unrelated	☐	☐	☐
	4 Unrelated	☐	☐	☐
Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Do you consider this a serious adverse experience by the definitions on previous page?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
➧ If yes, report experience to SB by telephone within 24 hours		AE Number	AE Number	AE Number
Investigator's Signature				➧ If patient died, complete Form D

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number		Page
29060	329	0 0			417

ADVERSE EXPERIENCE

▶ Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).

Experience				
For SmithKline Beecham				
Date Started		day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
Duration if less than 24 hours		hours minutes	hours minutes	hours minutes
Experience continuing		☐	☐	☐
Experience continuing at end of study		☐	☐	☐
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -	☐ Yes ☐ No -	☐ Yes ☐ No -
Intensity	1 Mild	☐	☐	☐
	2 Moderate	☐	☐	☐
	3 Severe	☐	☐	☐
Action Taken on Study Medication	1 None	☐	☐	☐
	2 Dose decreased	☐	☐	☐
	3 Dose increased	☐	☐	☐
	4 Drug stopped	☐	☐	☐
Suspected Relationship To Study Medication	1 Related	☐	☐	☐
	2 Possibly related	☐	☐	☐
	3 Probably unrelated	☐	☐	☐
	4 Unrelated	☐	☐	☐
Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Do you consider this a serious adverse experience by the definitions on previous page?		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
▶ If yes, report experience to SB by telephone within 24 hours		AE Number	AE Number	AE Number
Investigator's Signature				▶ If patient died, complete Form D

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number		Page
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STUDY CONCLUSION

Did the patient complete the study as planned?

☐ Yes
☐ No

➧ If 'No', mark the ONE most appropriate category

1	☐ Adverse experience (complete Adverse Experience section)
2	☐ Lack of efficacy
3	☐ Deviation from protocol (including non-compliance)
4	☐ Lost to follow-up
6	☐ Termination by sponsor
7	☐ Other

Comments on reason for withdrawal:

Date of Last Visit ⌊_ _ _ _ _ _⌋
day month year

Date of Last Dose ⌊_ _ _ _ _ _⌋
day month year

I certify that I have reviewed the data on this case report form (pages 233-418) and that all information is complete and accurate.

Investigator's Signature _____ _____
Date

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	
29060	329	0 0		Continuation Phase	

MODULE PARAMETERS - STUDY CONCLUSION

For SmithKline Beecham Use	Project	* 2 9 0 6 0 *
	Protocol	* 3 2 9 *
	Center	
	Patient Number	
	Module Pages	* V 2 2 1 7 *

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Project	Protocol	Center		Page
29060	329	0 0		D

PATIENT LOG - CONTINUATION PHASE

Investigator ______________________________

Directions: Enter ALL patients who have been considered for the study and who have been interviewed. For patients not entering the Continuation Phase, note the reason for exclusion in the designated column.

Patient Initials	Initial Interview (day month year)	Reason for Exclusion

SmithKline Beecham Pharmaceuticals

Project	Protocol	Center		Page
29060	329	0 0		E

PATIENT ASSIGNMENT SHEET - CONTINUATION PHASE

Investigator _____ For SB Date ___ day ___ month ___ year

Directions: Do not enter the patient on the patient assignment sheet until he/she starts continuation phase medication.

Final Dose Status: C = Completed all treatment visits
W = Withdrawn prior to completing all treatment visits

	Patient Initials	Patient Number	Date of First Dose of Continuation Phase (day month year)	Date of Last Dose (day month year)	Status (C/W)
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					

Investigator CVs

CURRICULUM VITAE - [redacted]

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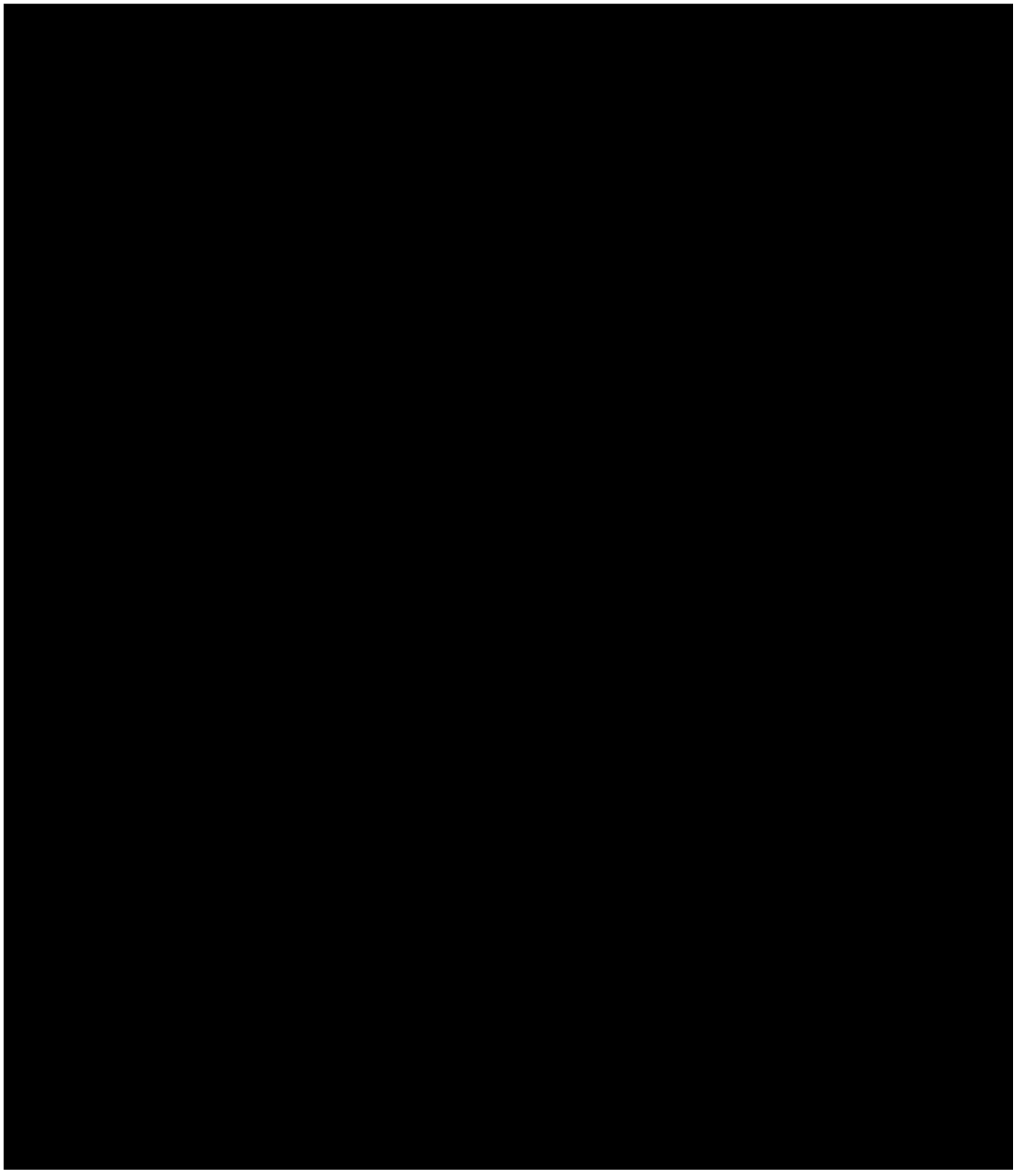

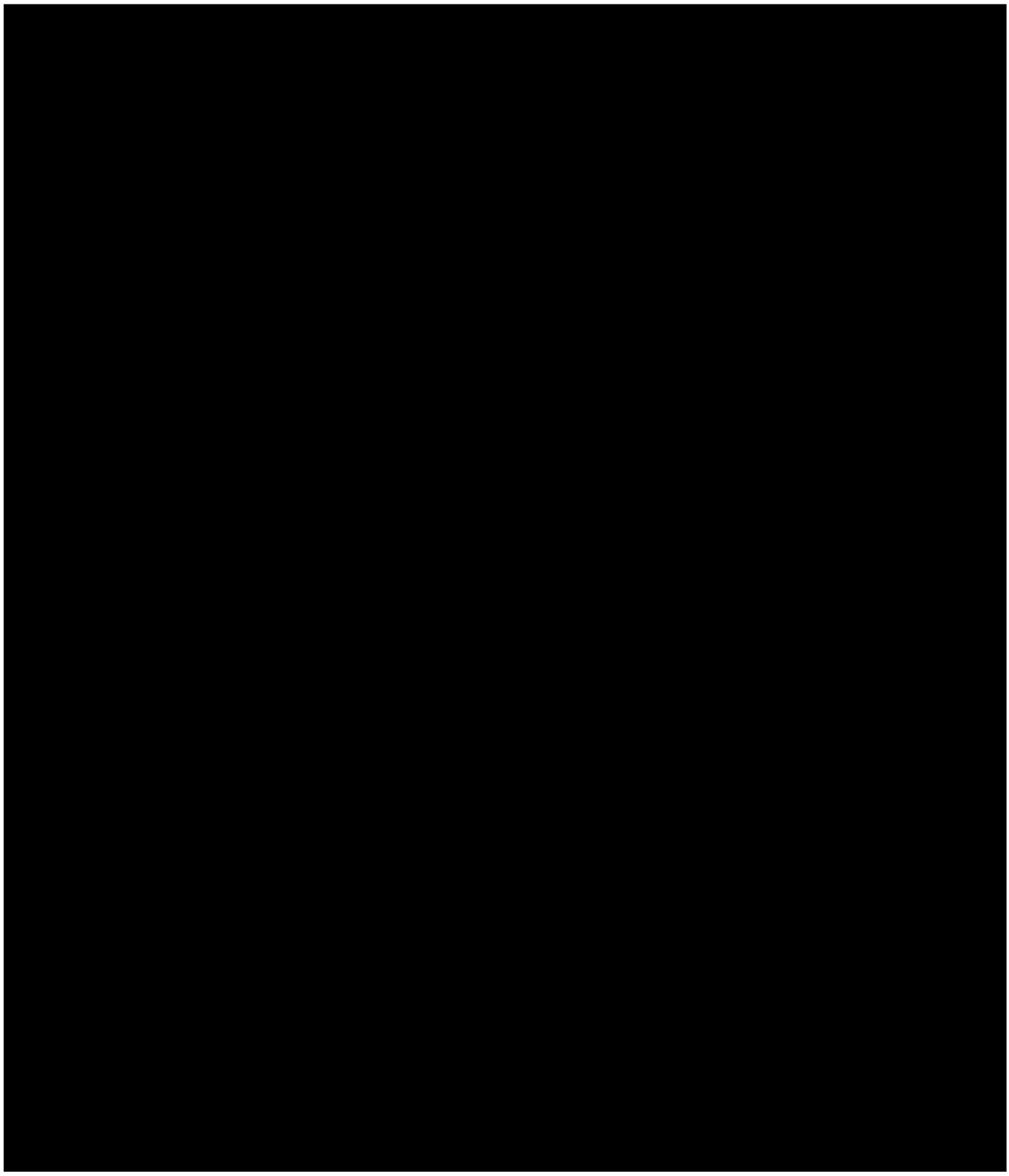

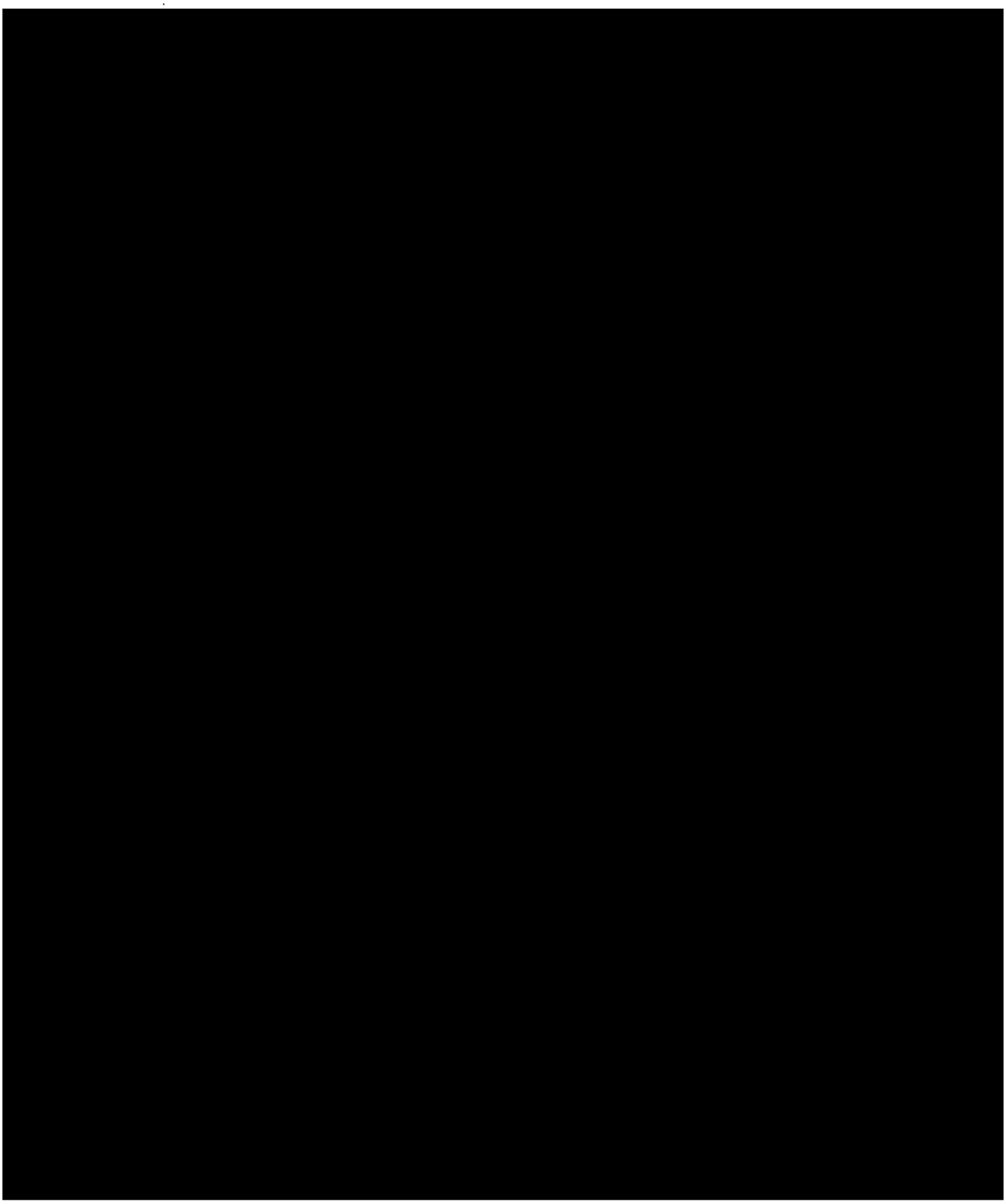

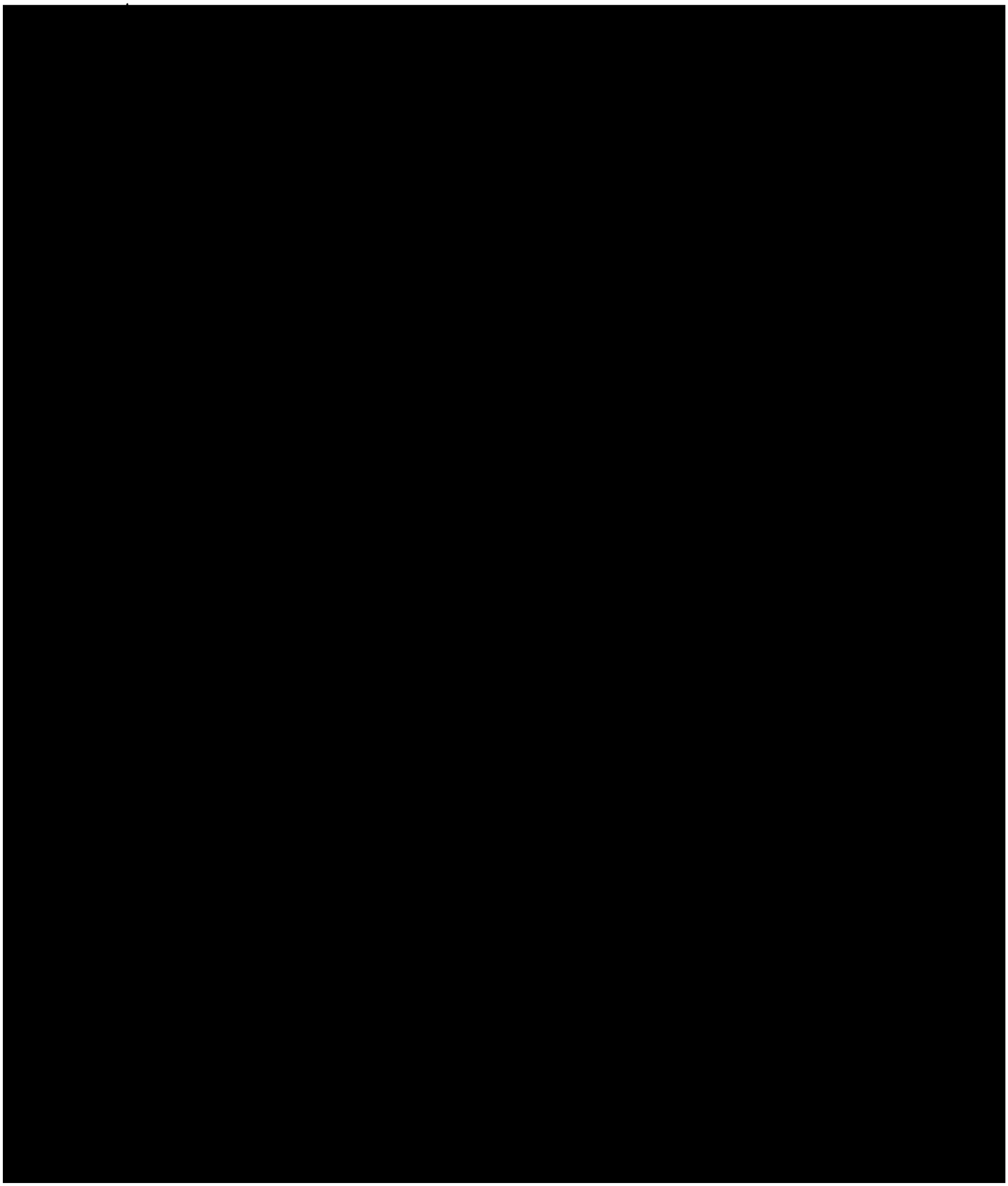

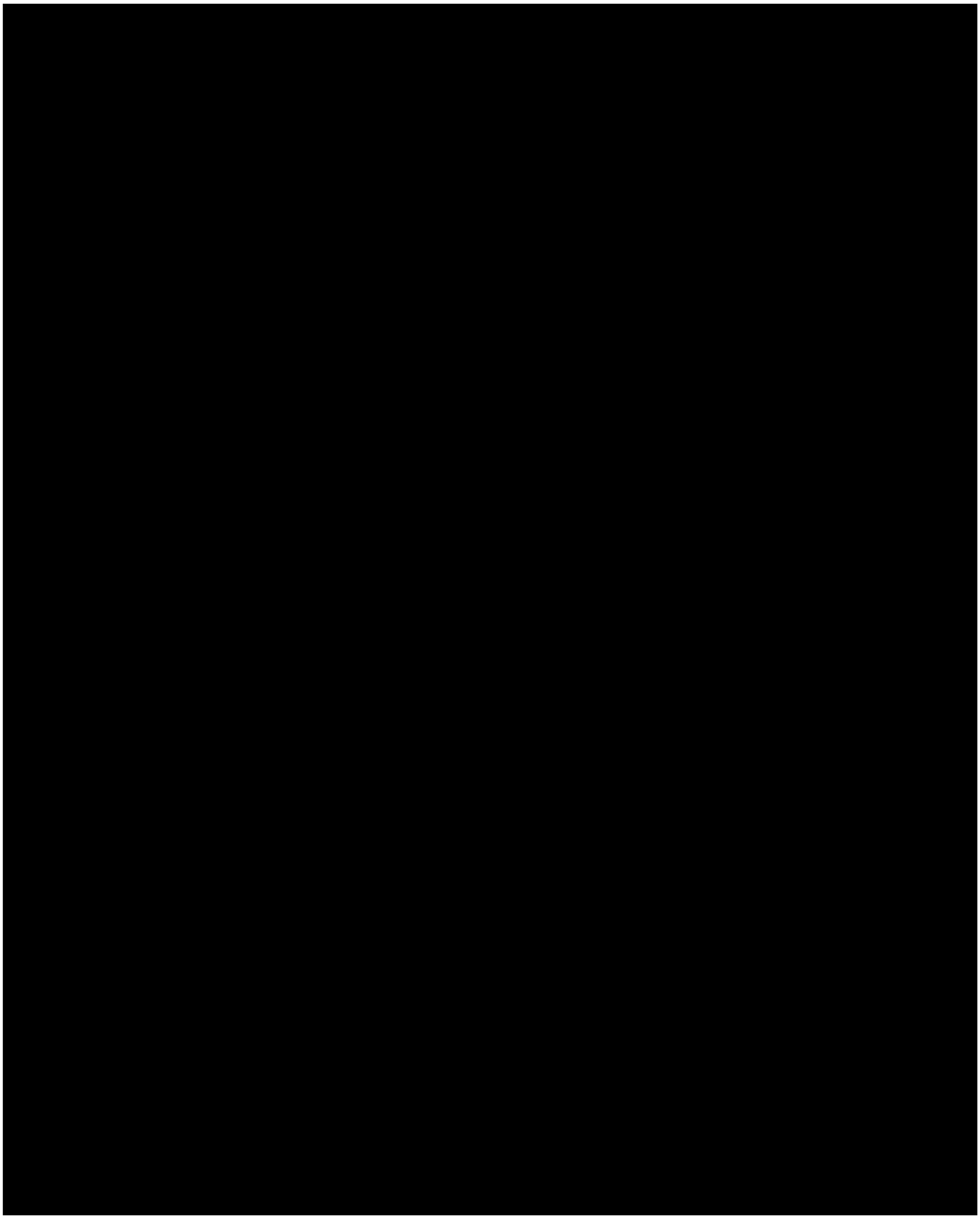

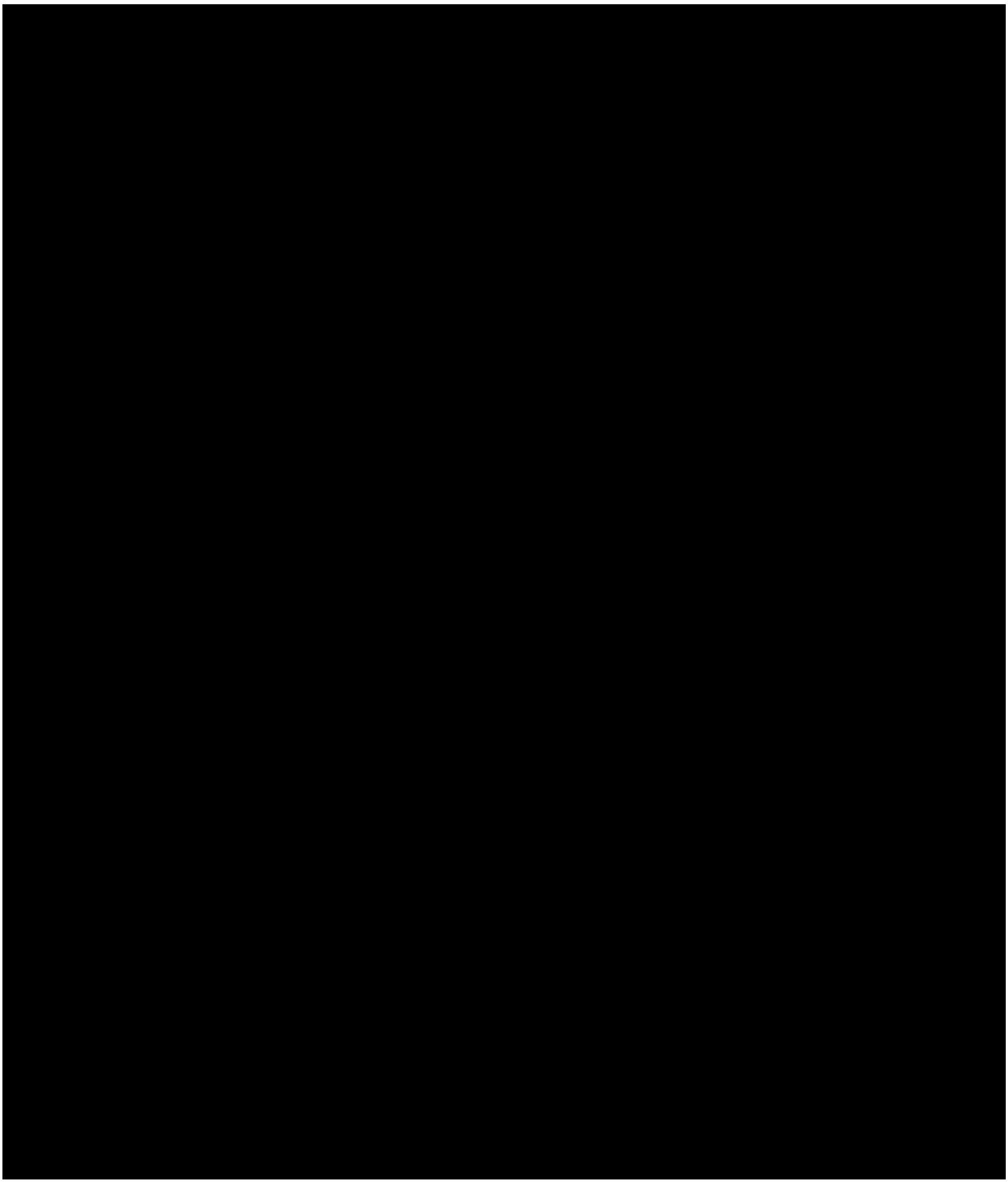

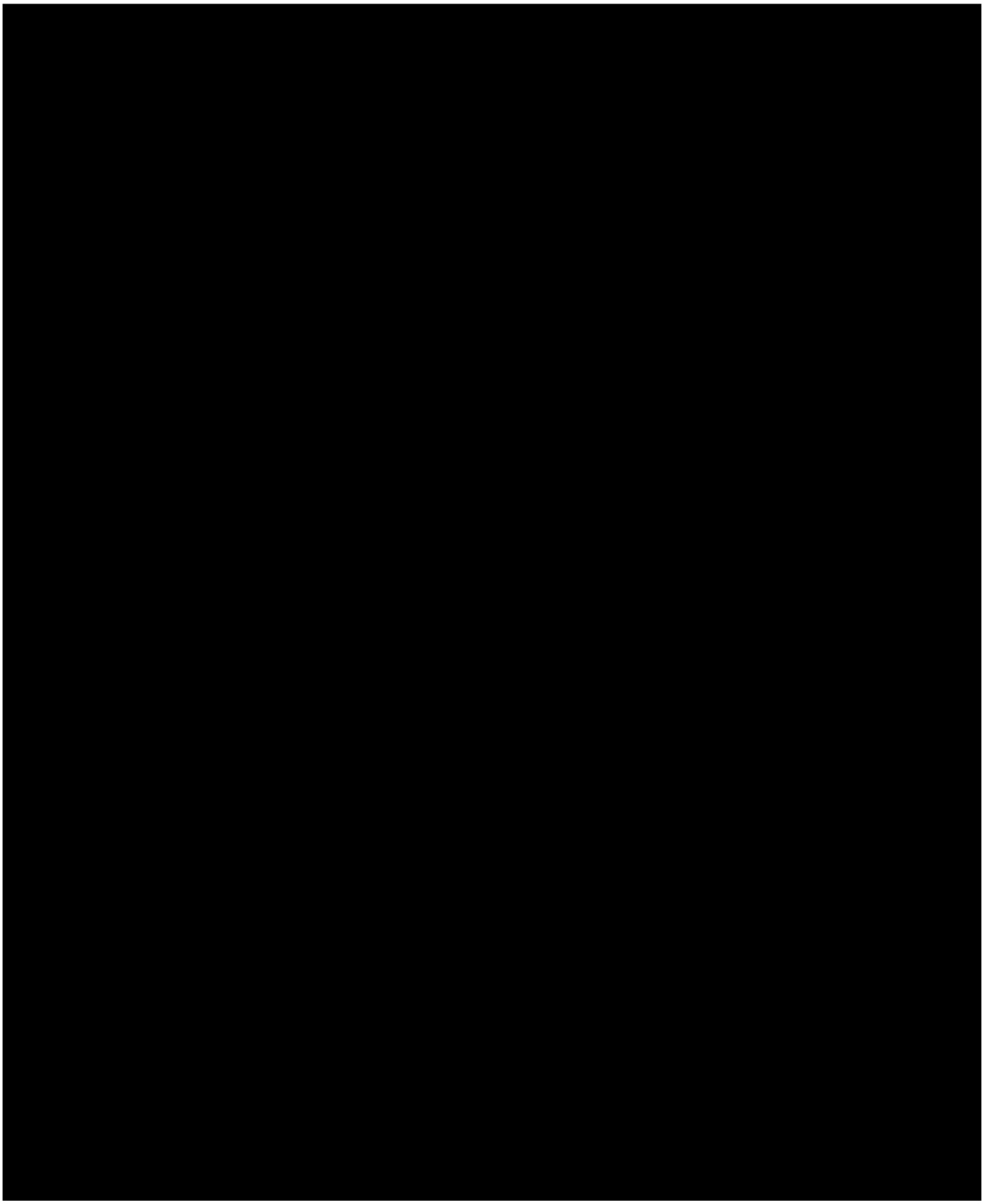

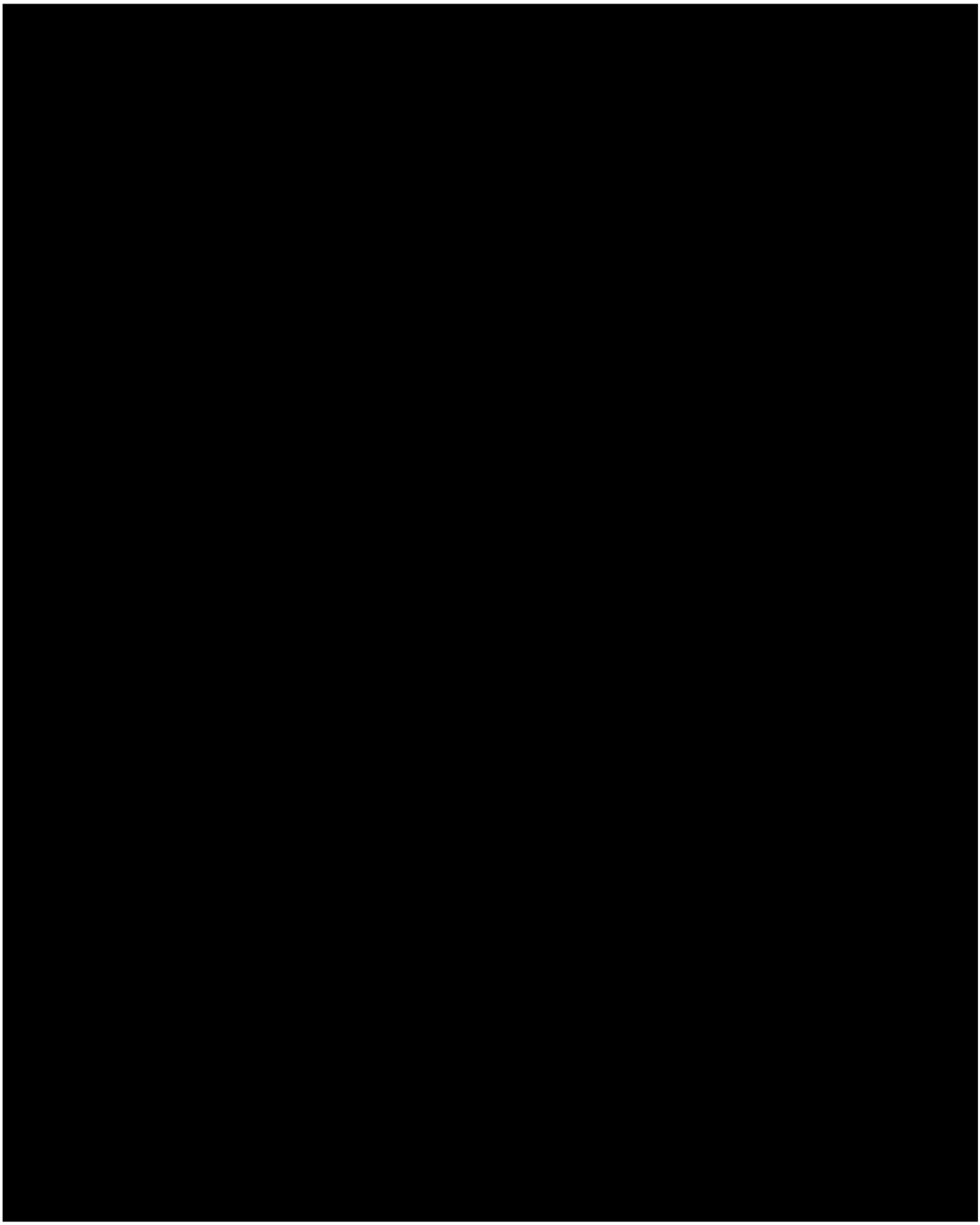

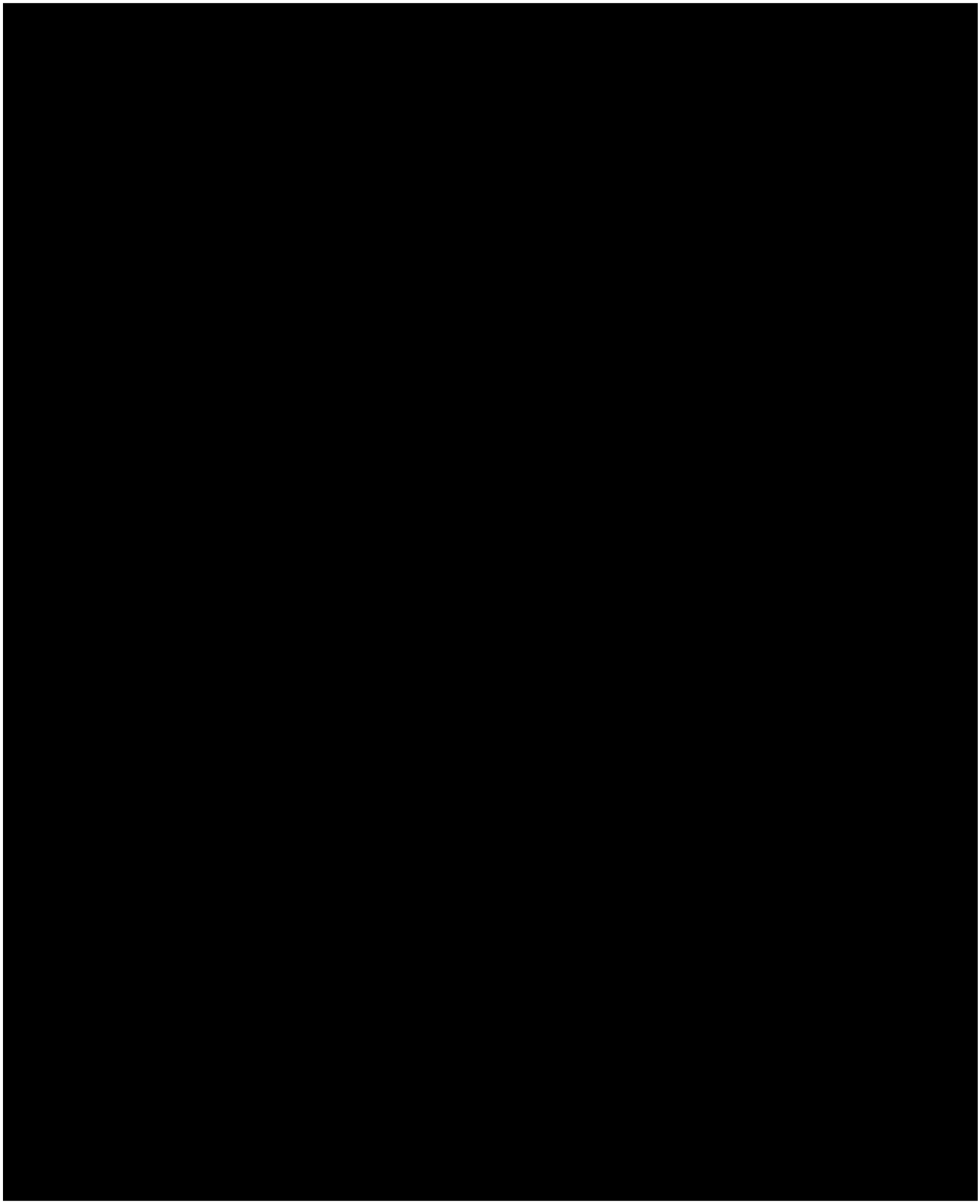

CURRICULUM VITAE

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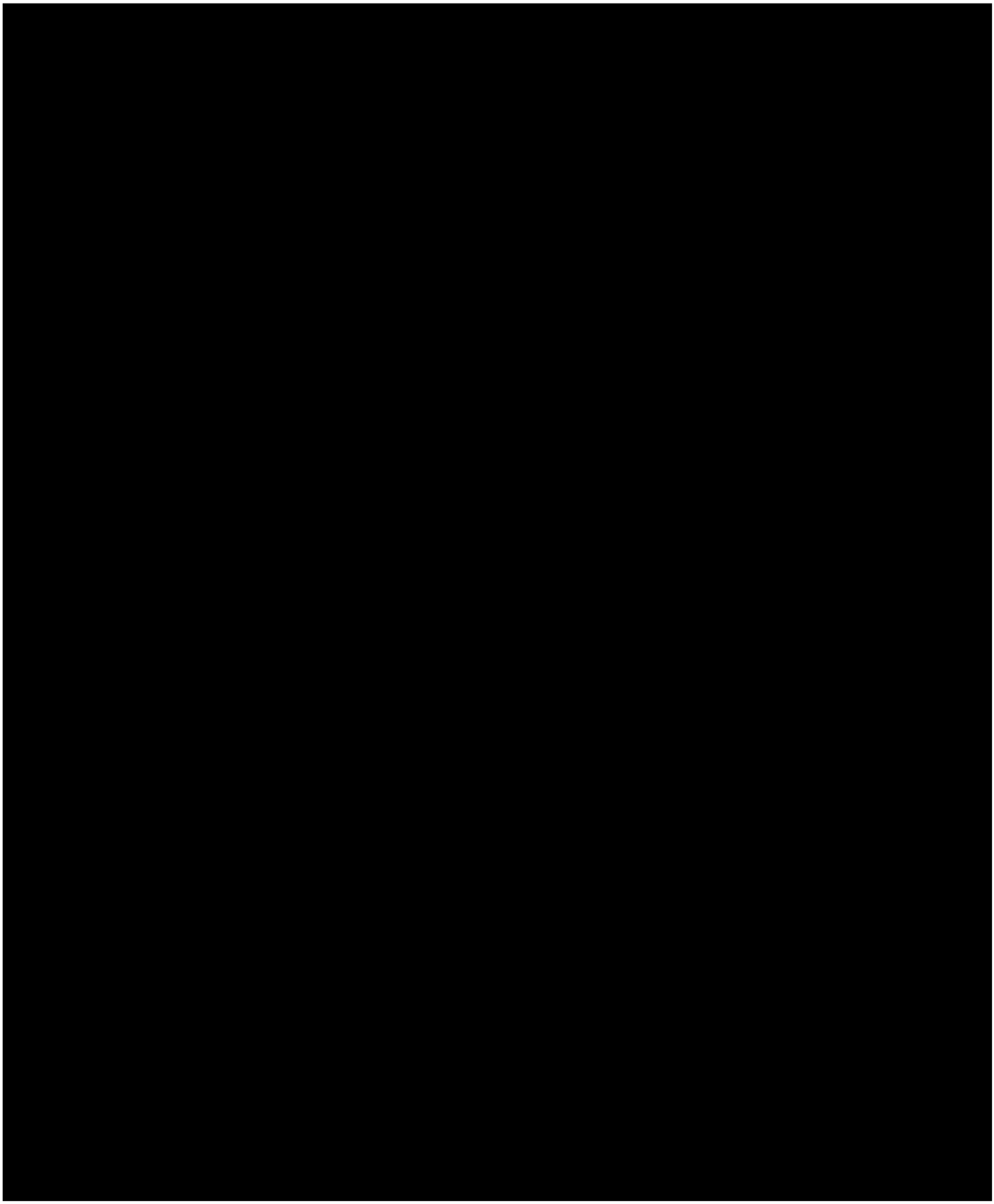

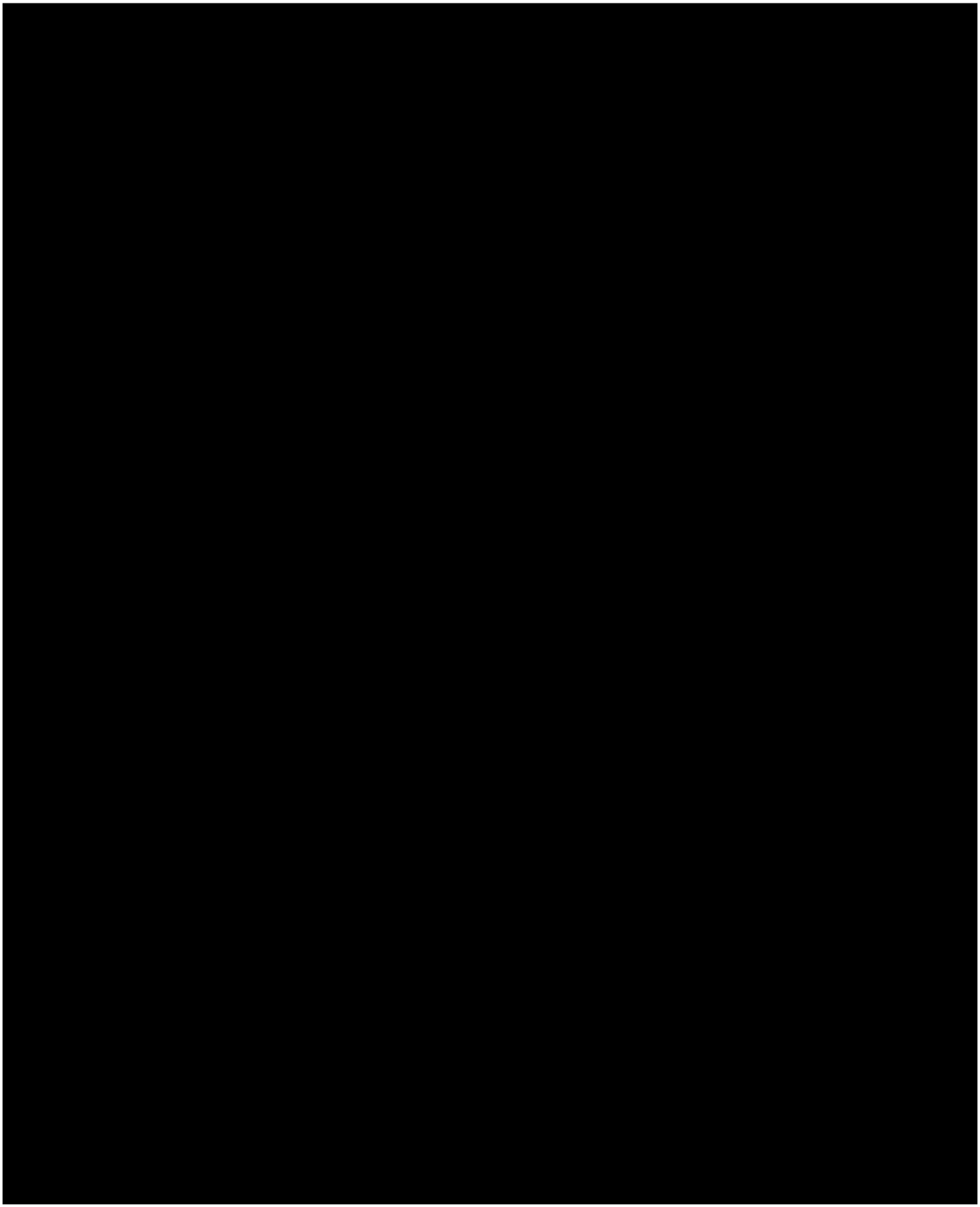

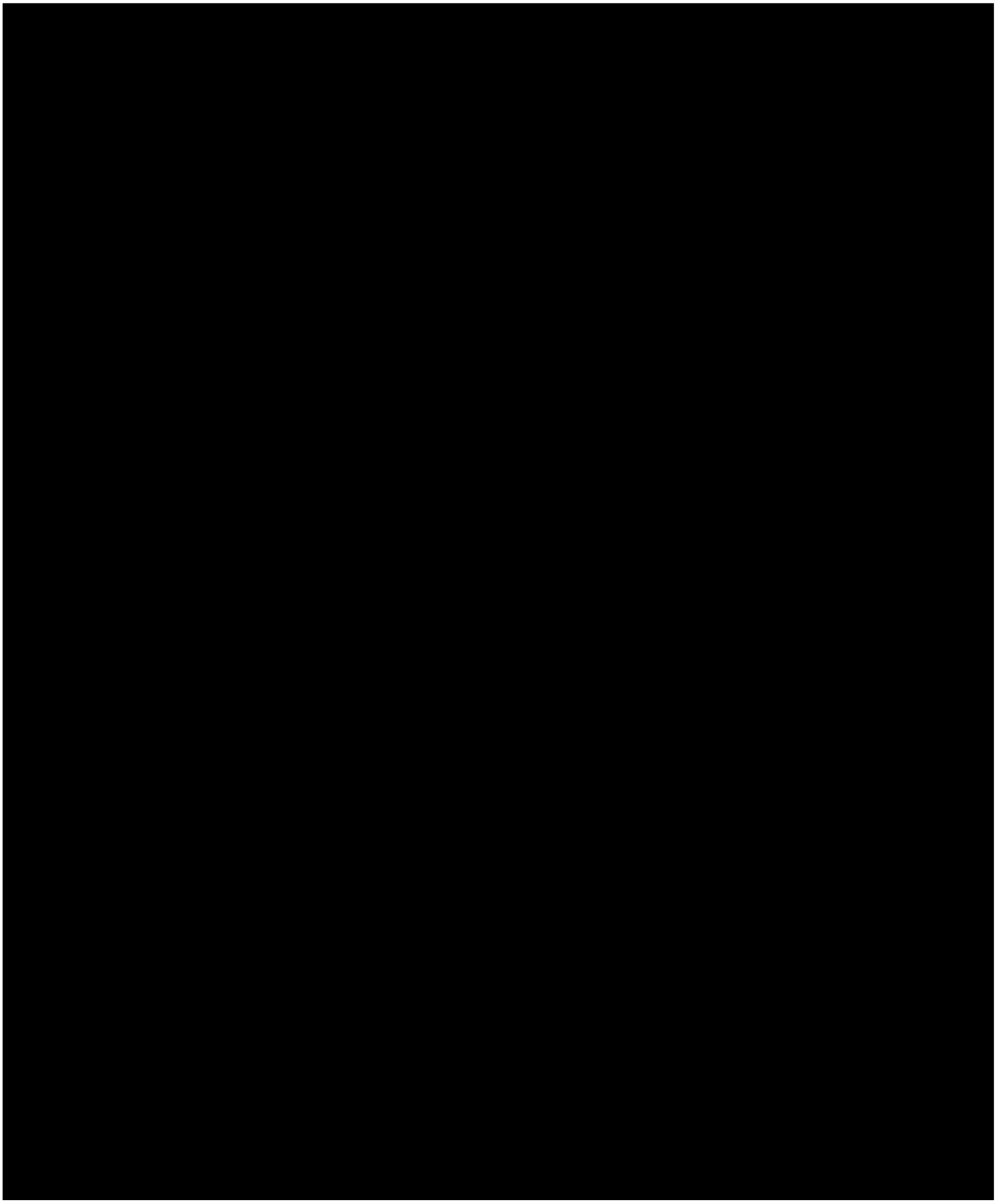

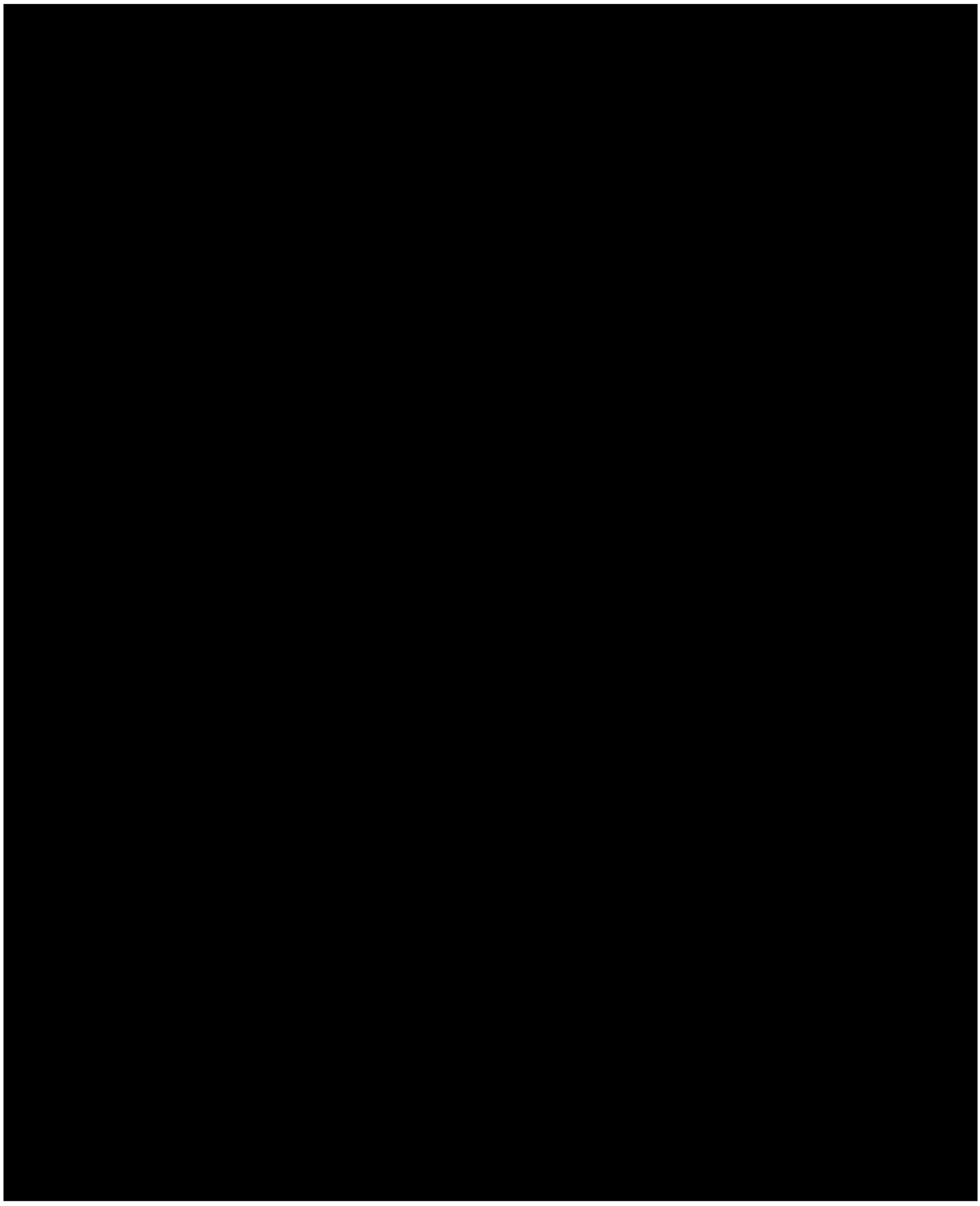

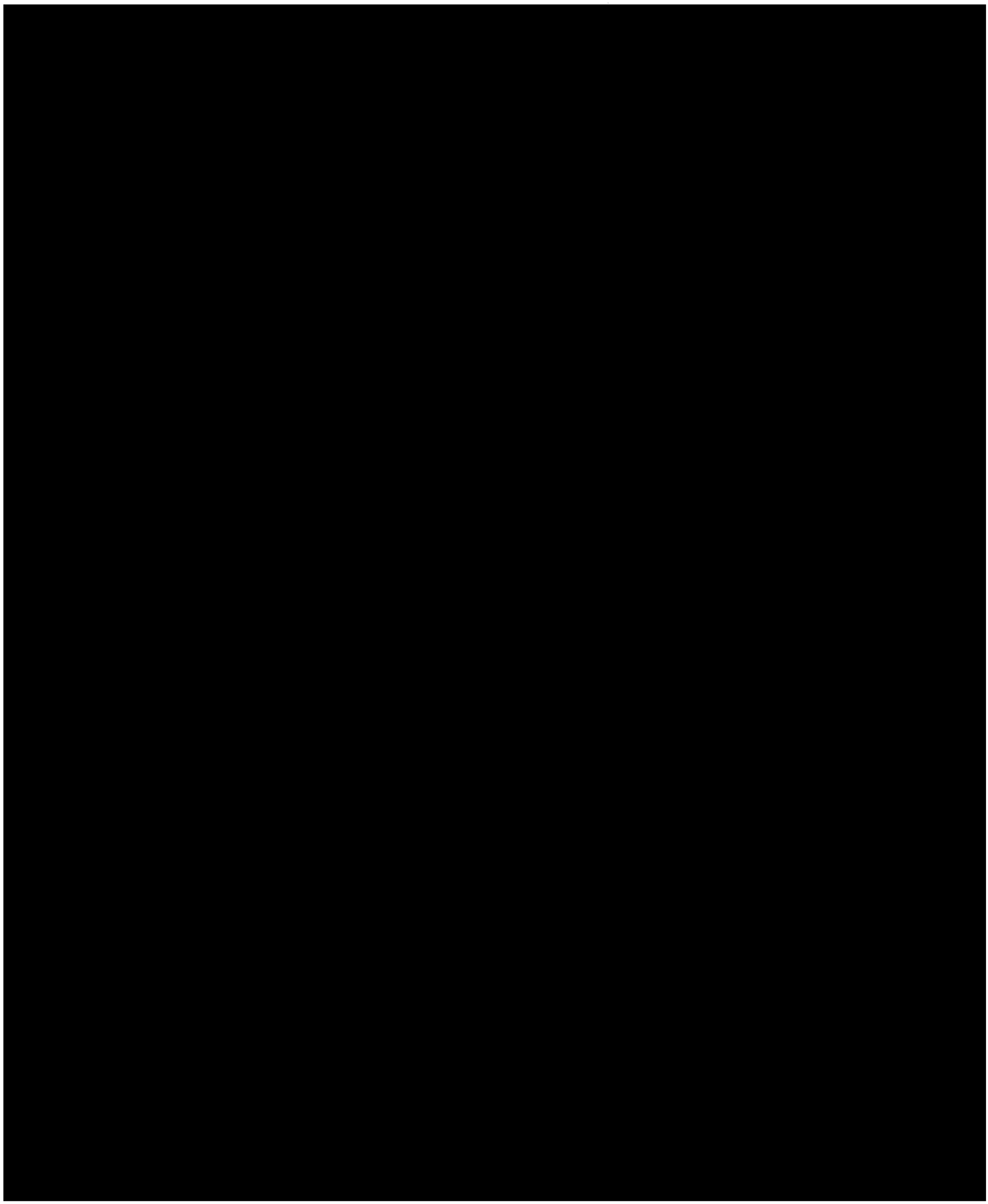

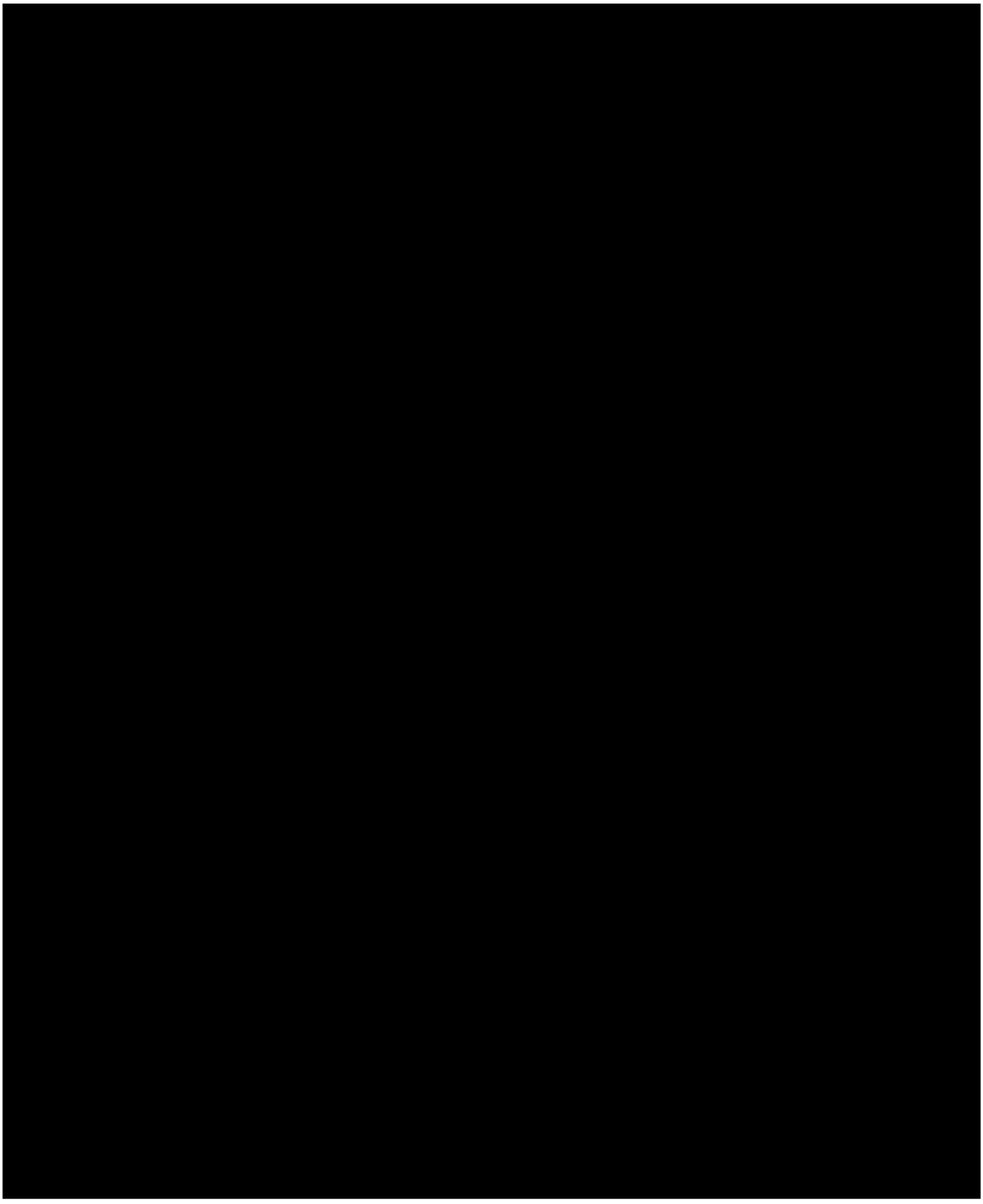

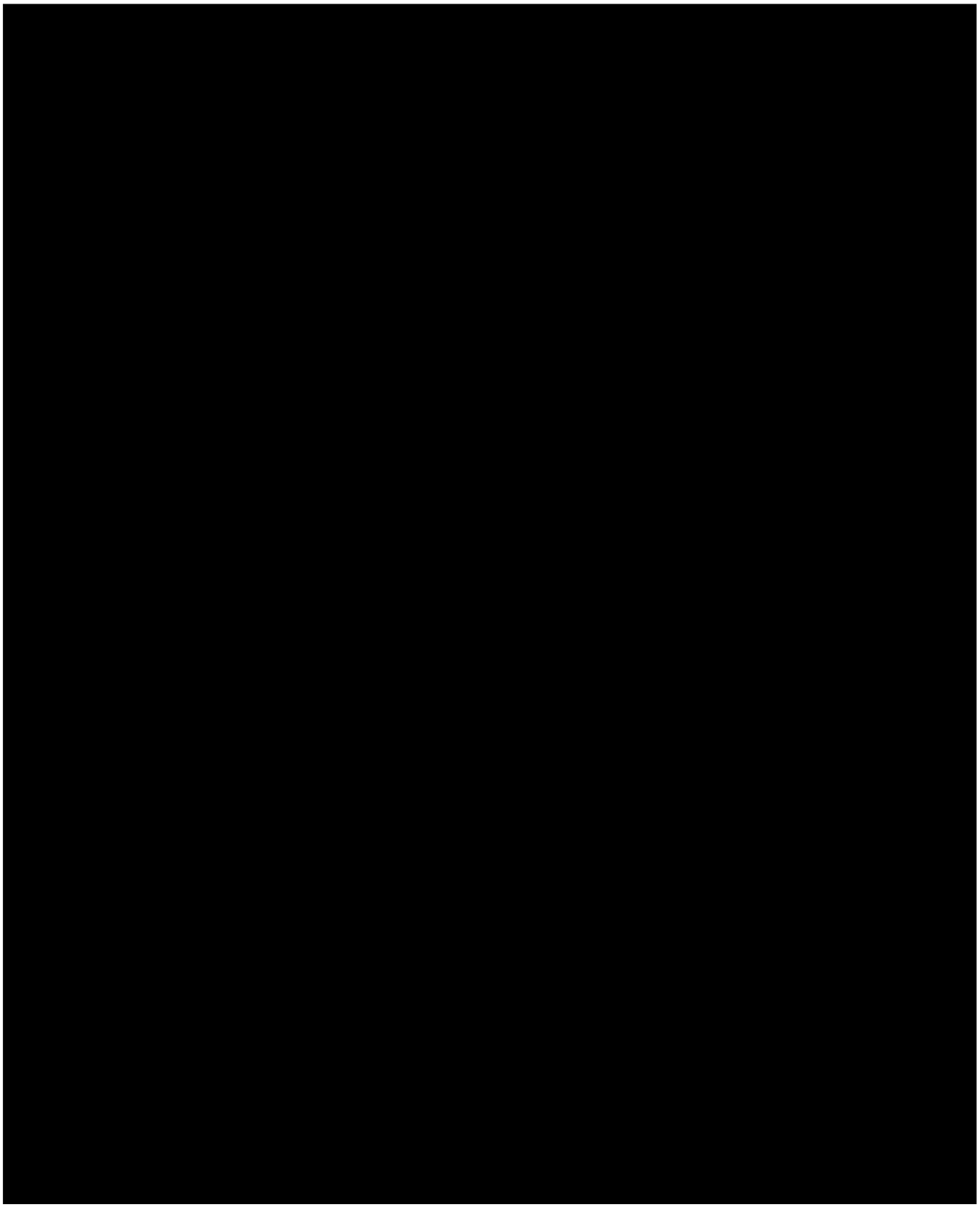

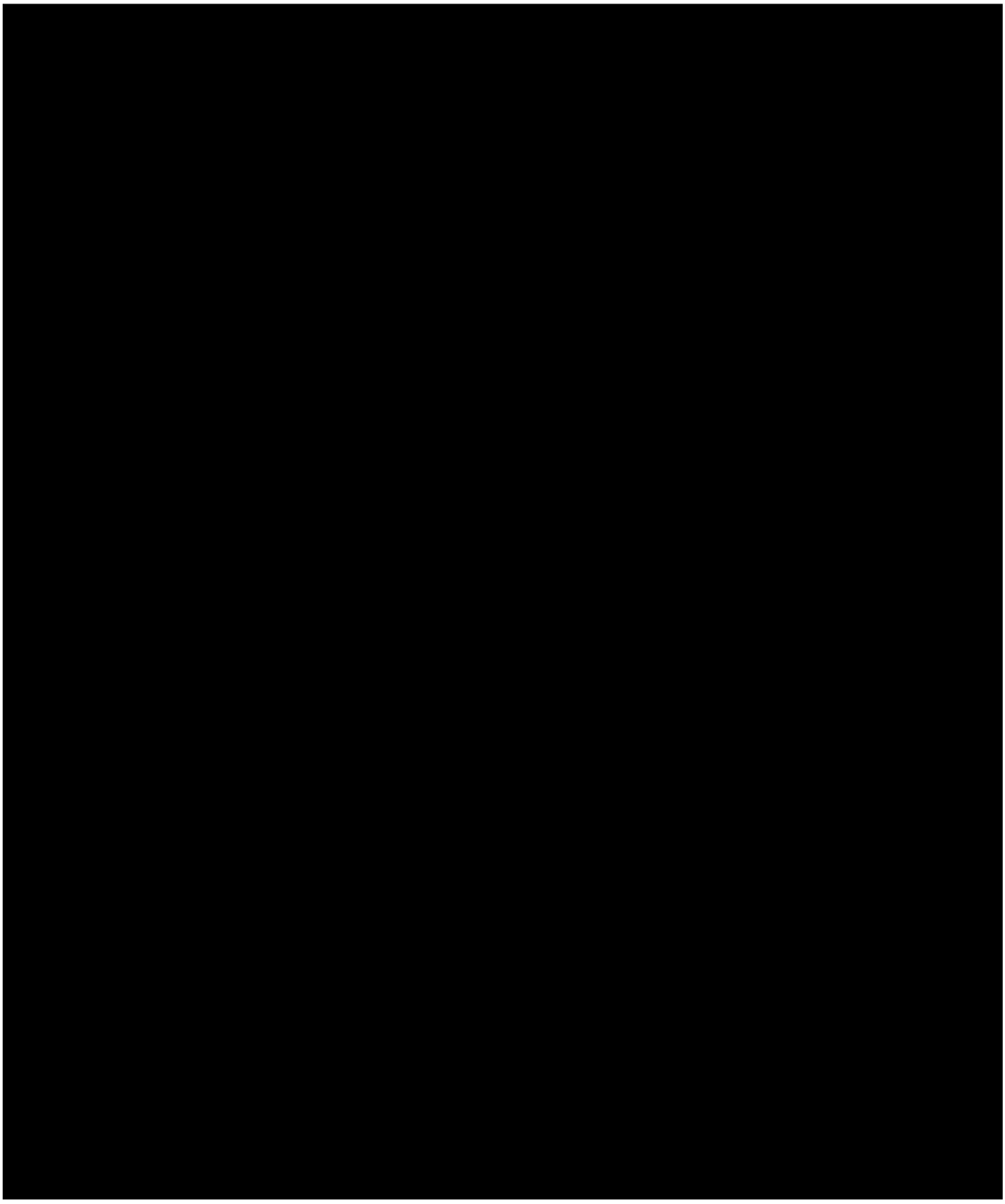

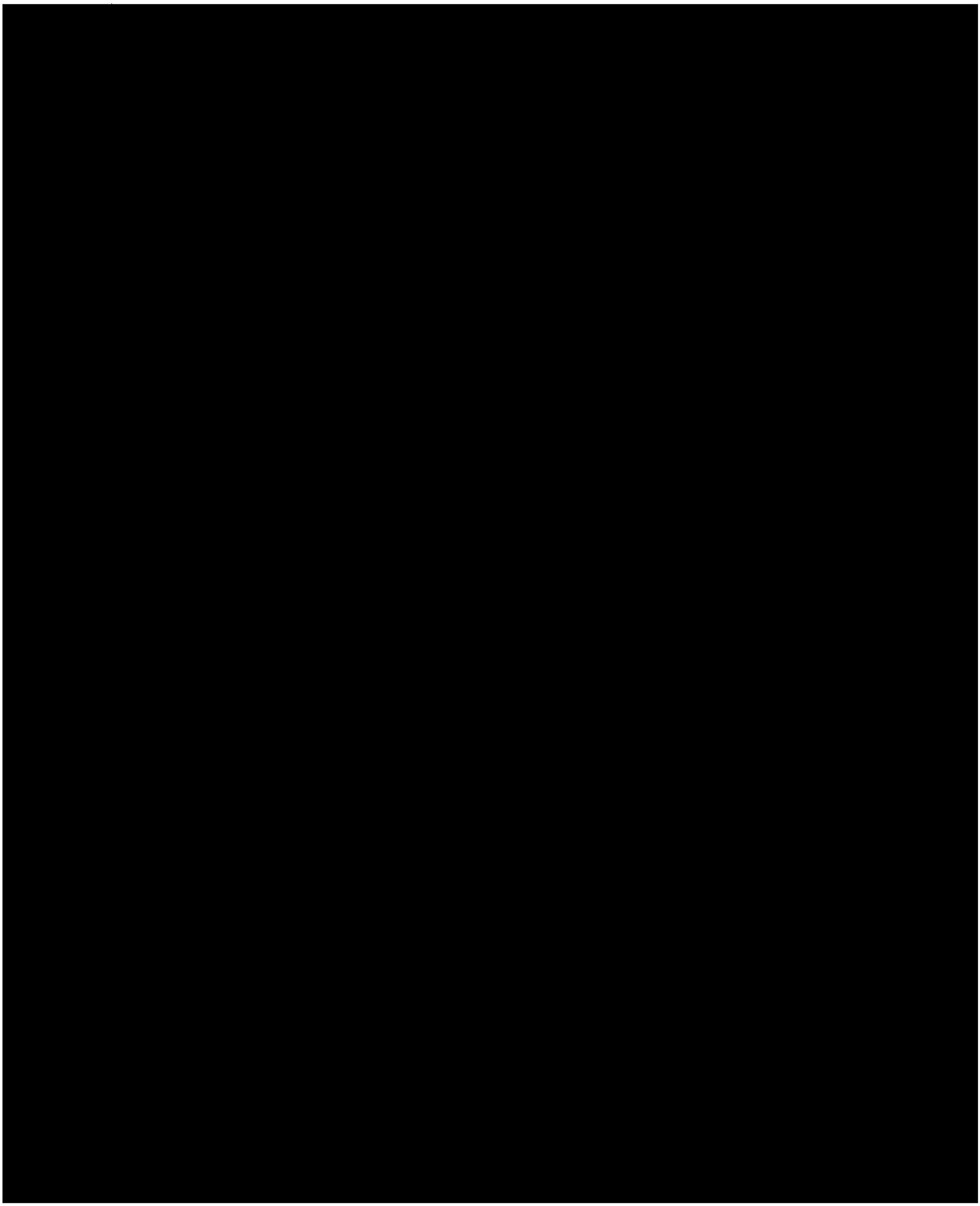

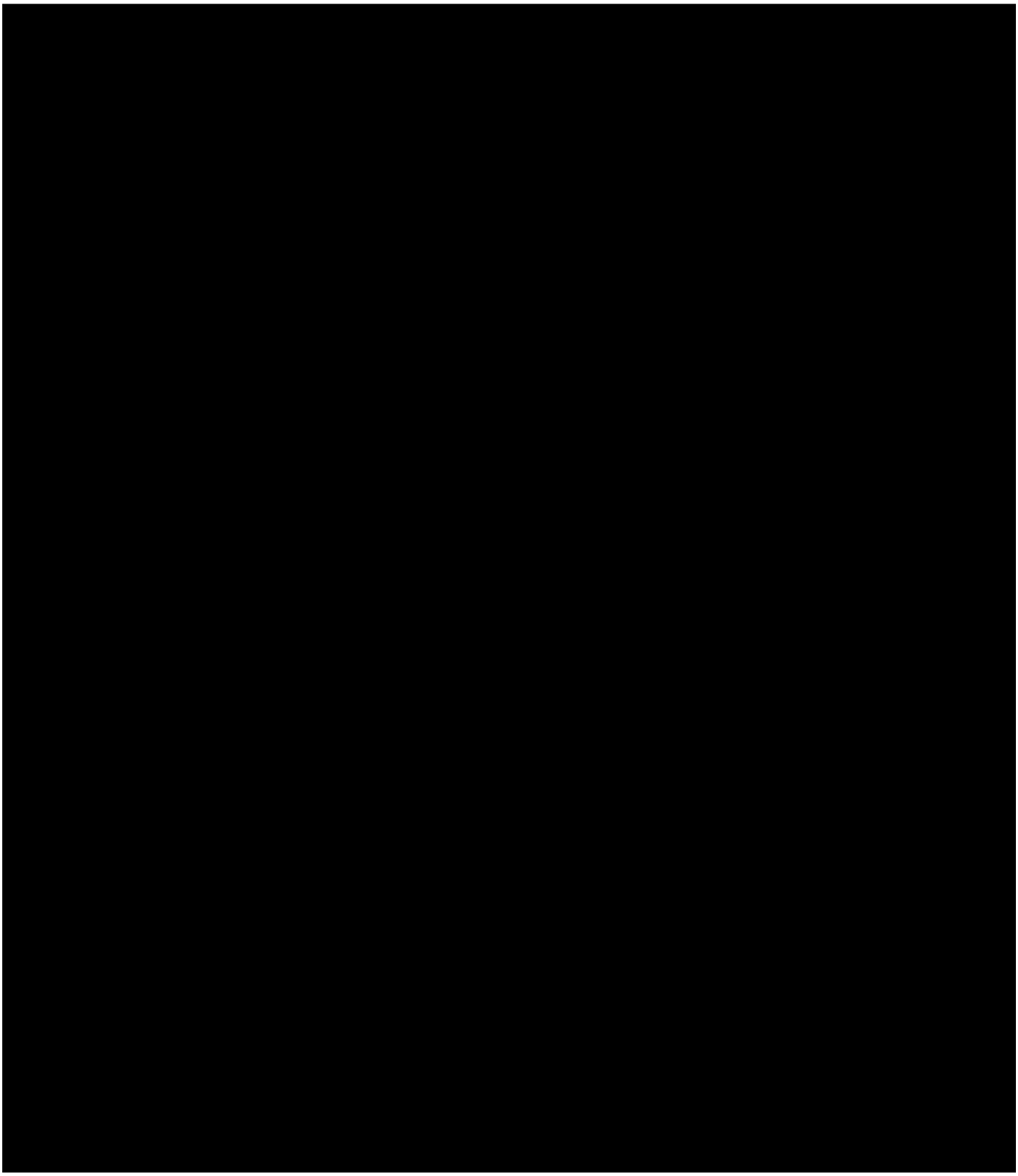

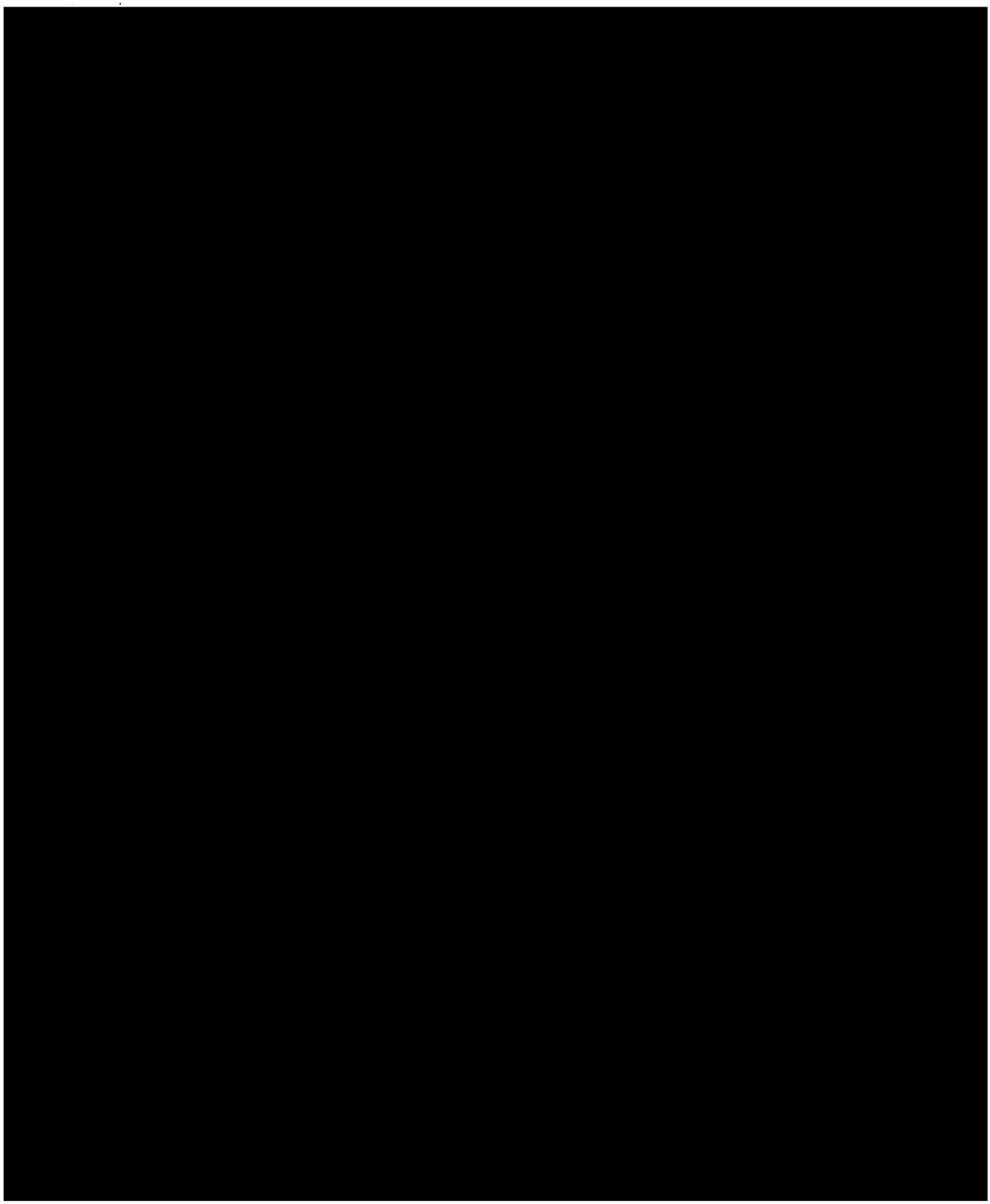

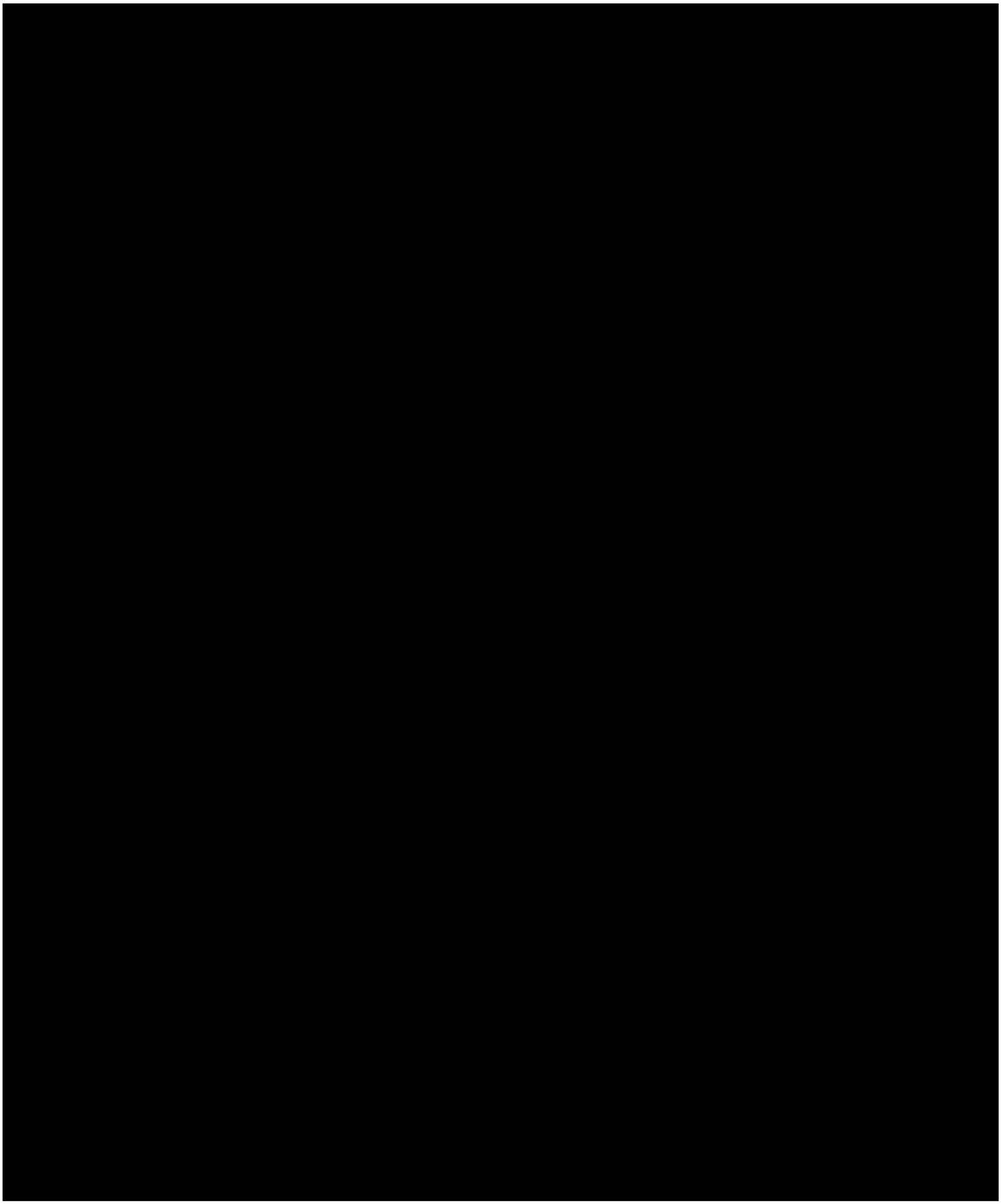

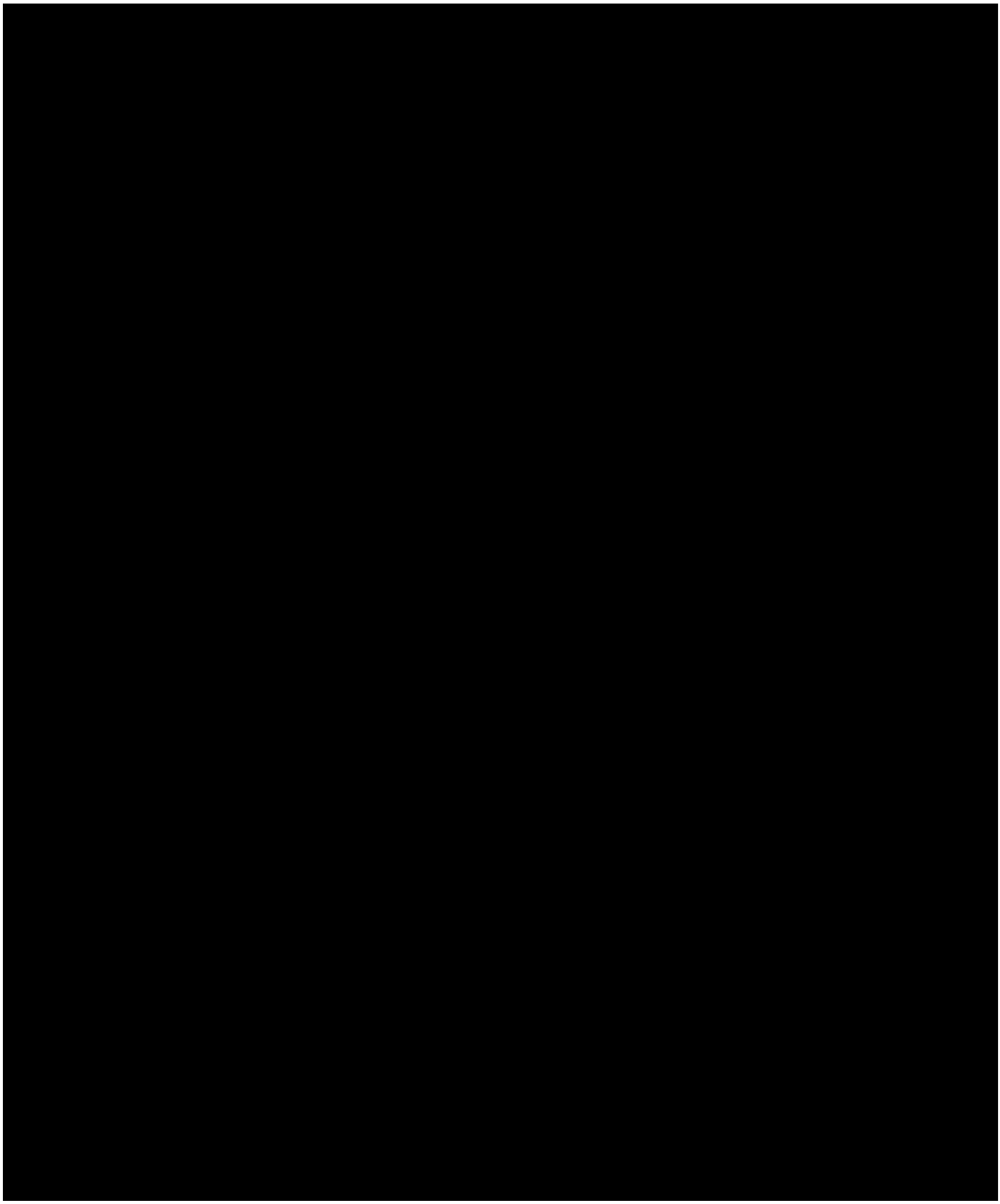

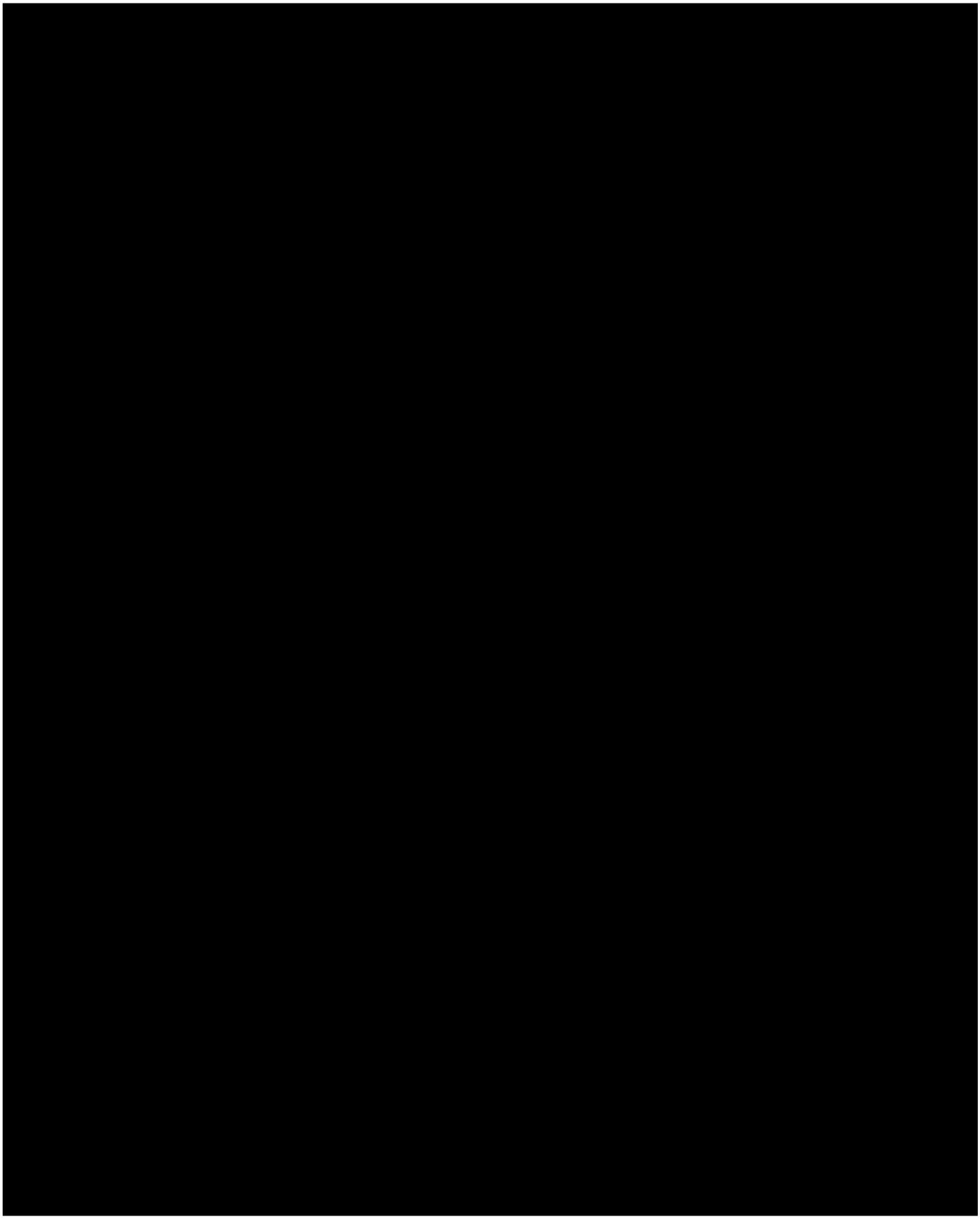

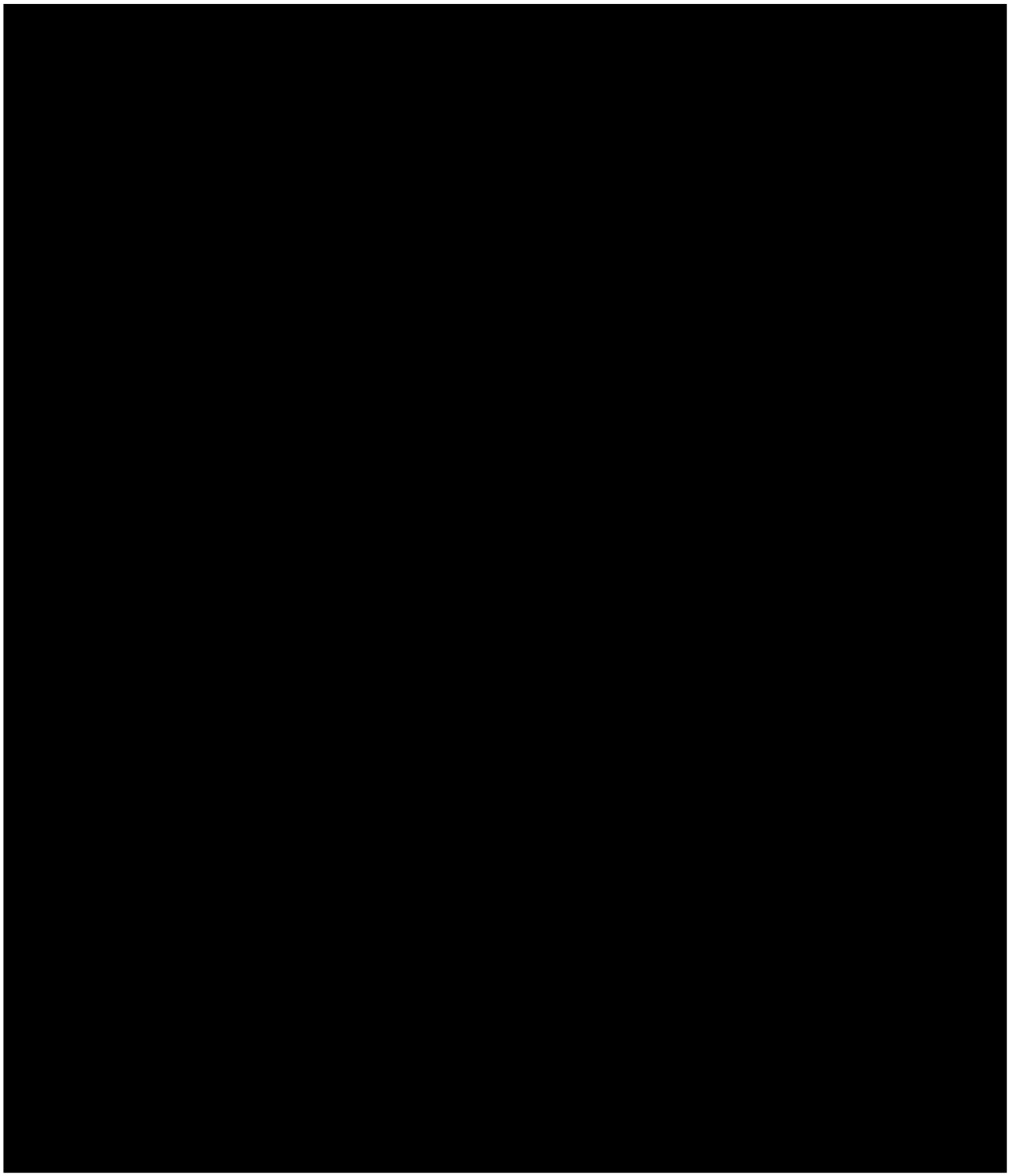

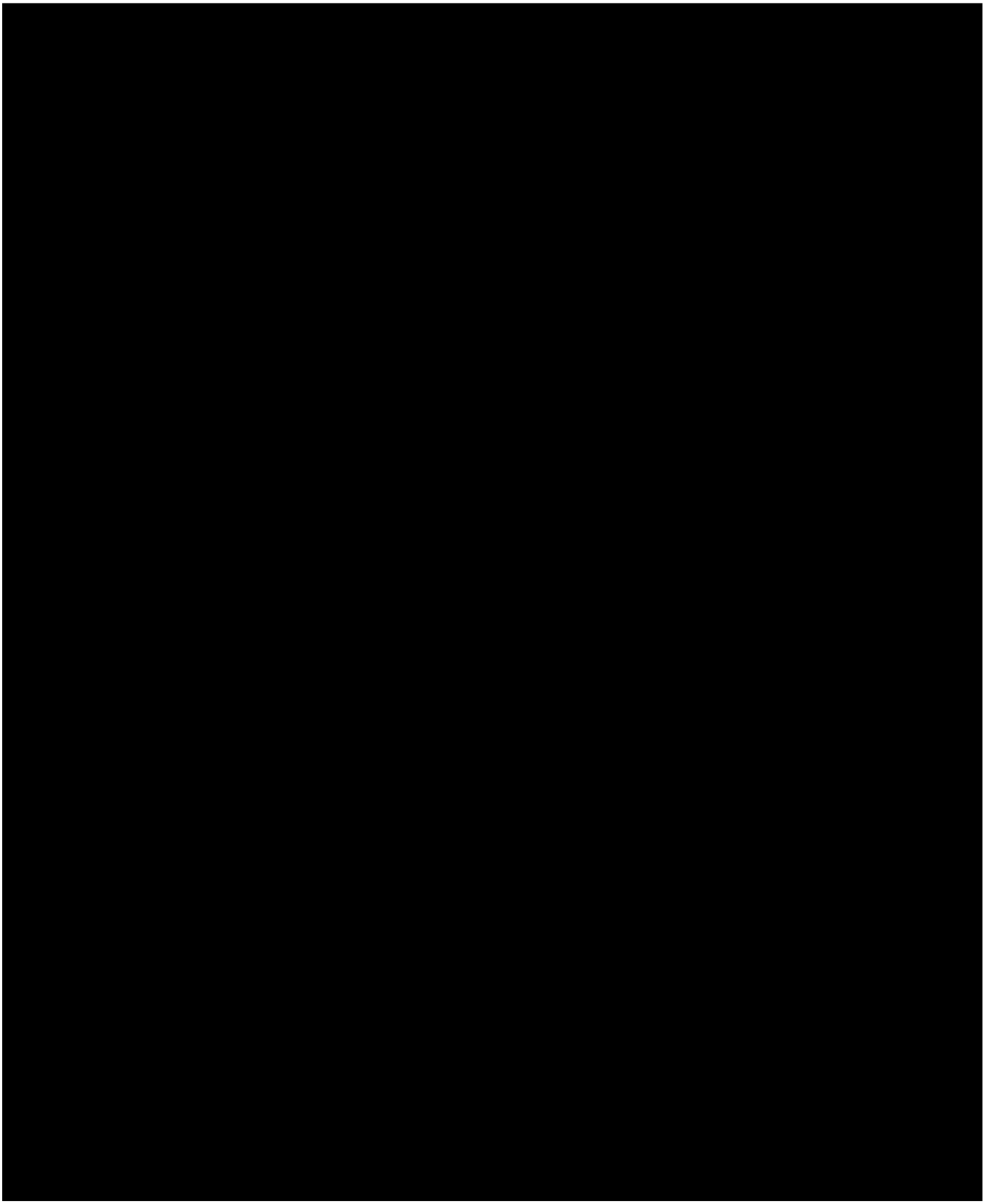

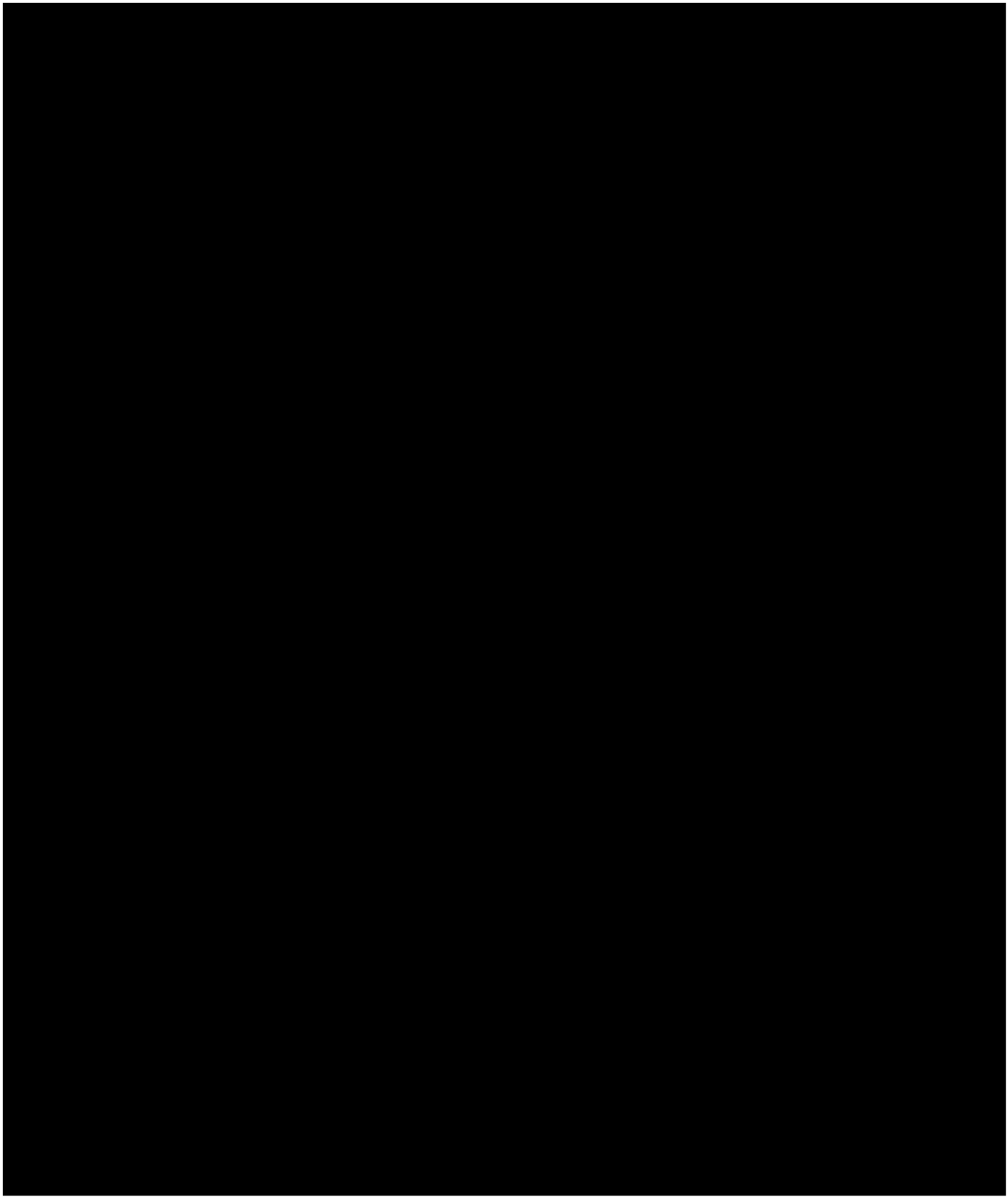

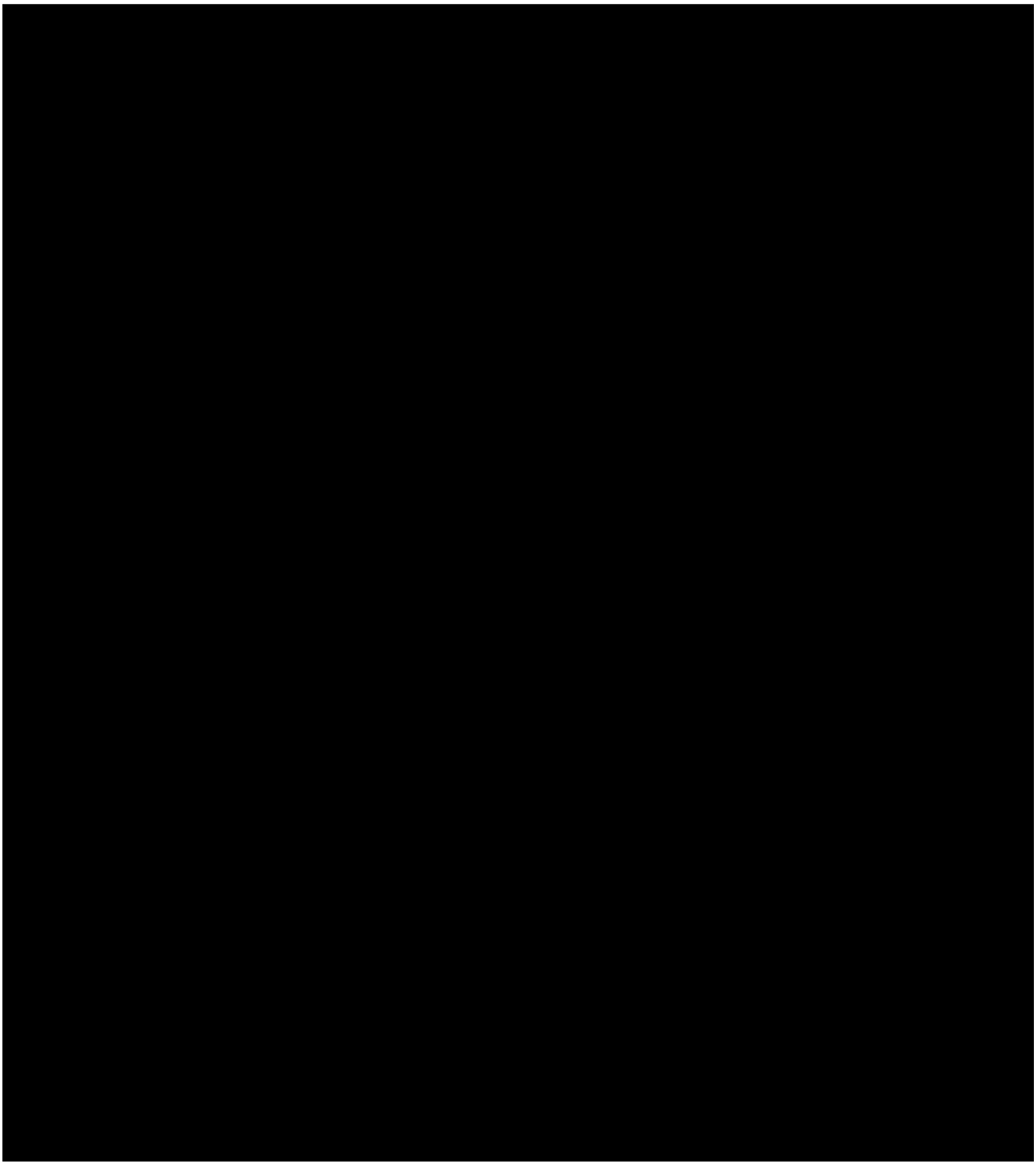

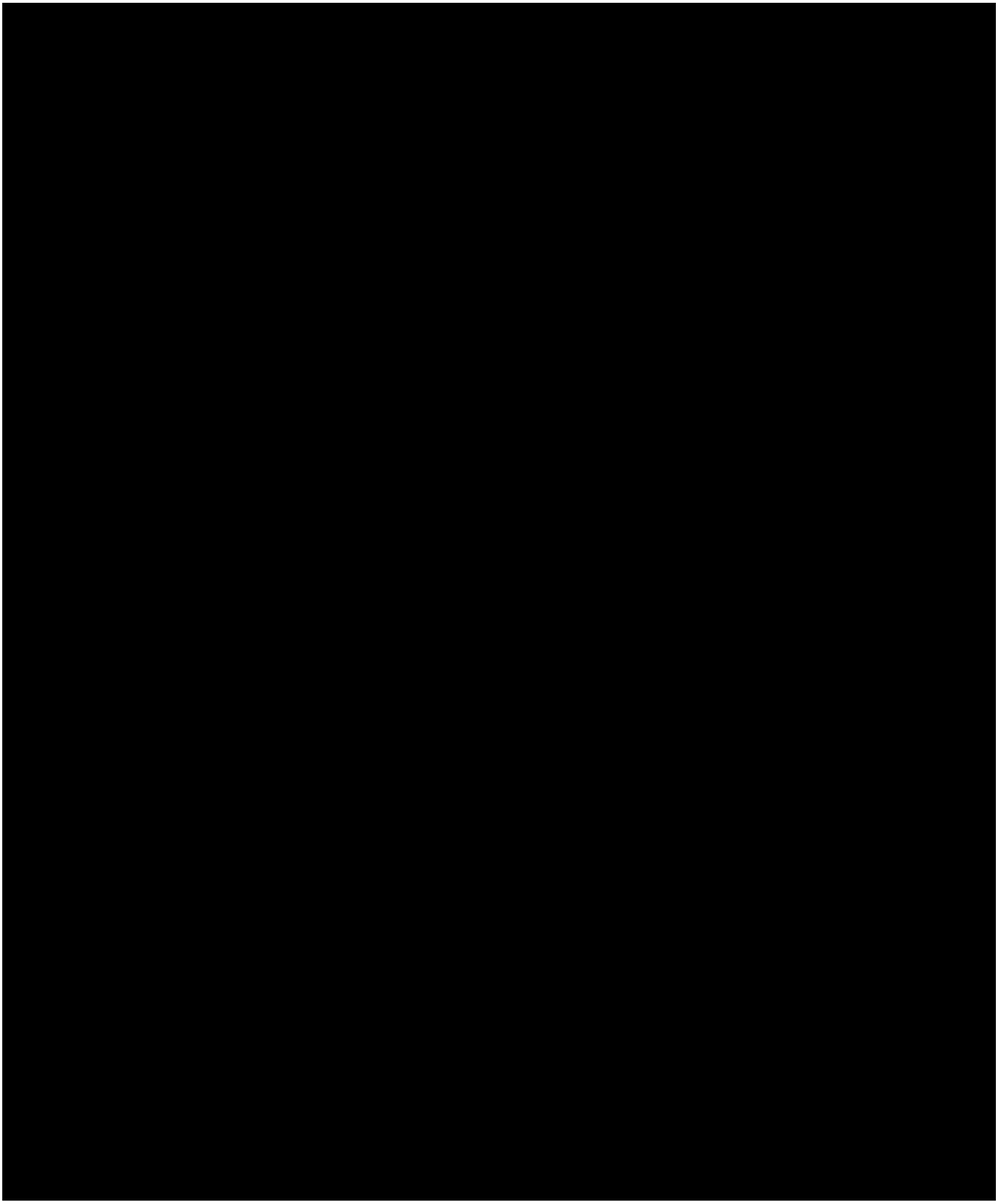

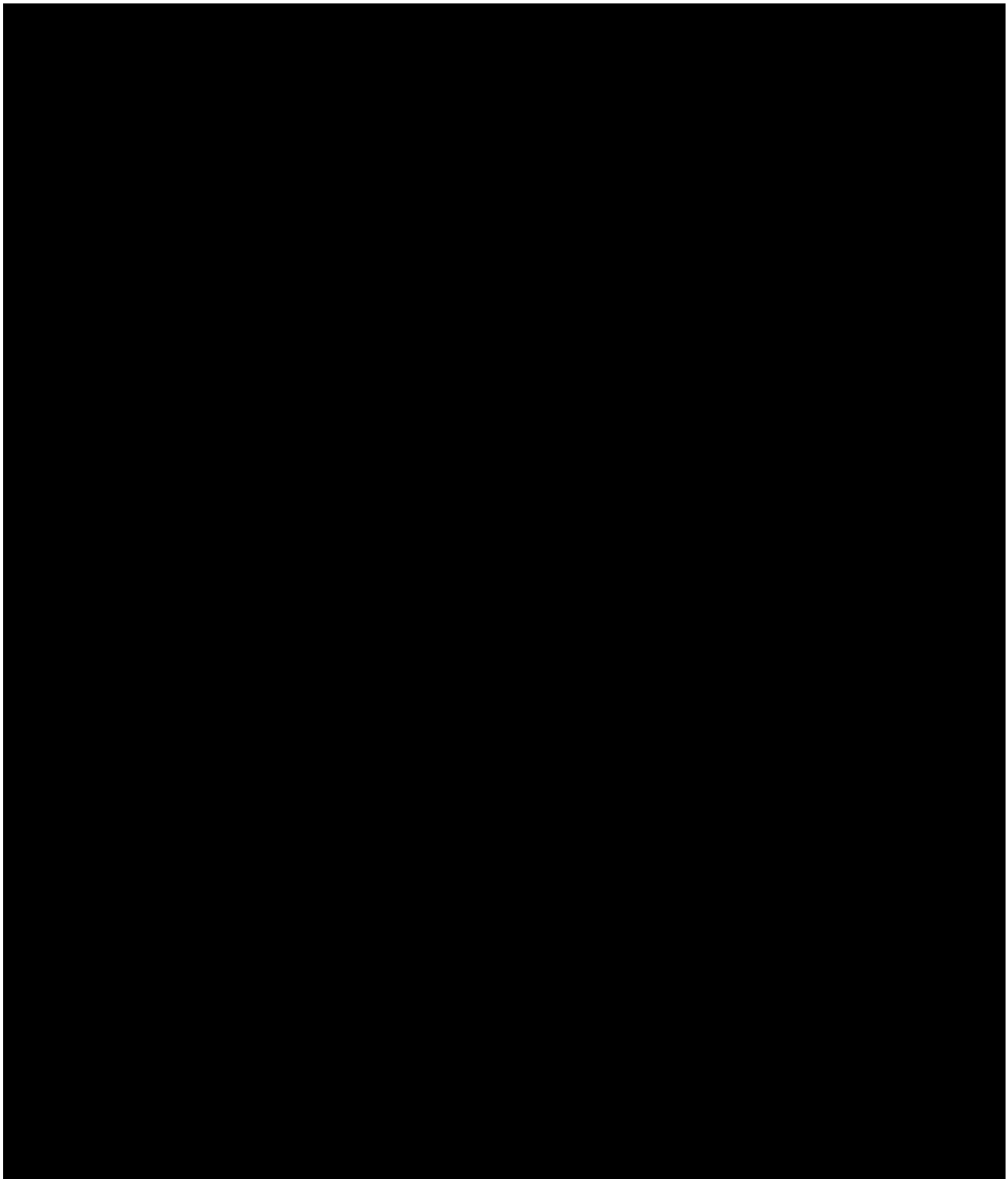

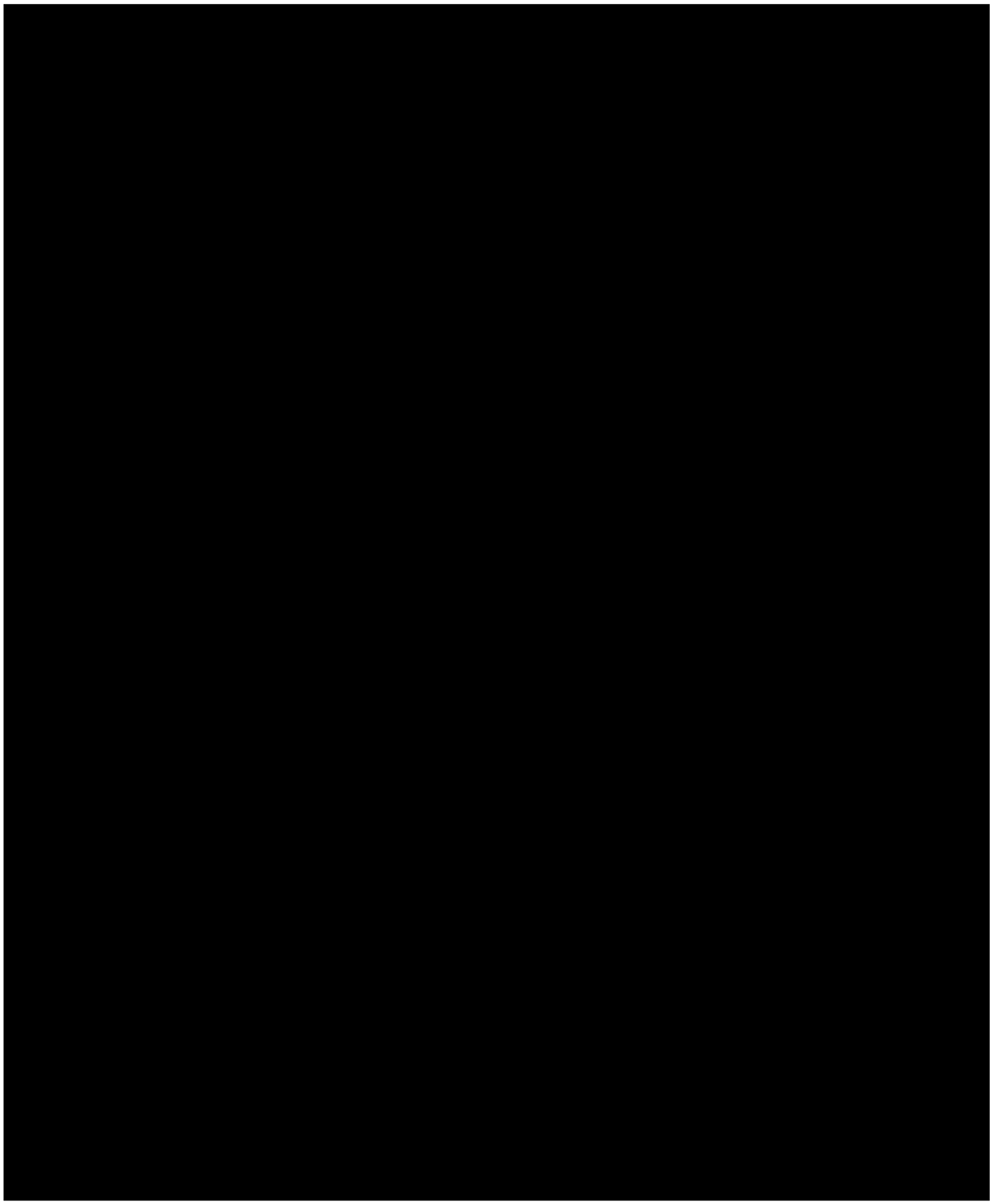

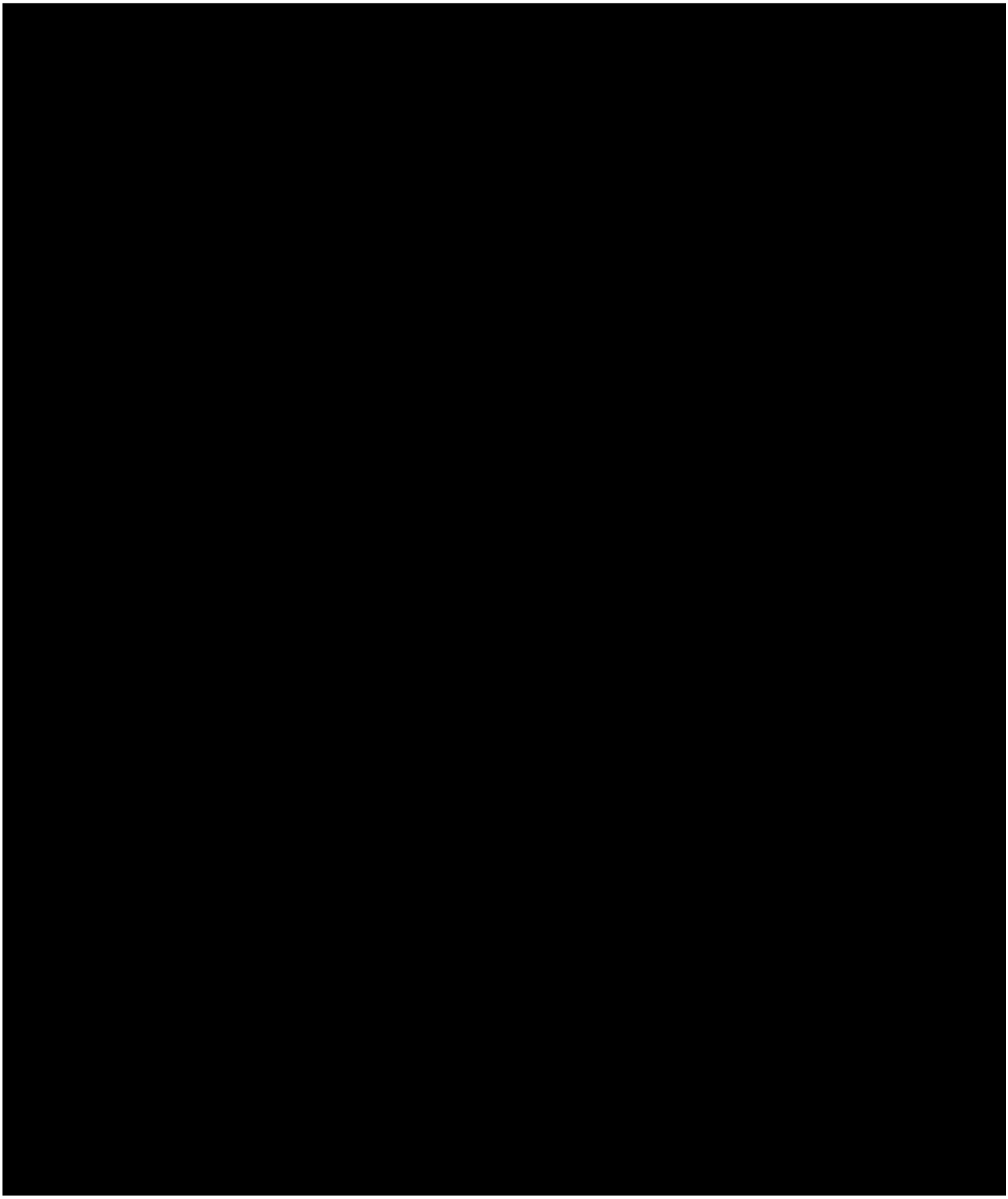

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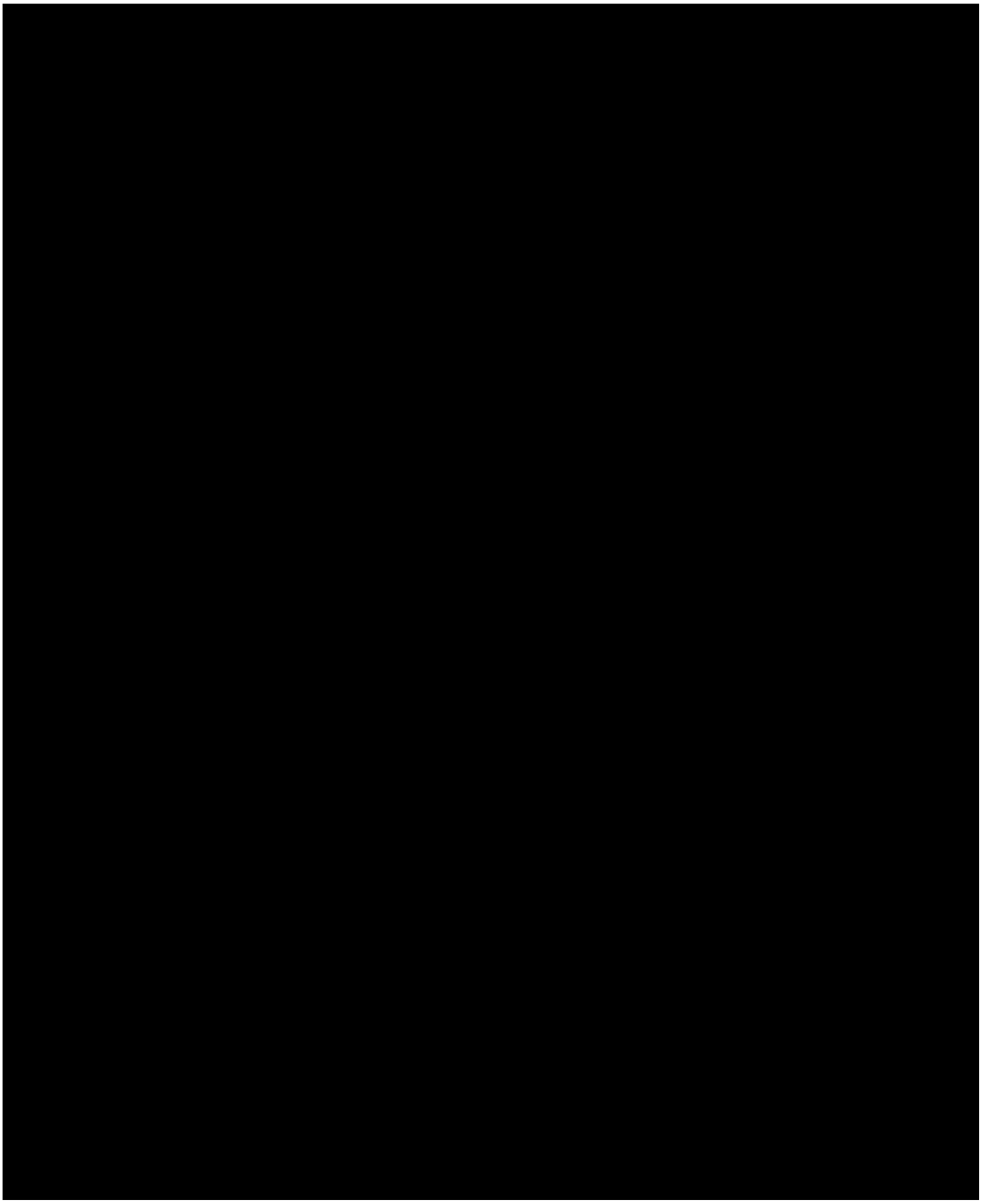

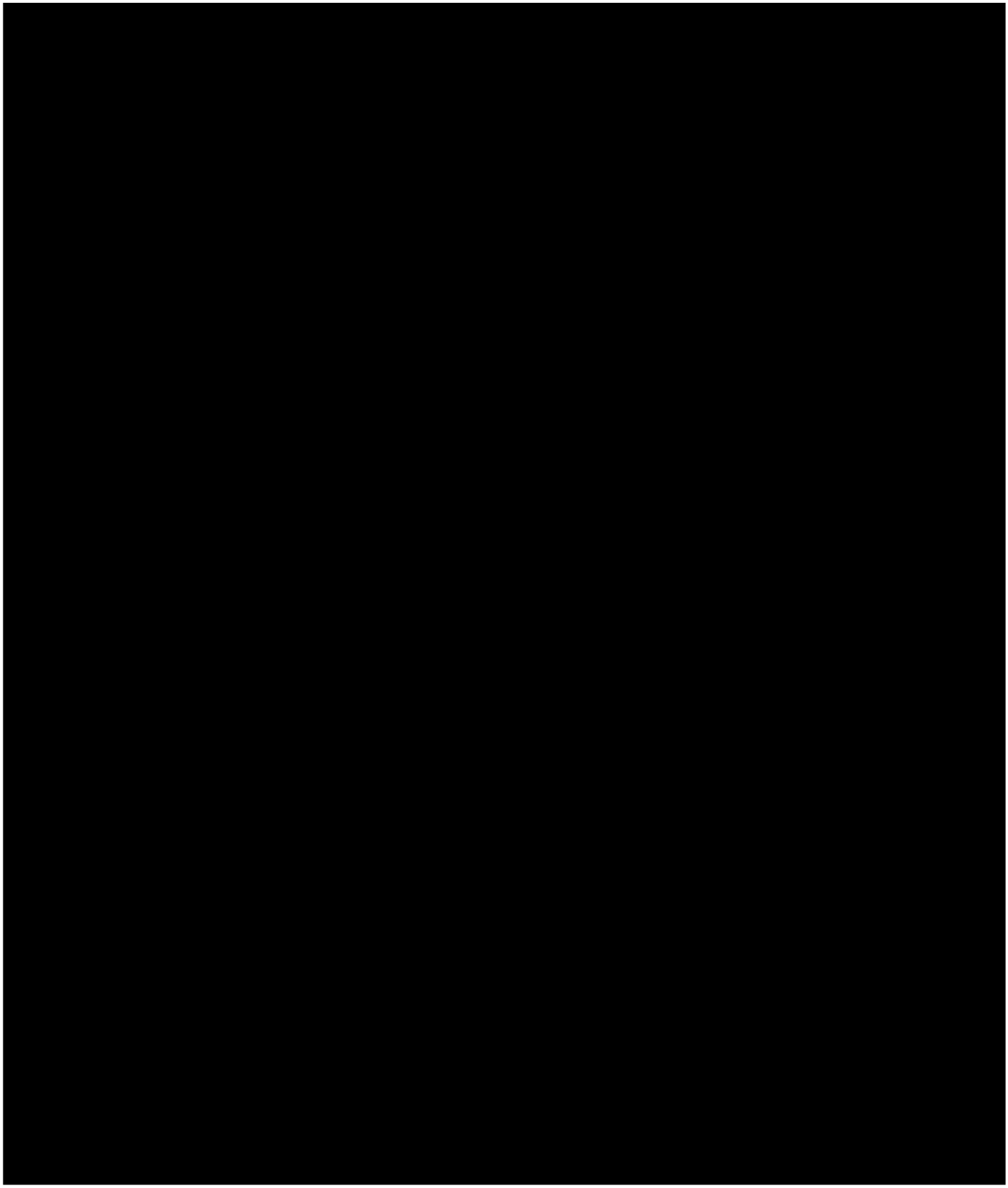

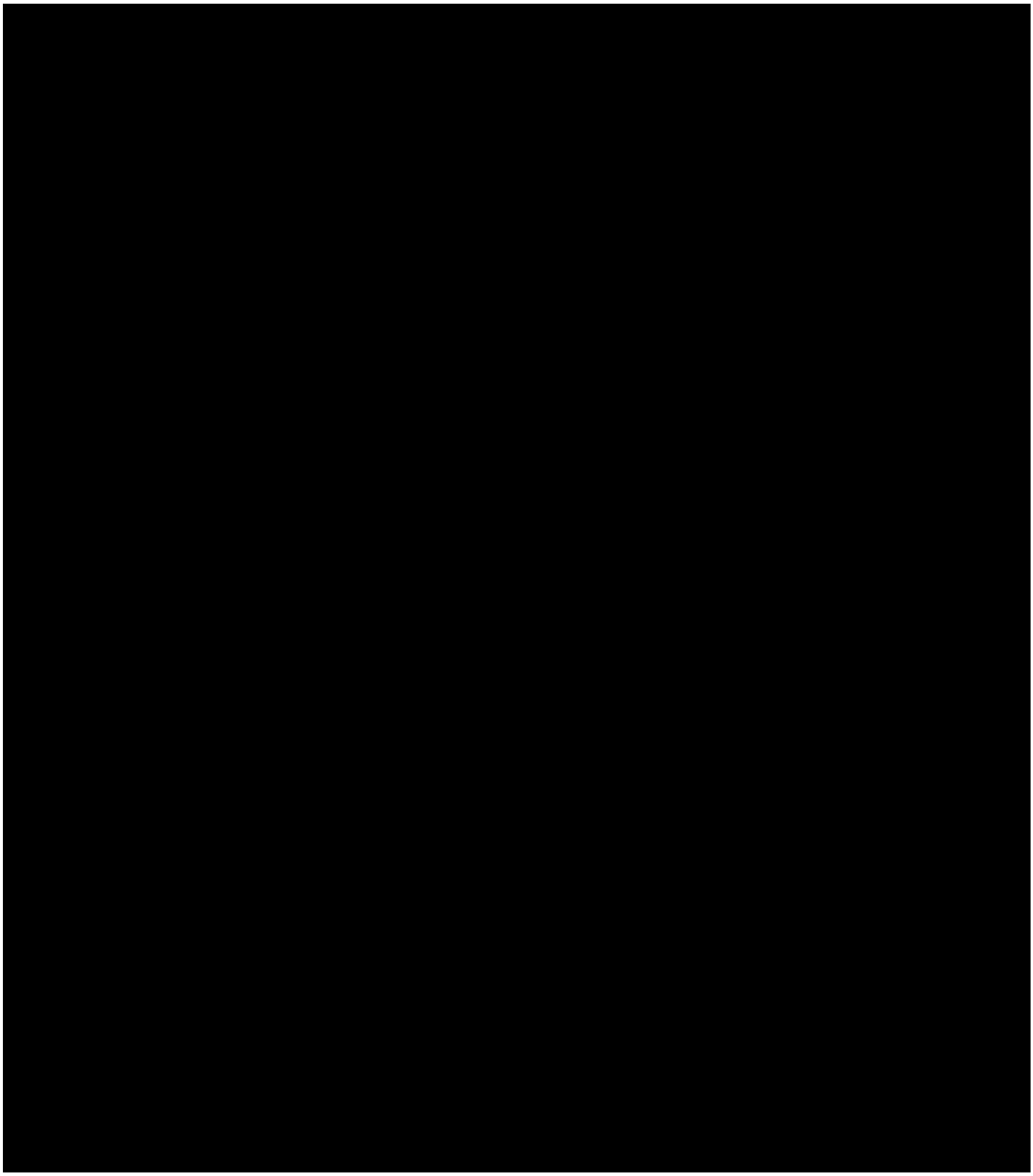

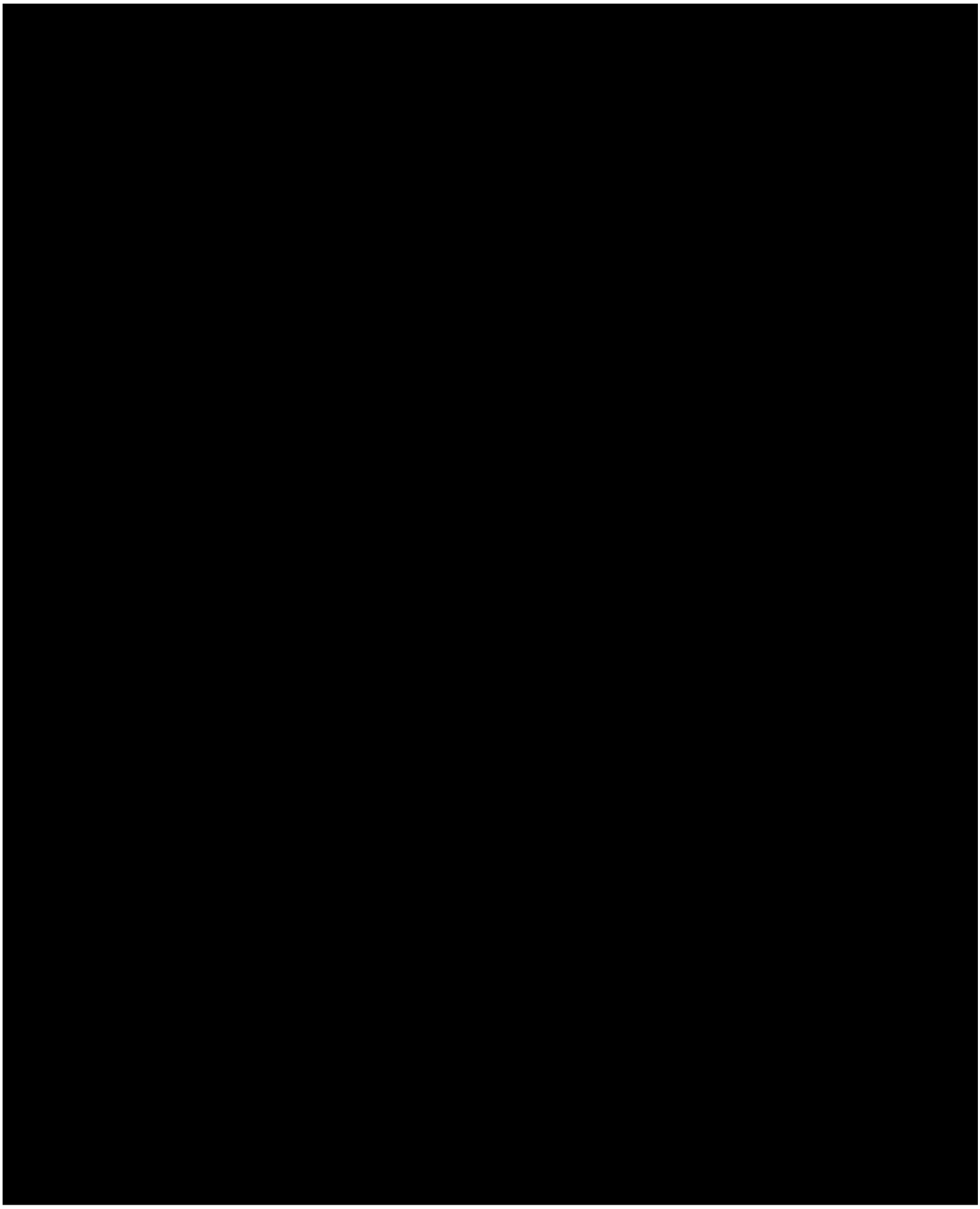

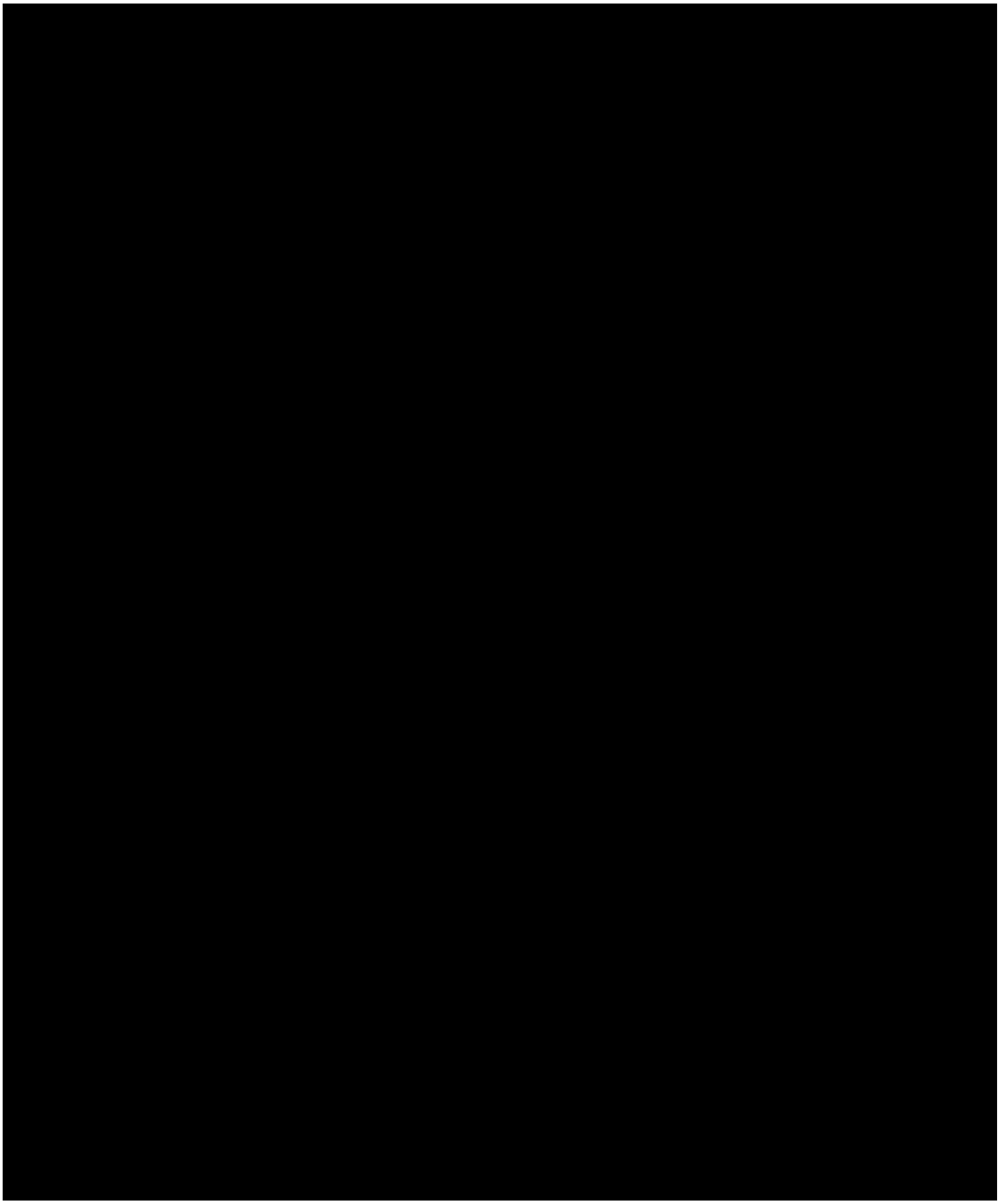

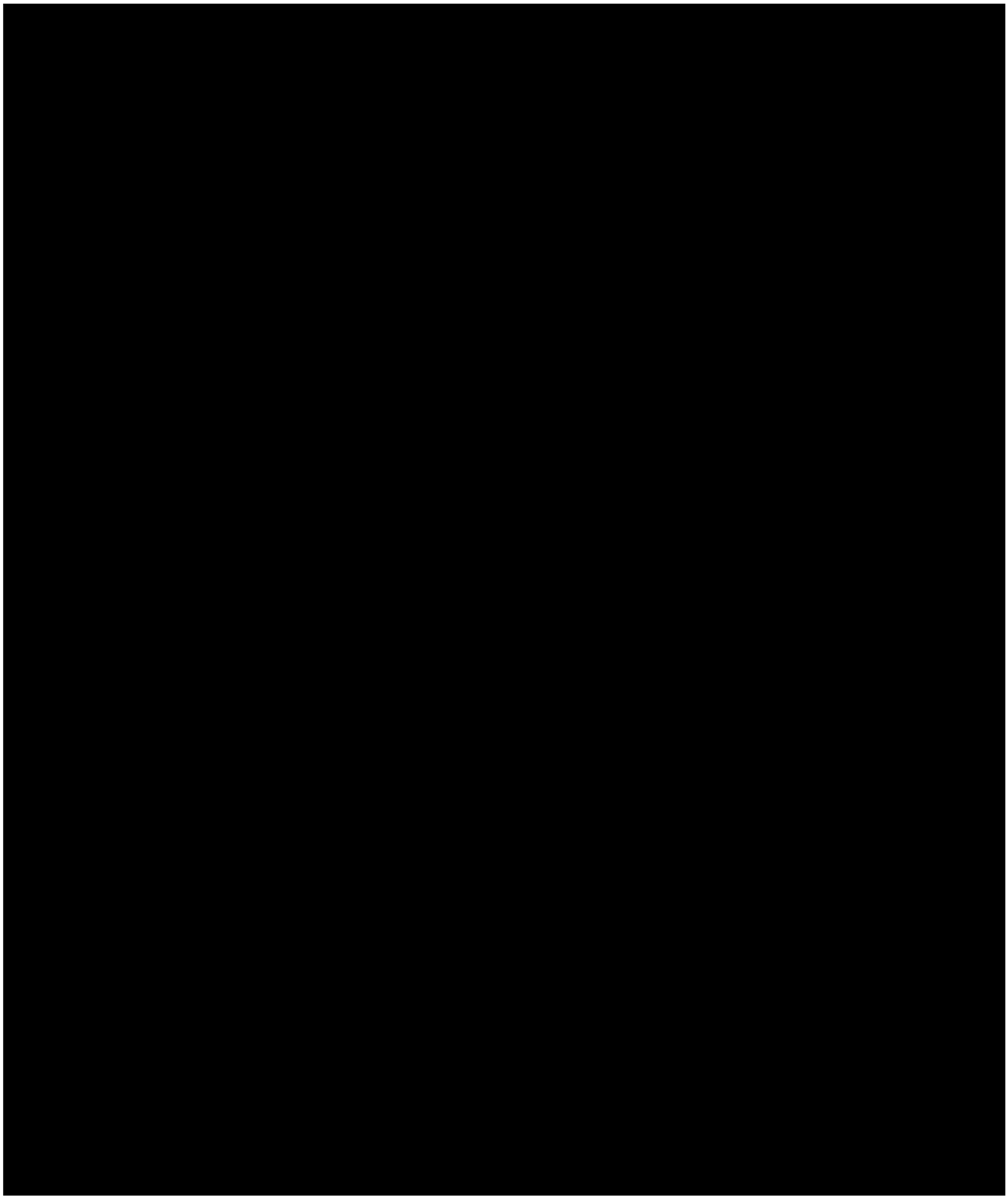

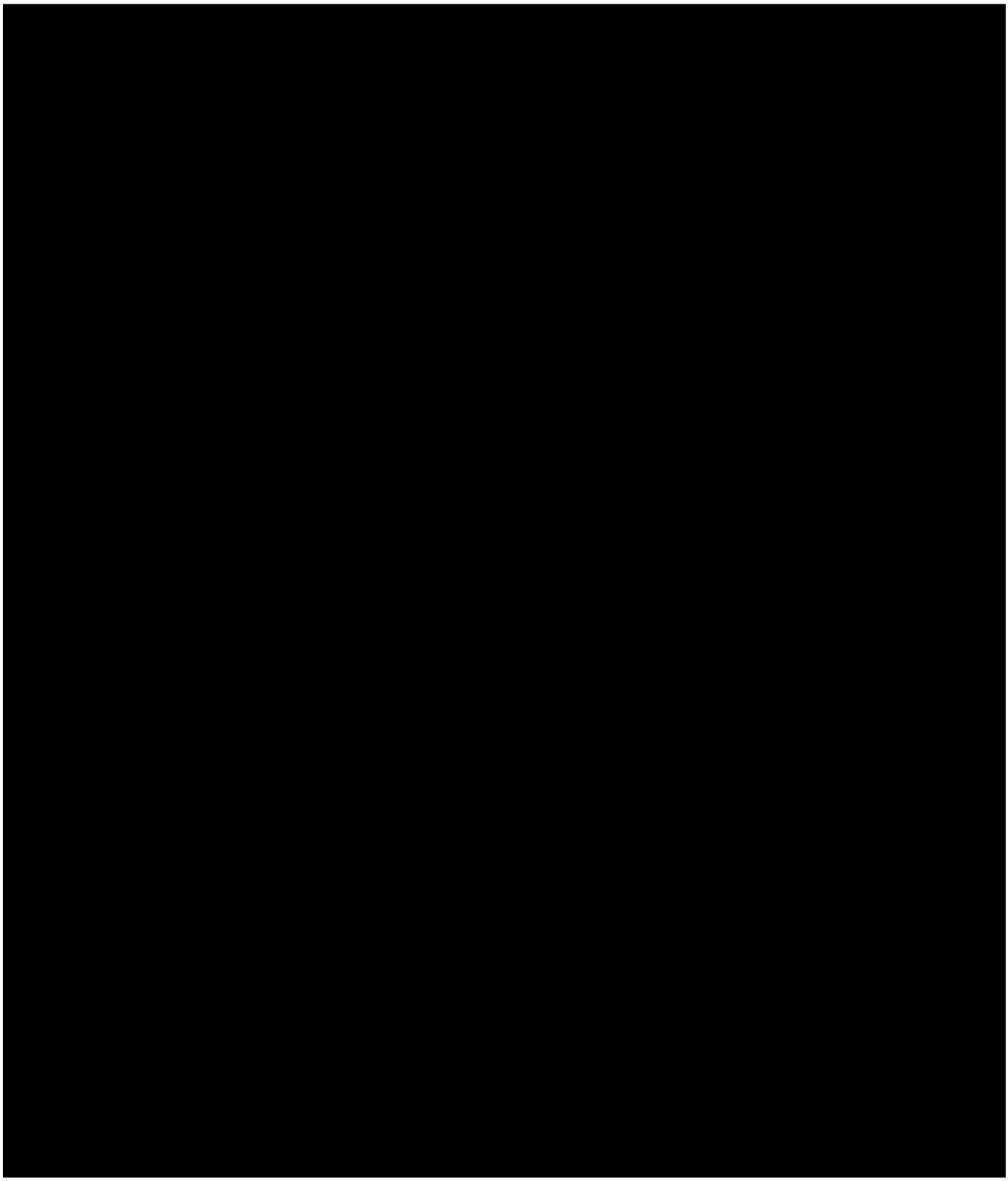

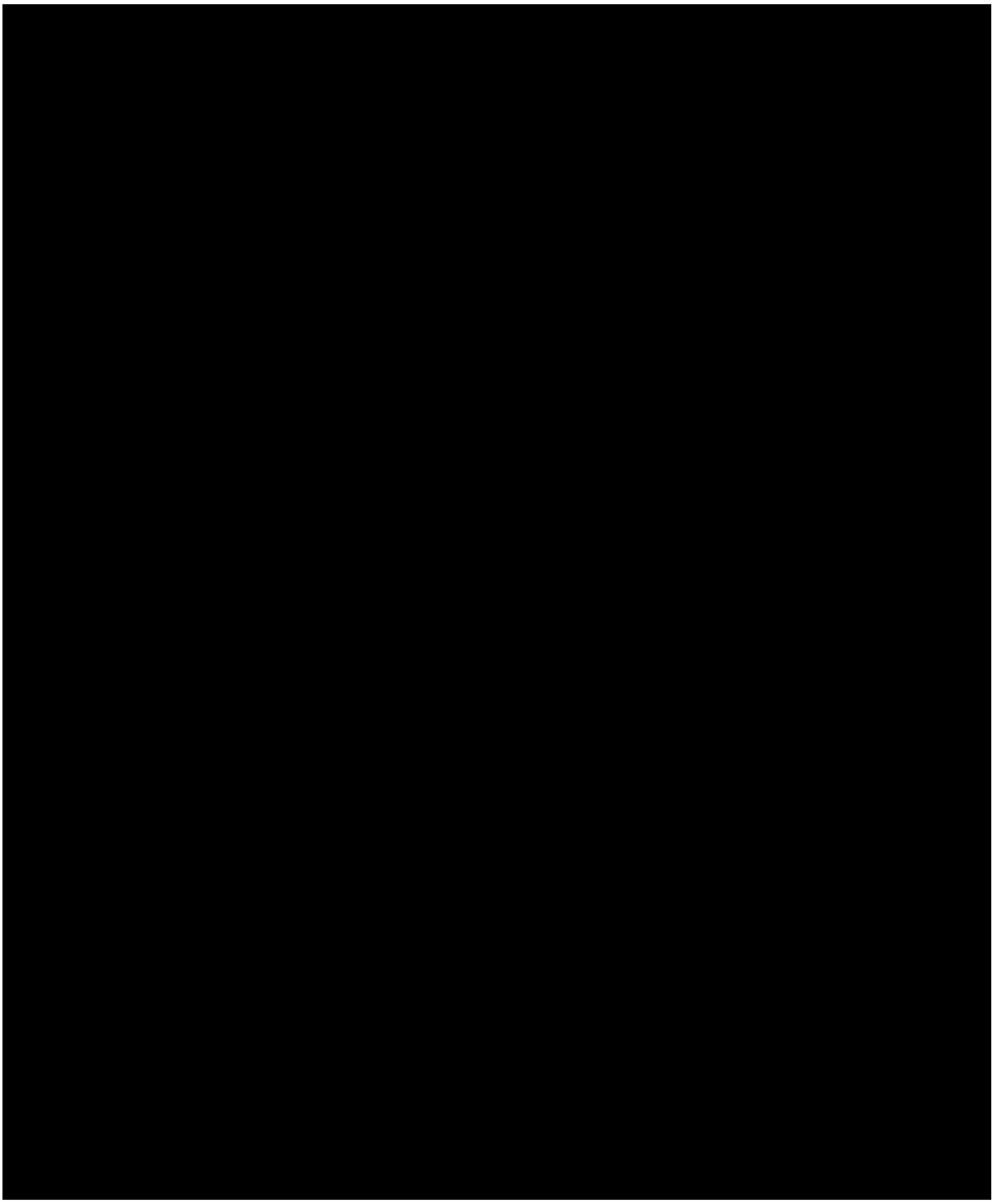

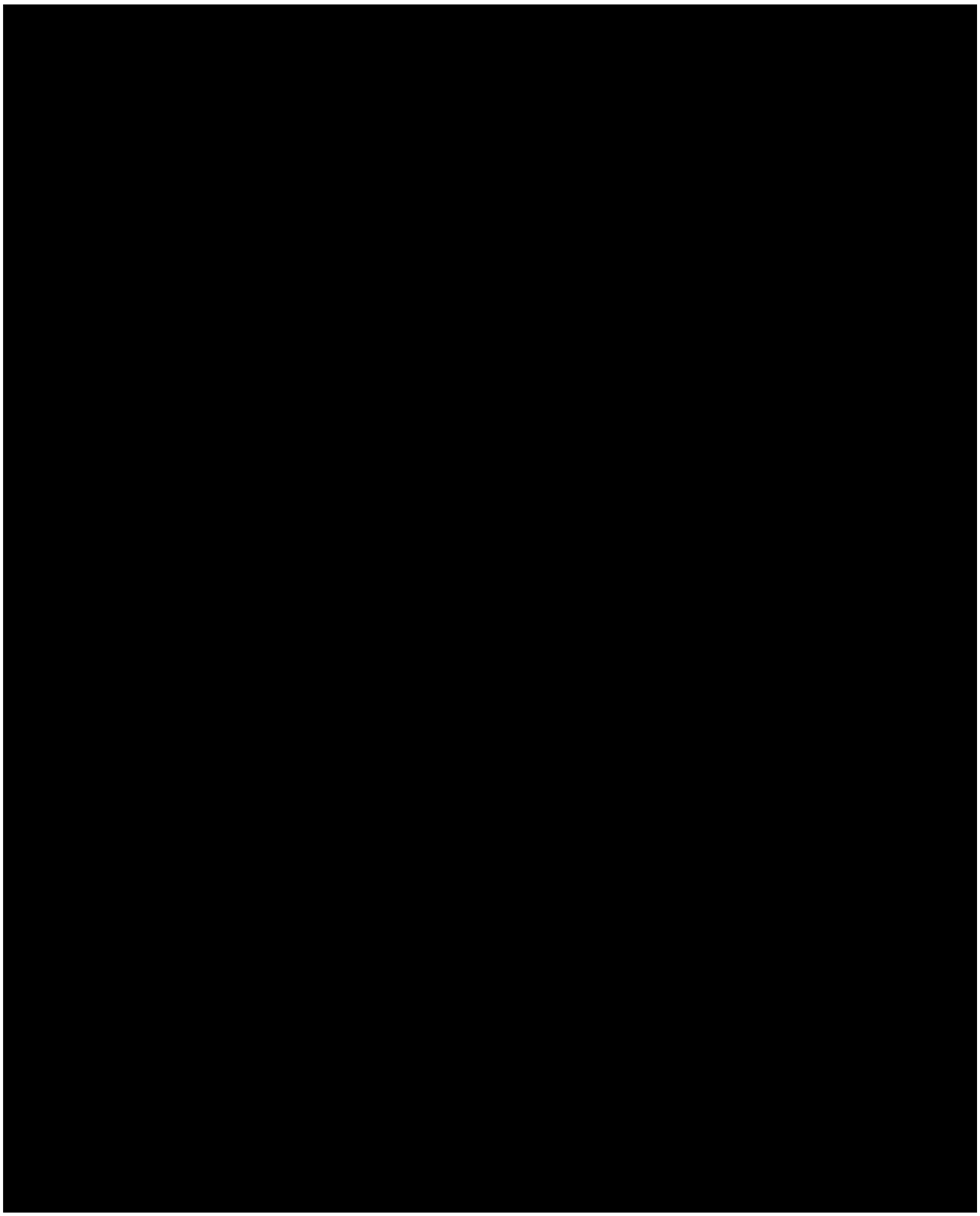

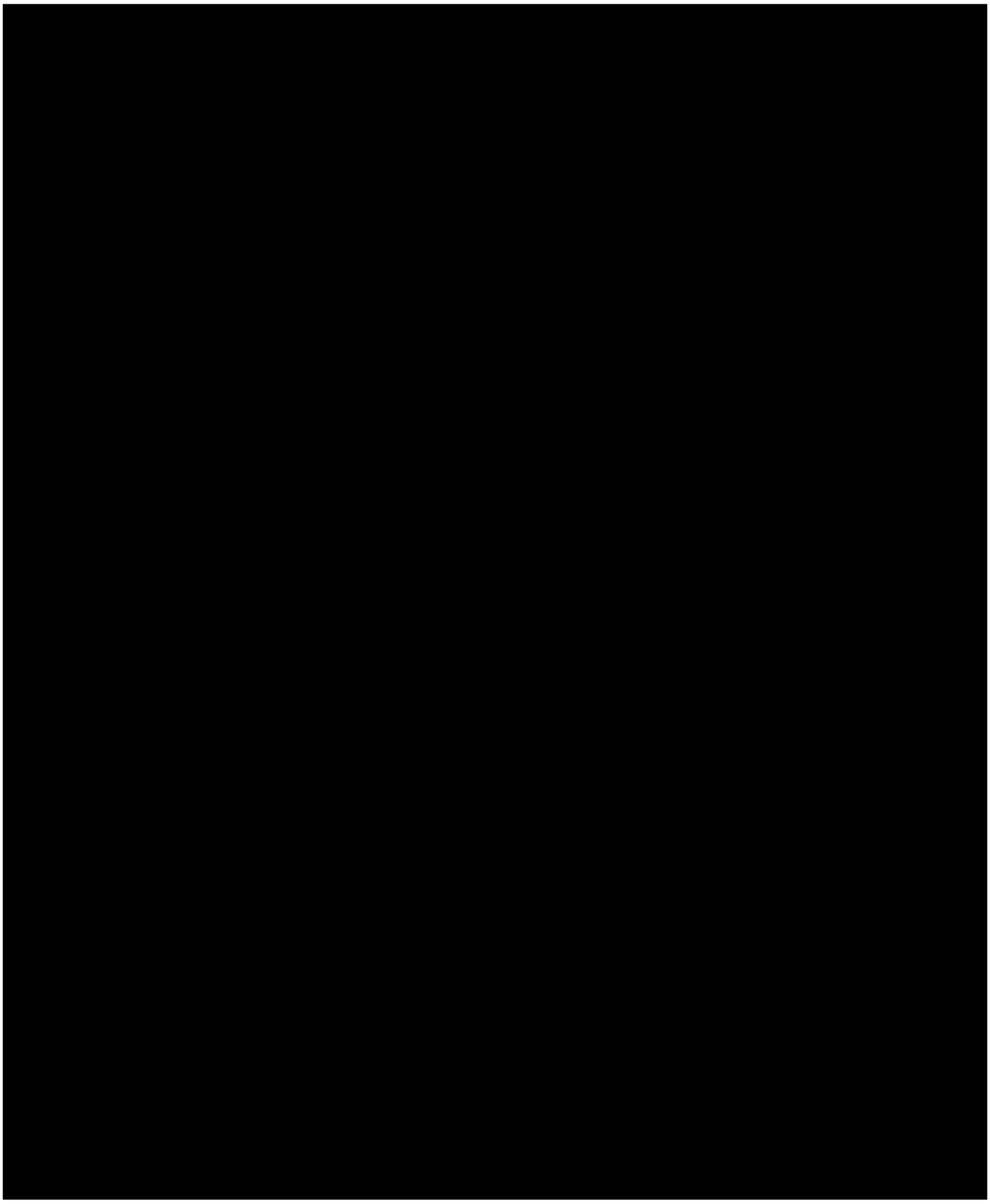

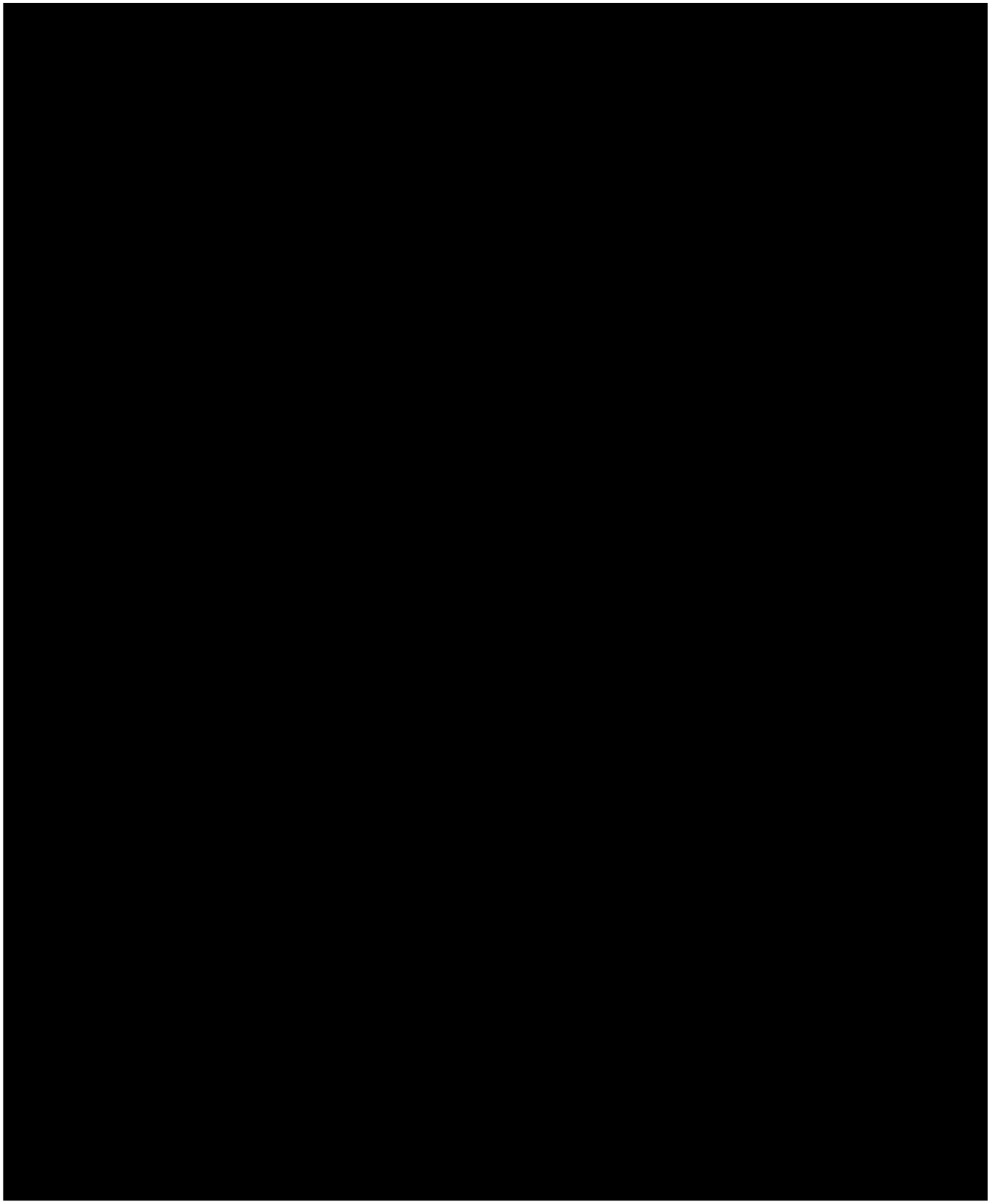

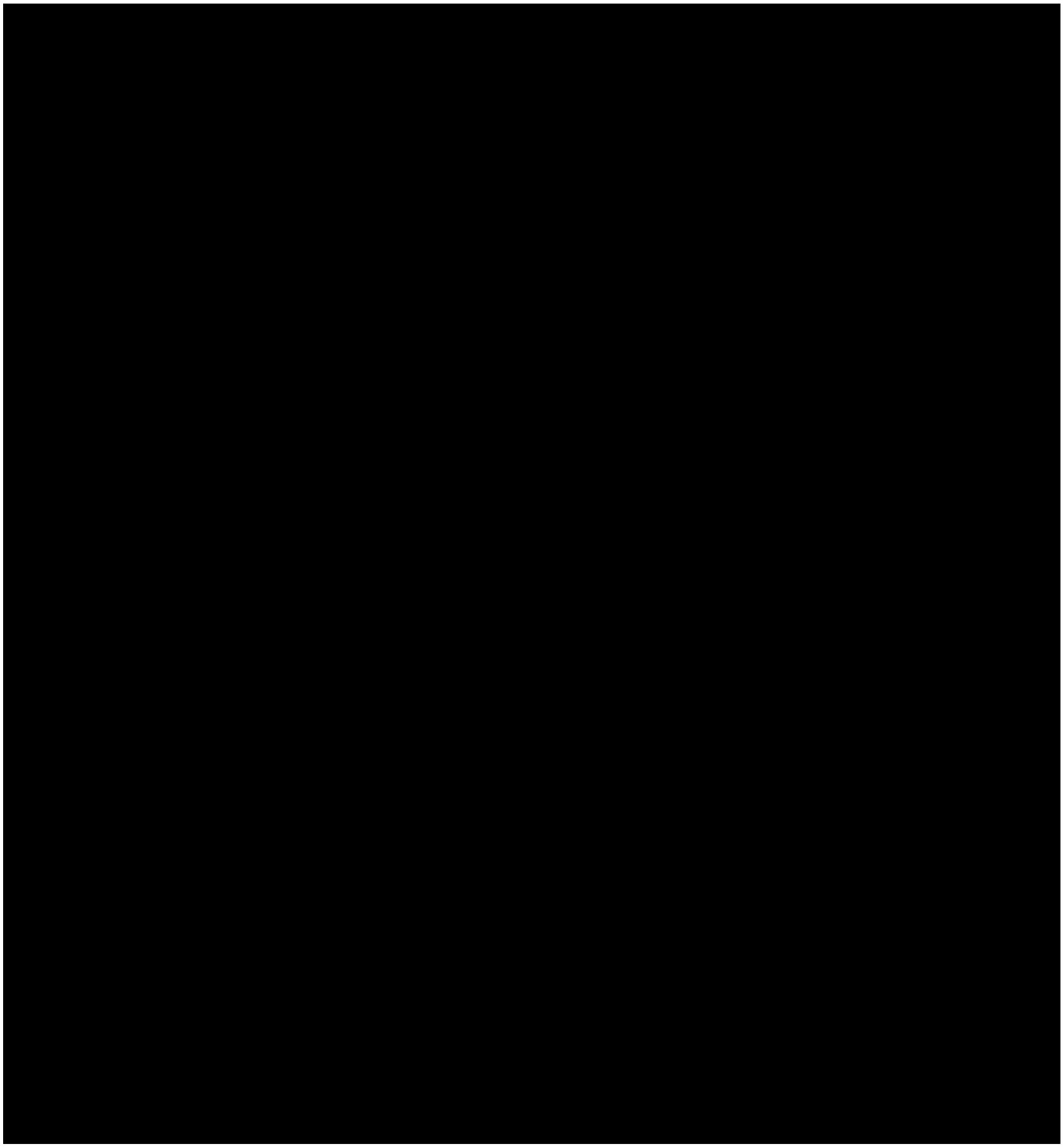

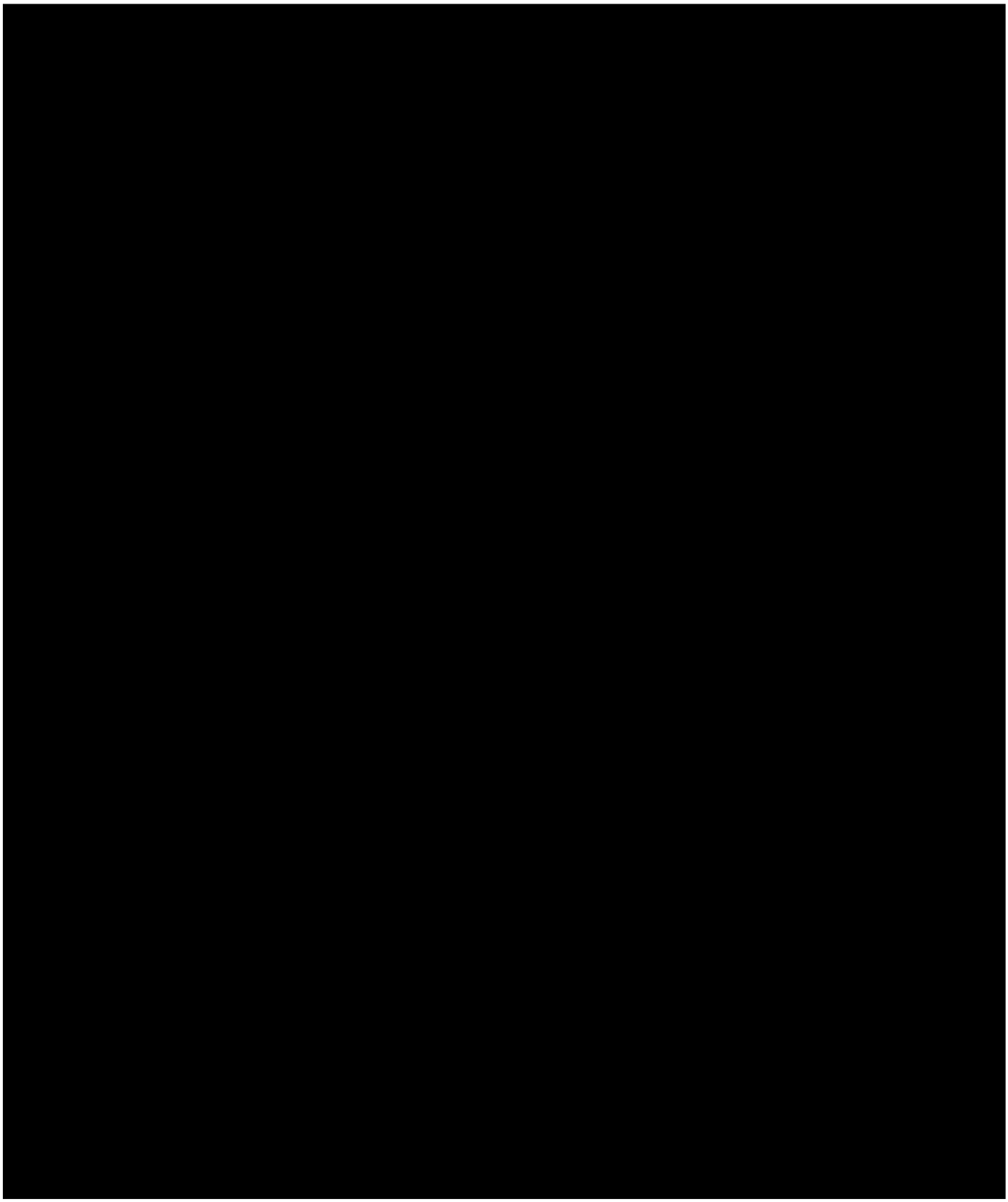

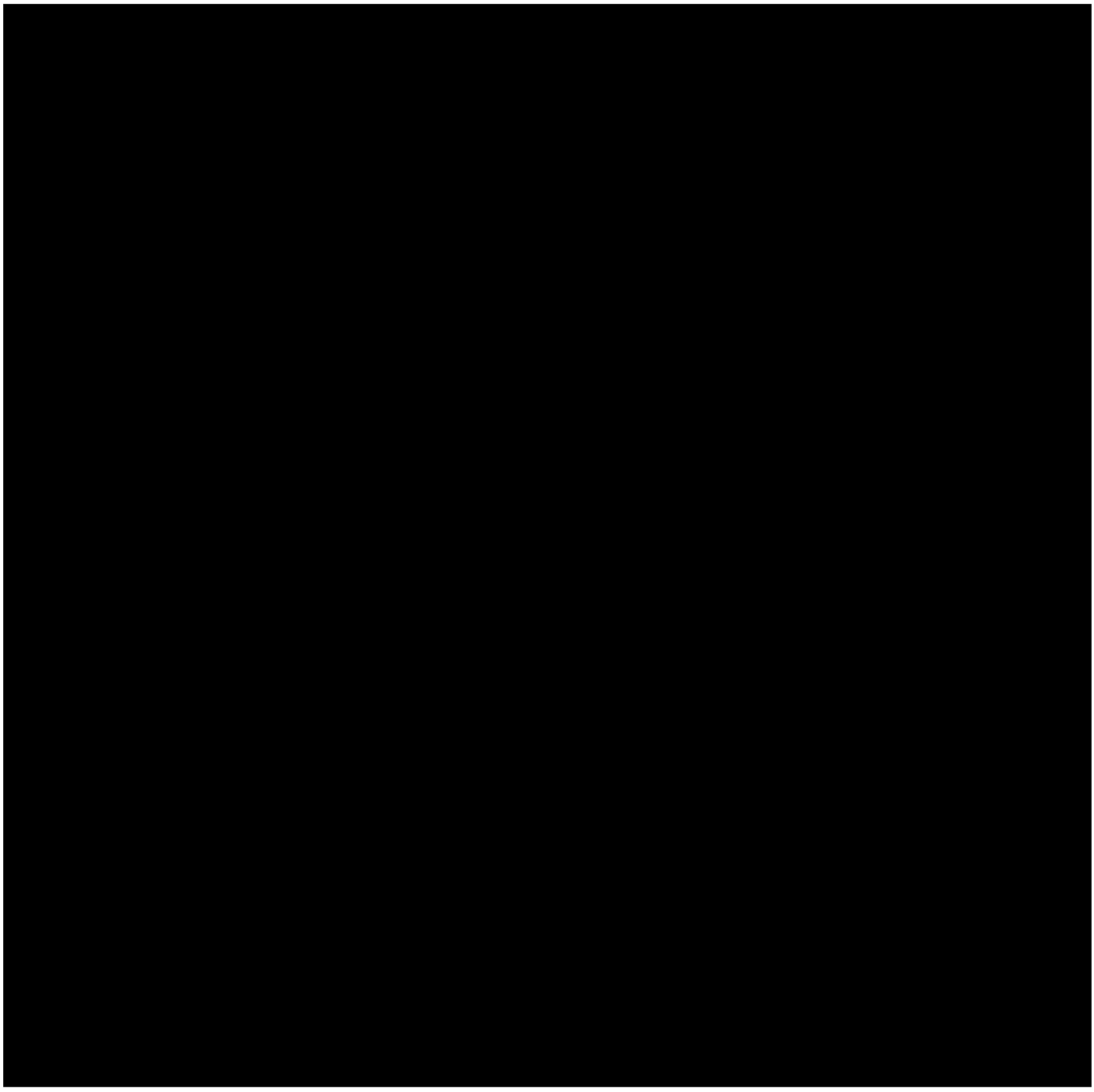

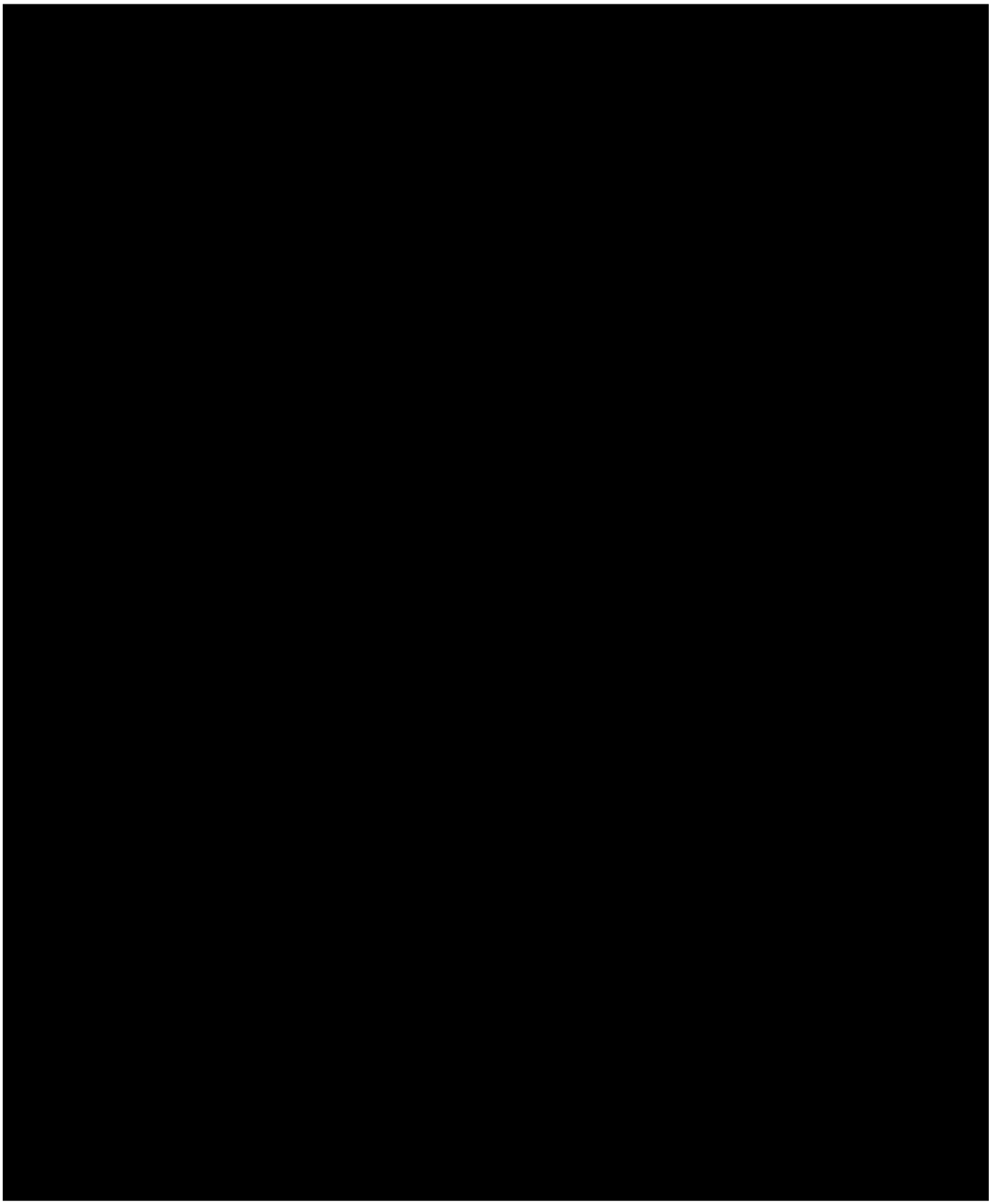

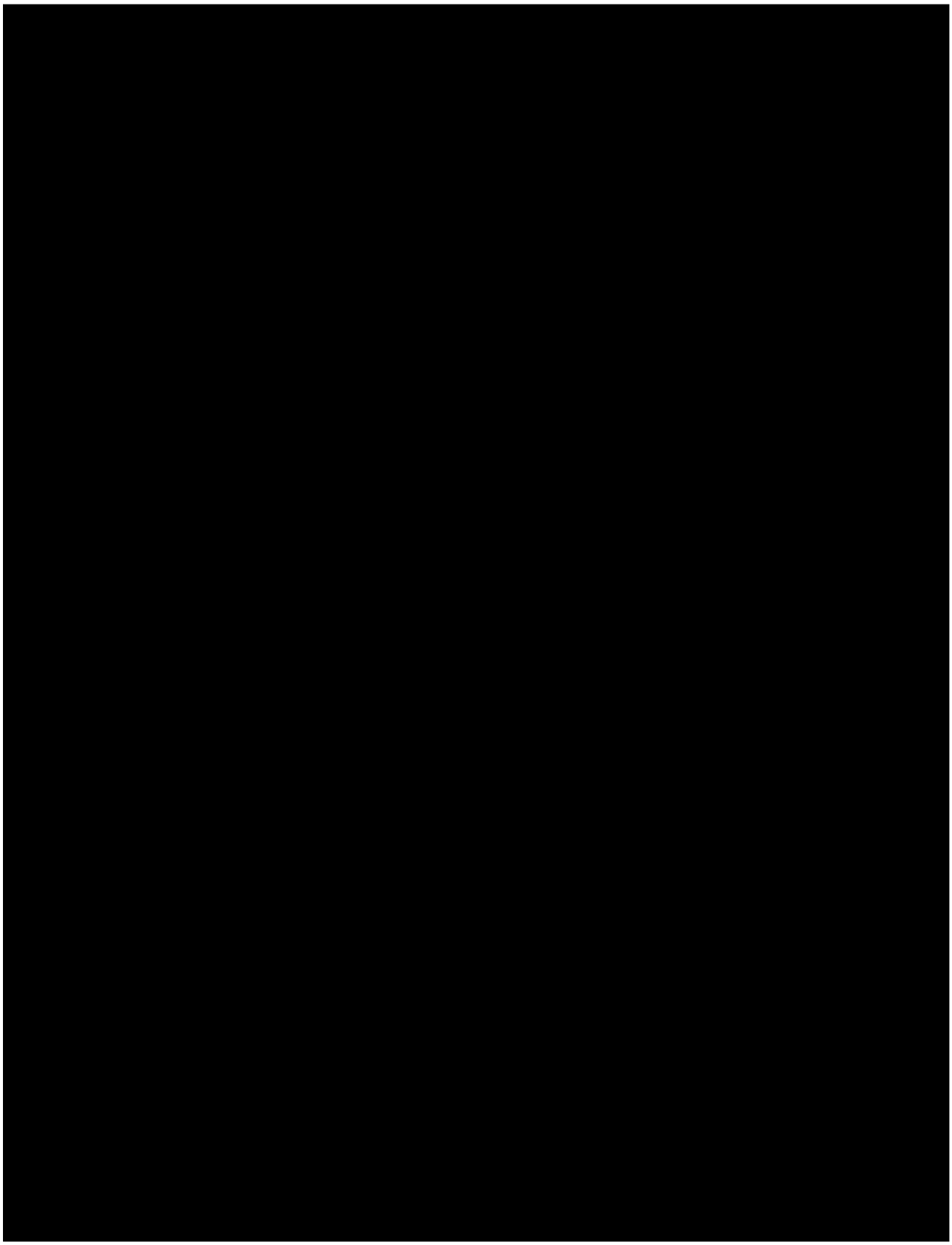

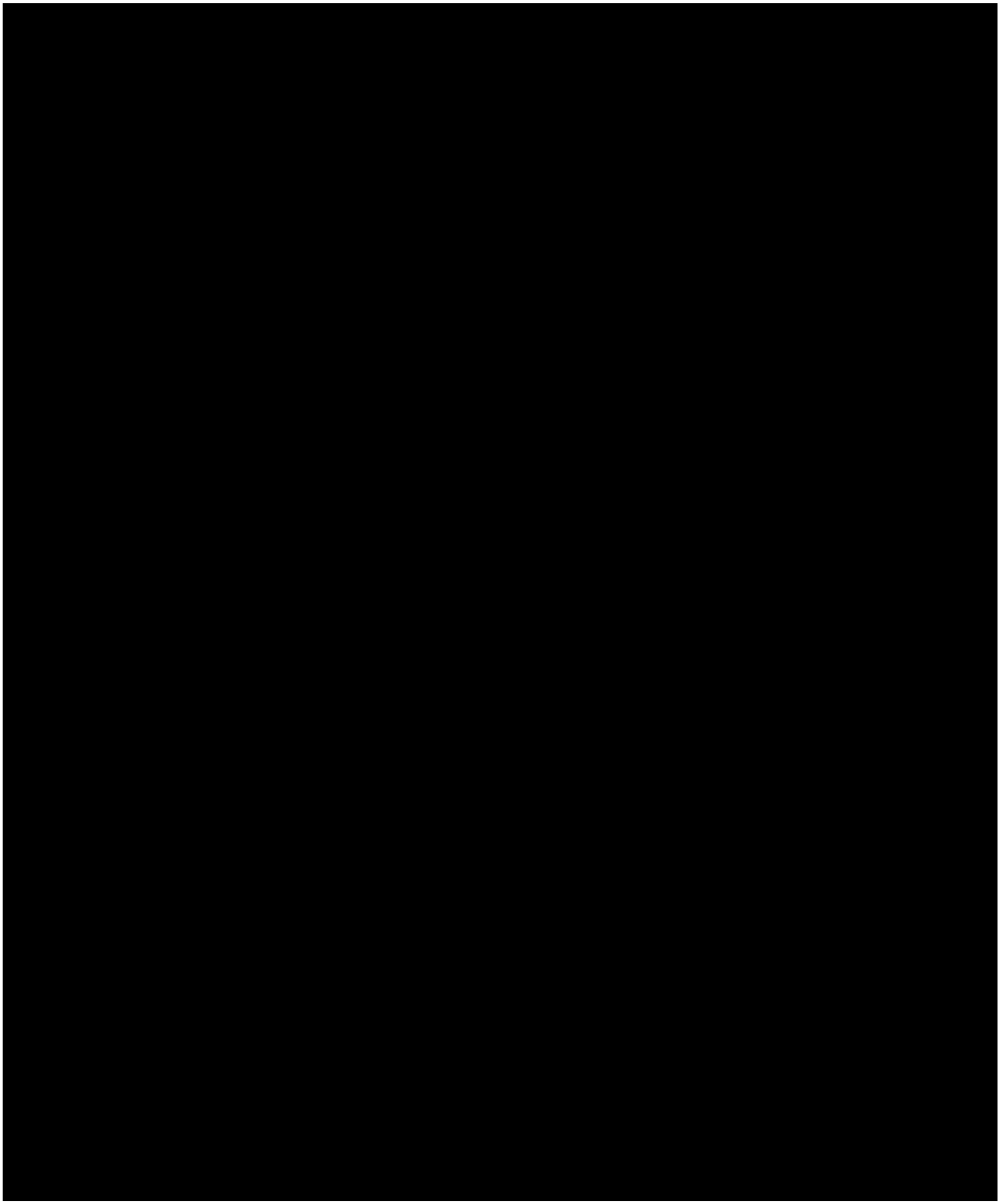

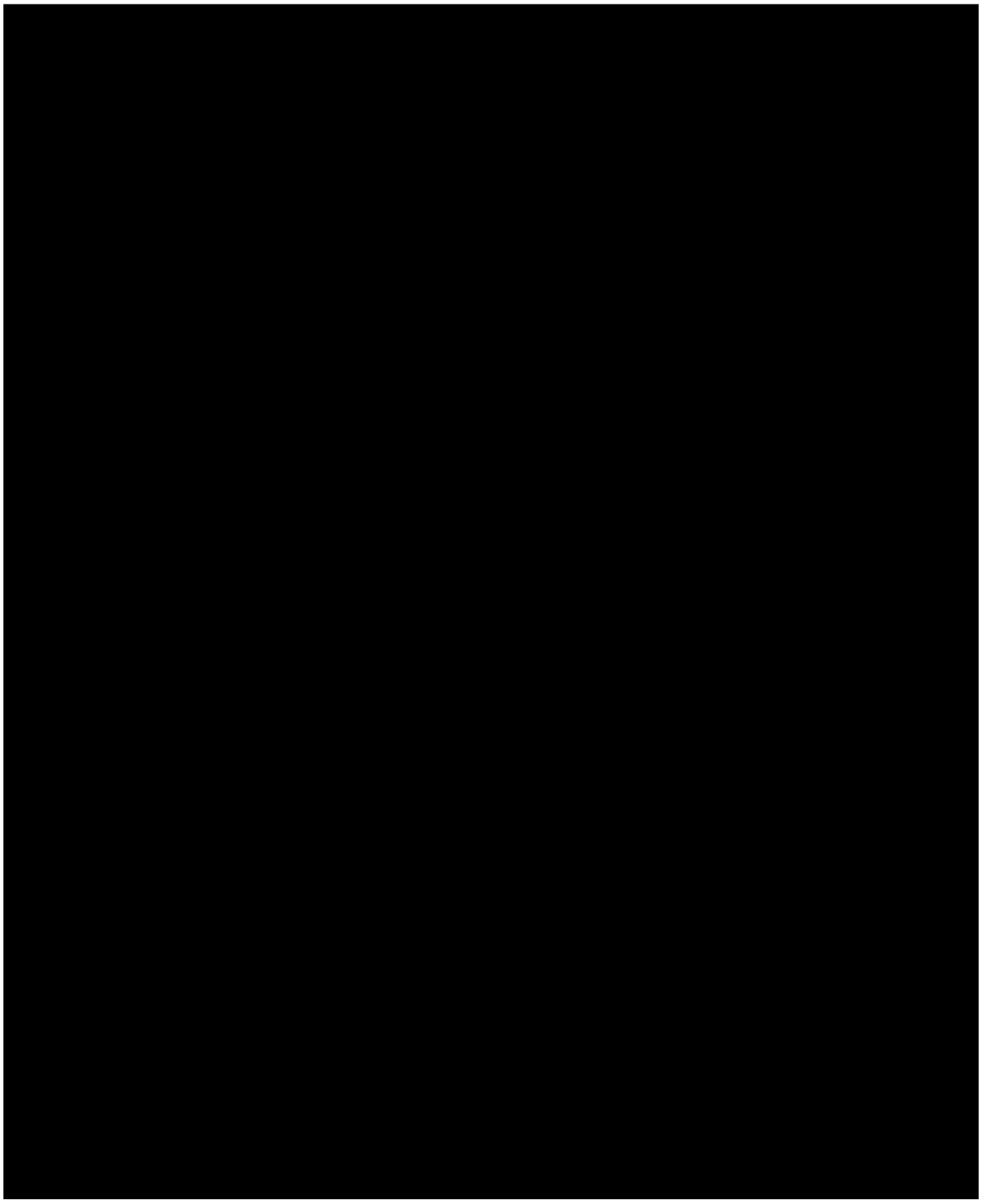

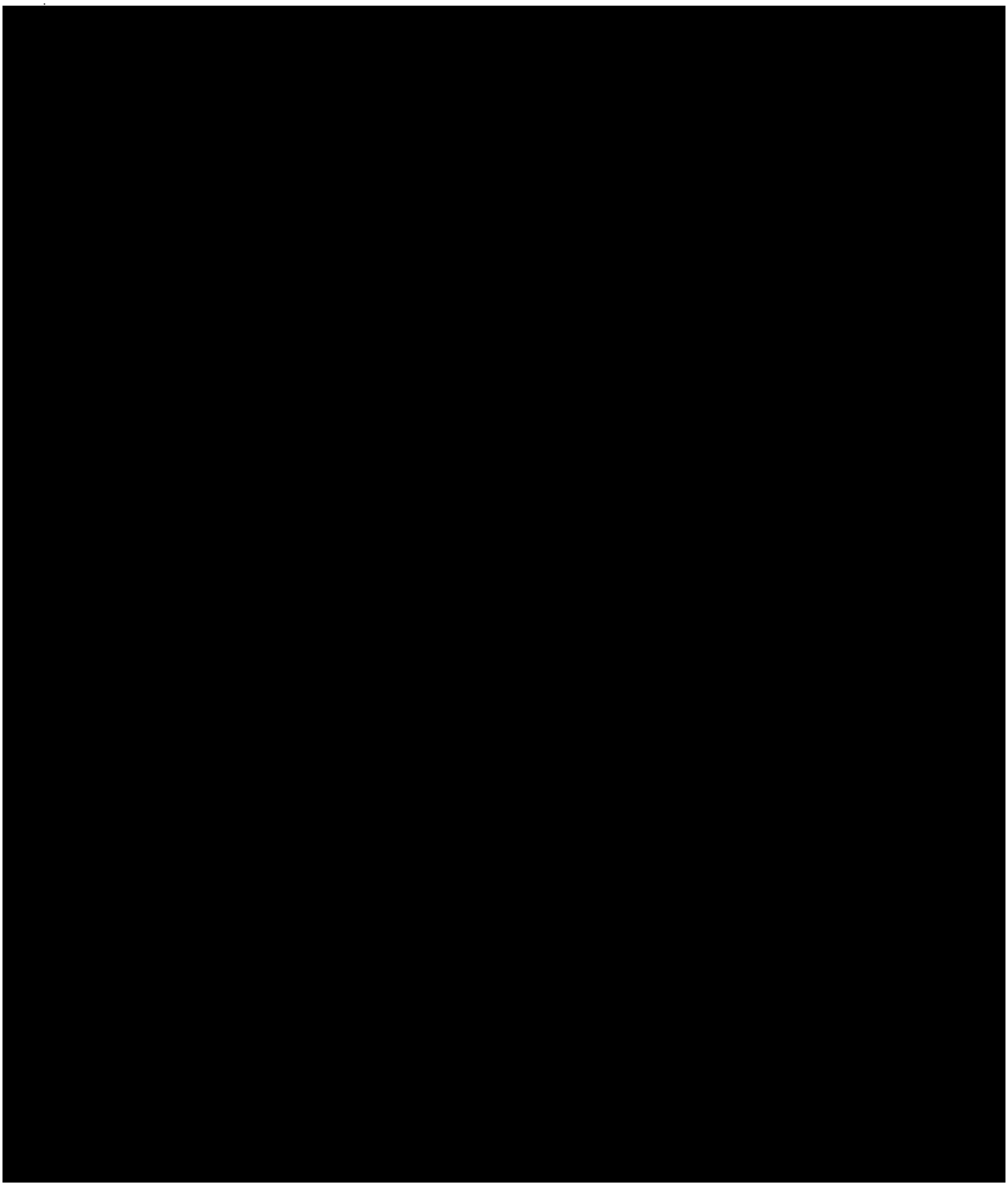

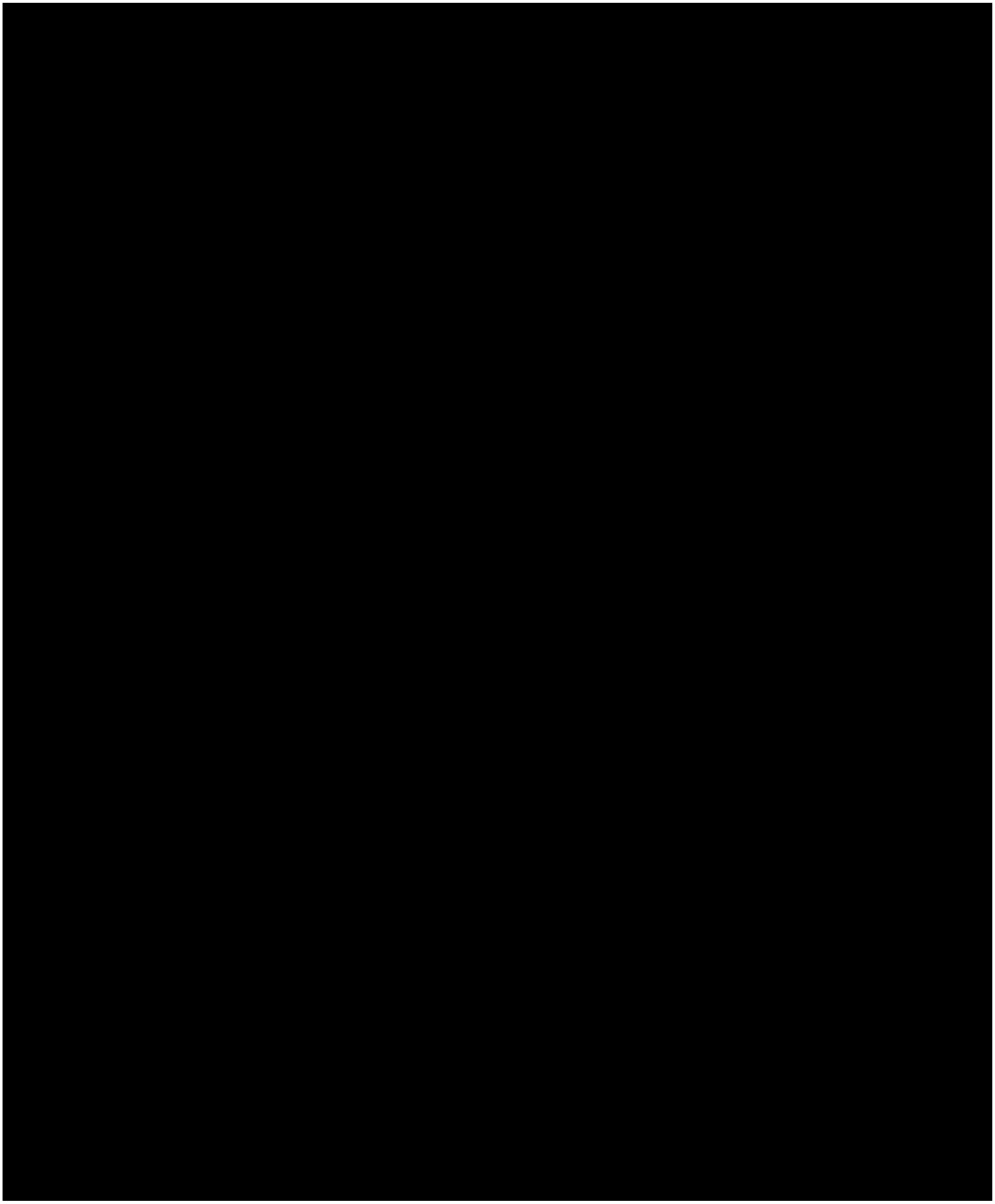

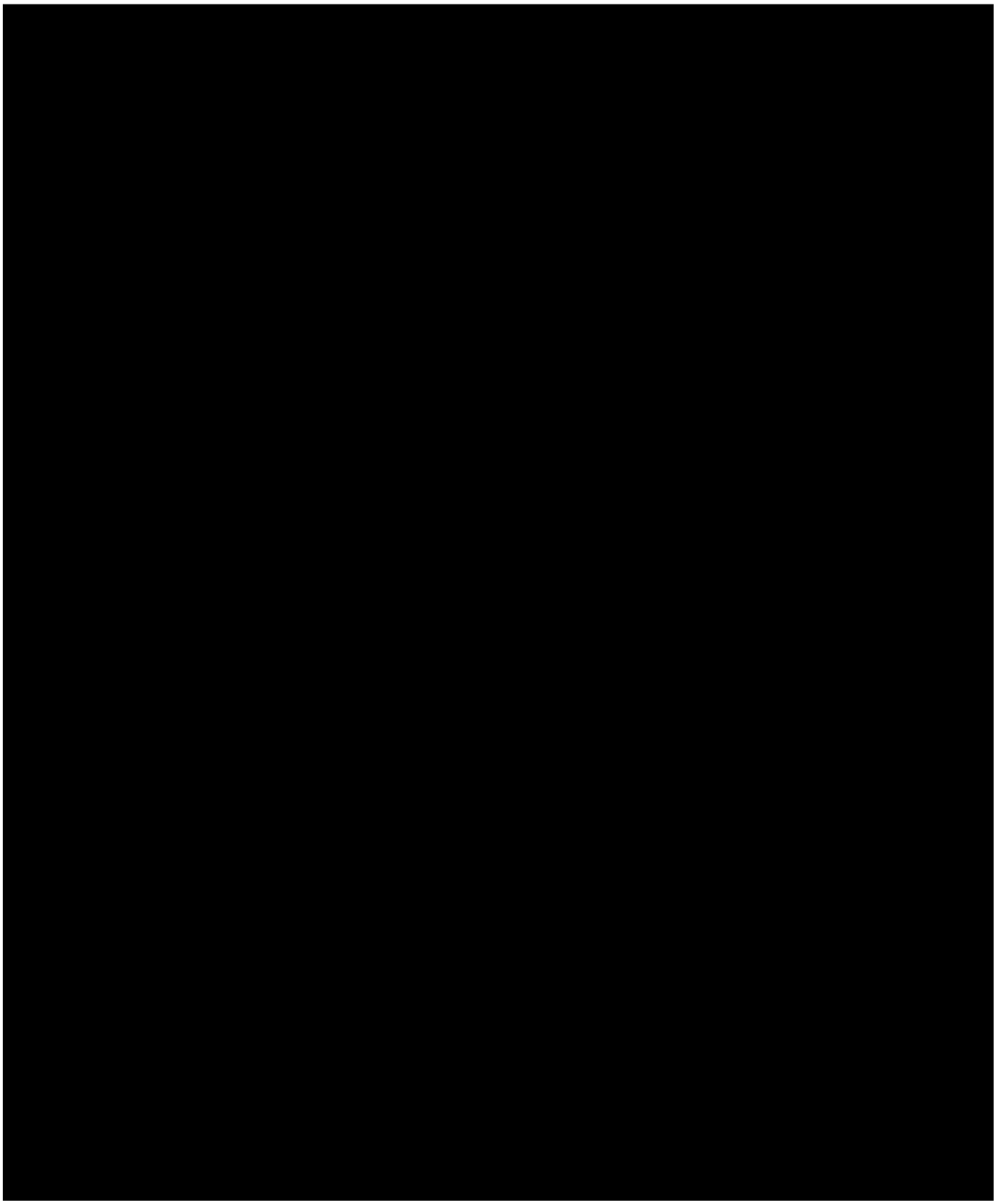

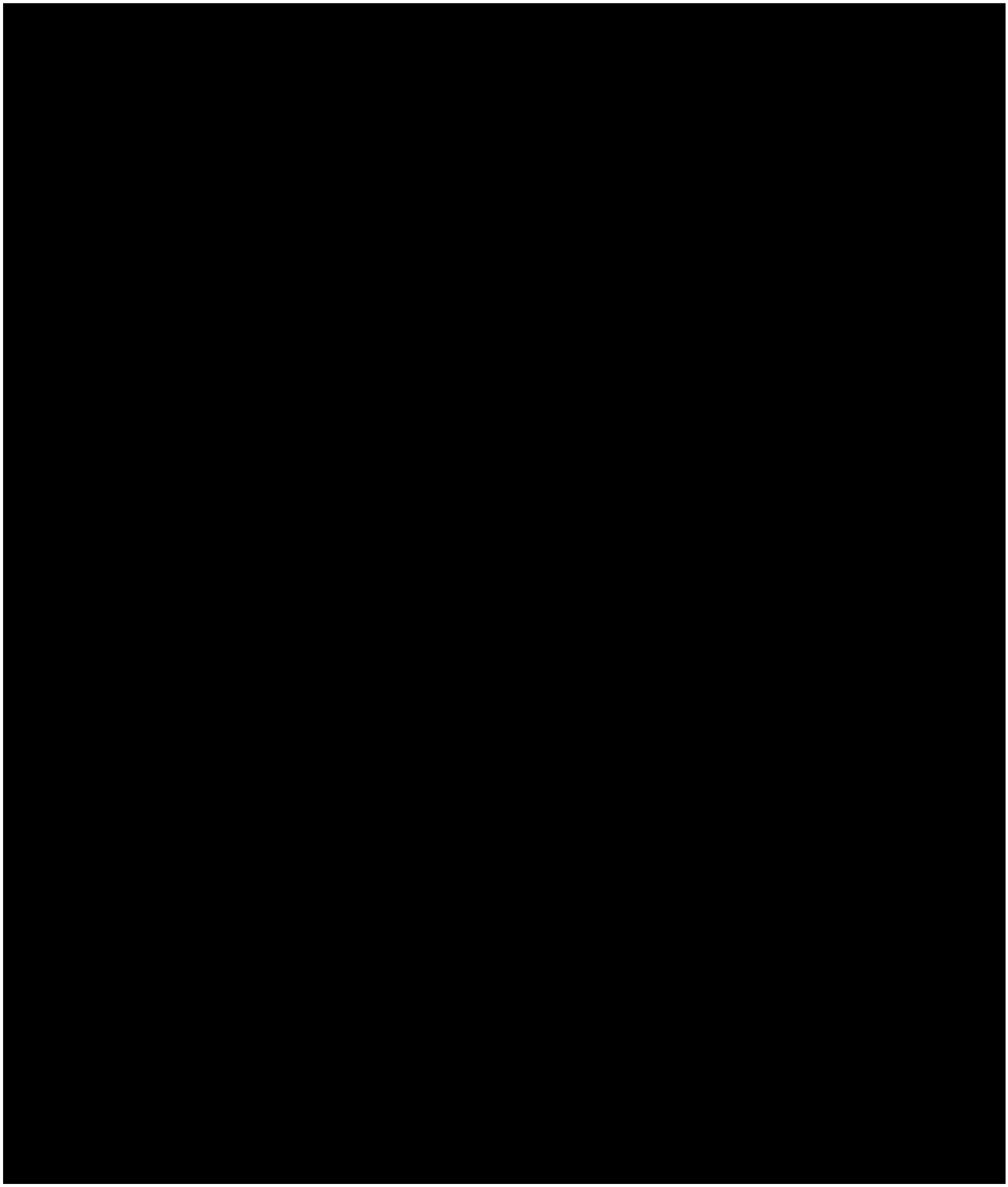

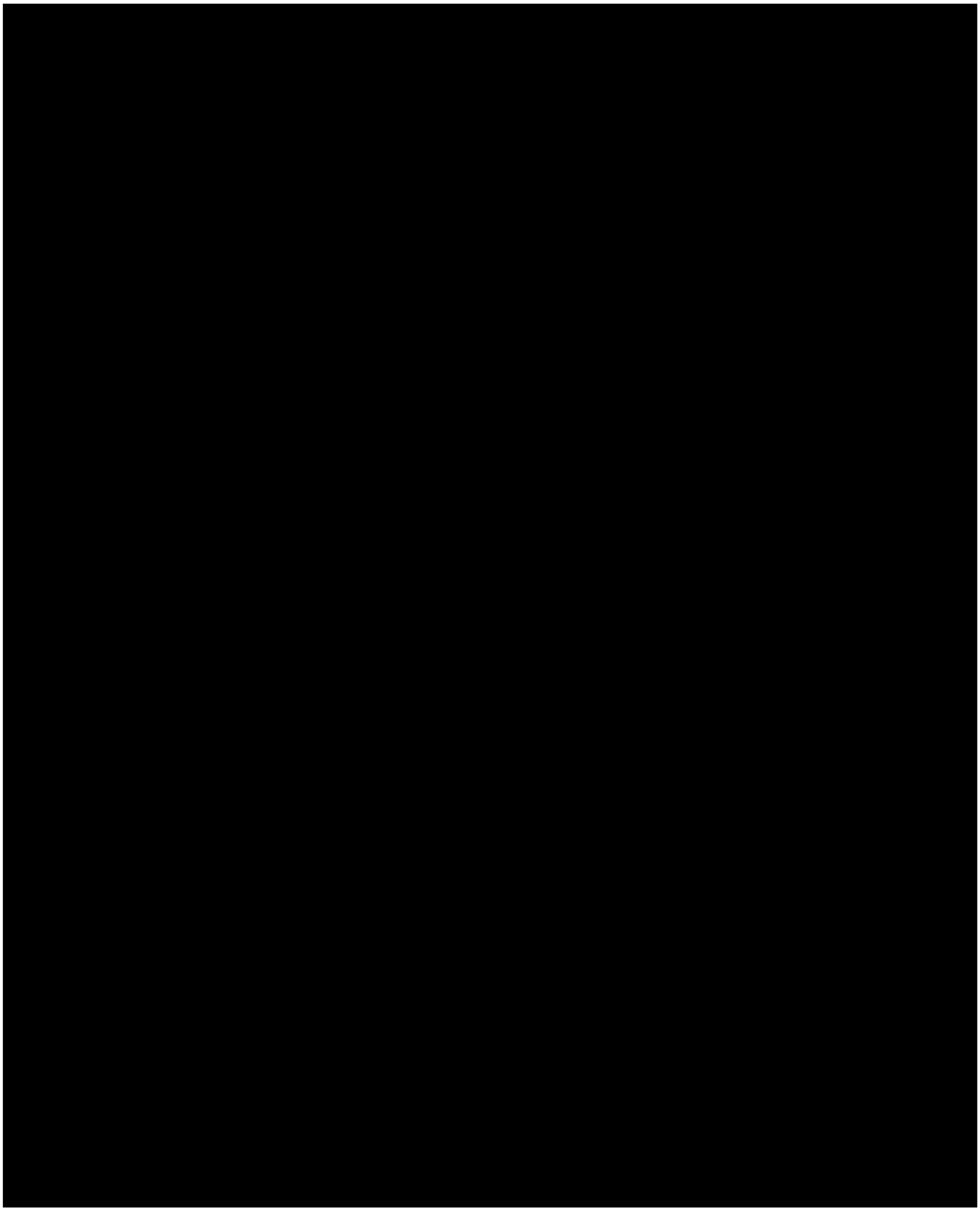

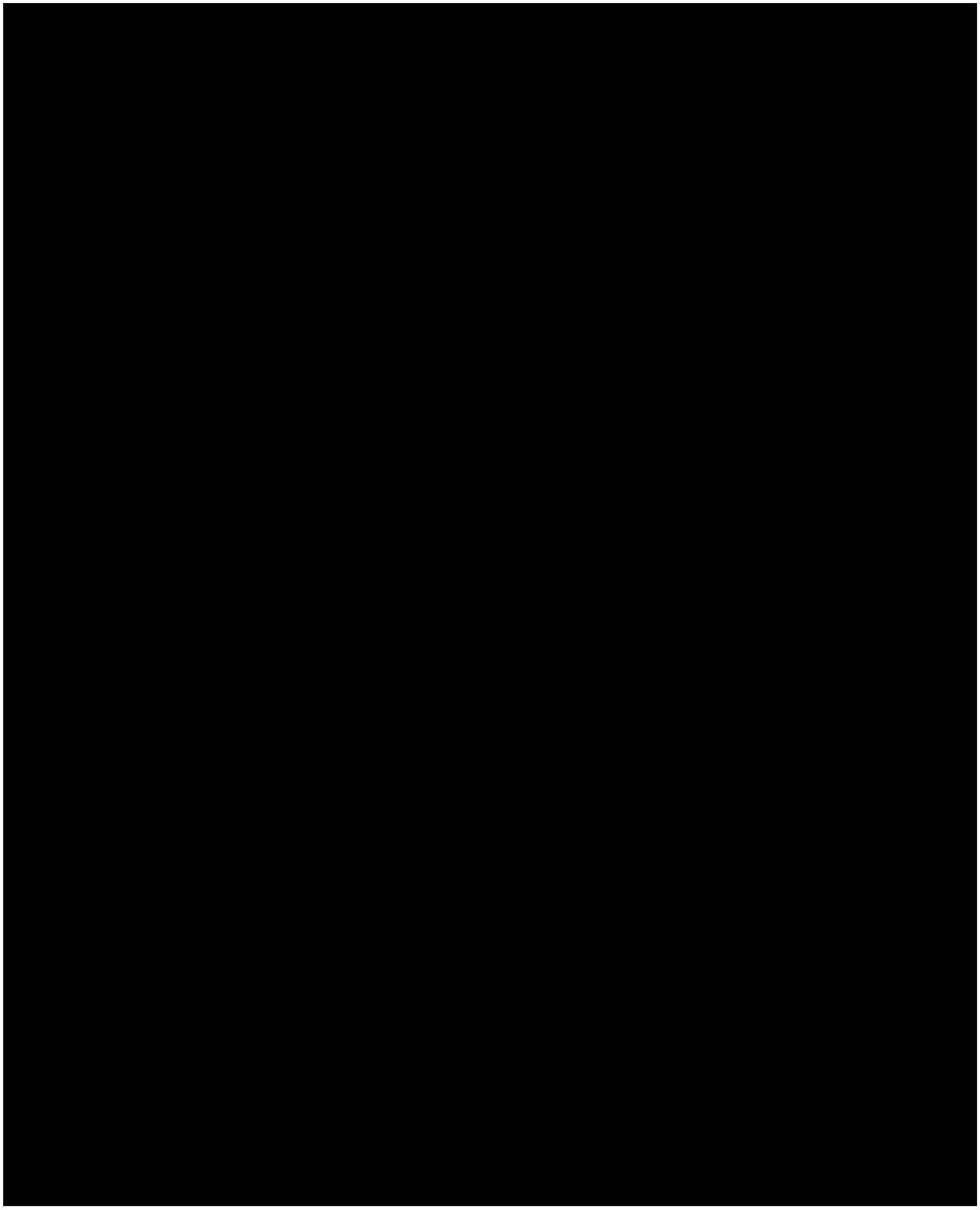

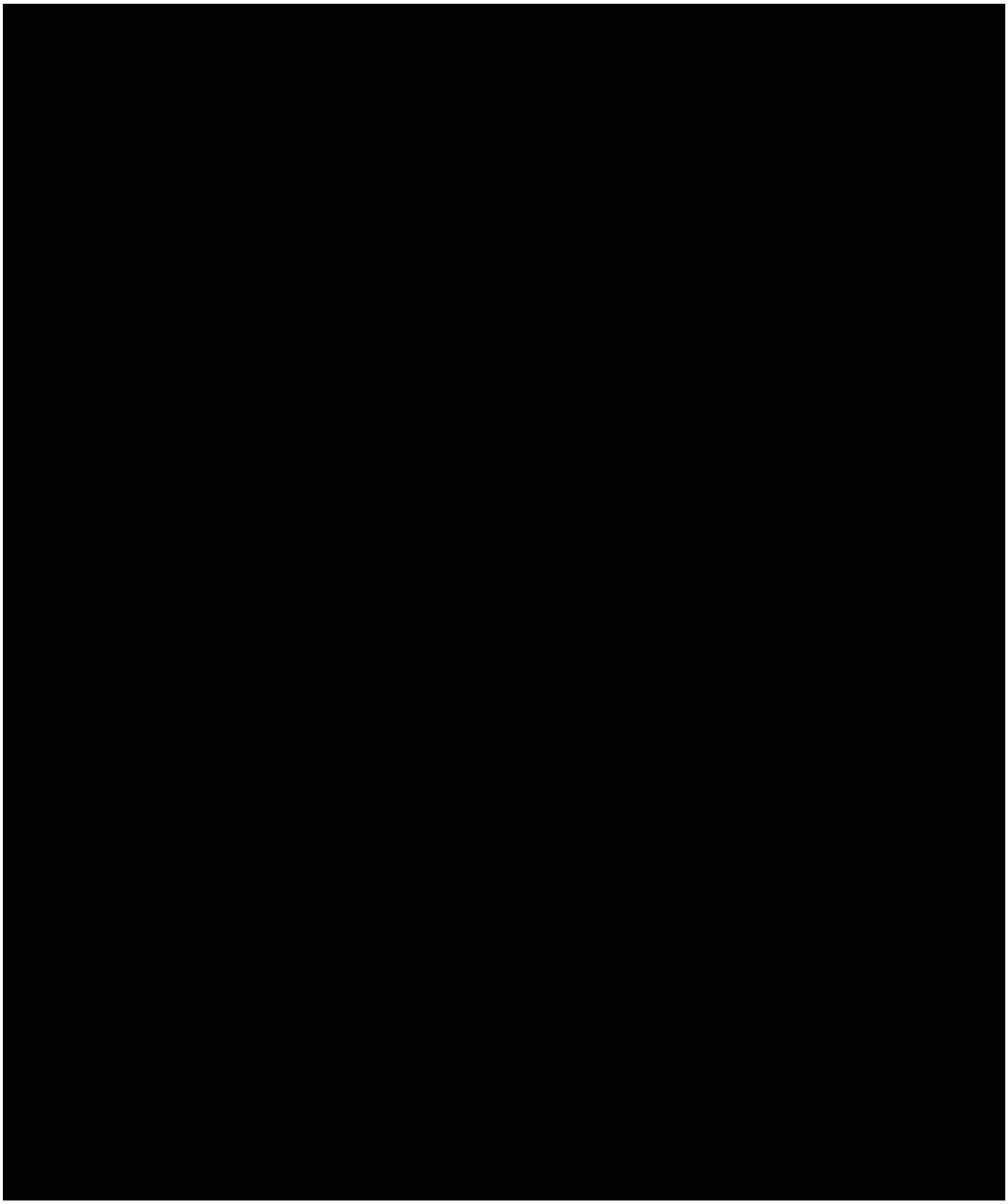

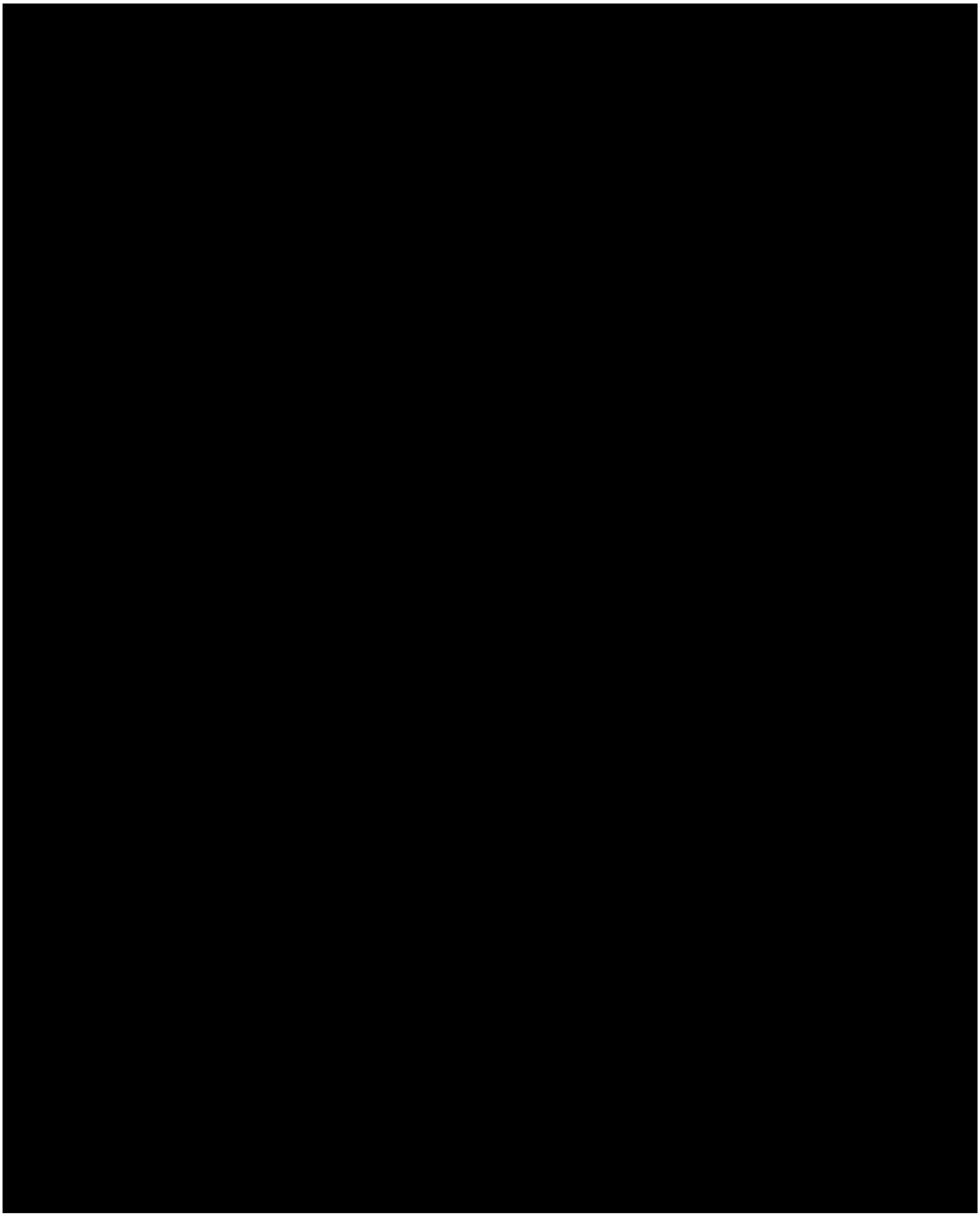

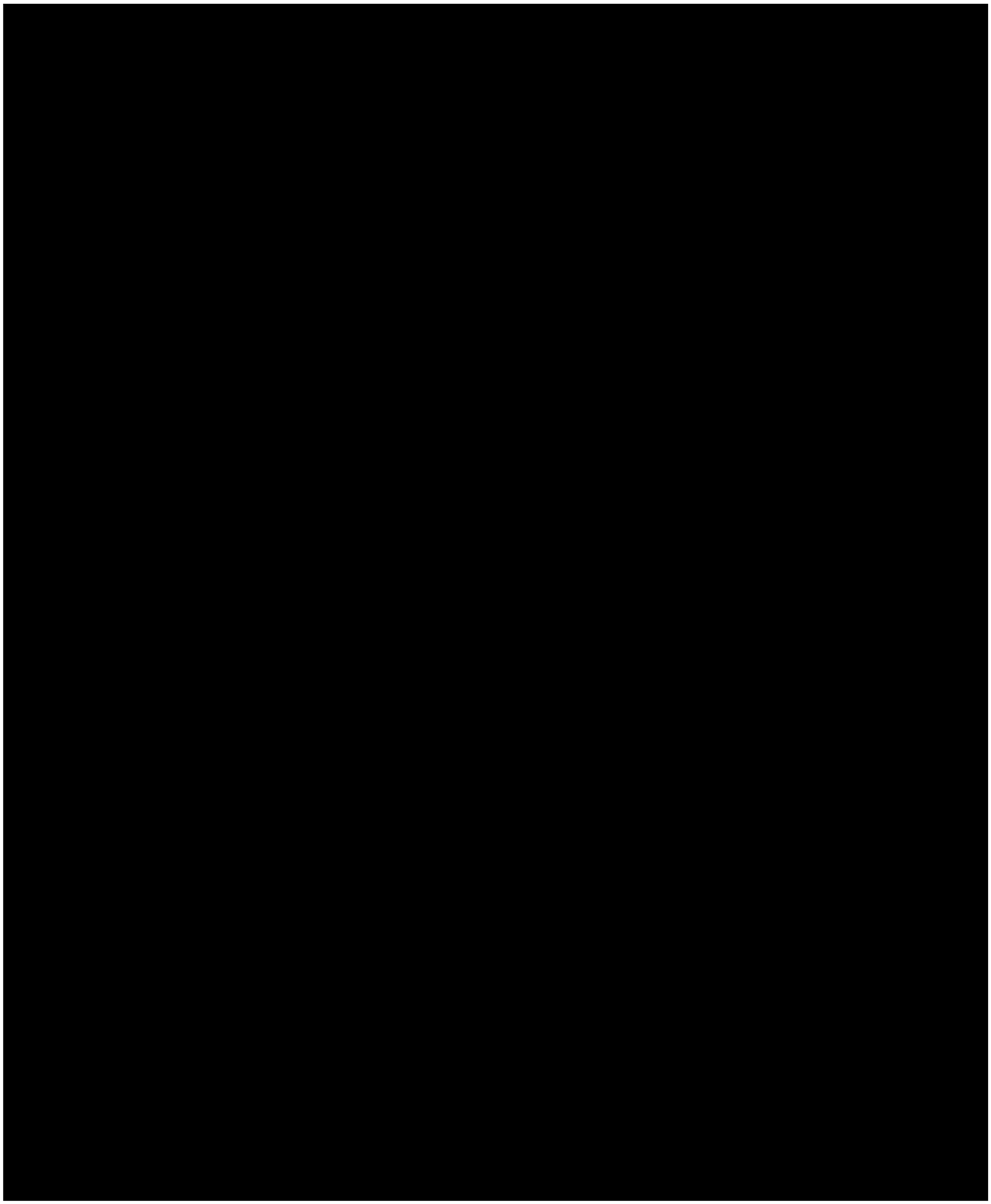

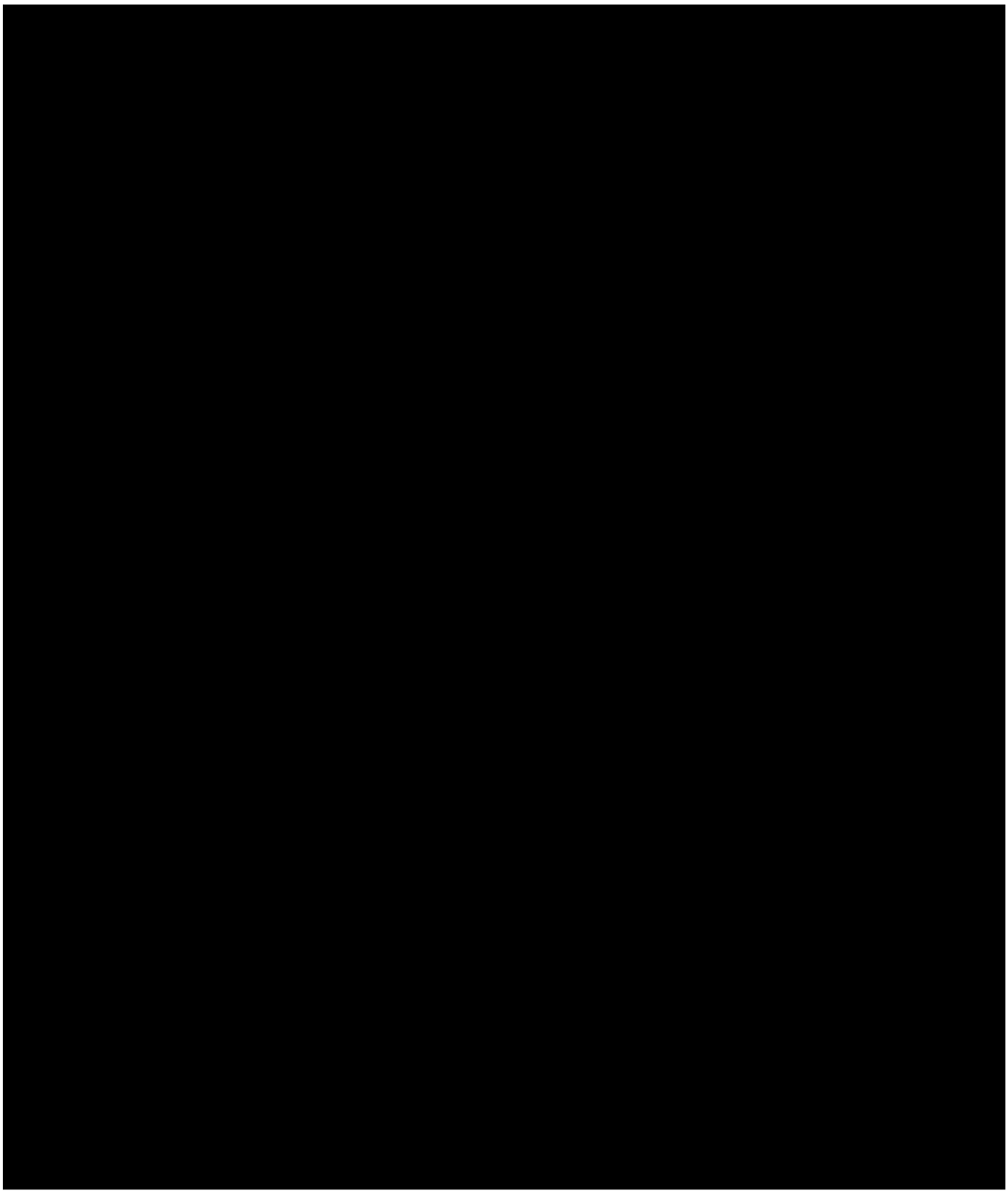

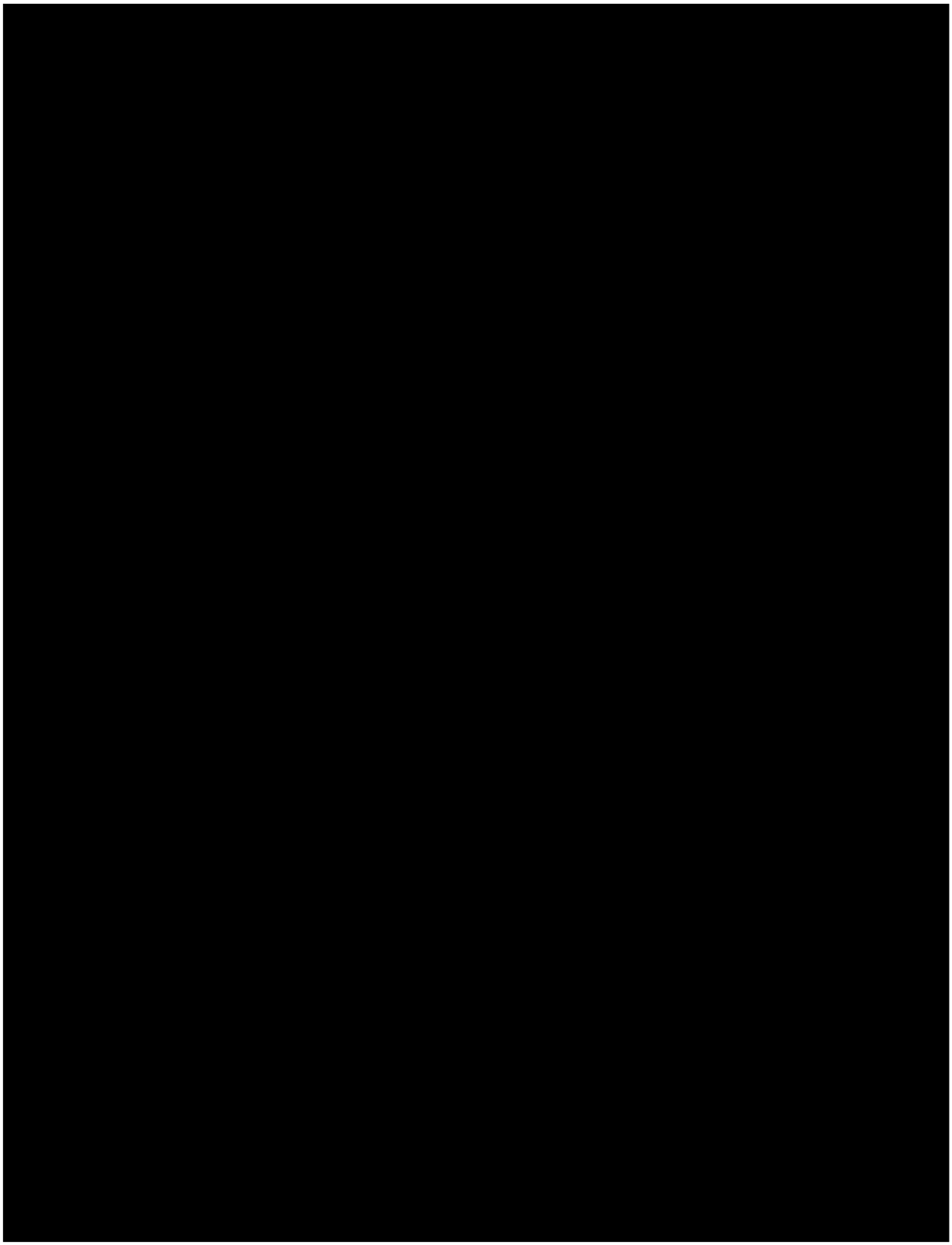

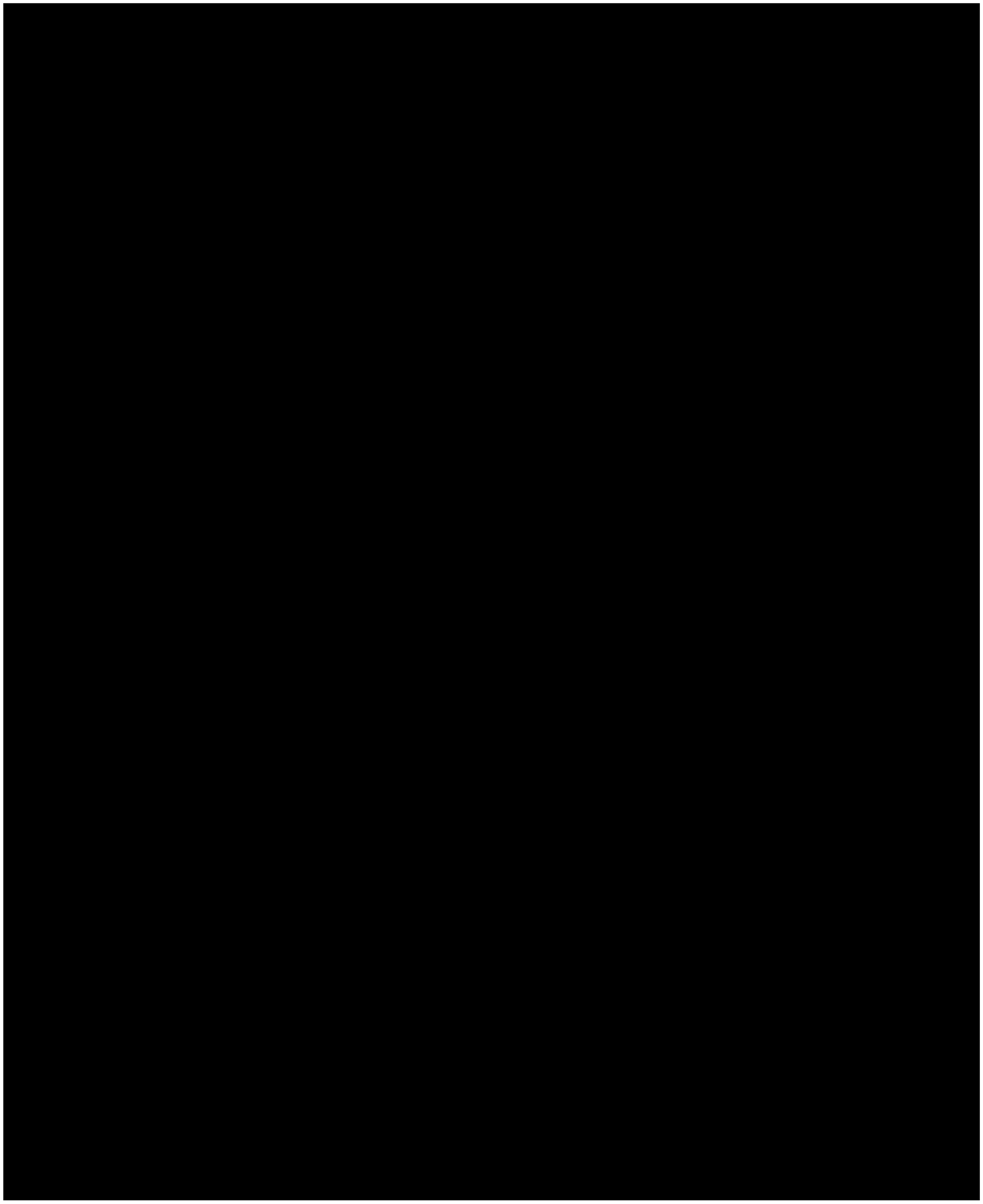

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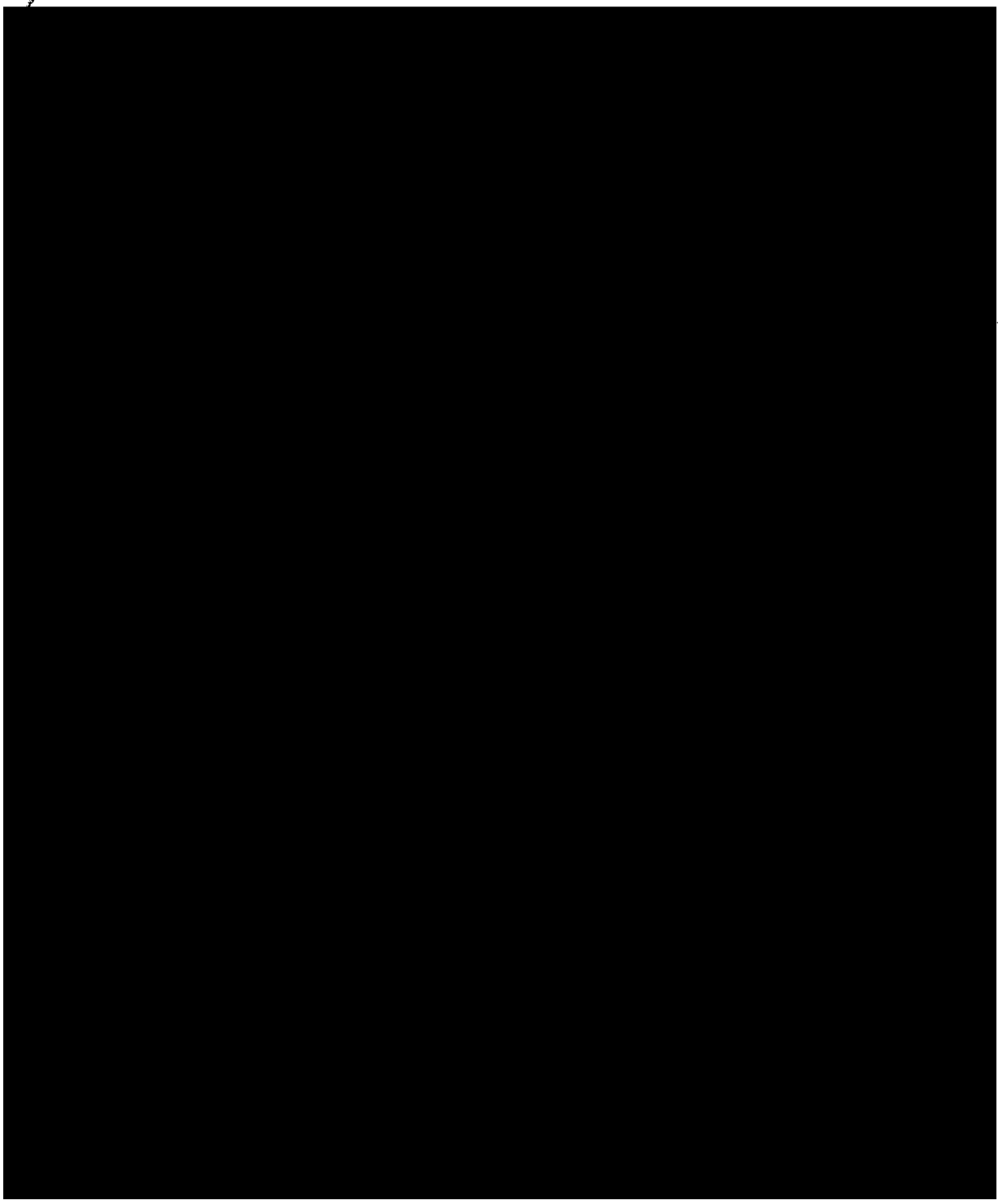

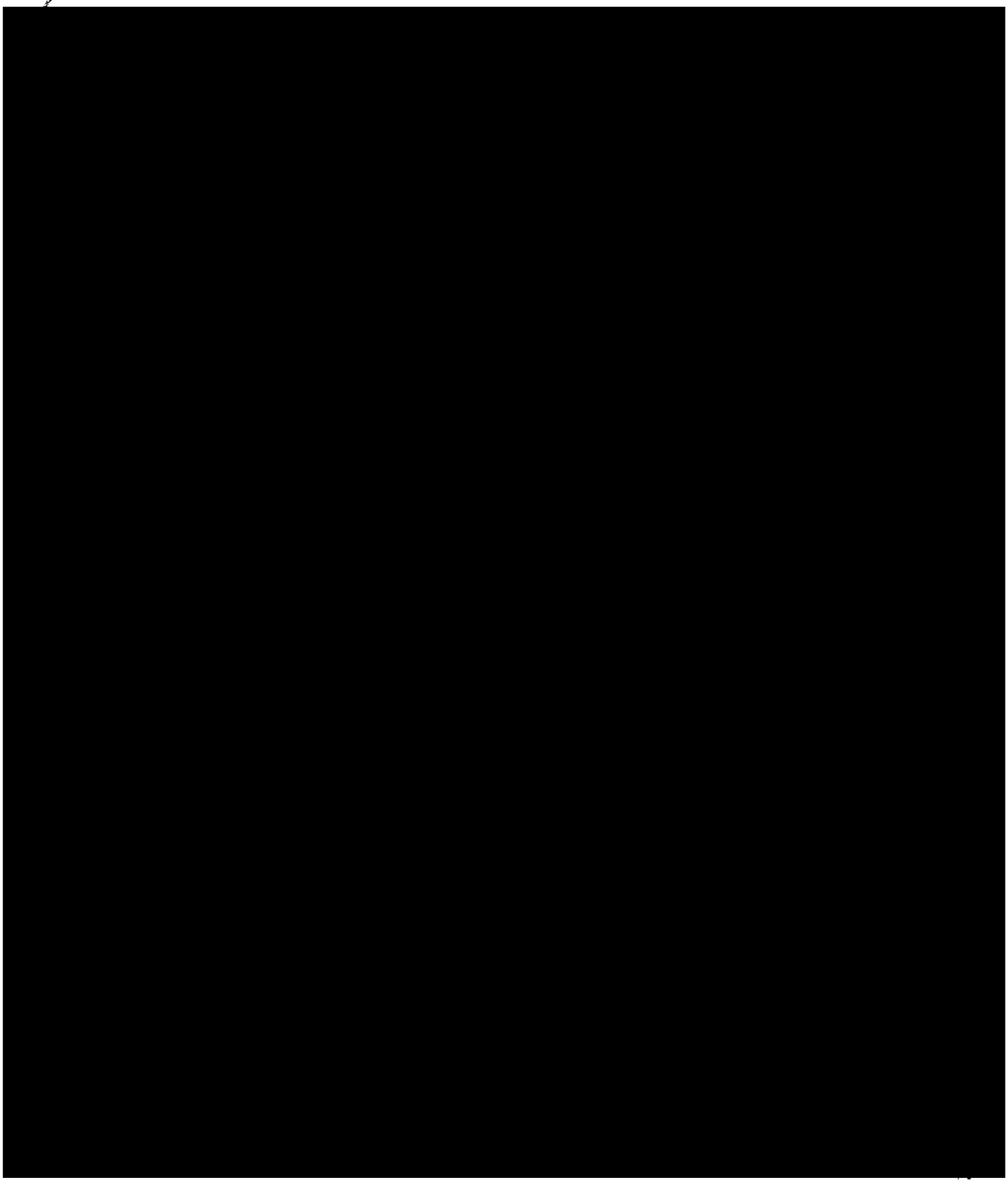

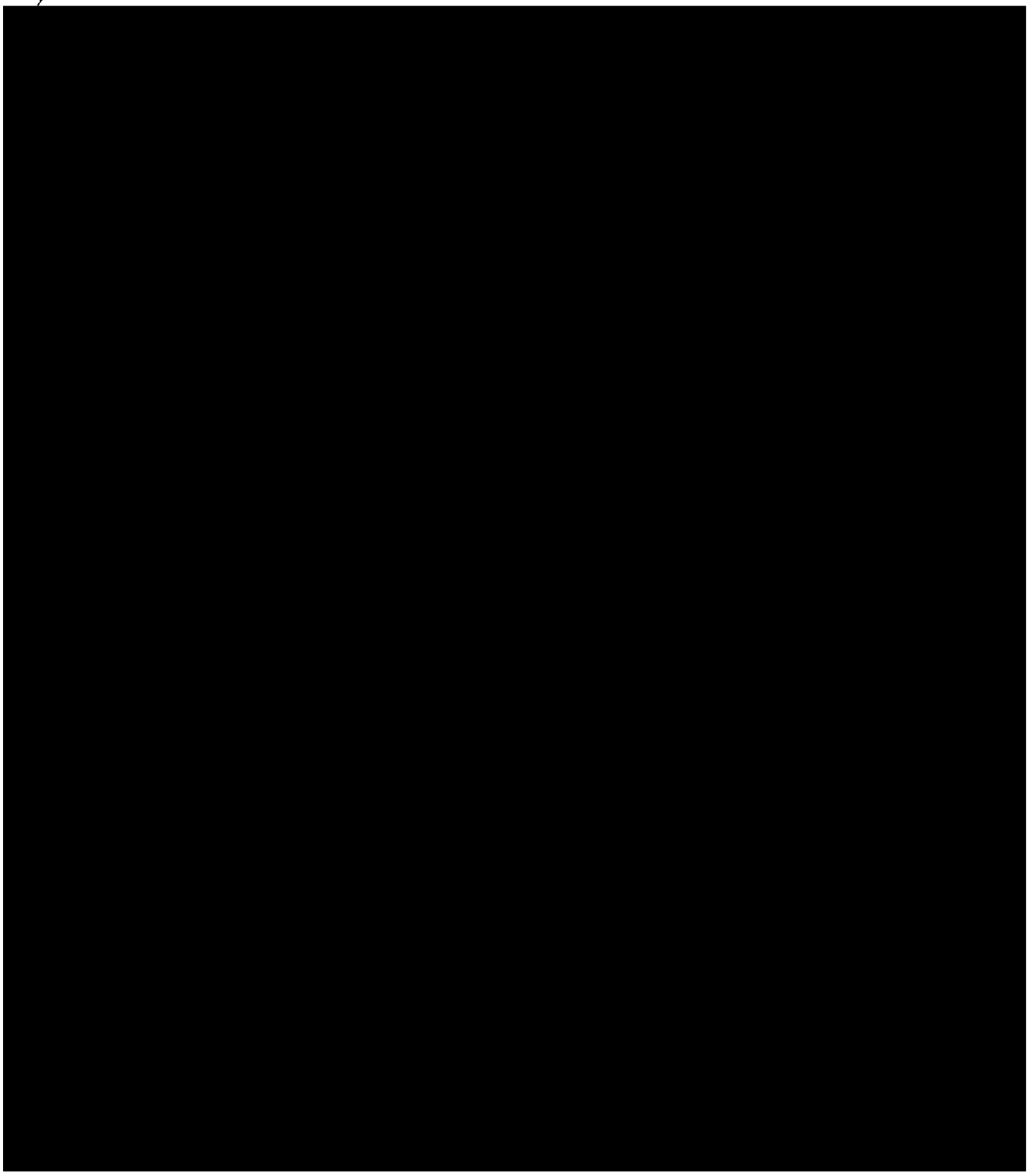

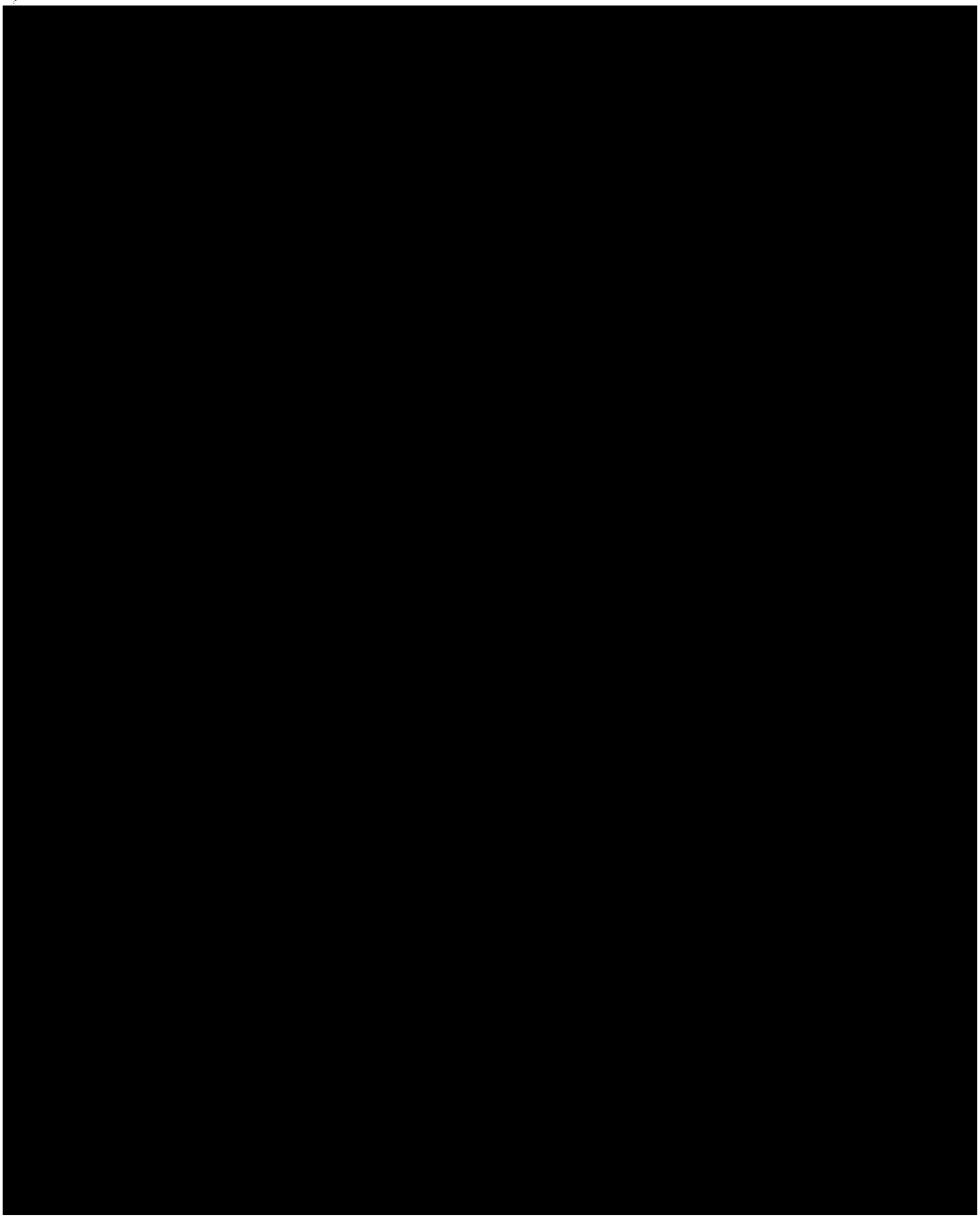

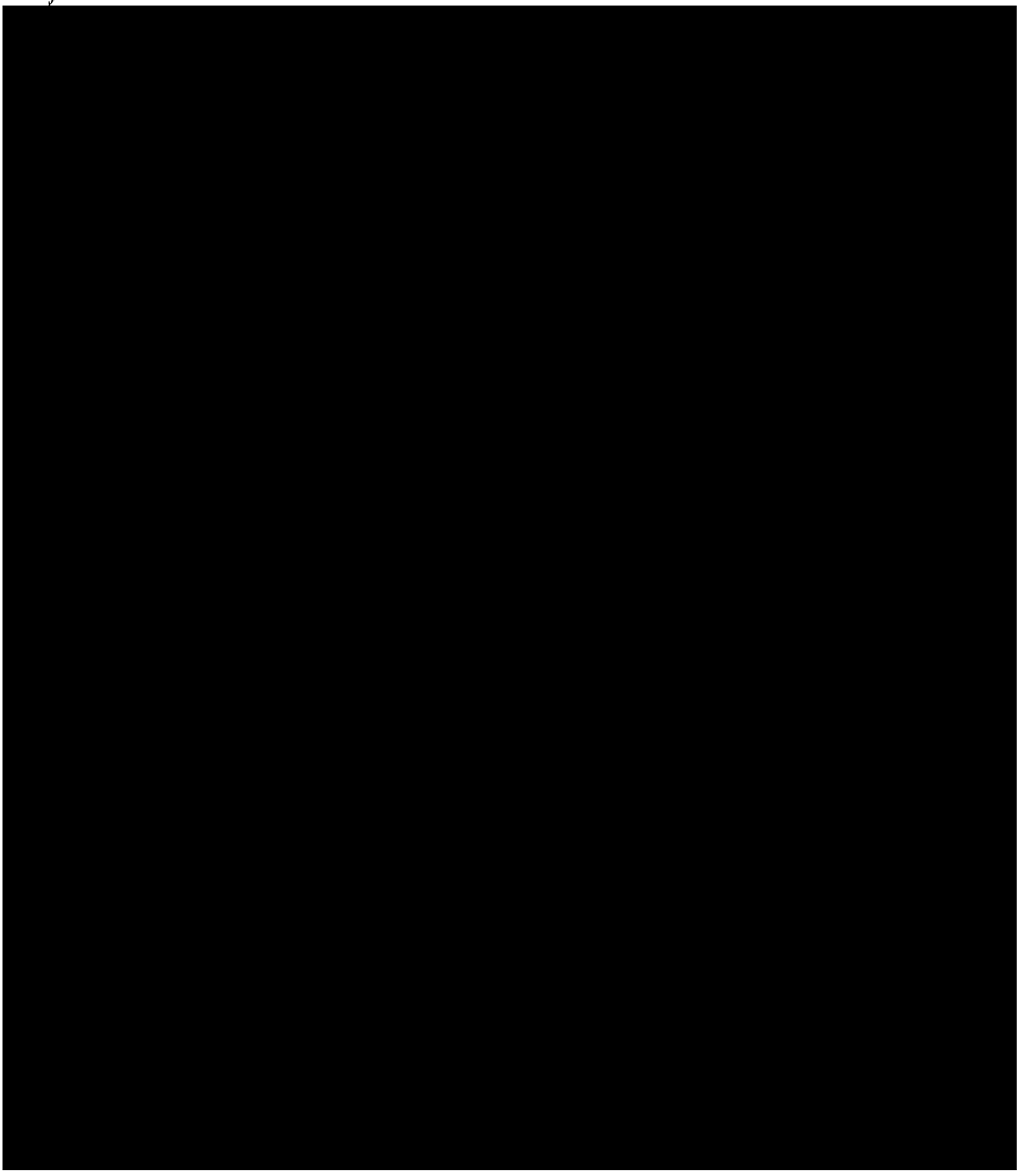

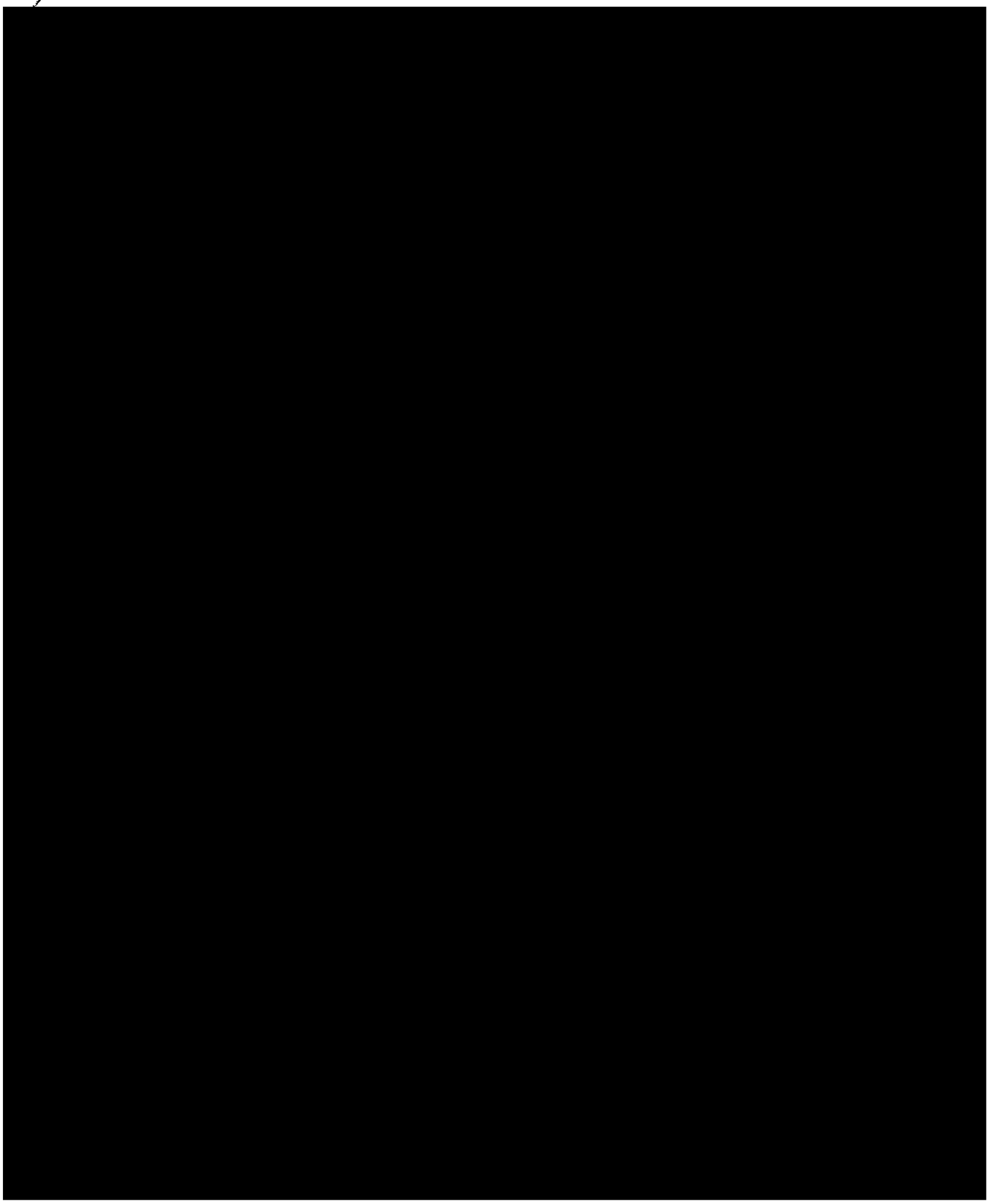

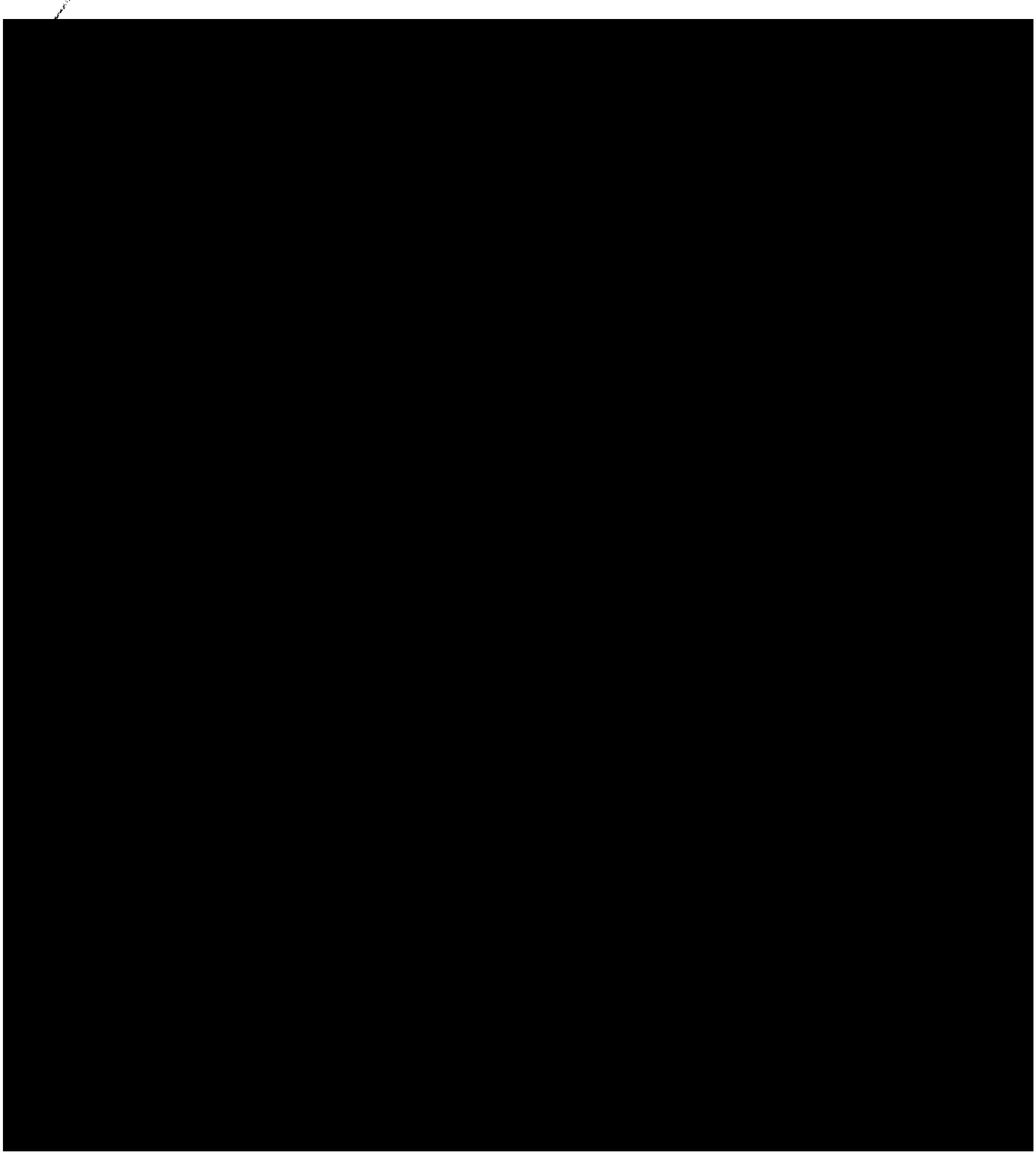

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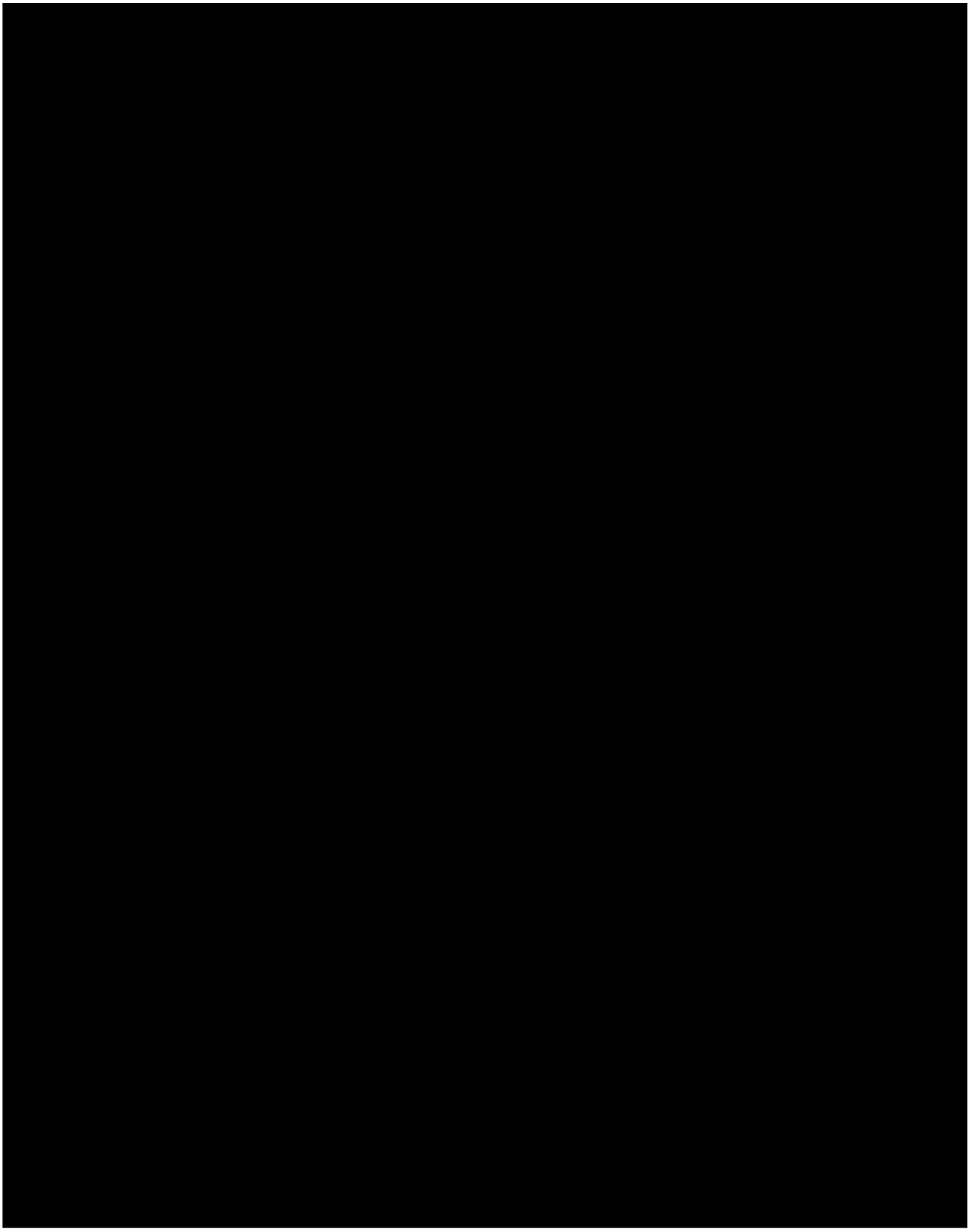

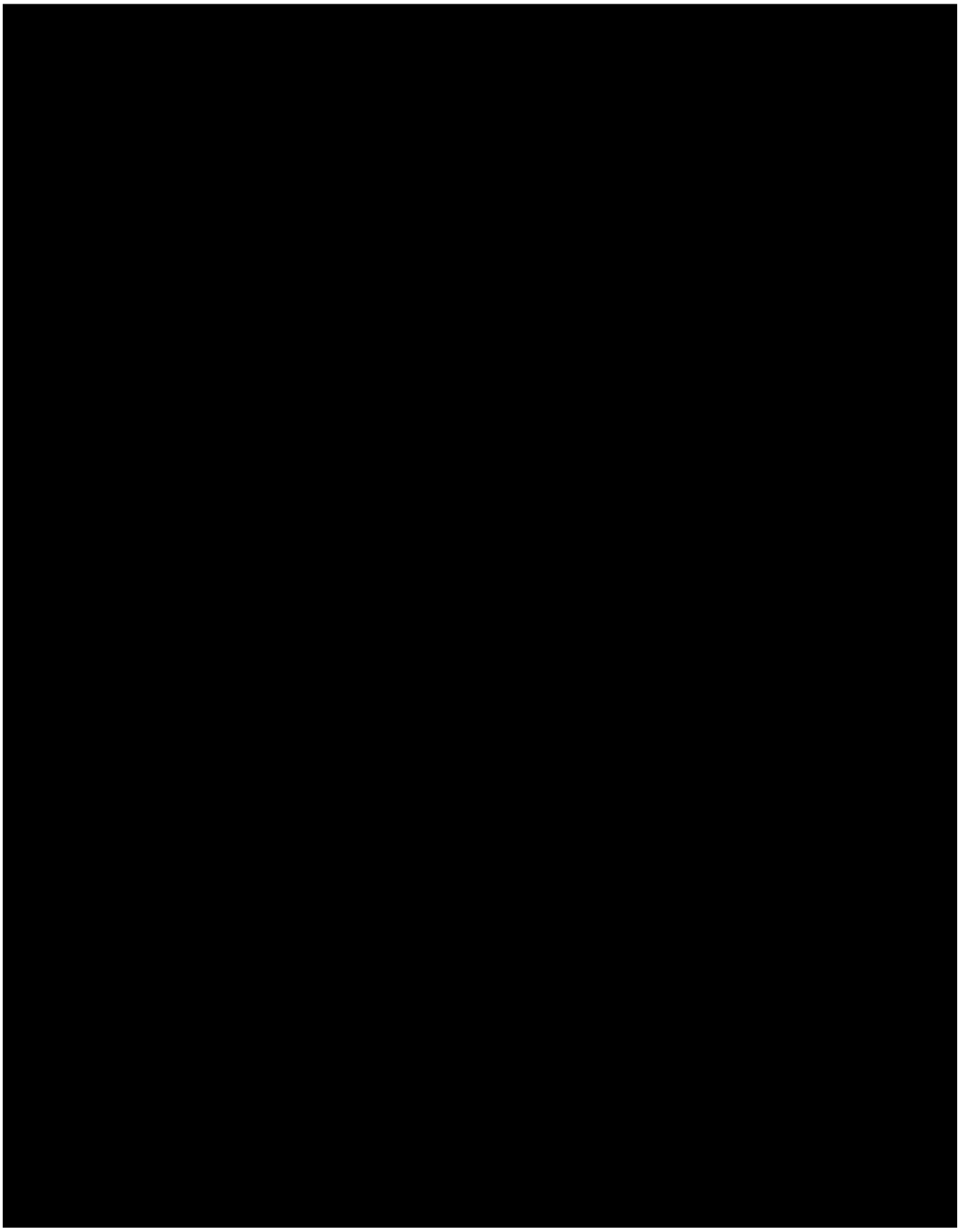

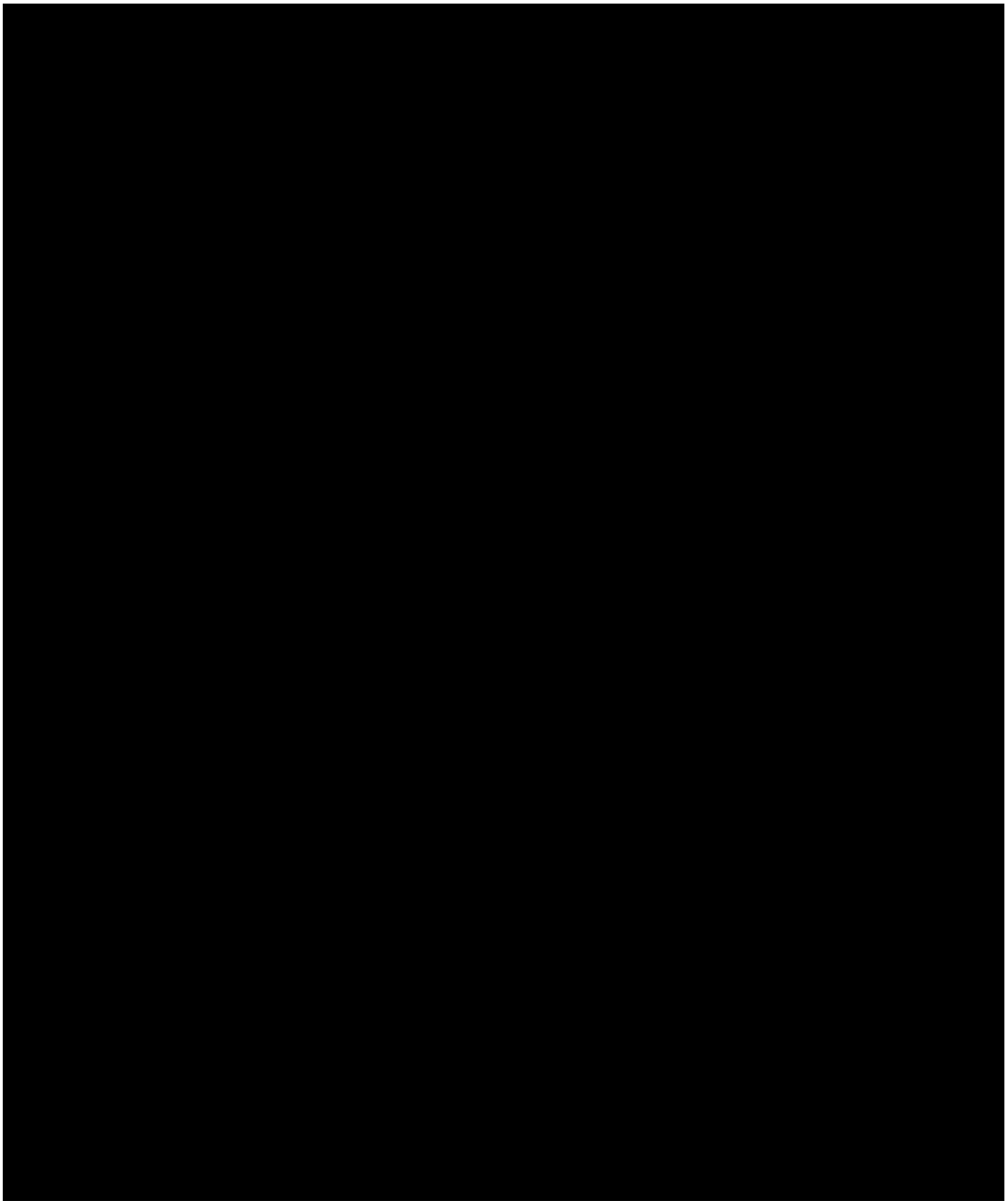

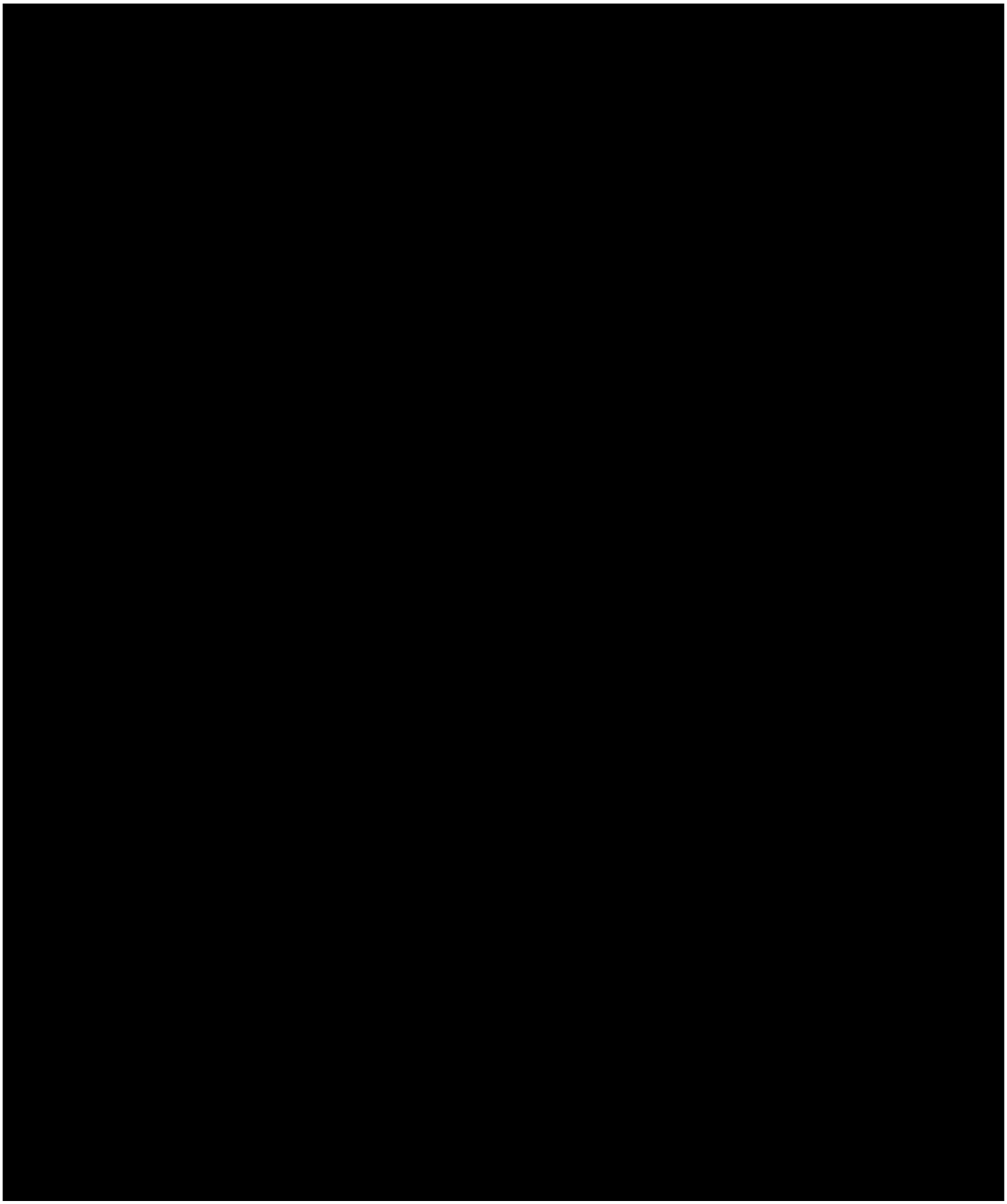

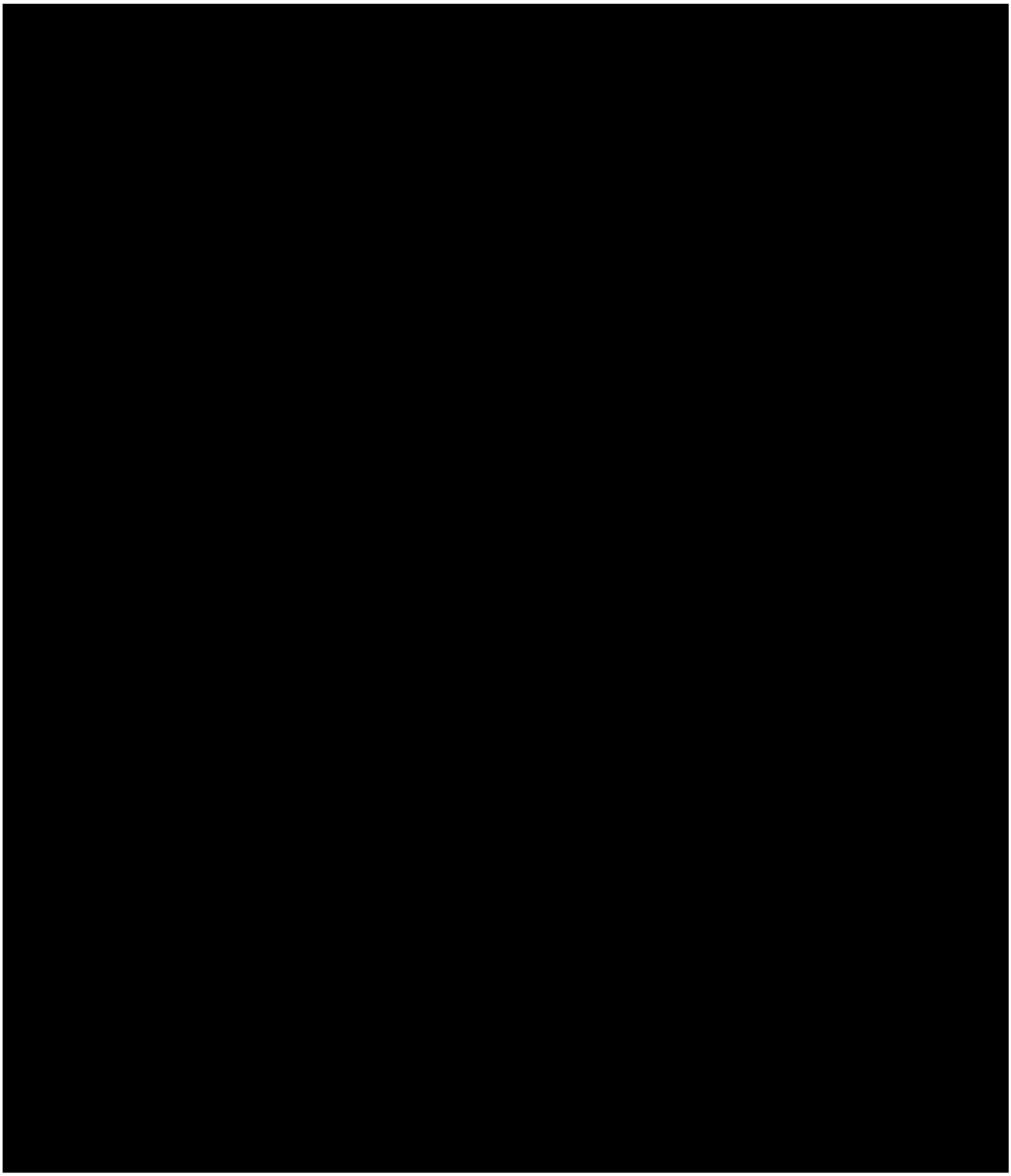

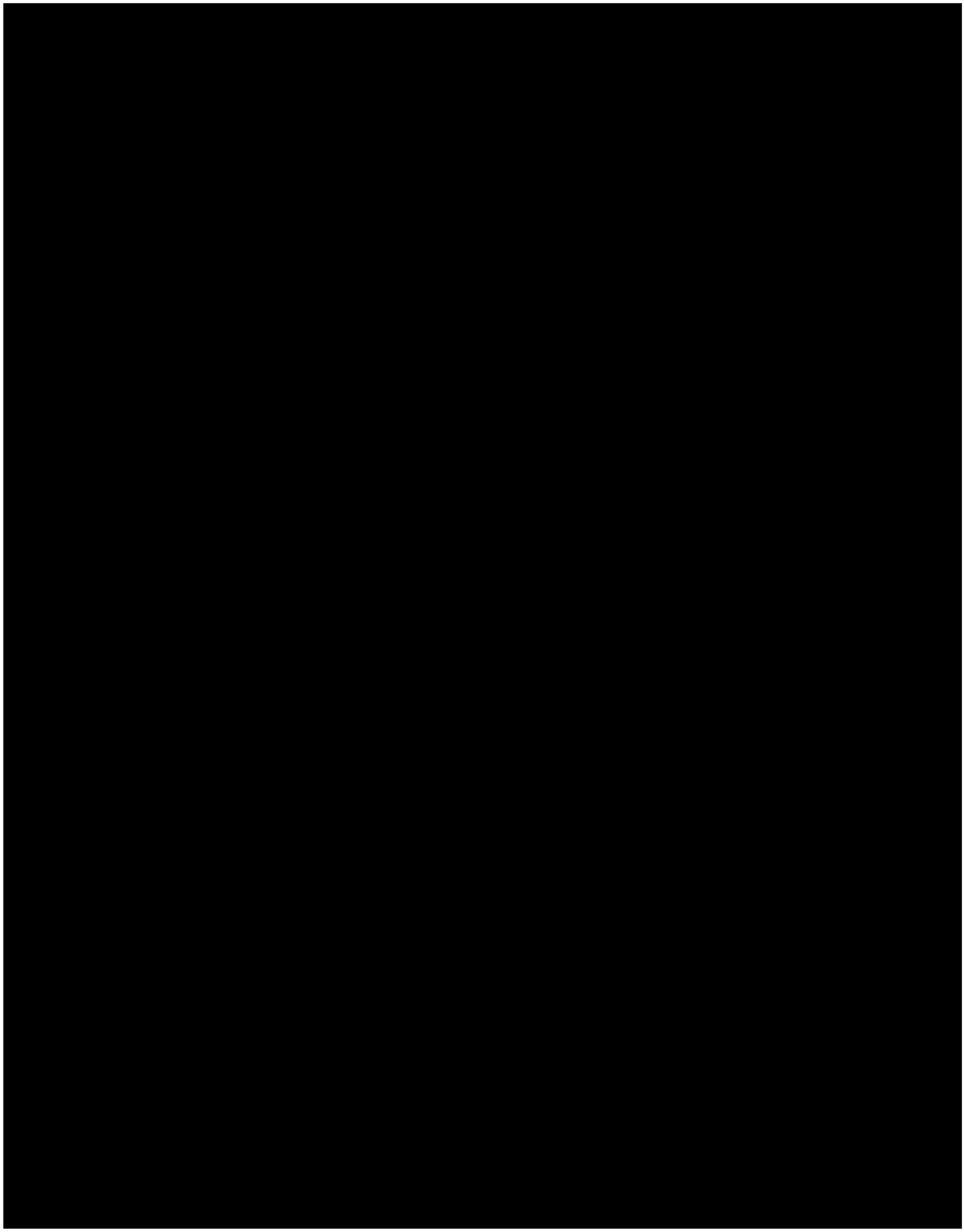

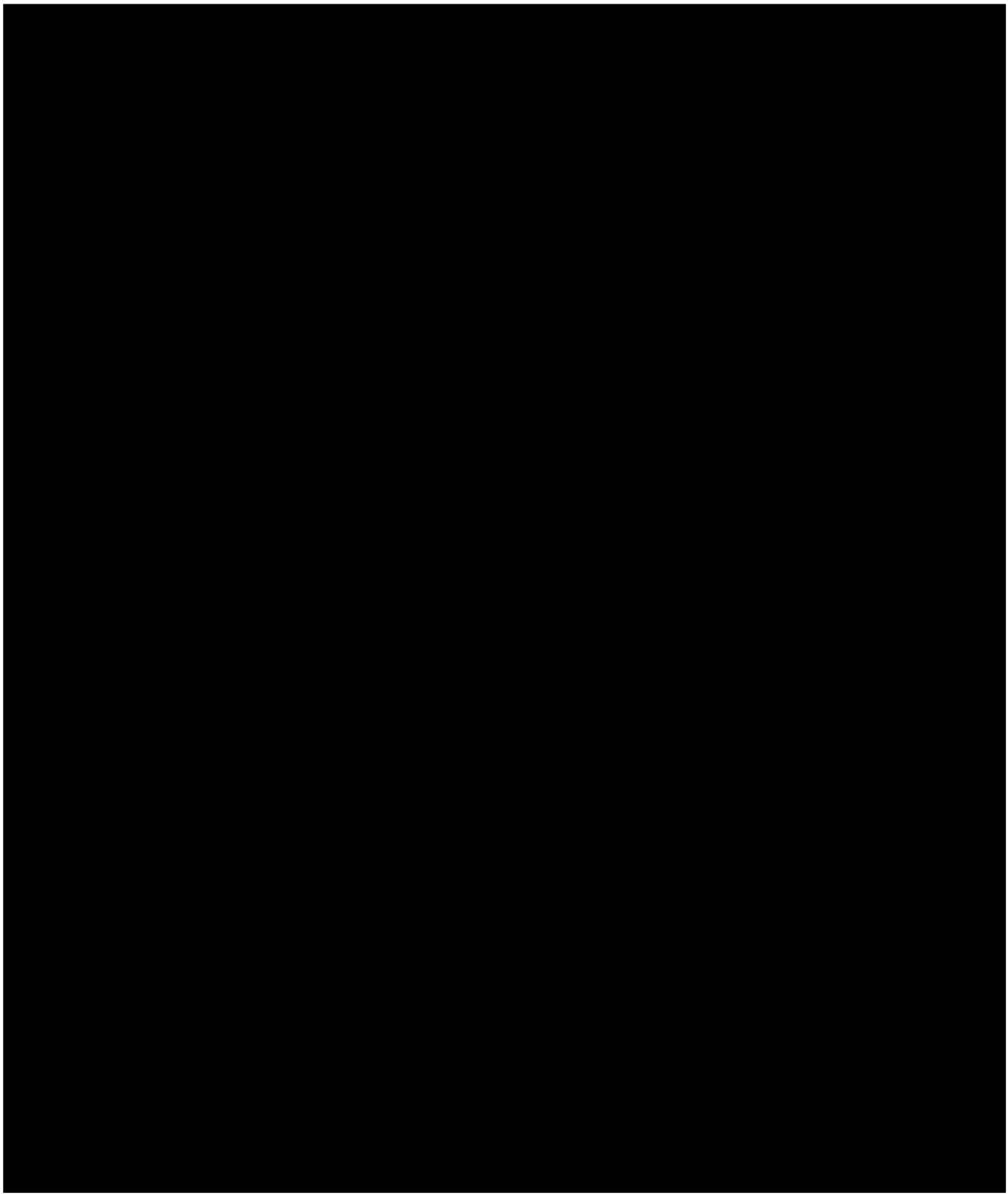

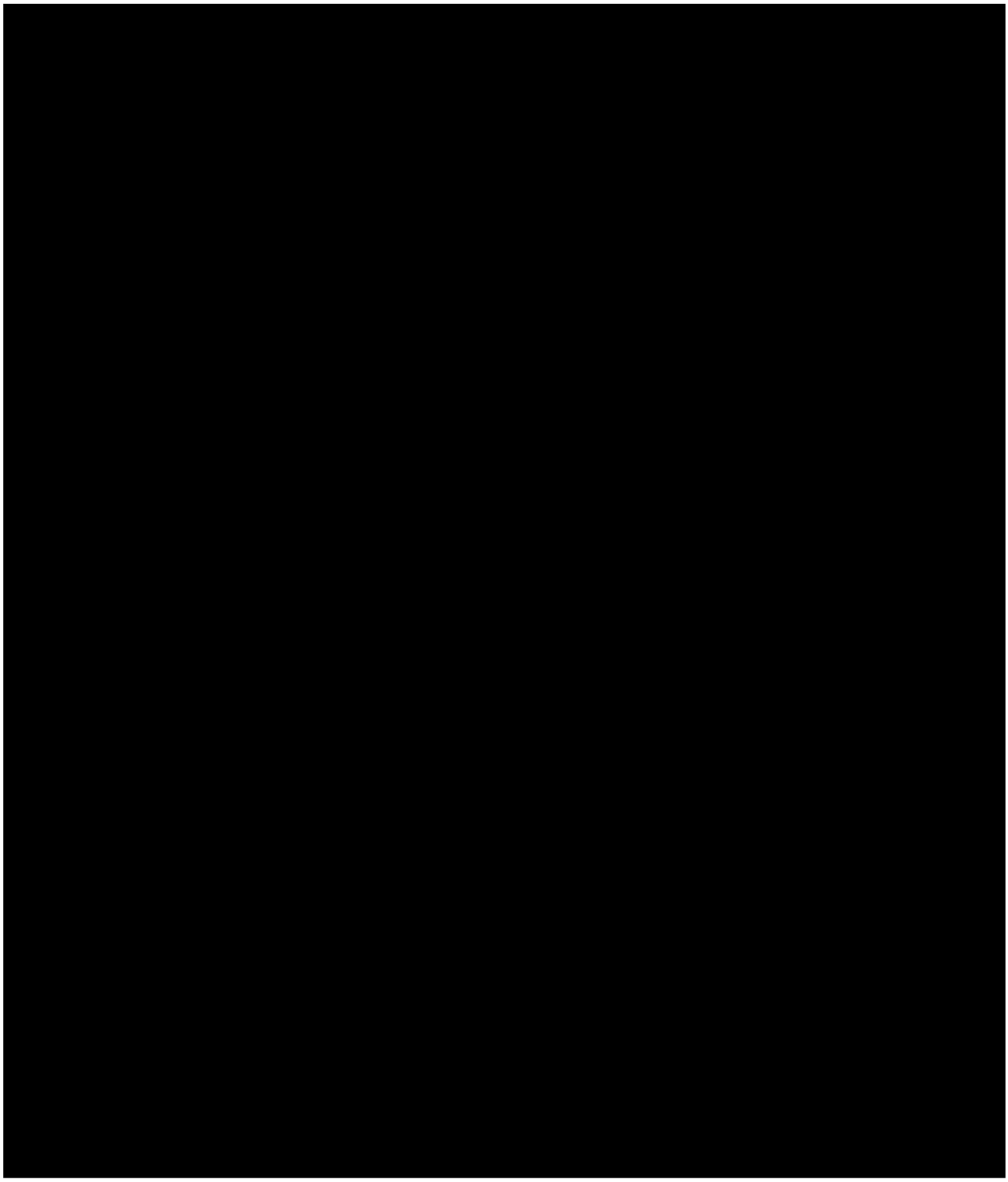

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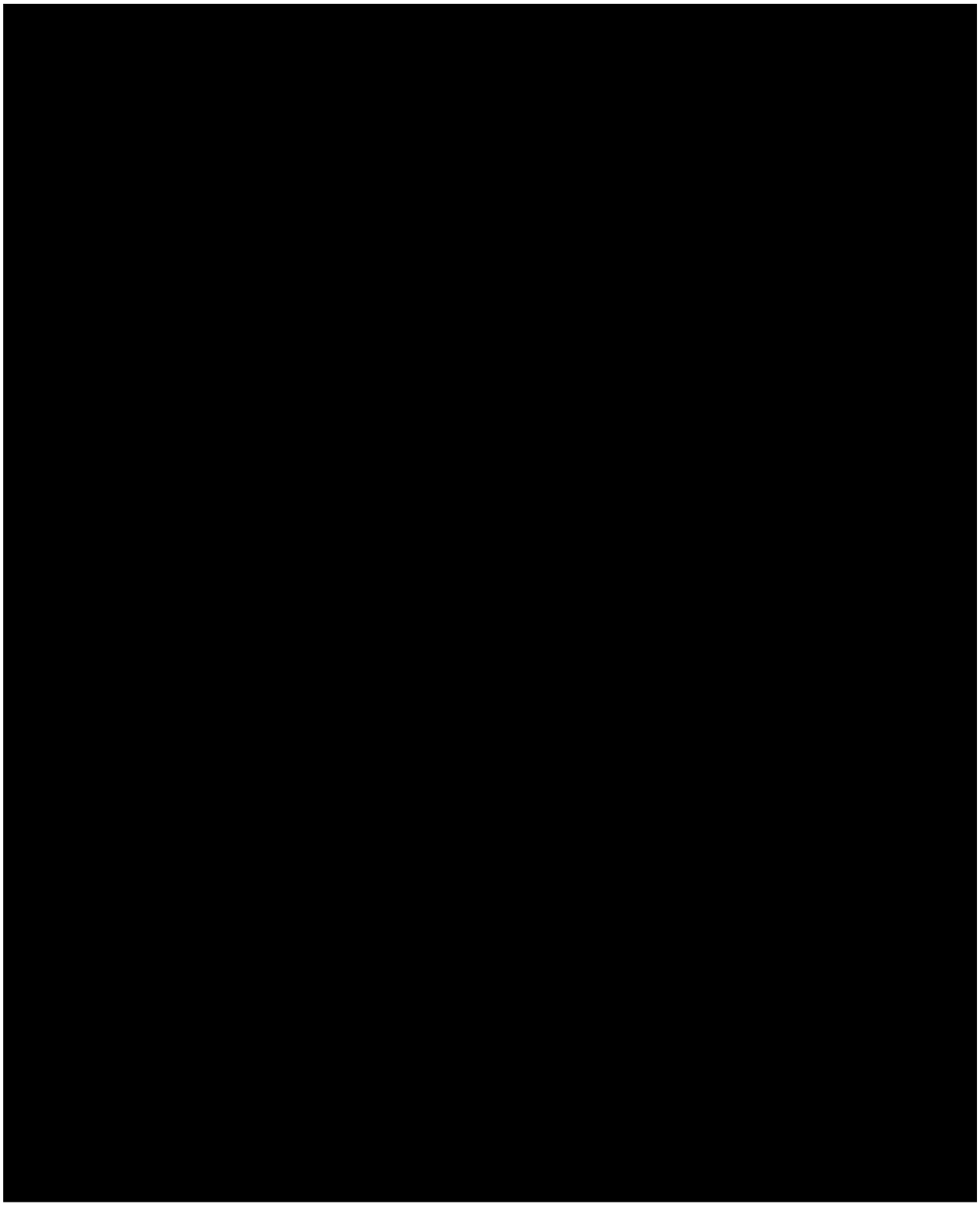
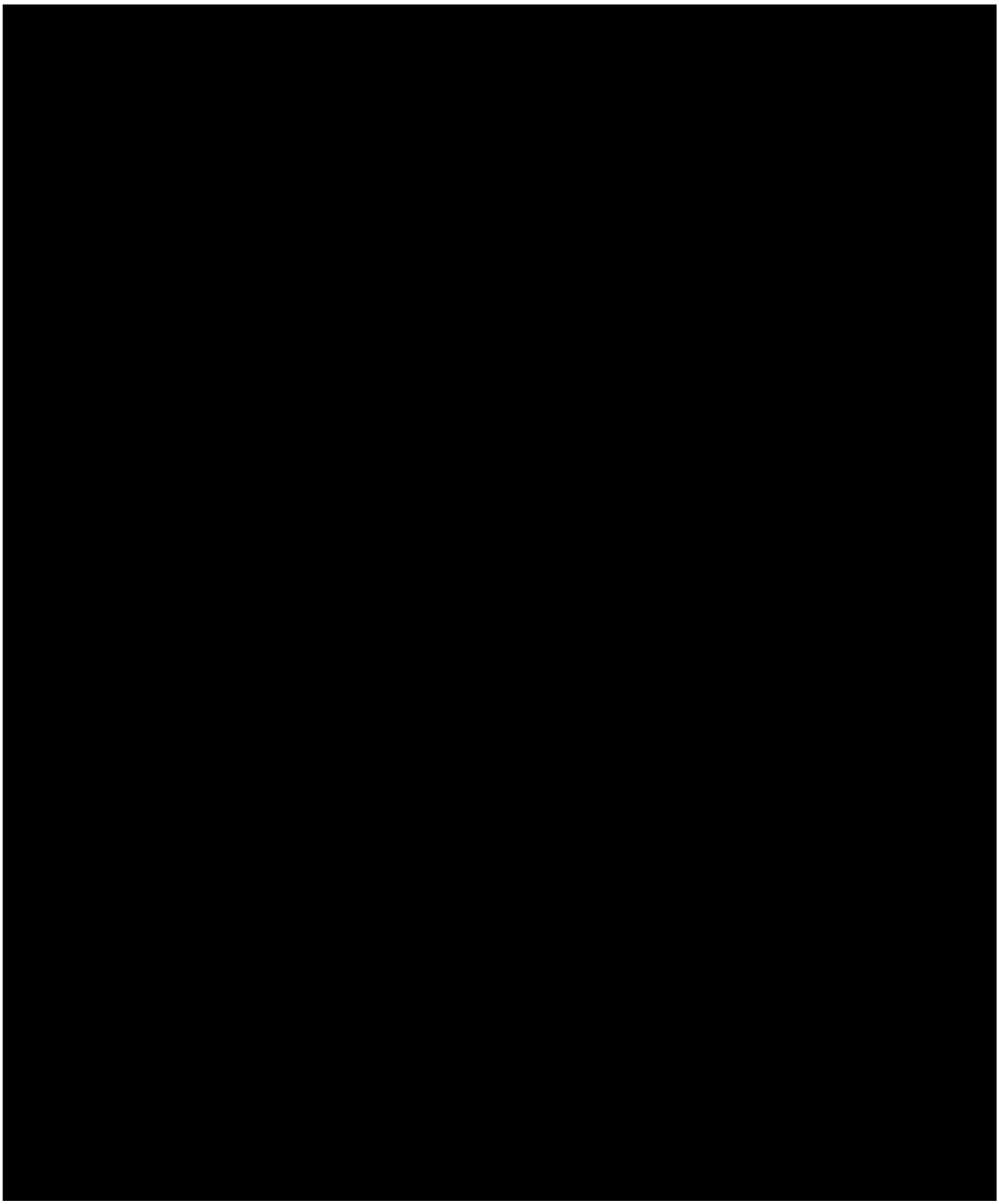
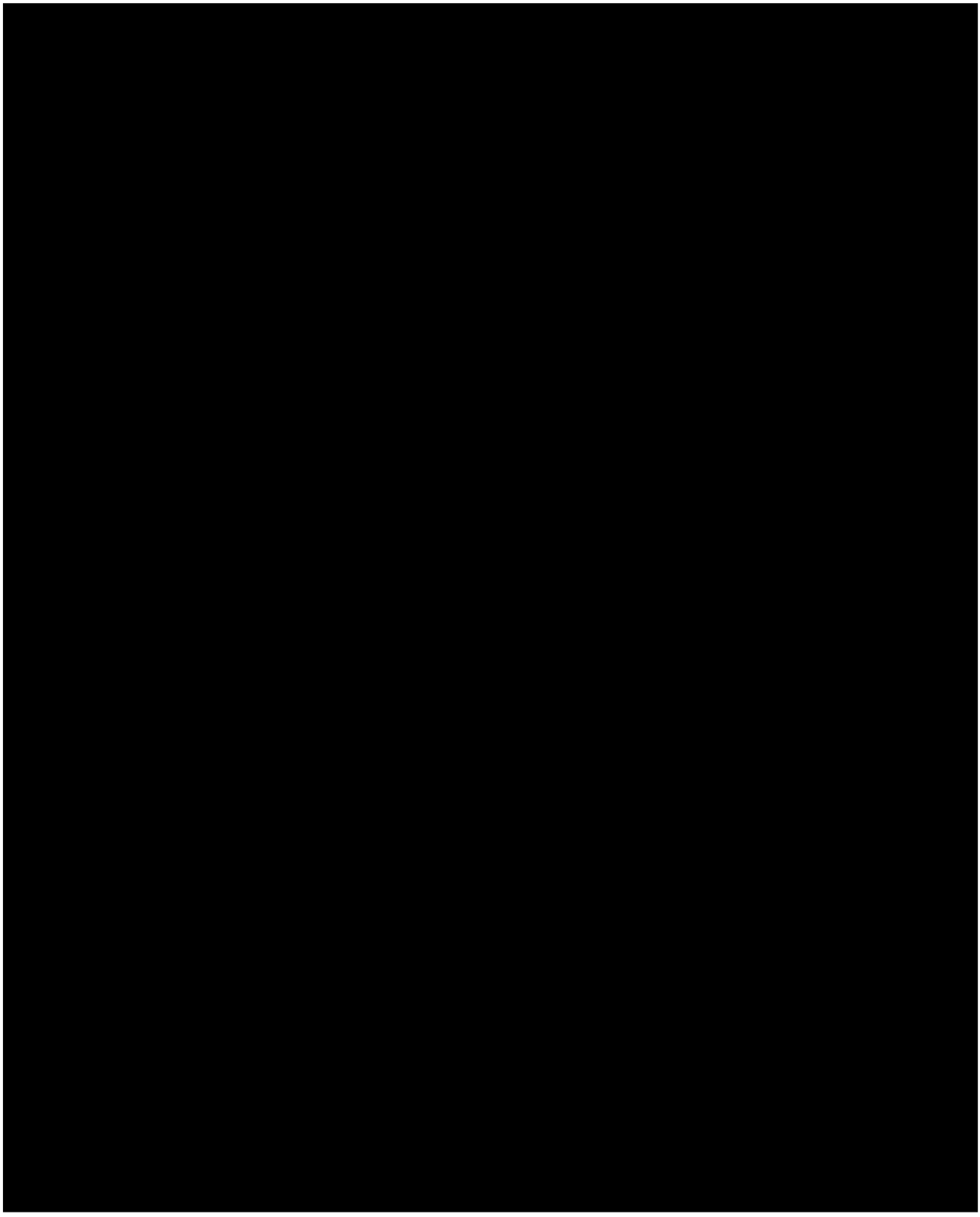
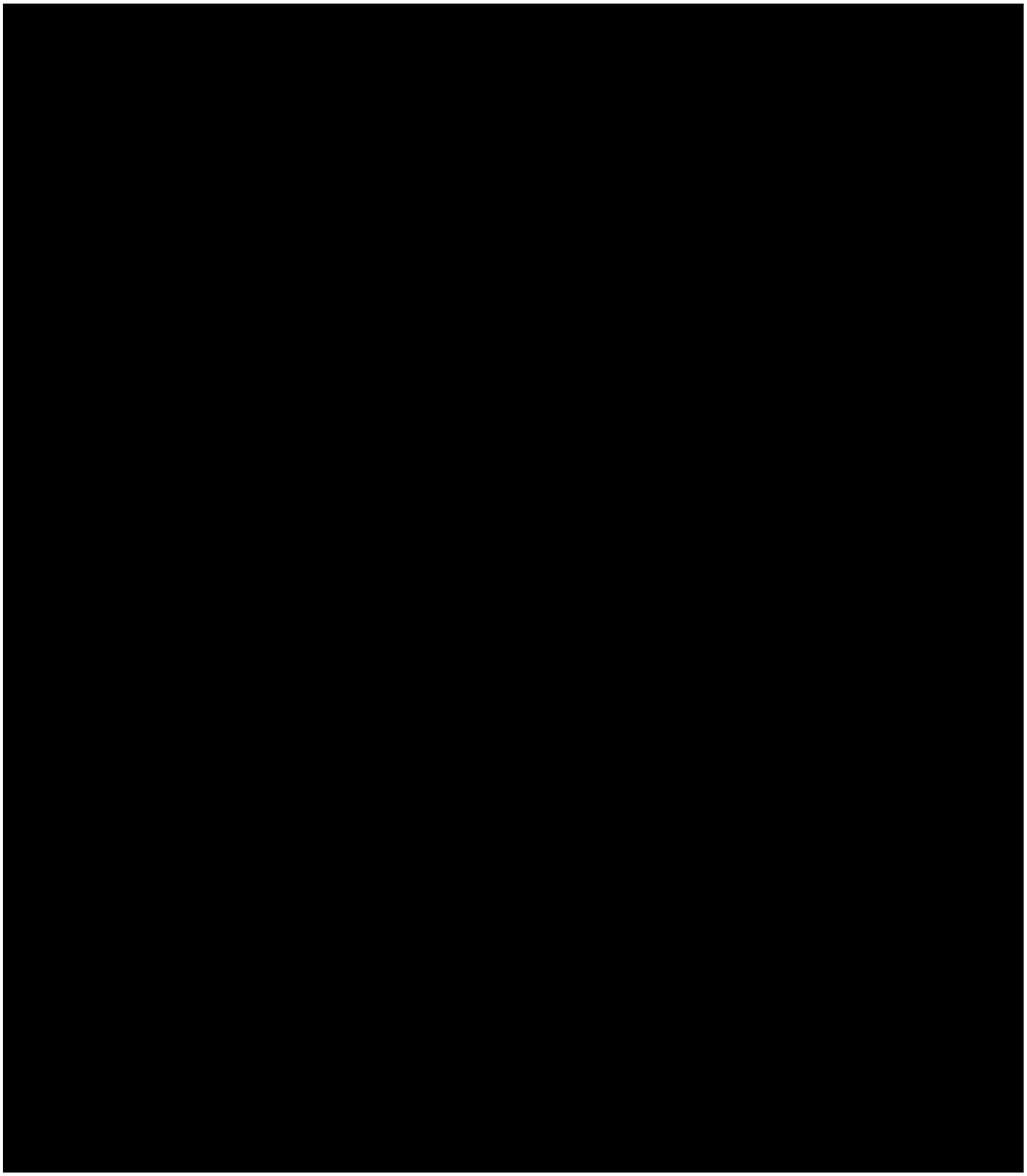
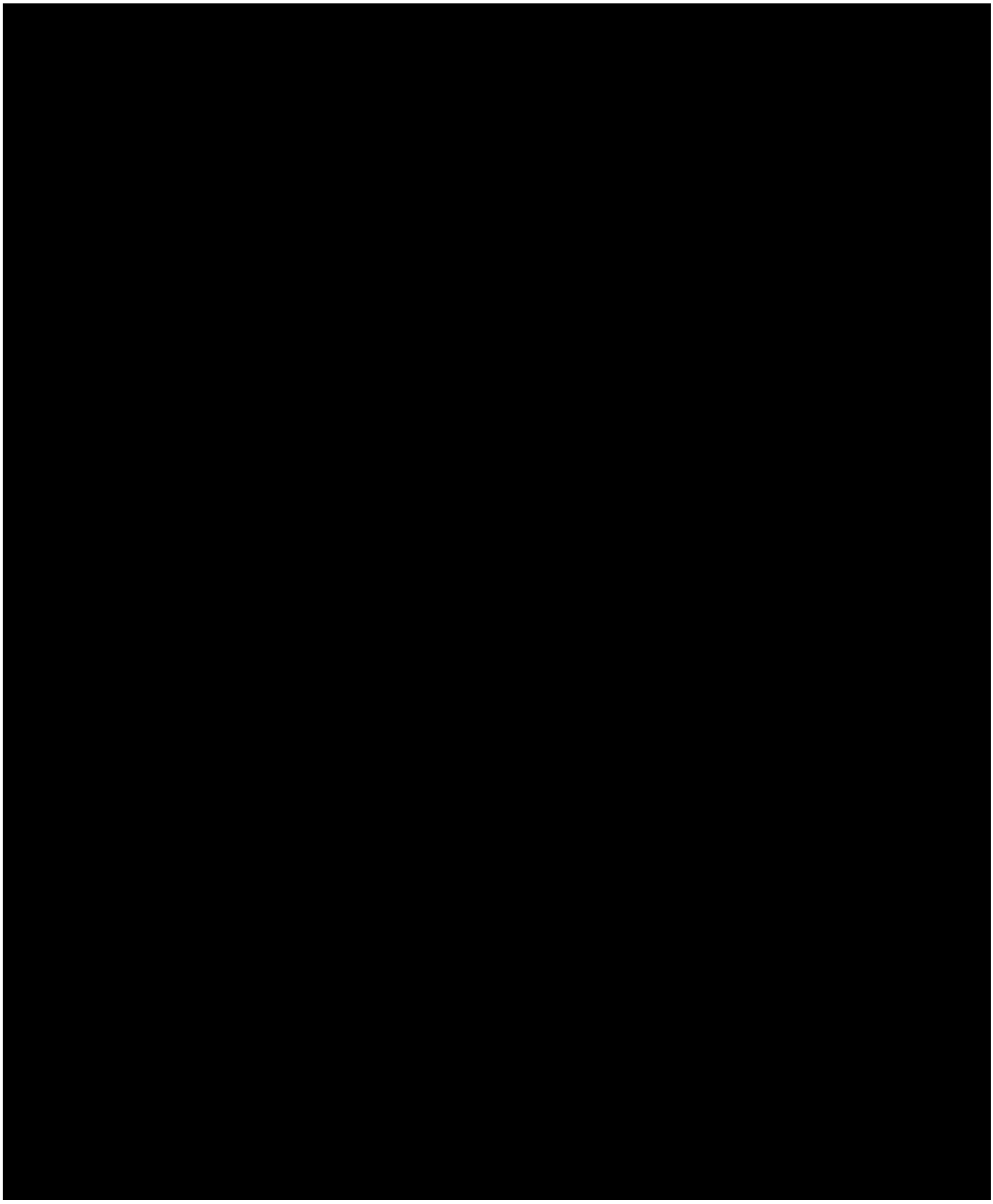
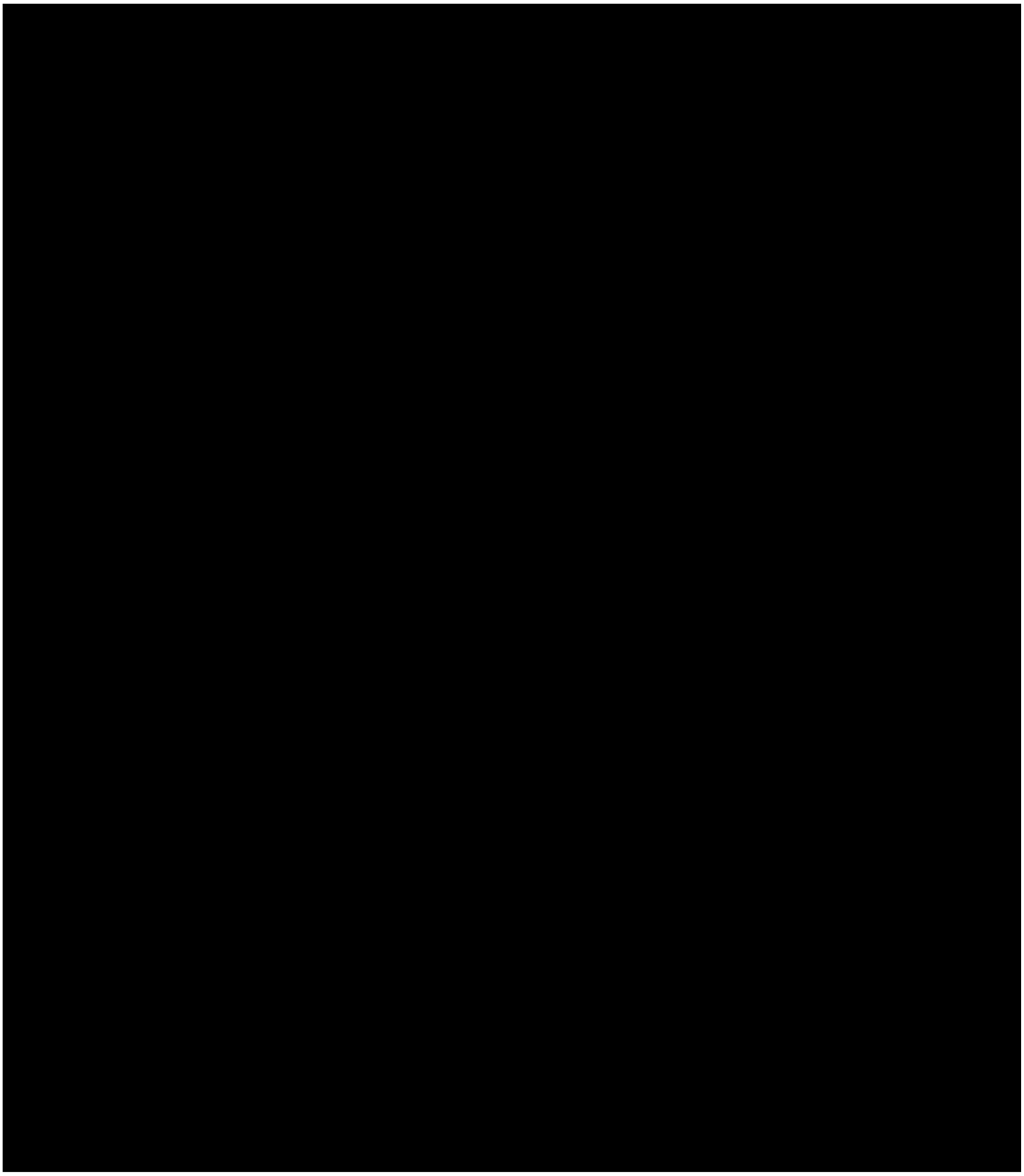


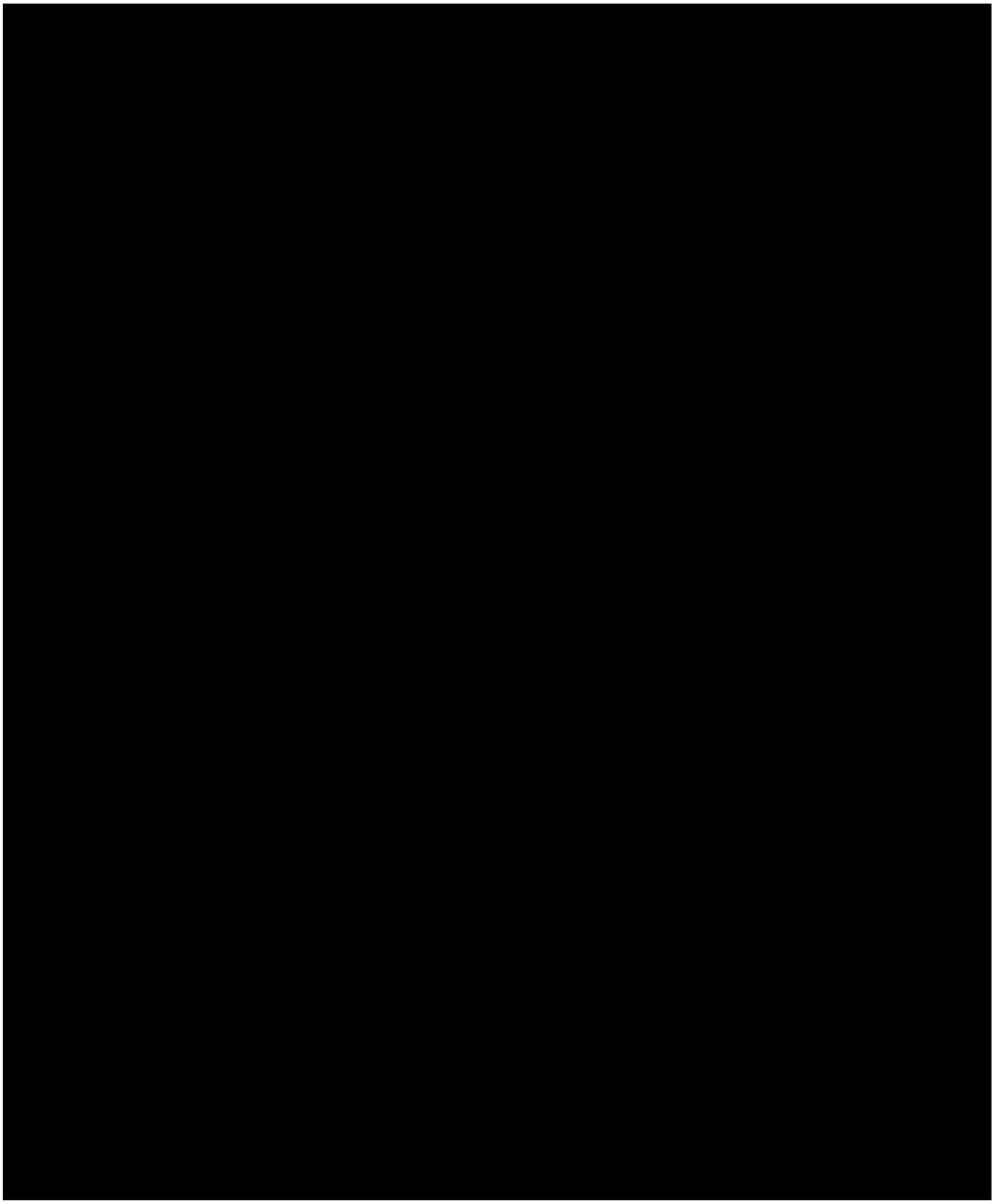


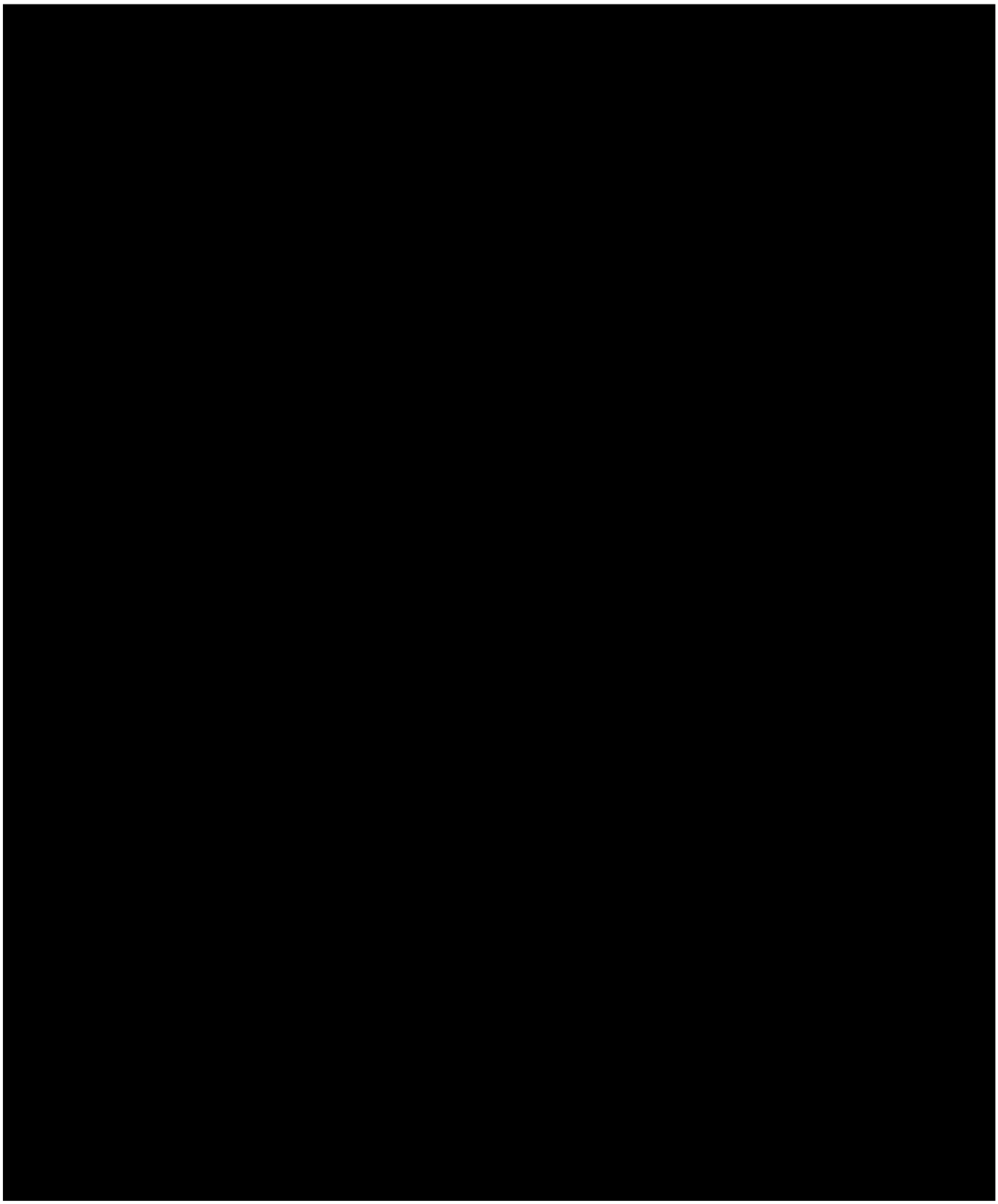


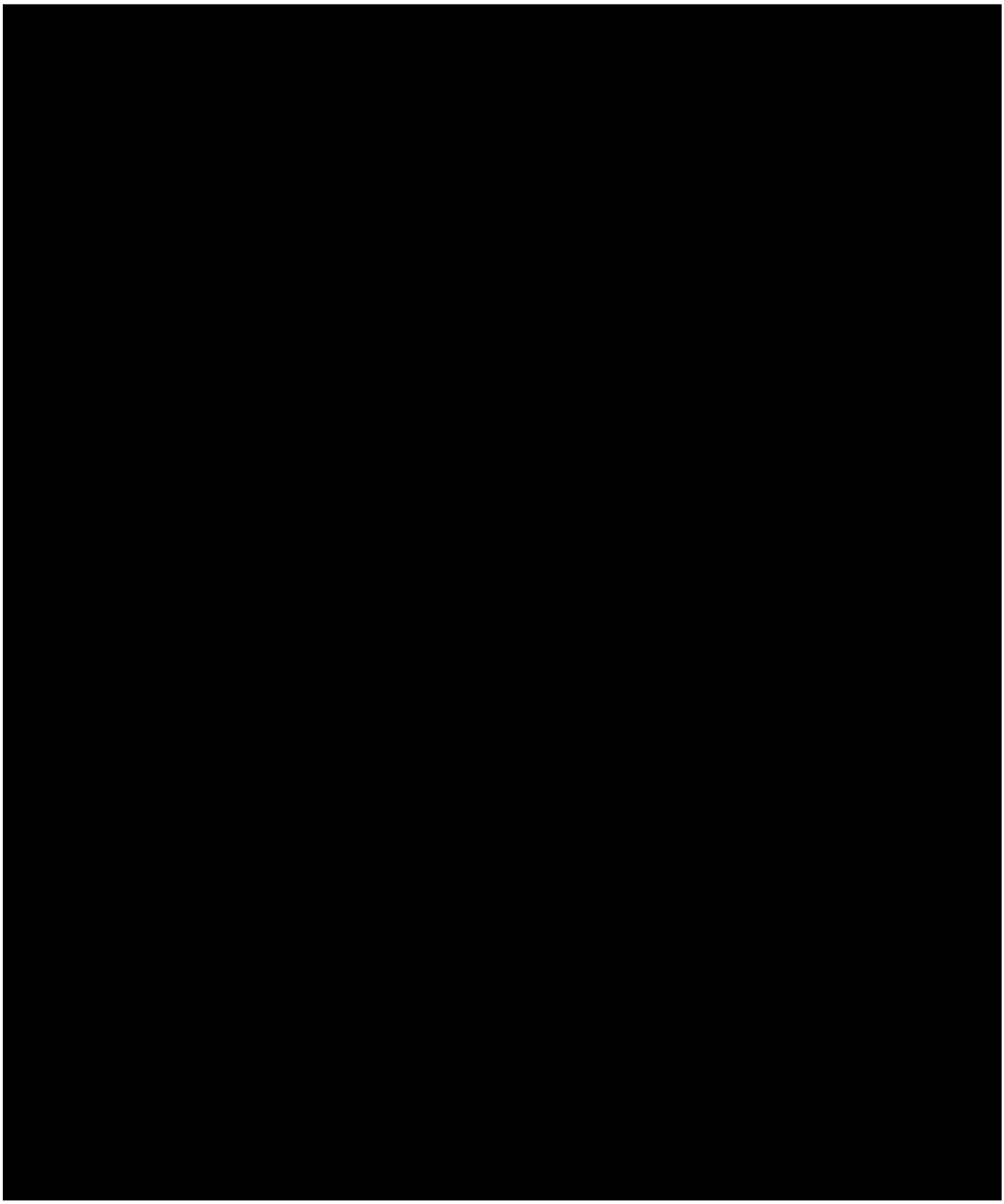


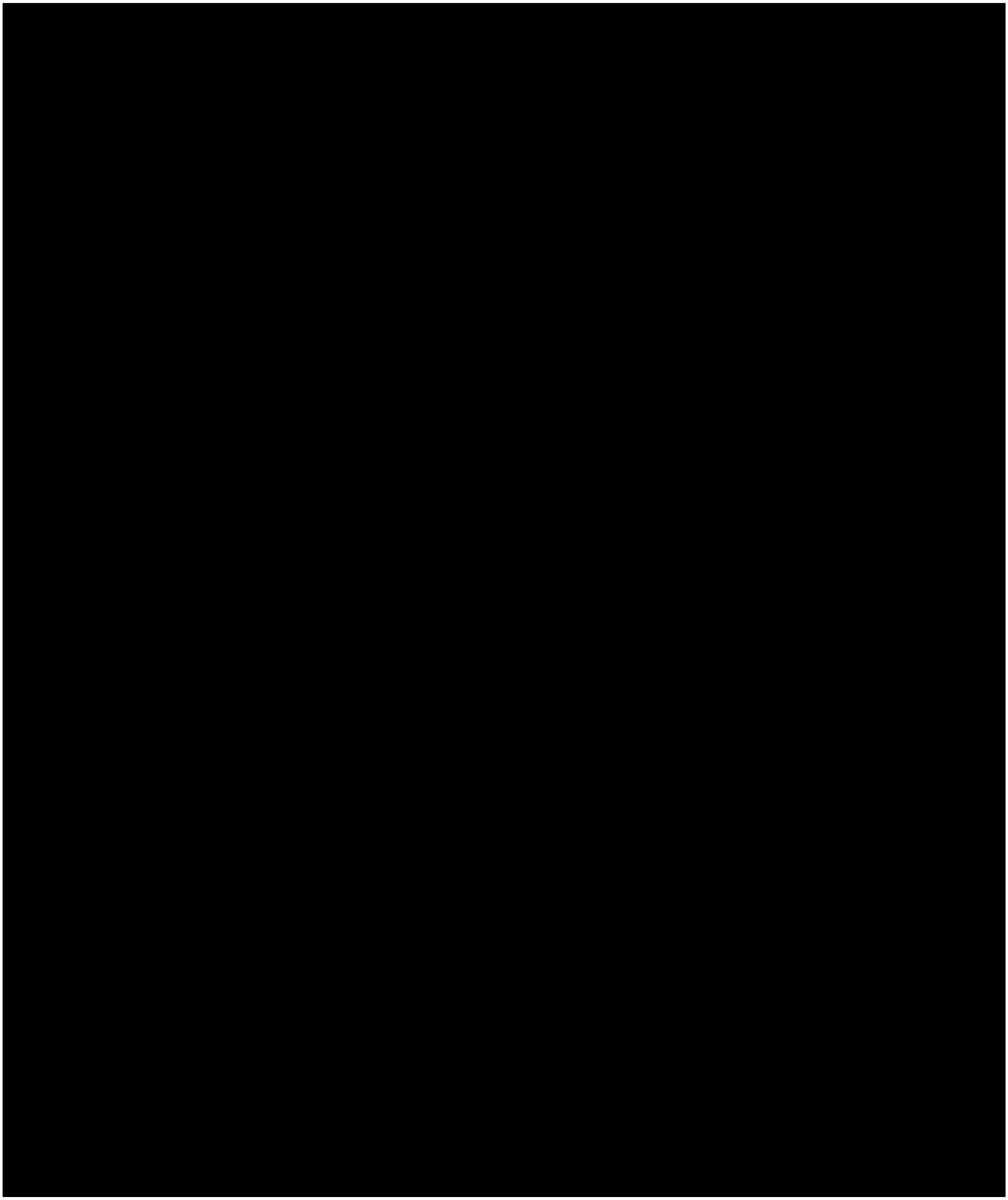


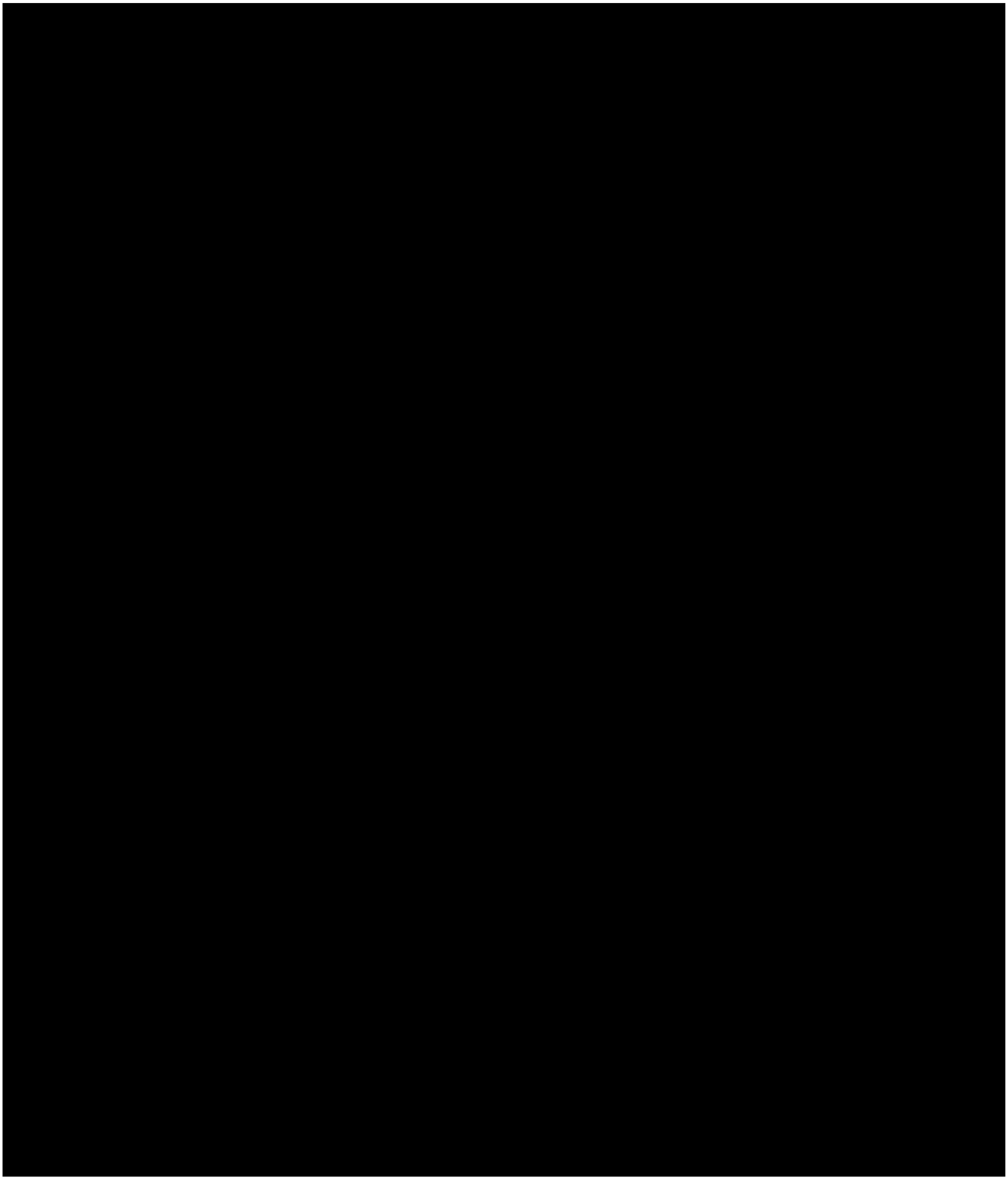


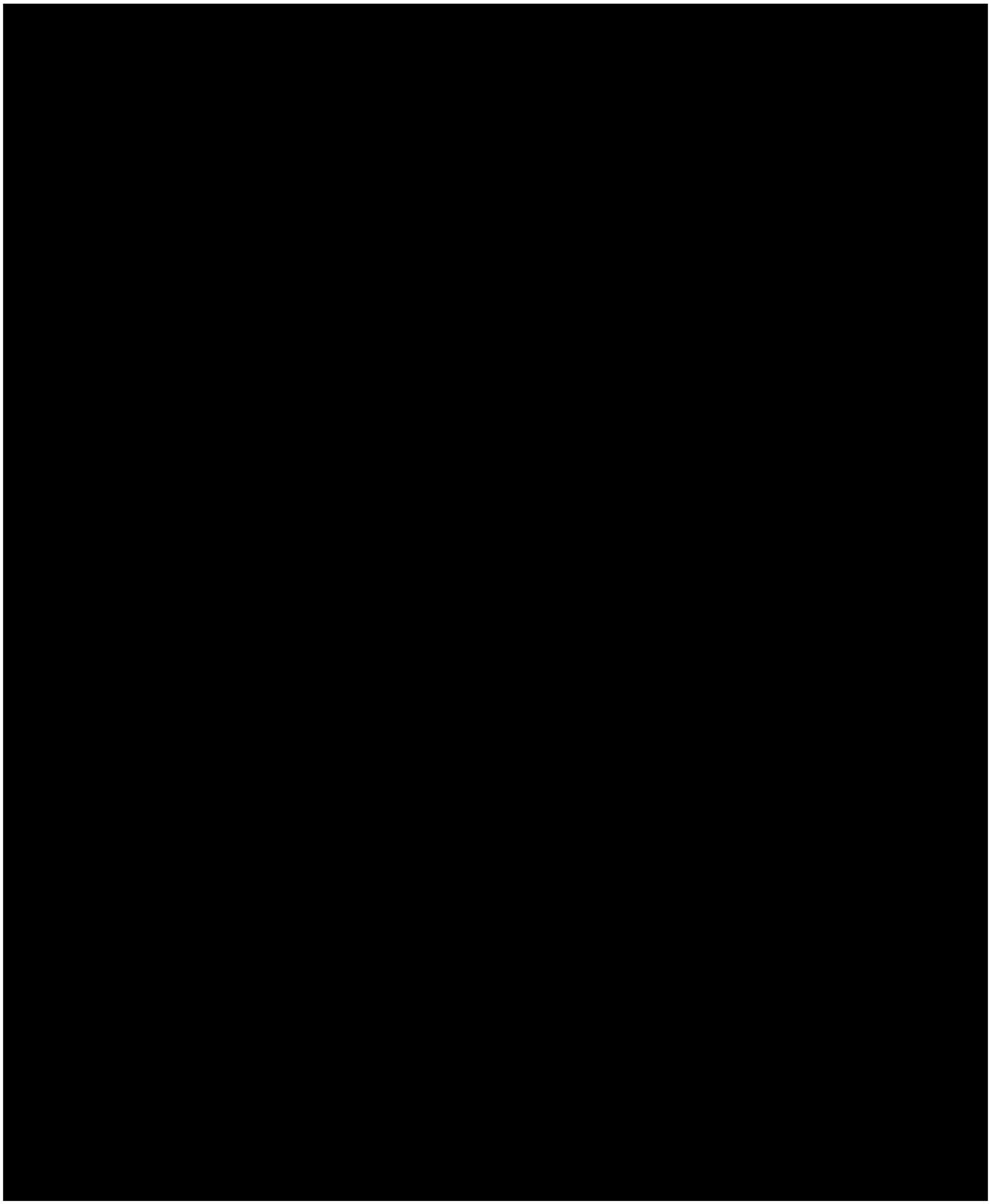


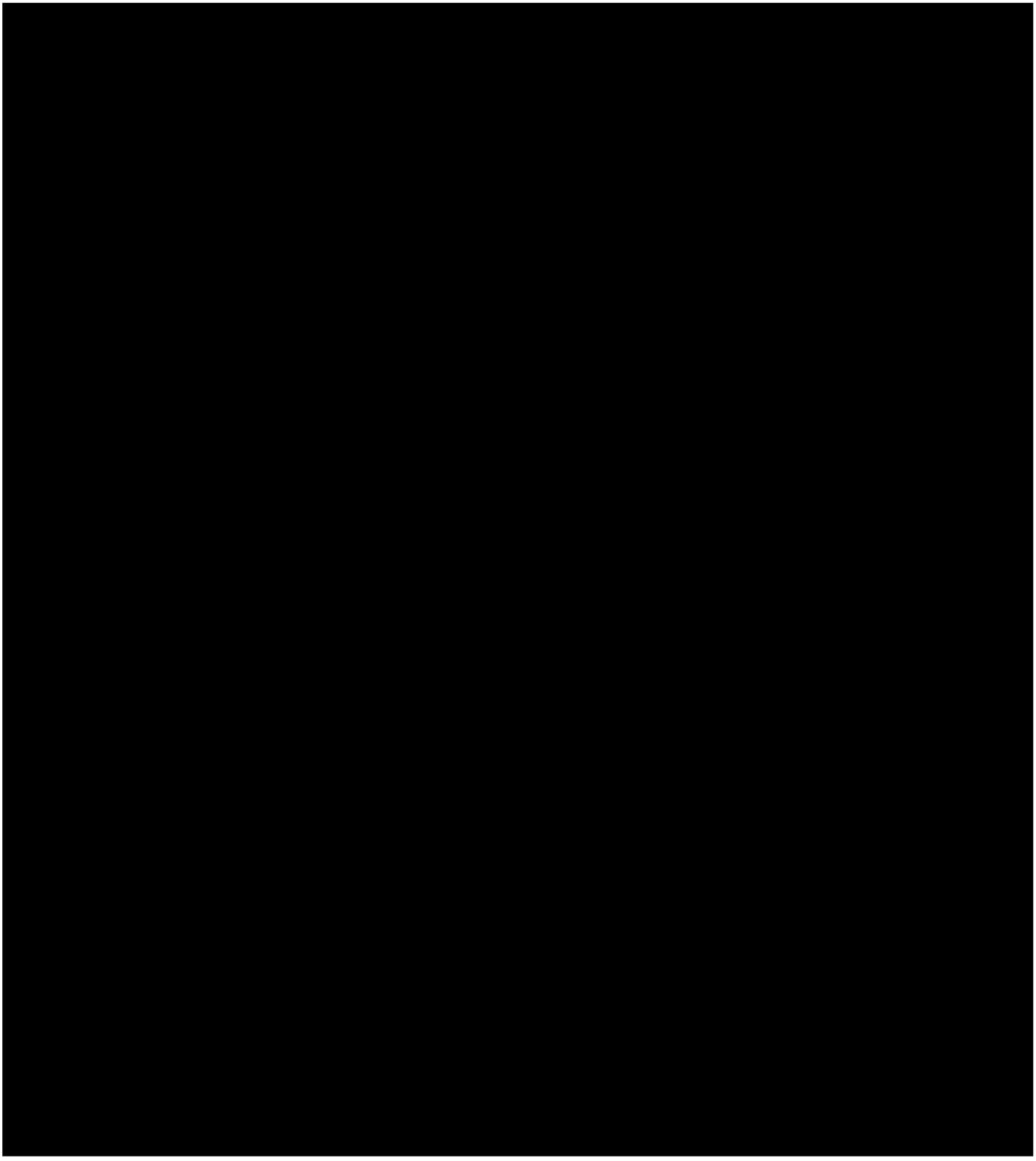


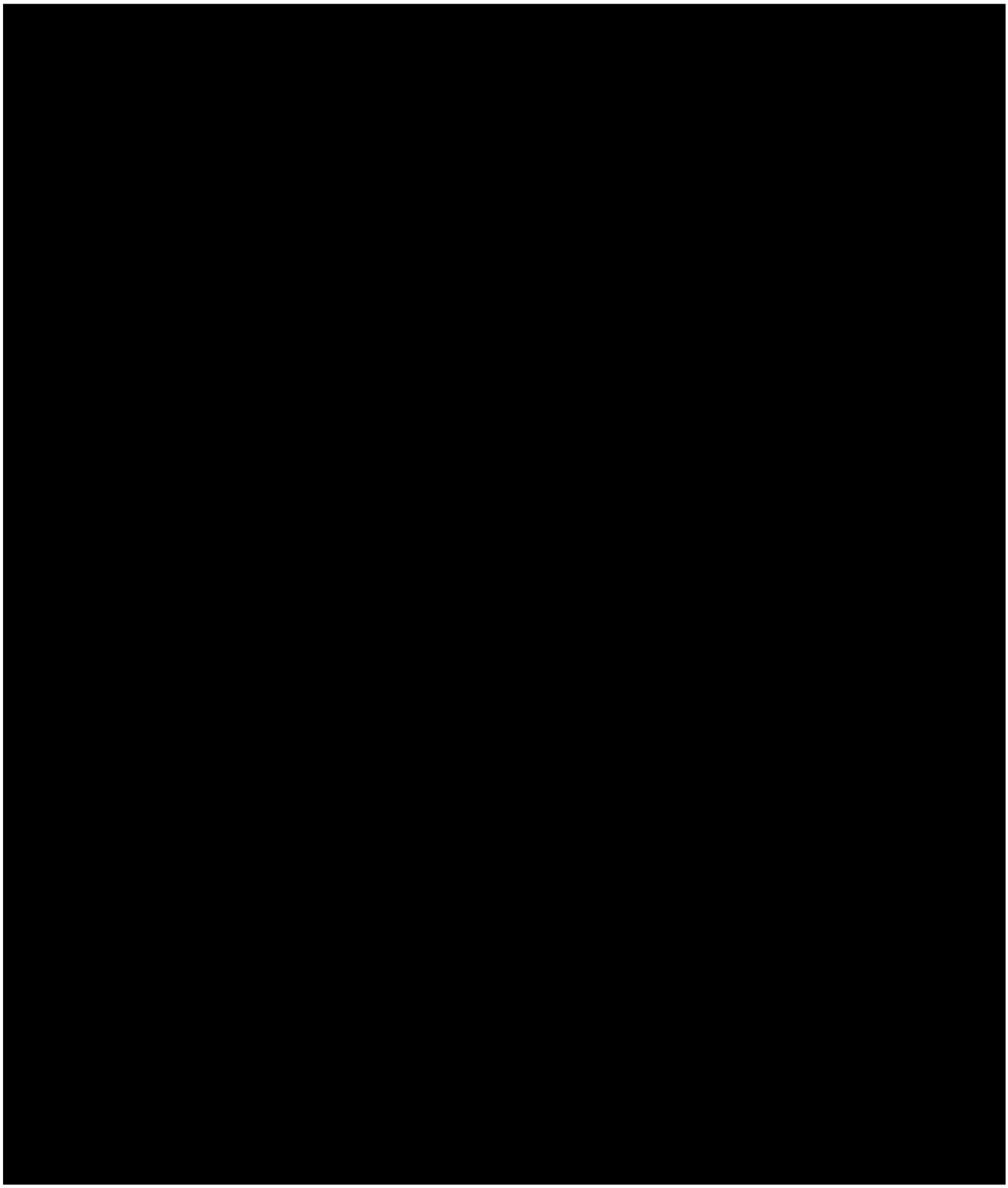


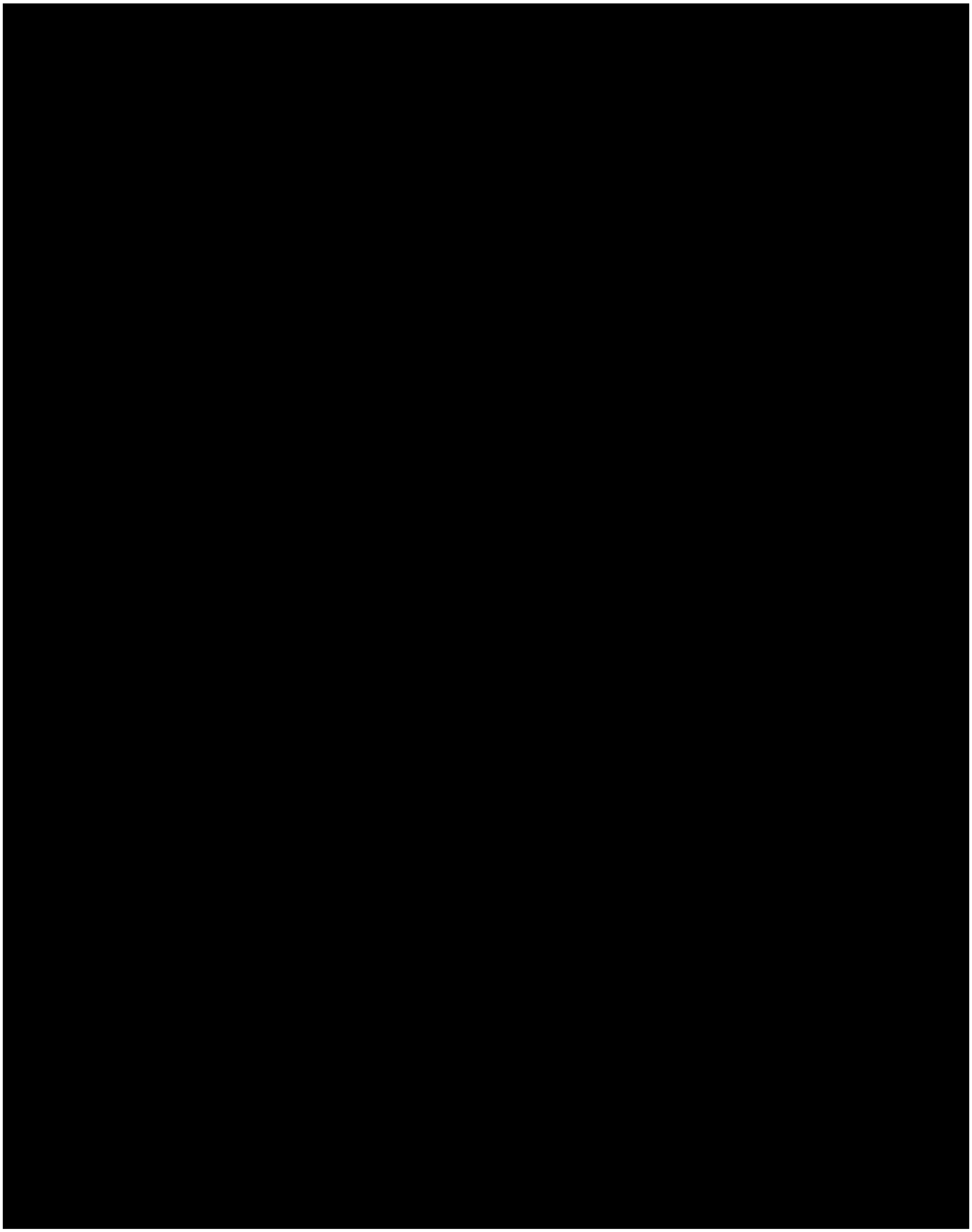


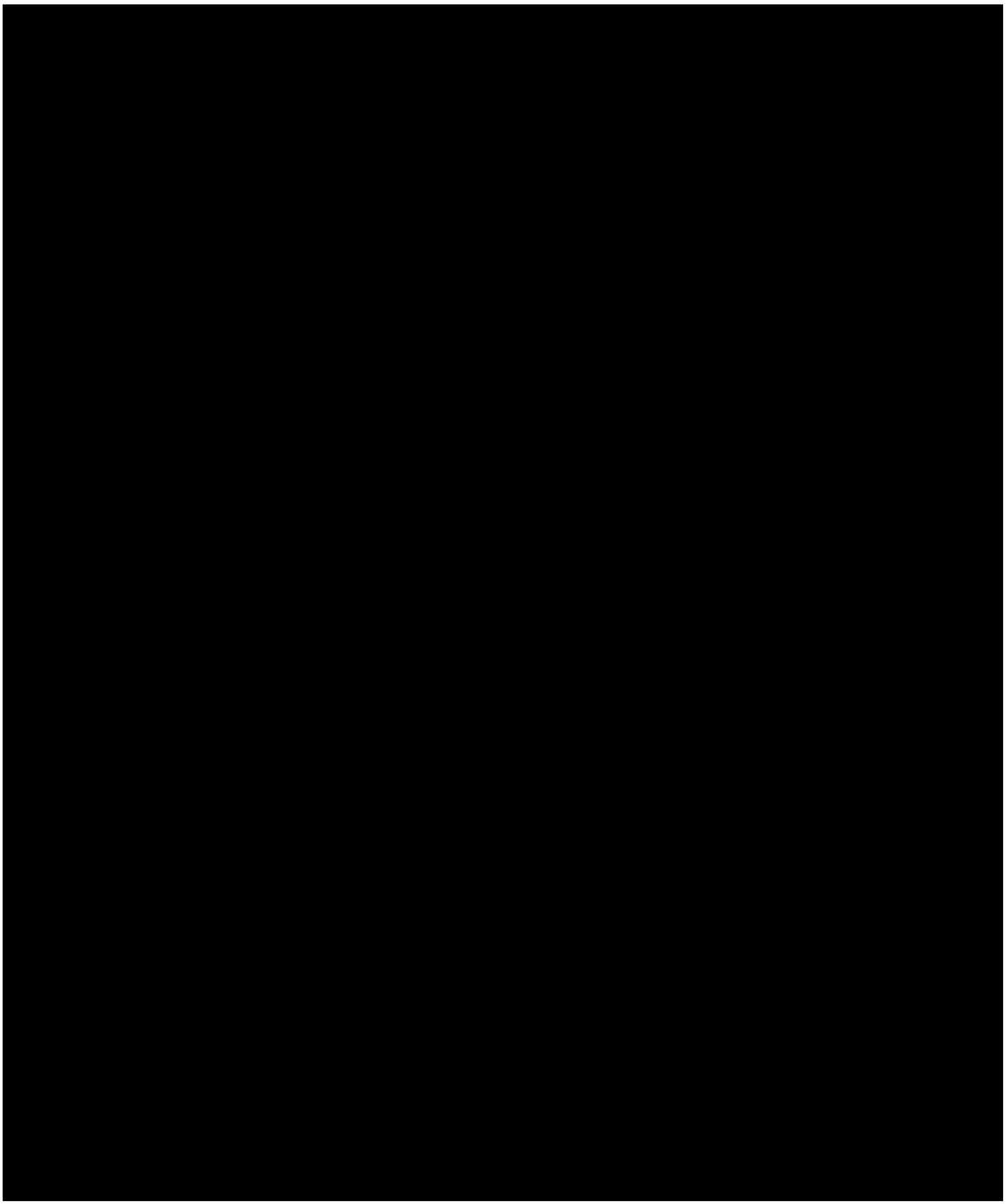


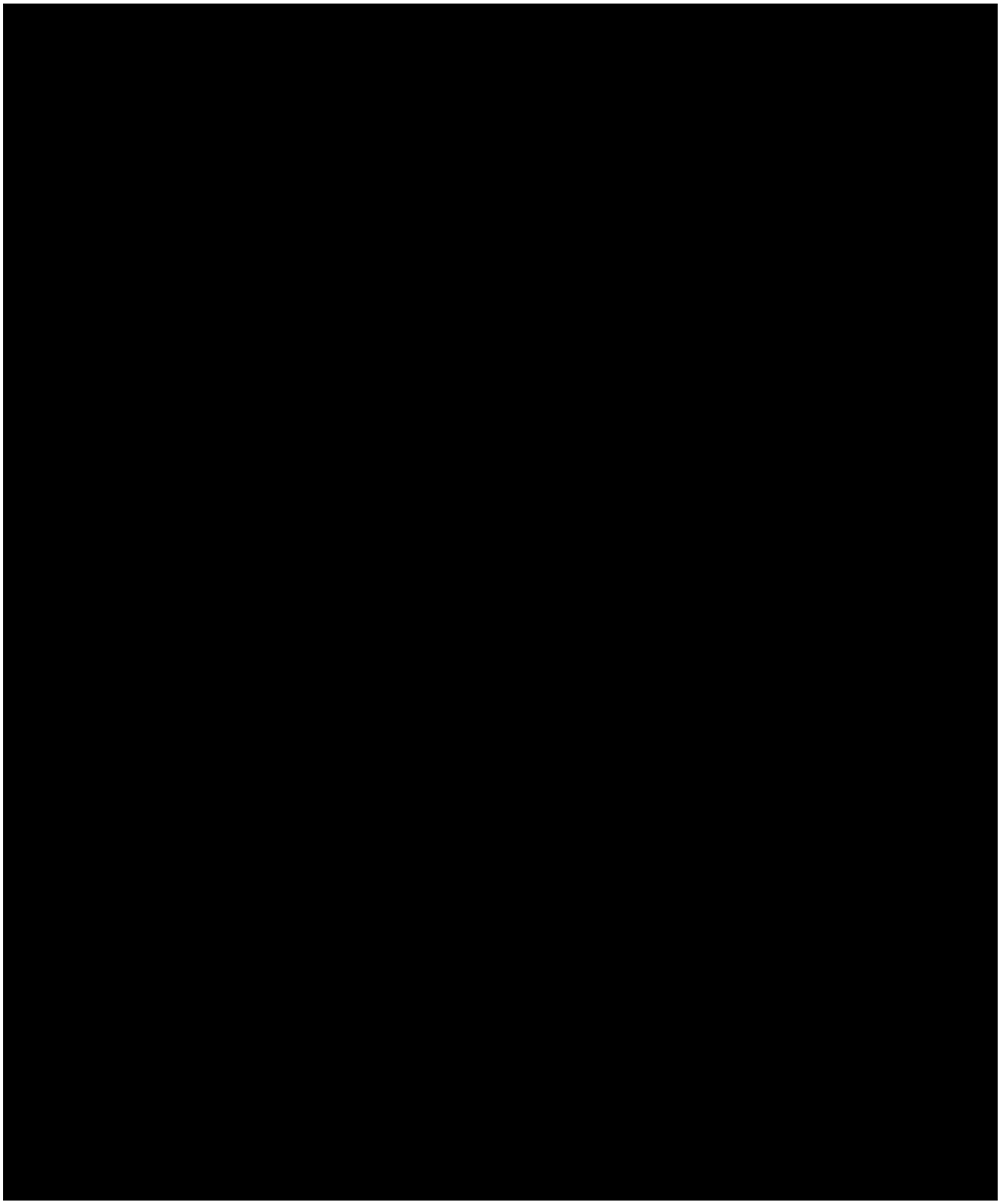


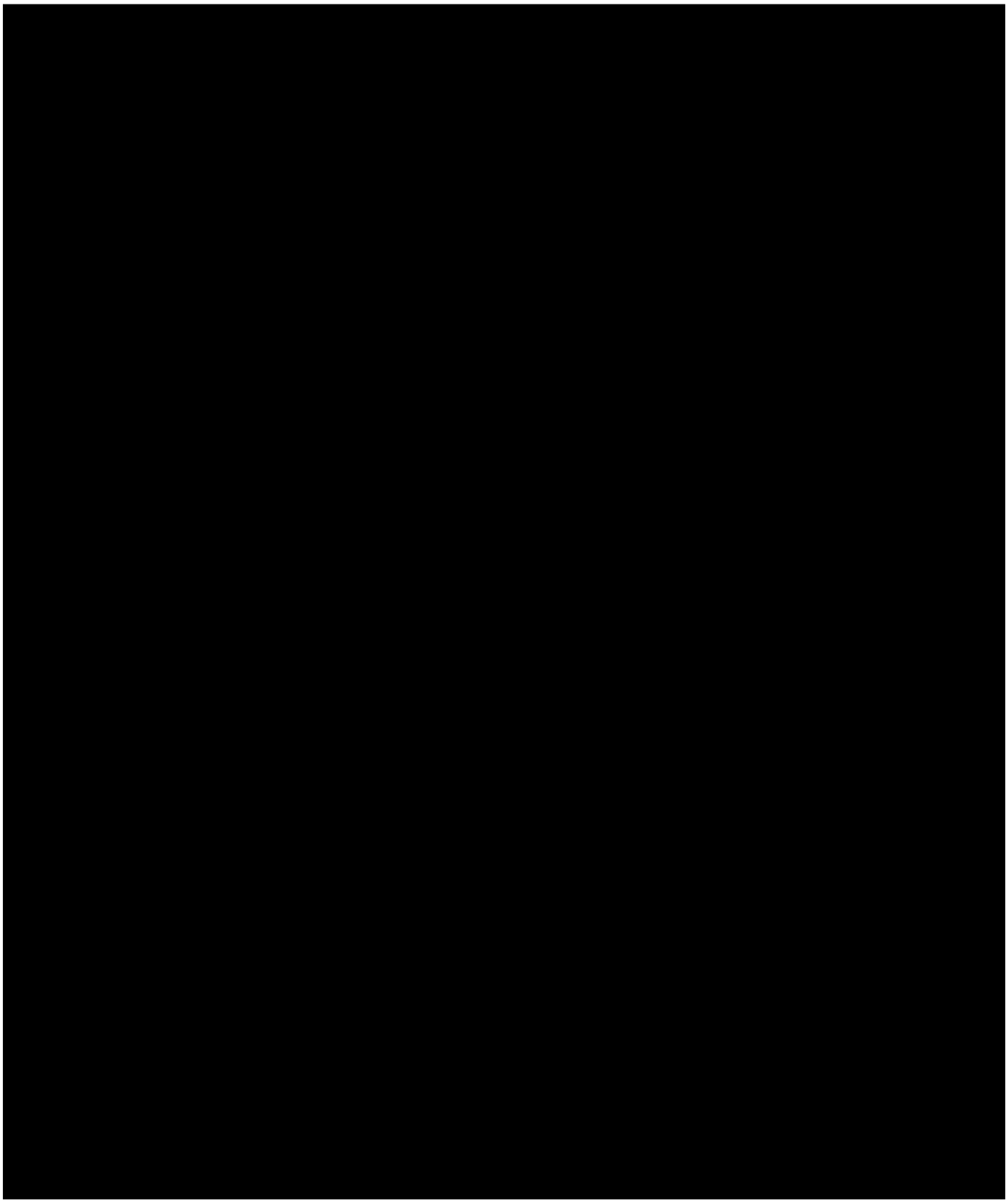


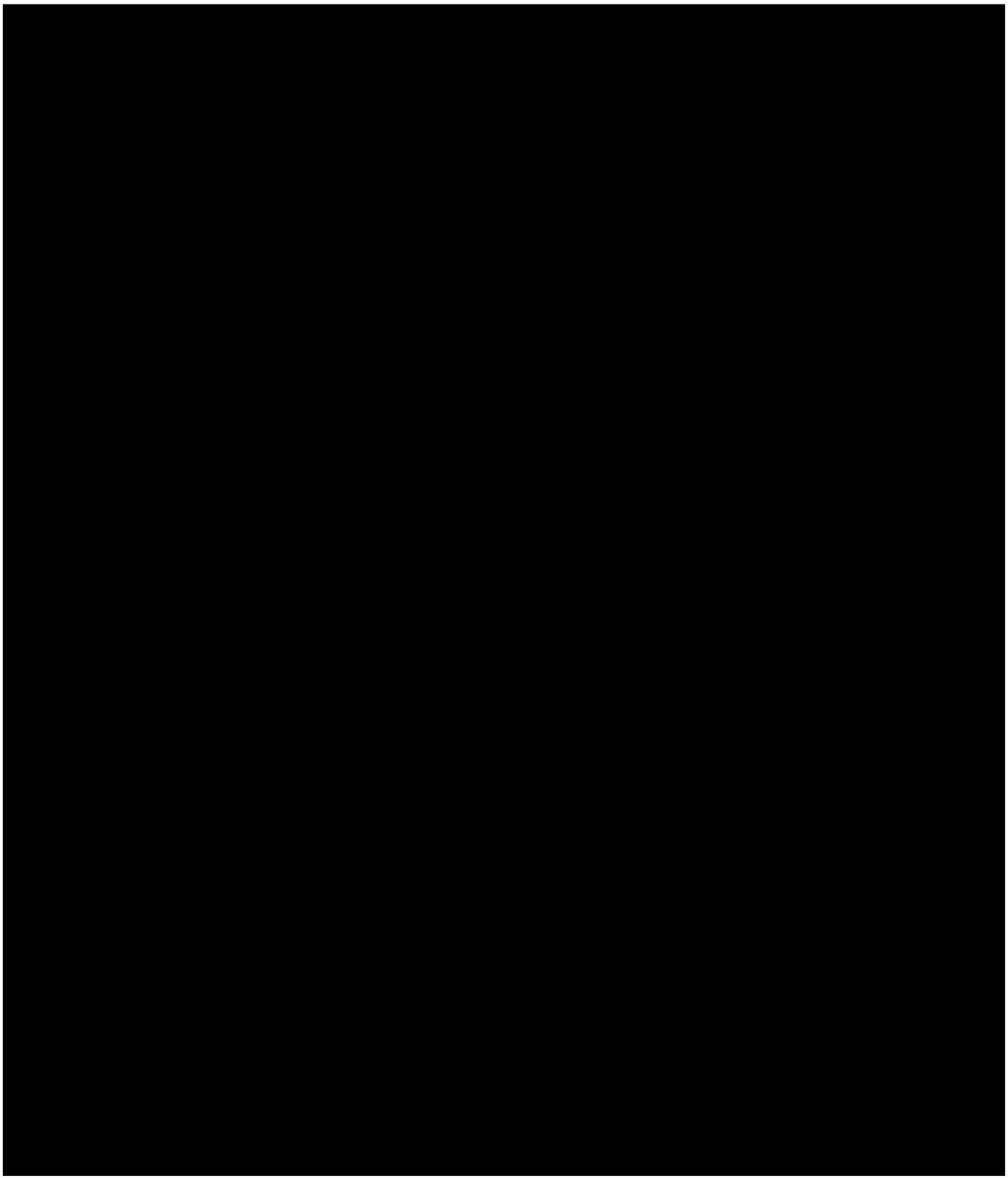


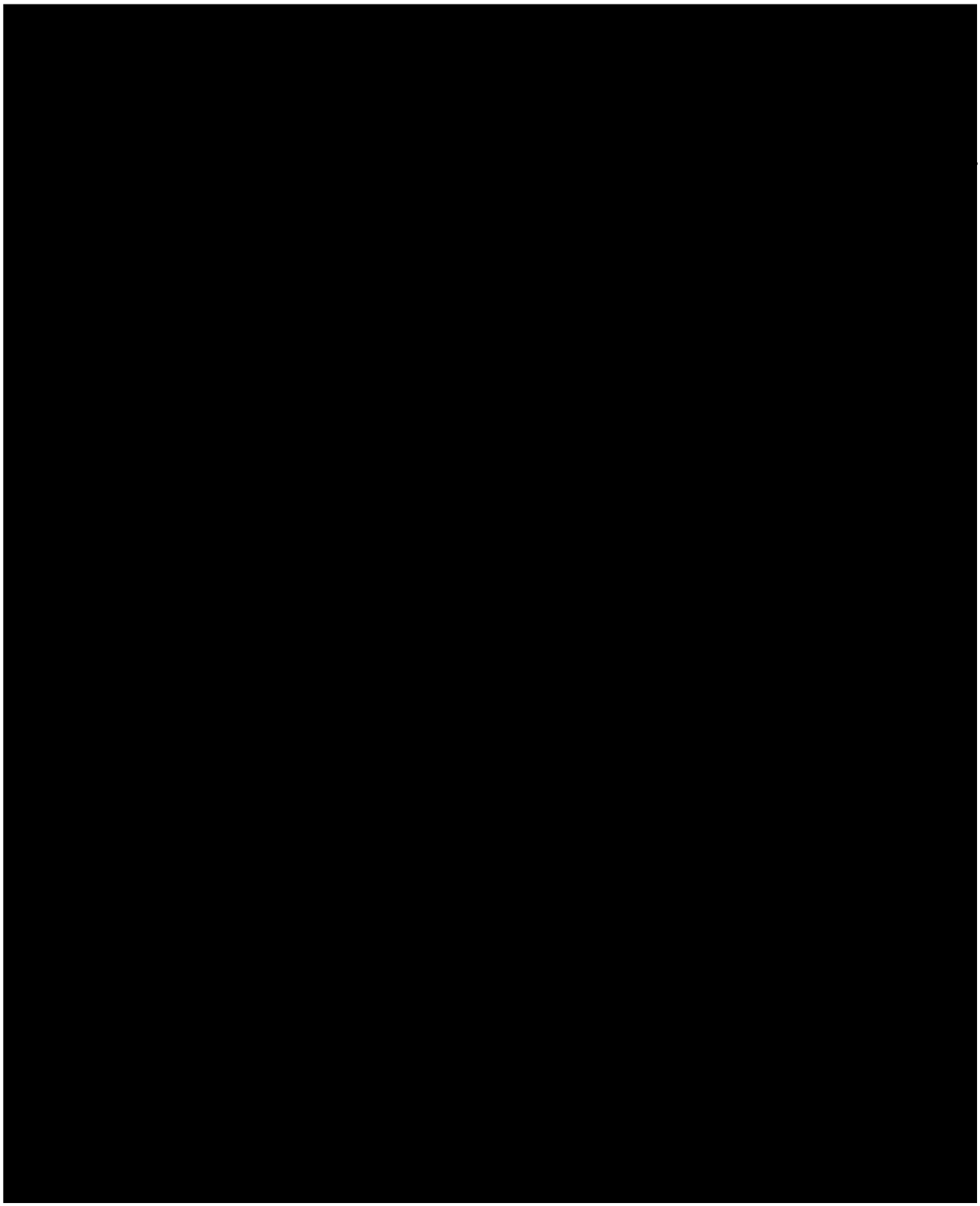


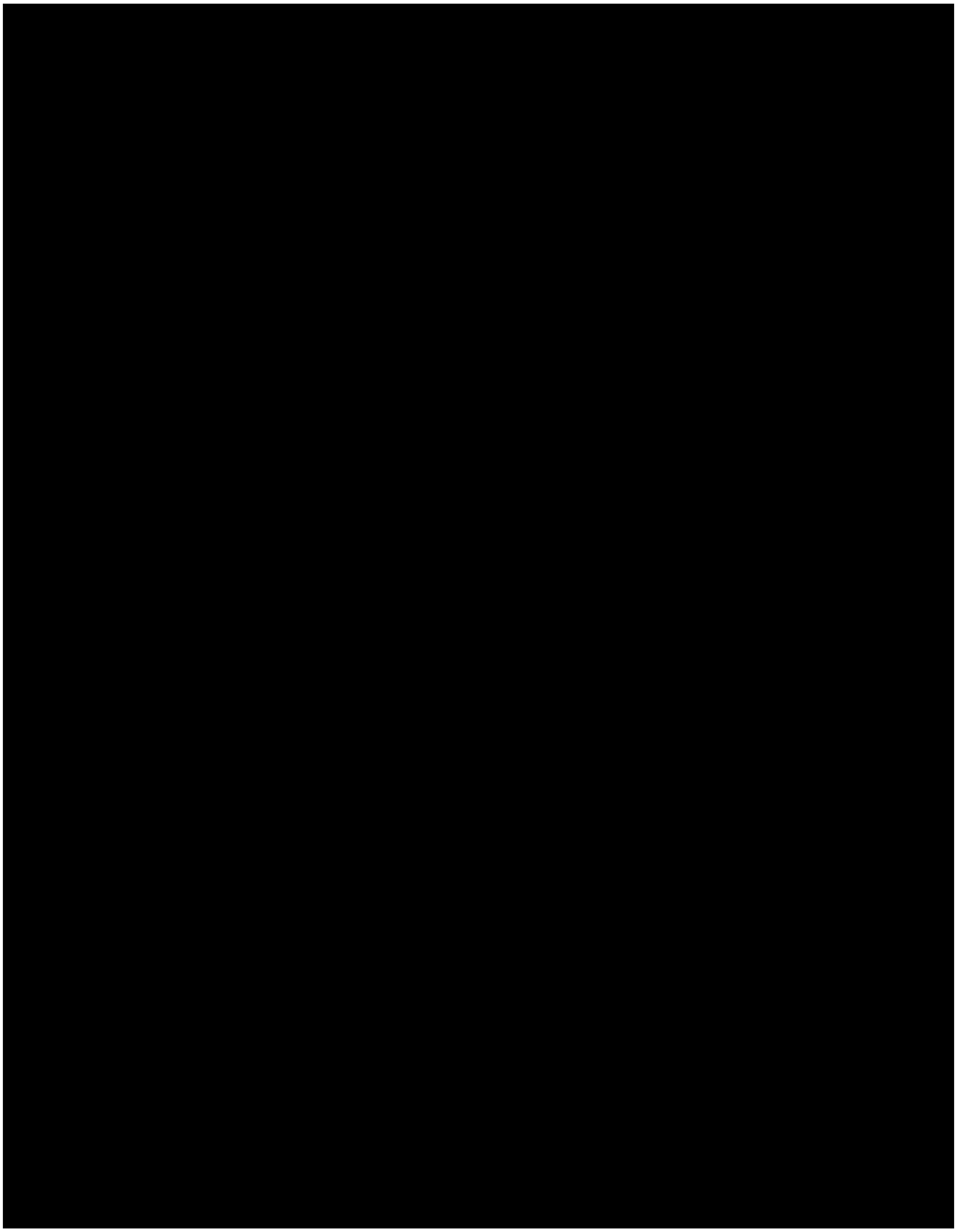


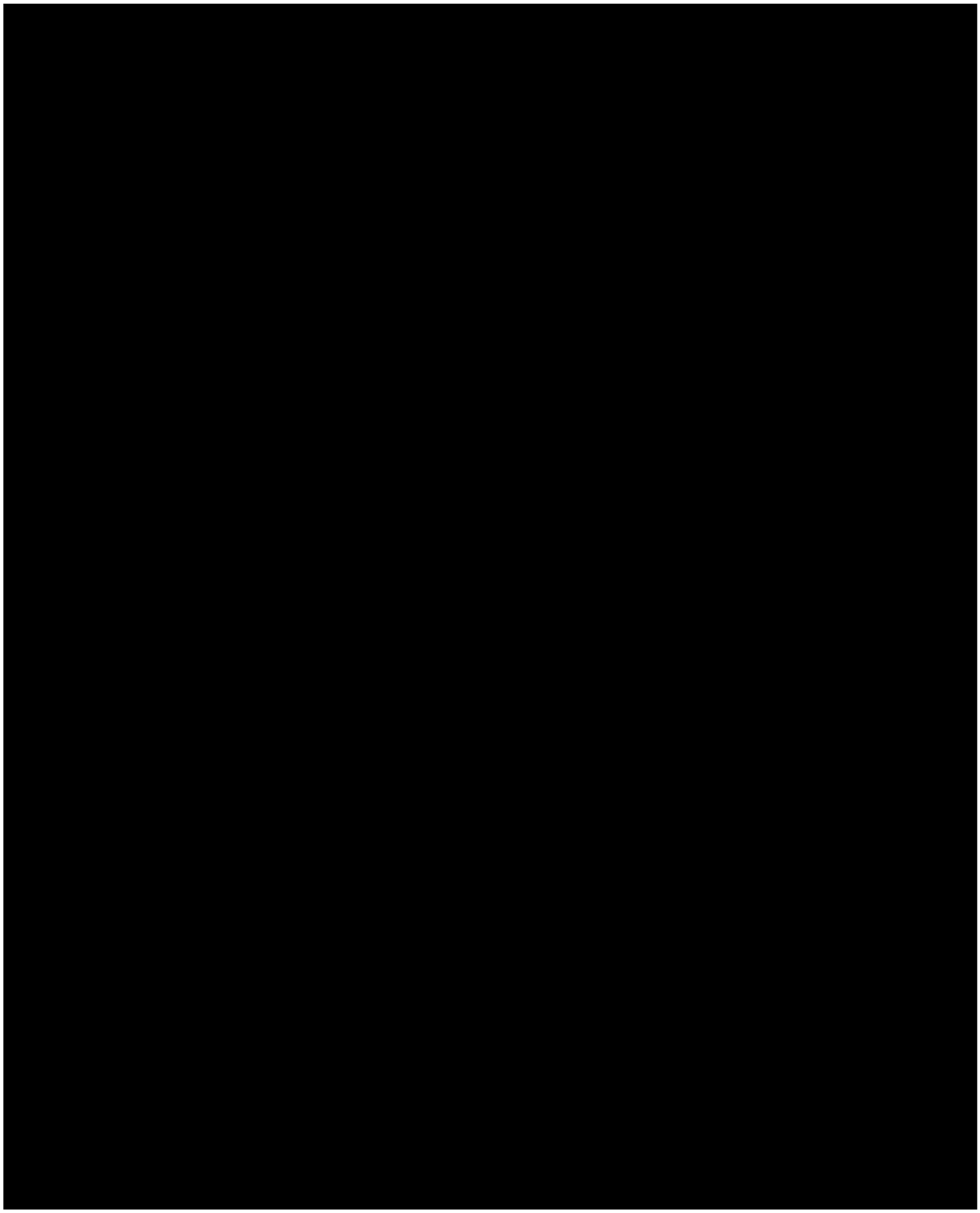


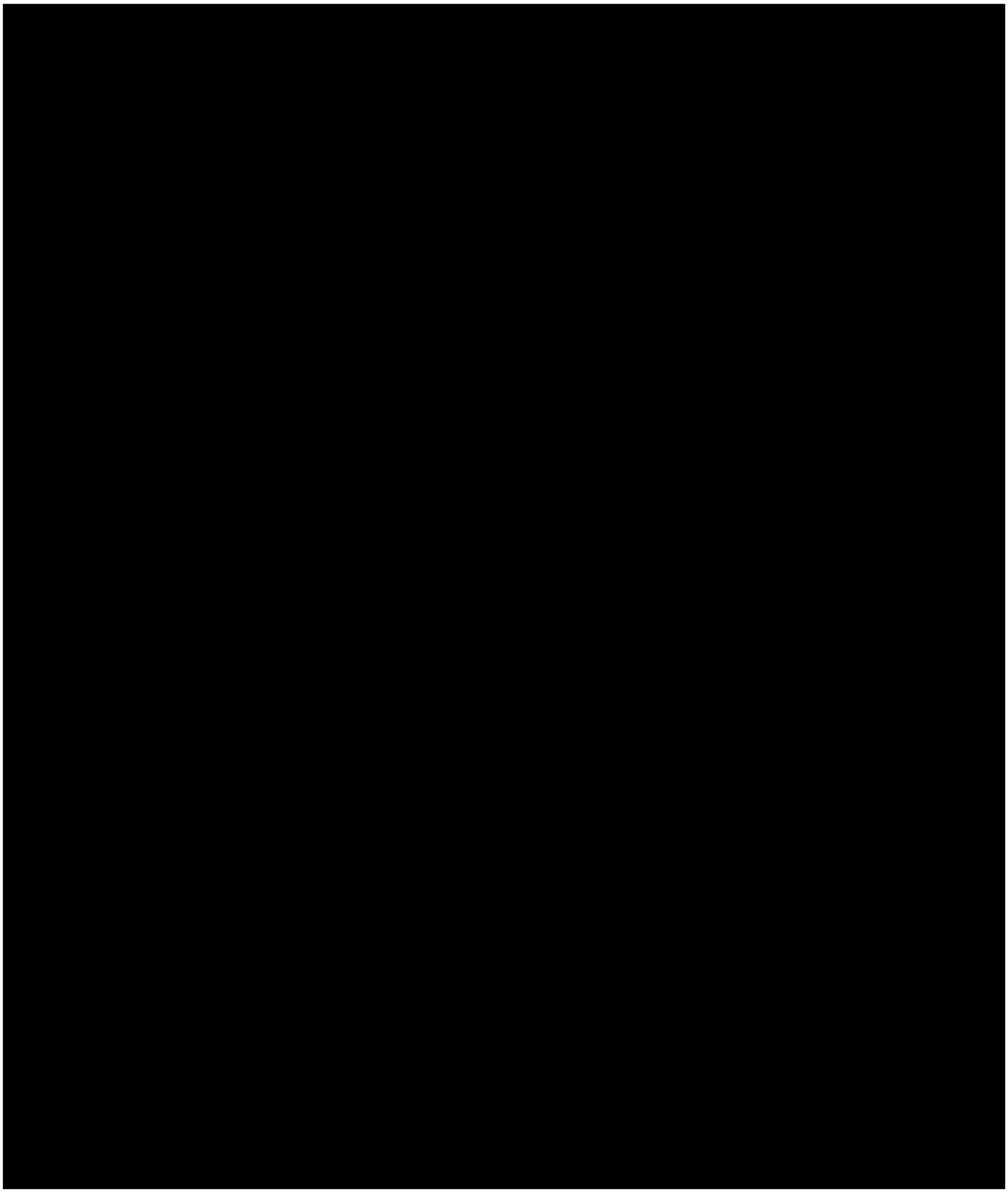


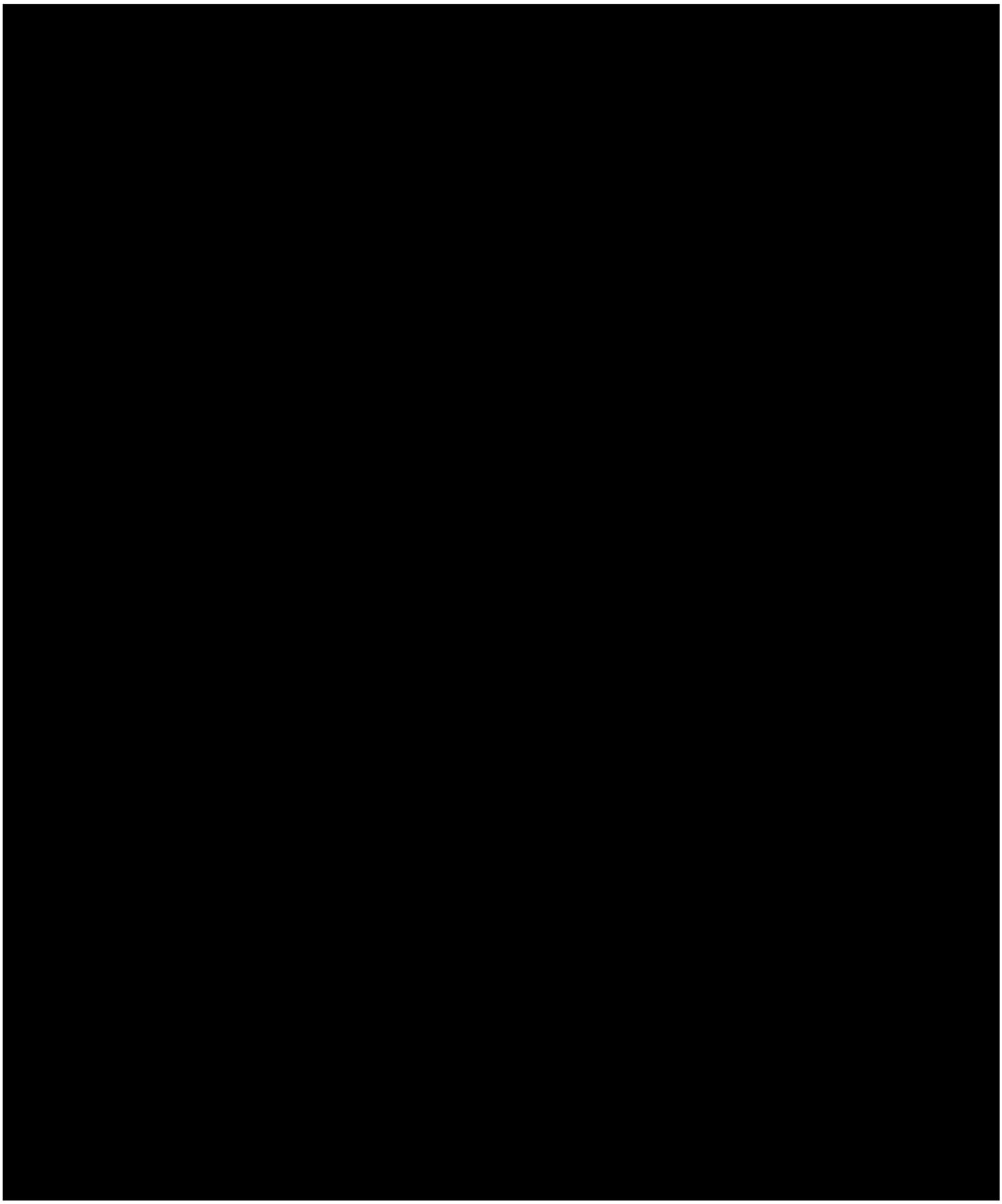


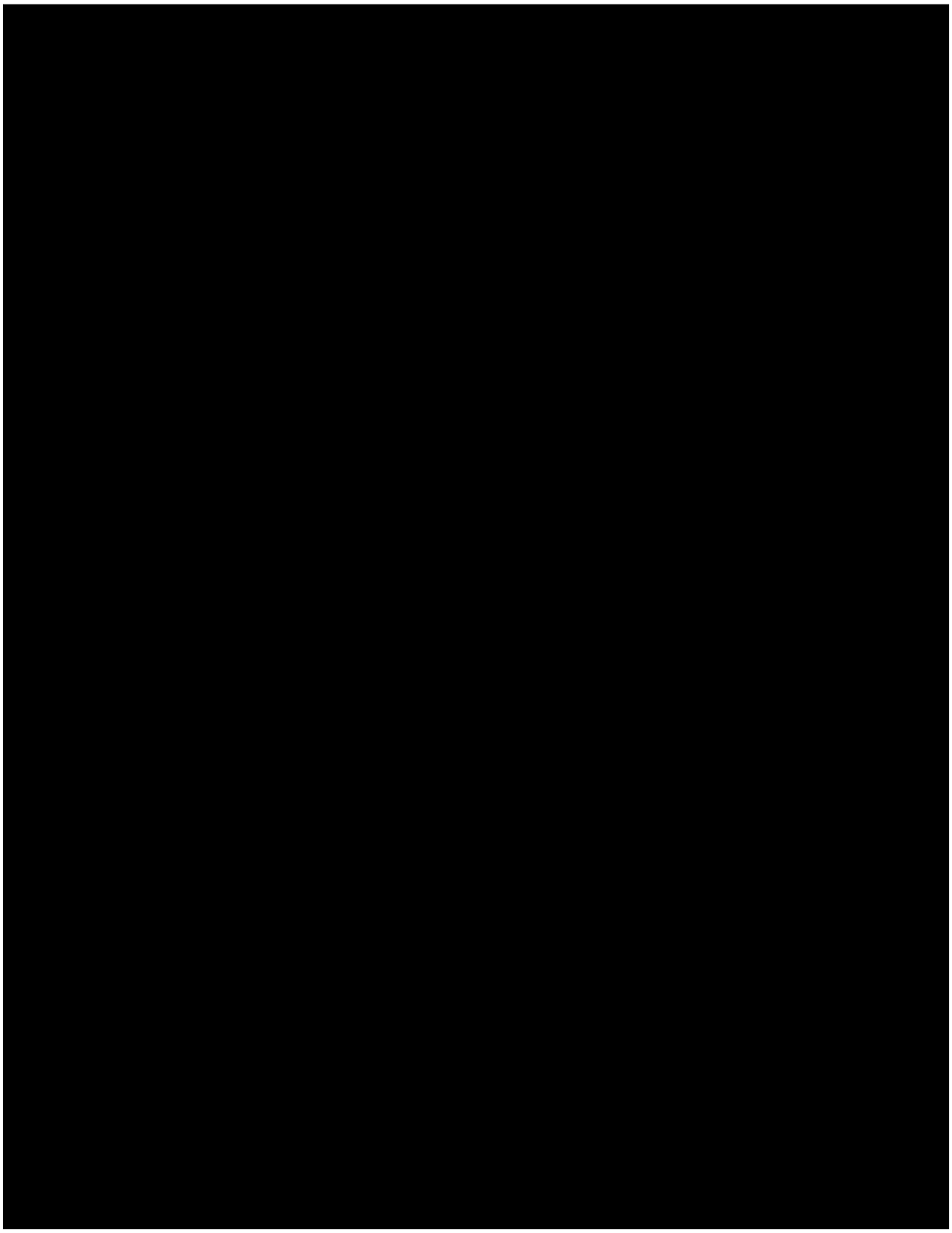


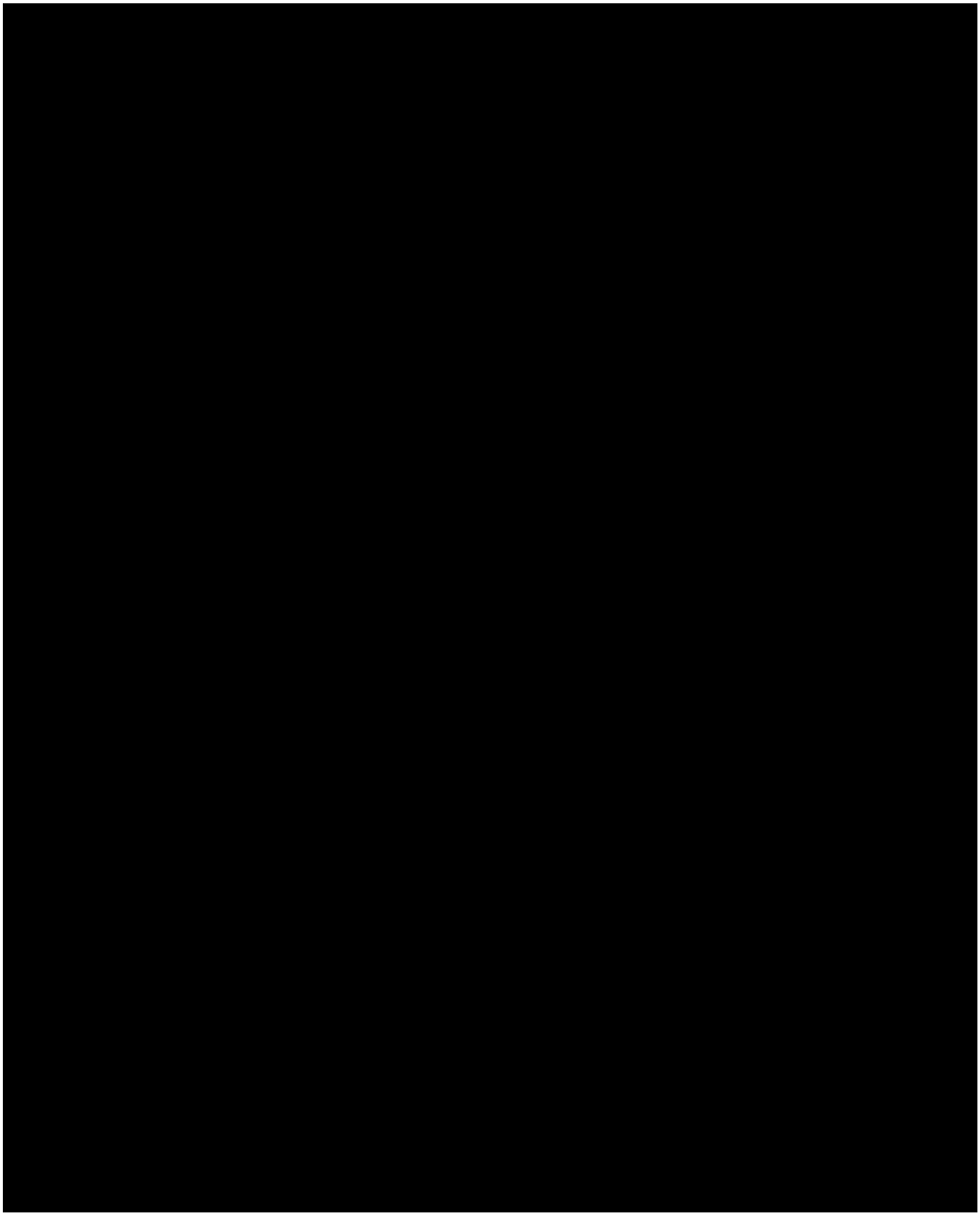


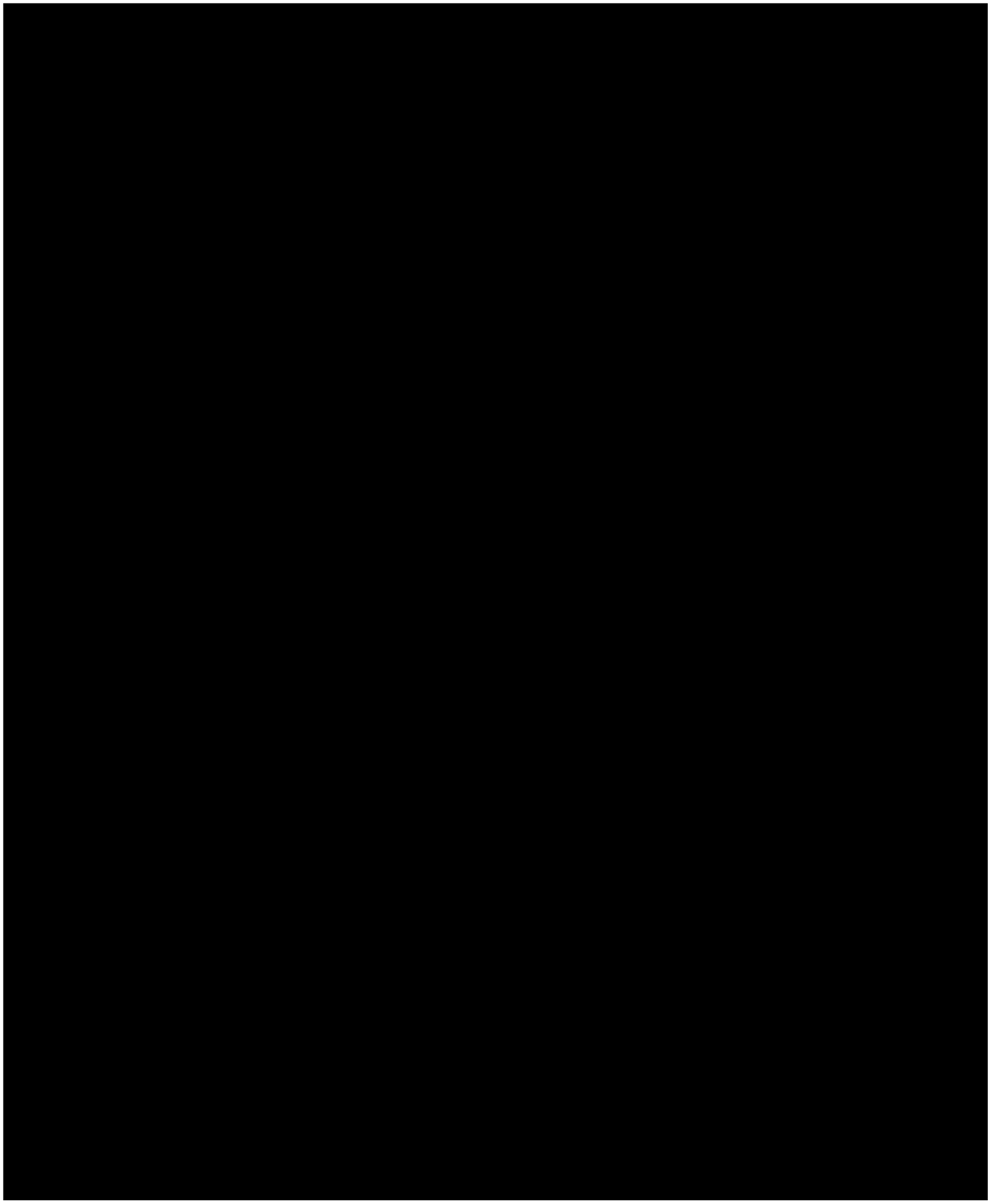


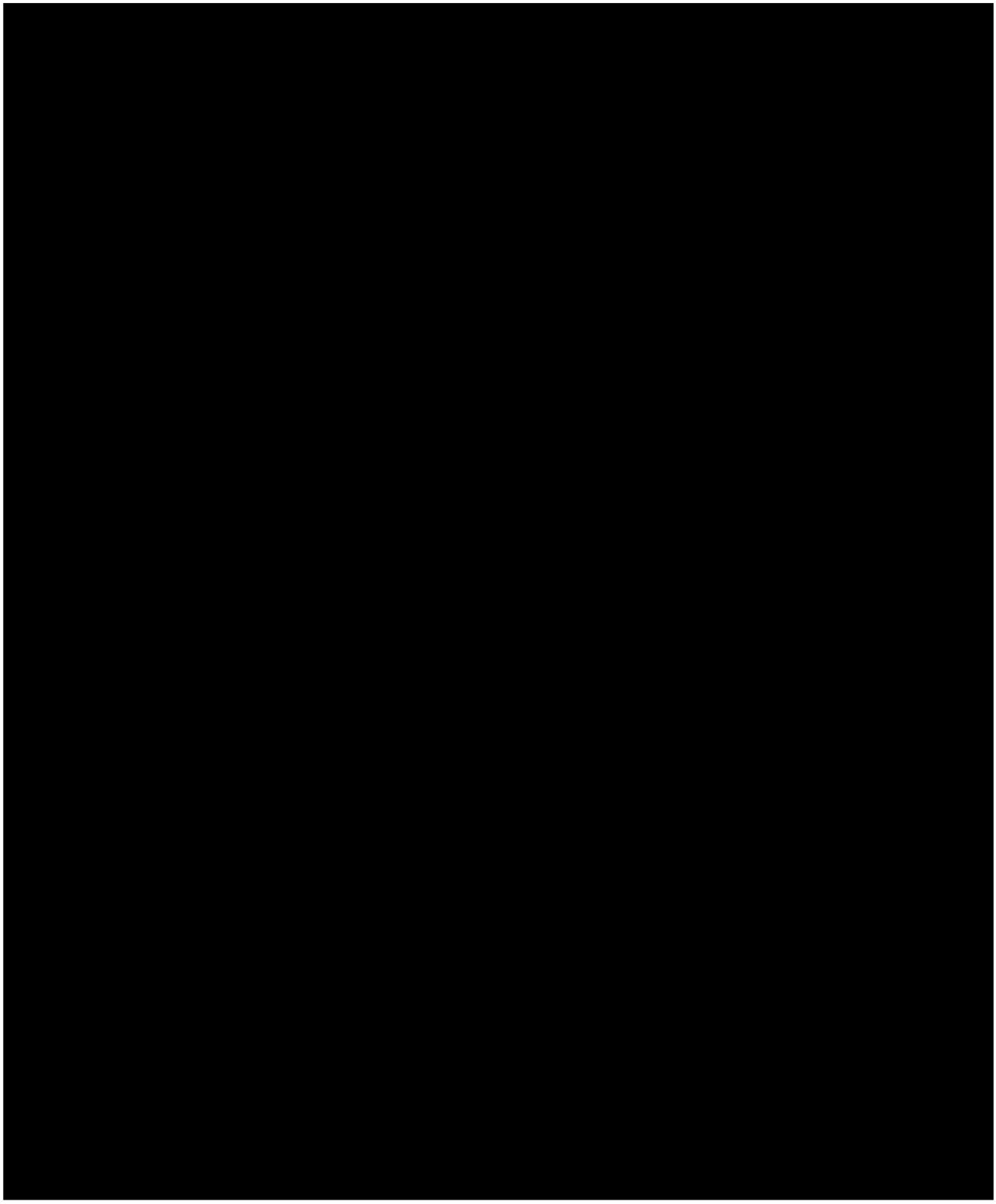


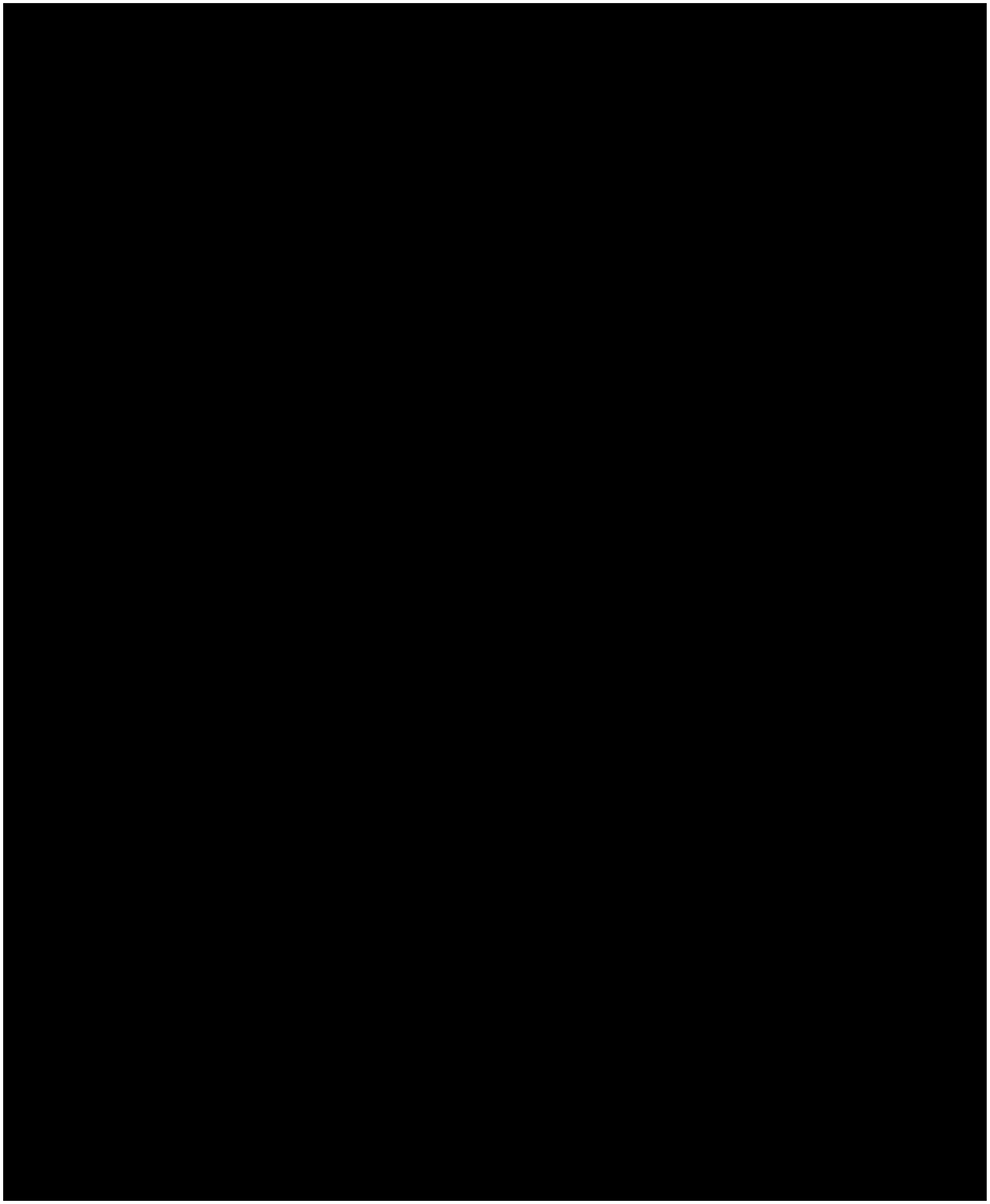


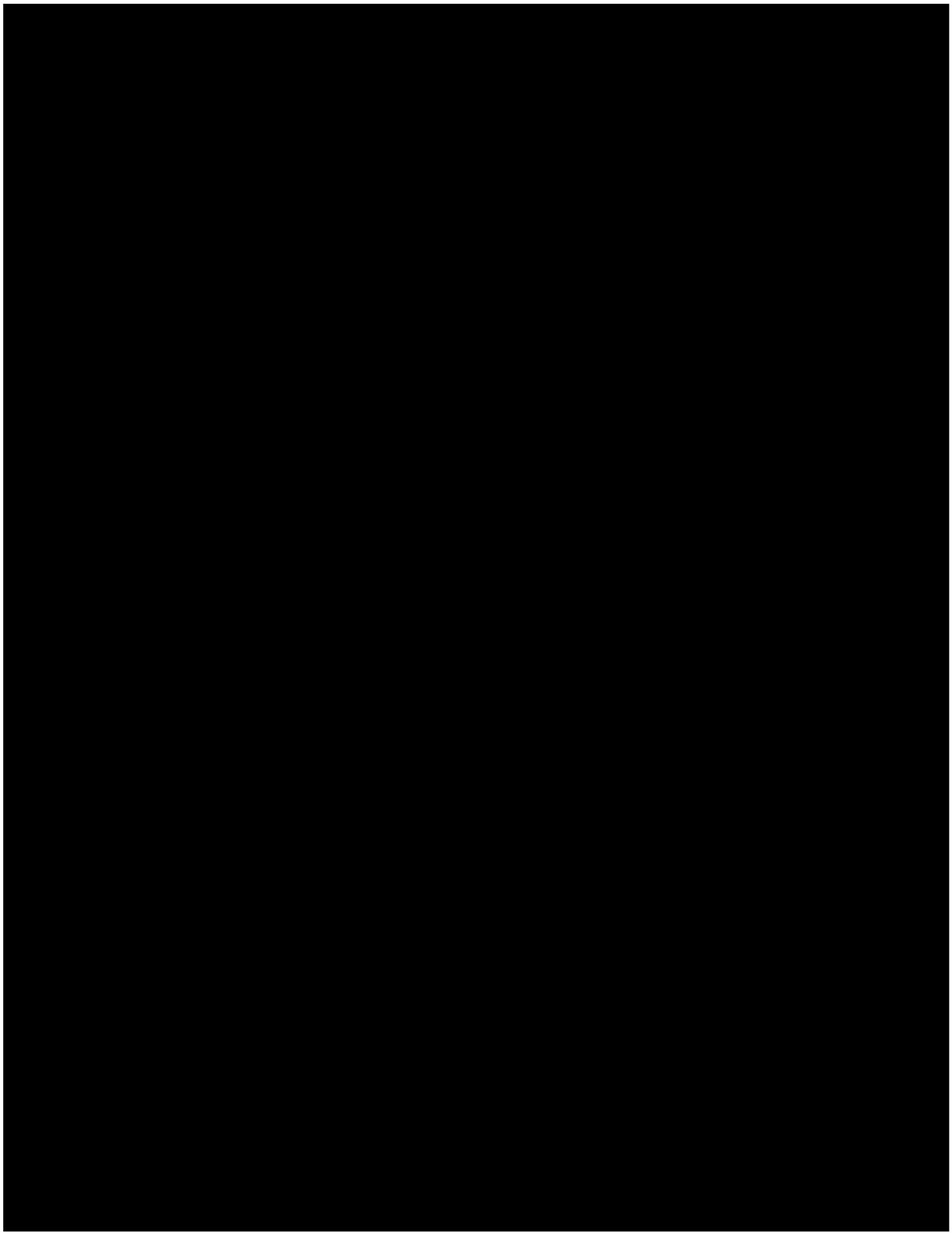


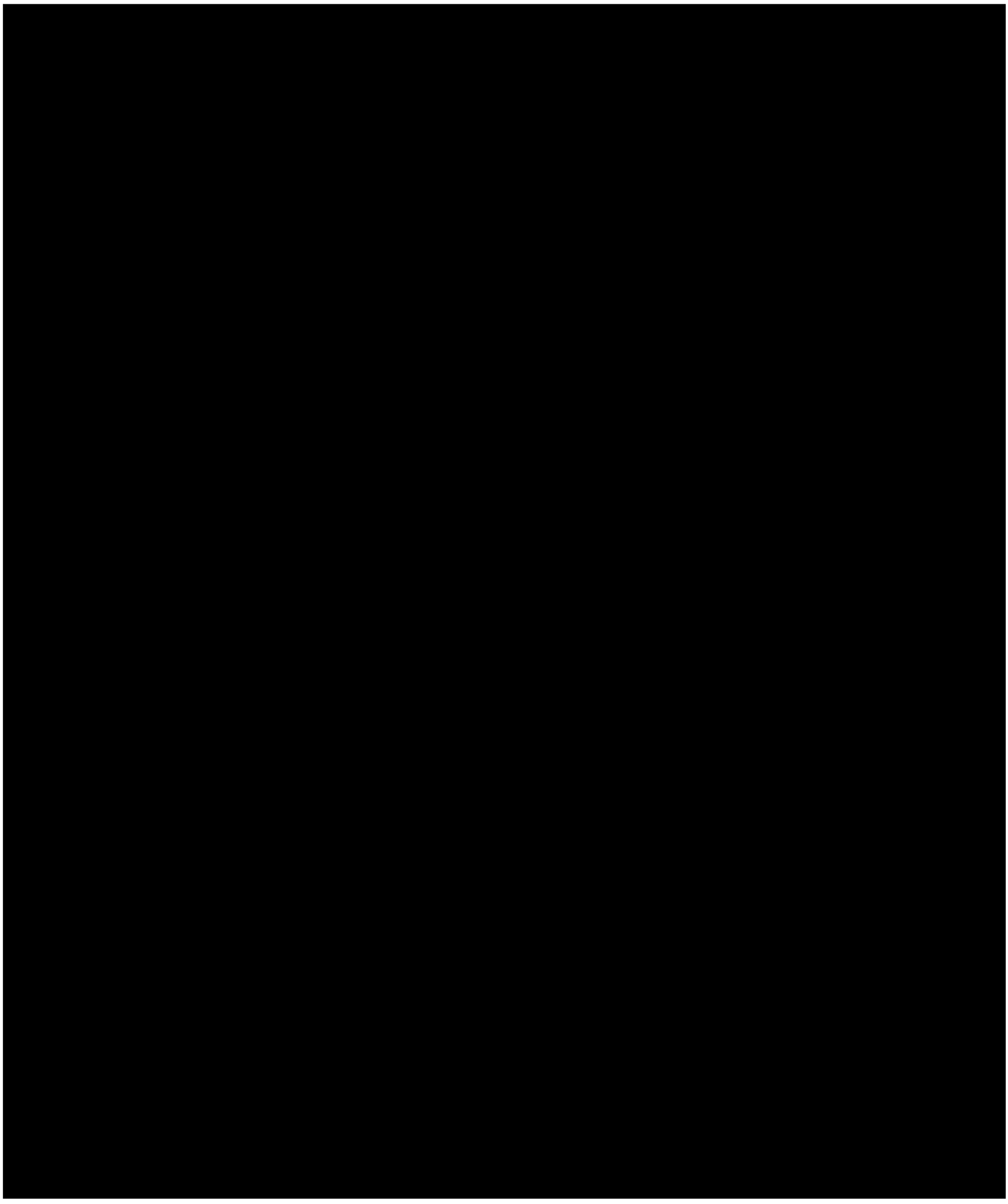


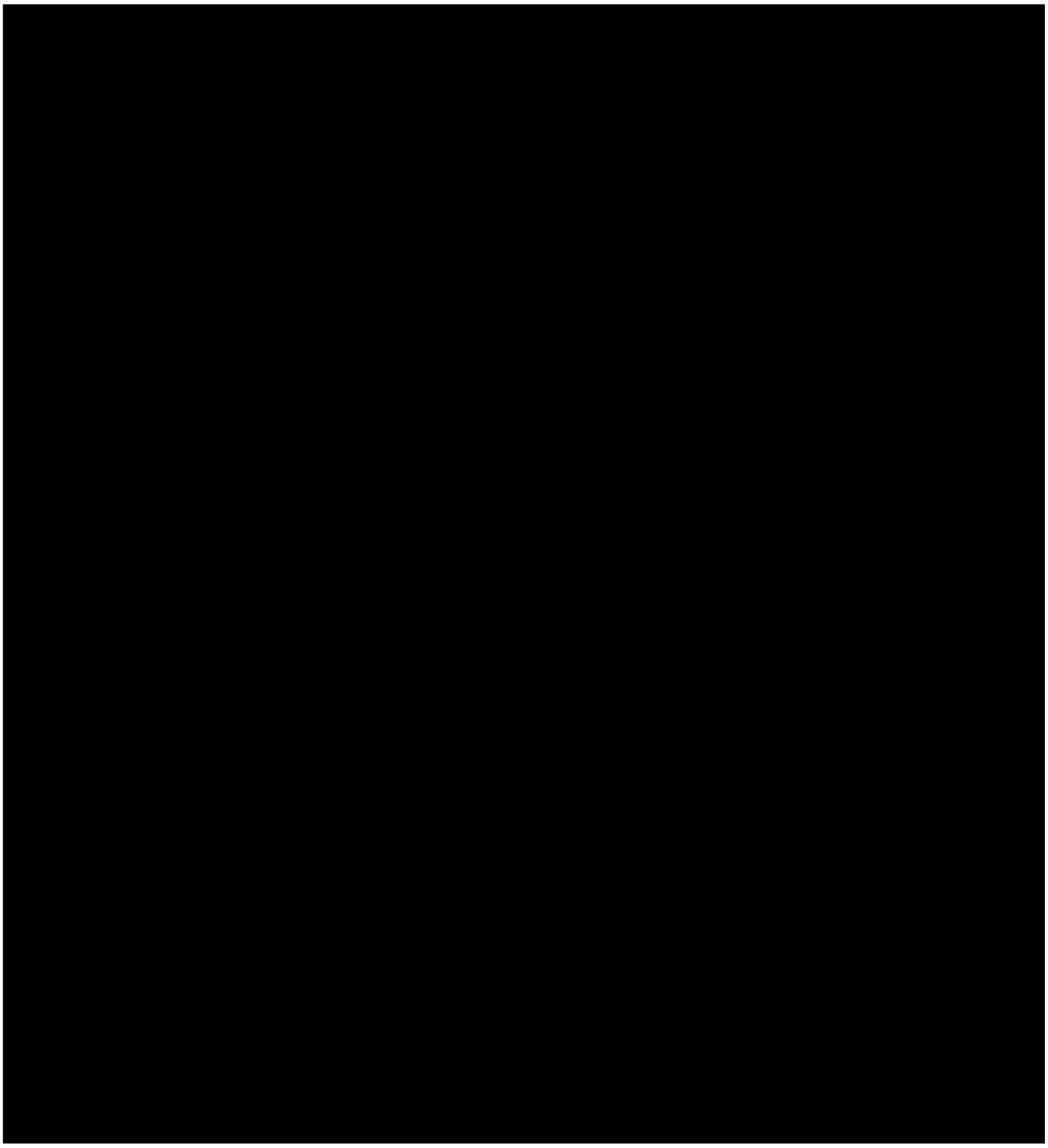


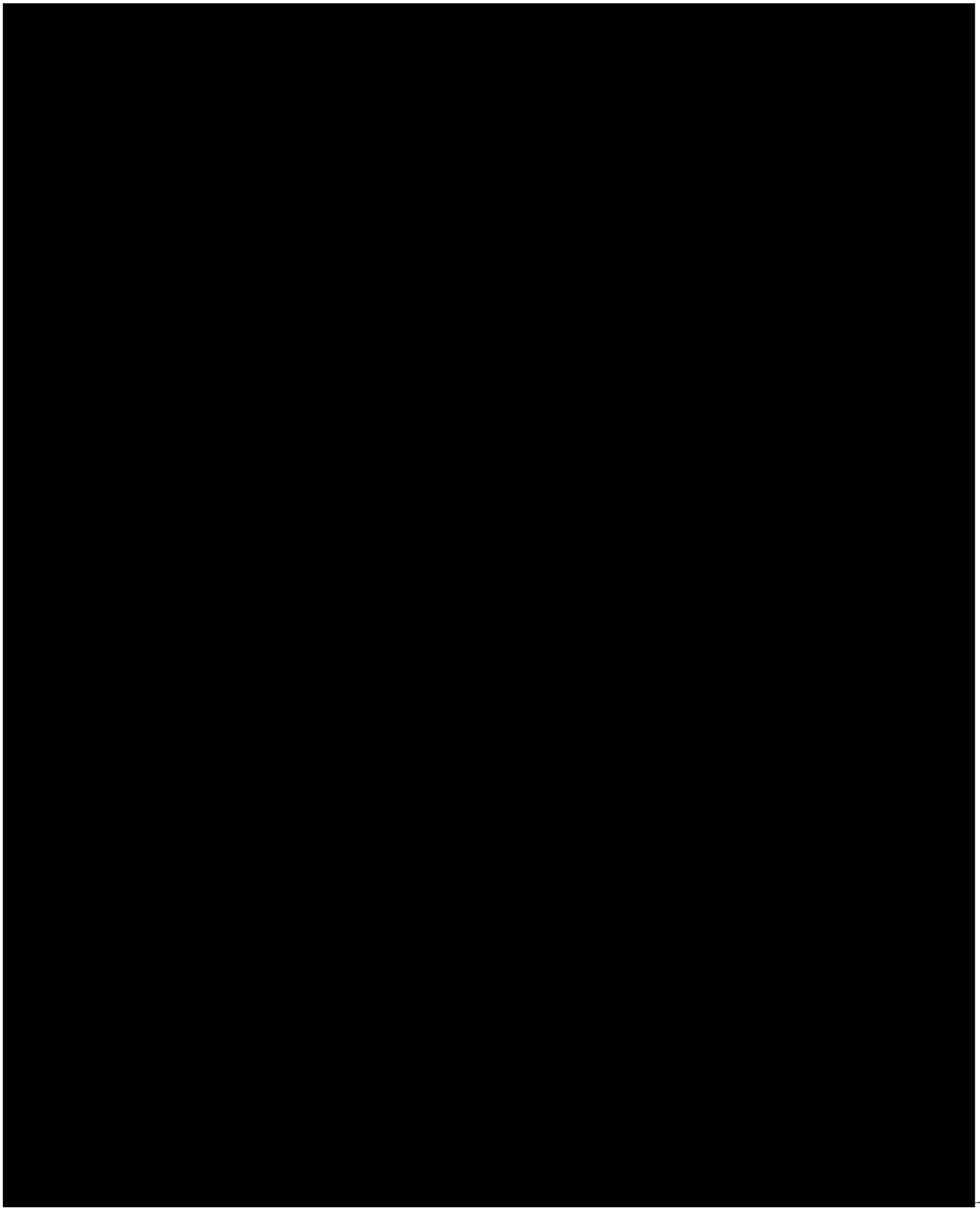


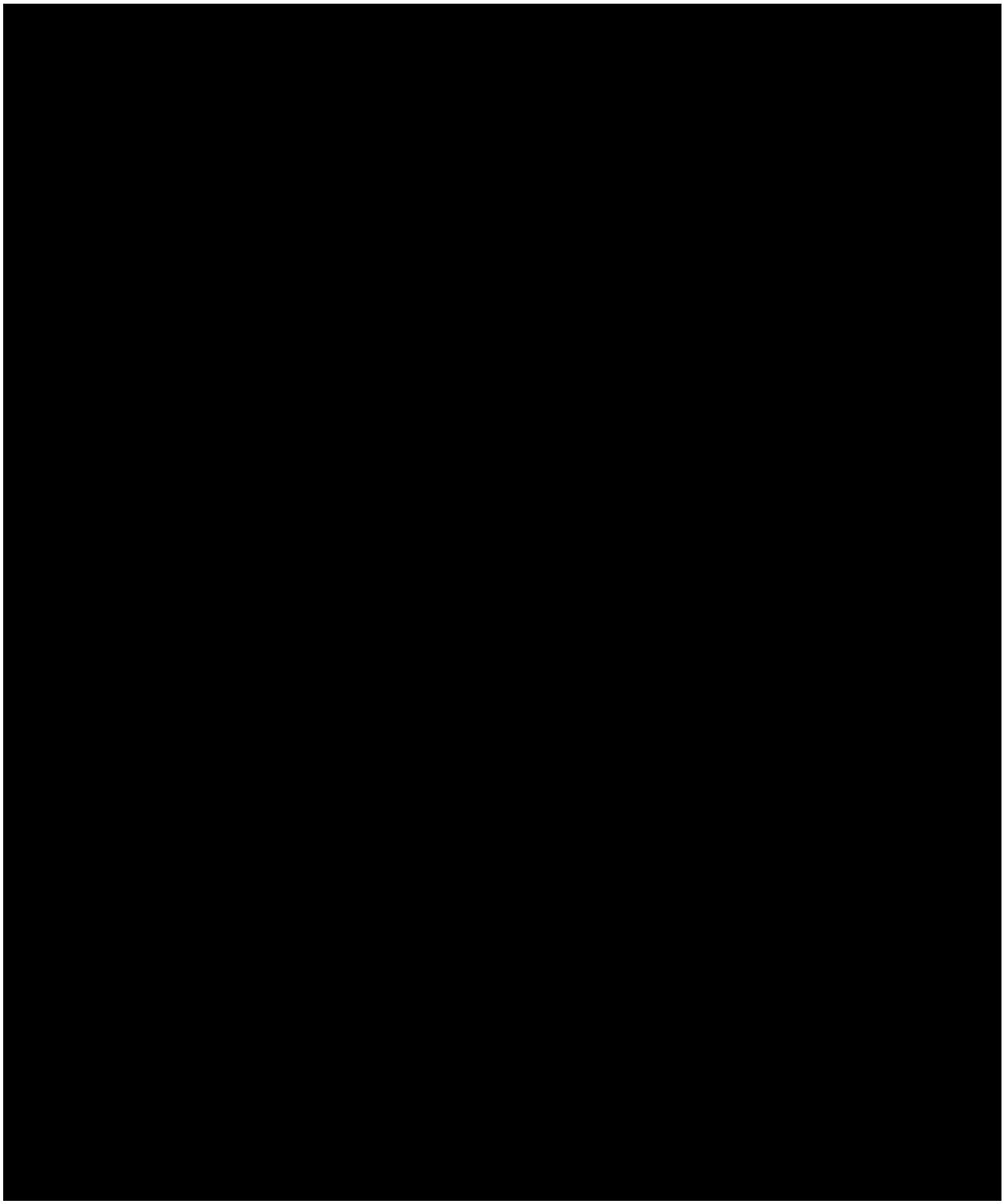


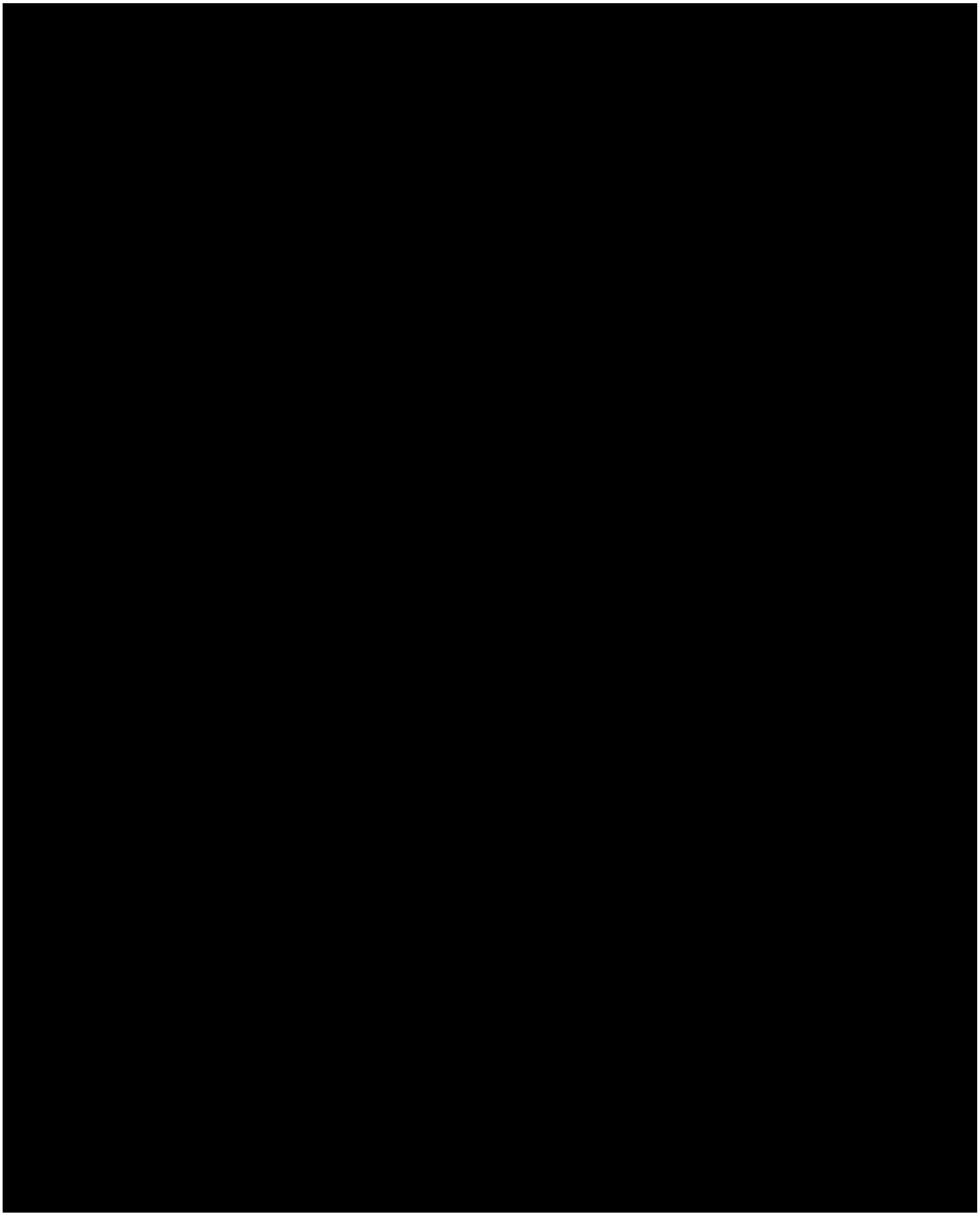


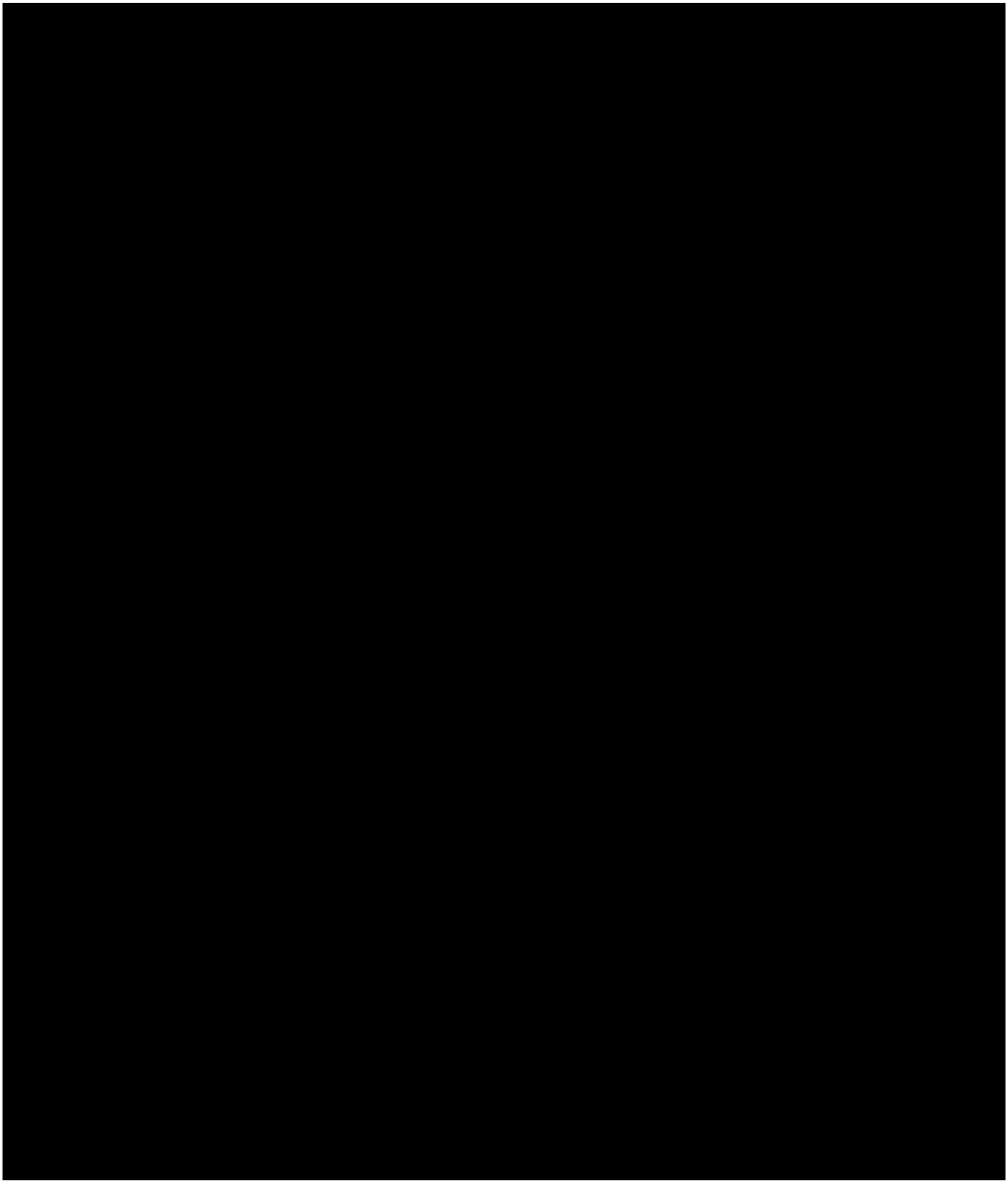


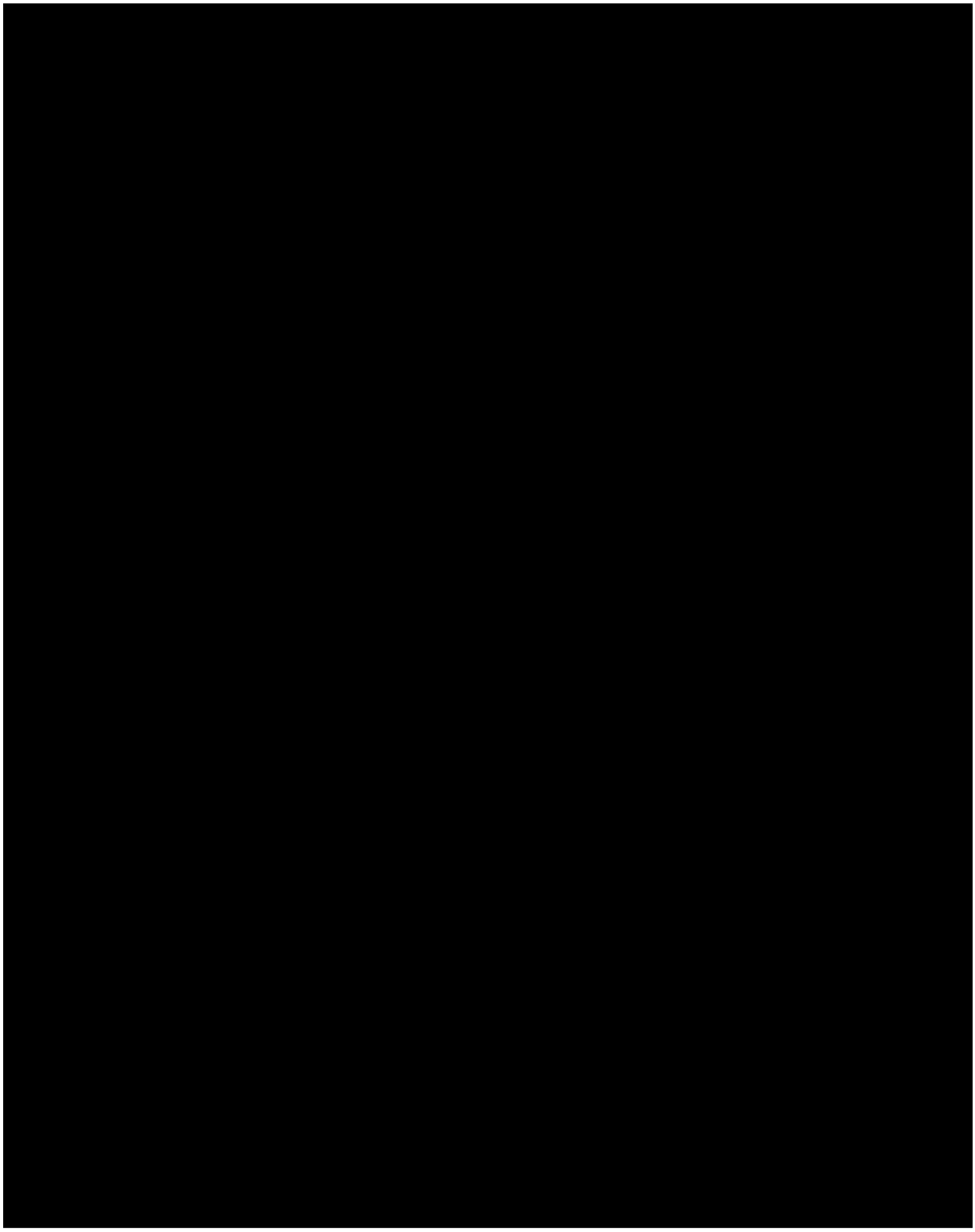


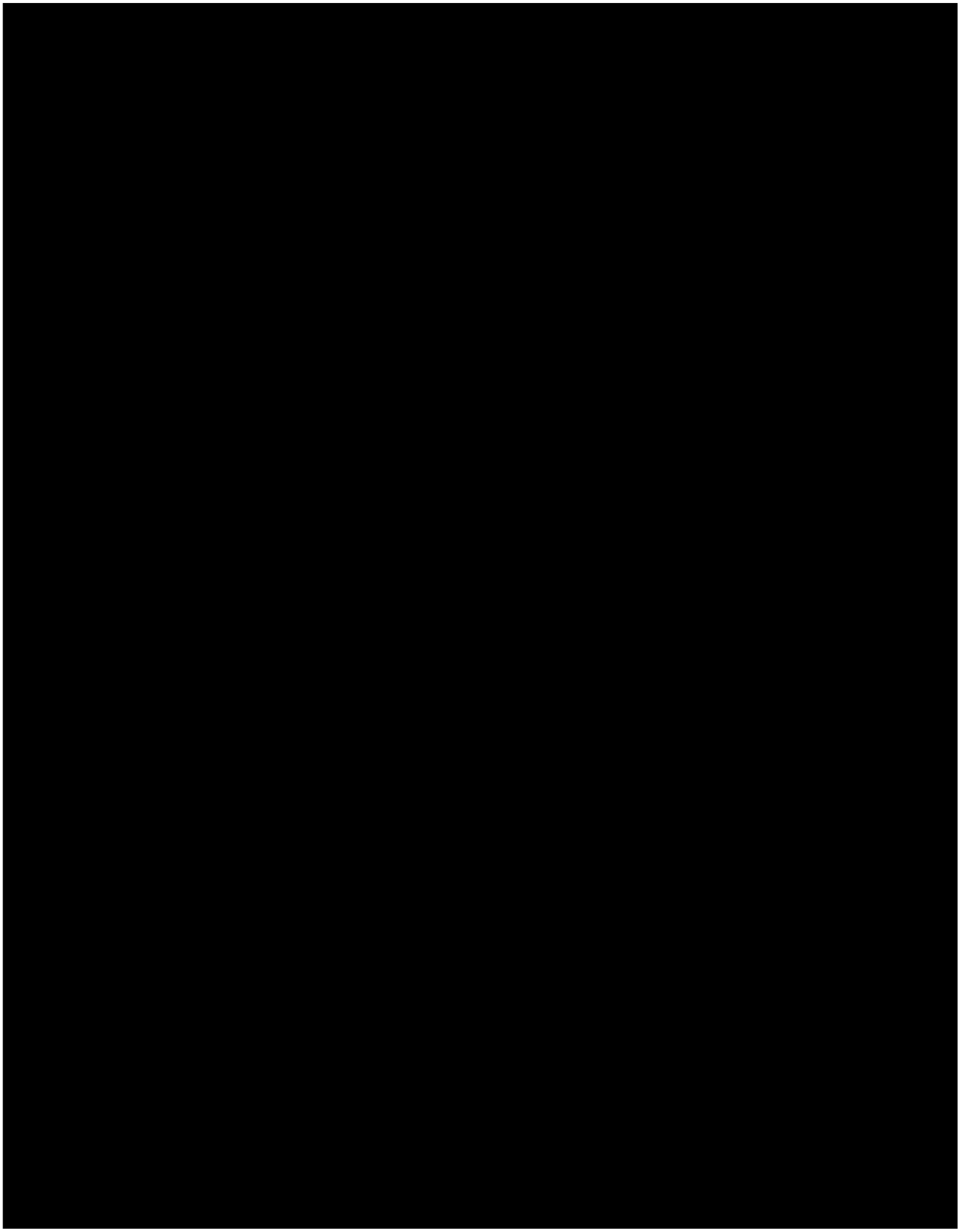


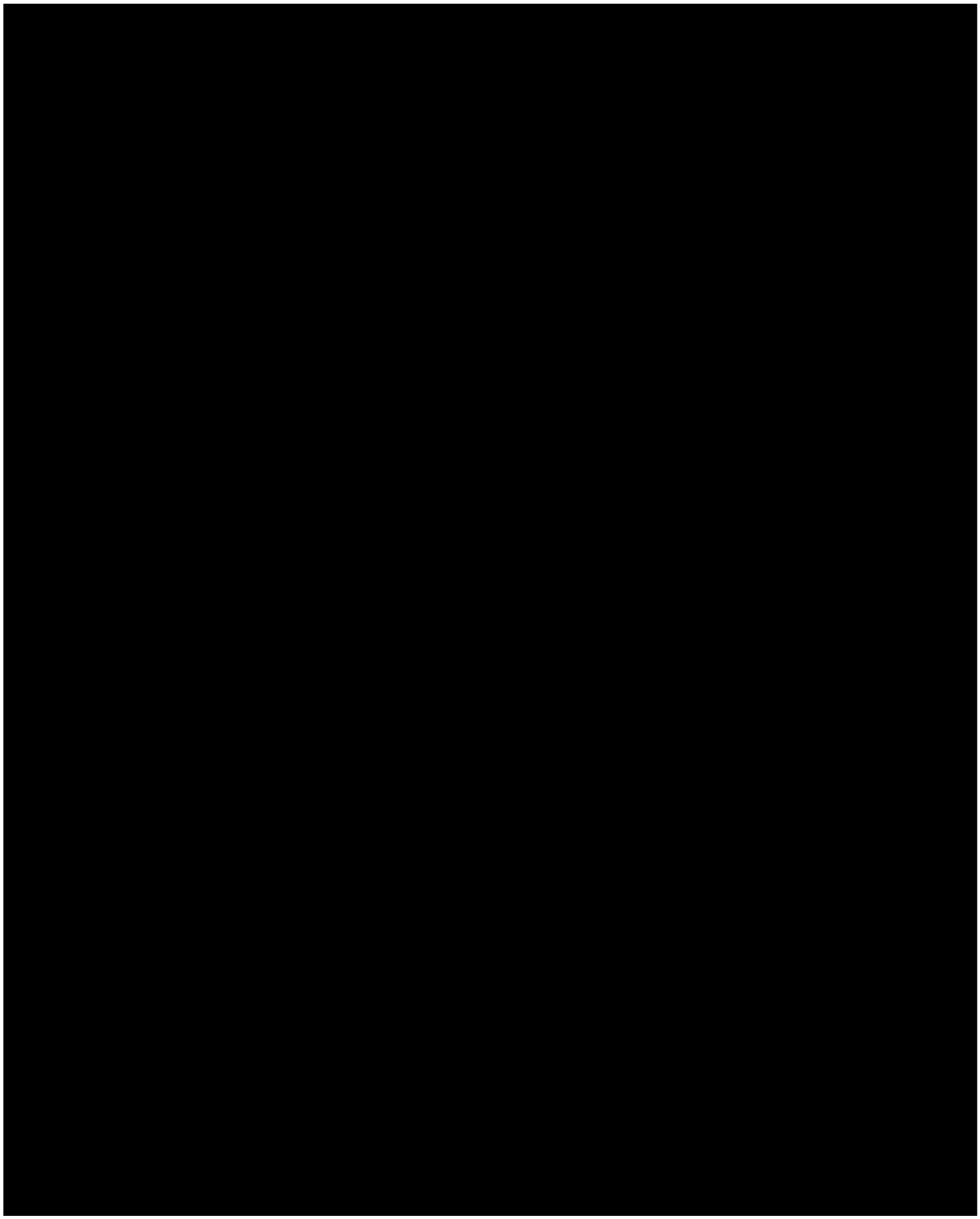


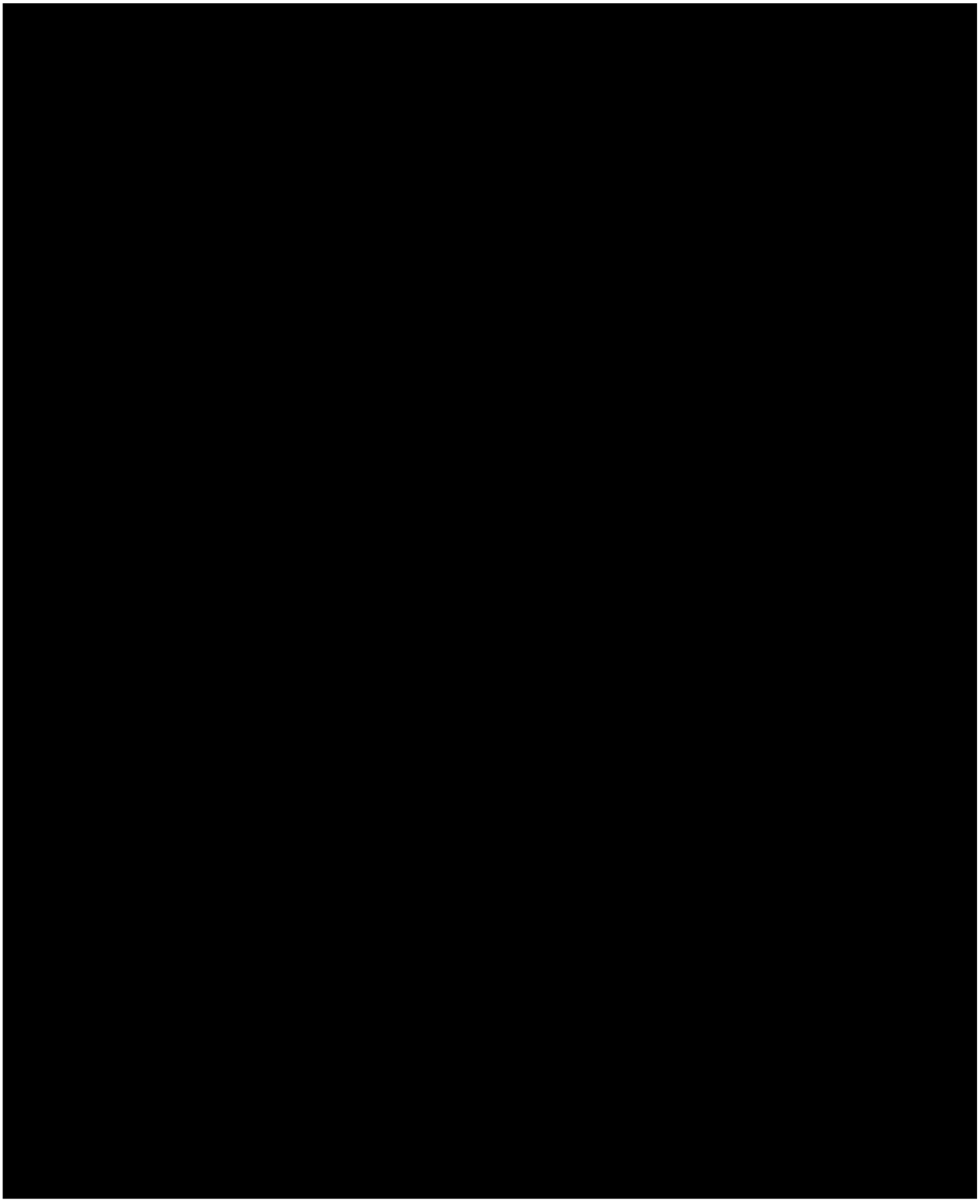


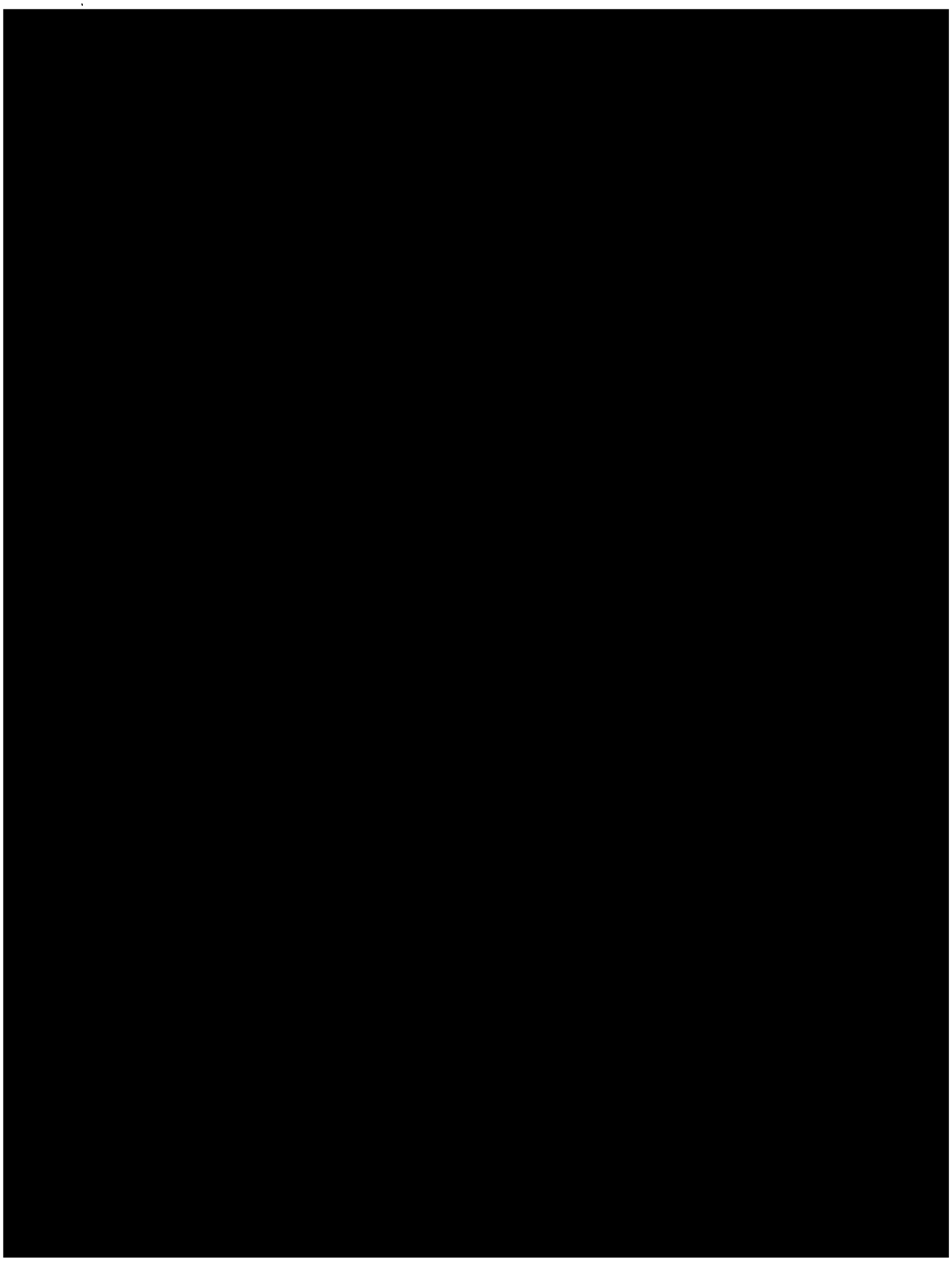


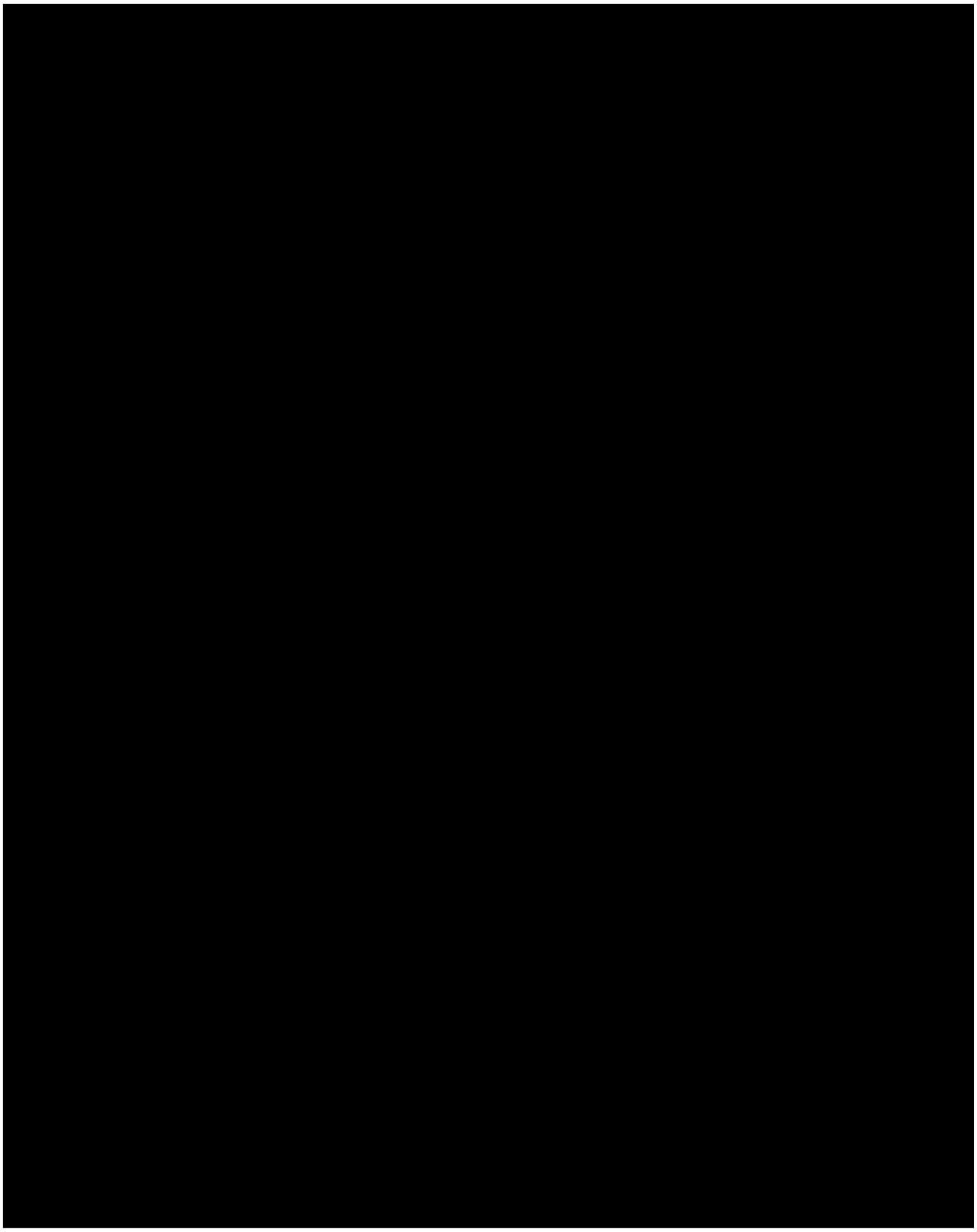


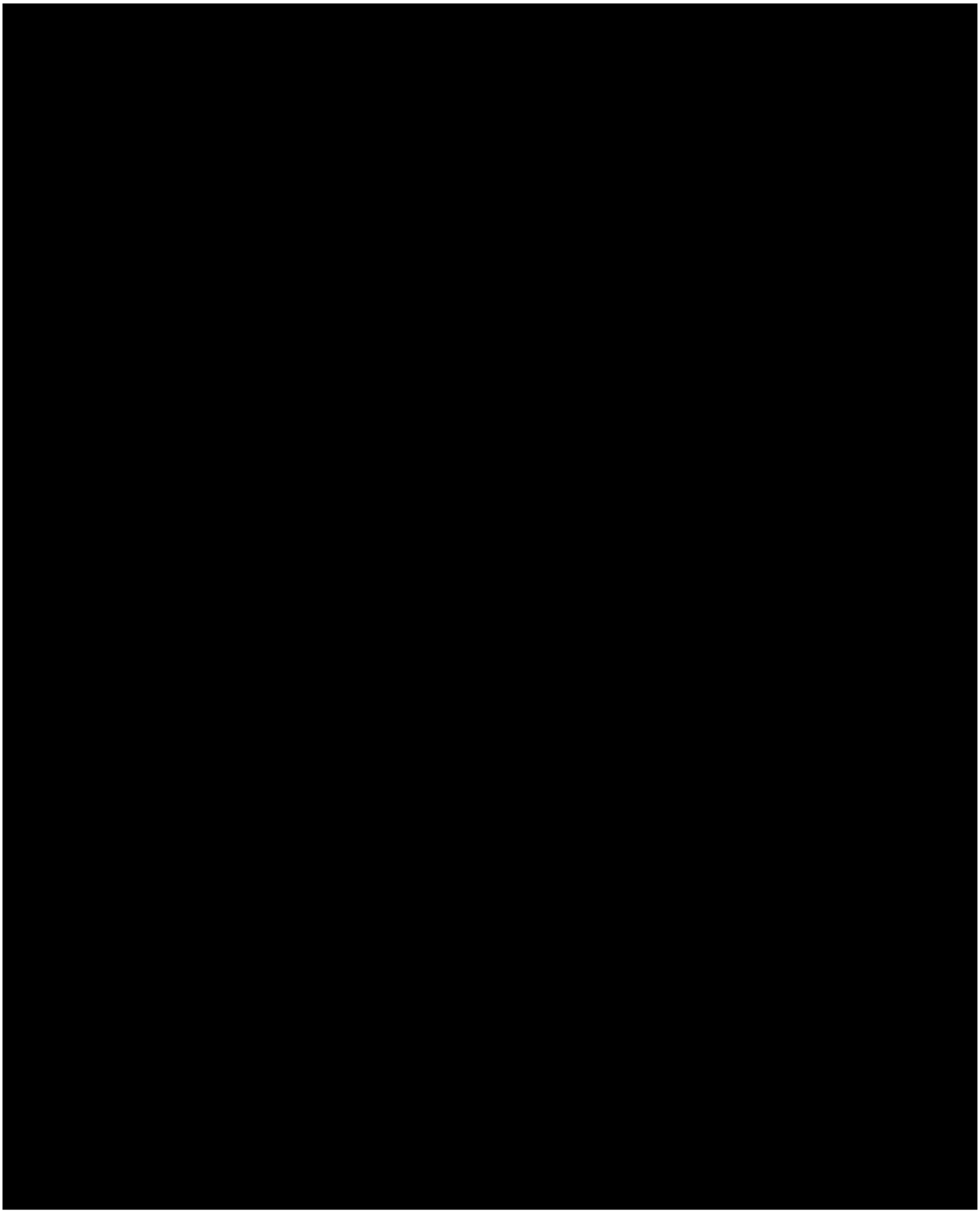


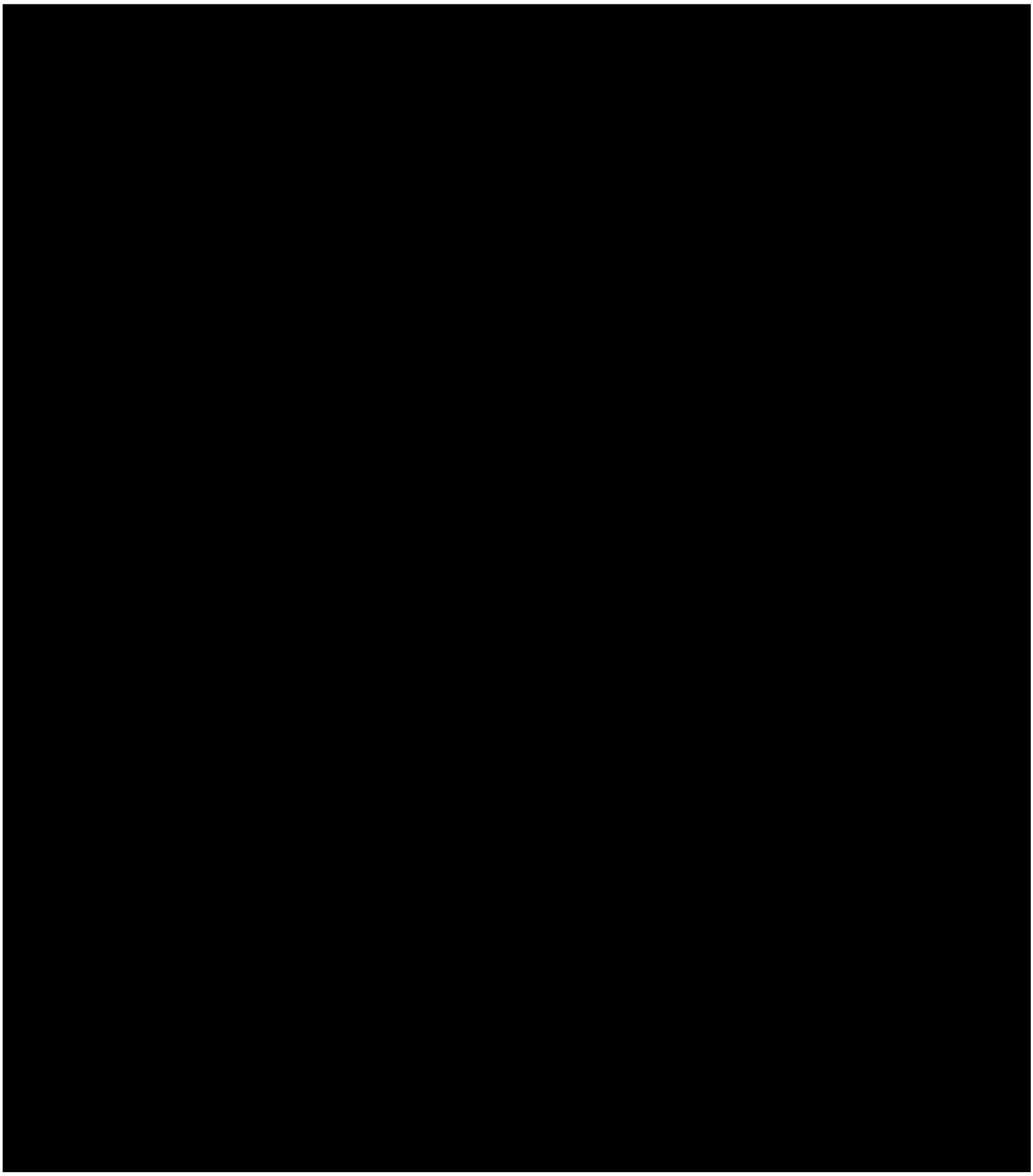




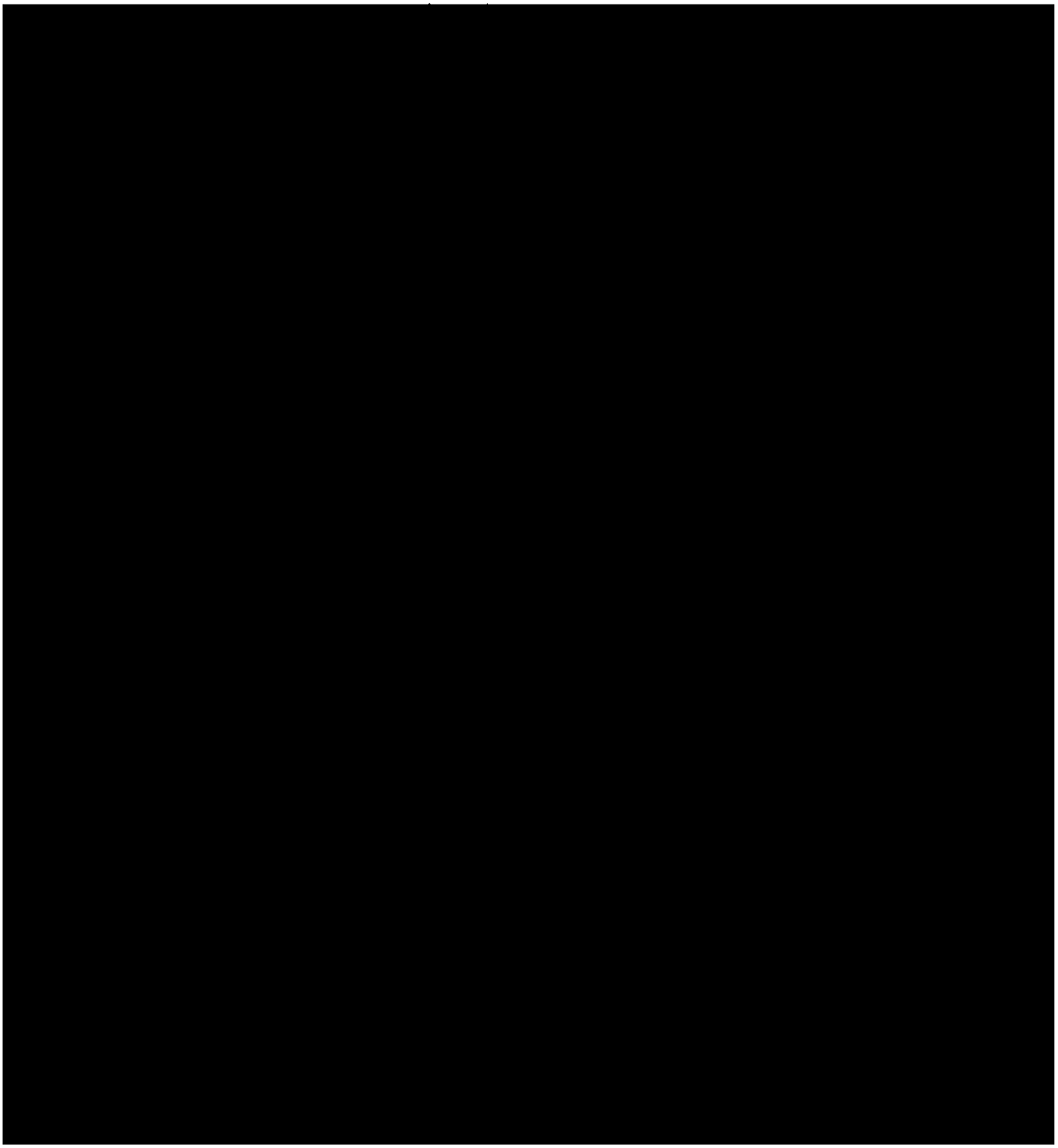


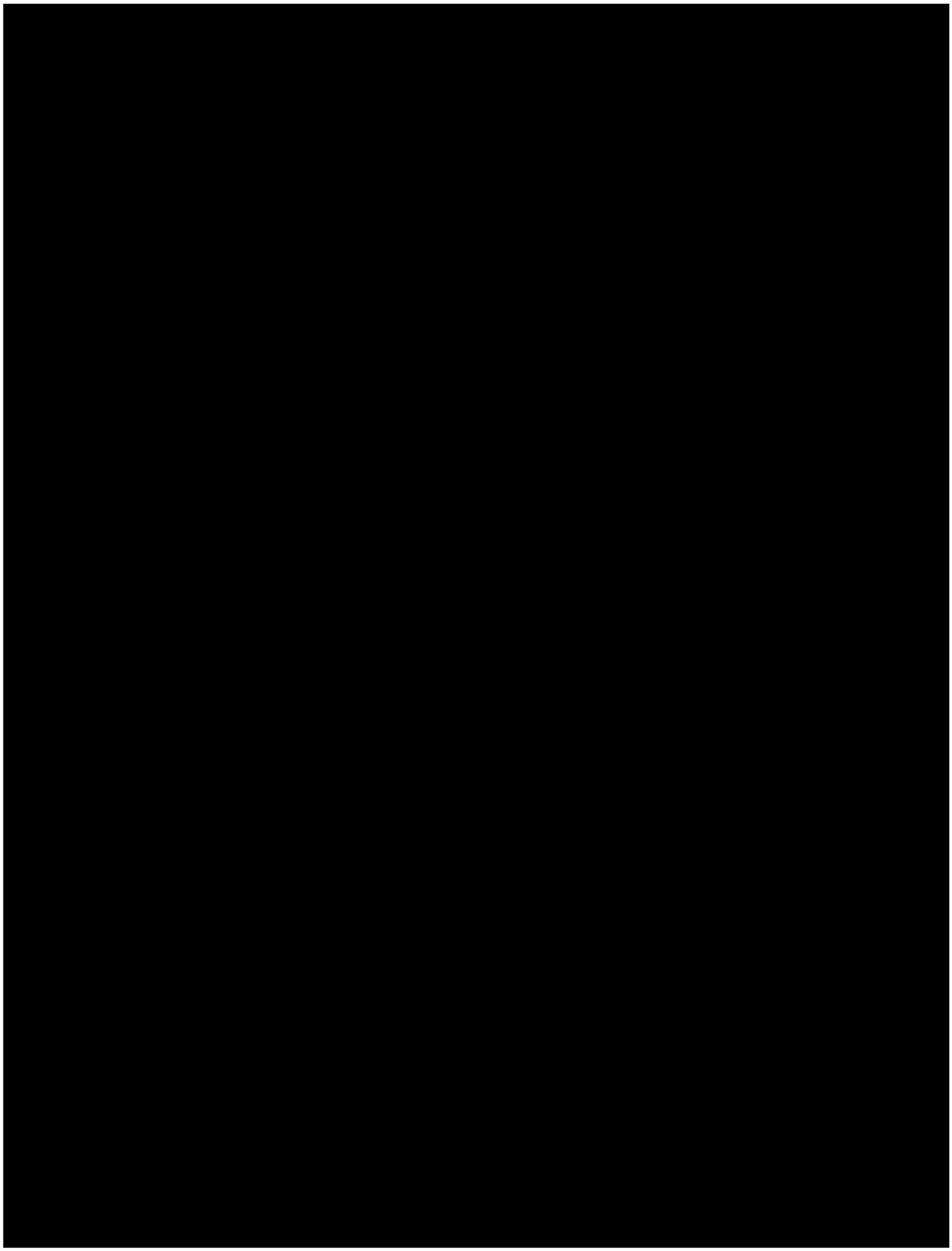


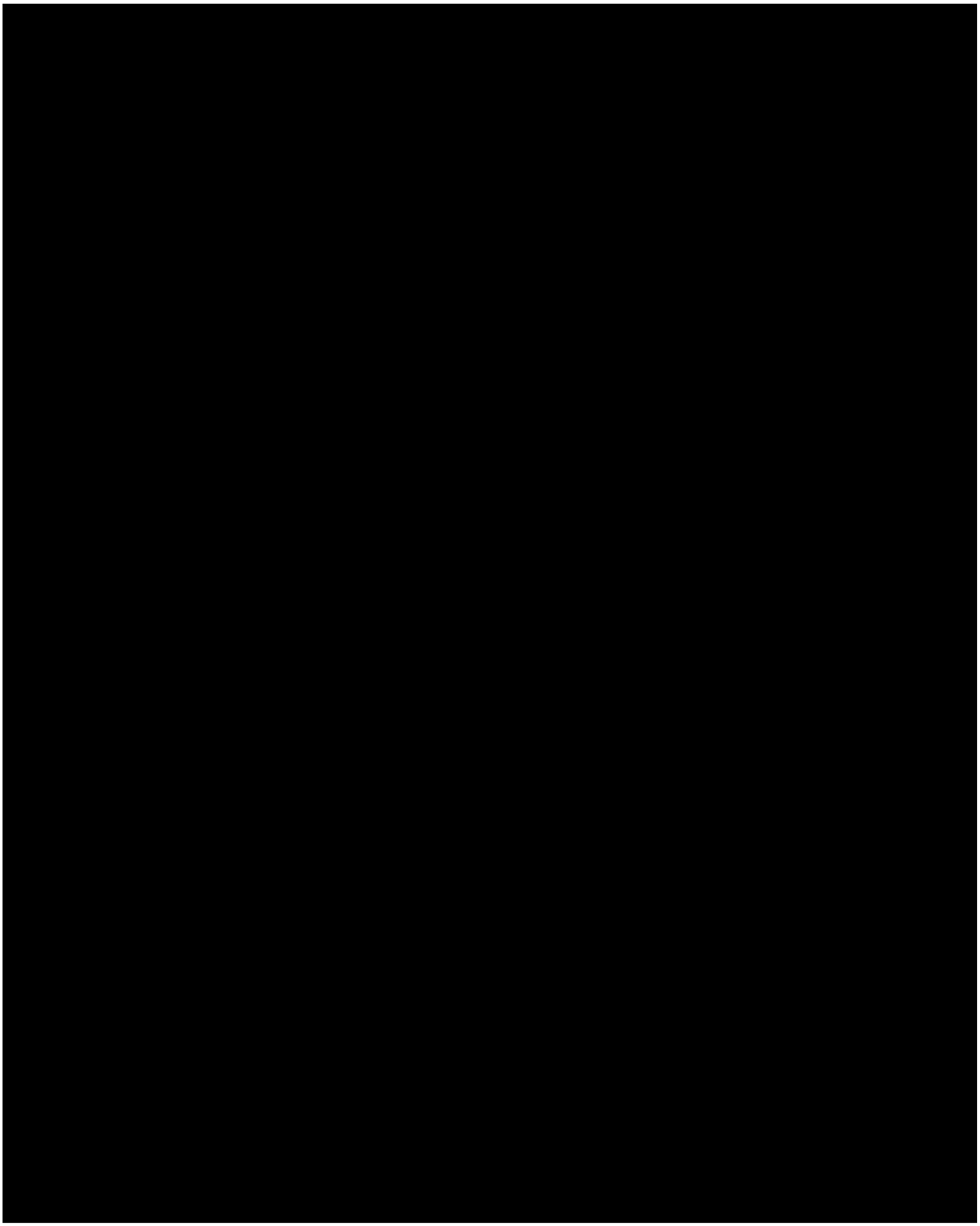


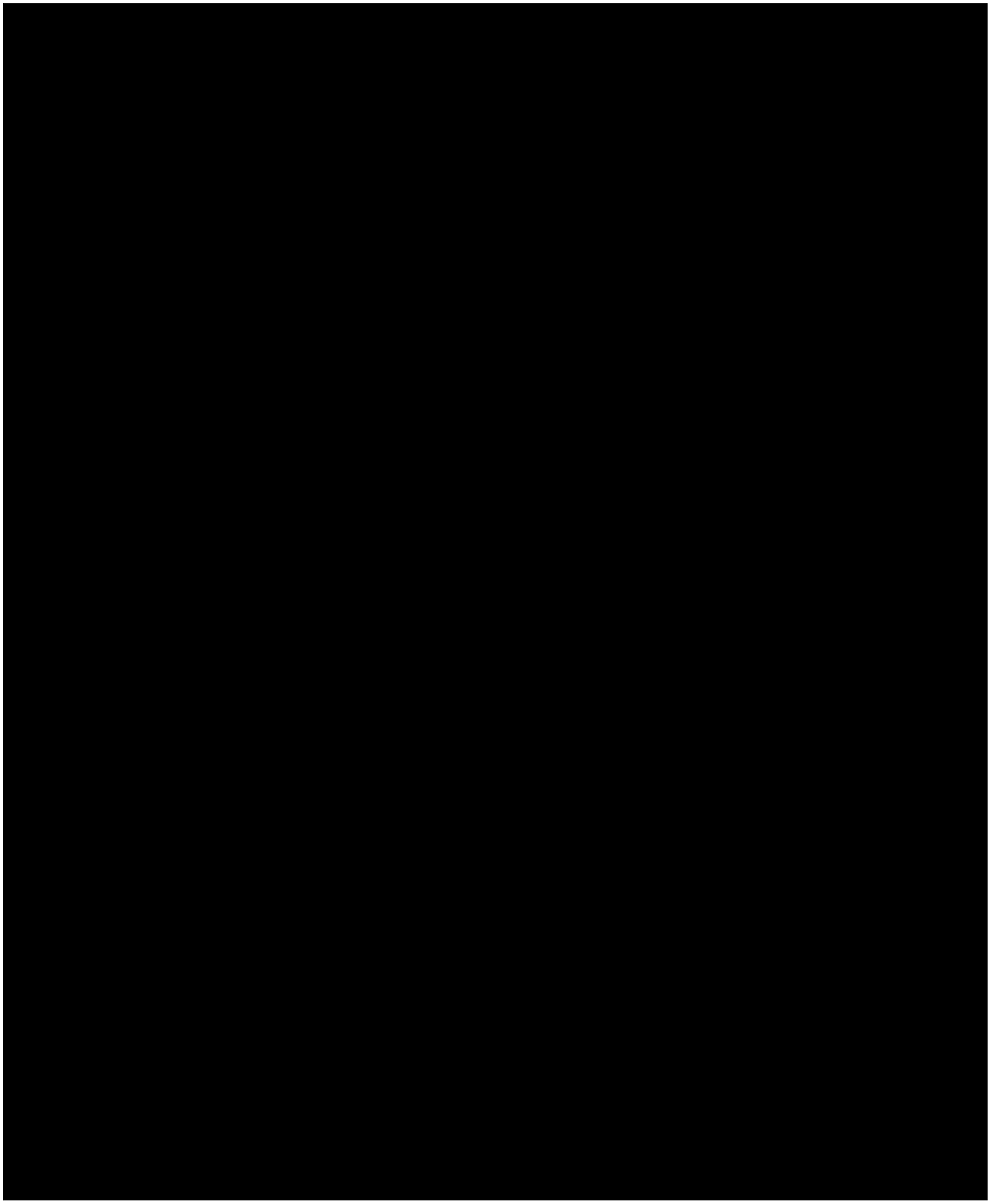


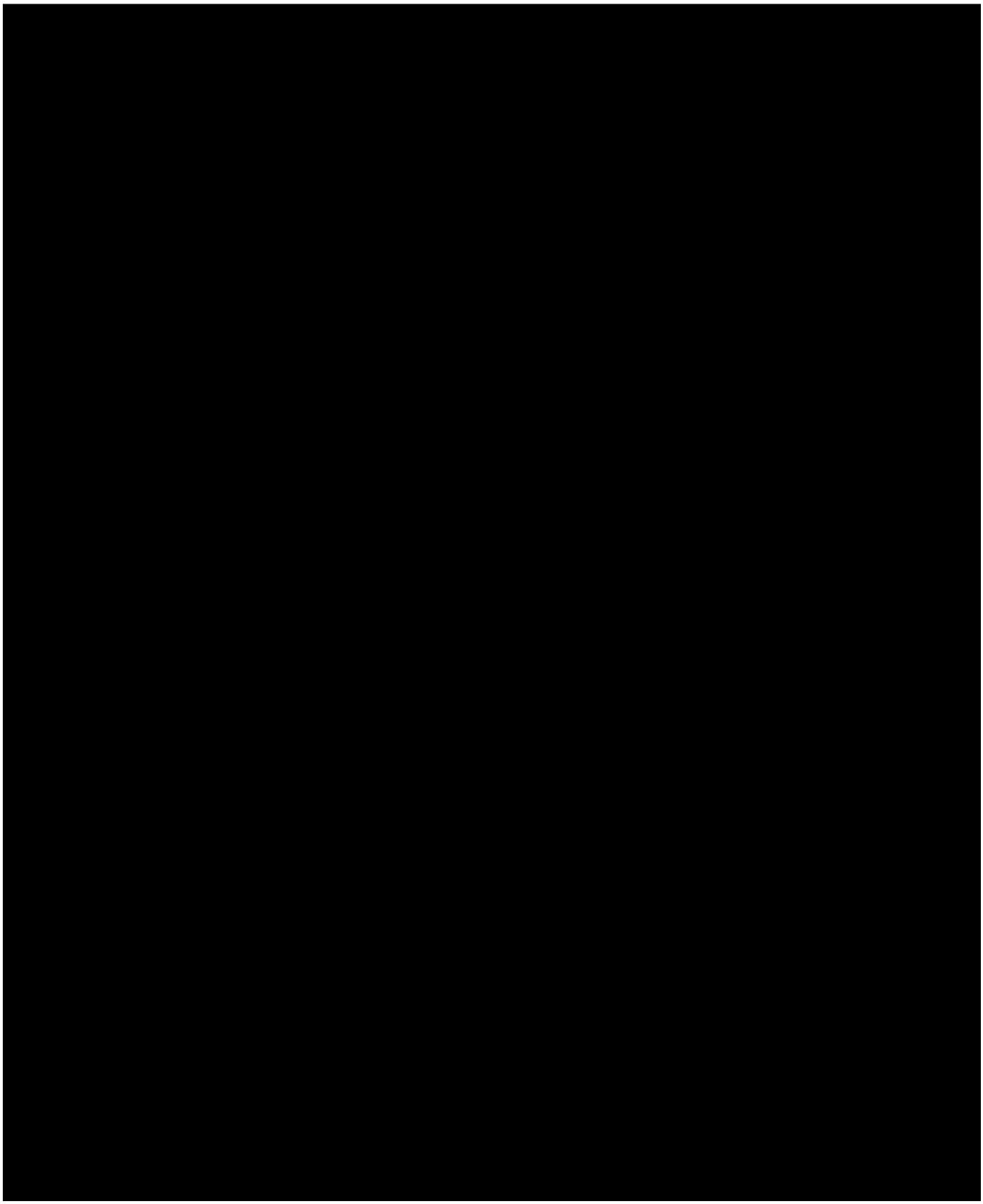
CURRICULUM VITAE

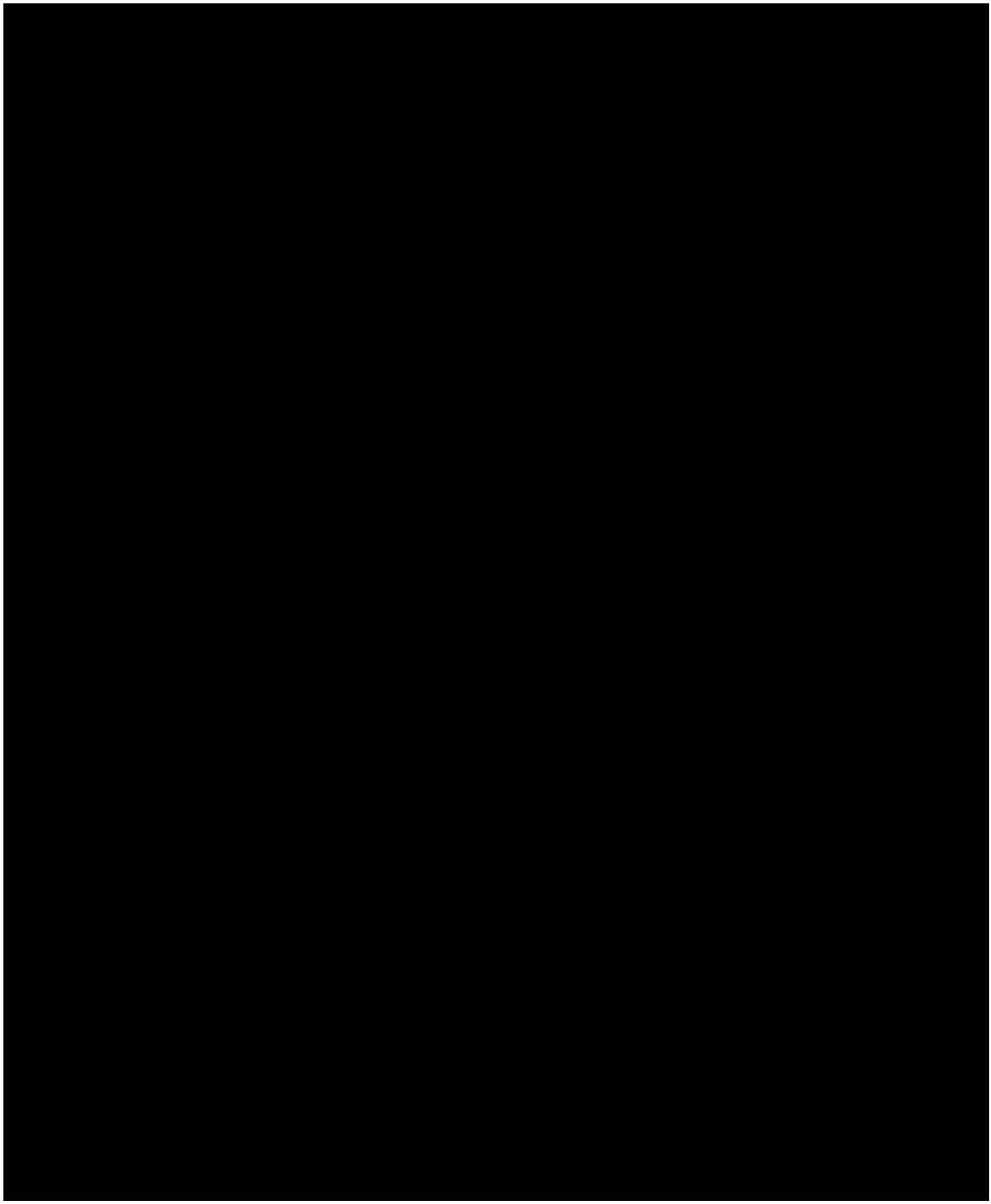


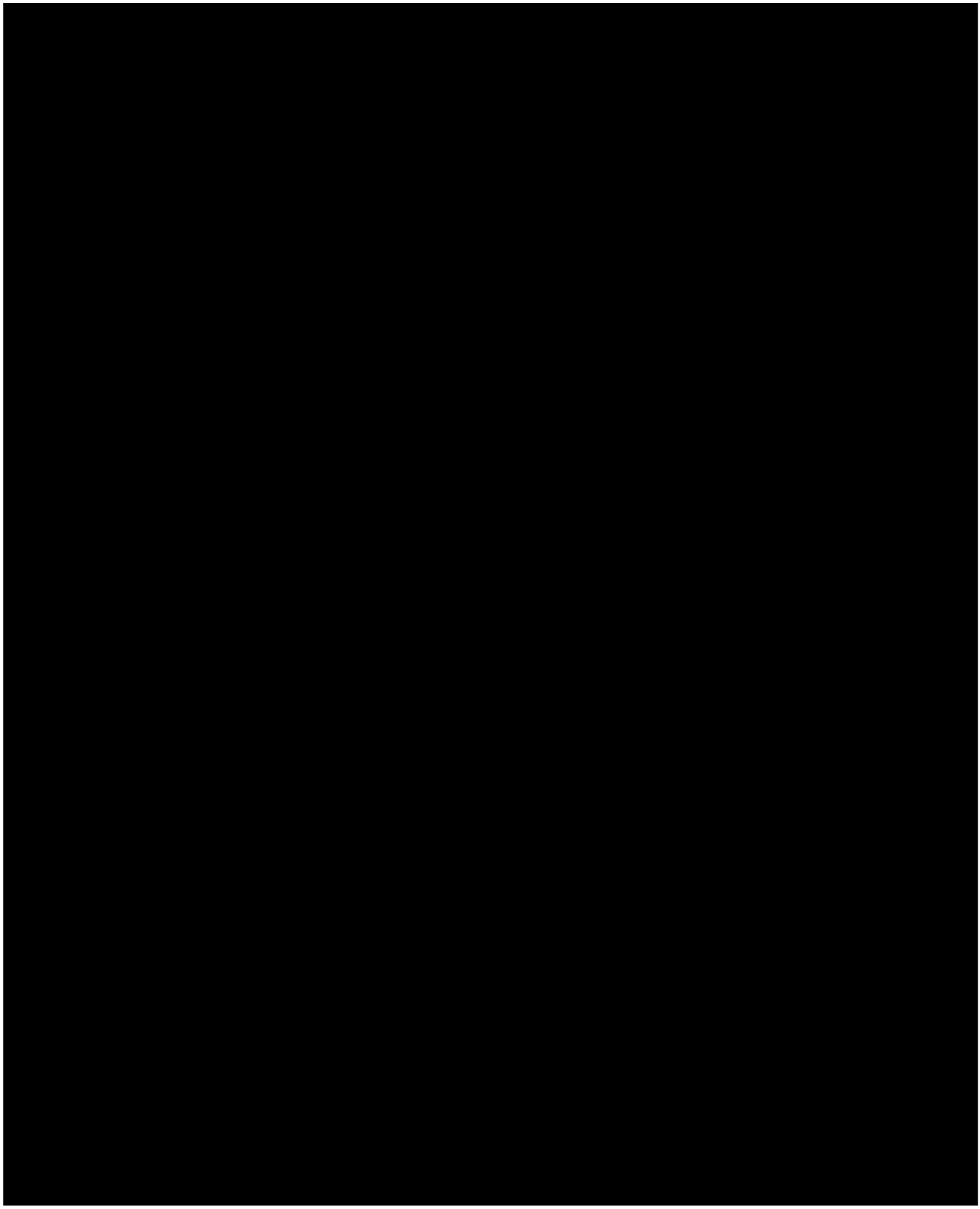


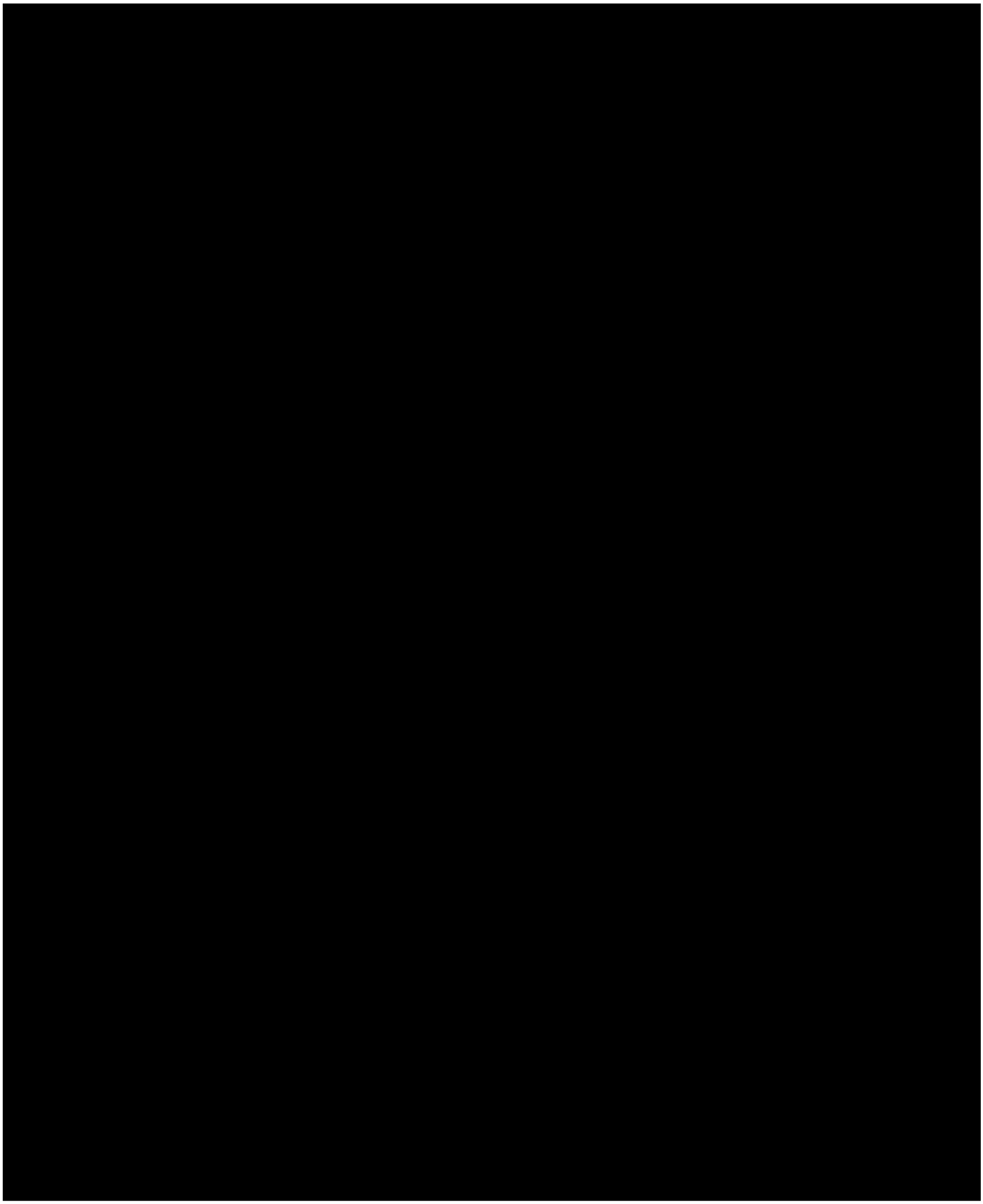


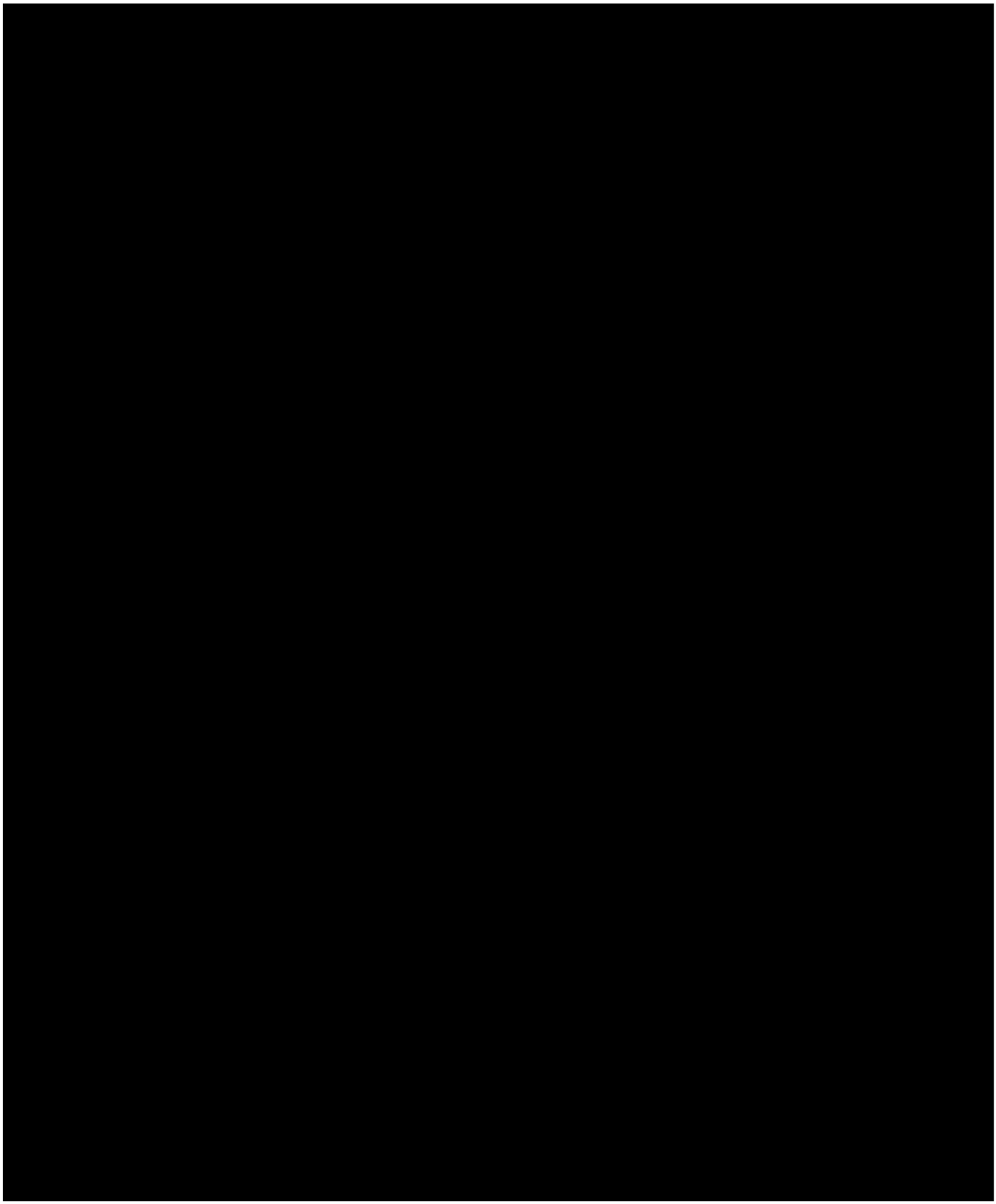


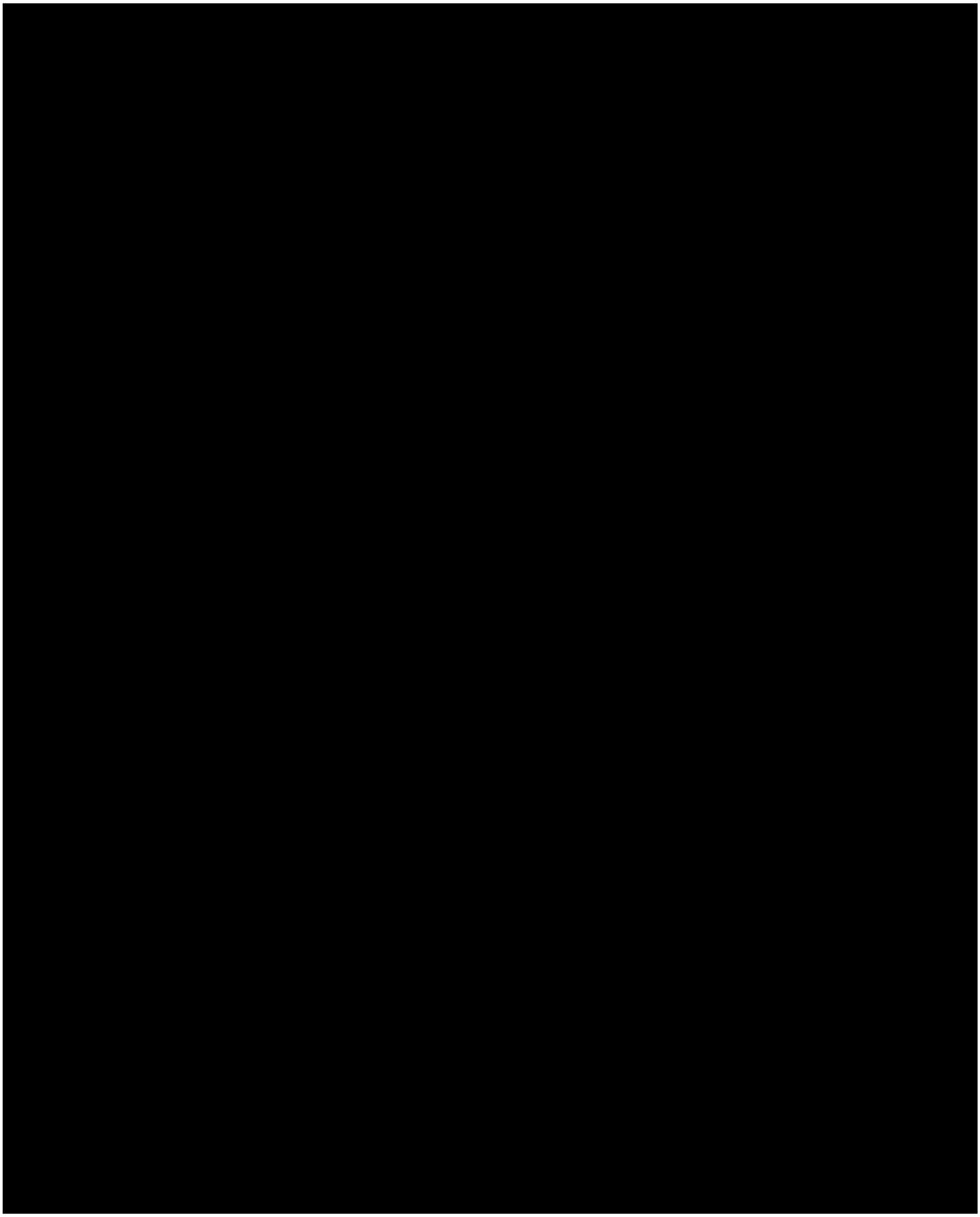


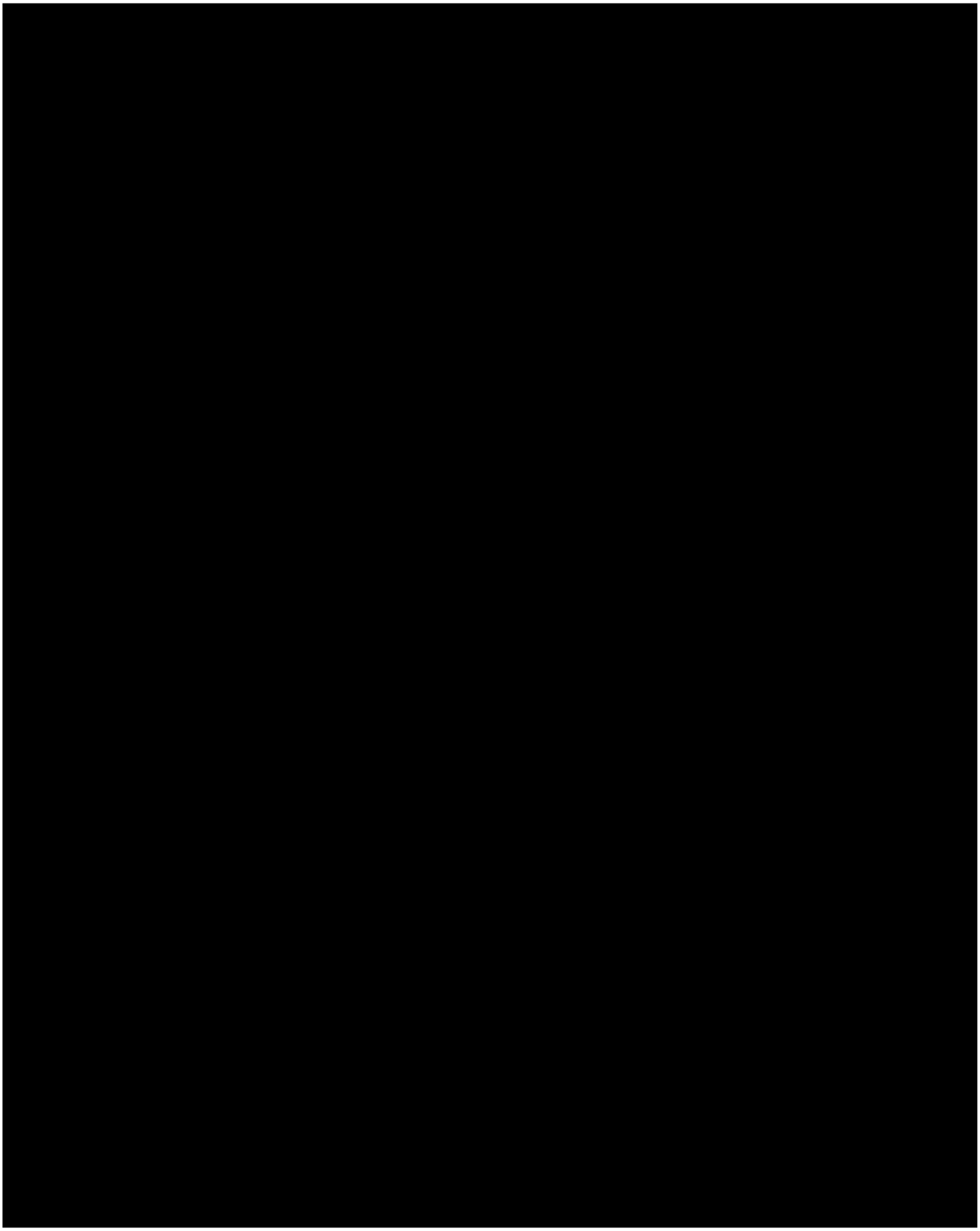












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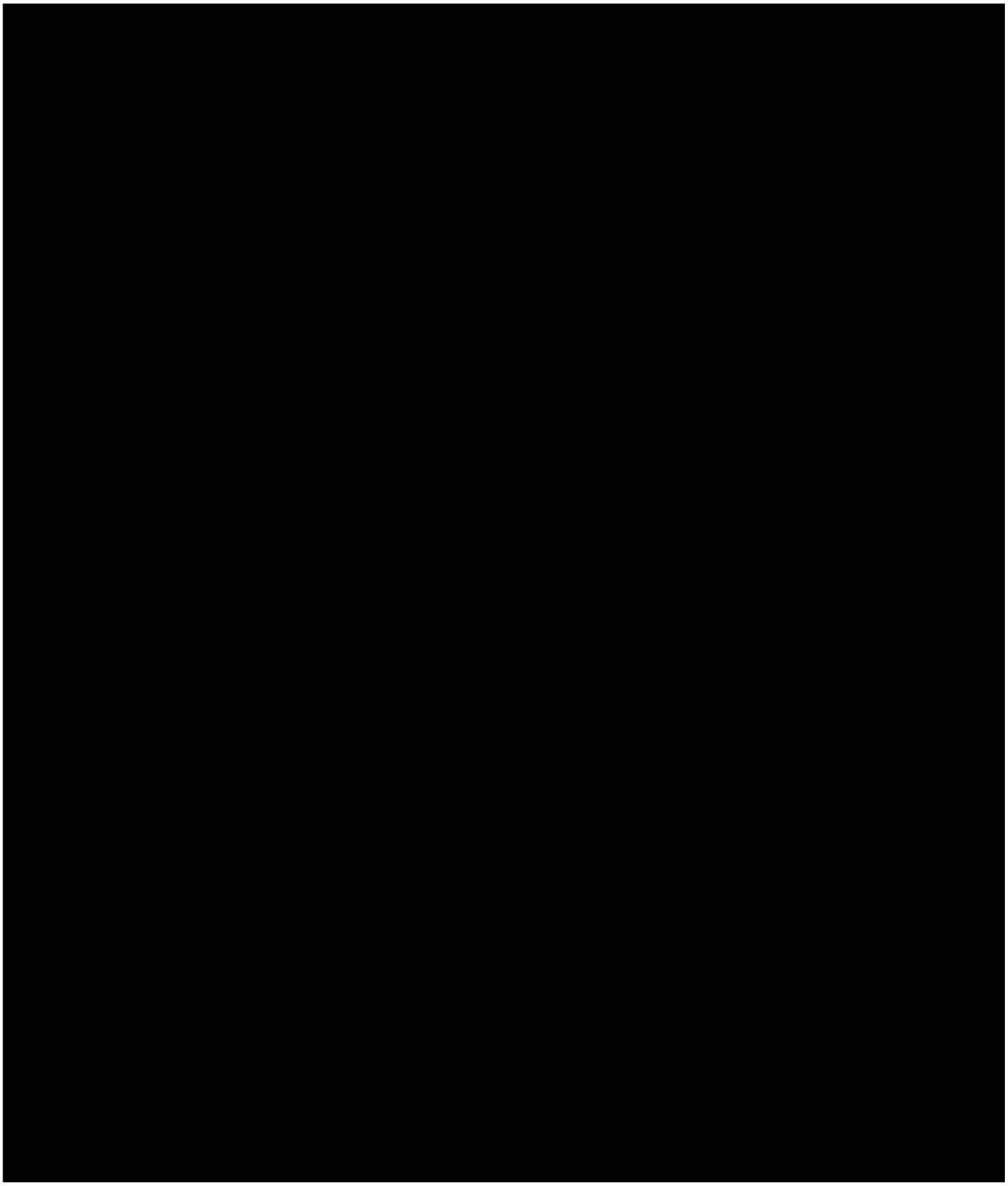

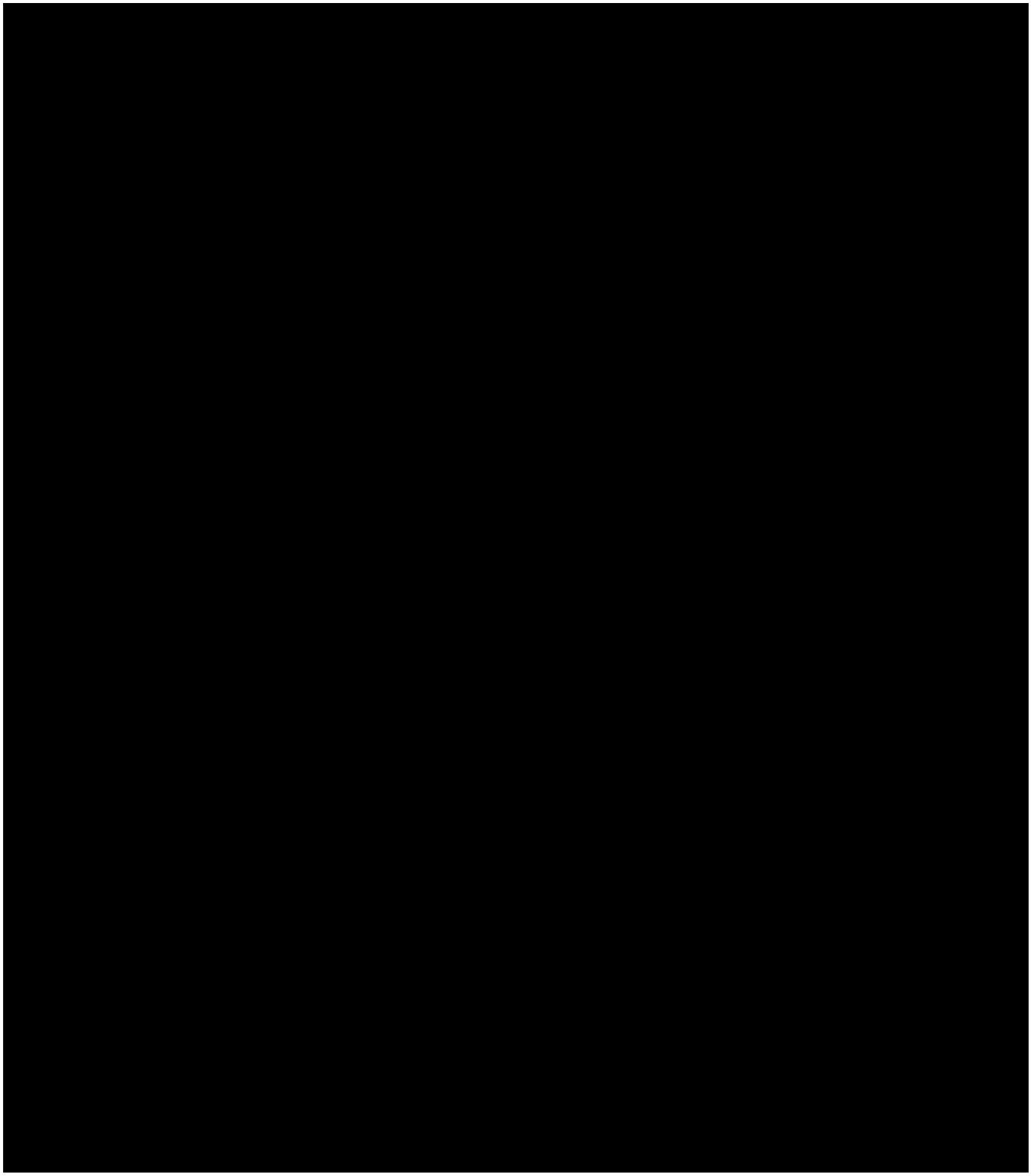

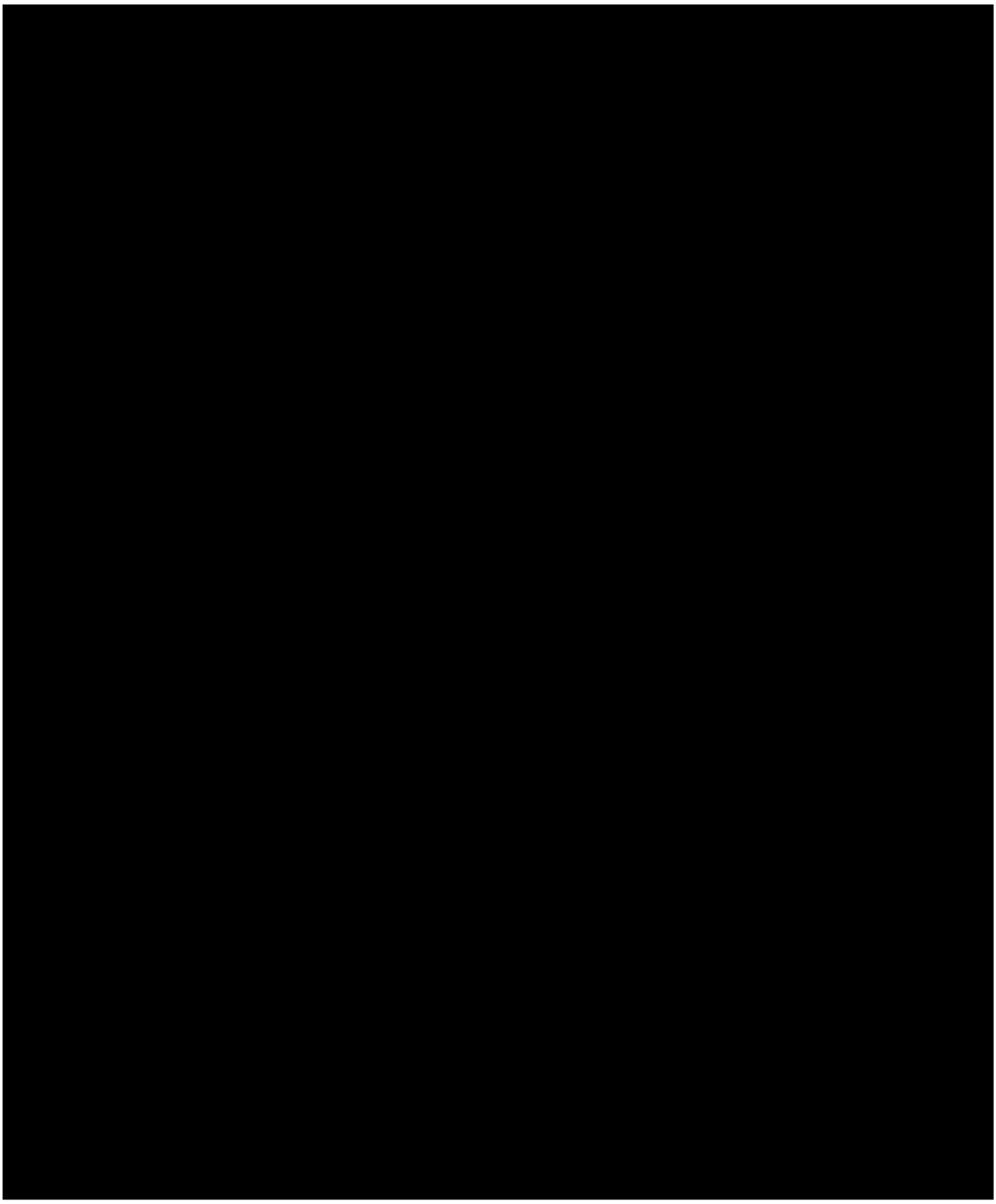

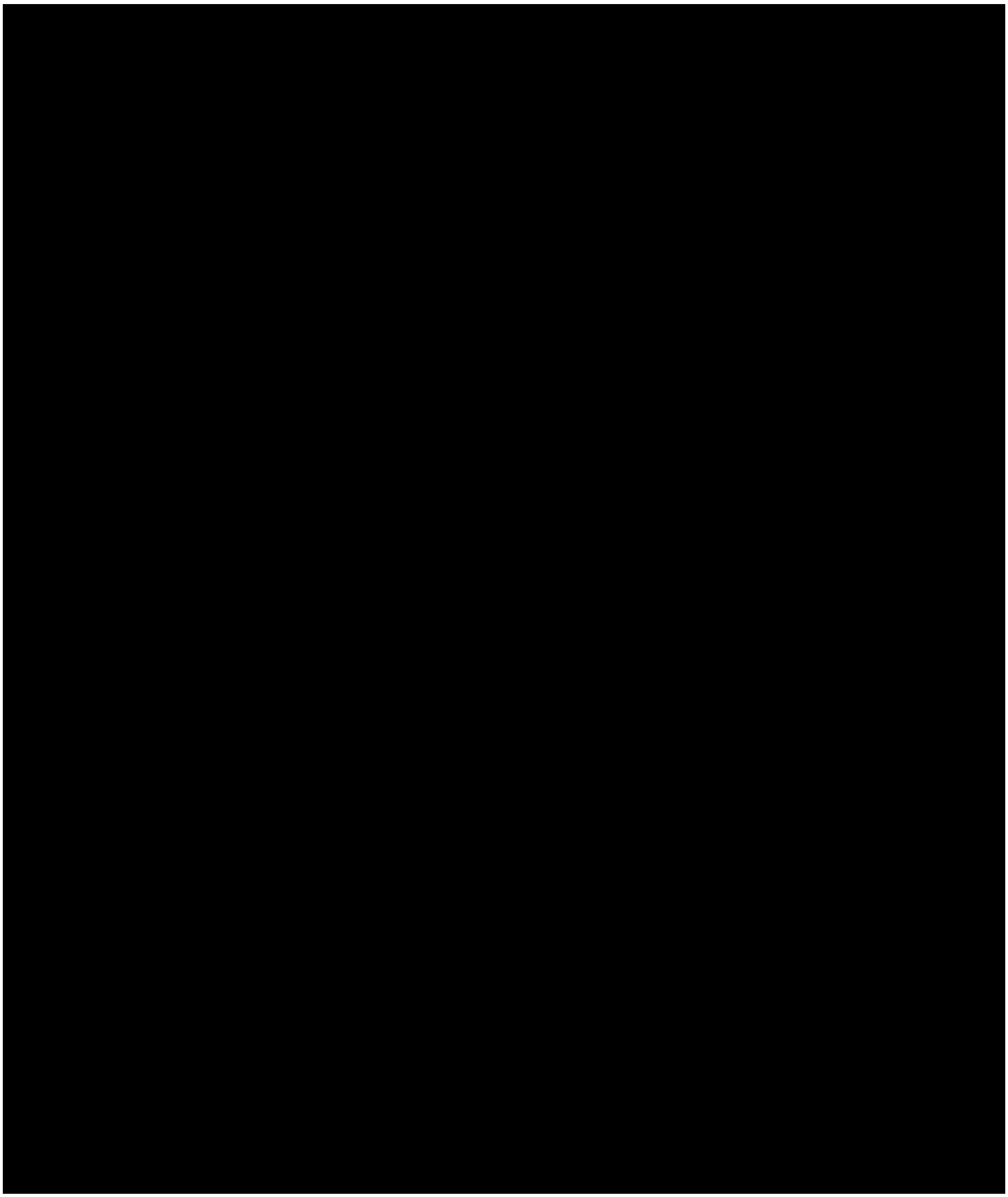

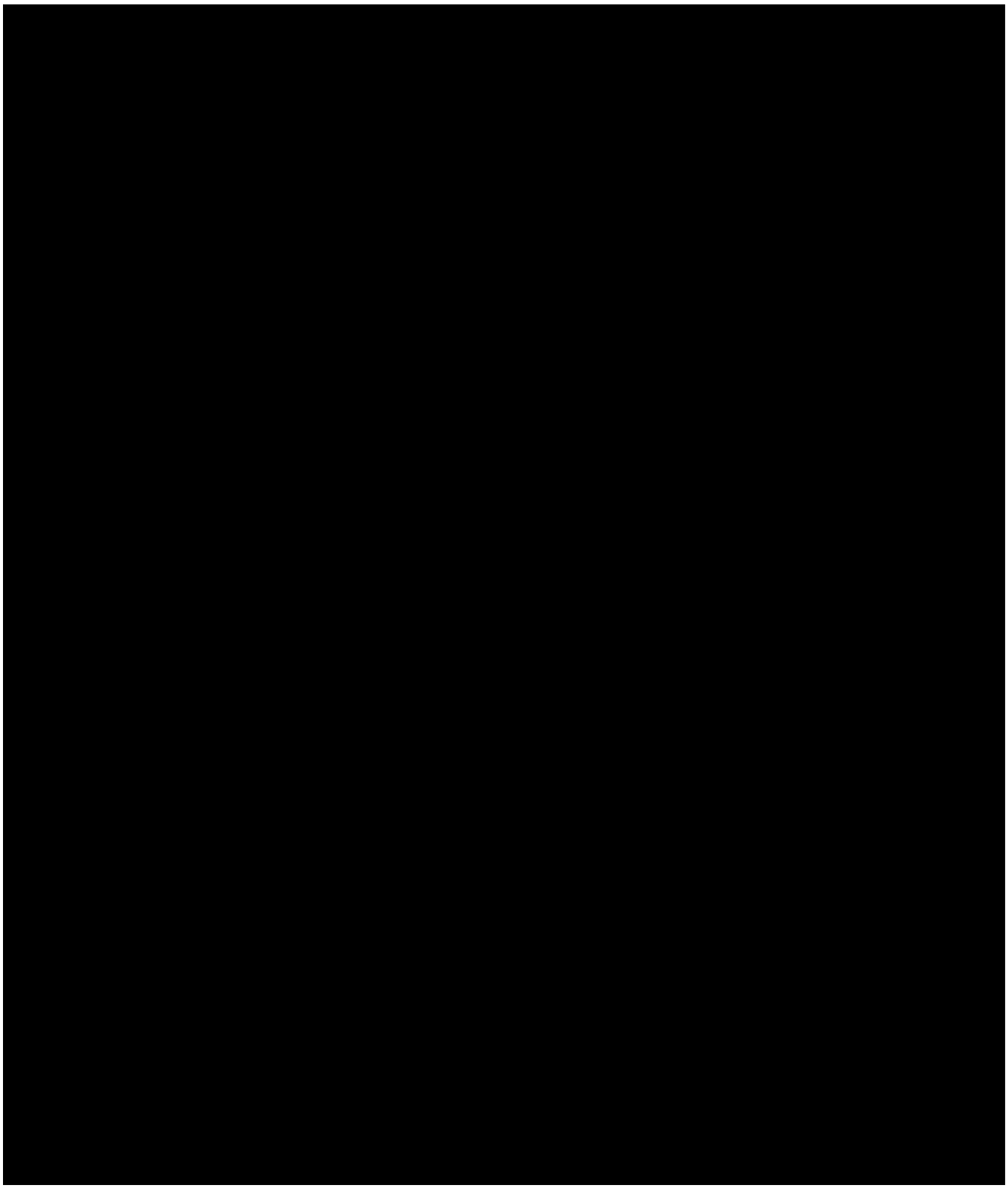

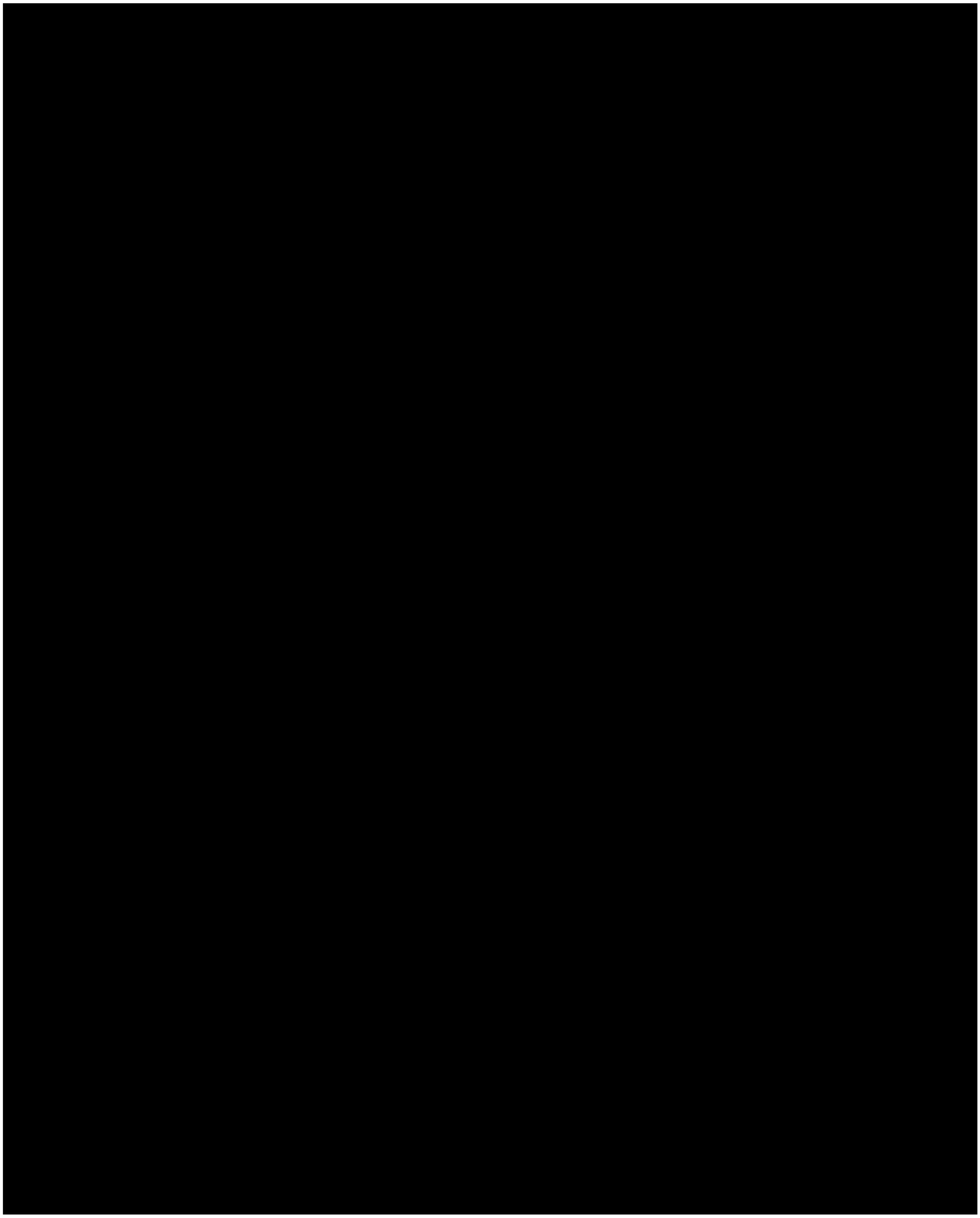

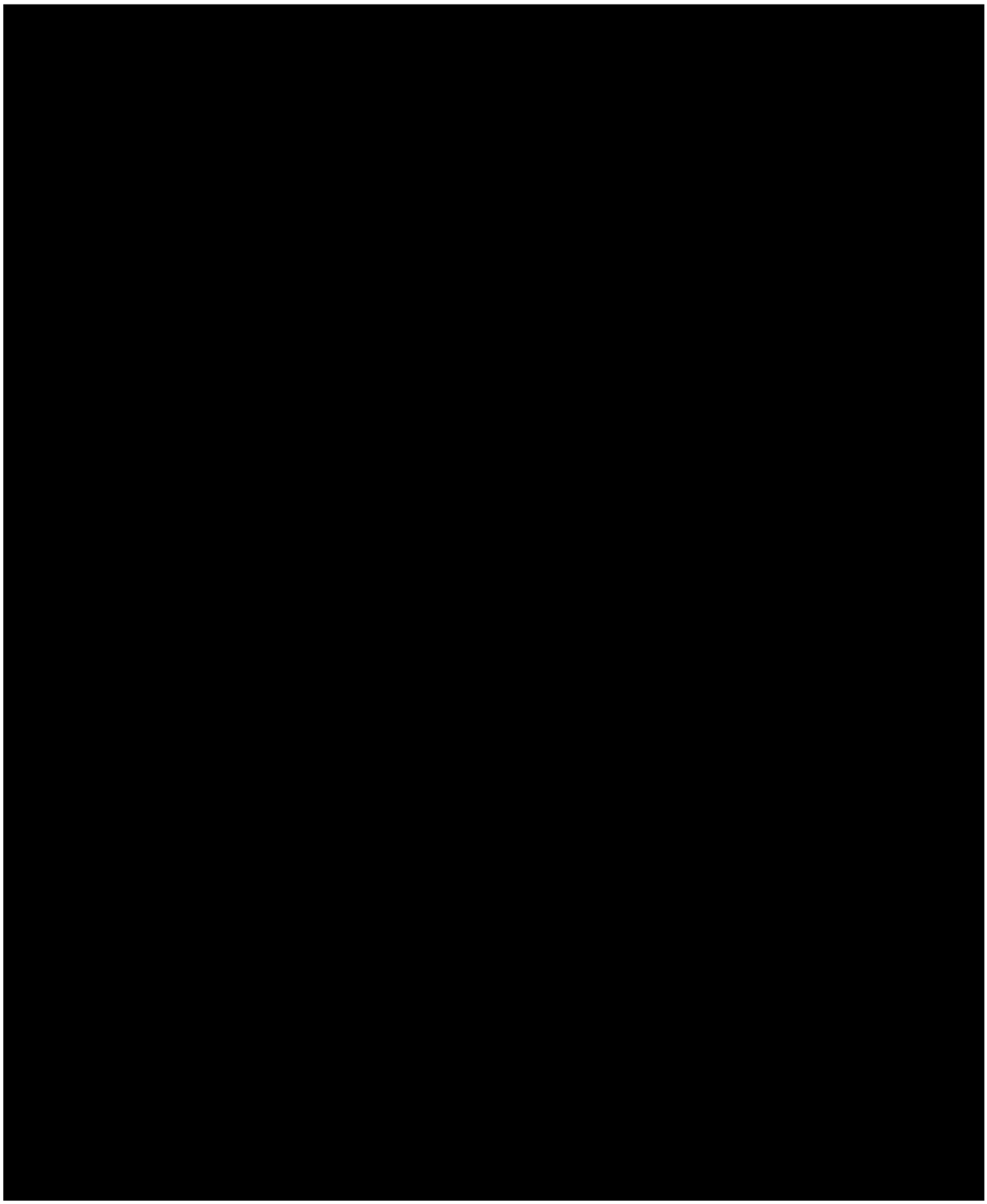

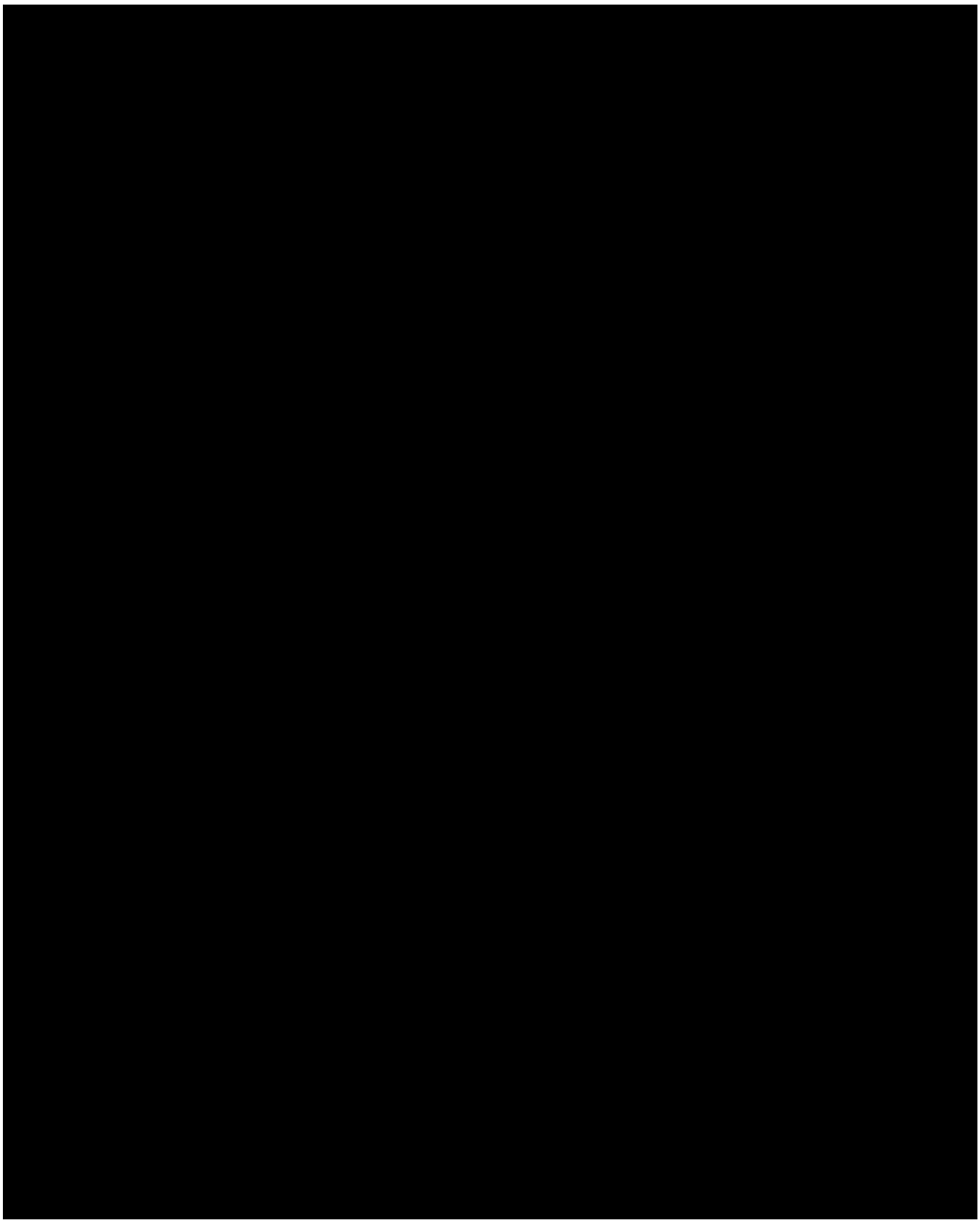

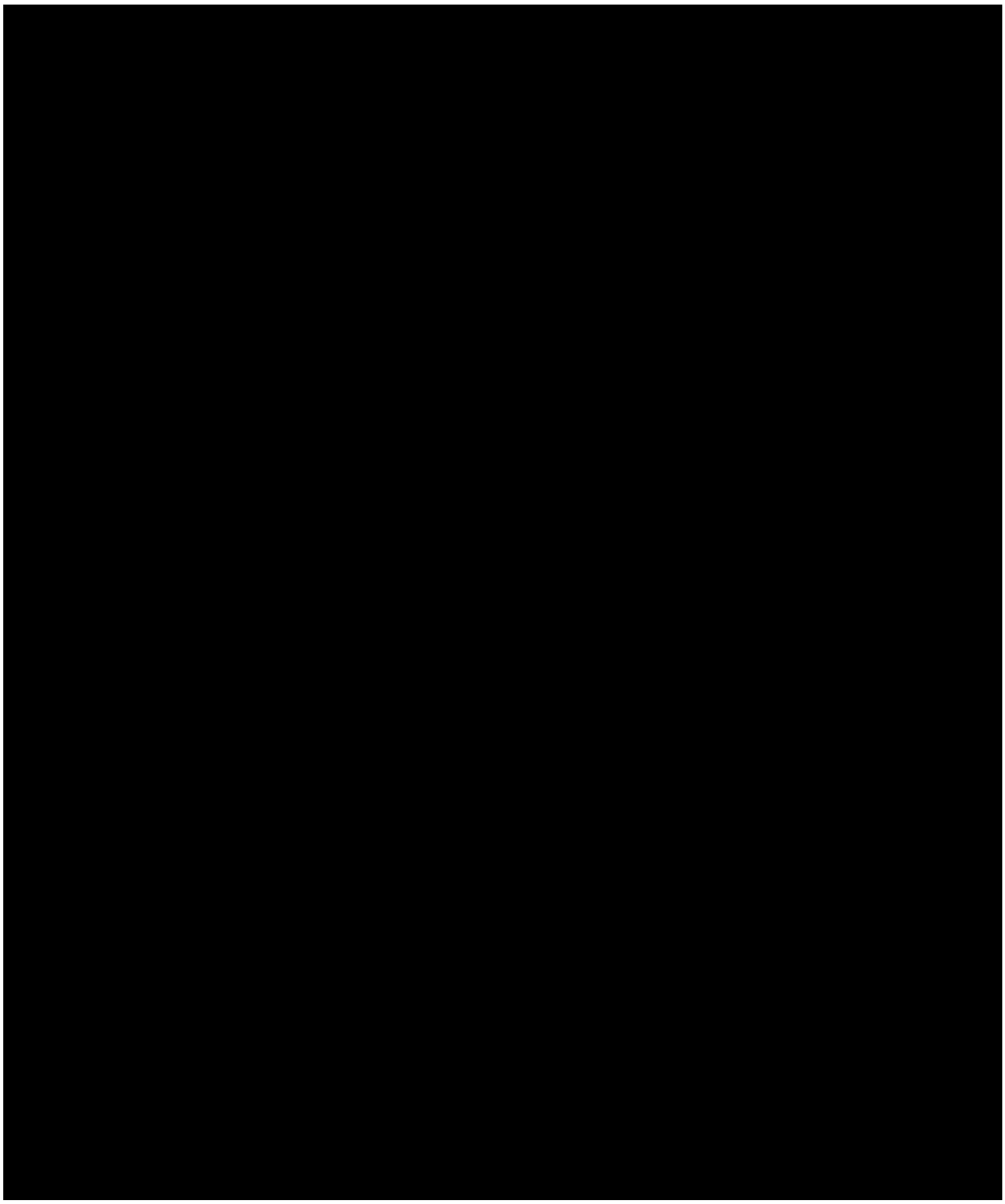

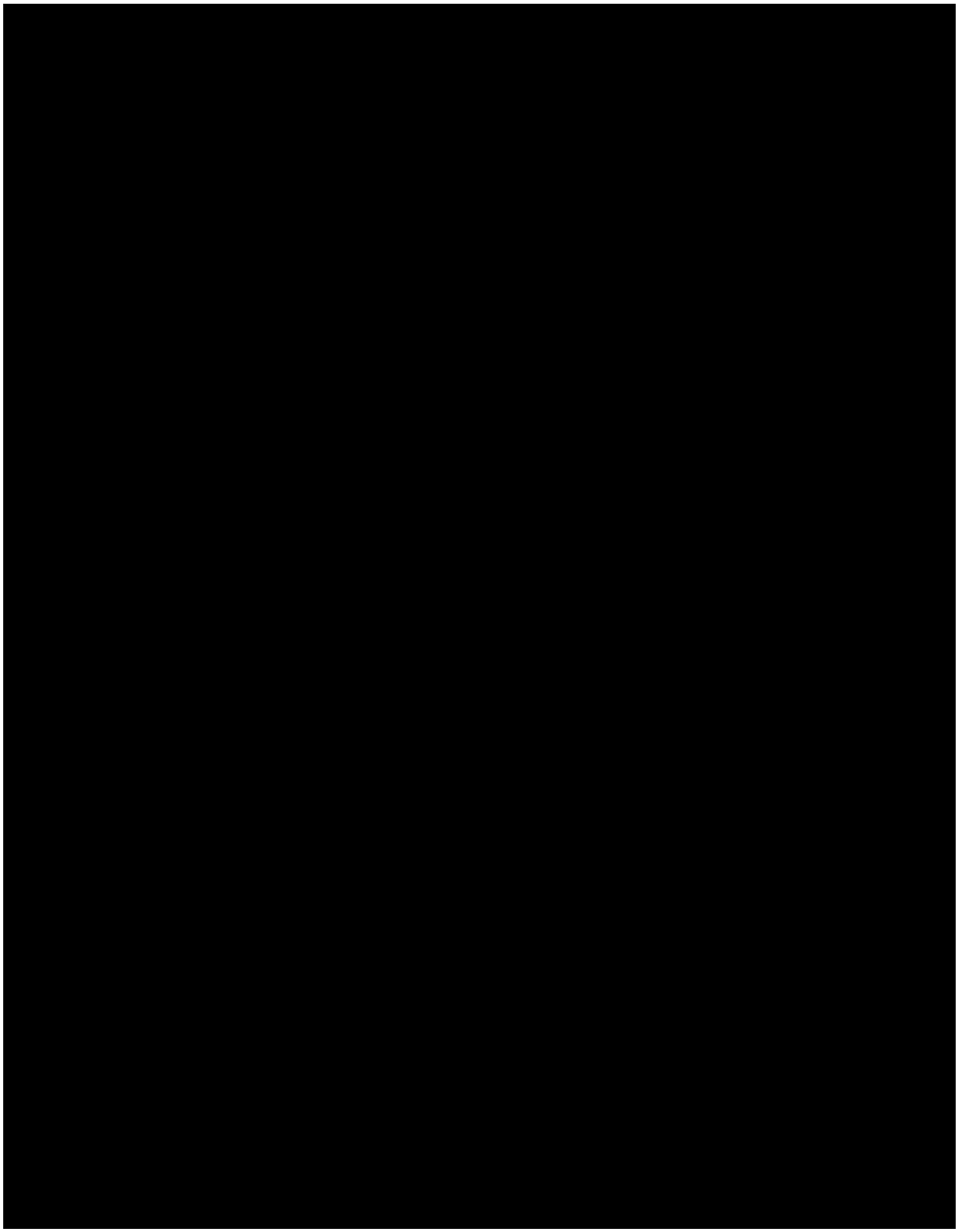

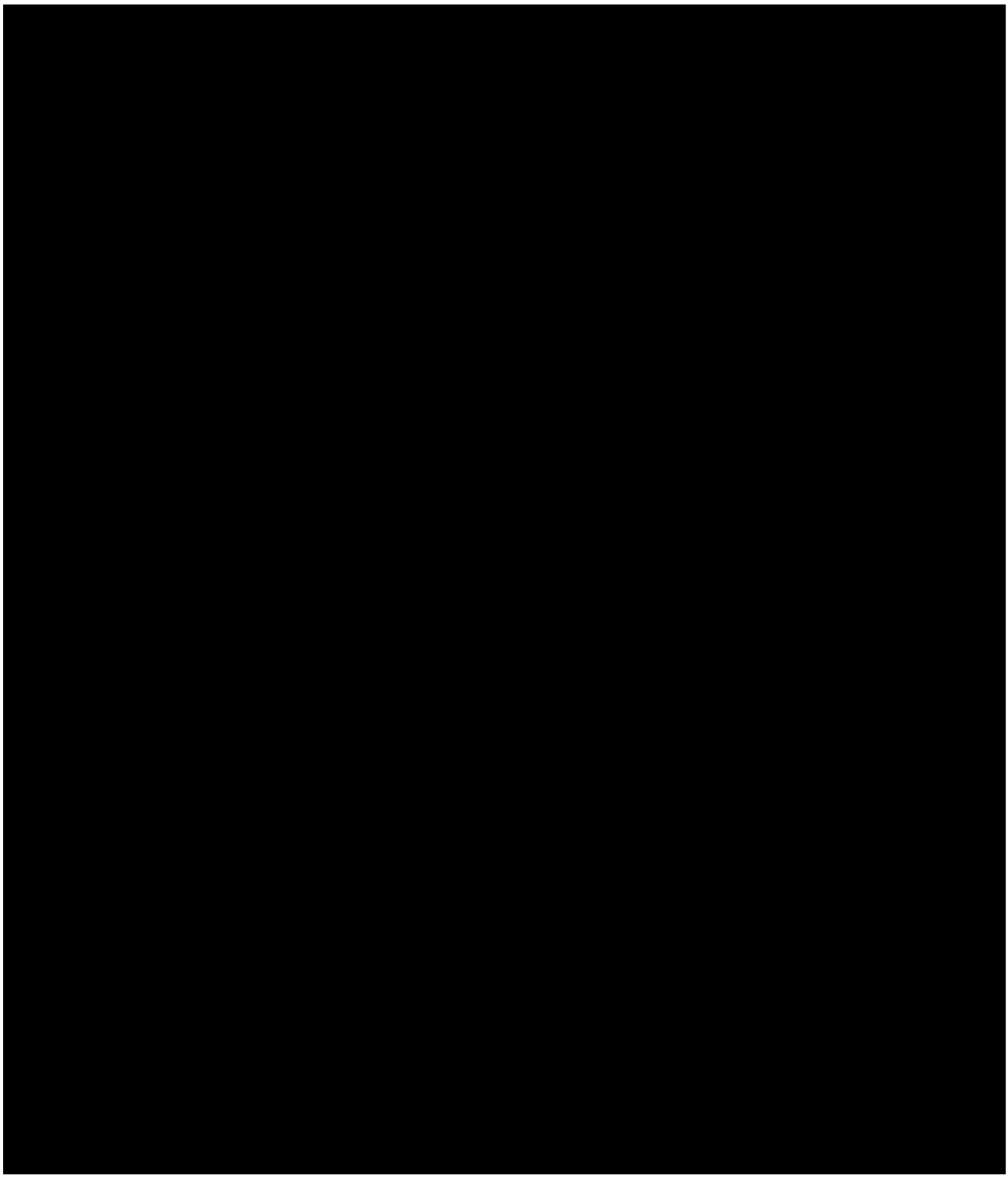

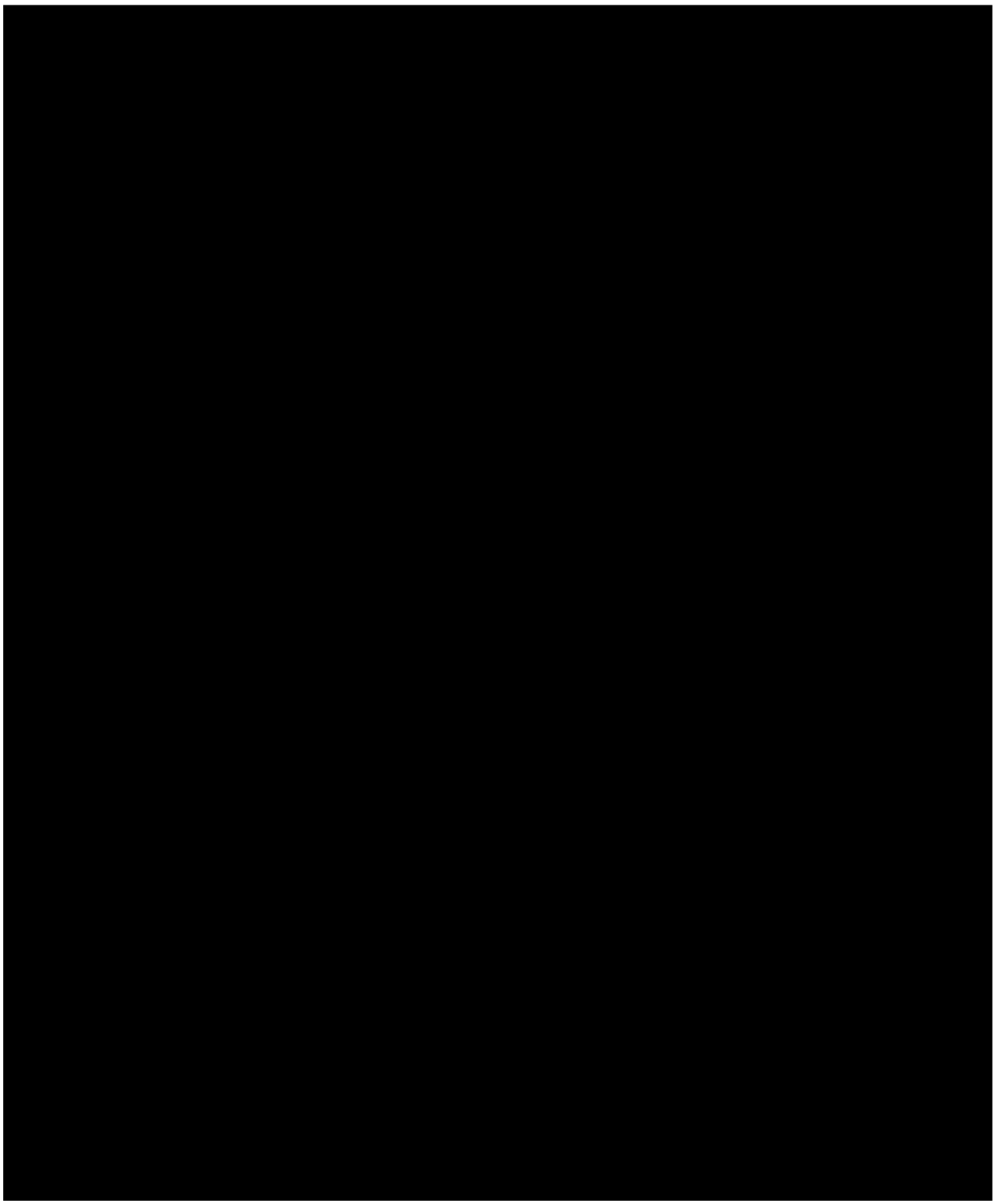

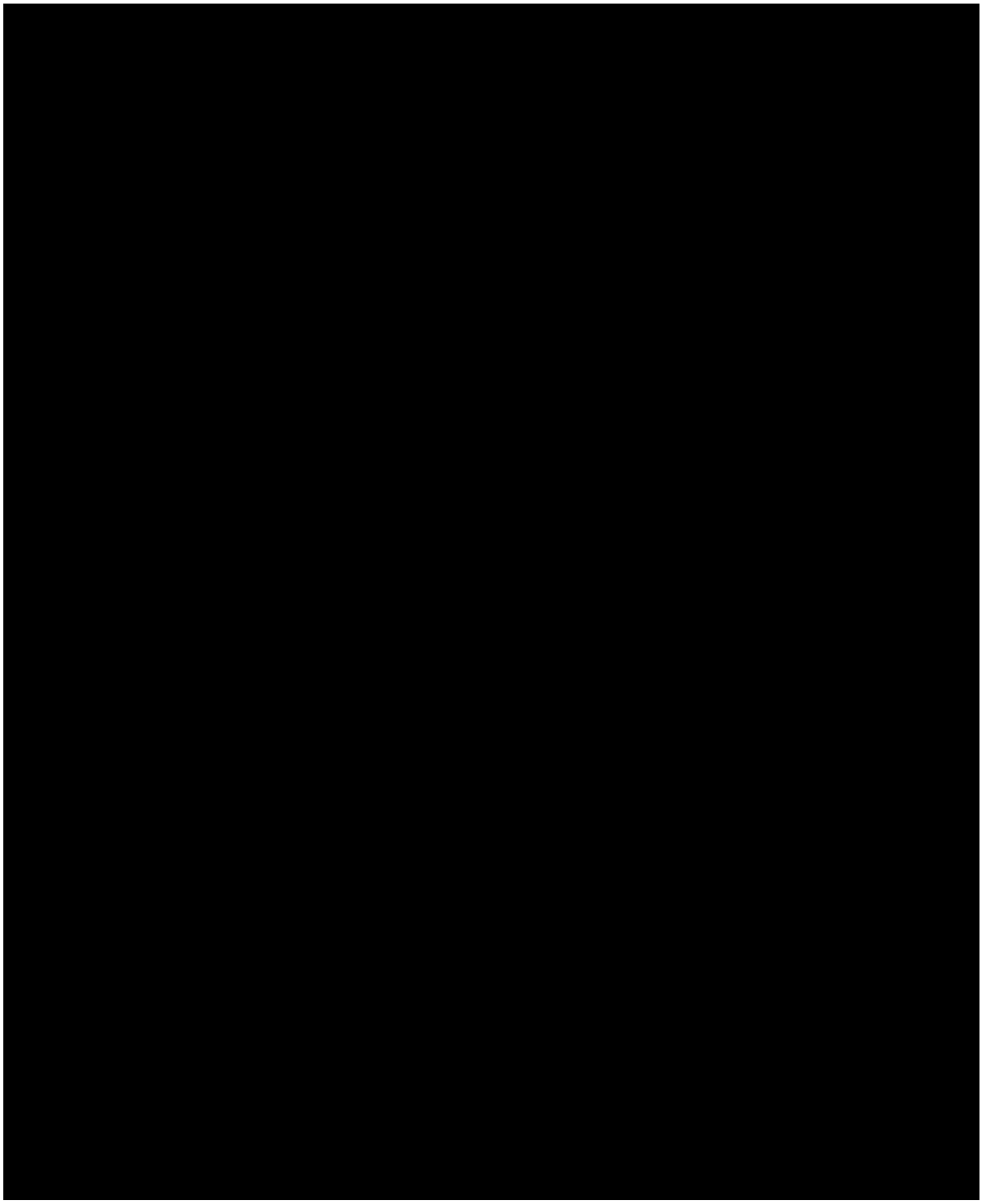

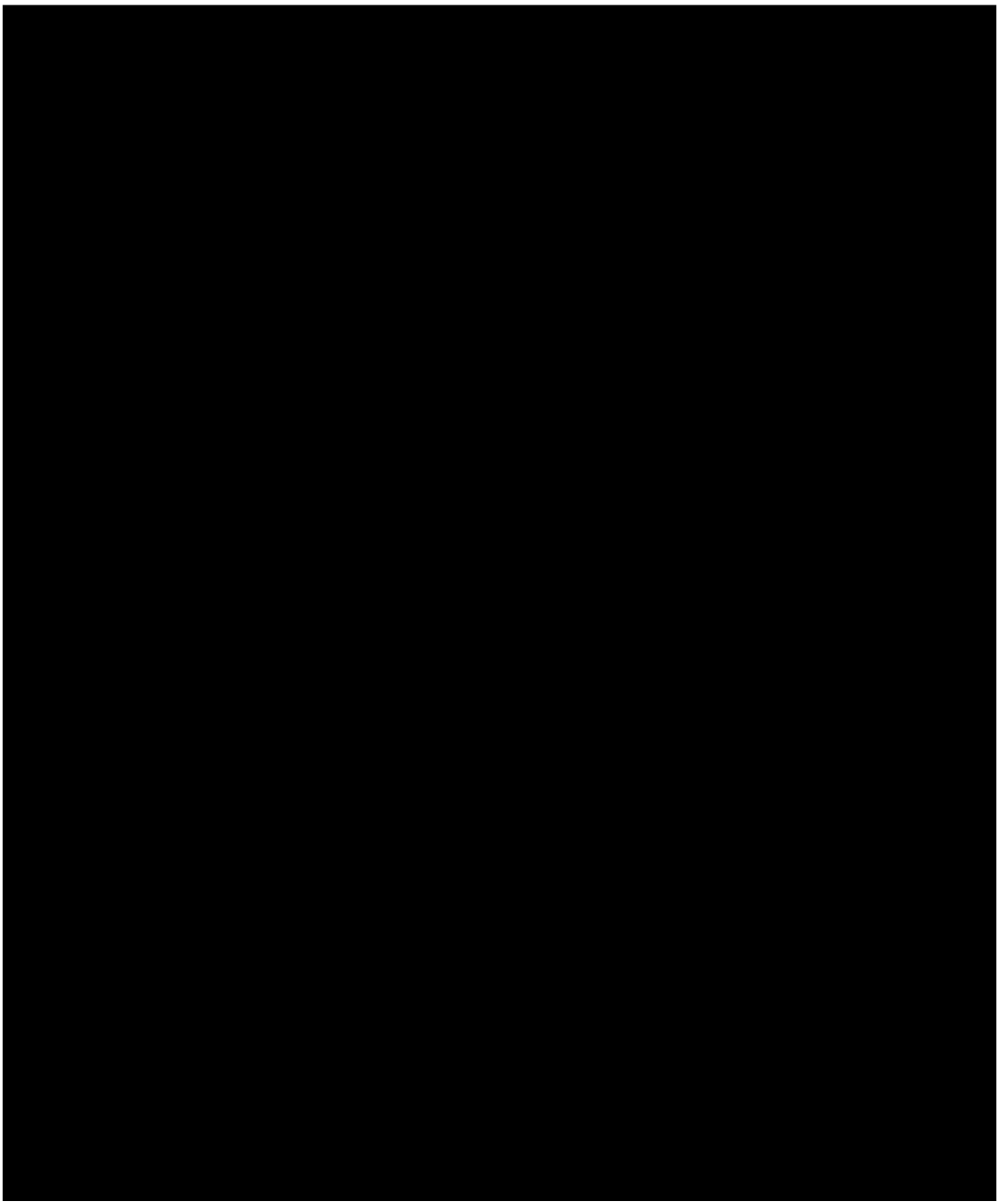

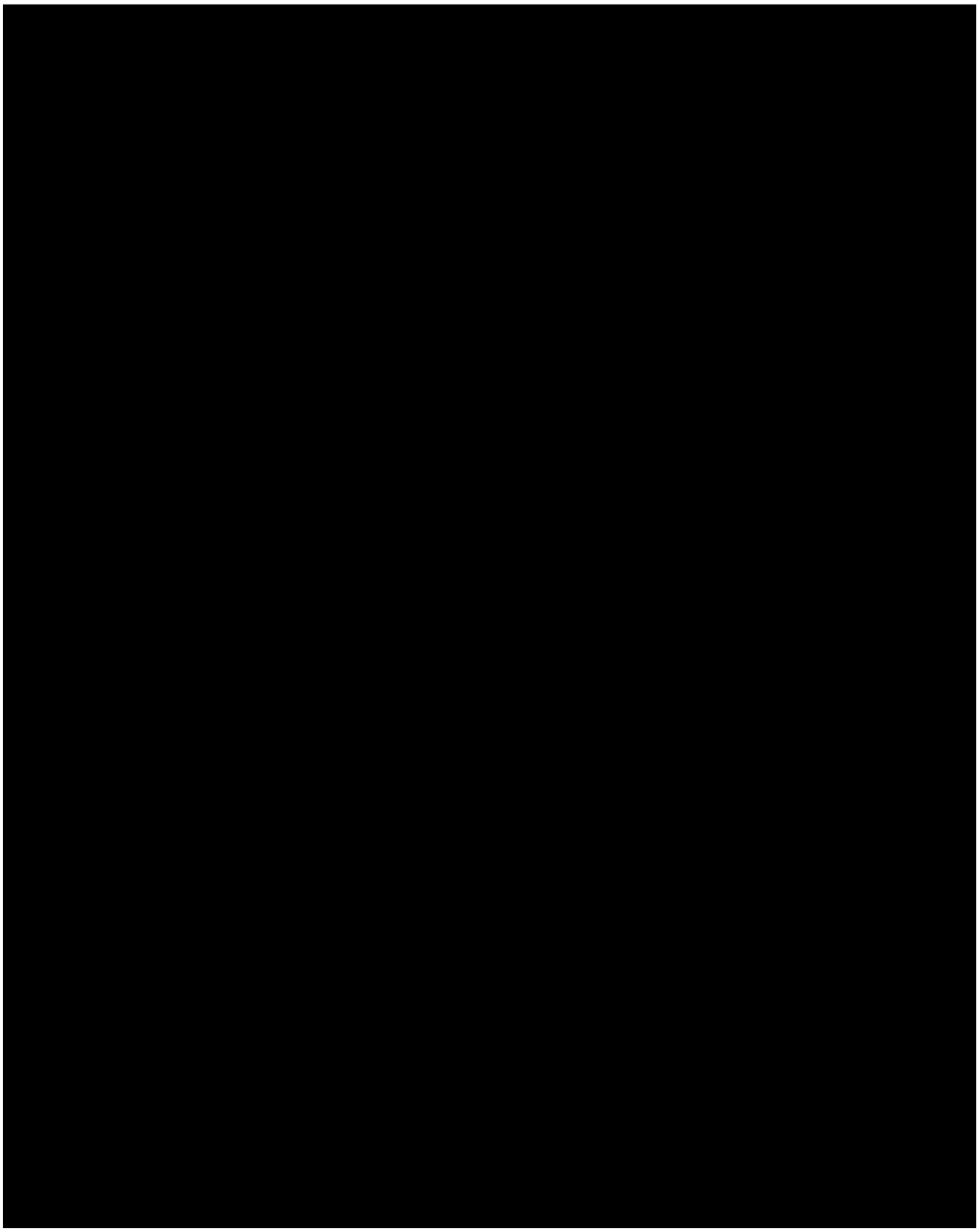

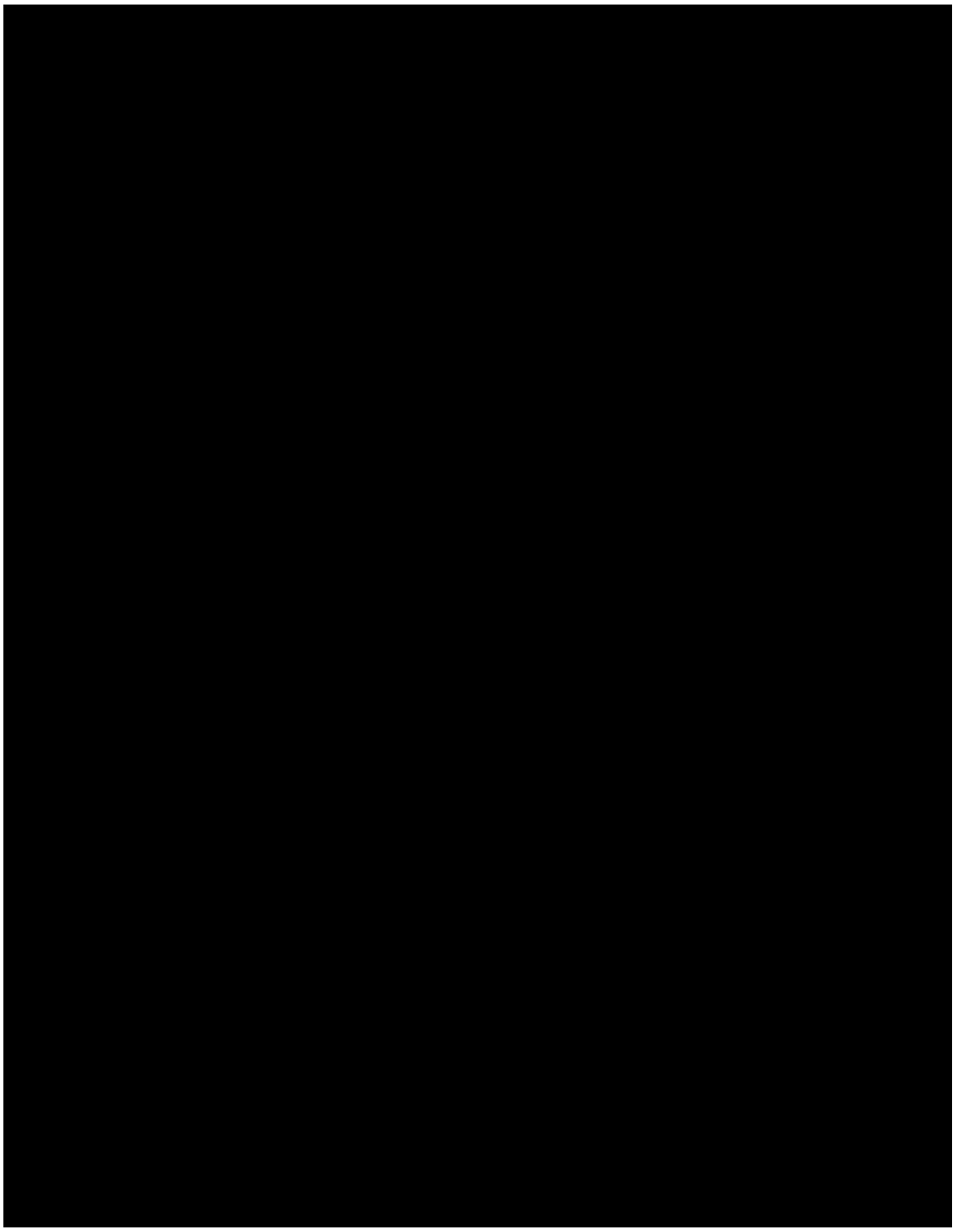

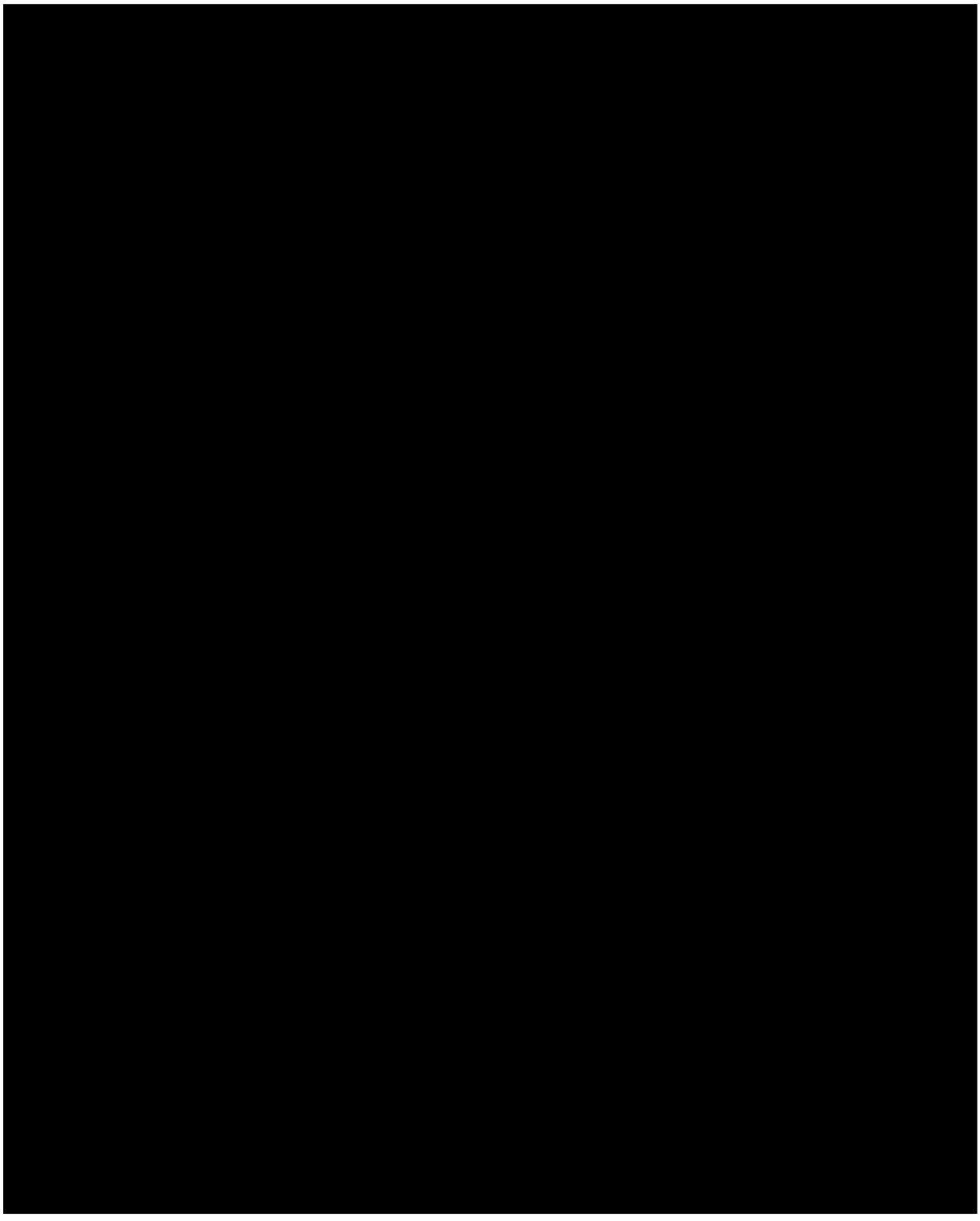

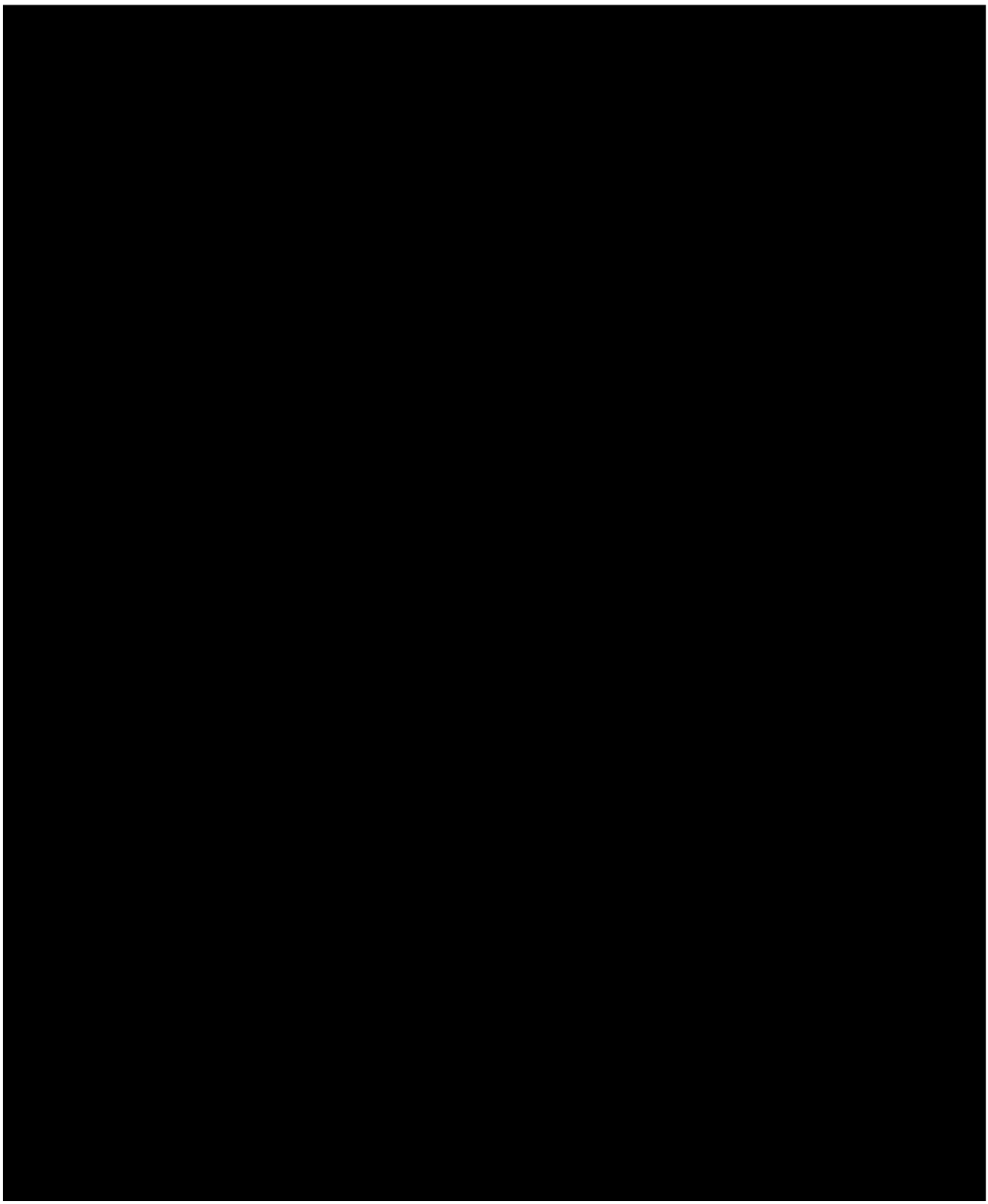

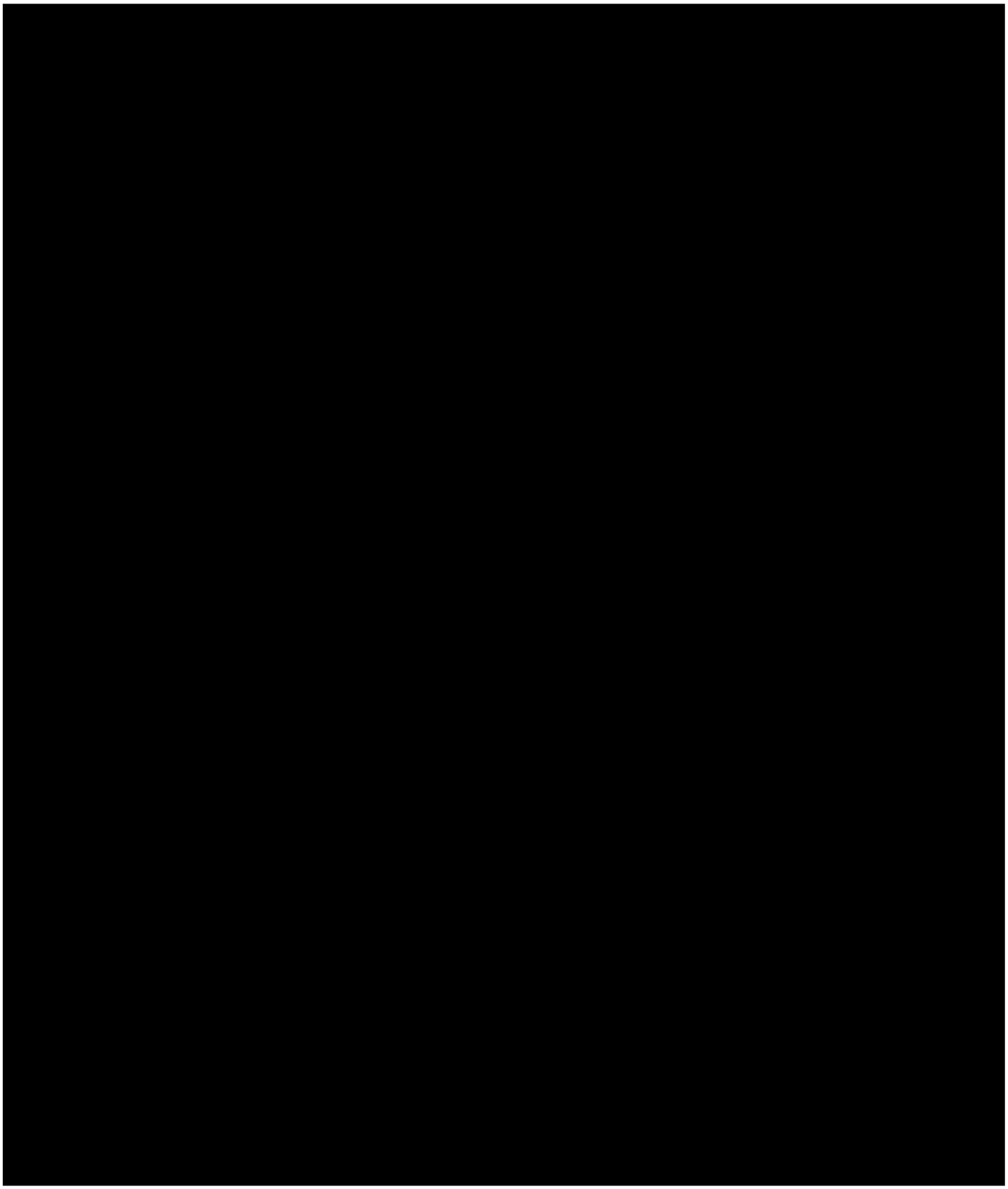

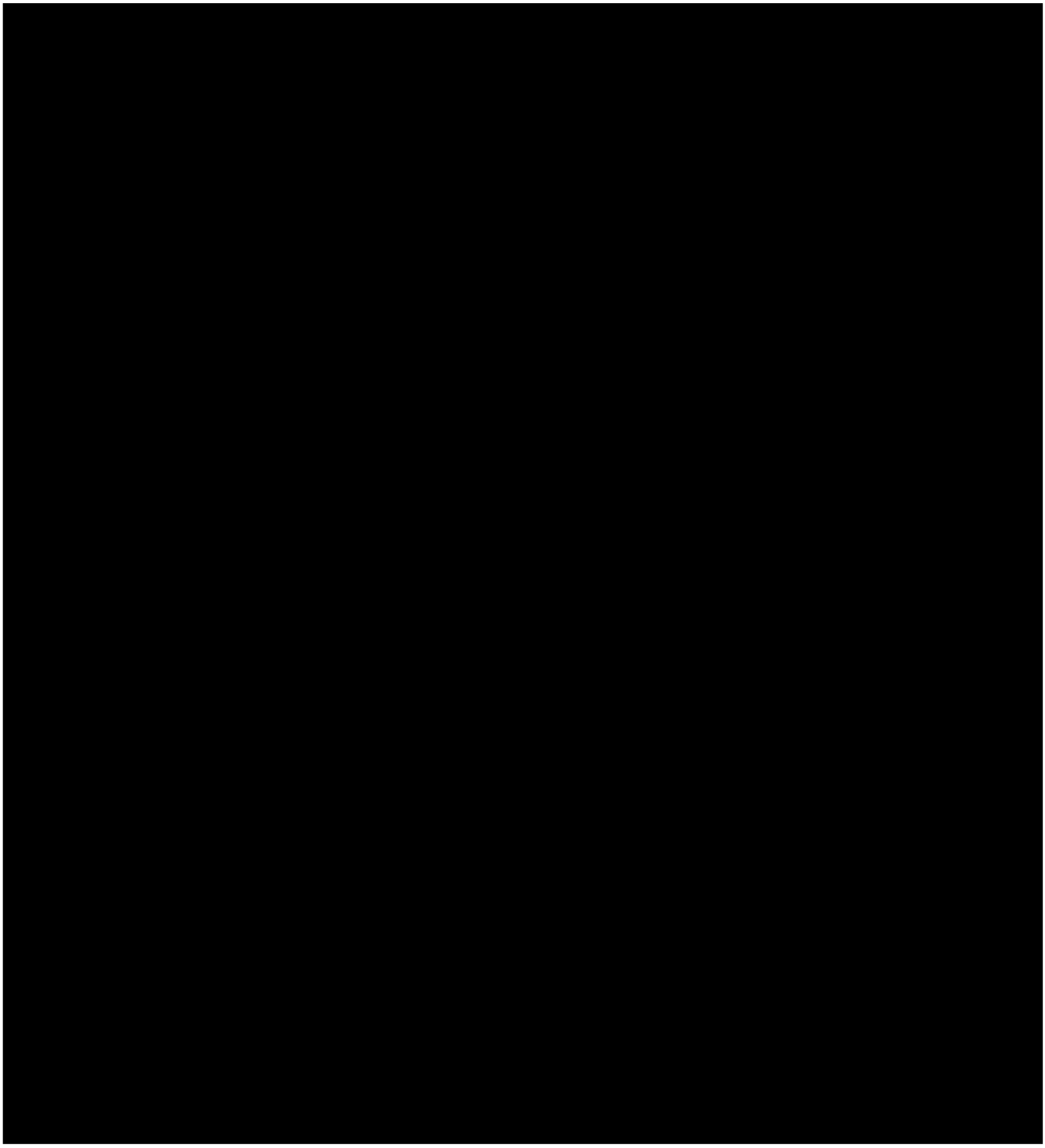

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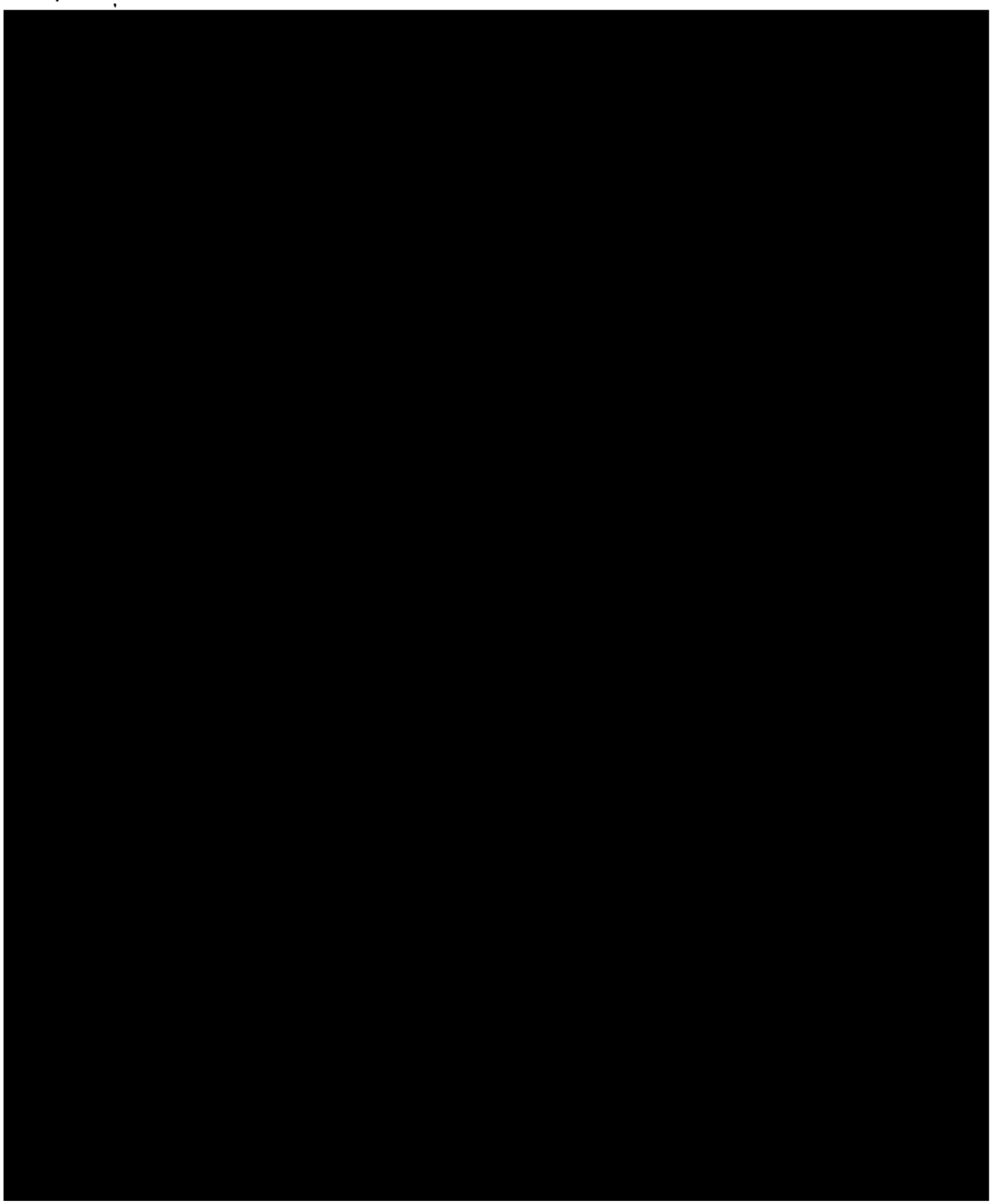

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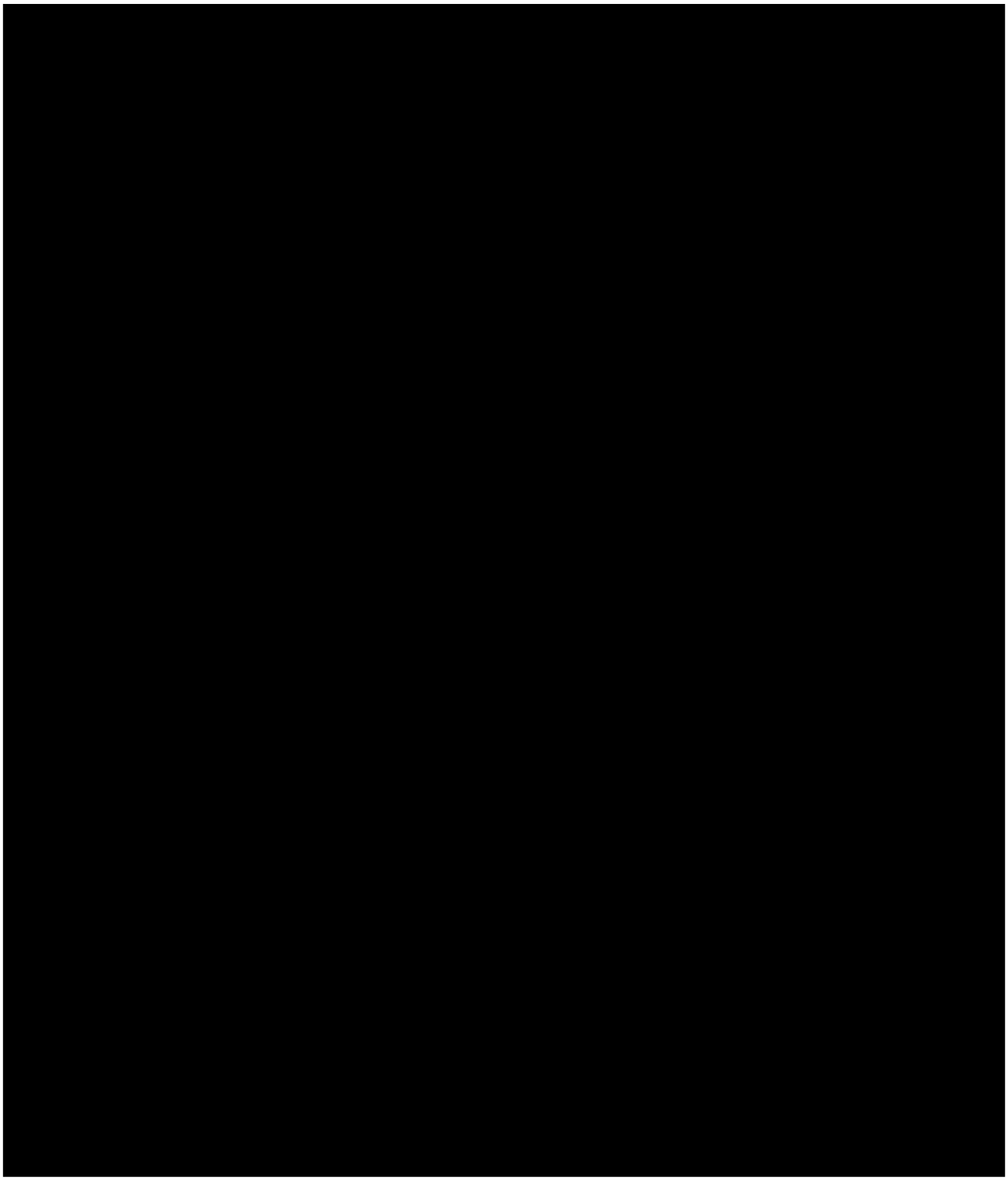

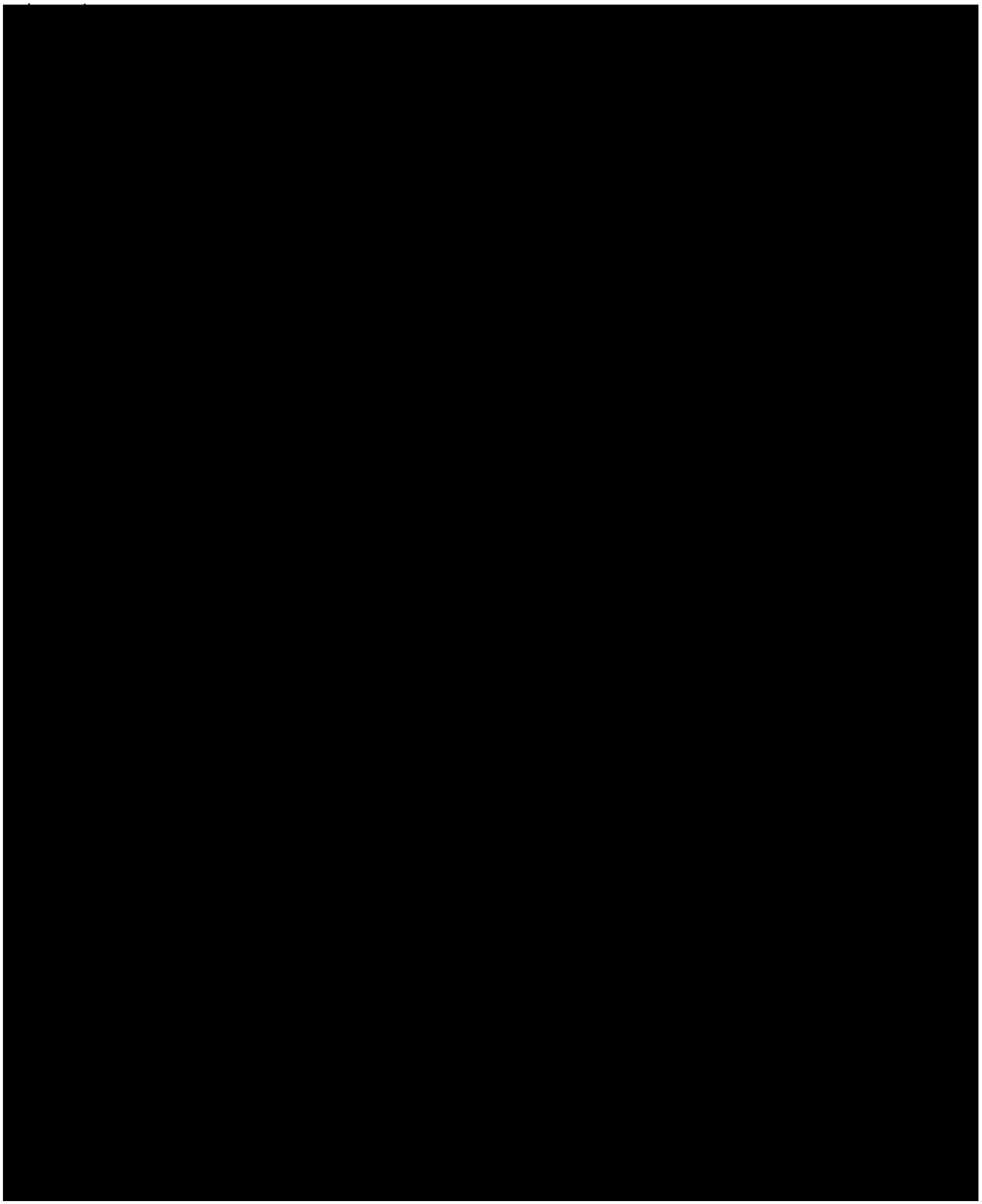

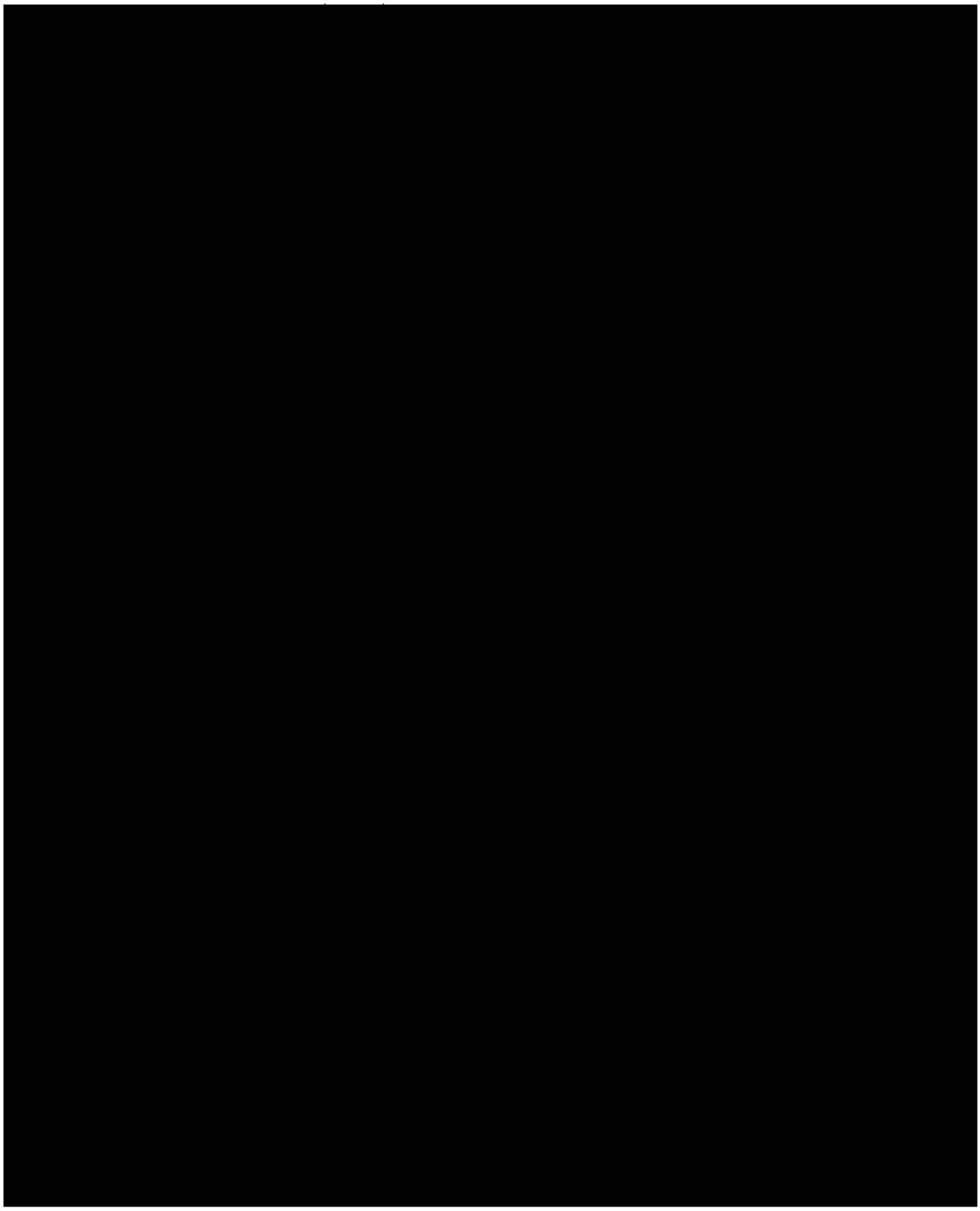

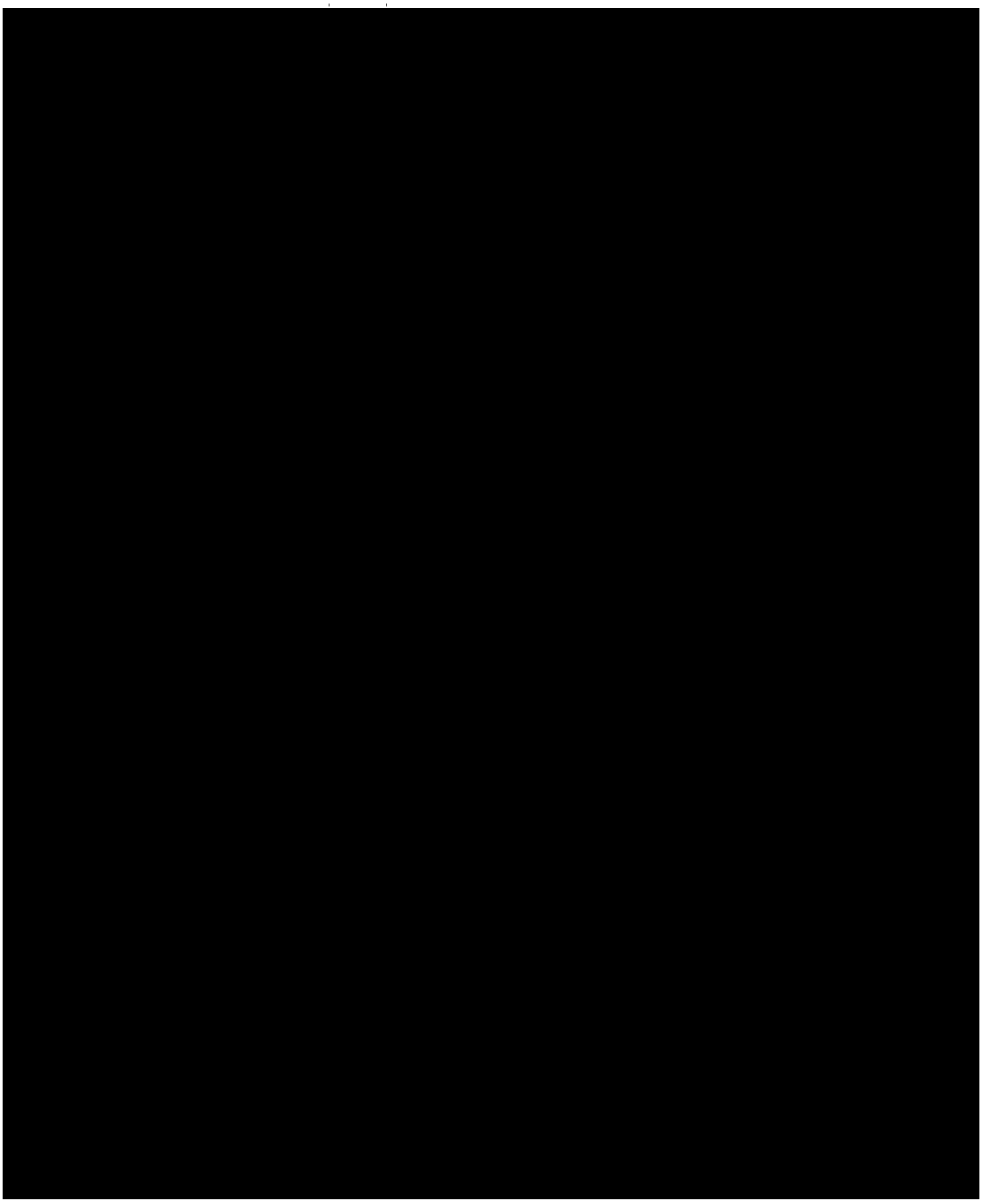

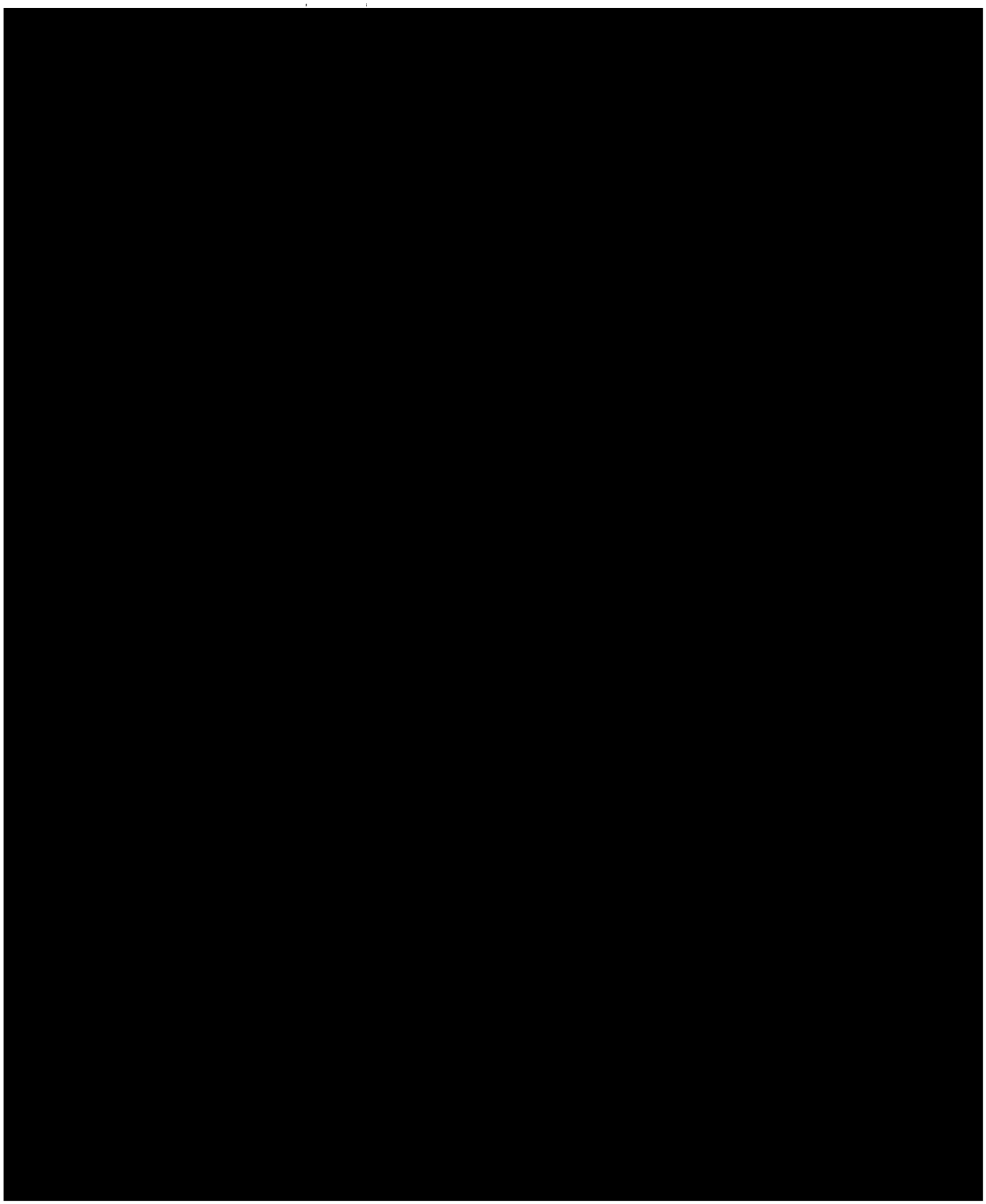

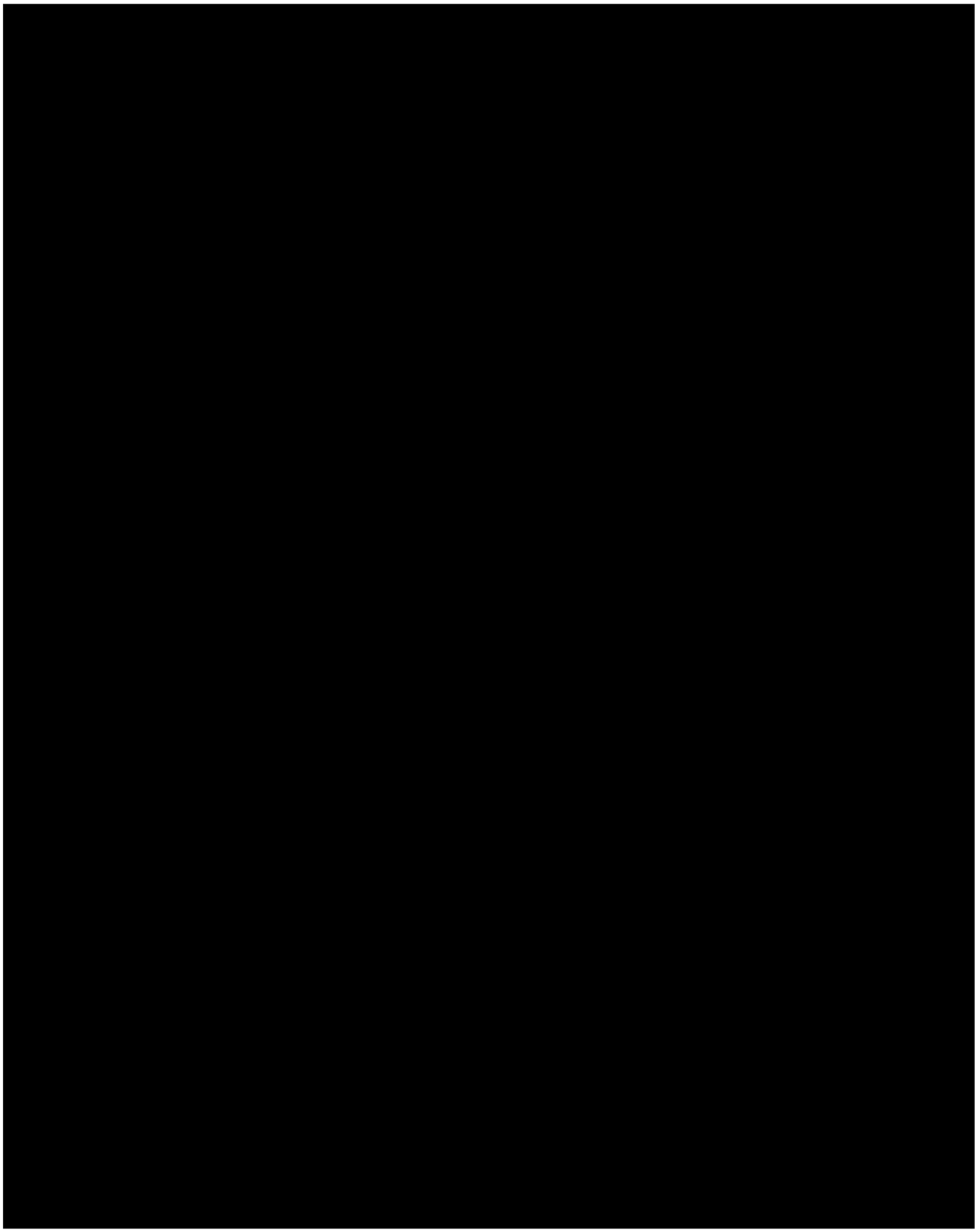

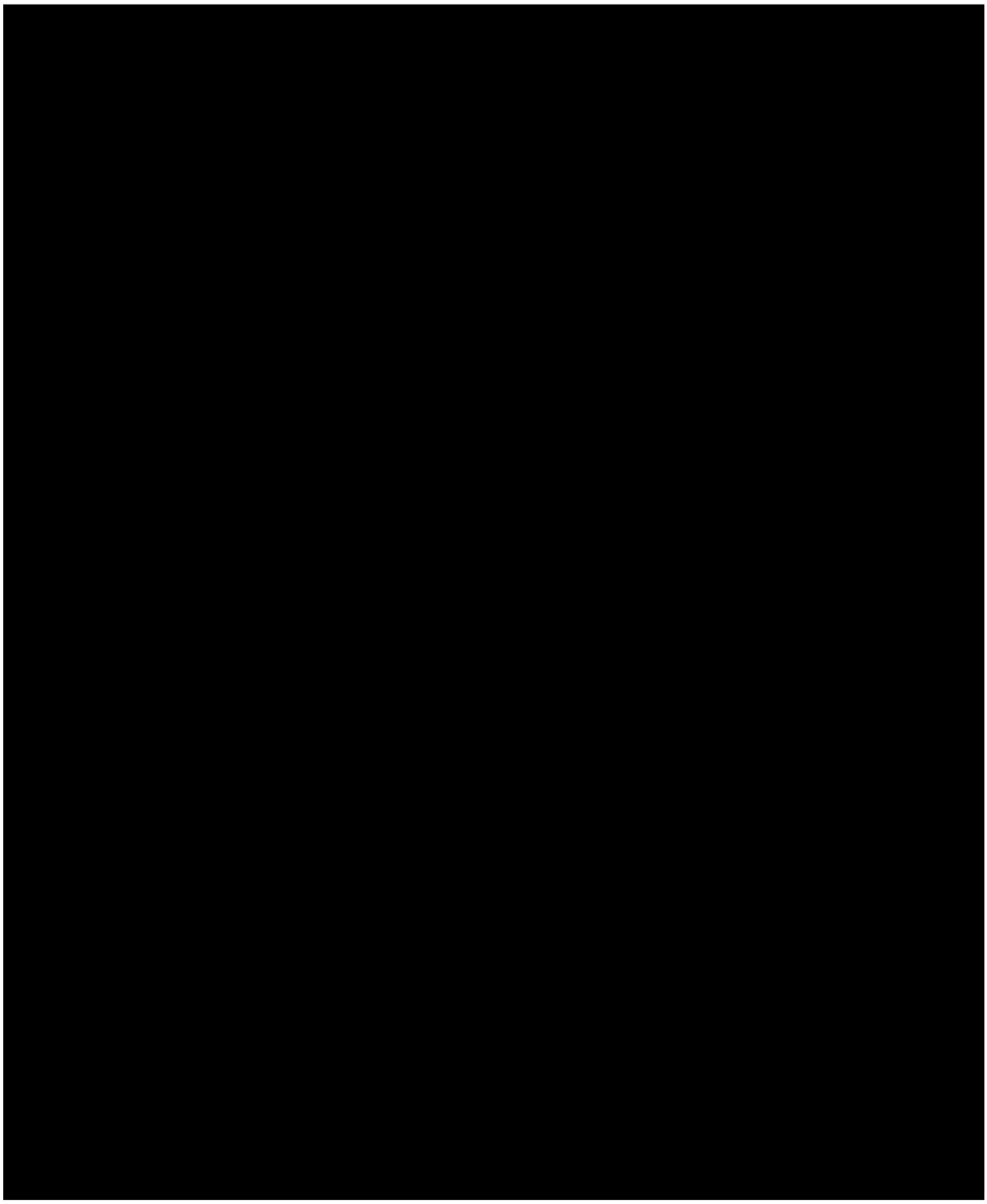

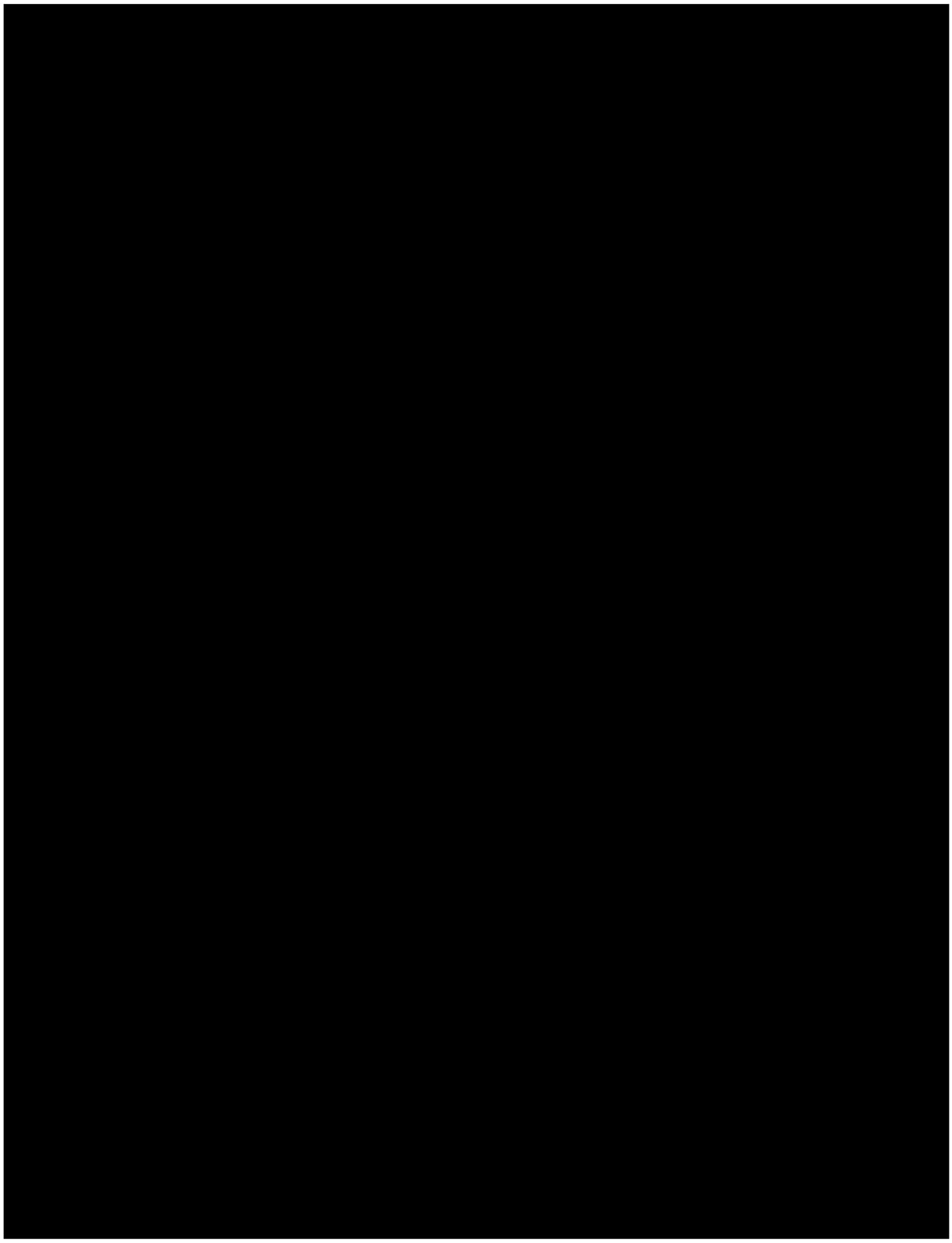

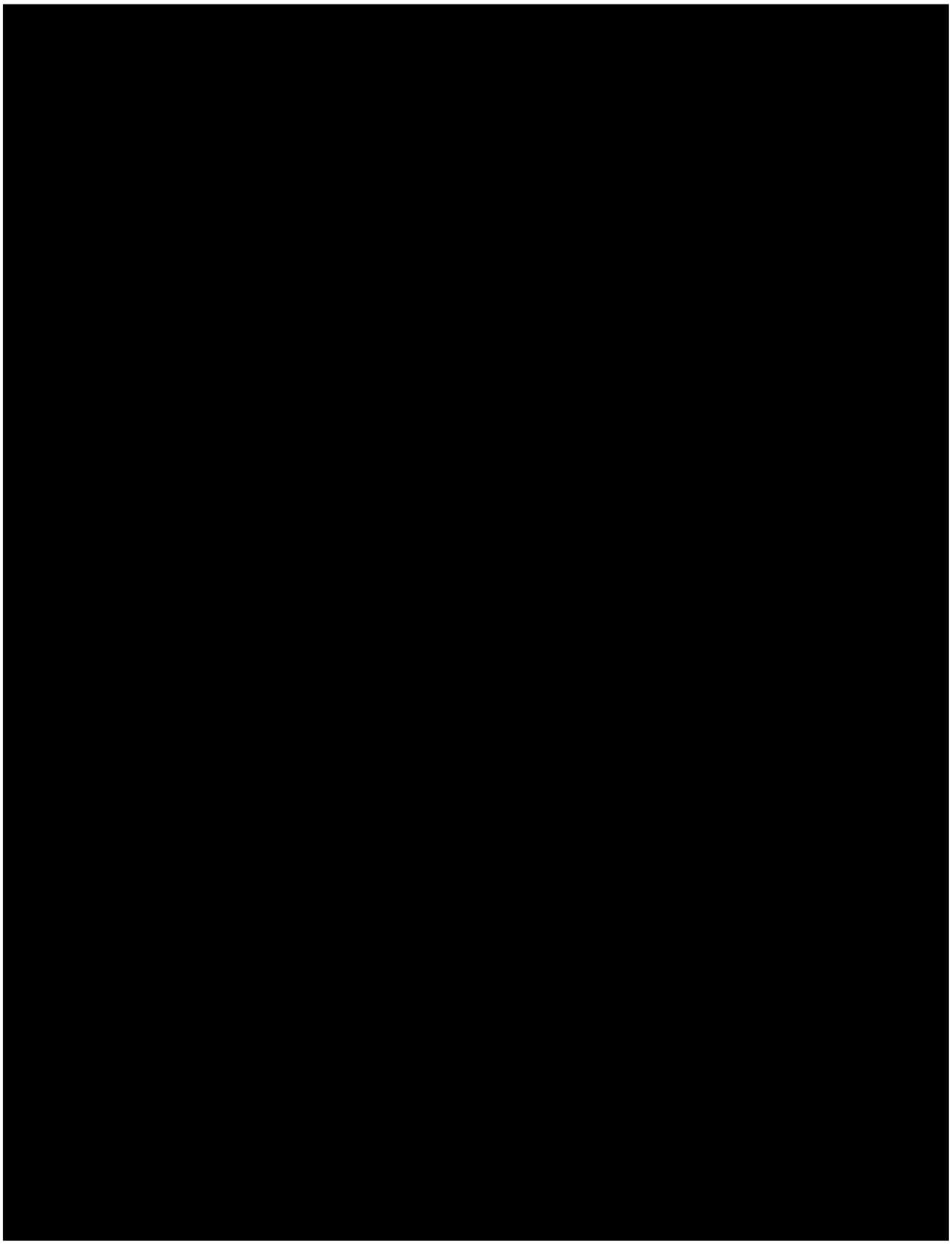

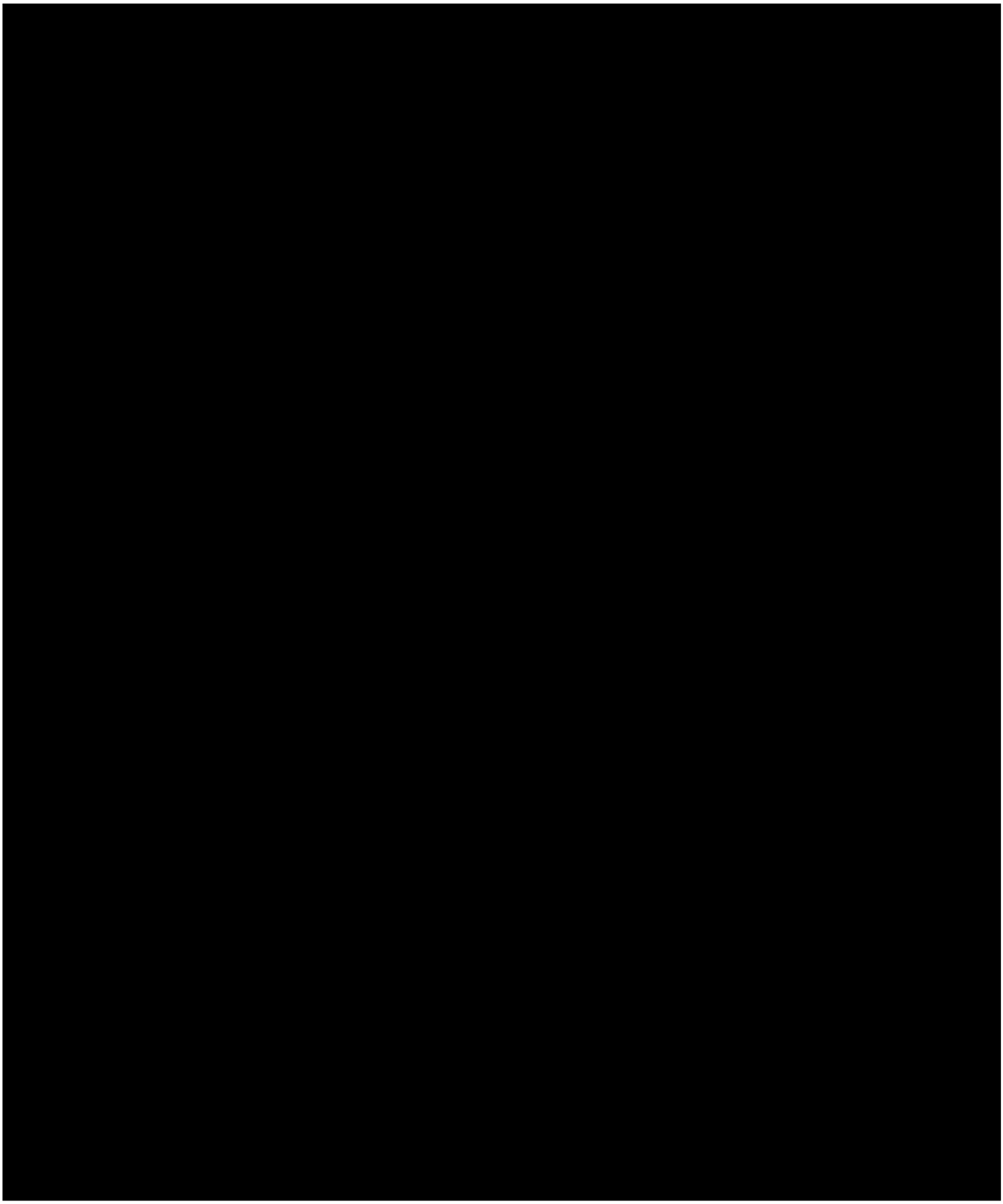

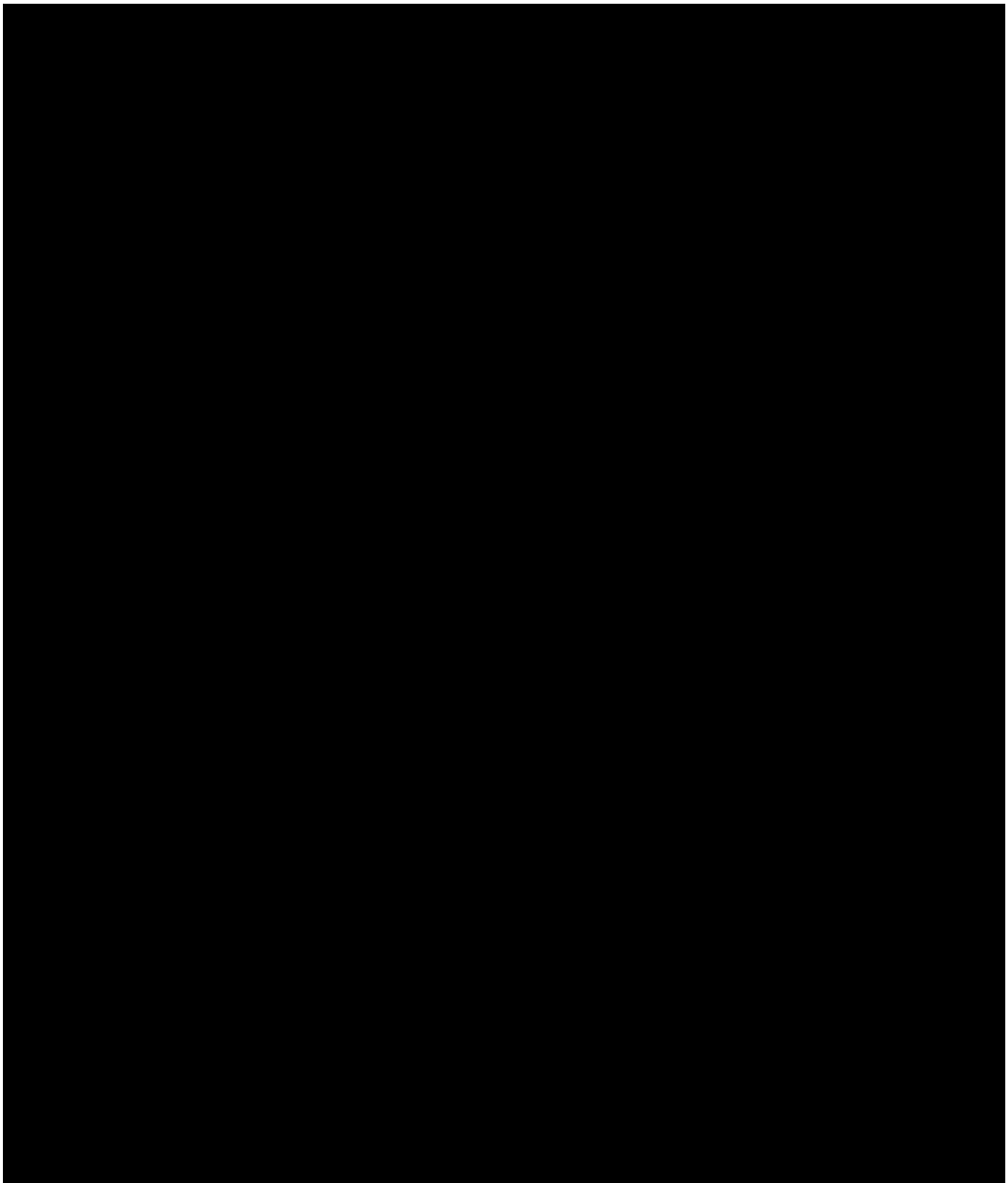

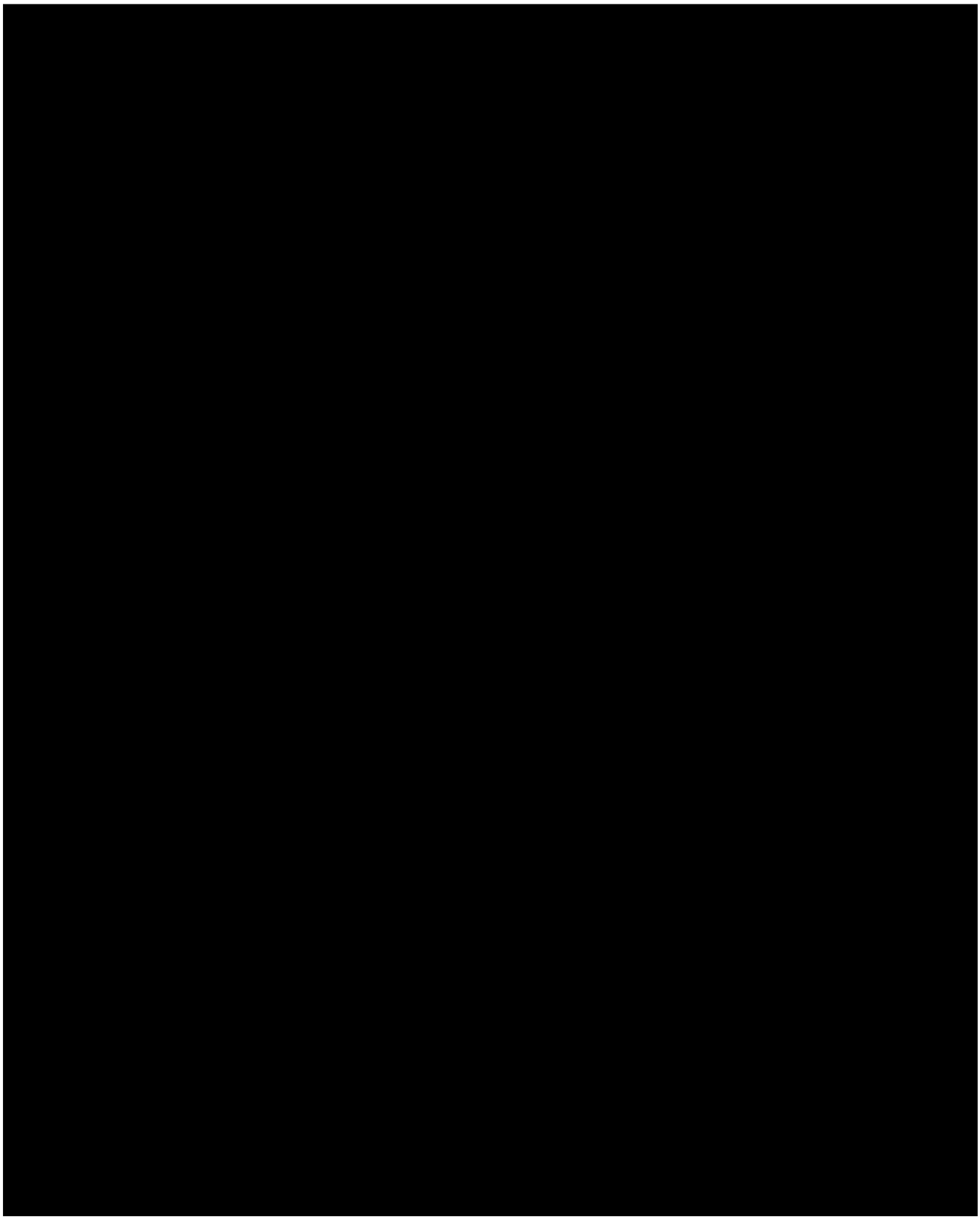

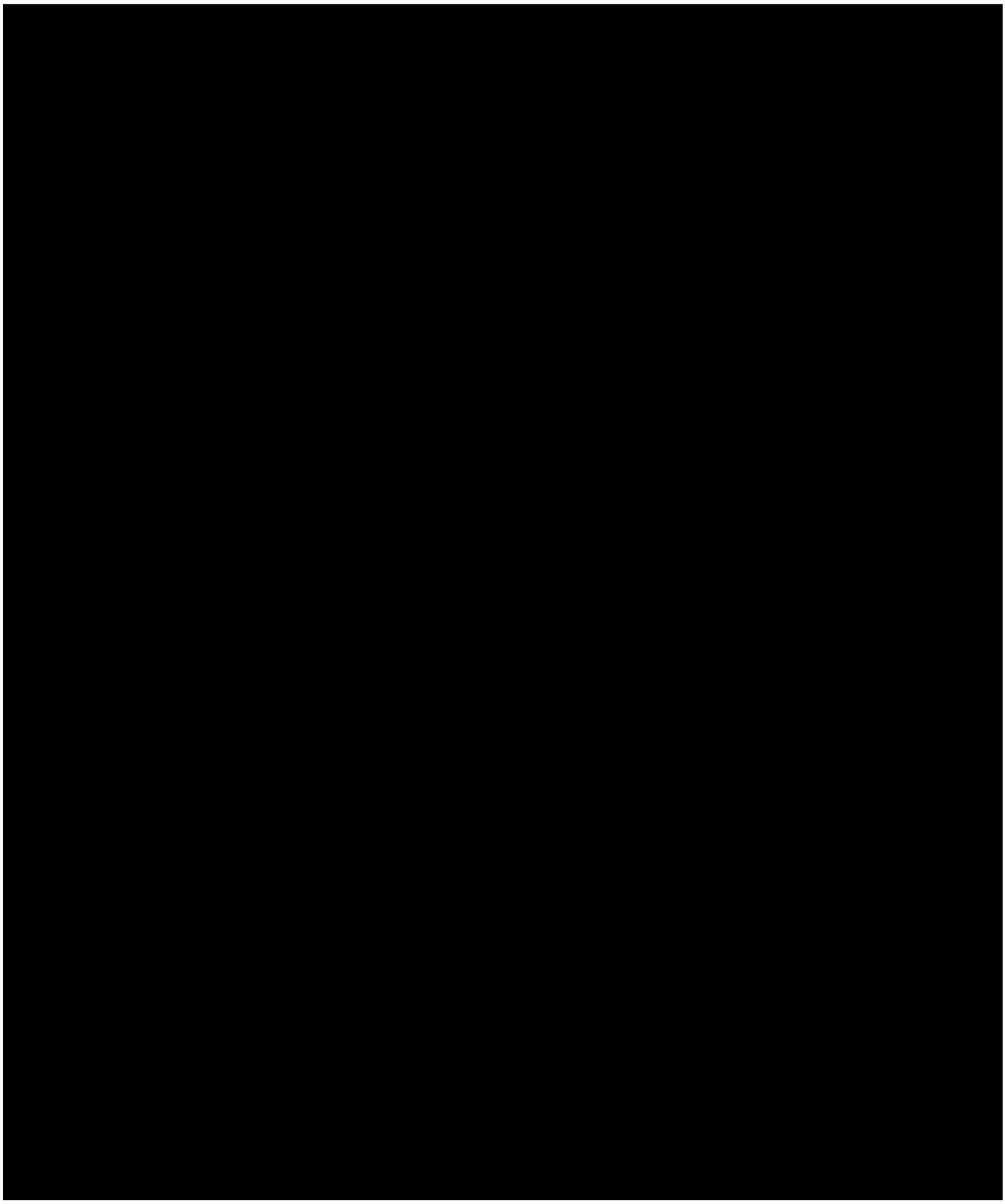

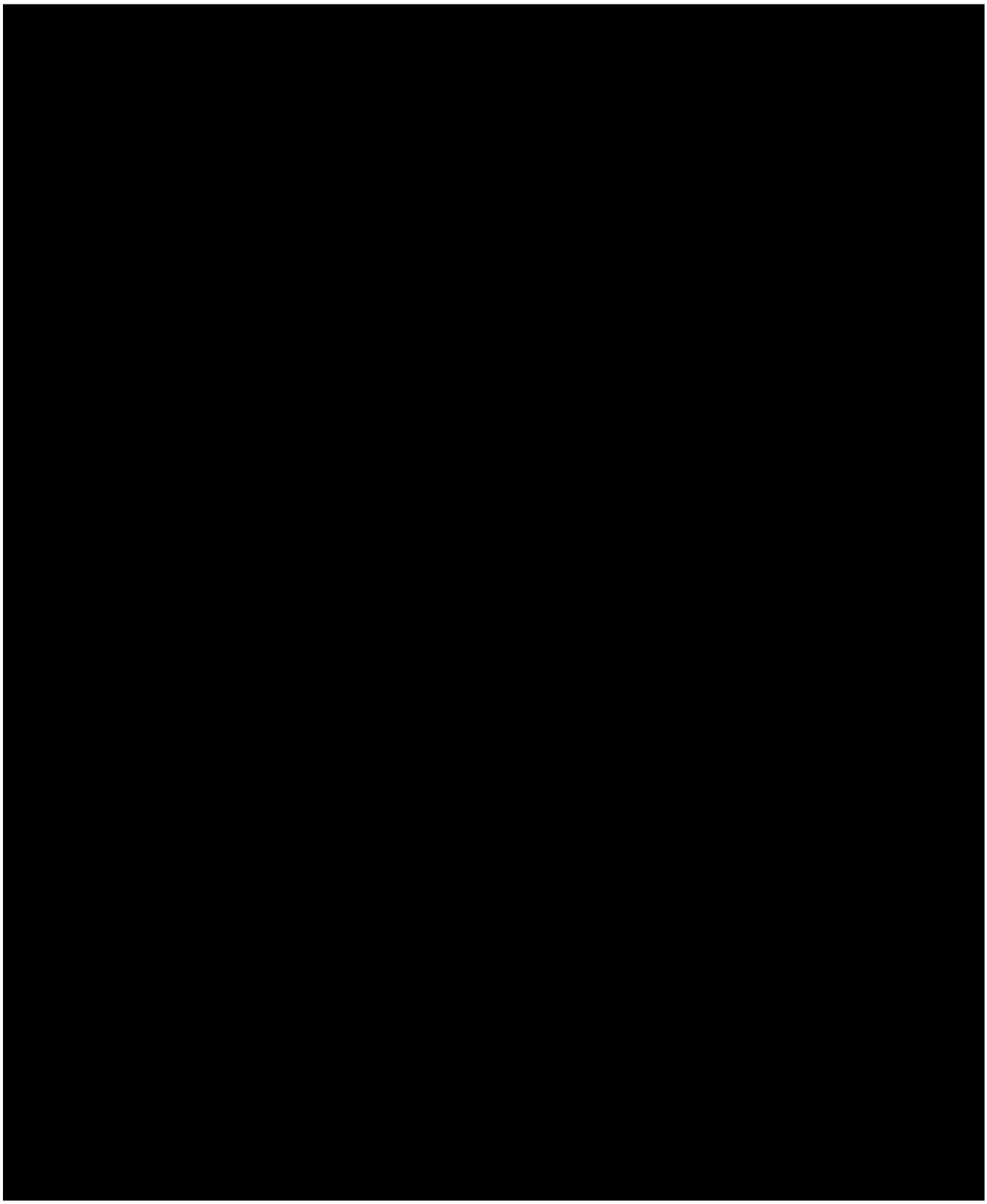

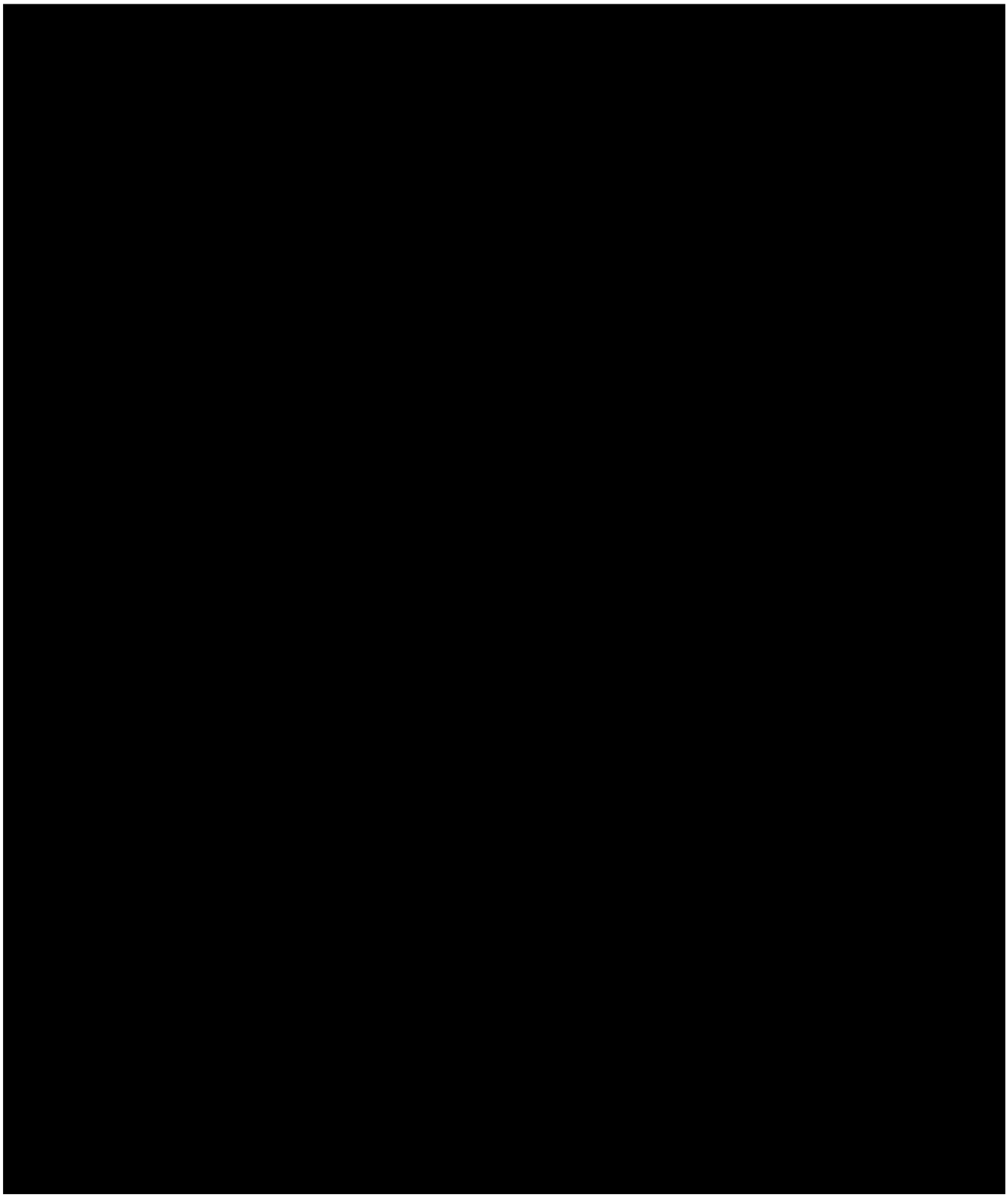

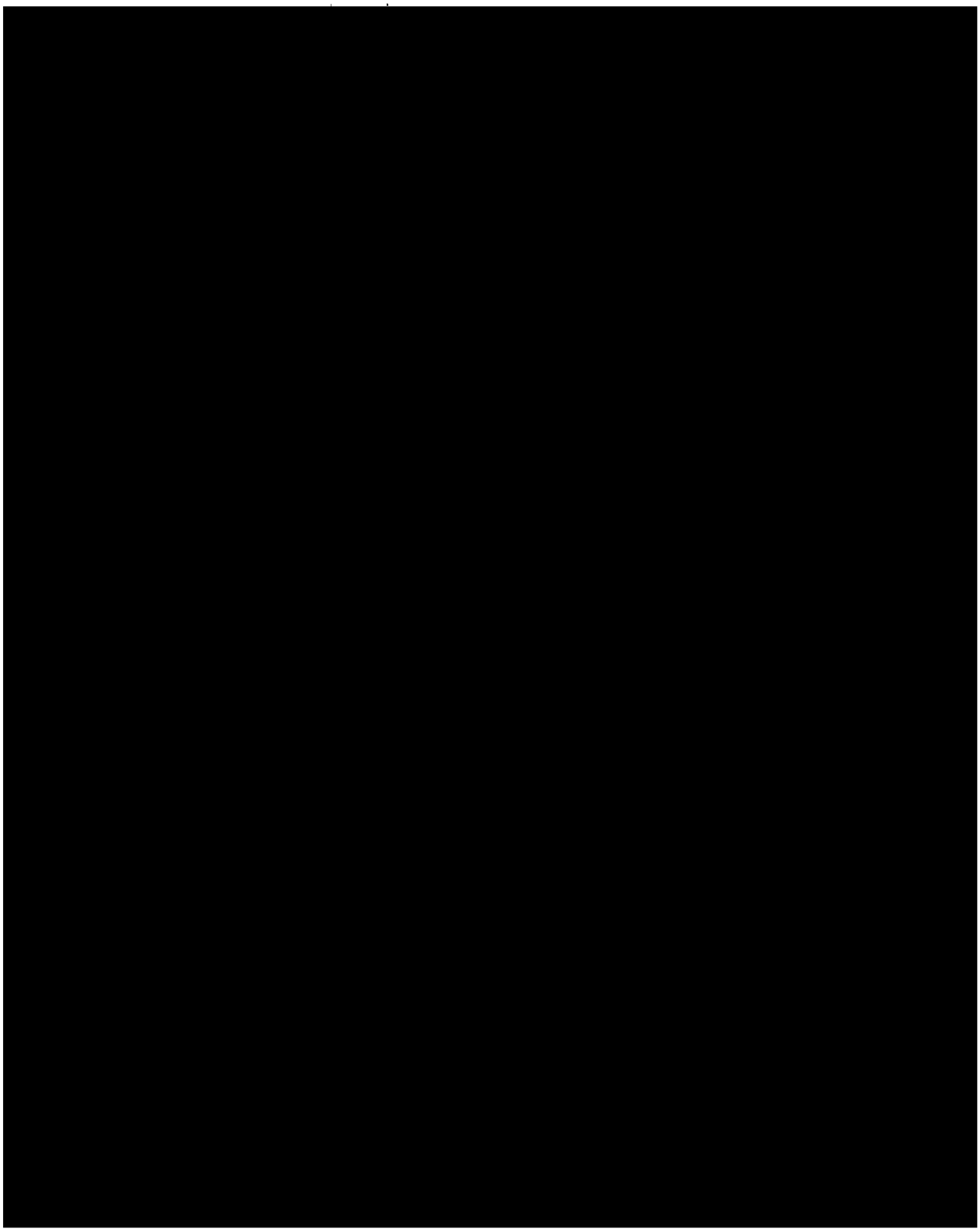

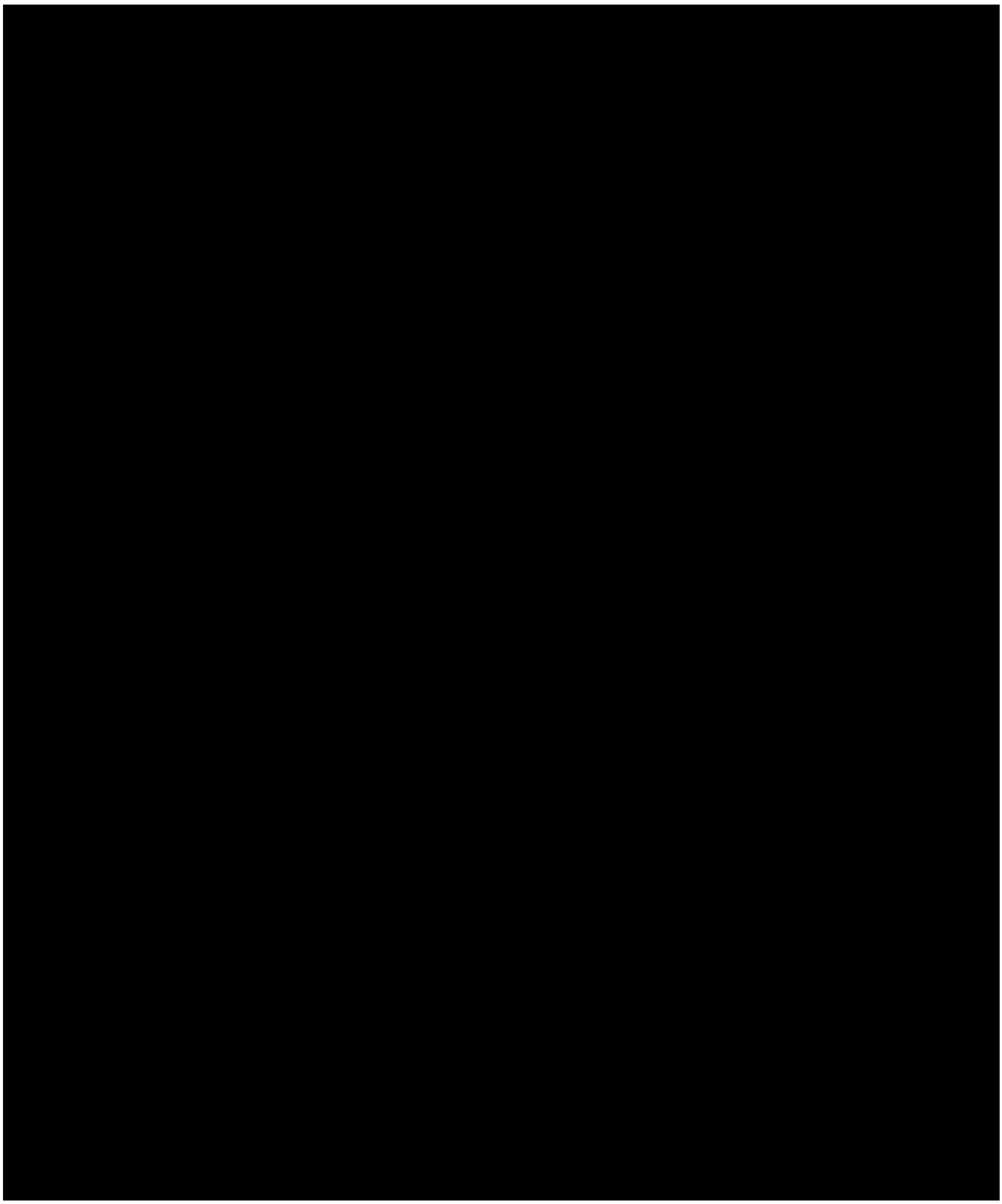

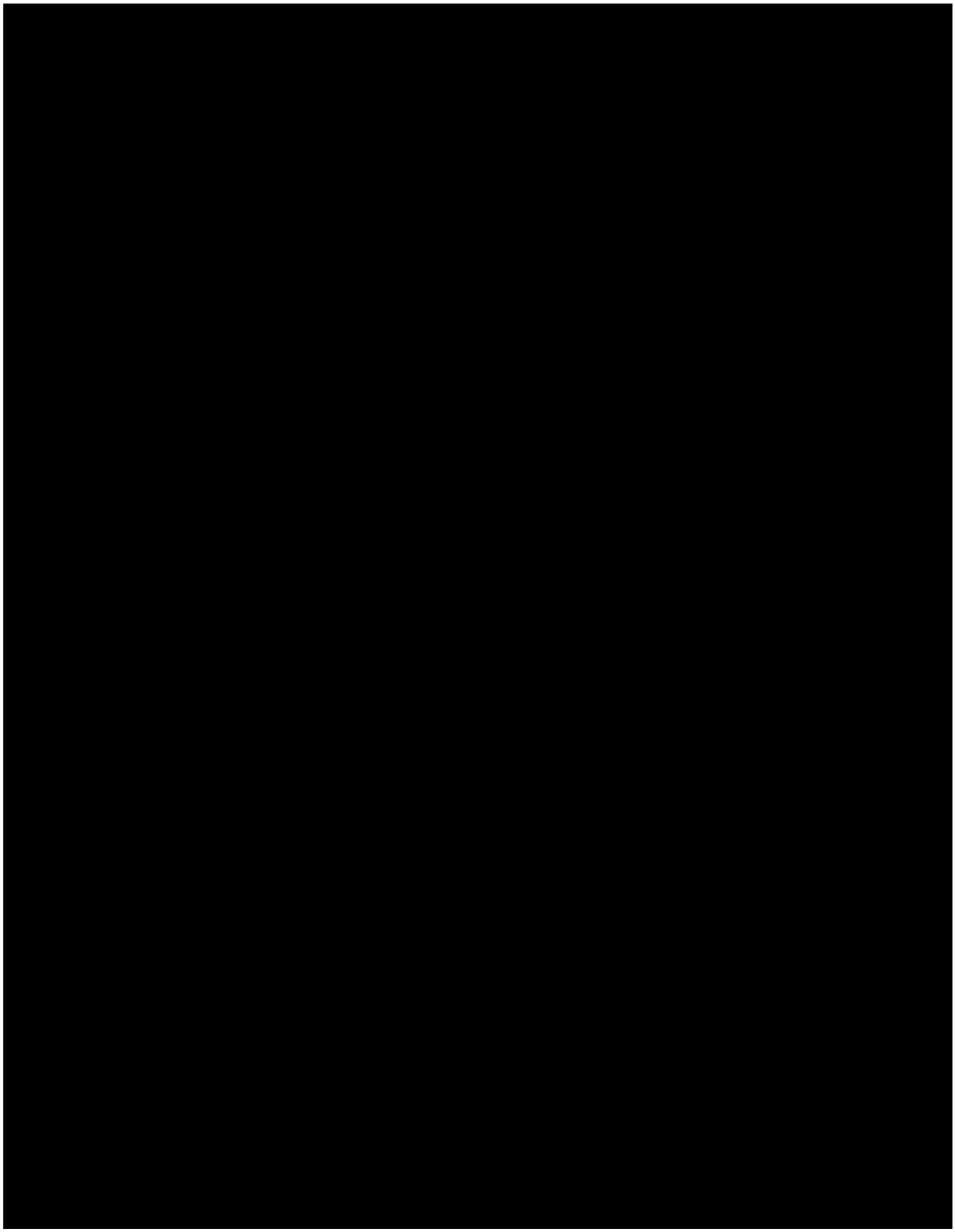

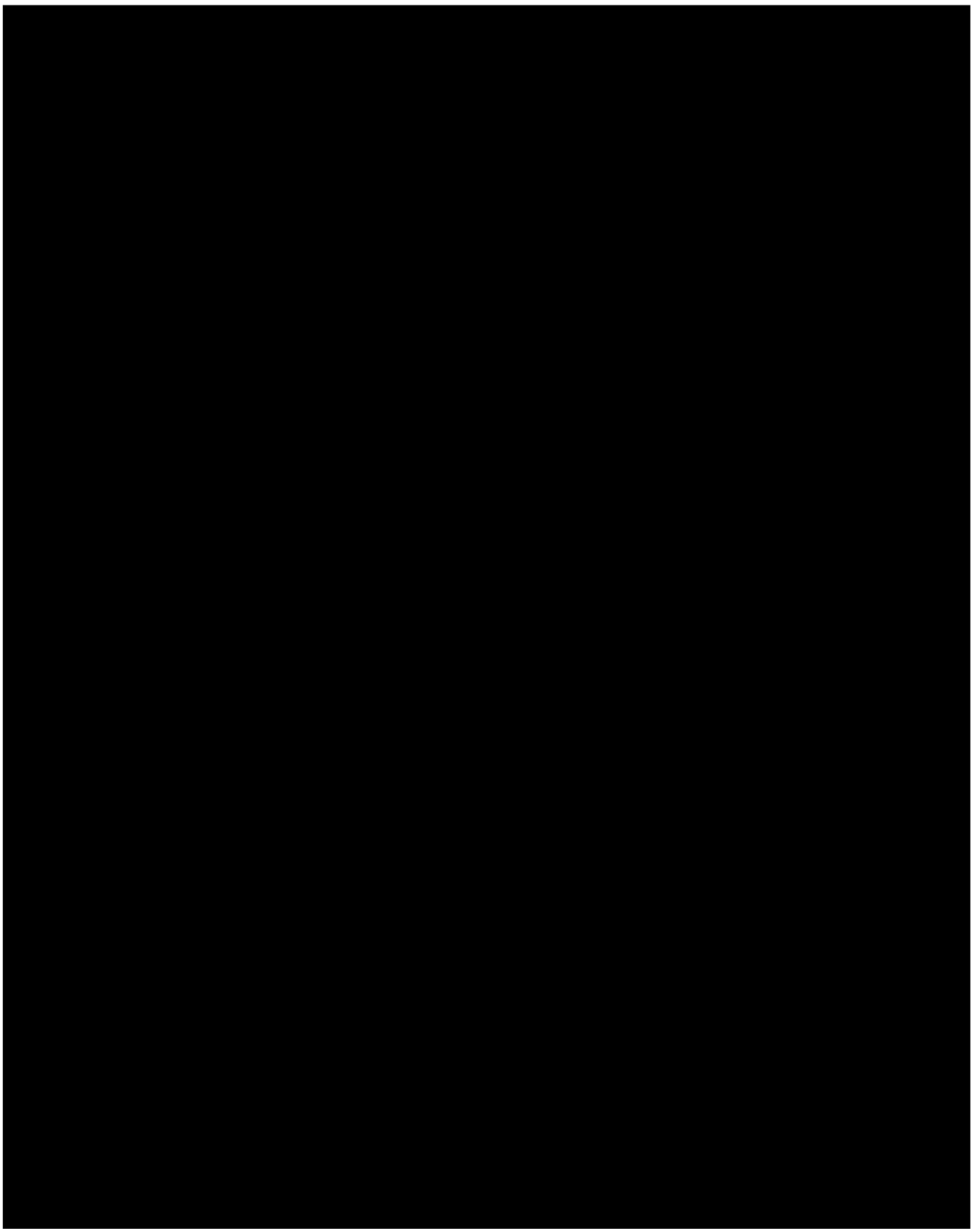

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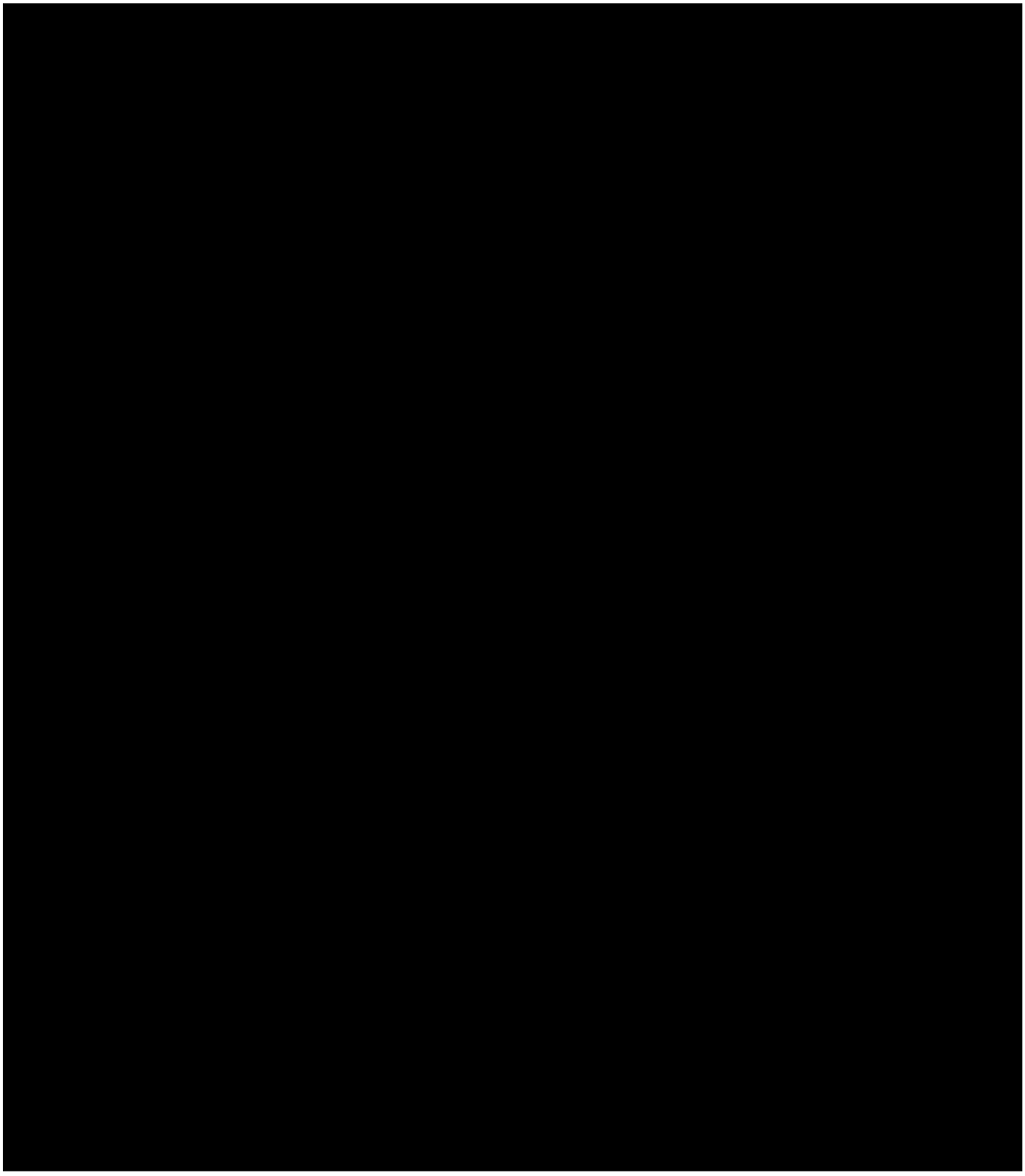

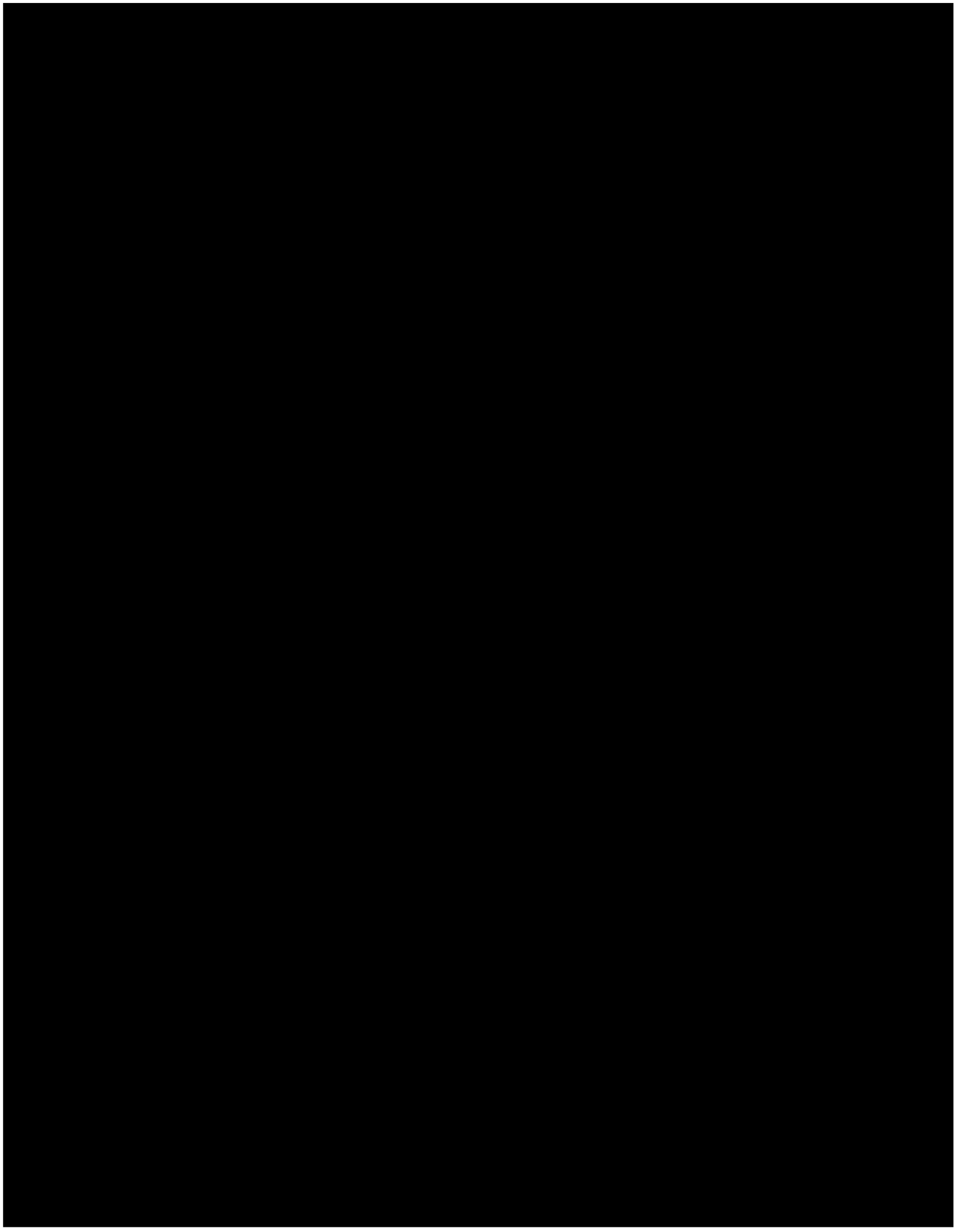

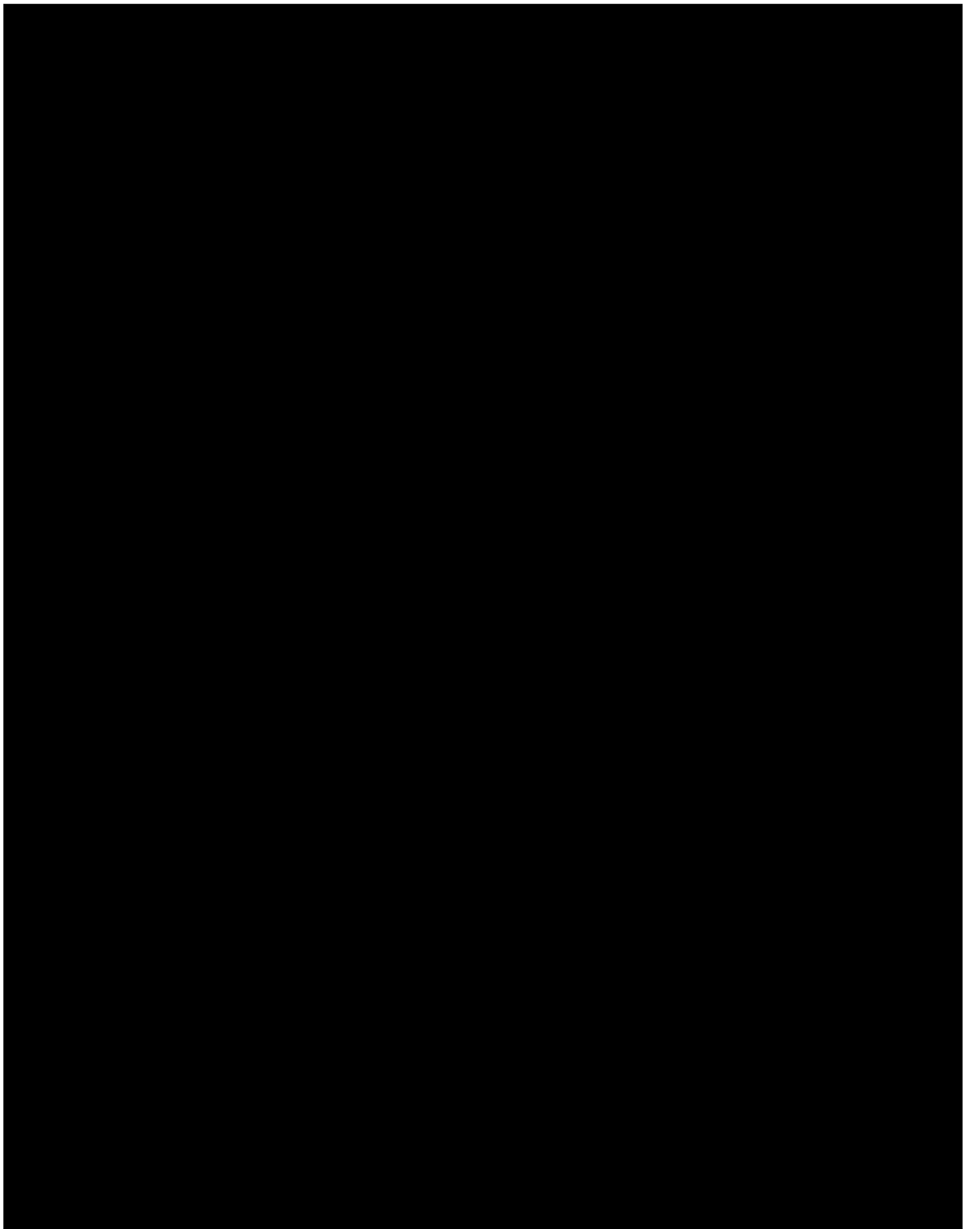

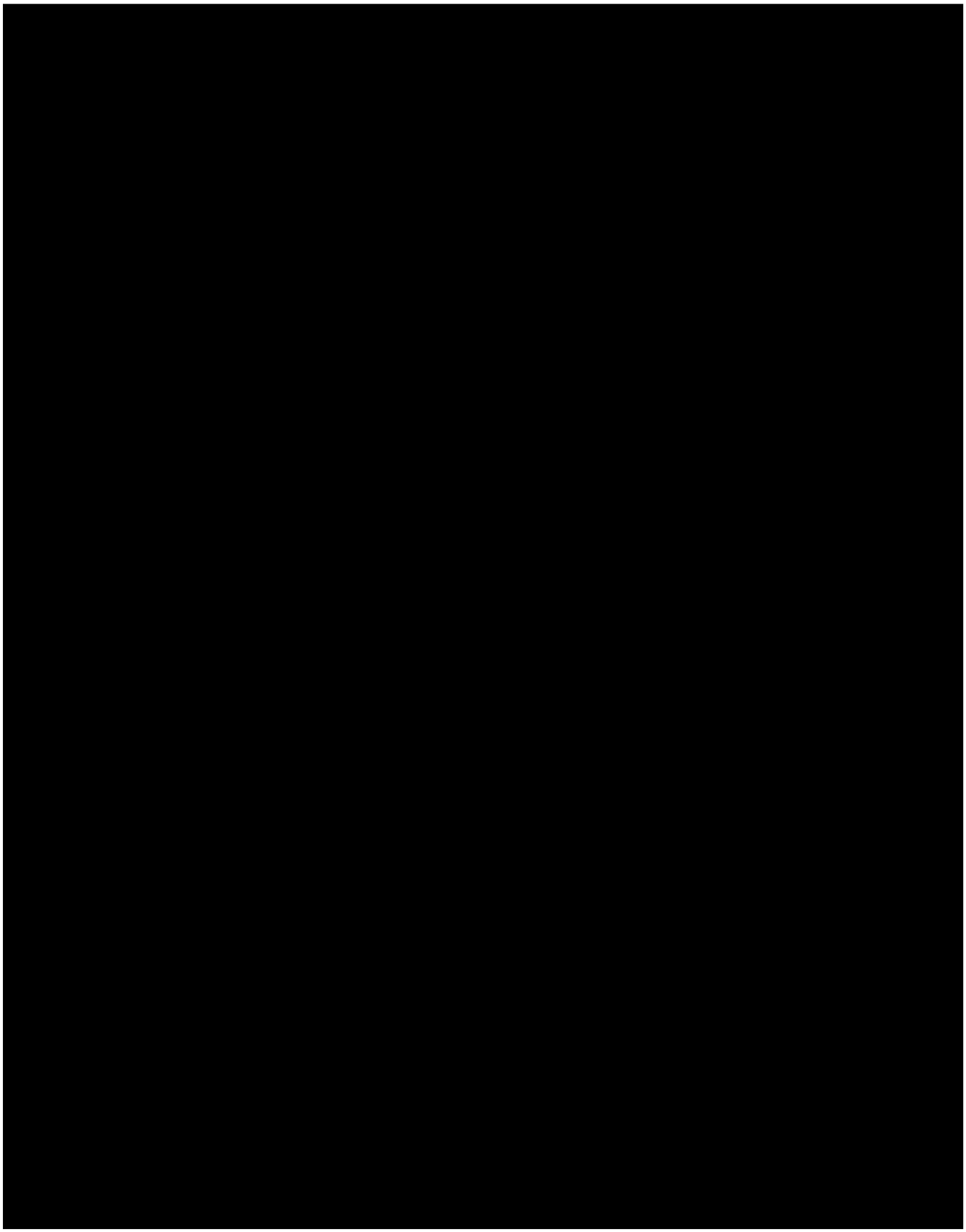

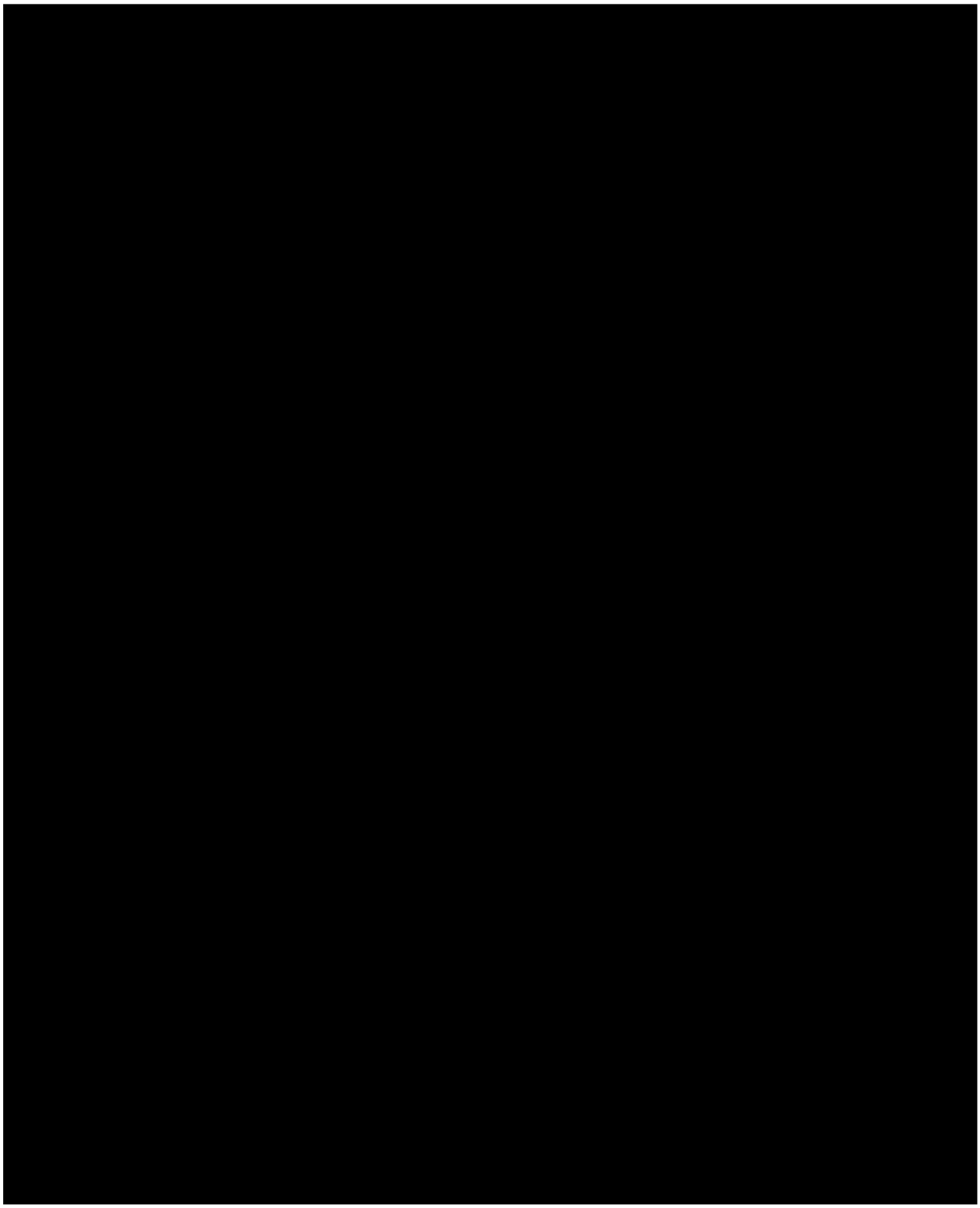

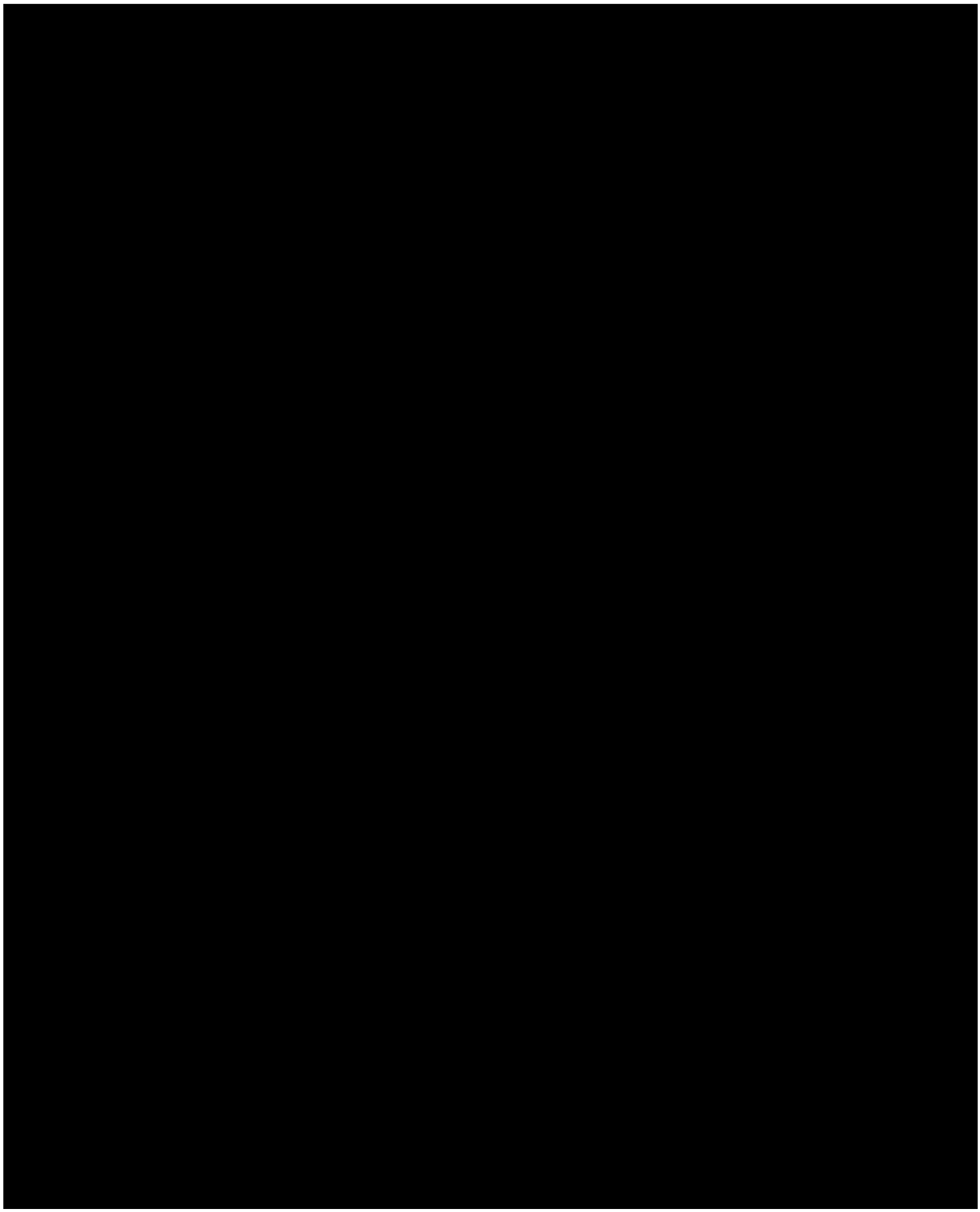

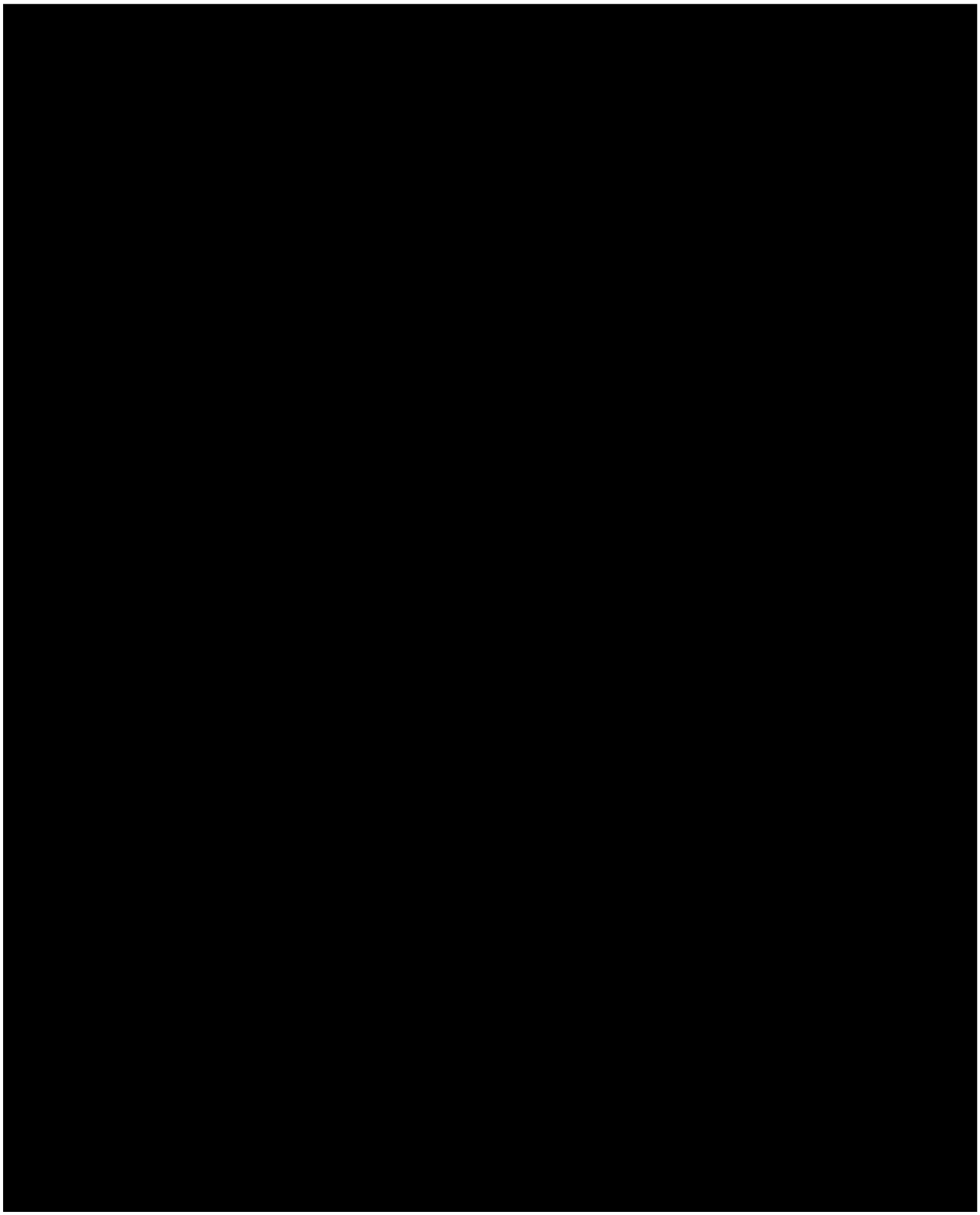

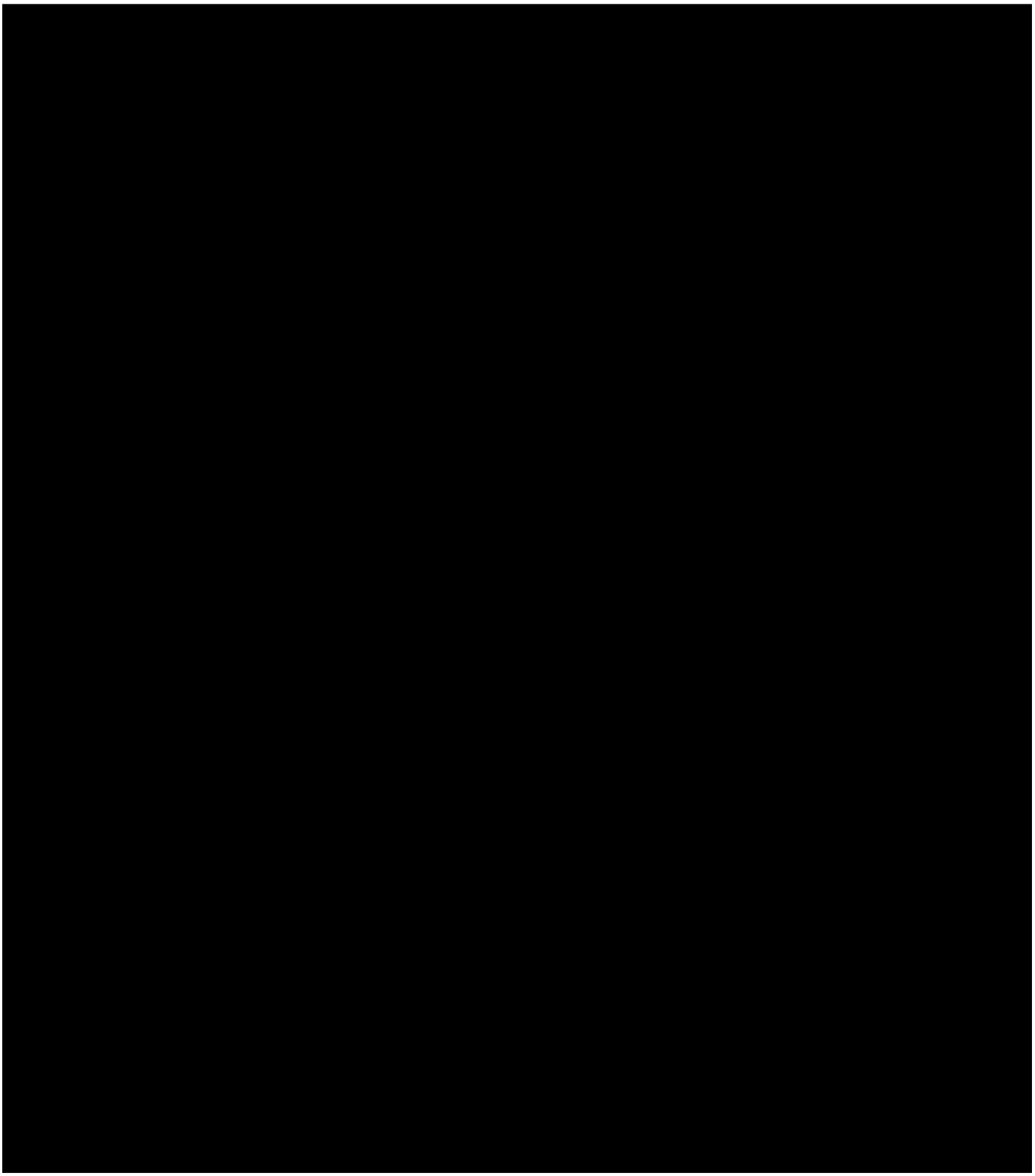

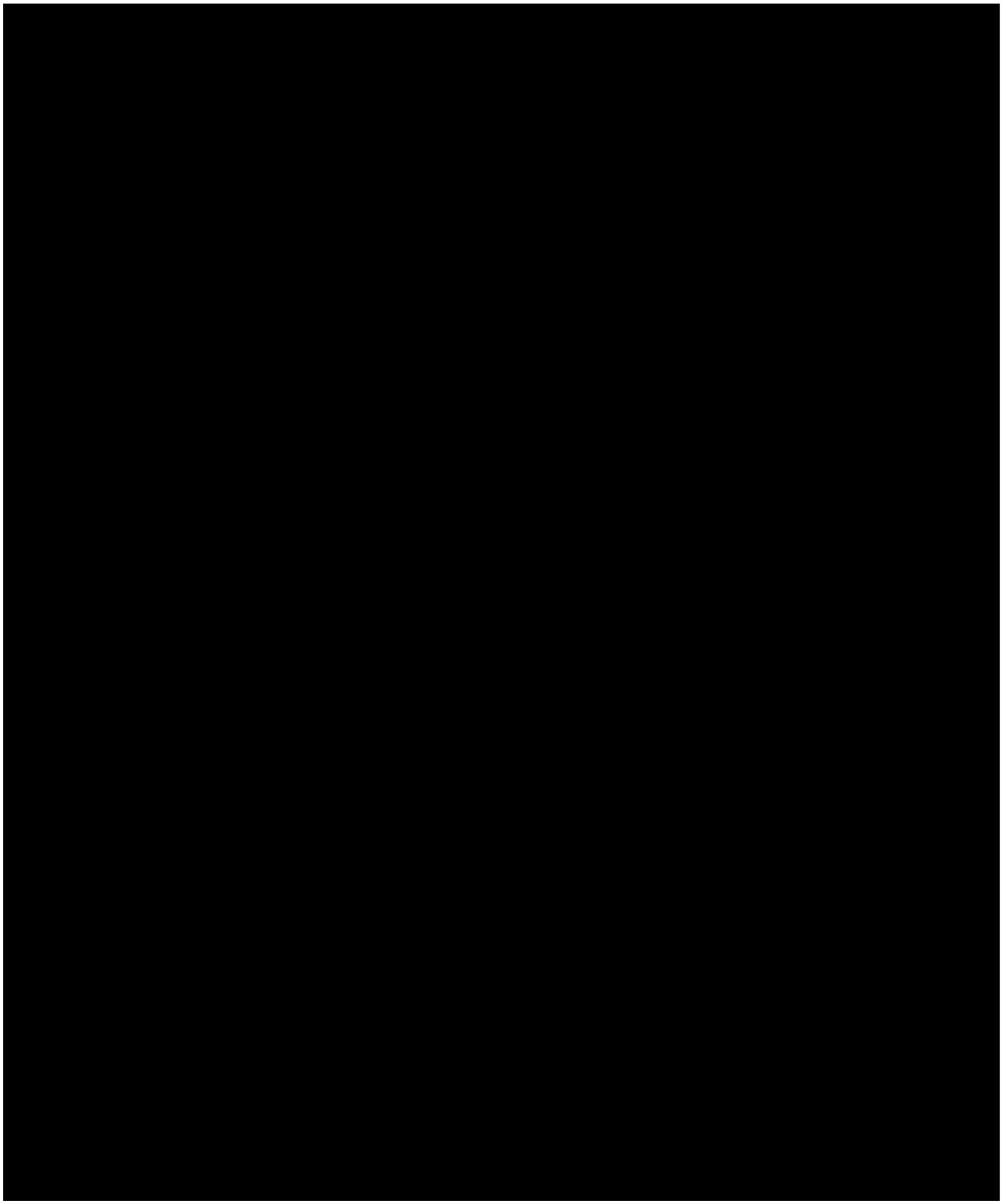

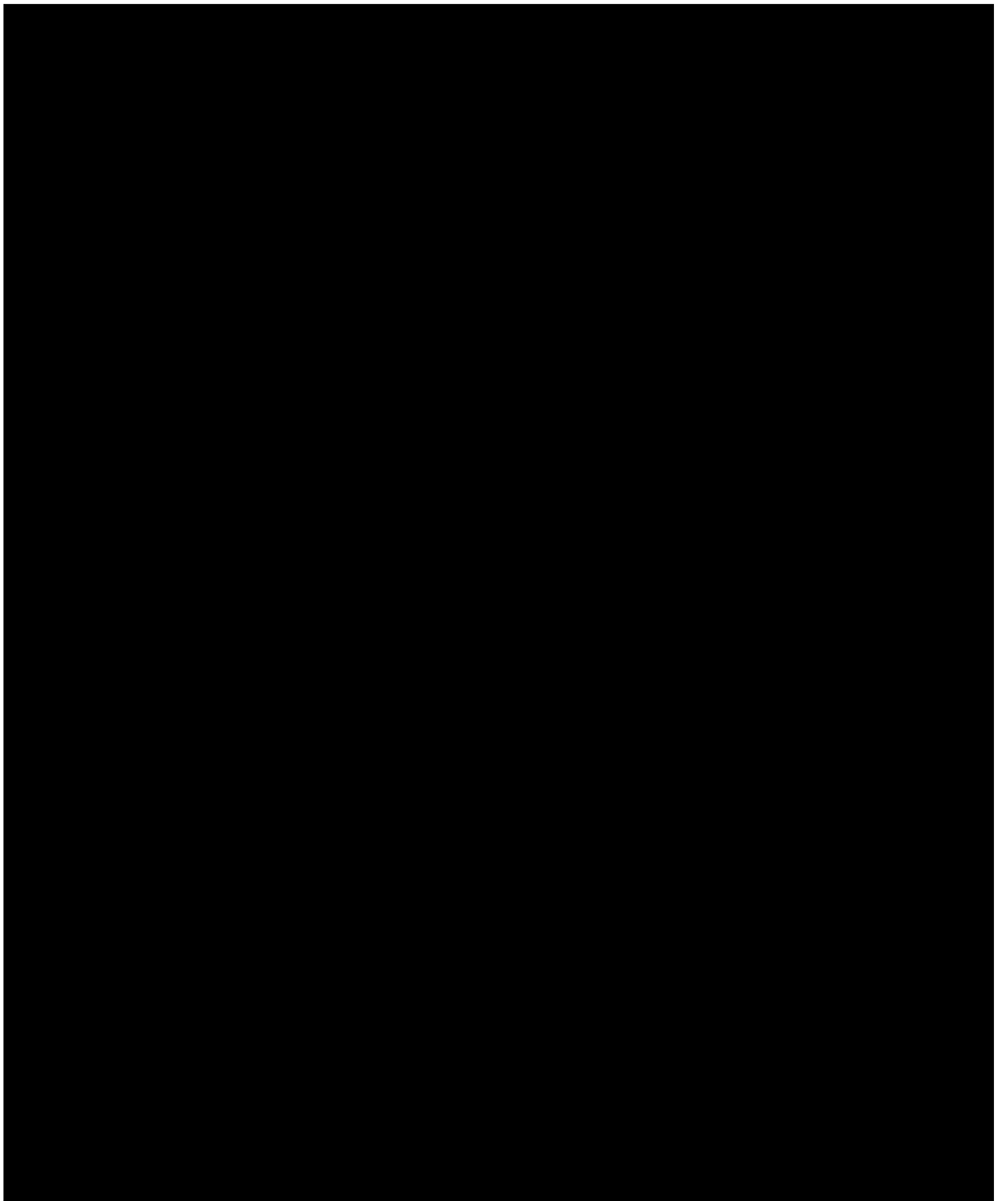

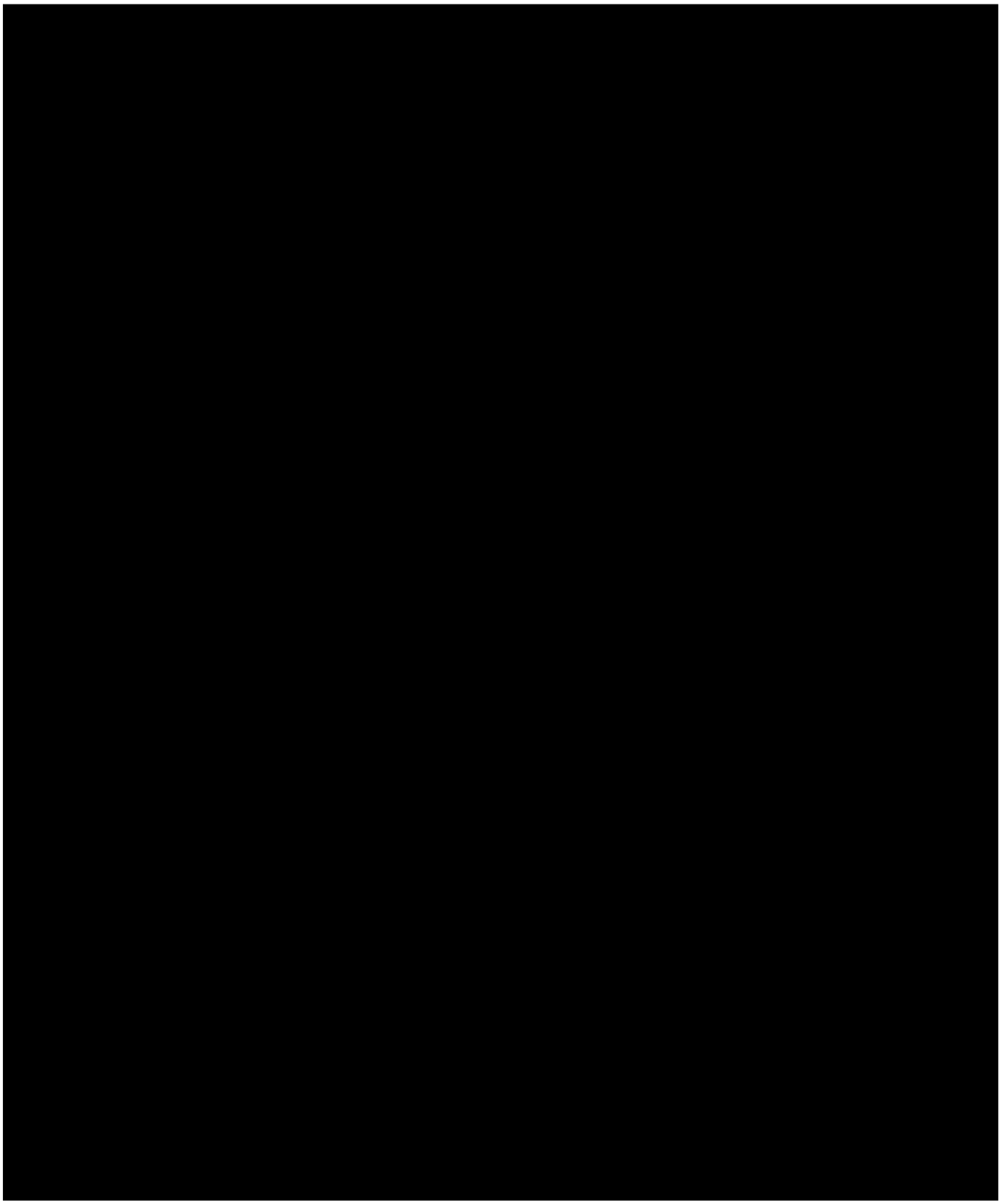

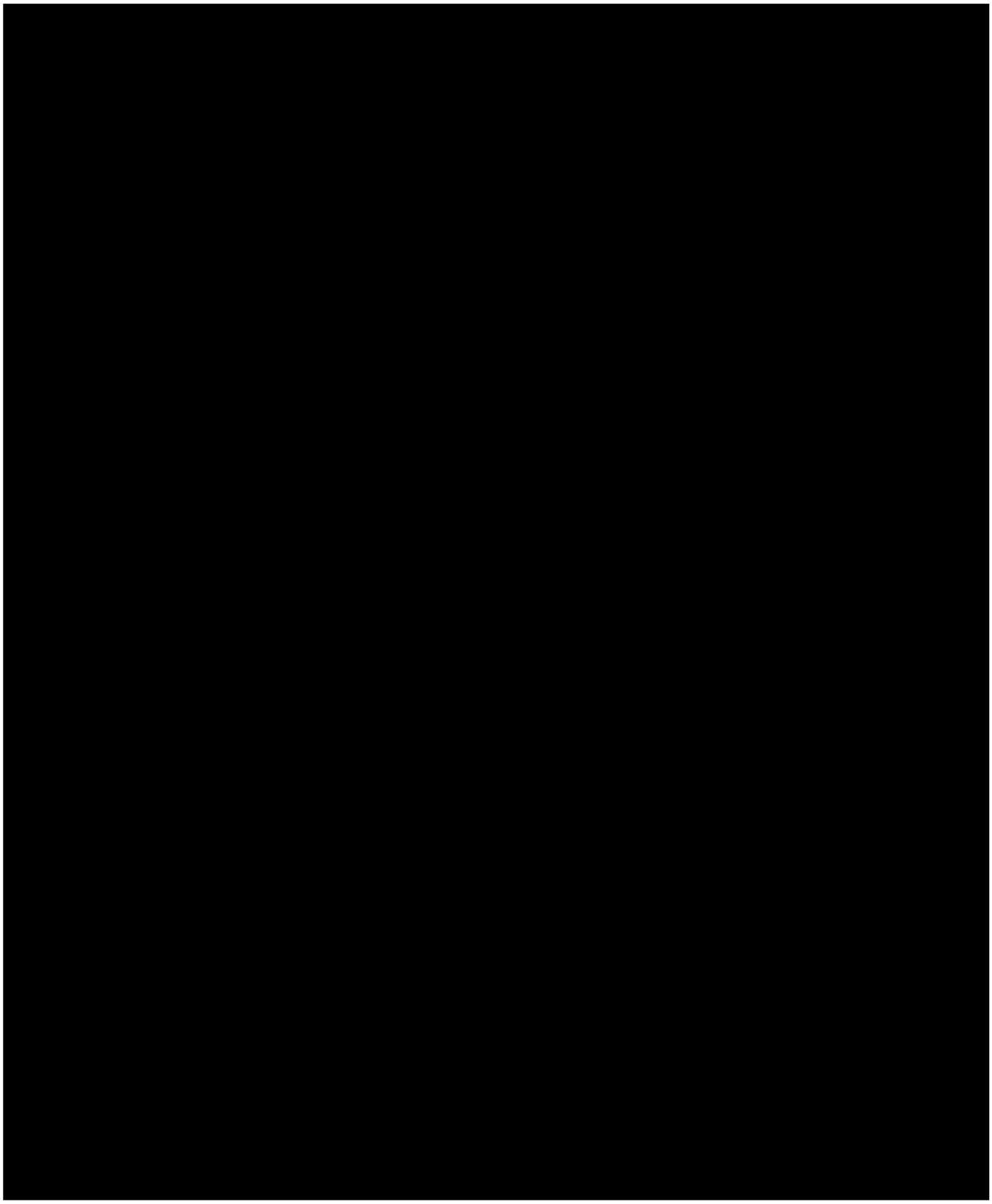

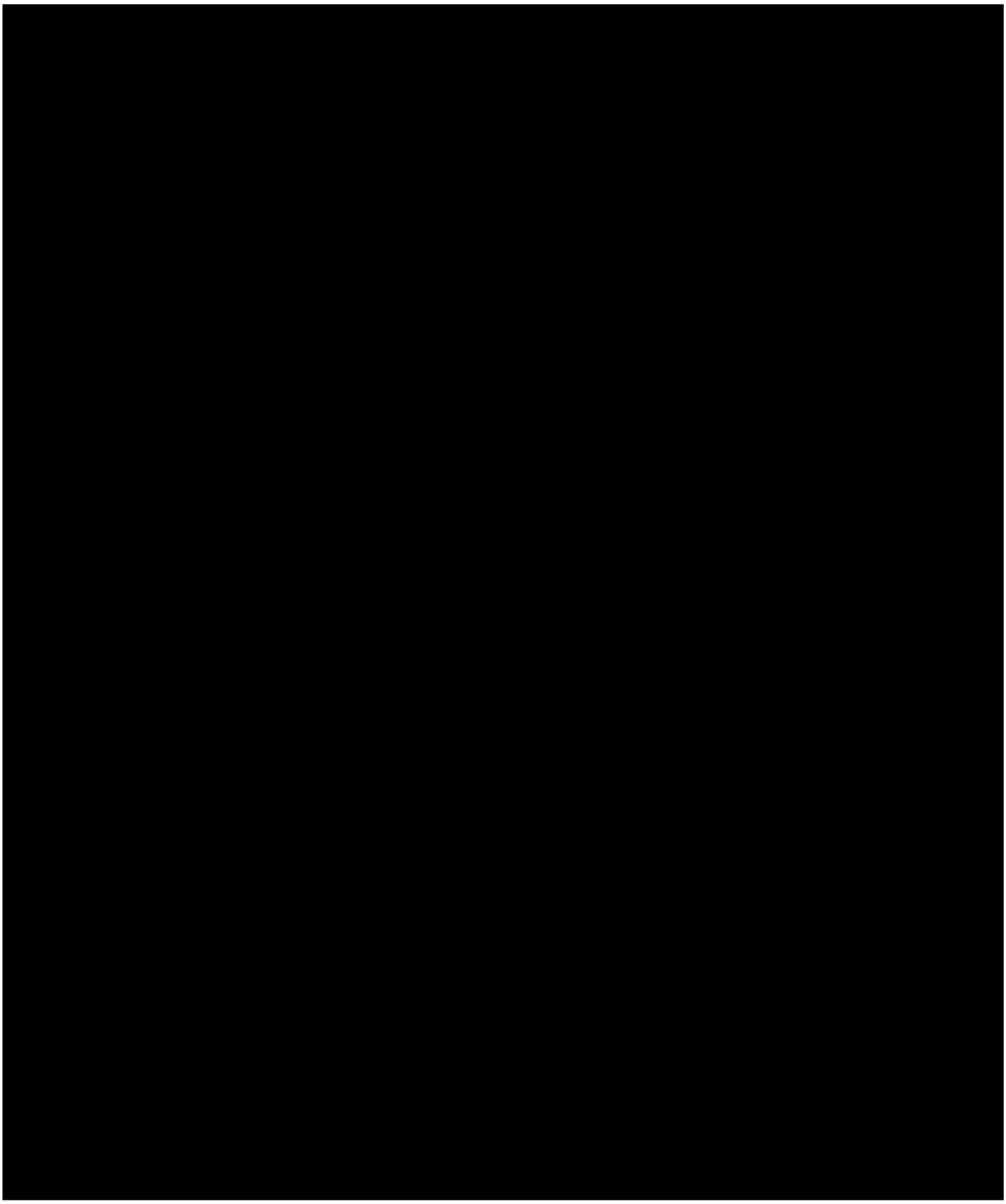

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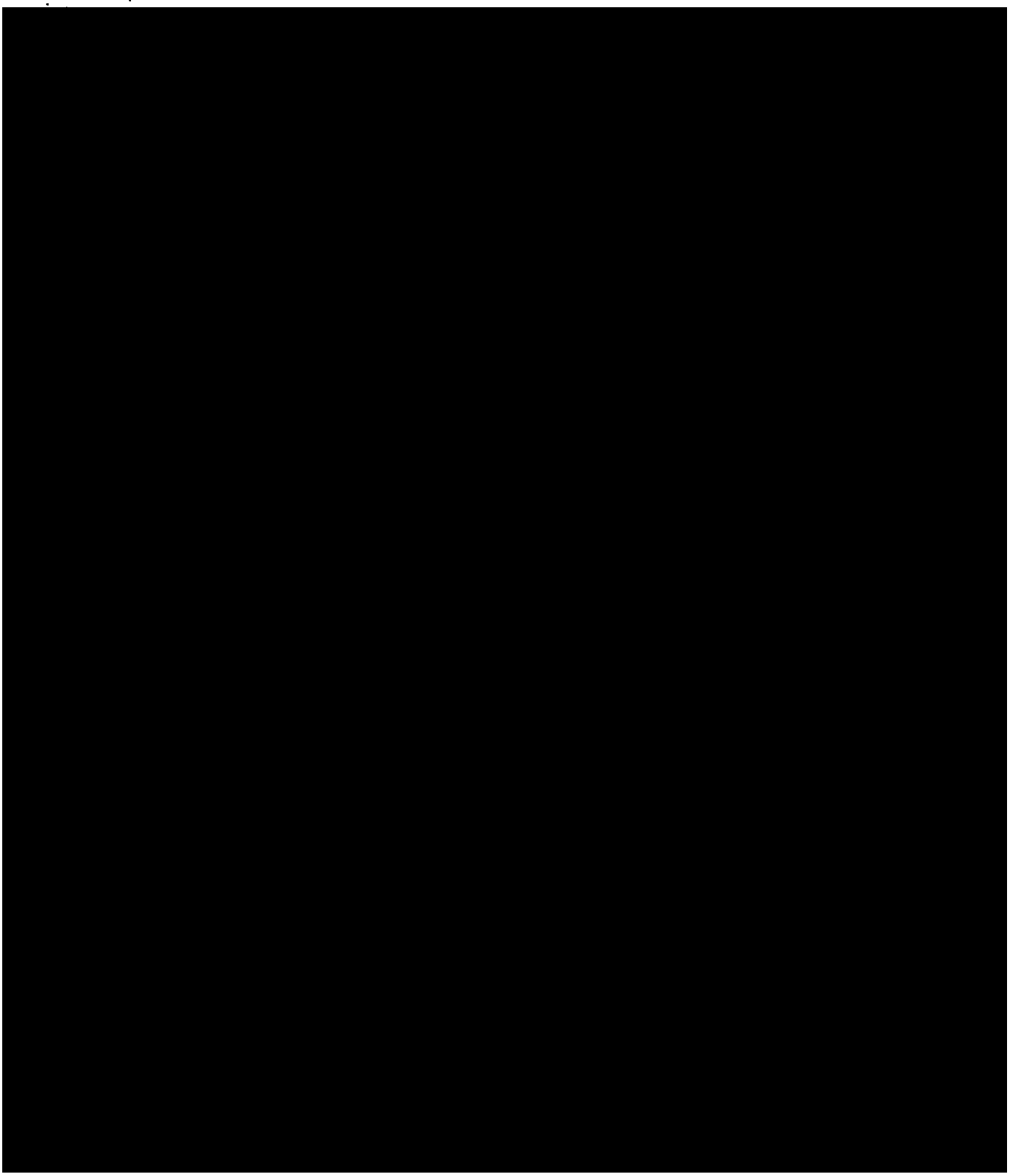

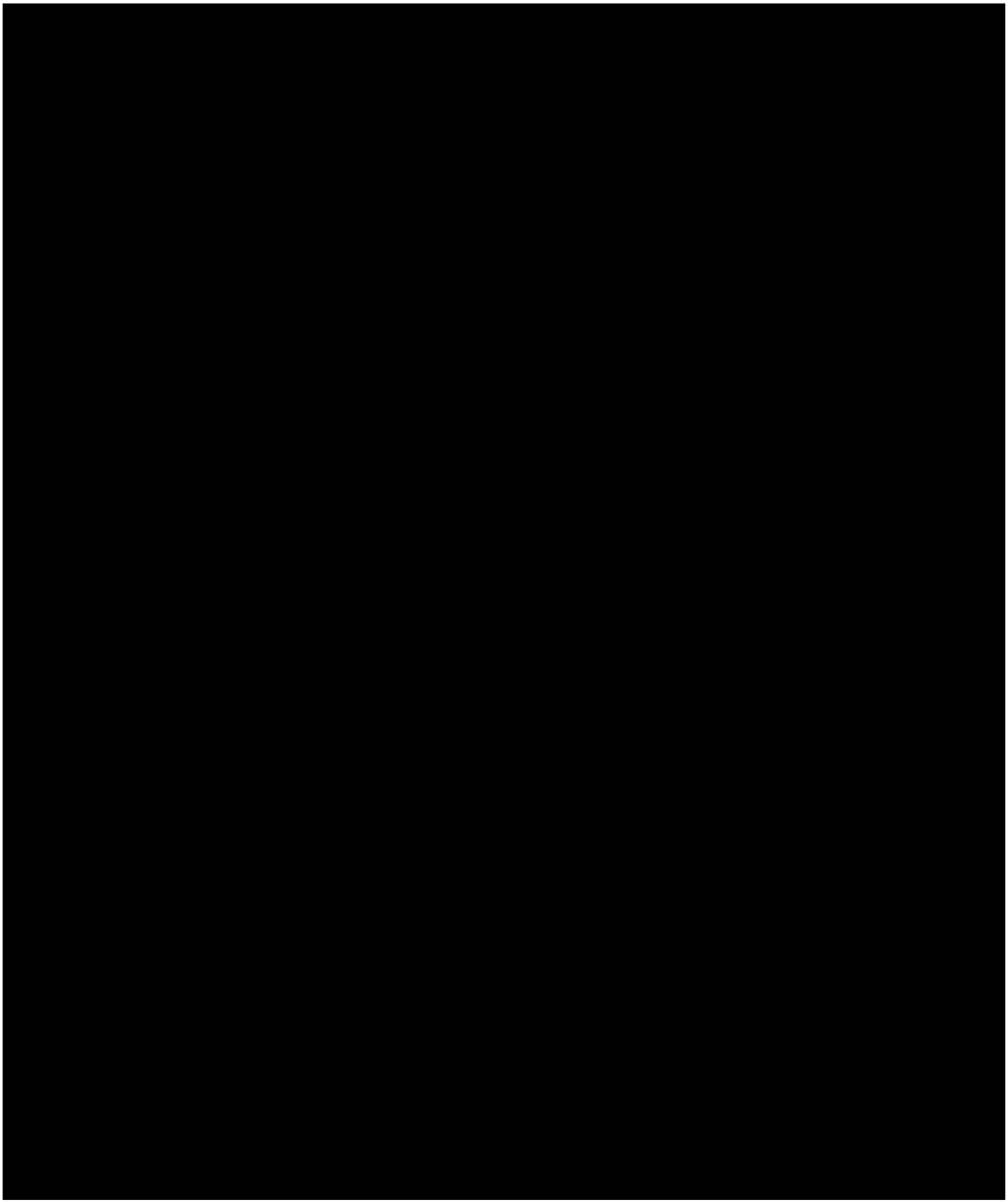

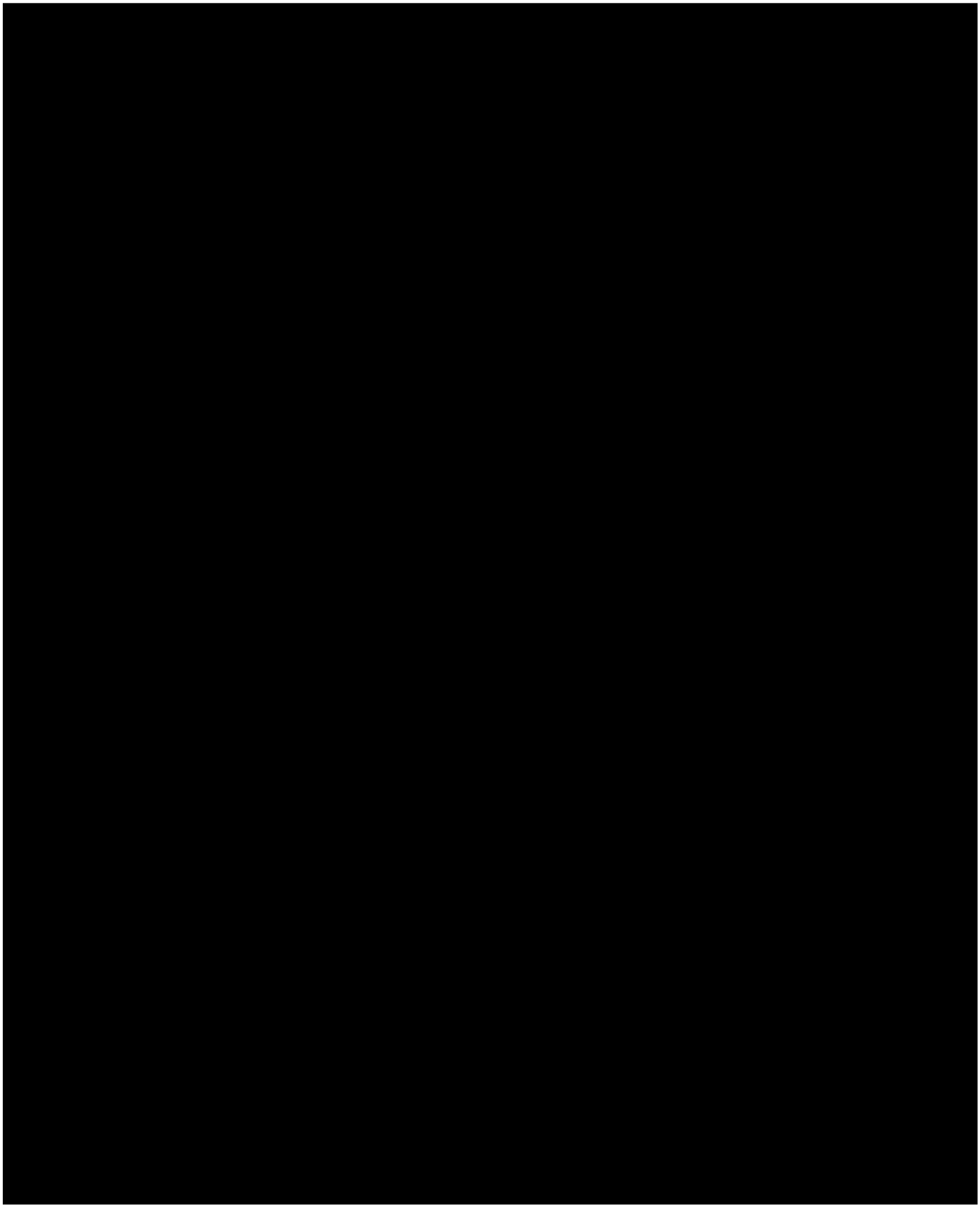

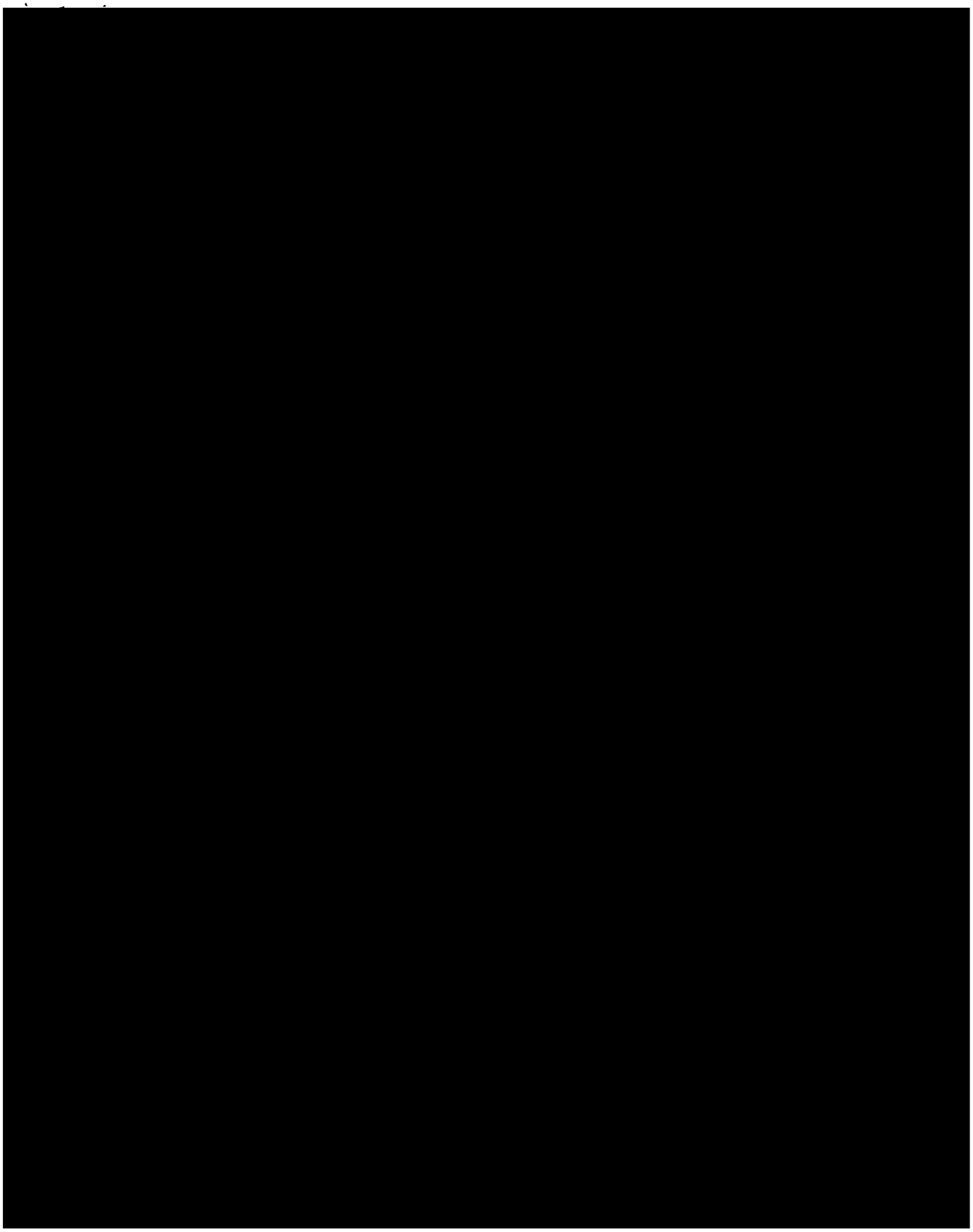

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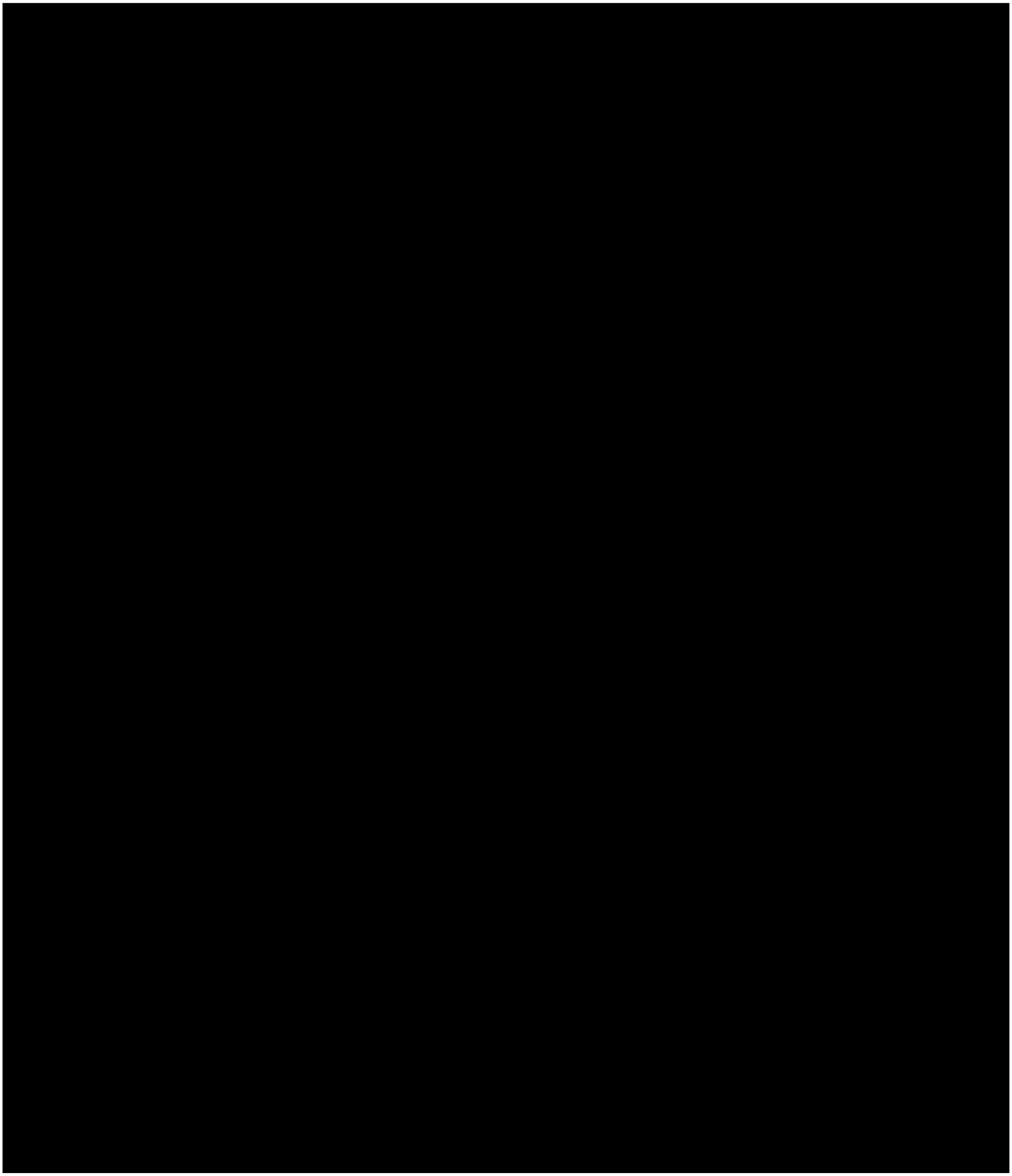

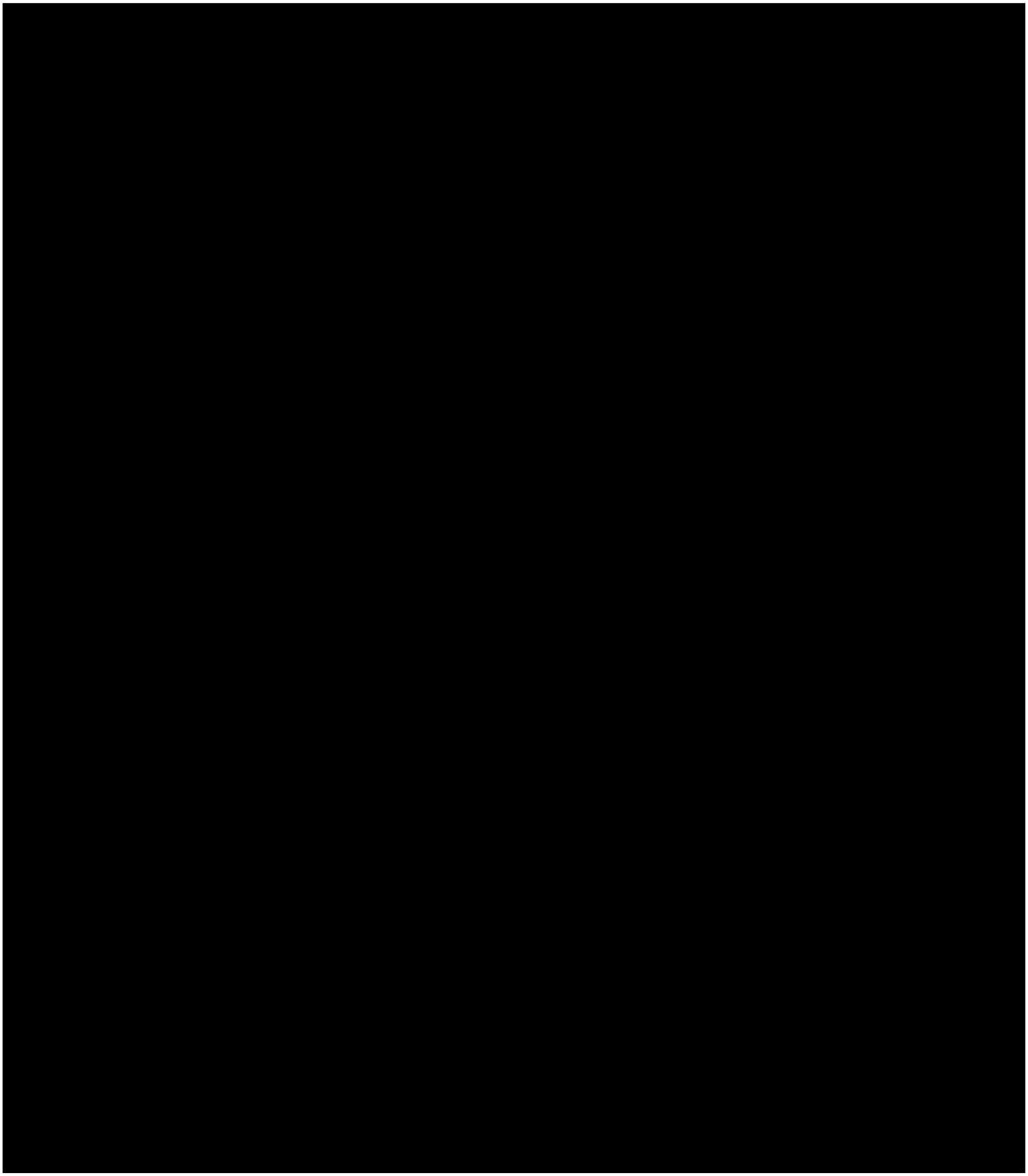

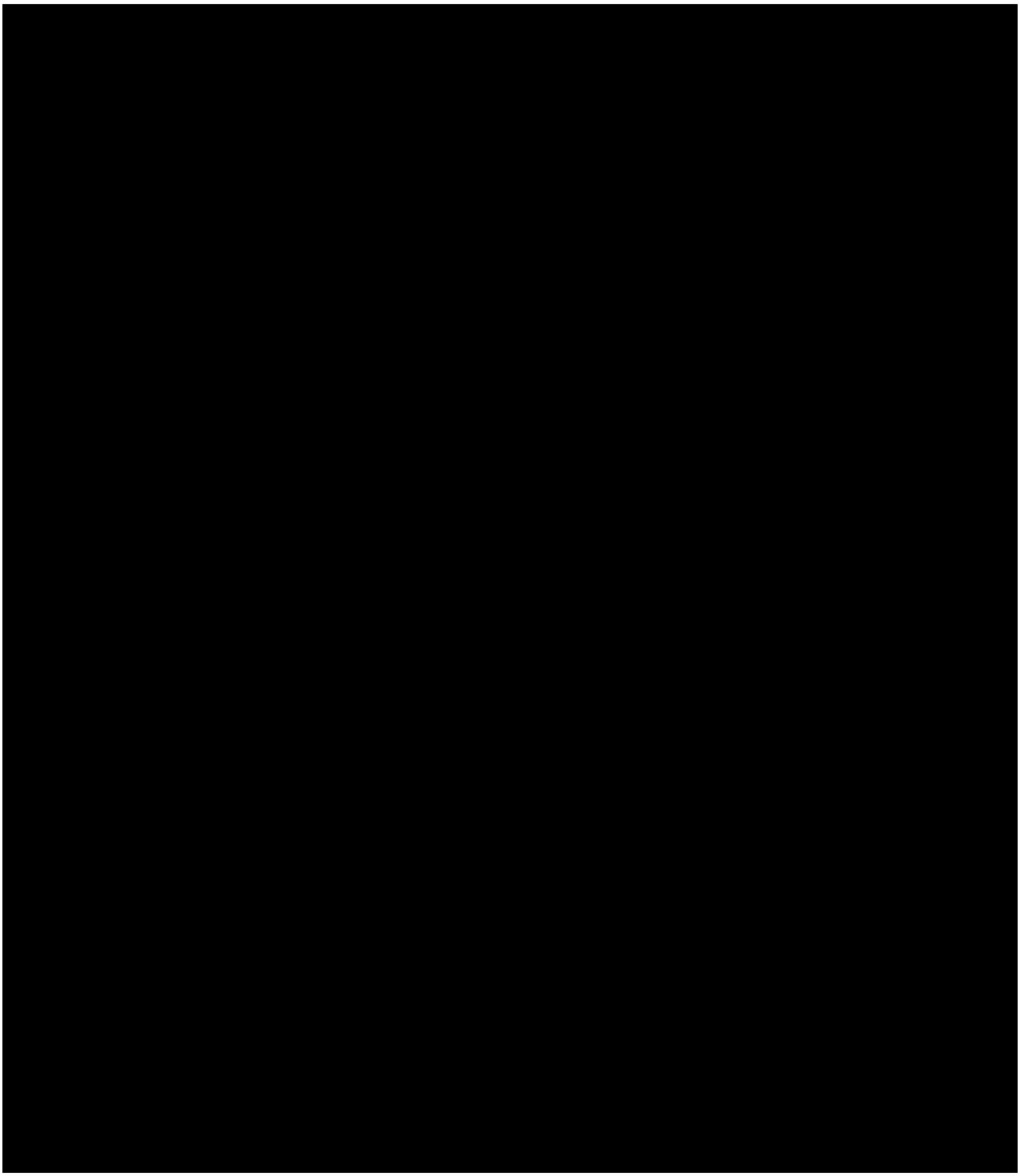

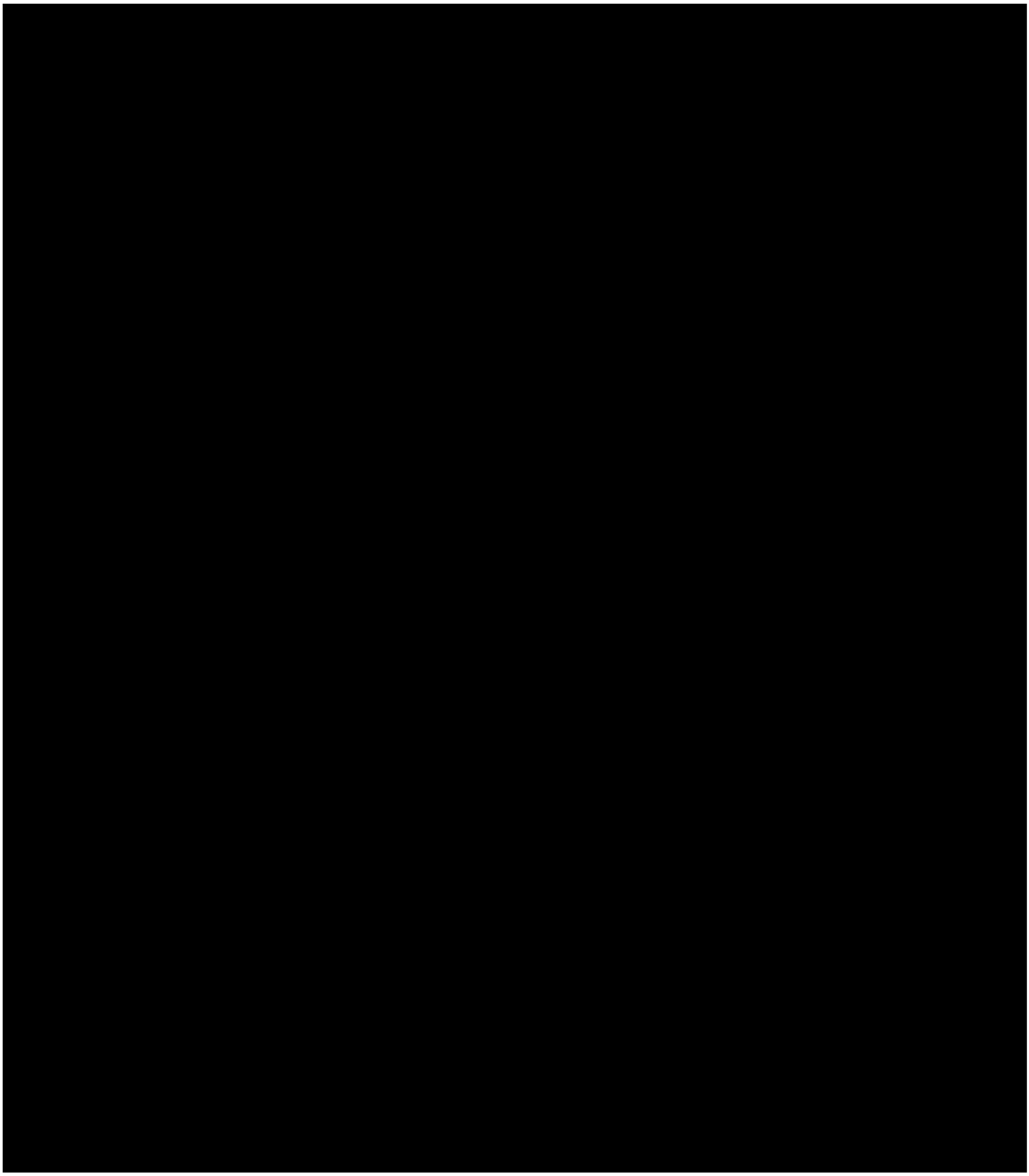

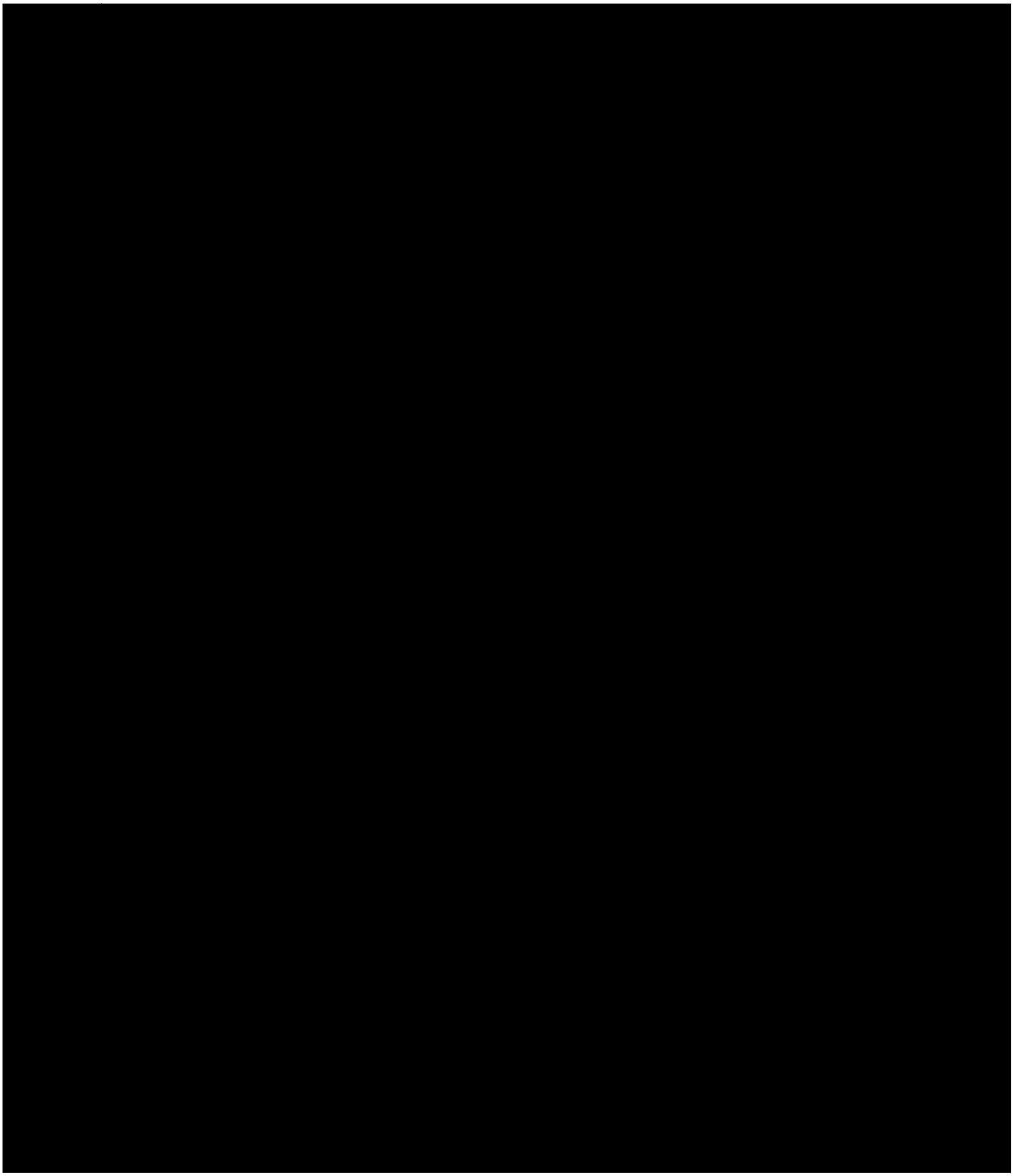

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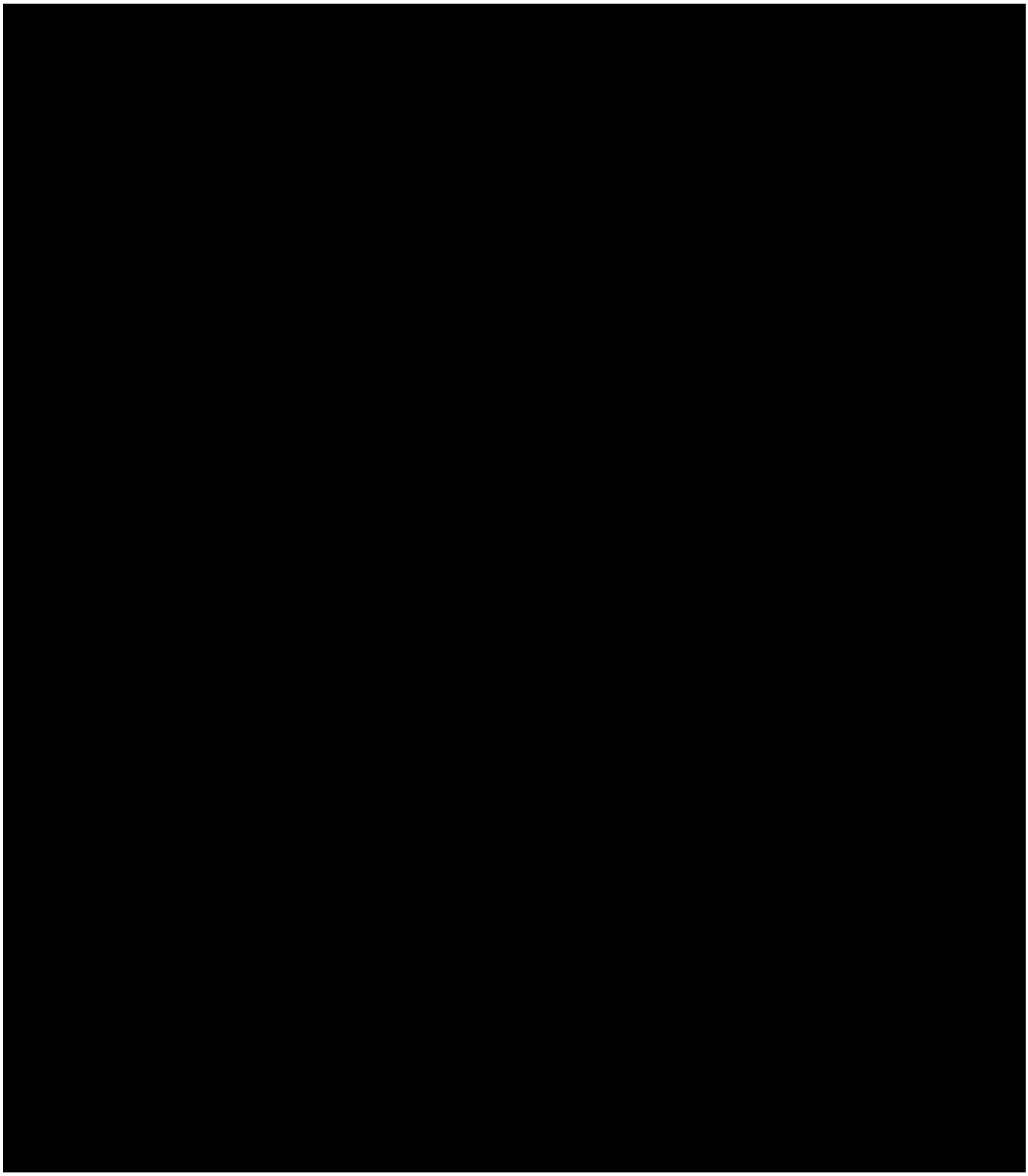

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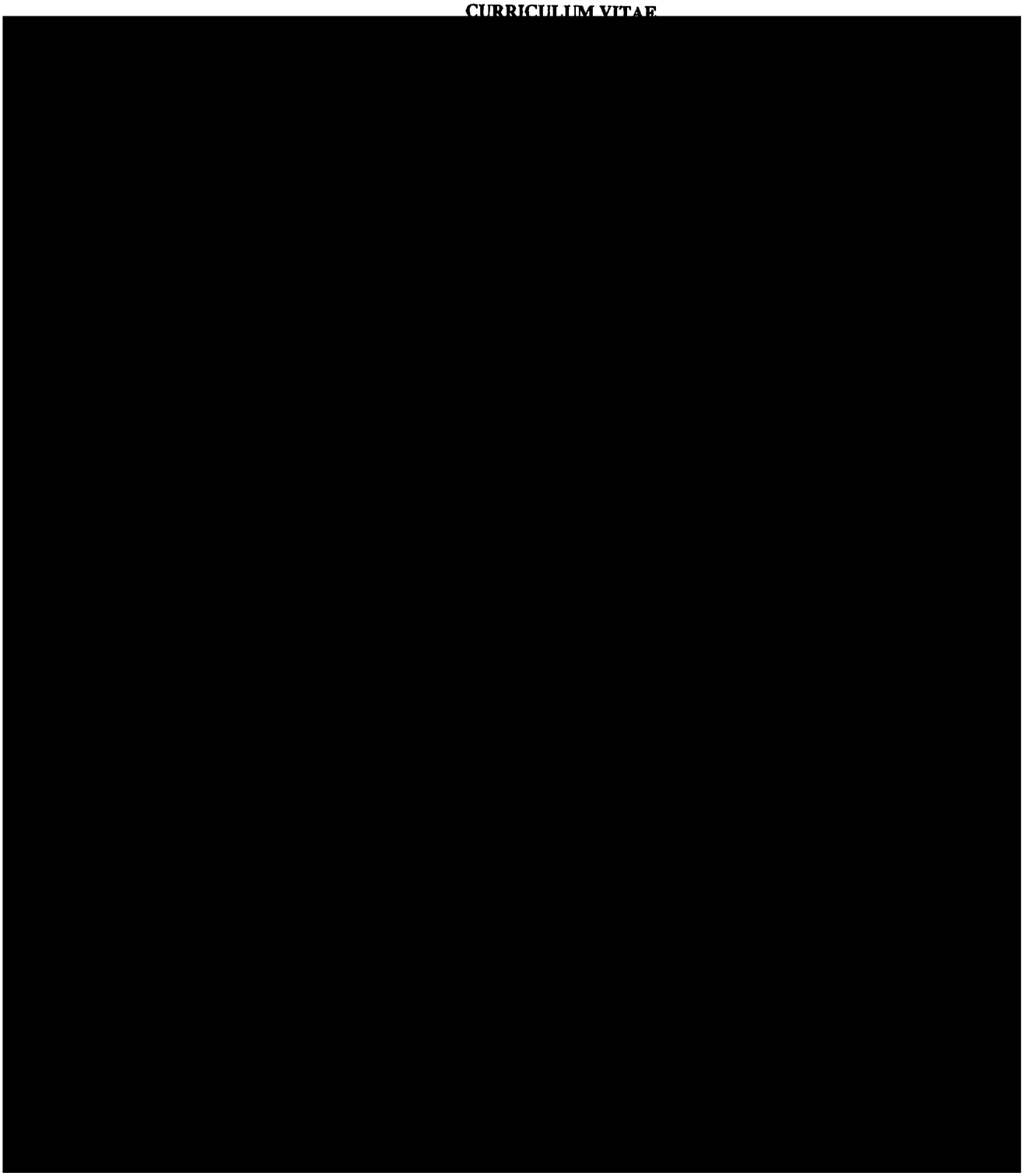

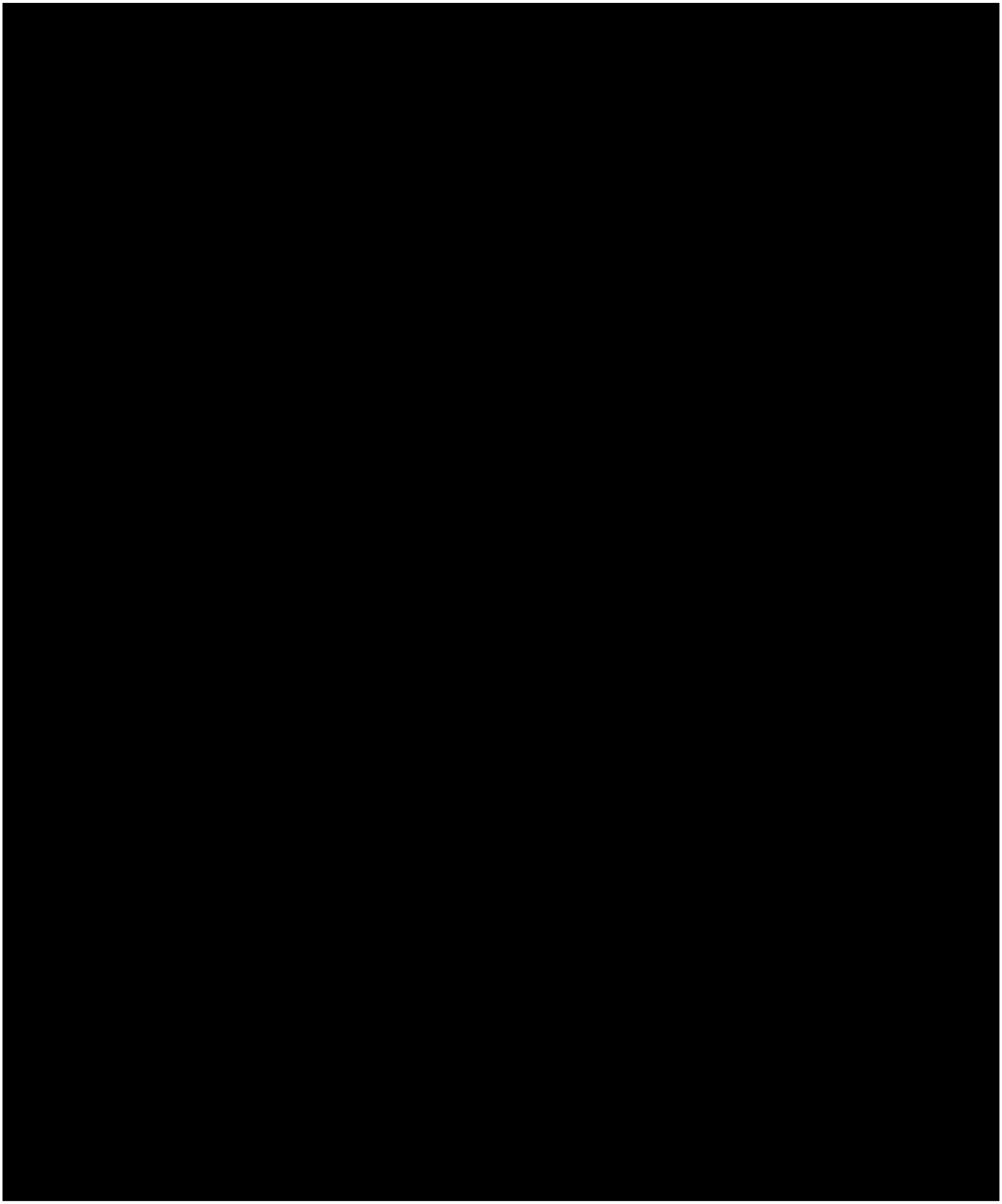

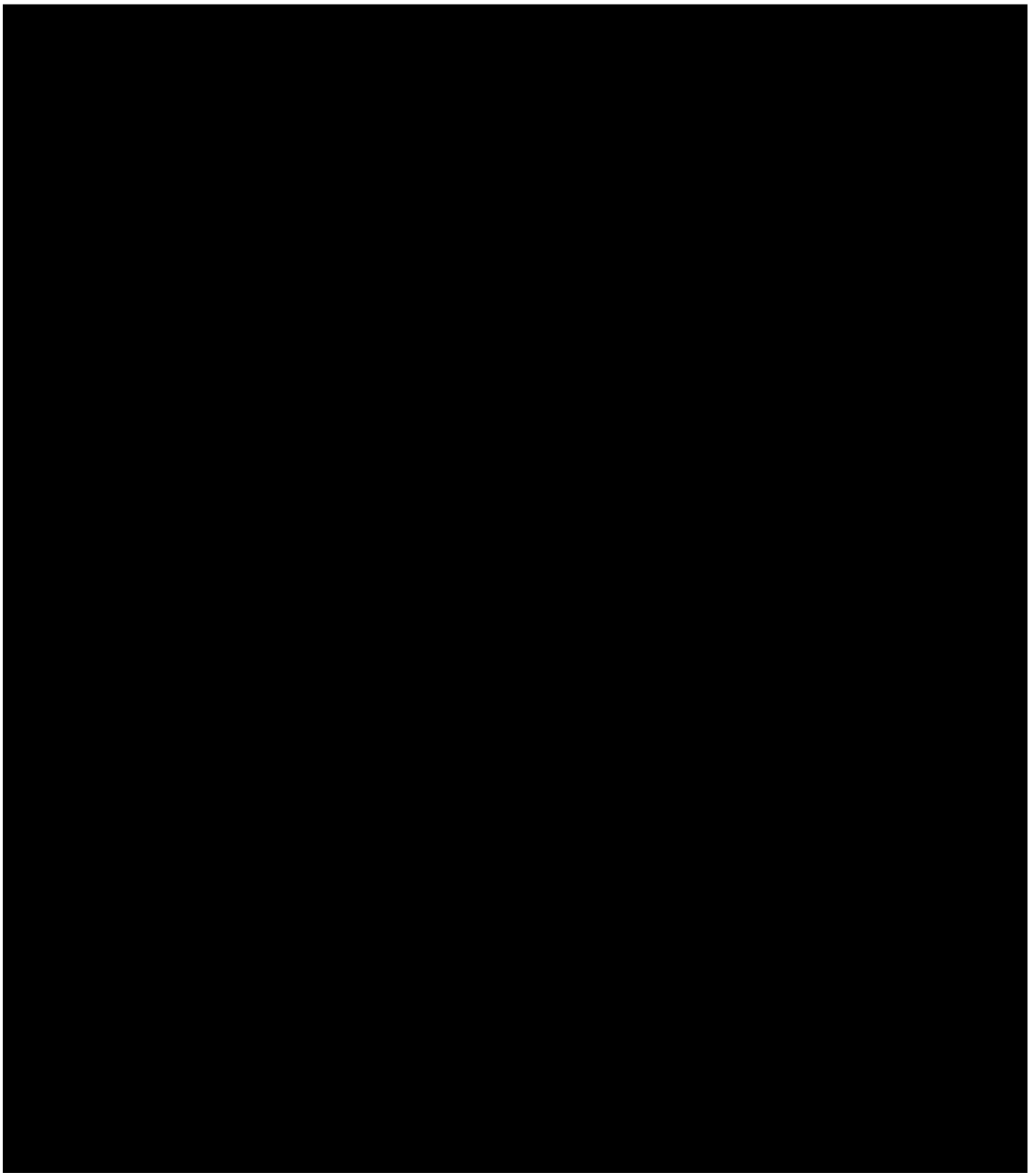

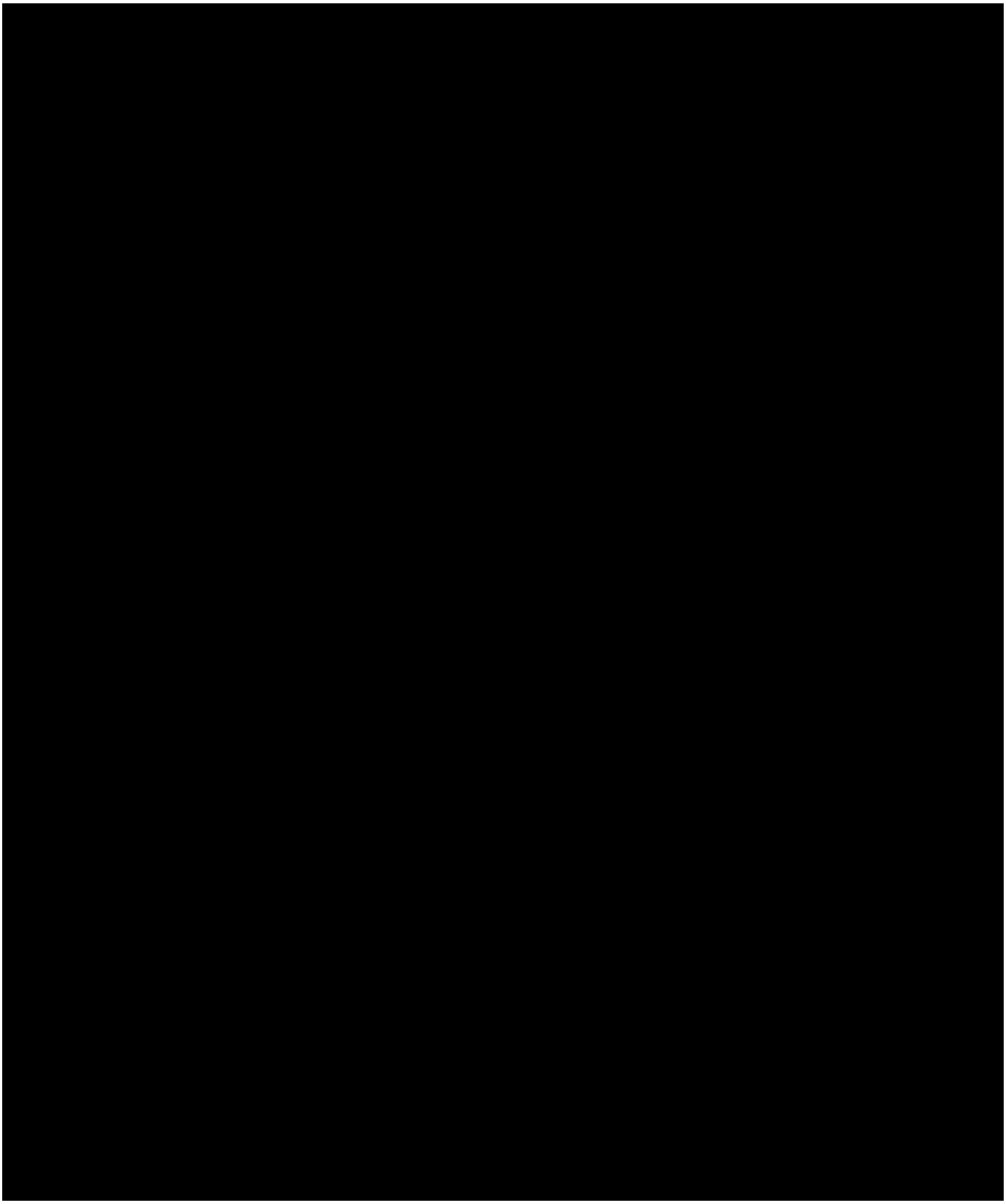

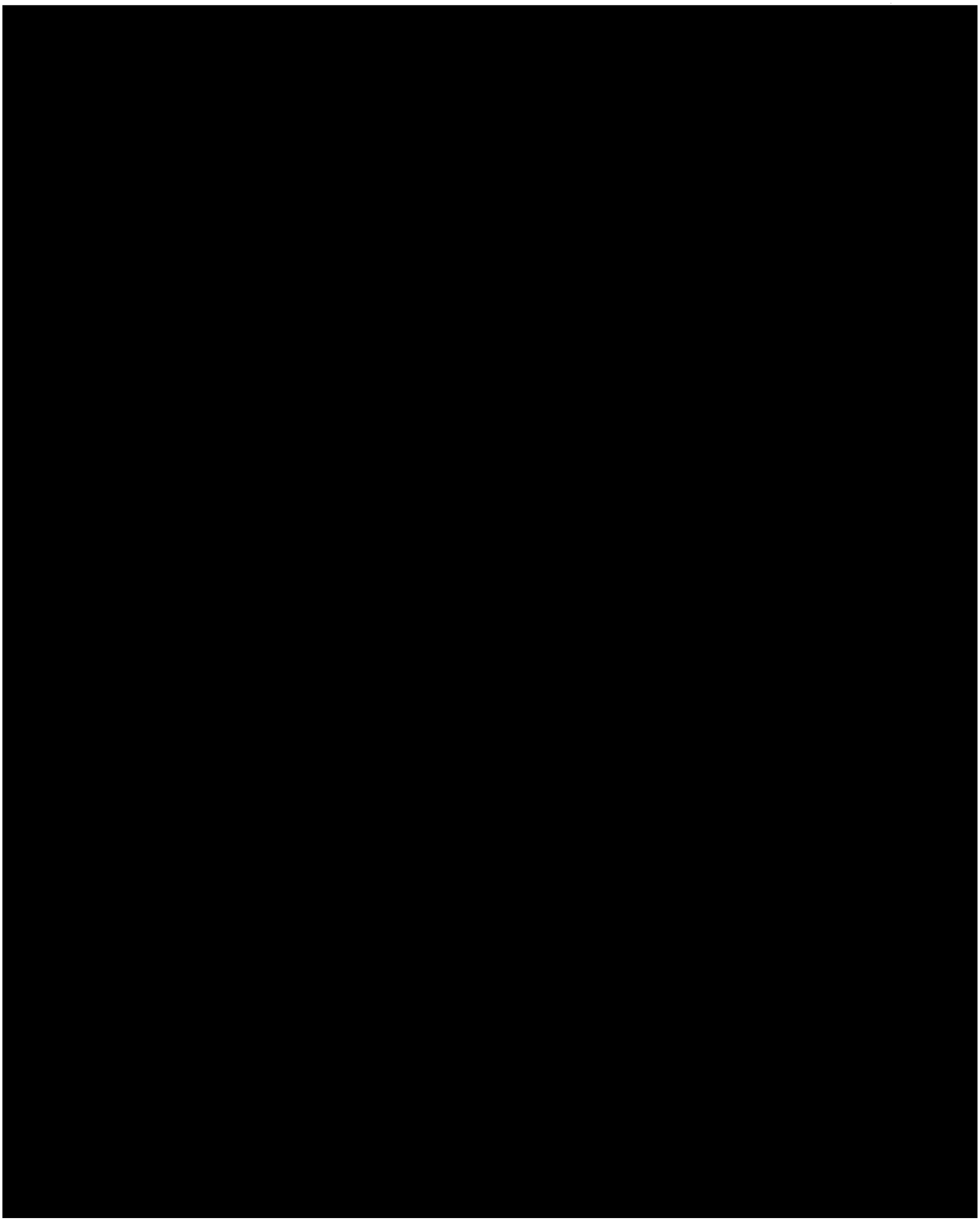

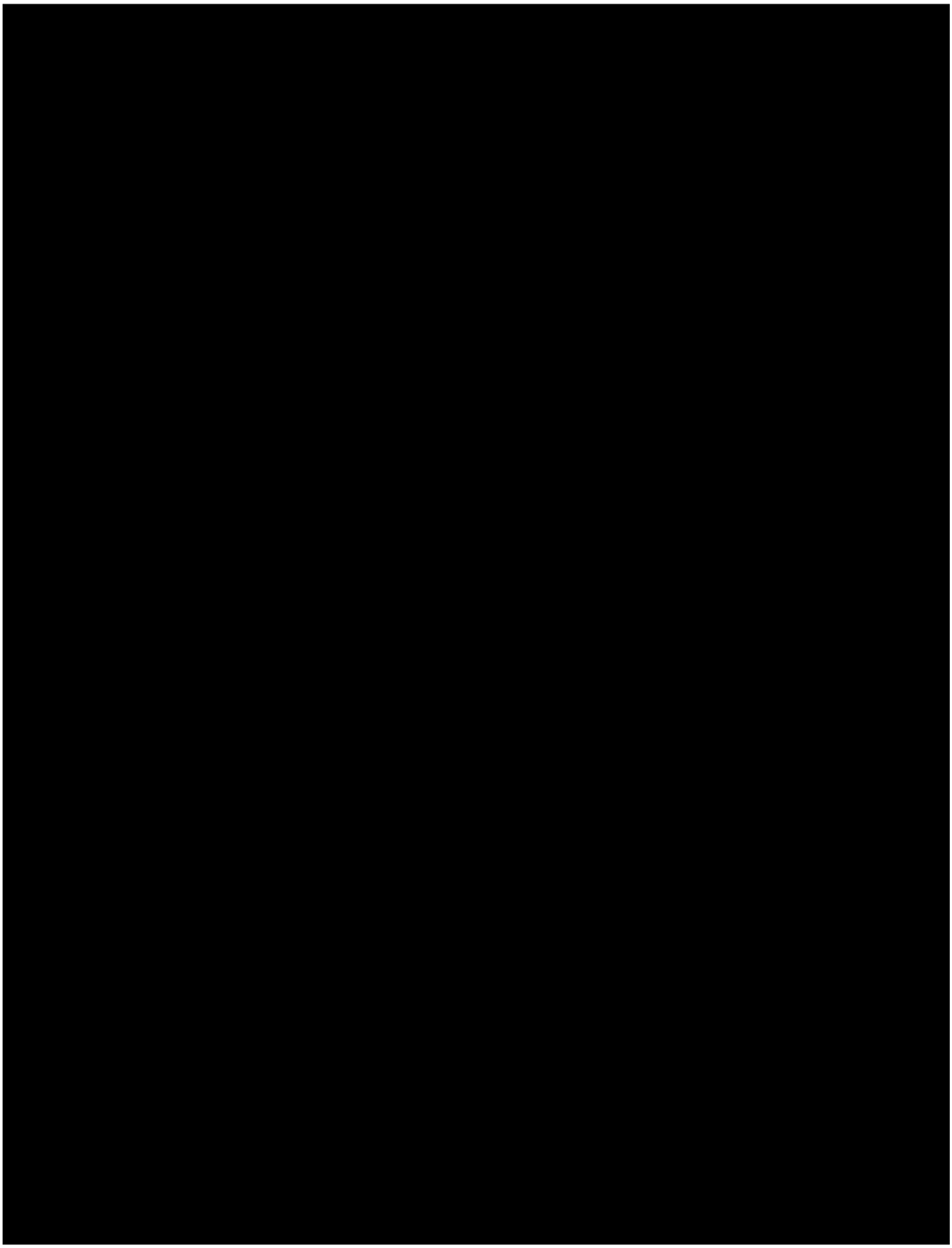

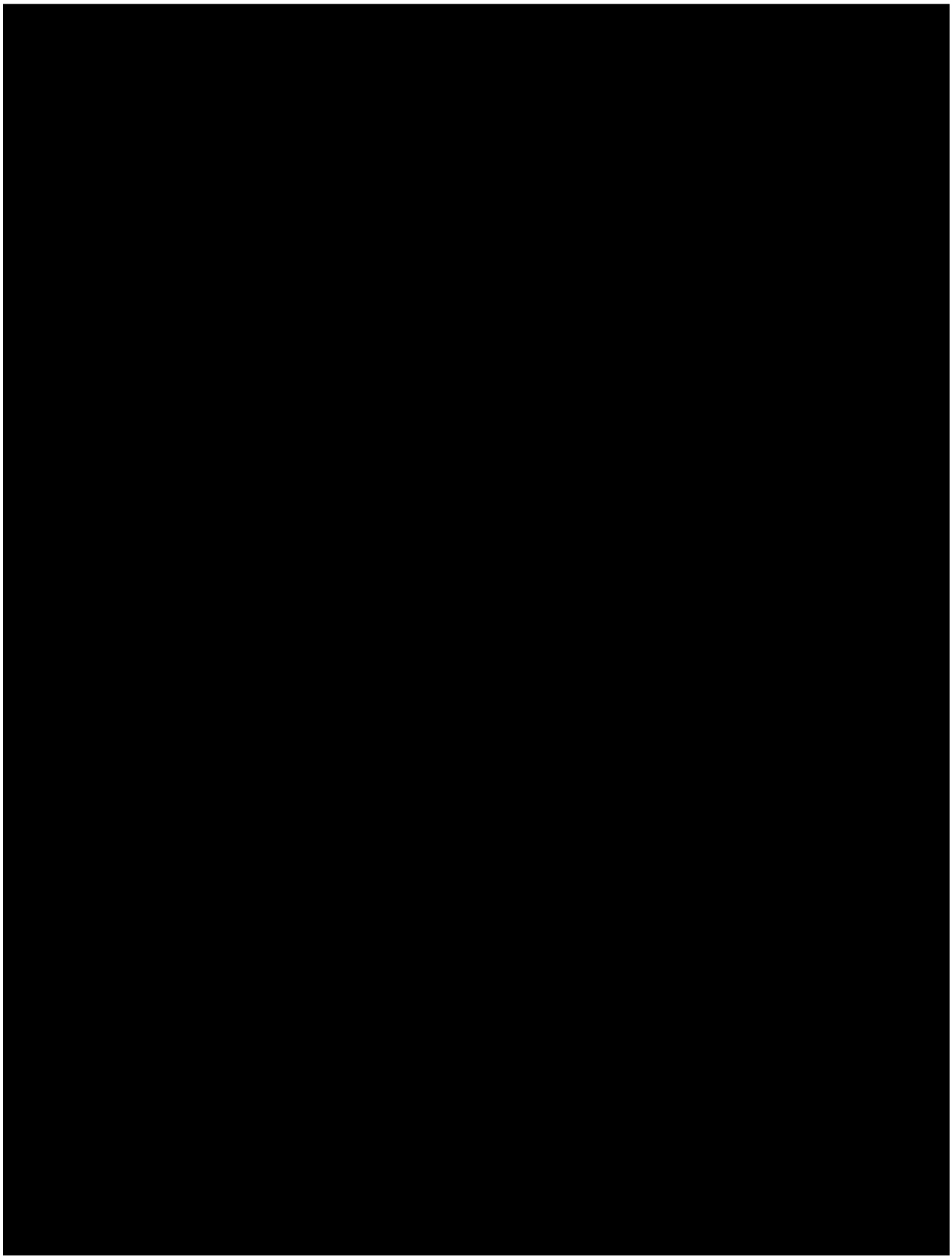

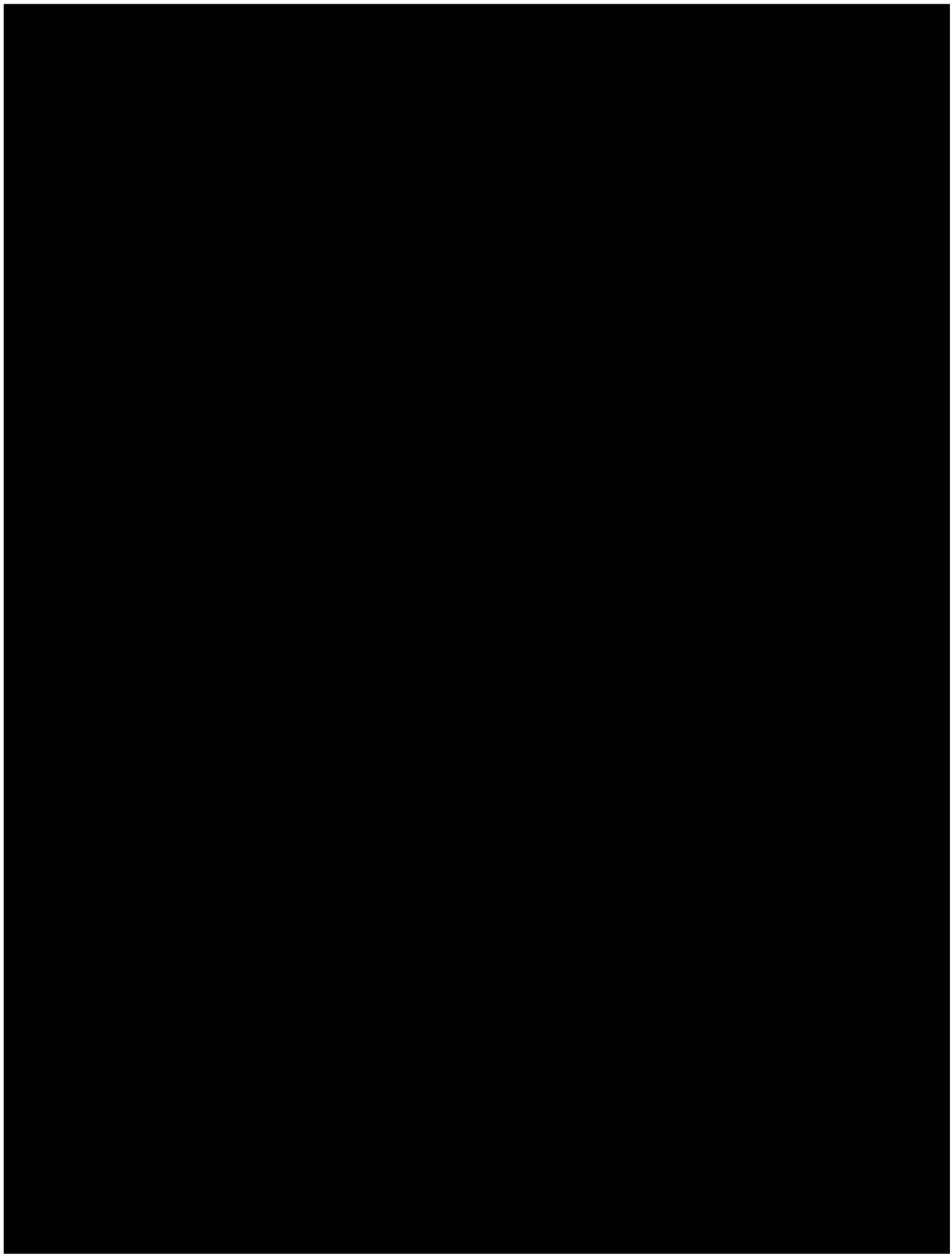

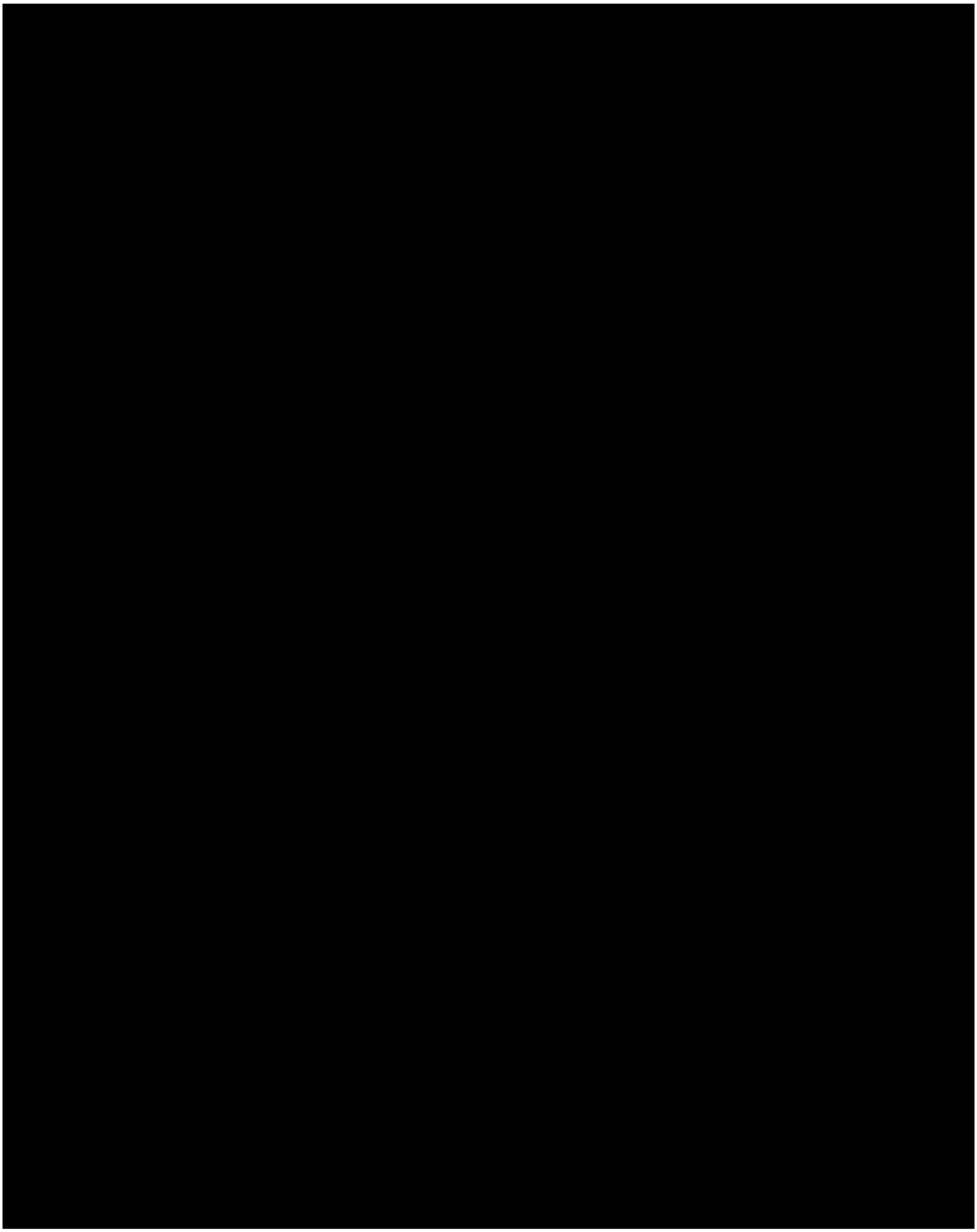

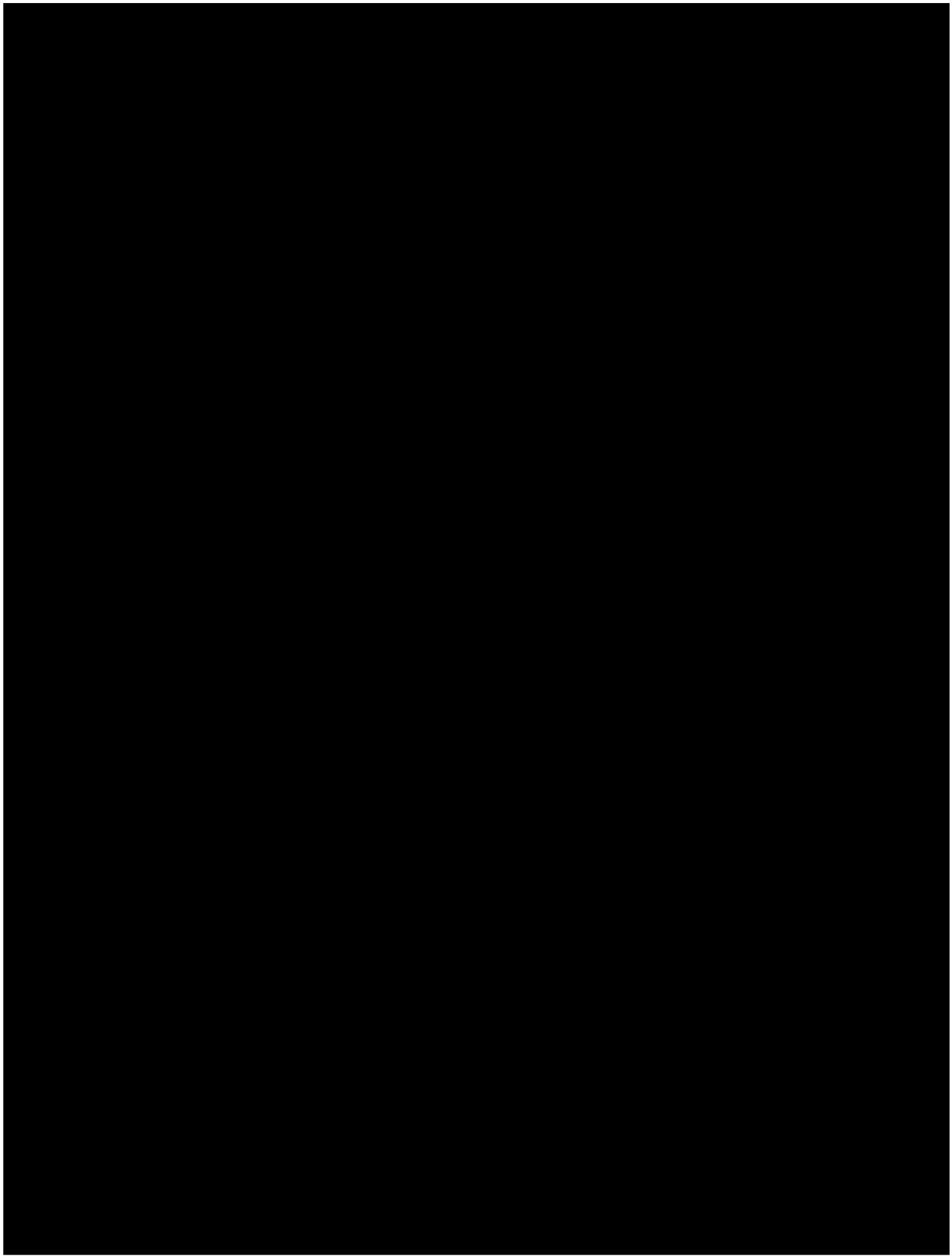

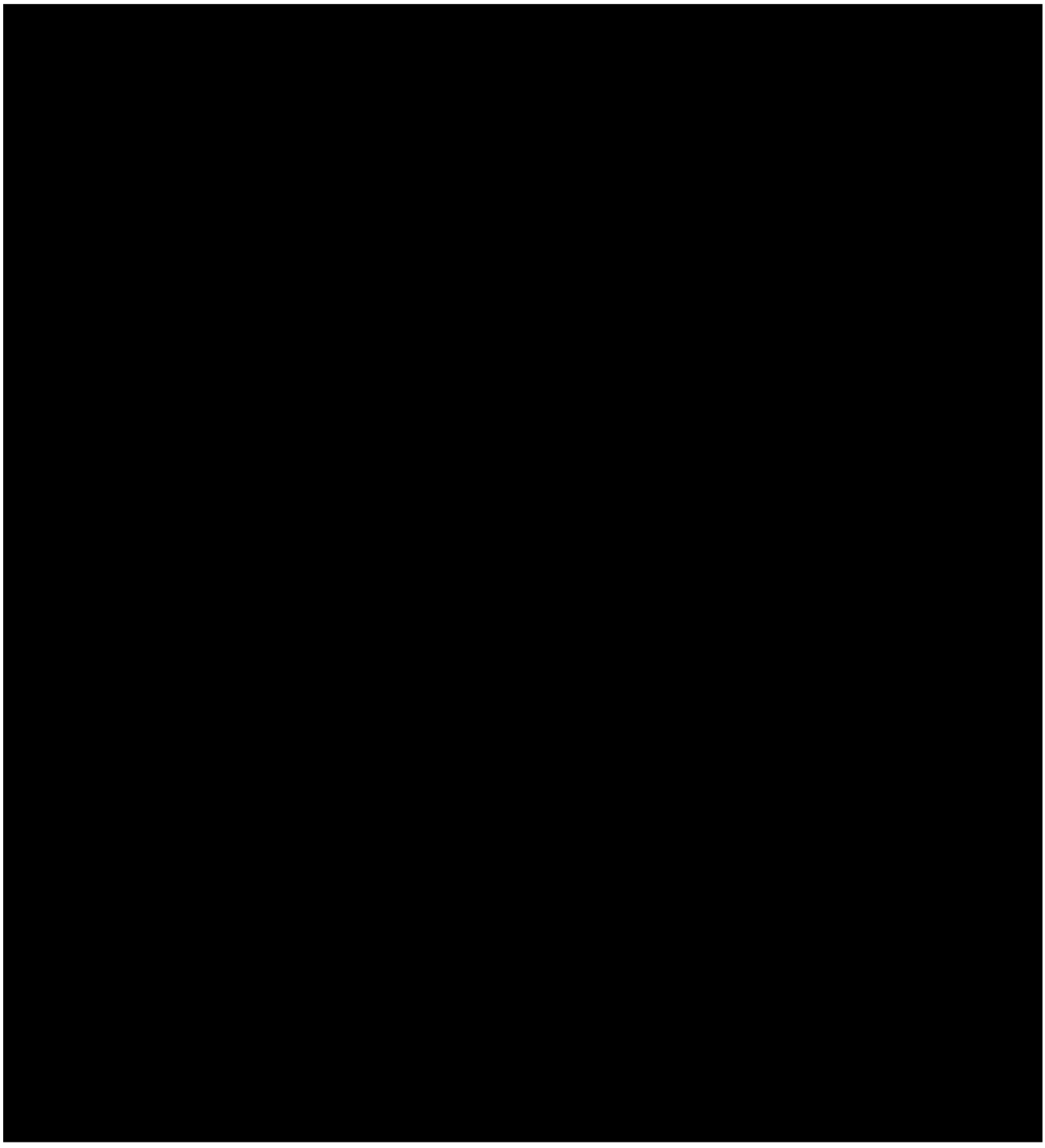

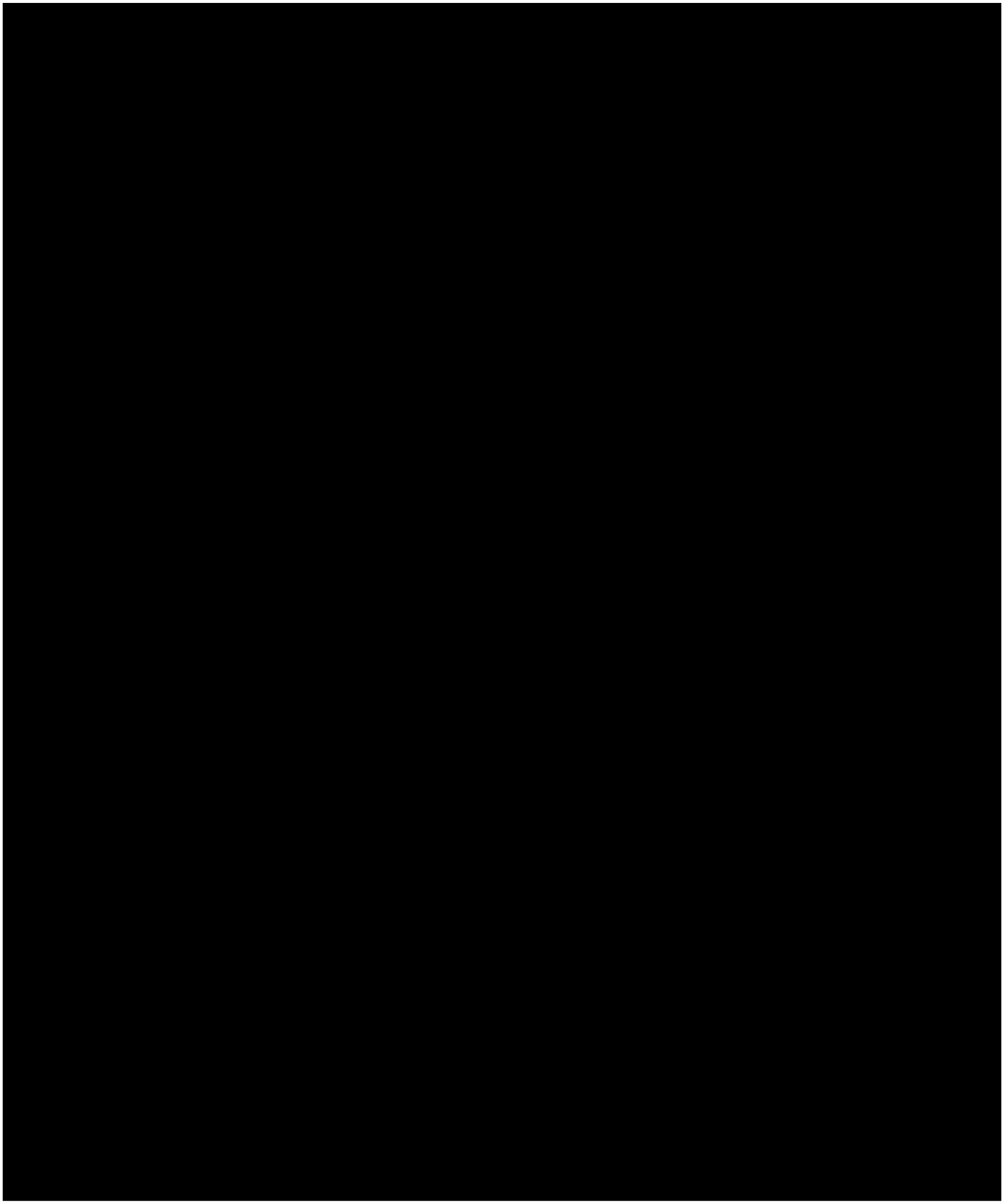

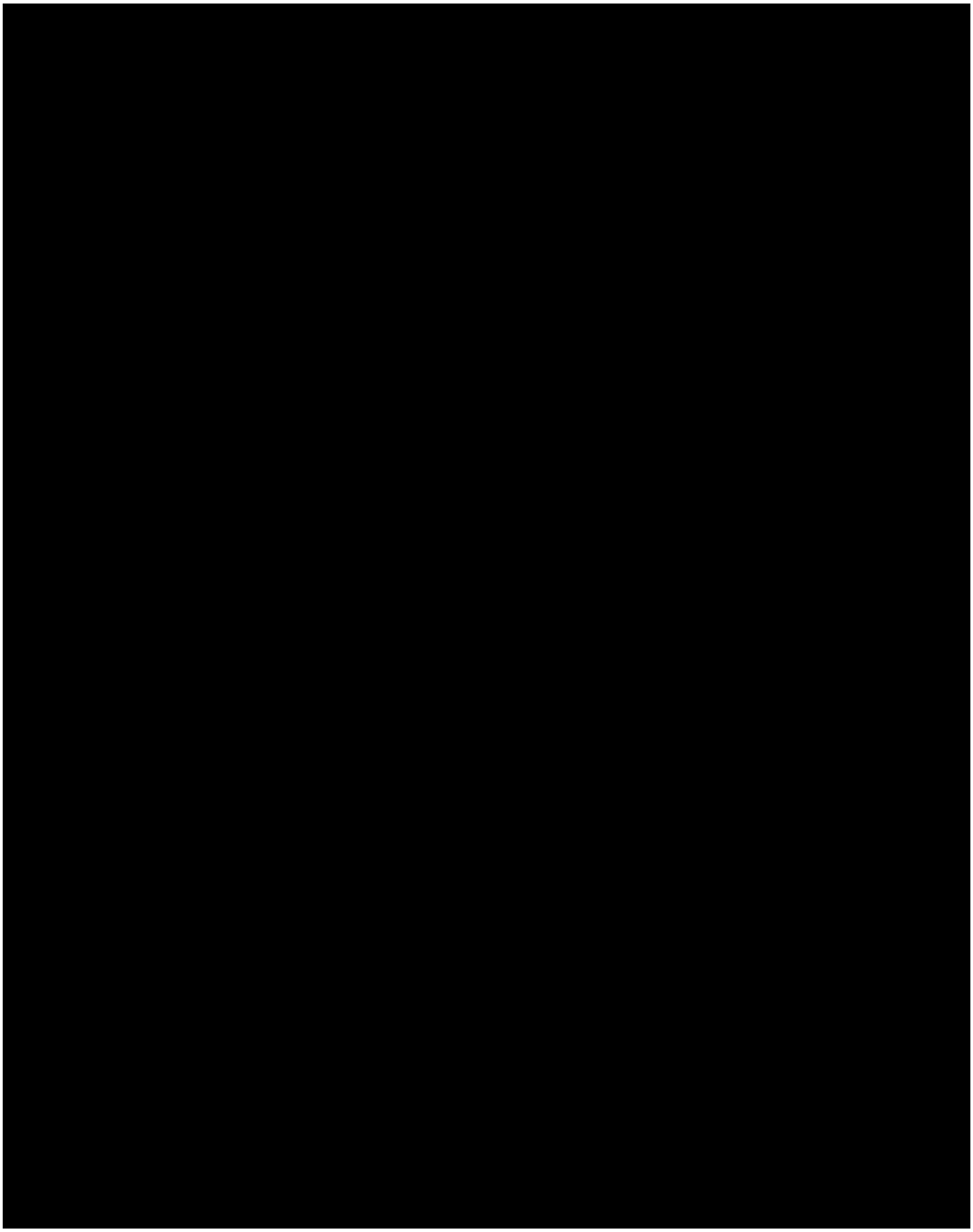

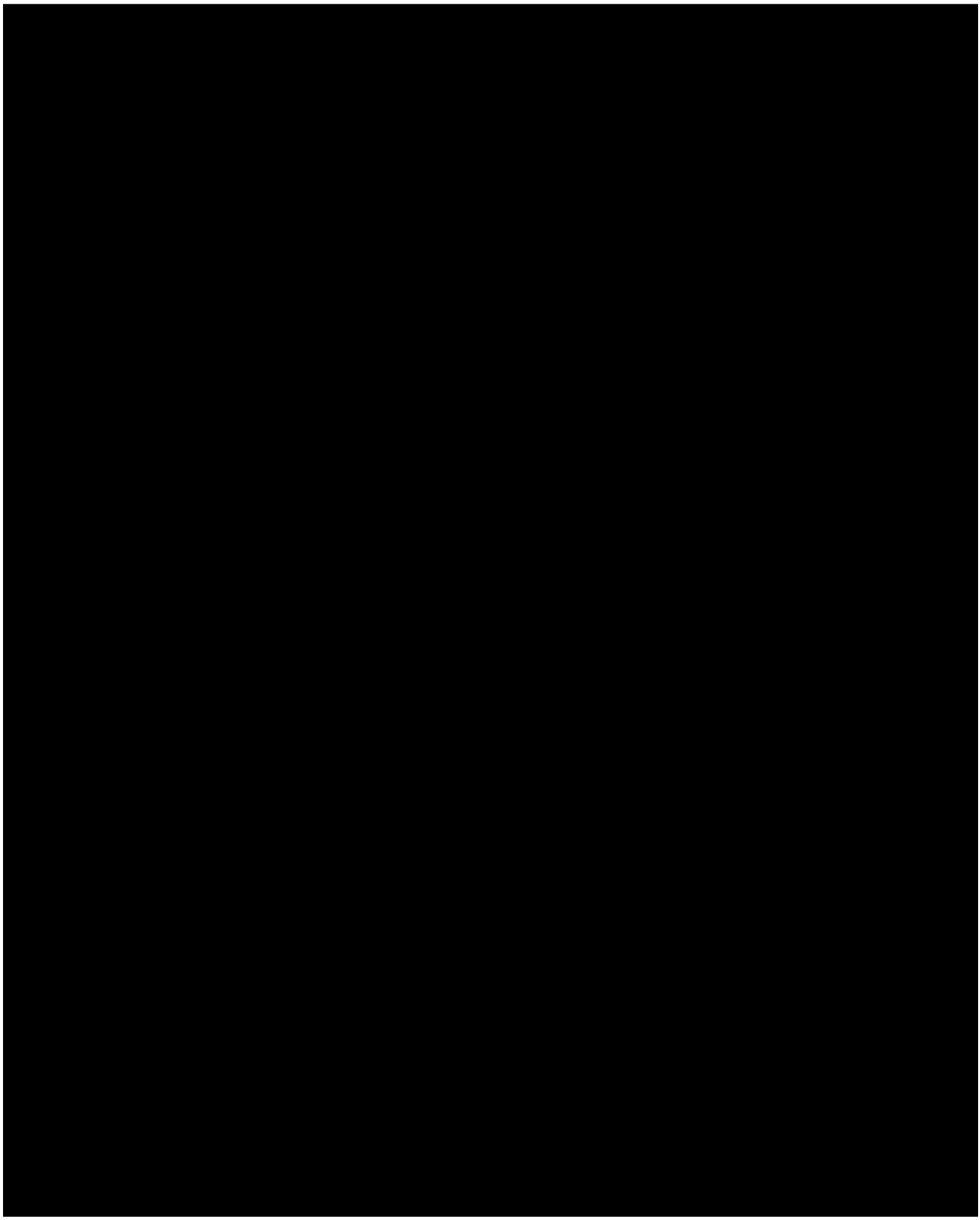

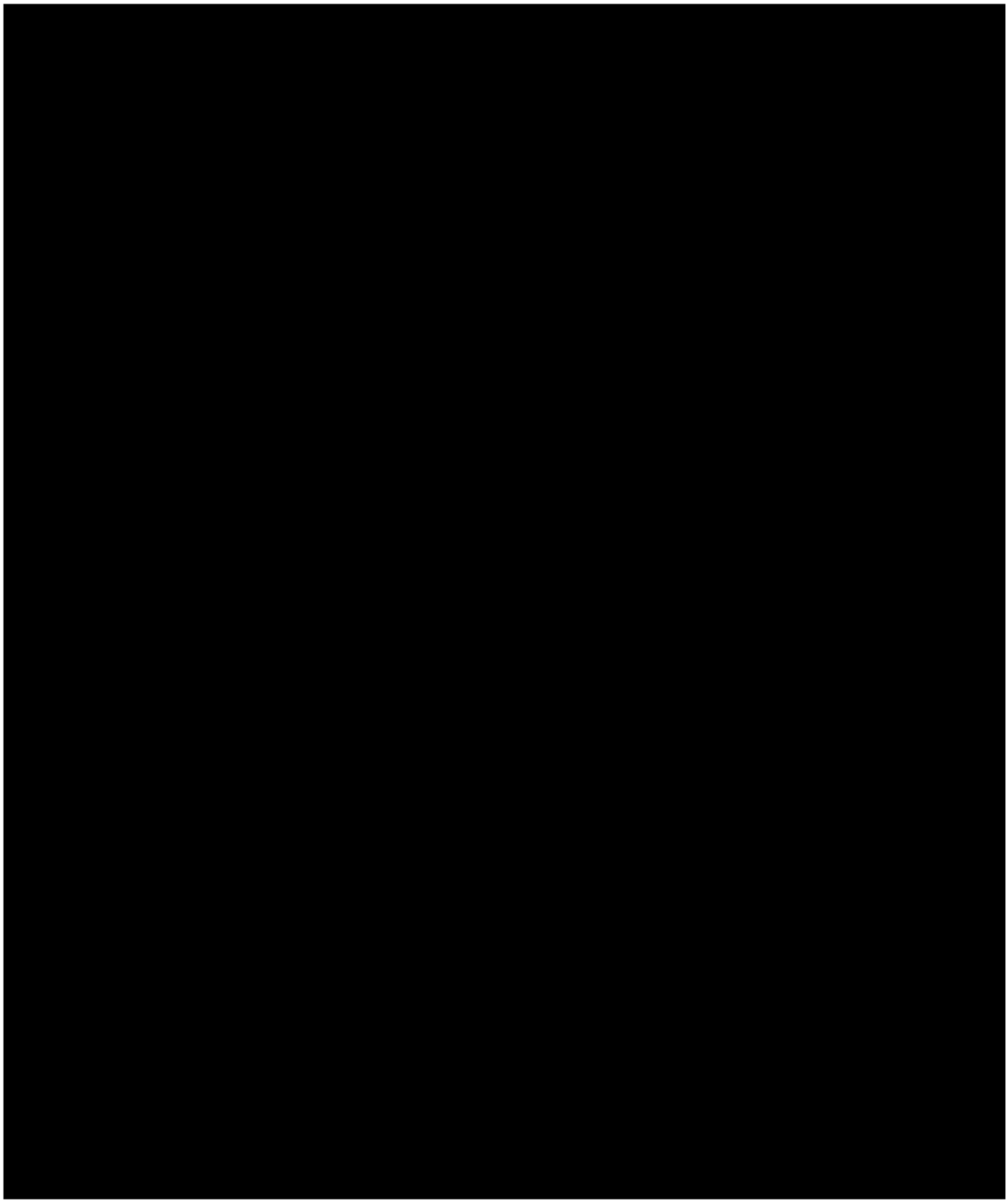

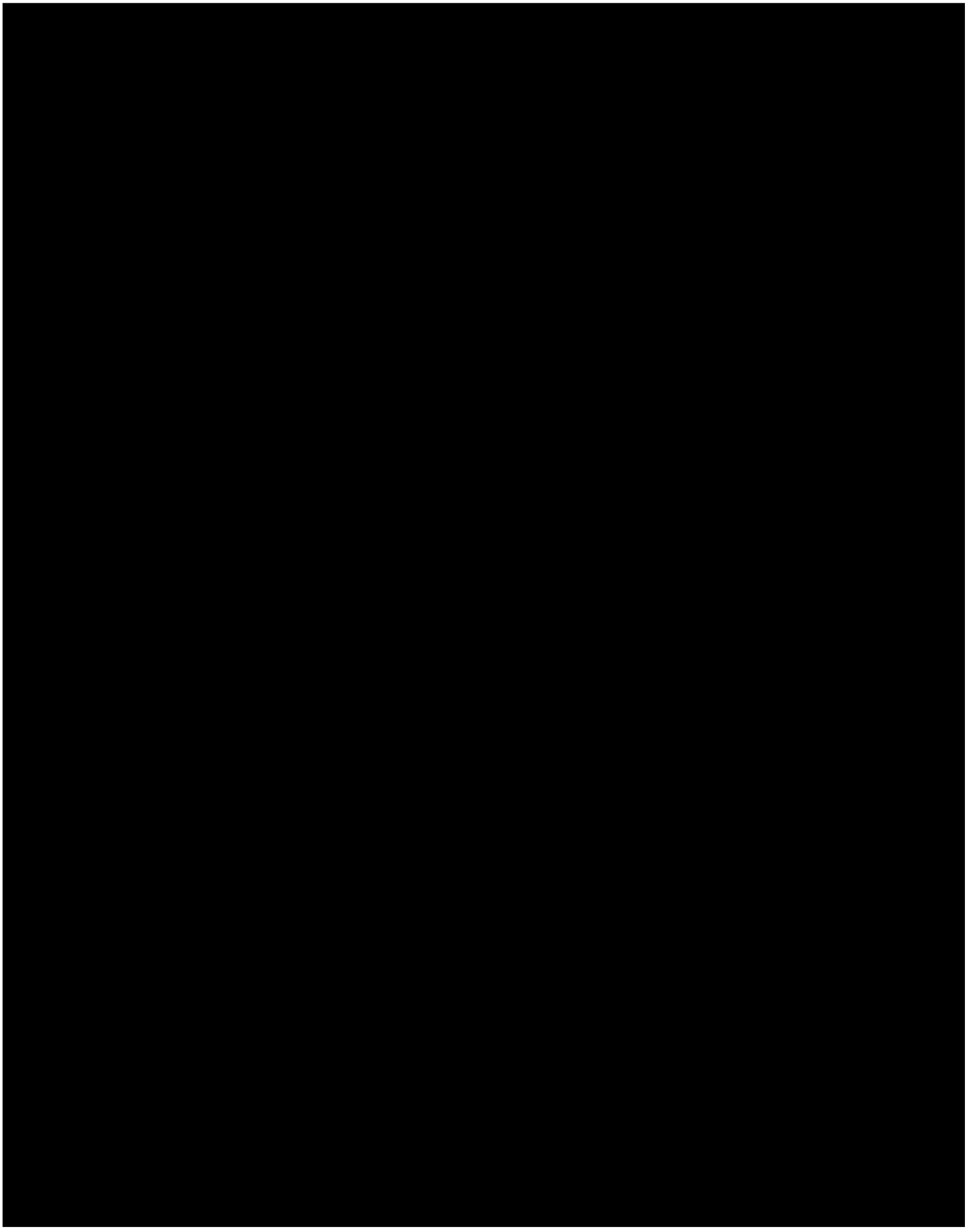

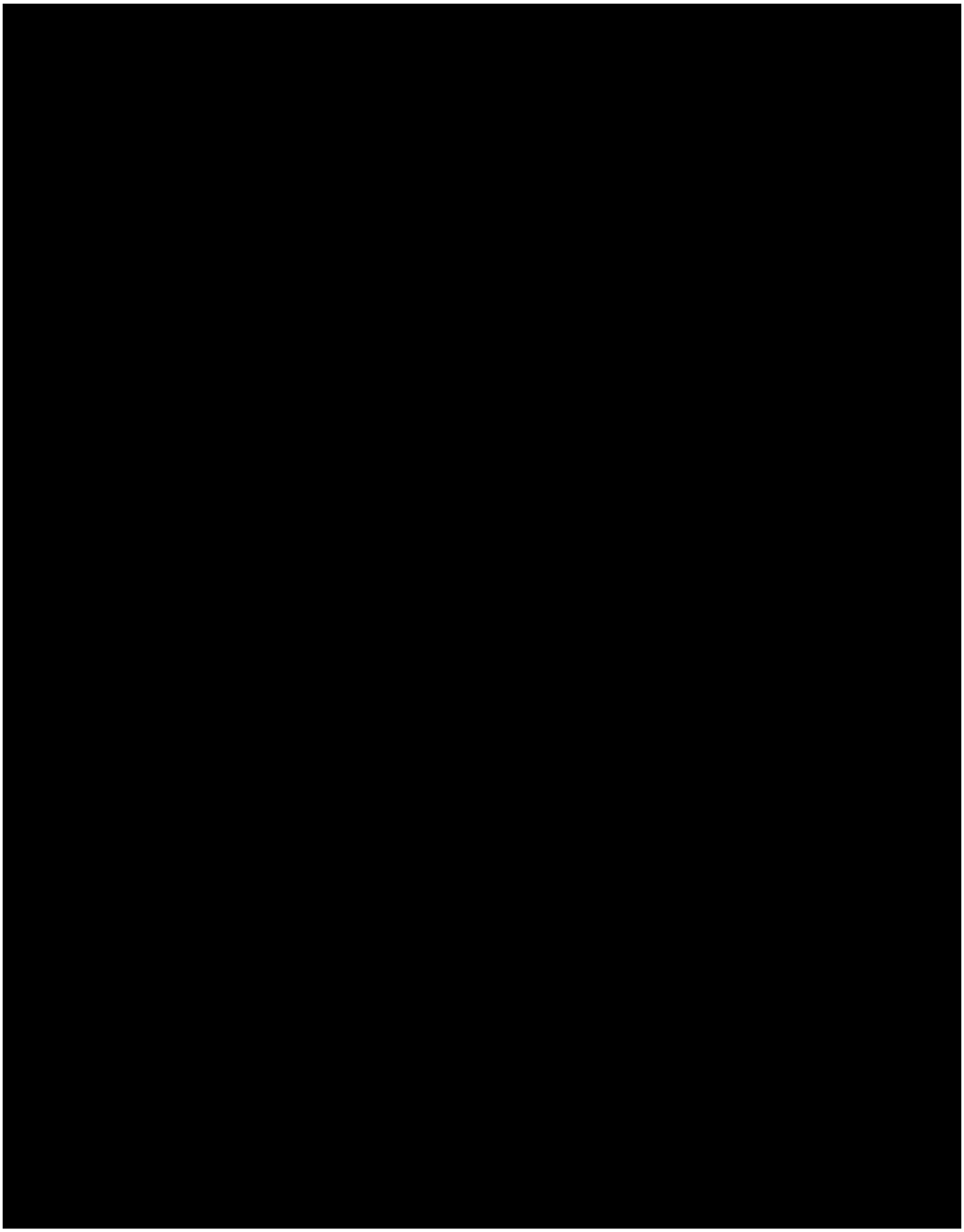

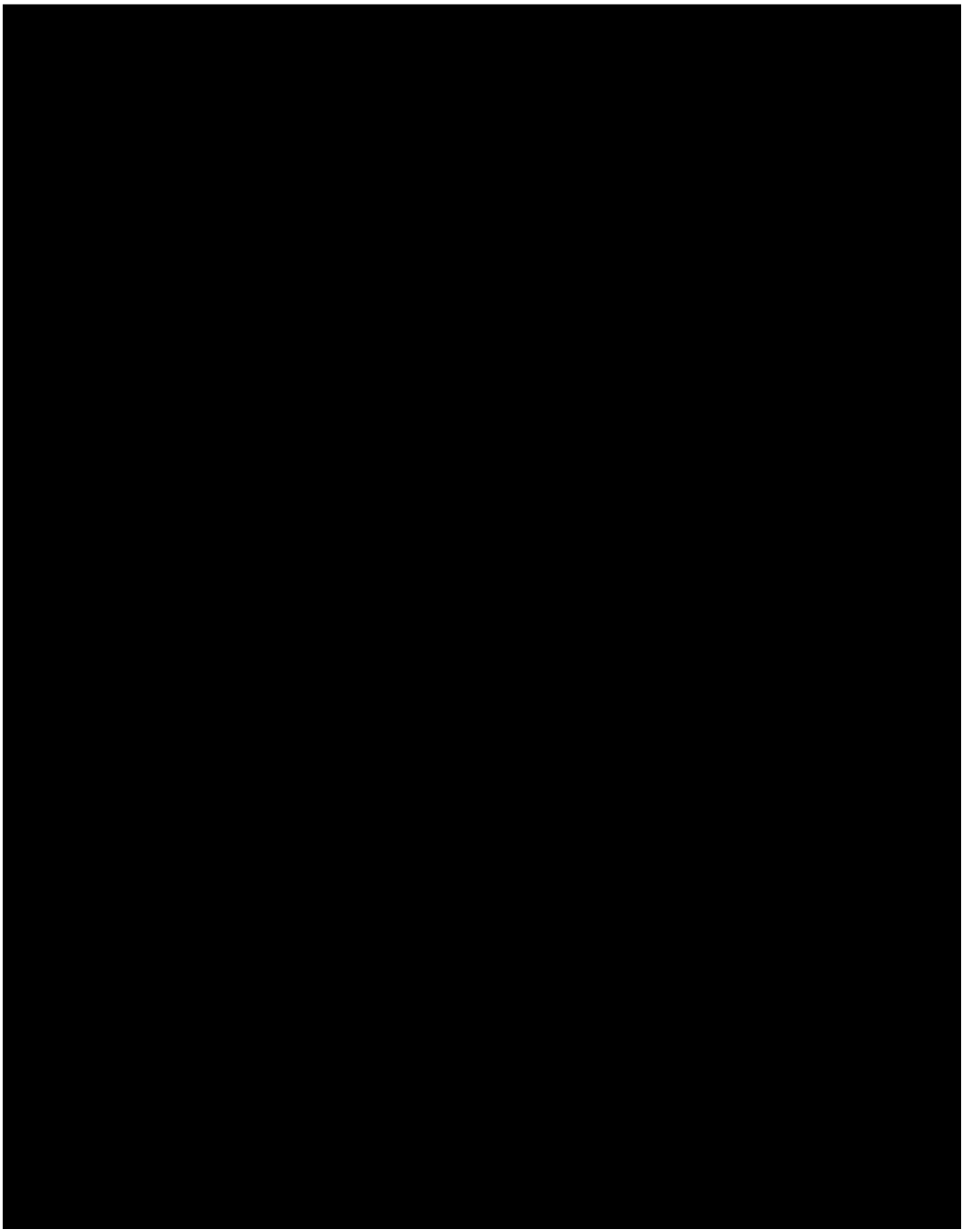

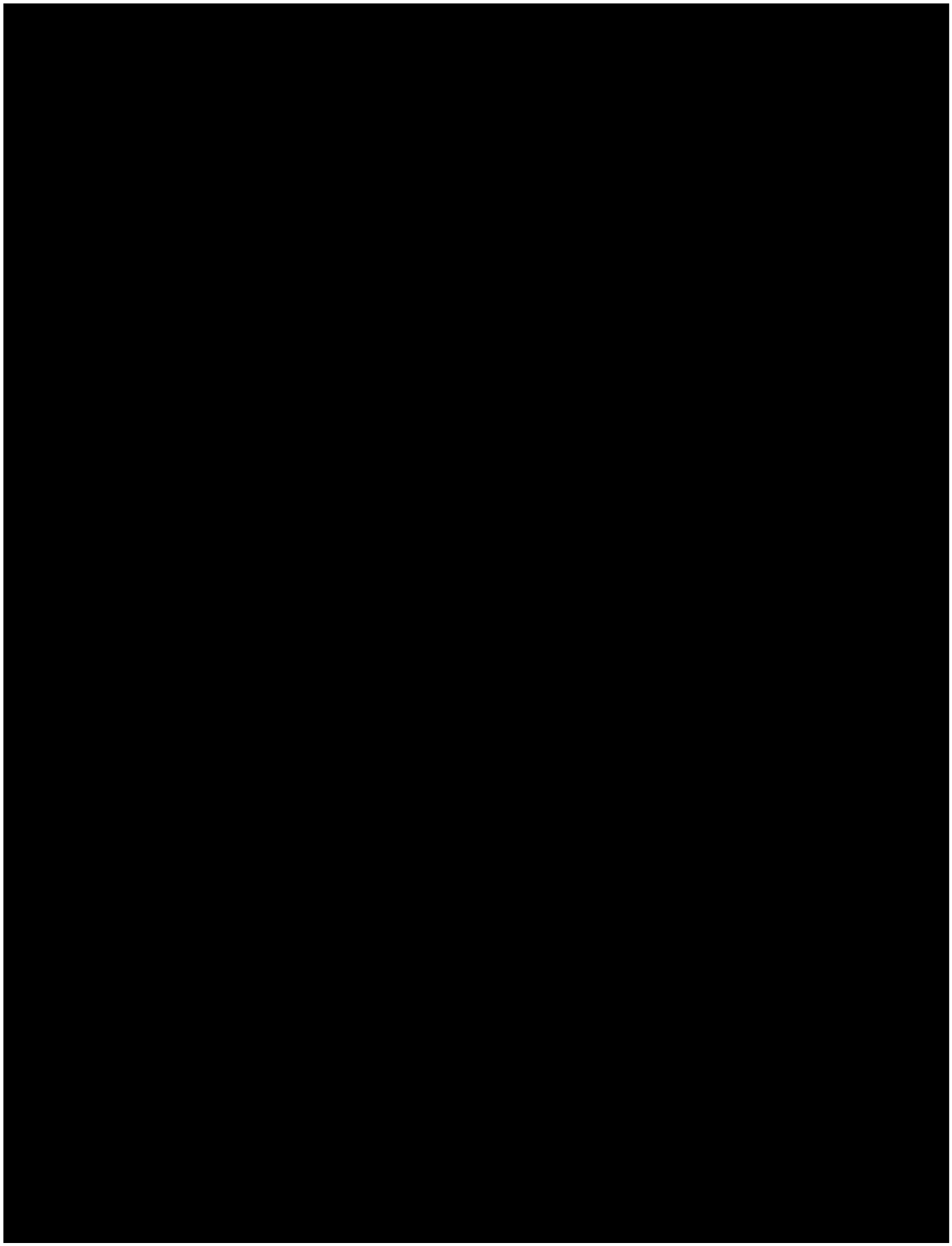

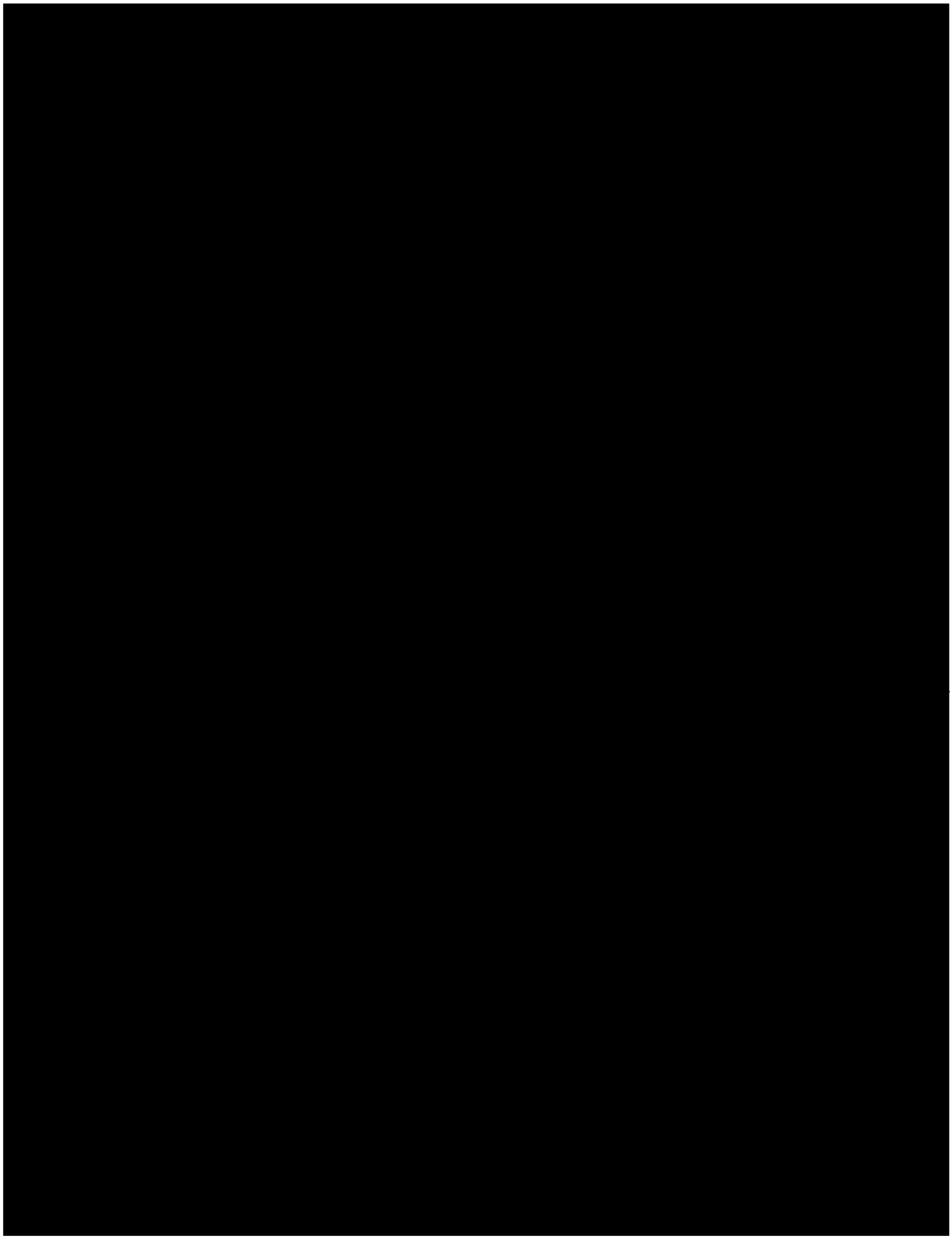

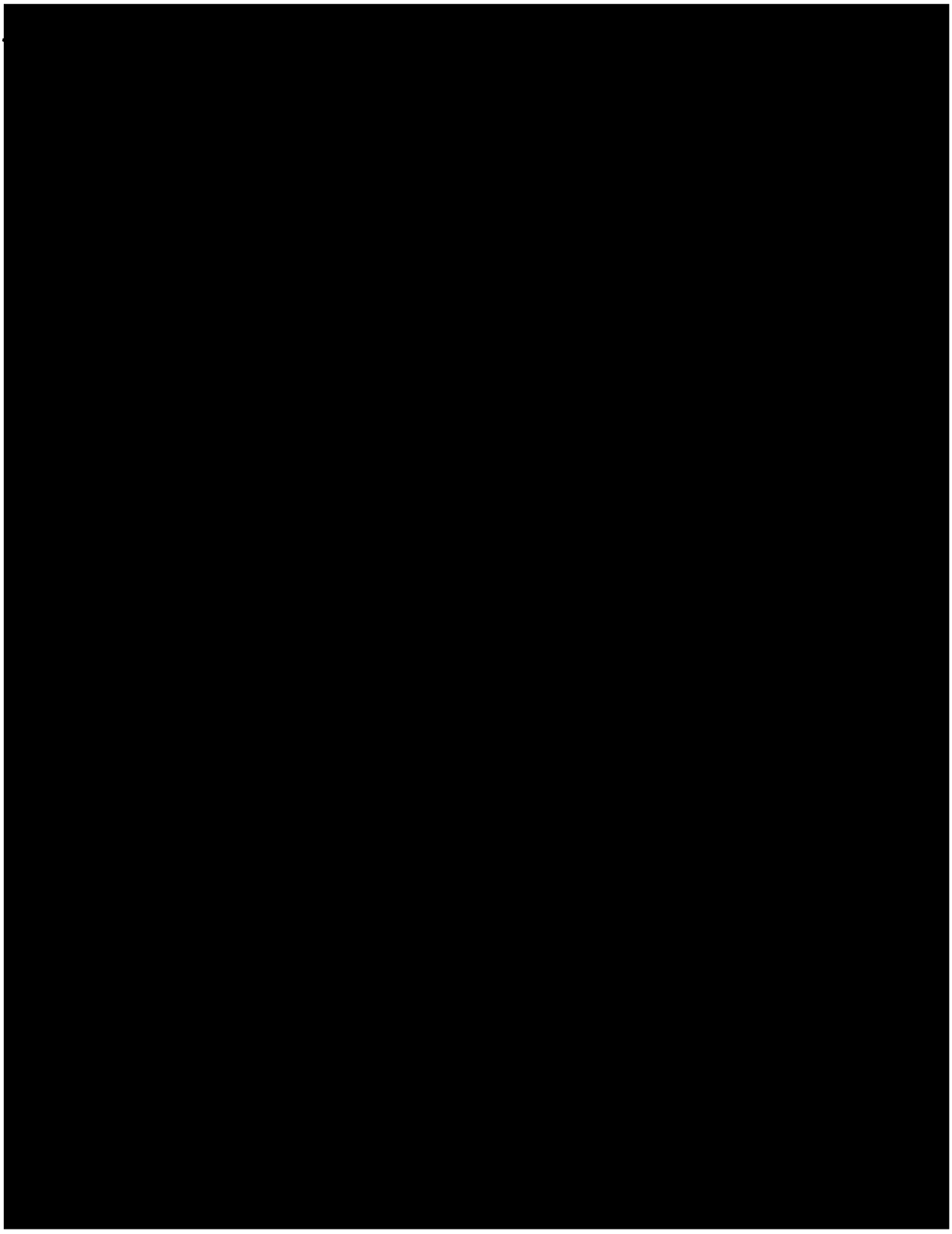

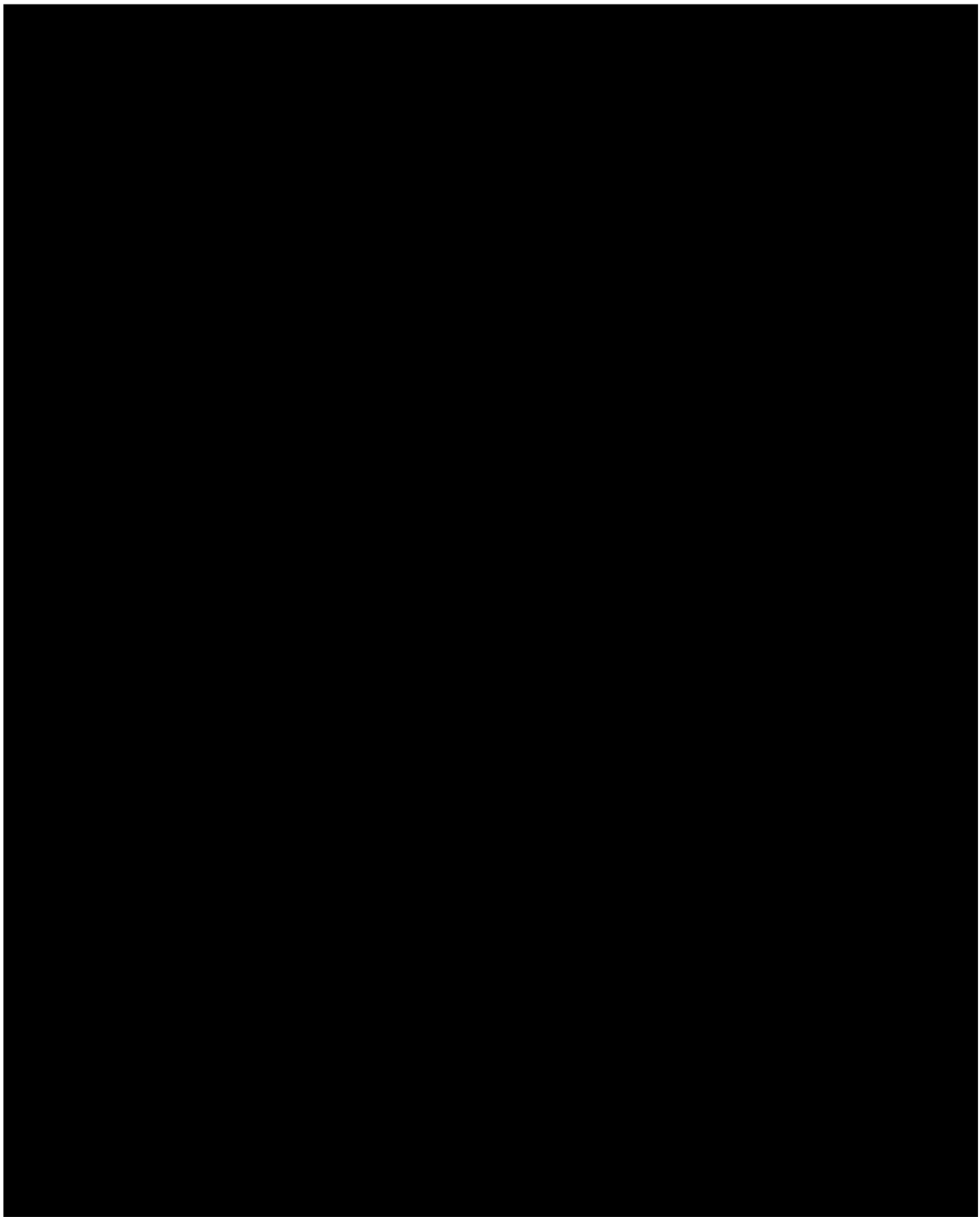

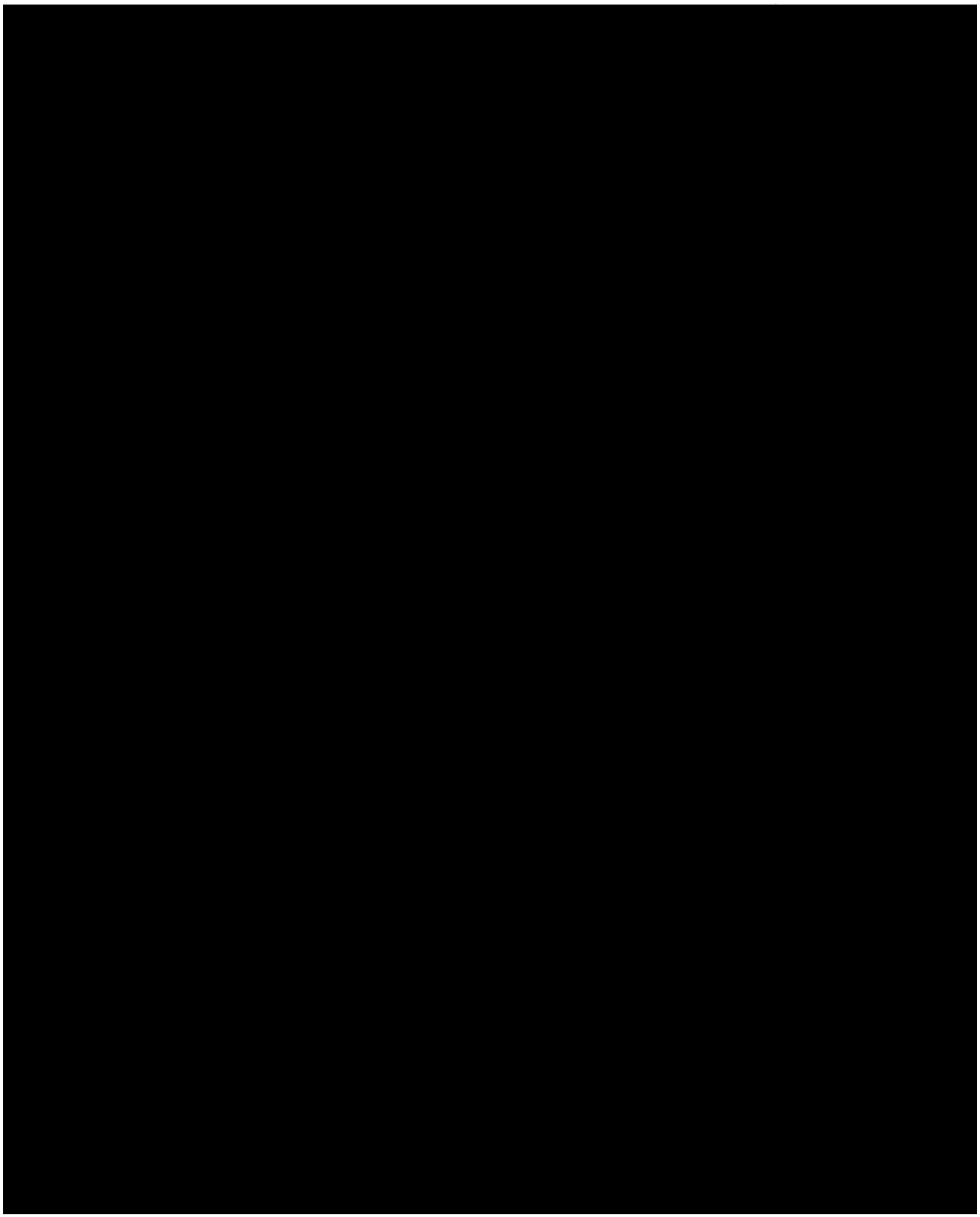

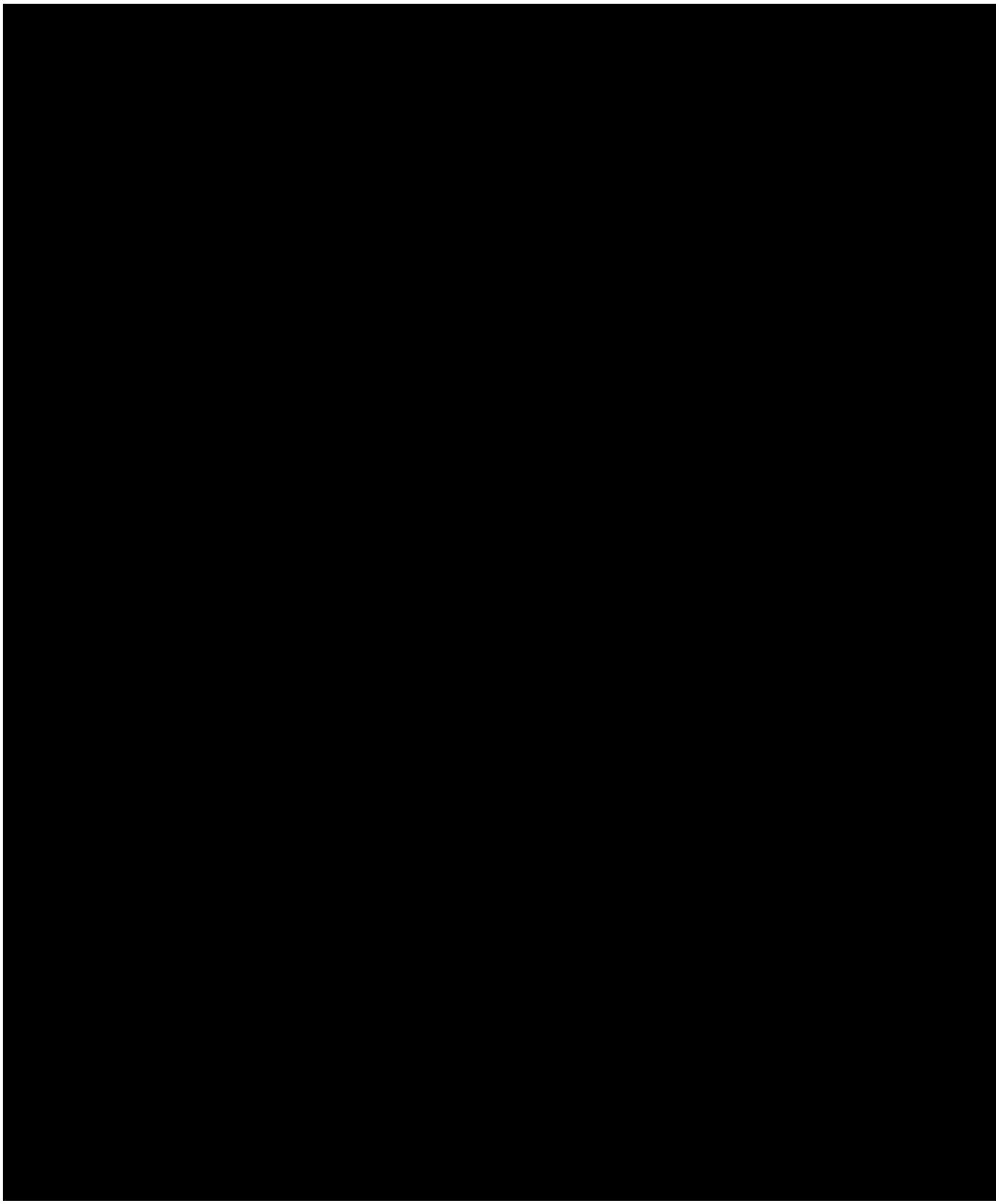

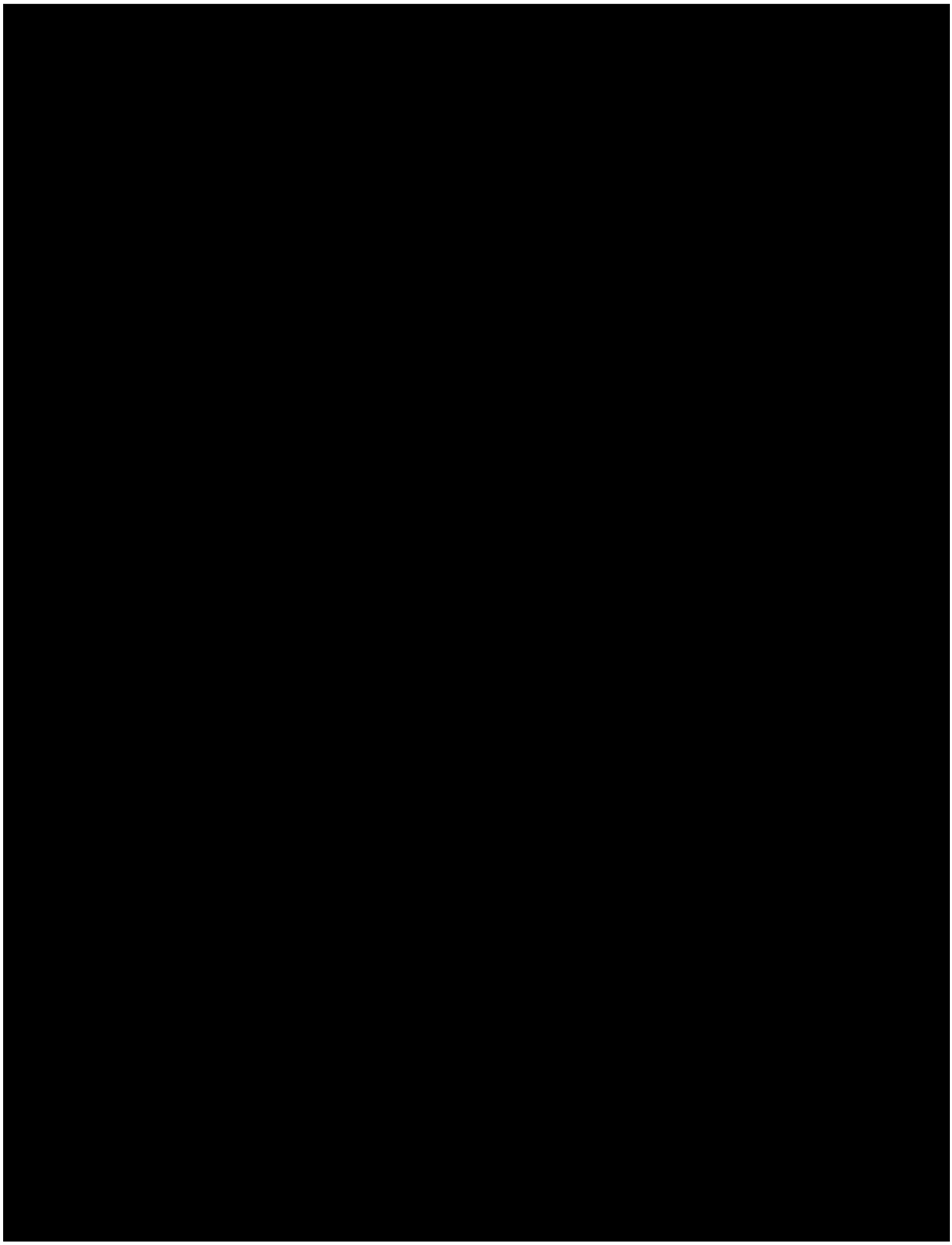

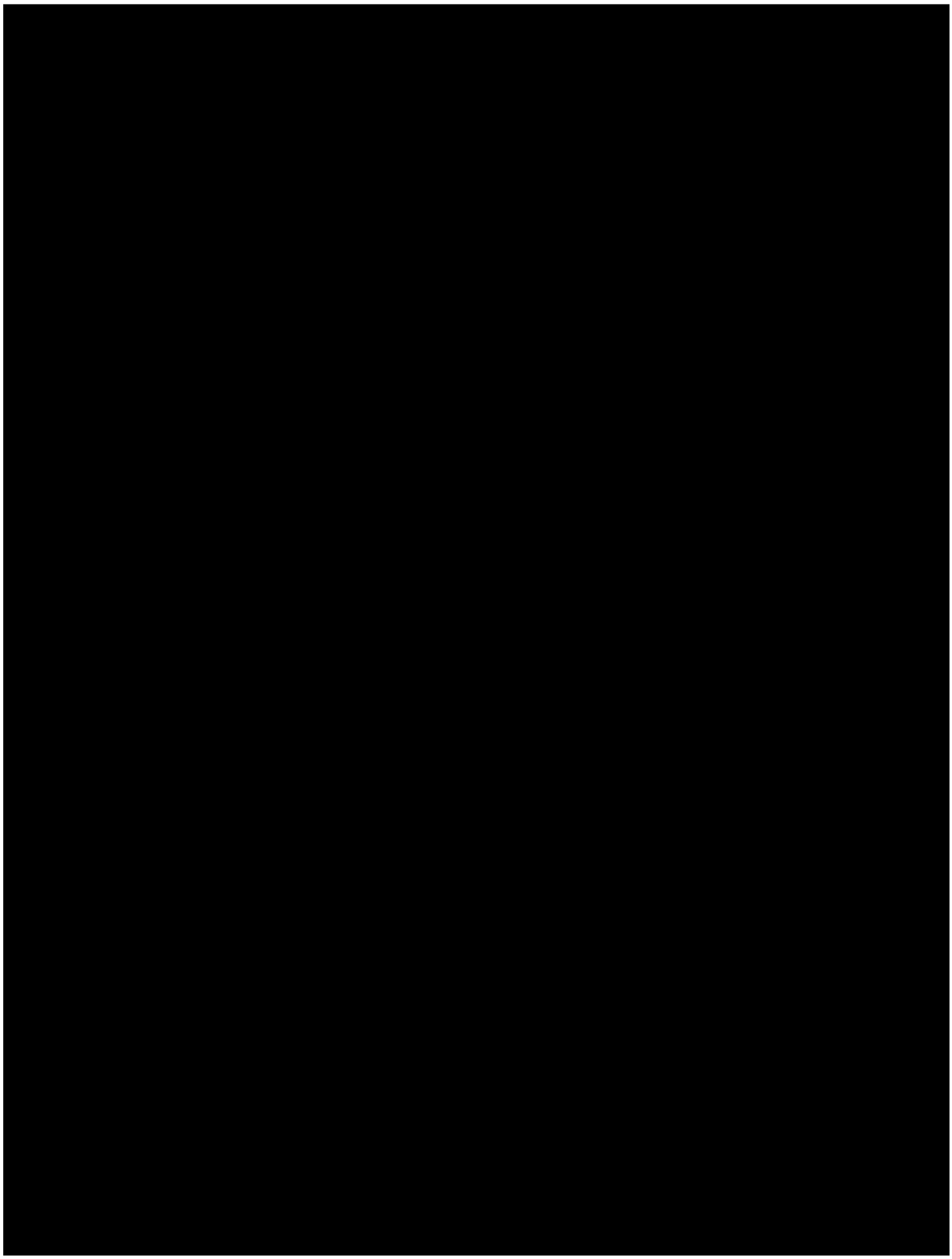

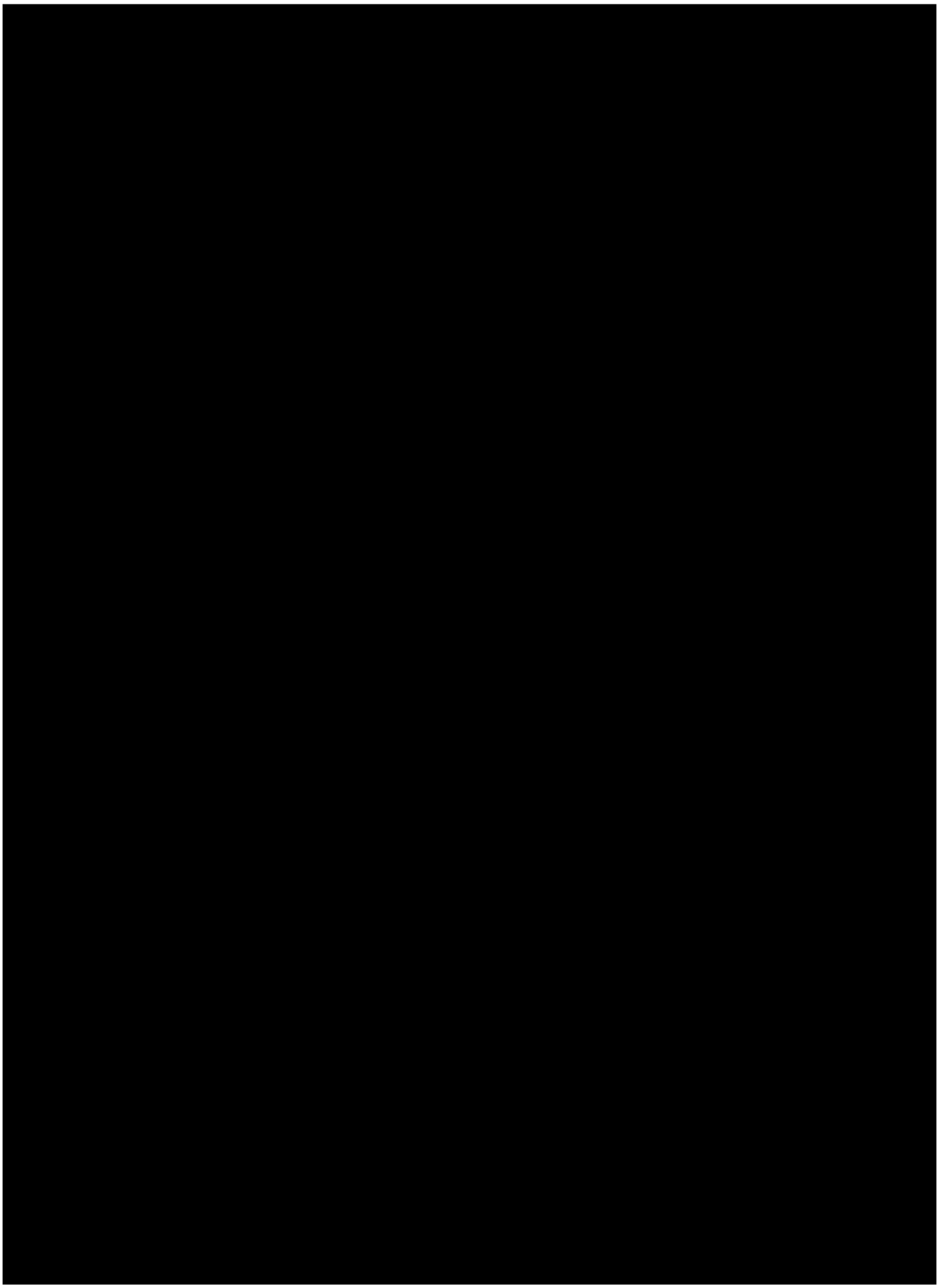

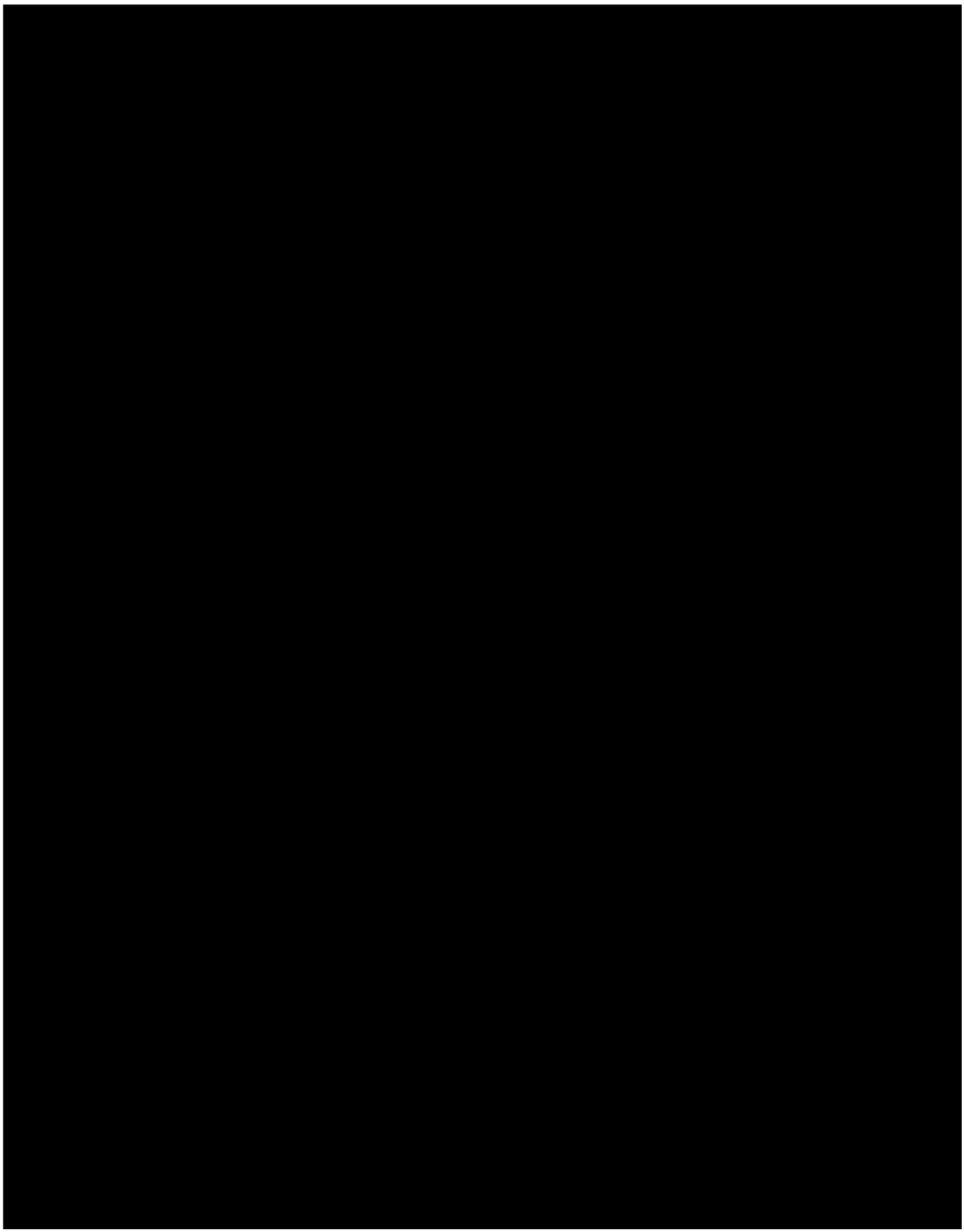

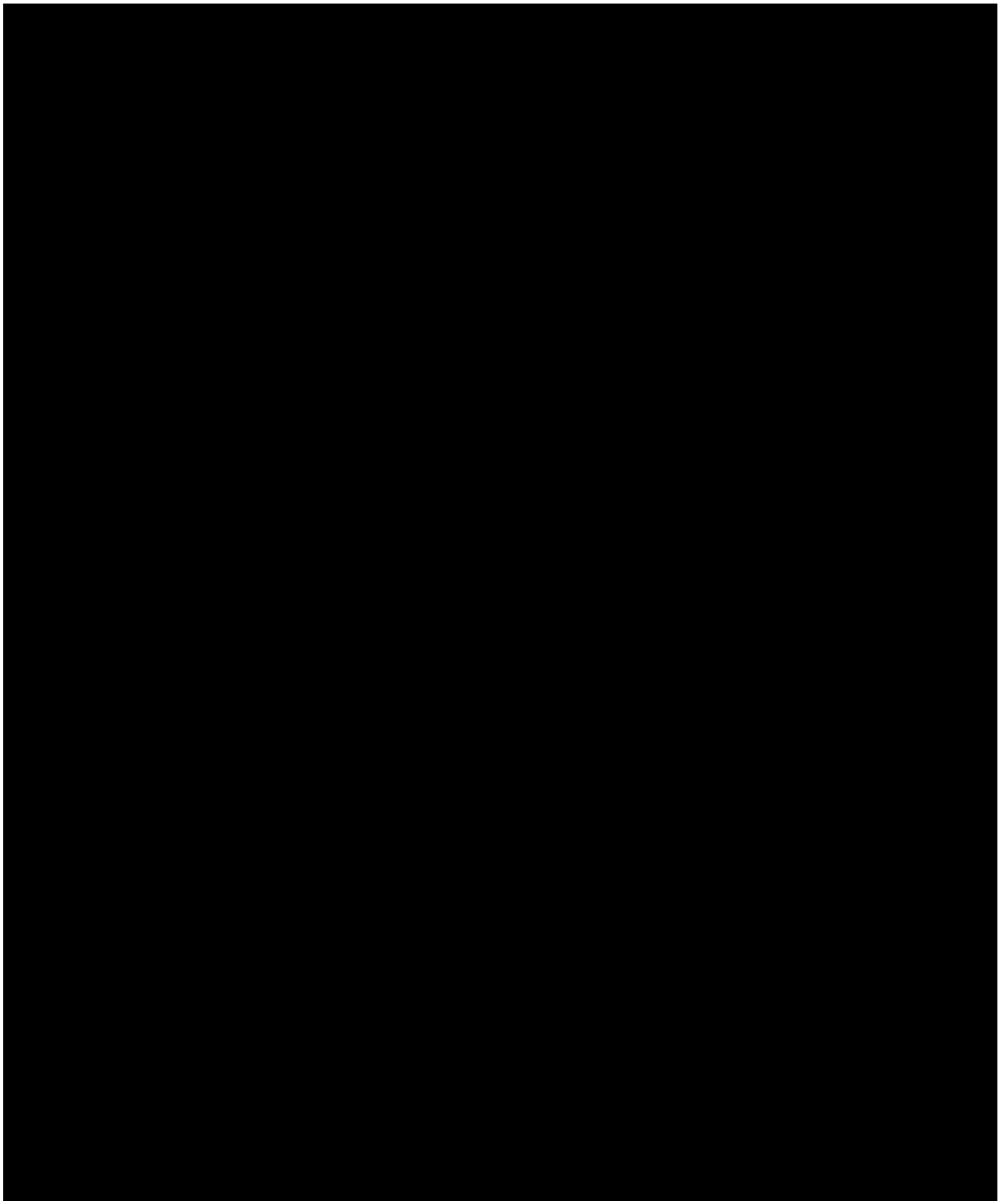

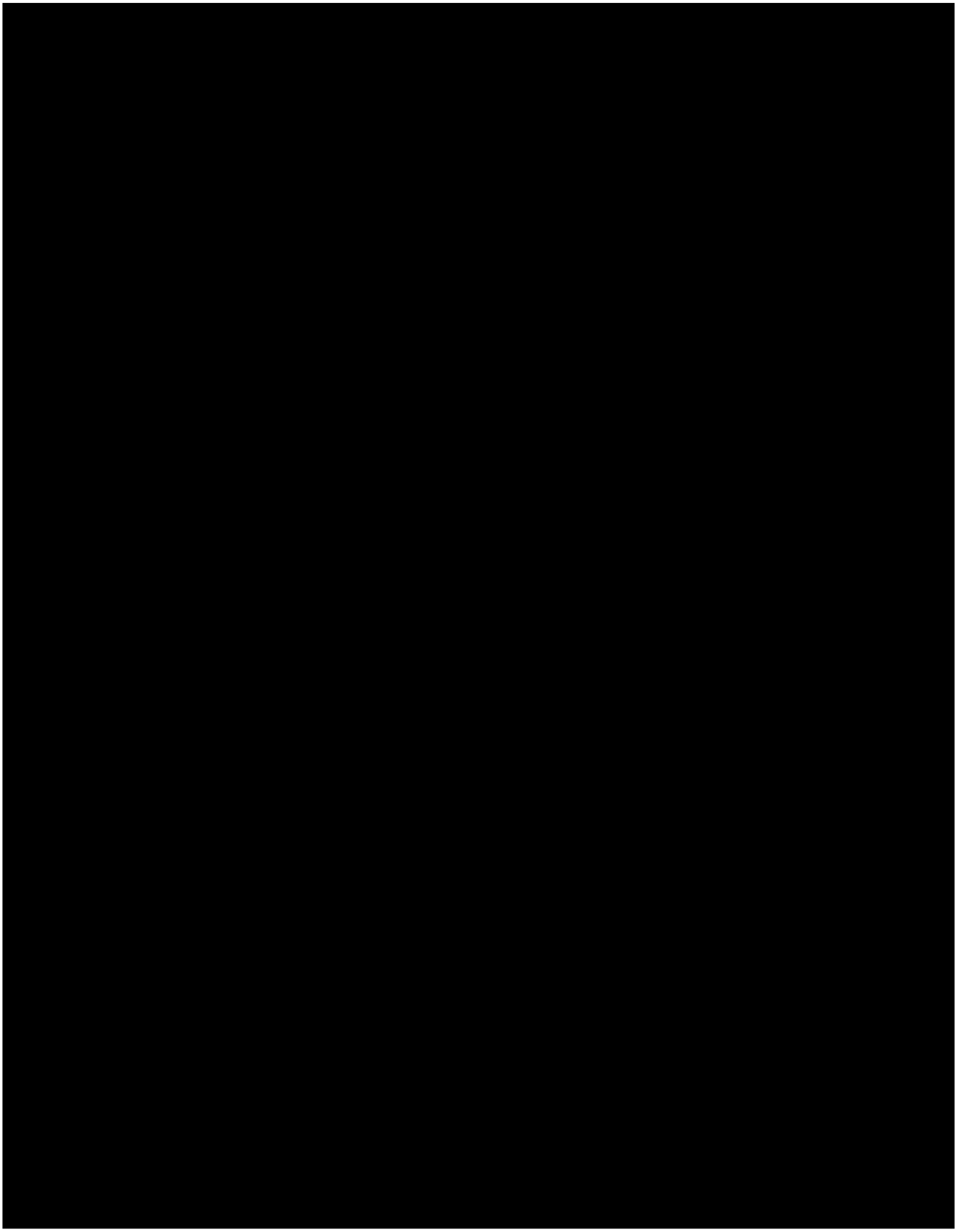

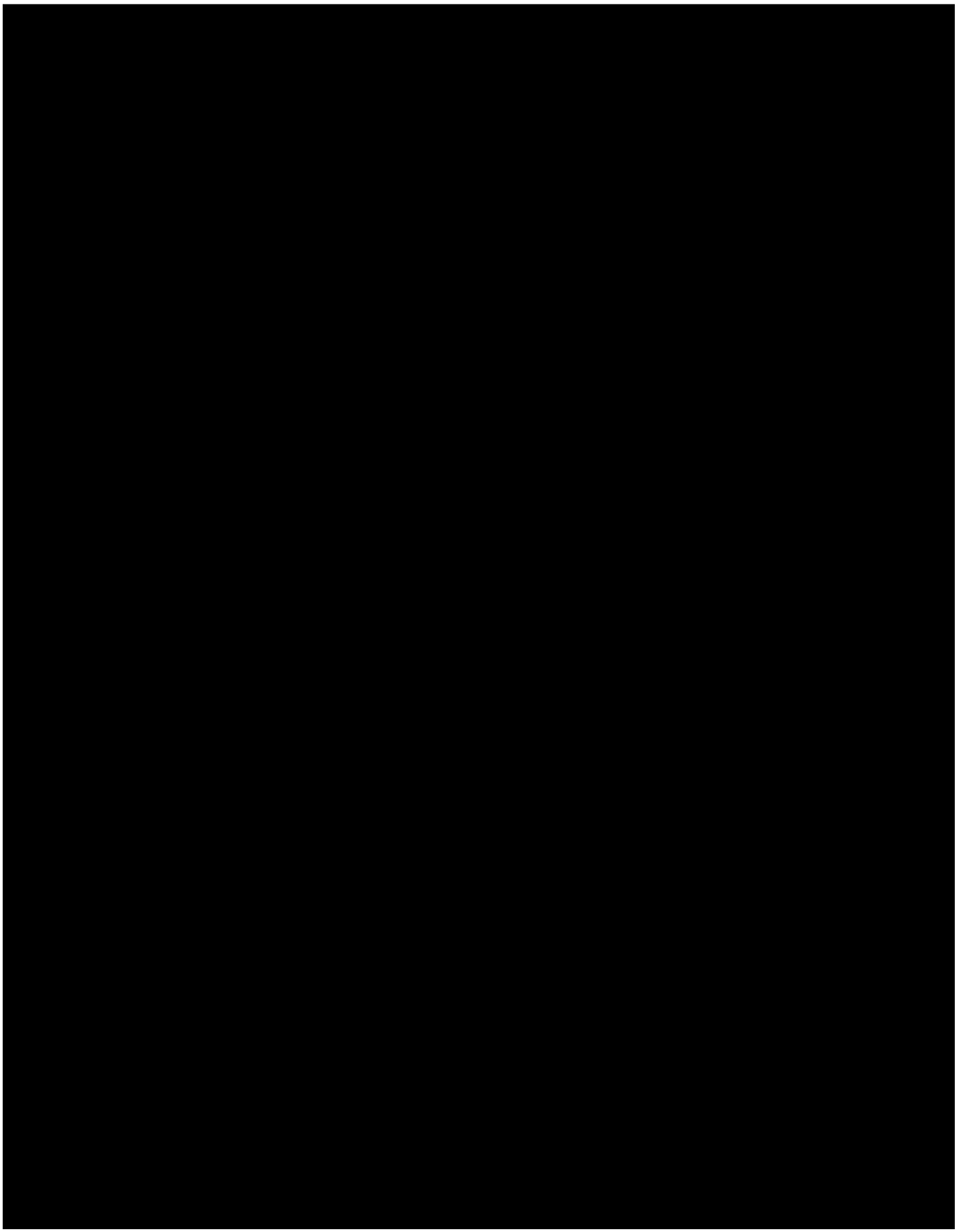

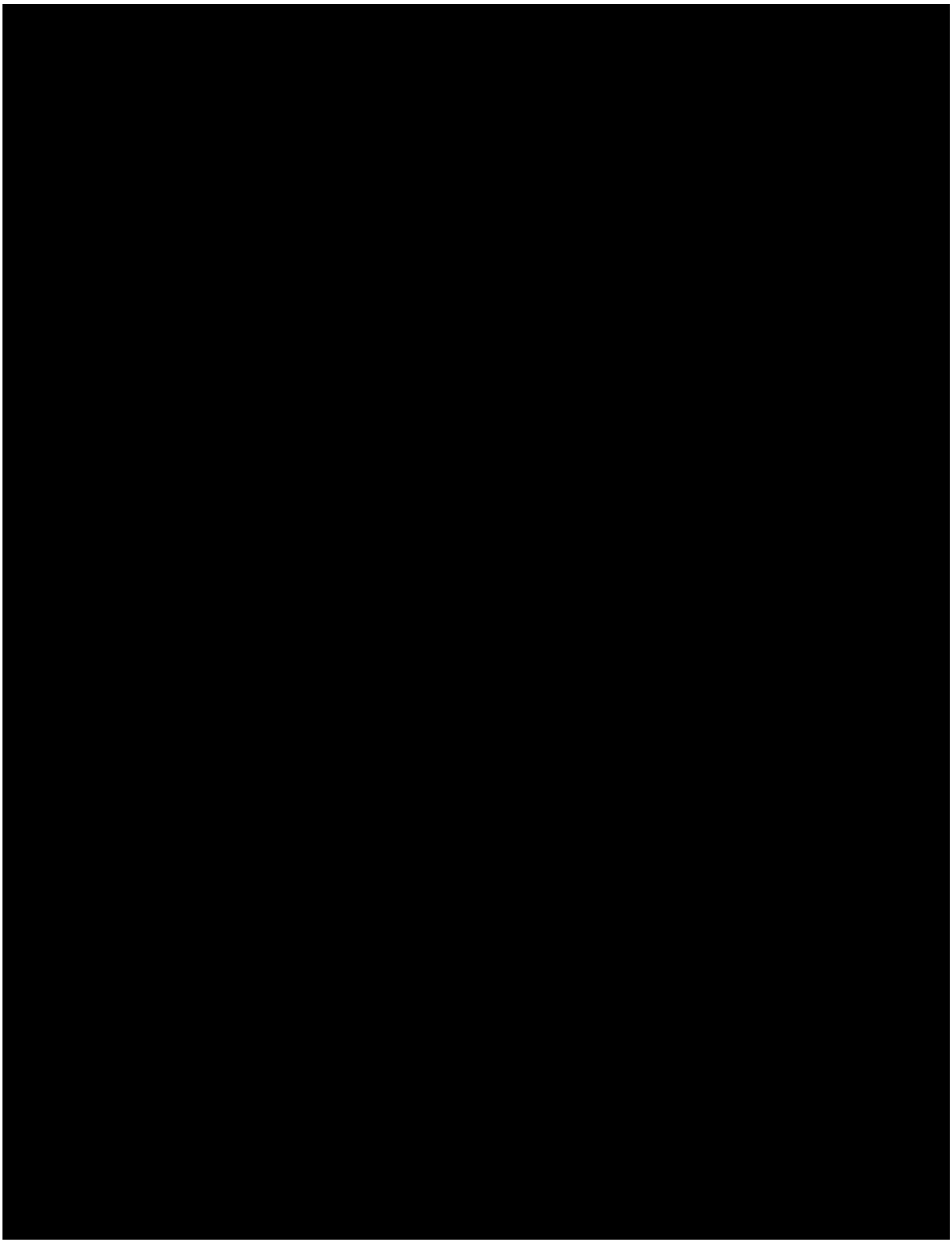

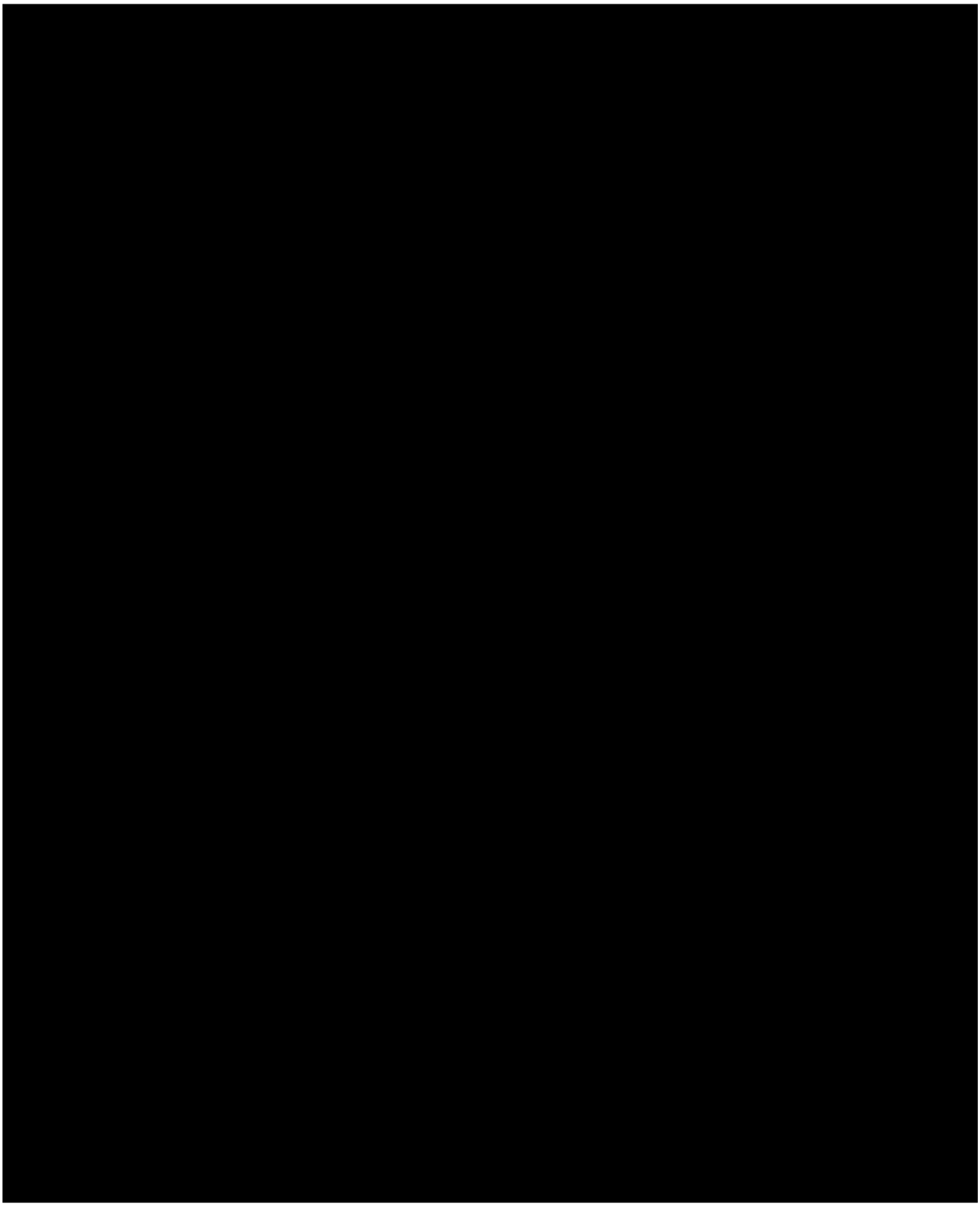

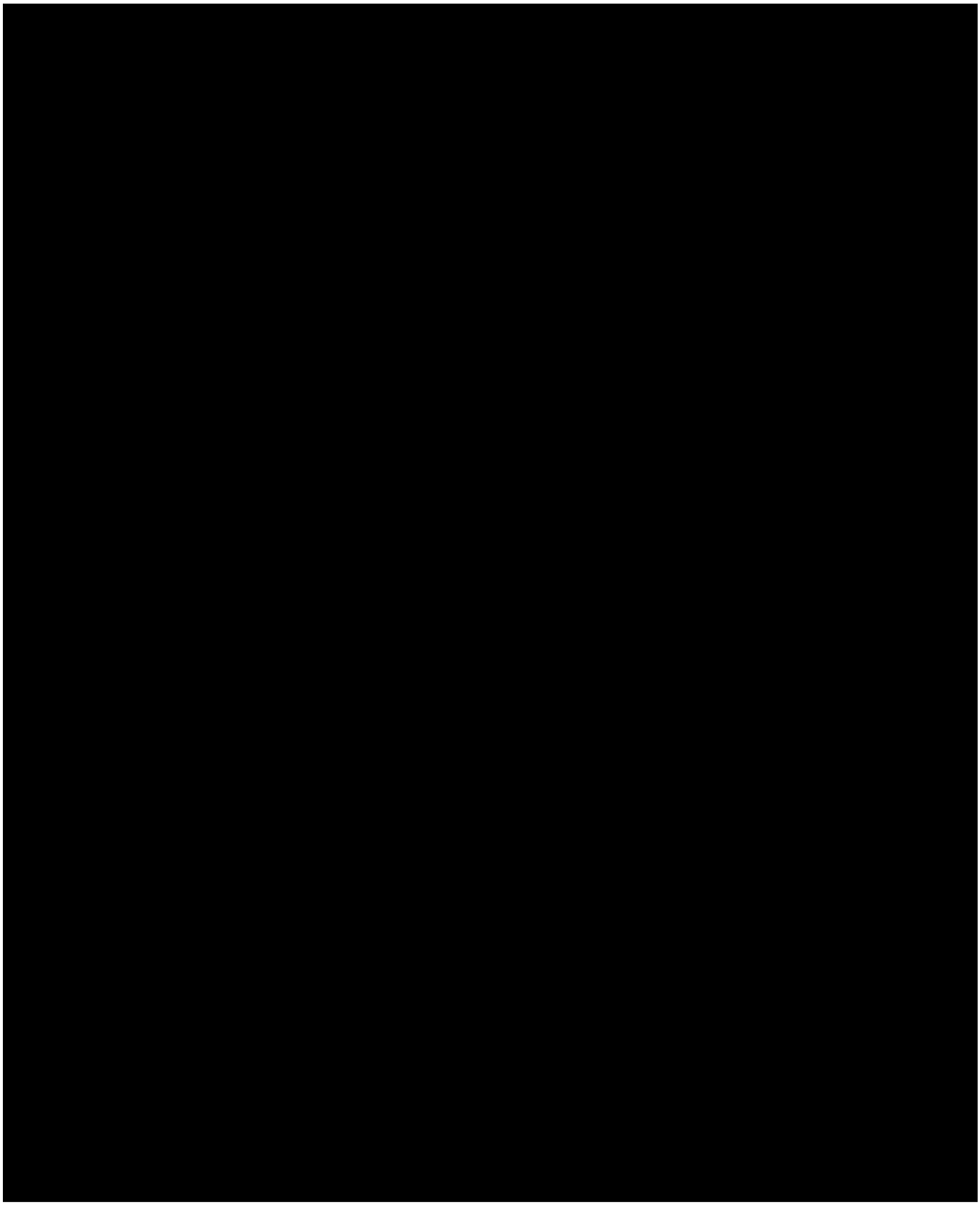

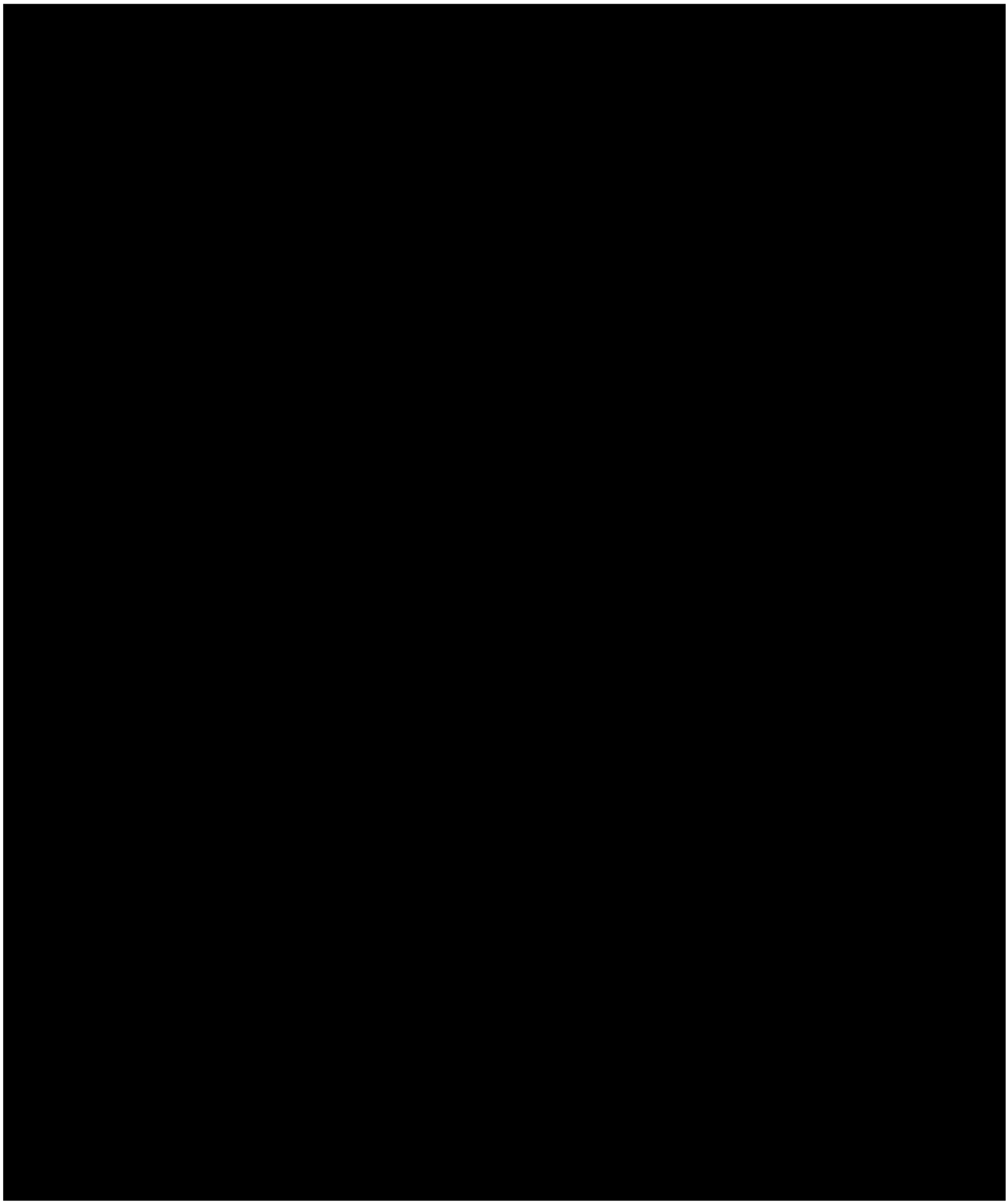

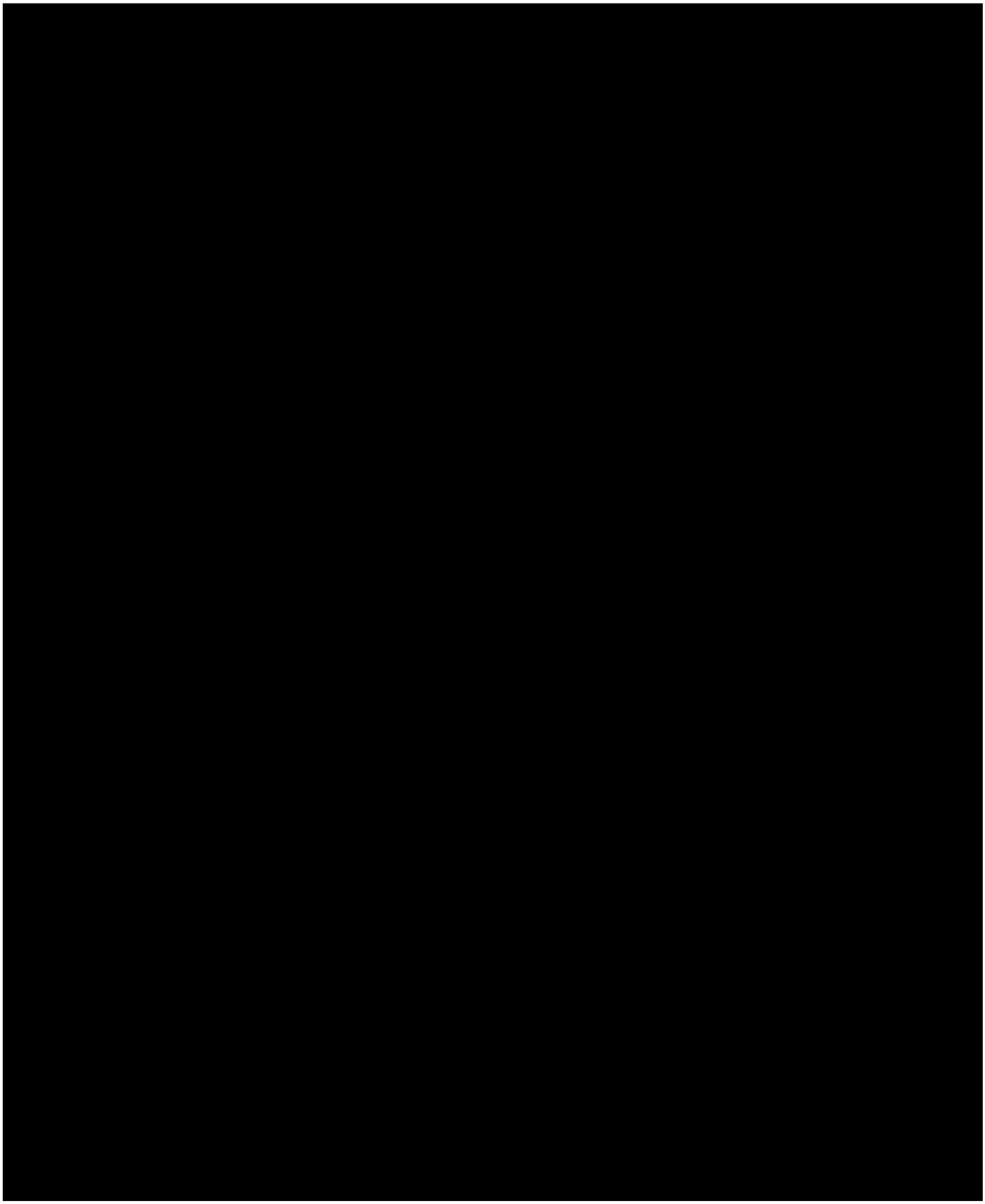

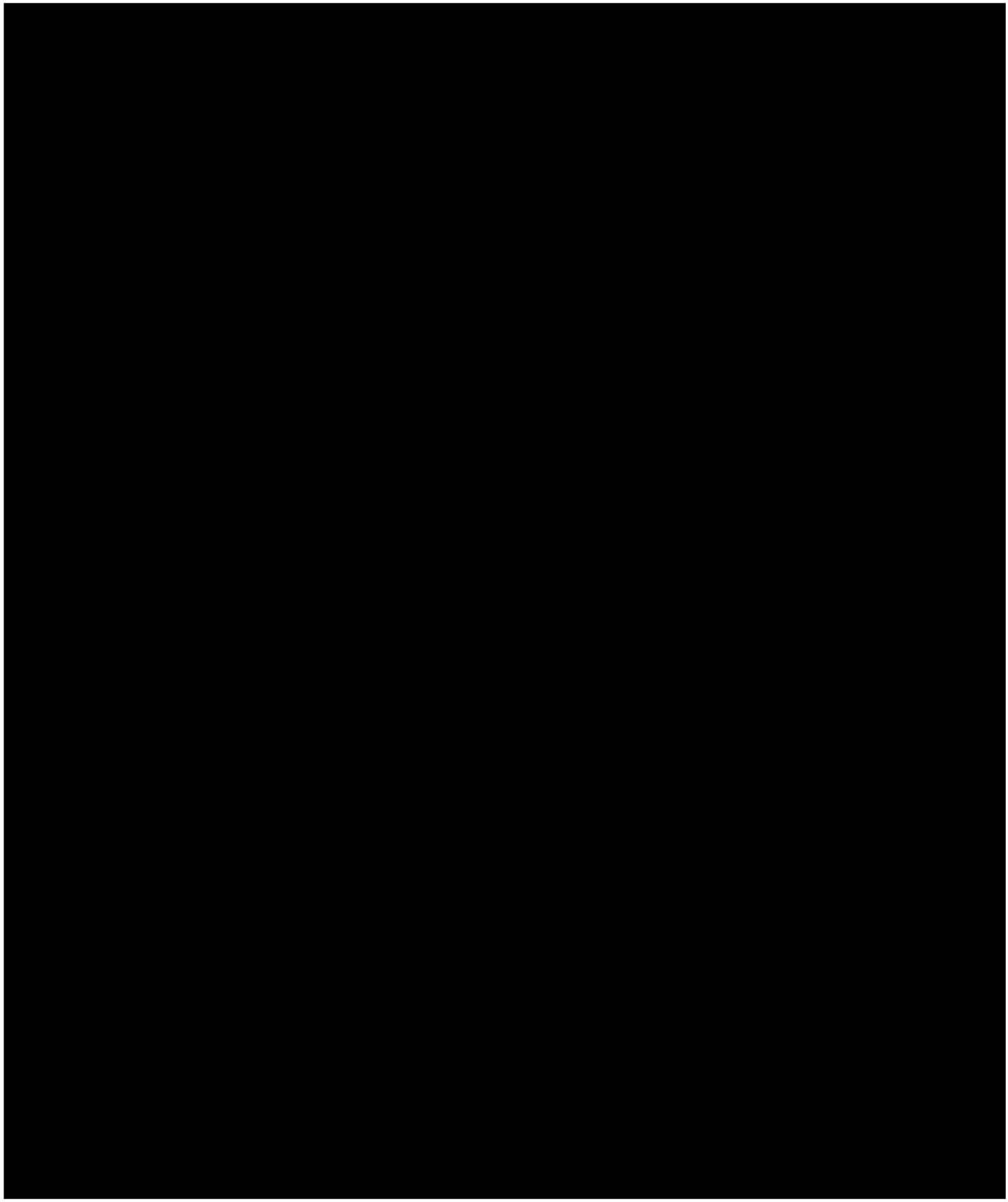

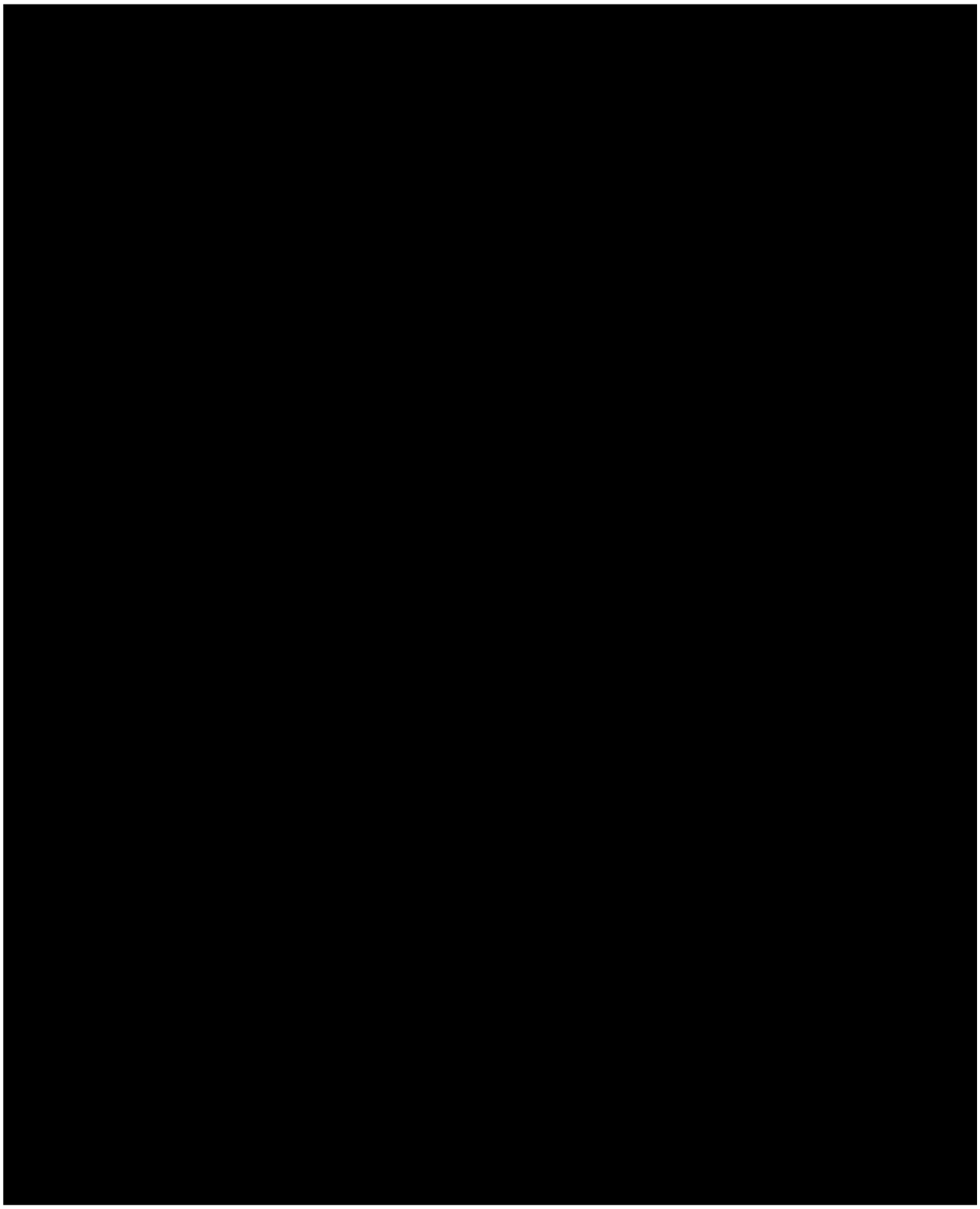

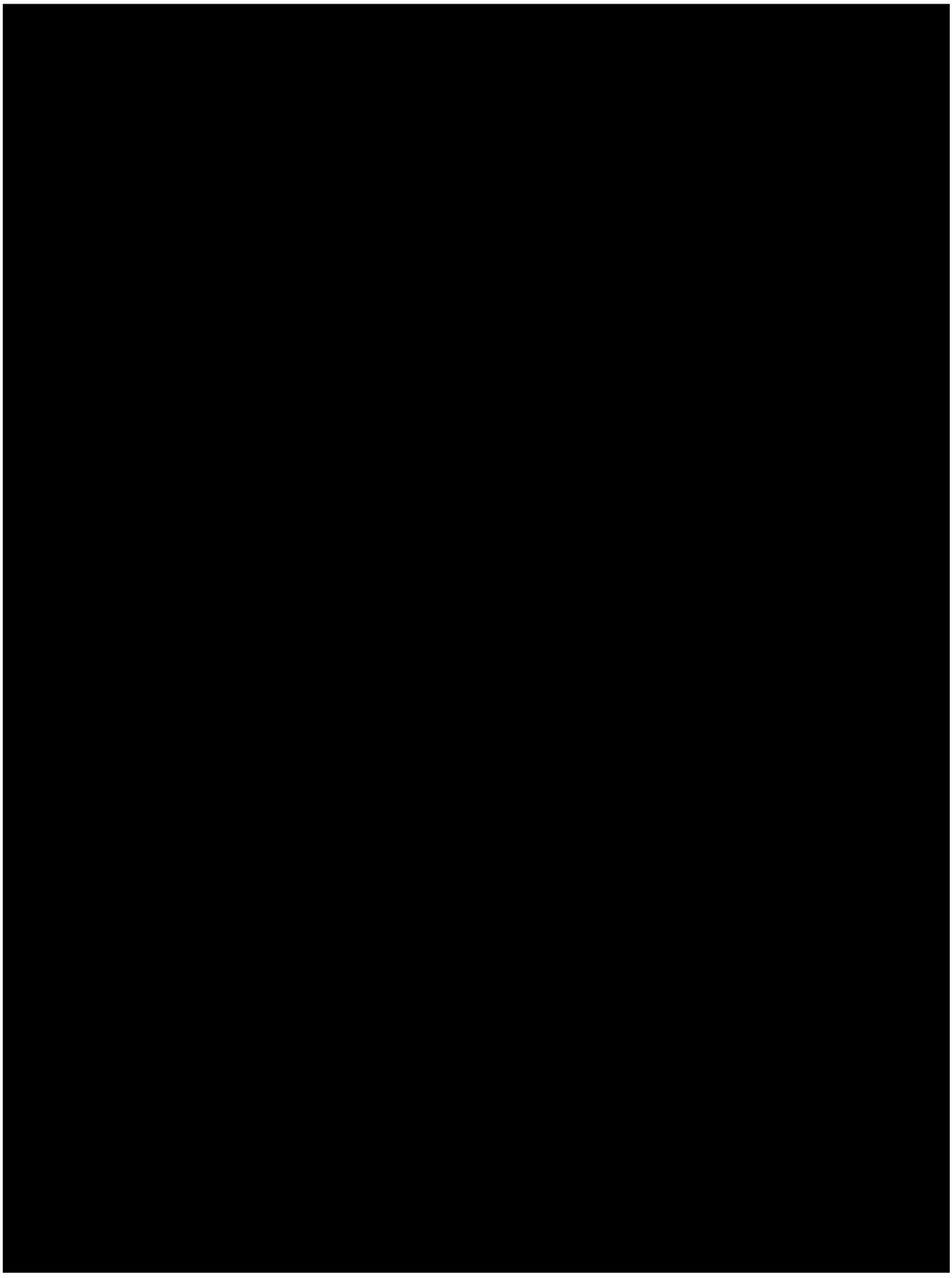

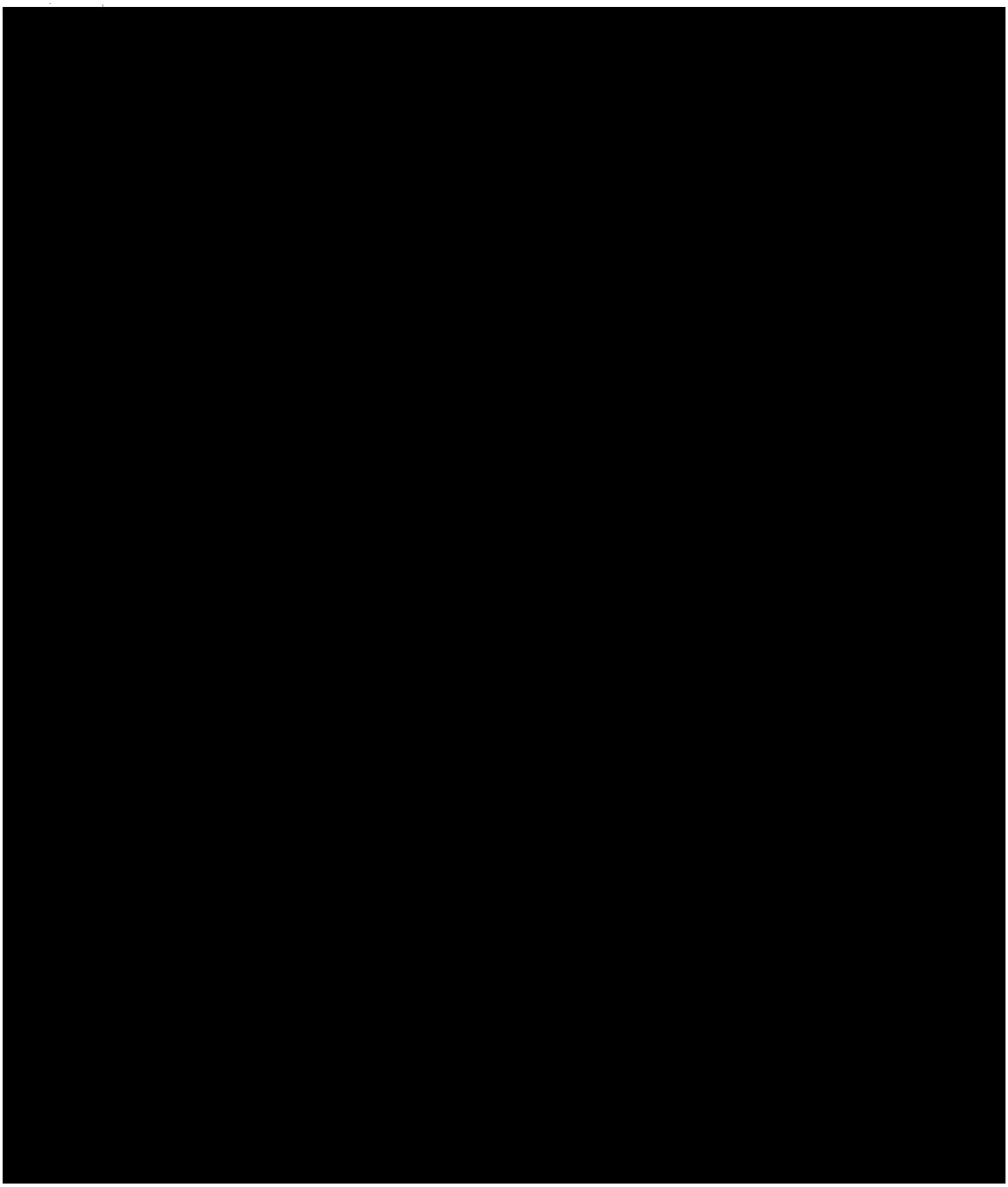

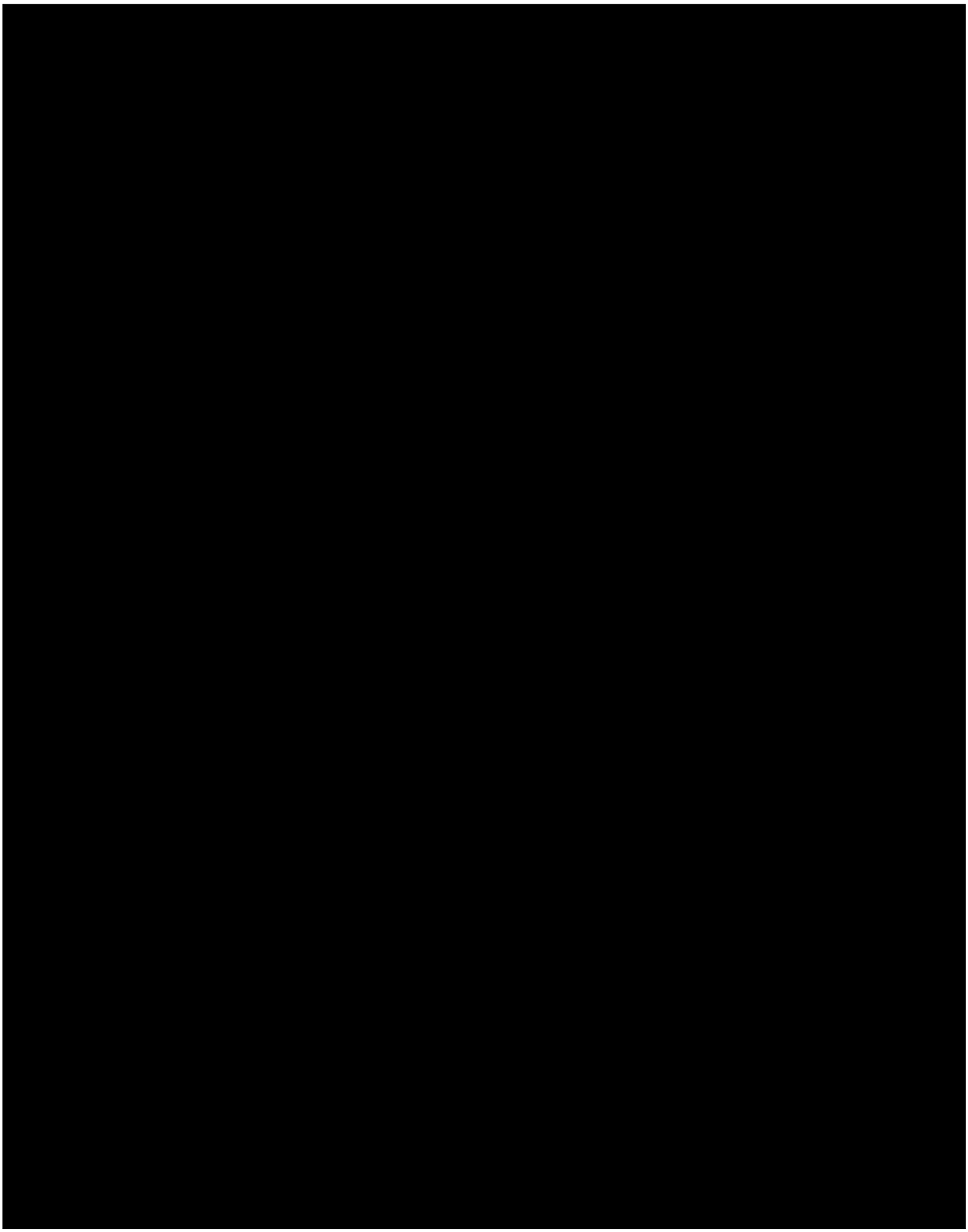

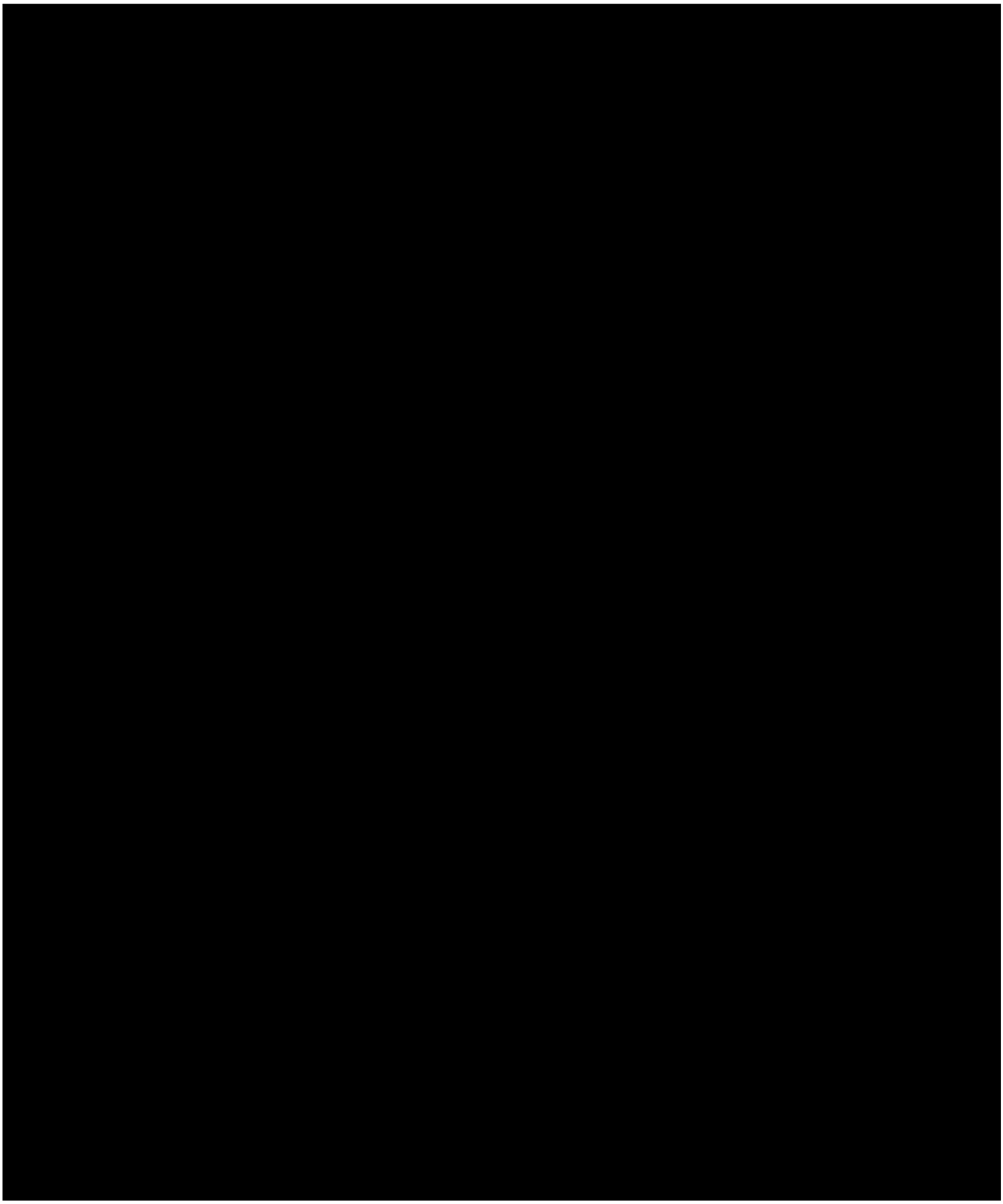

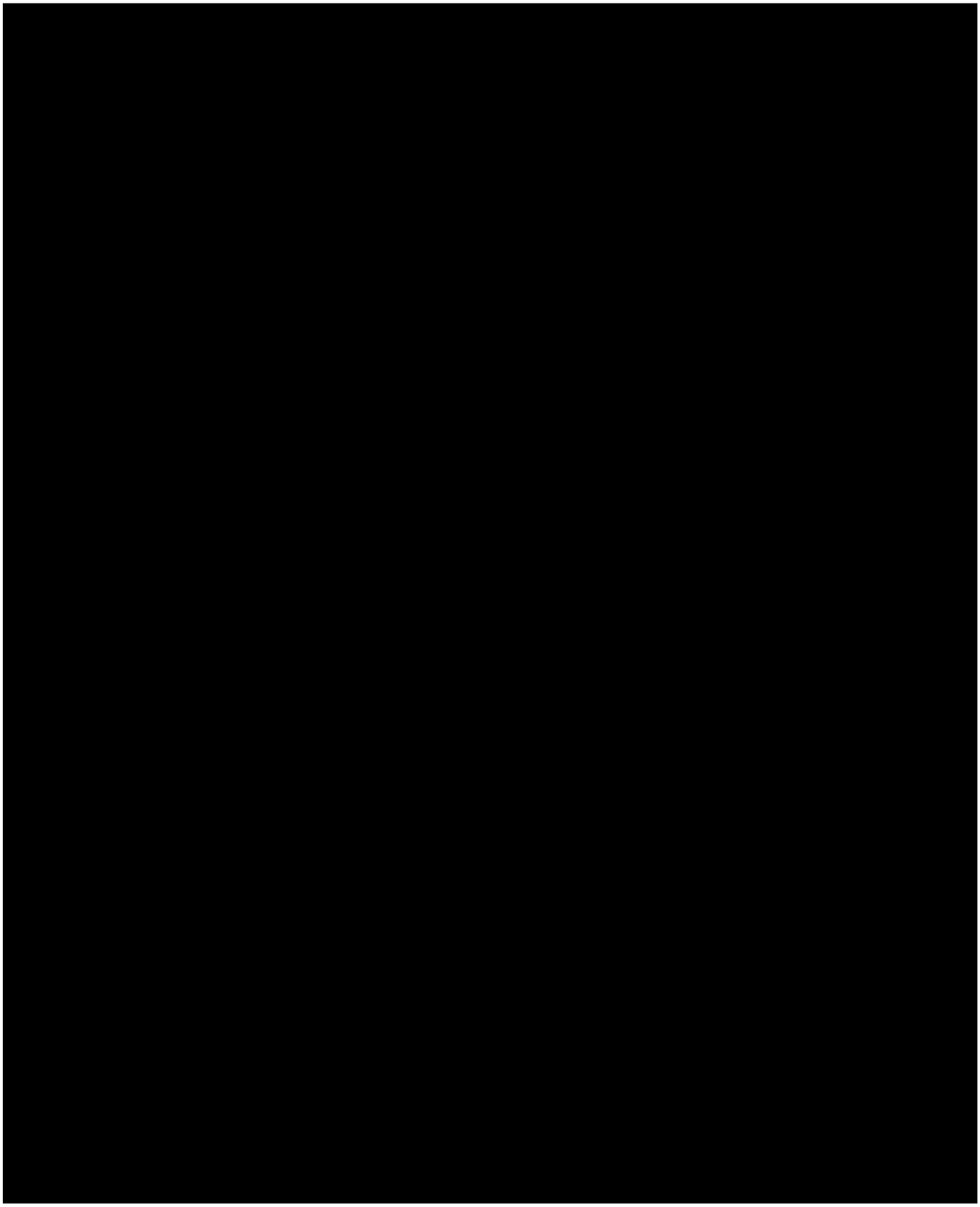

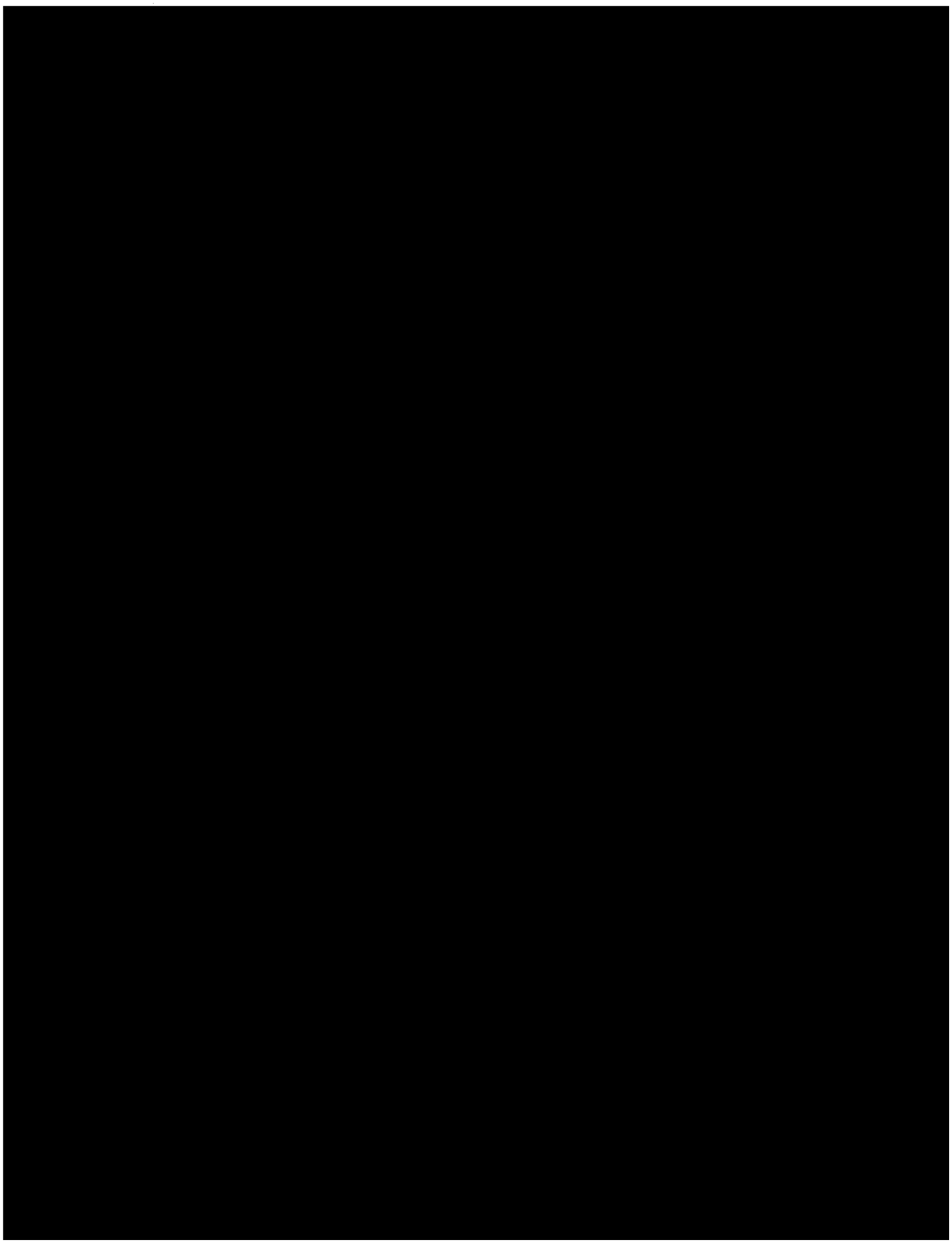

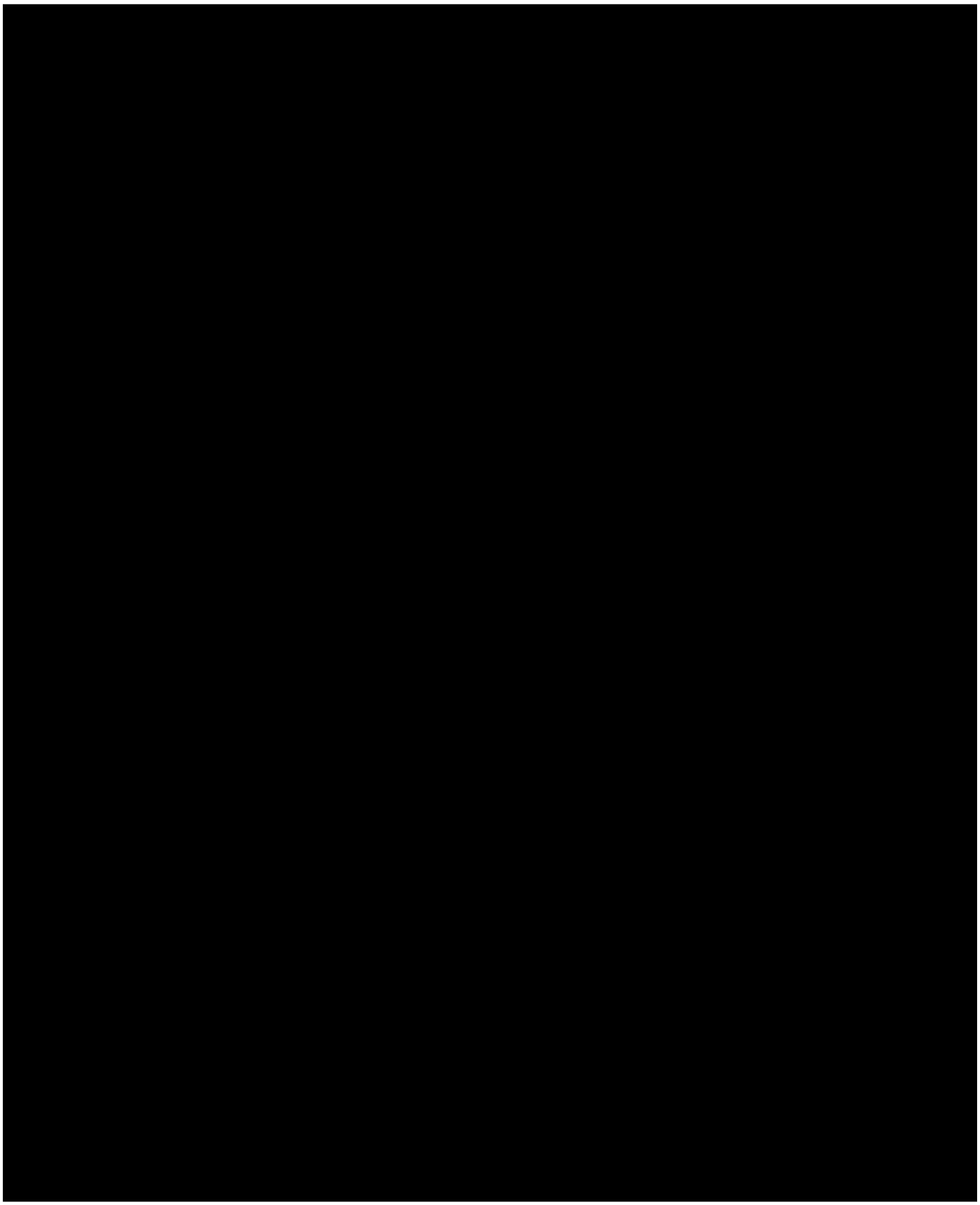

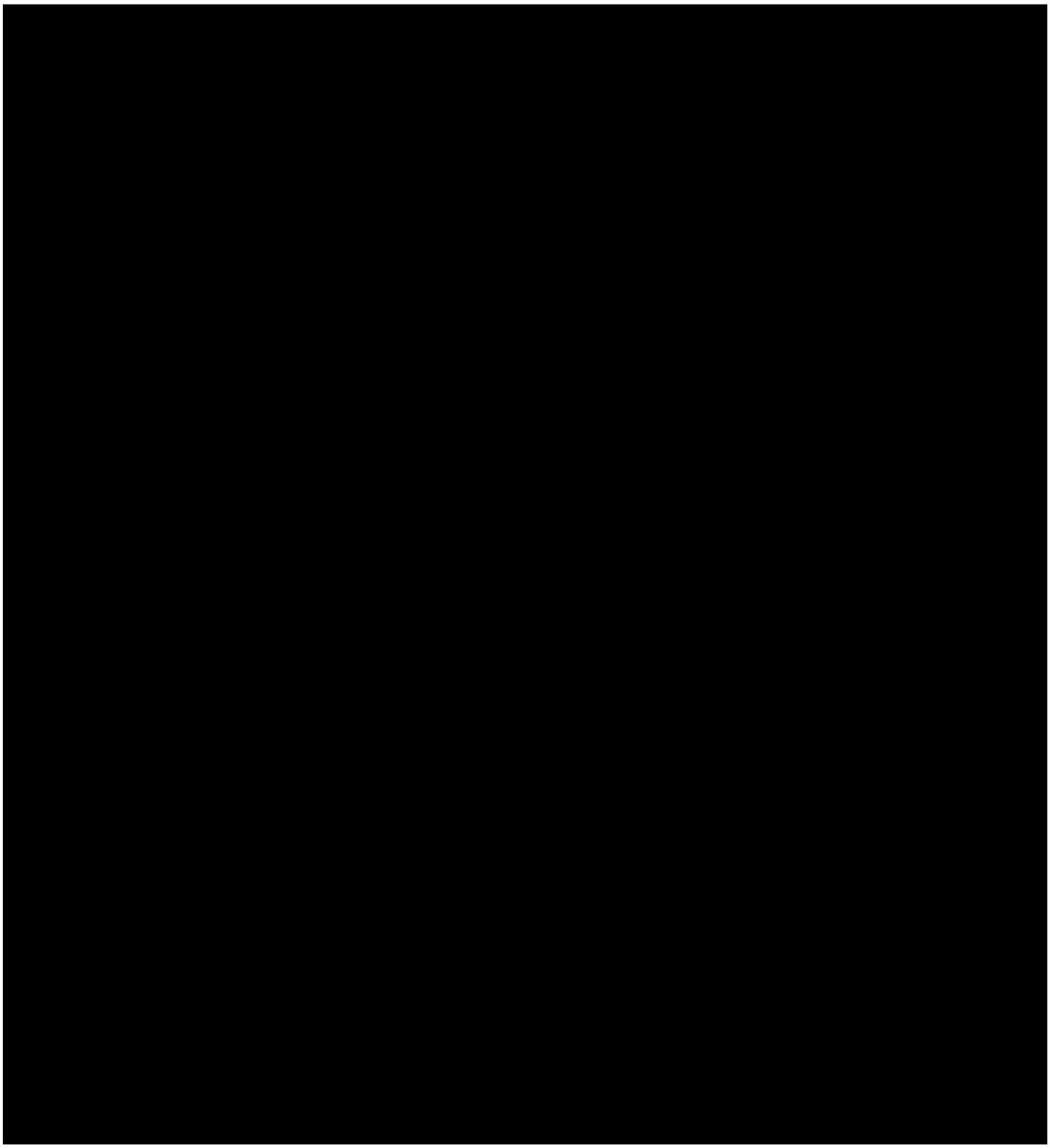

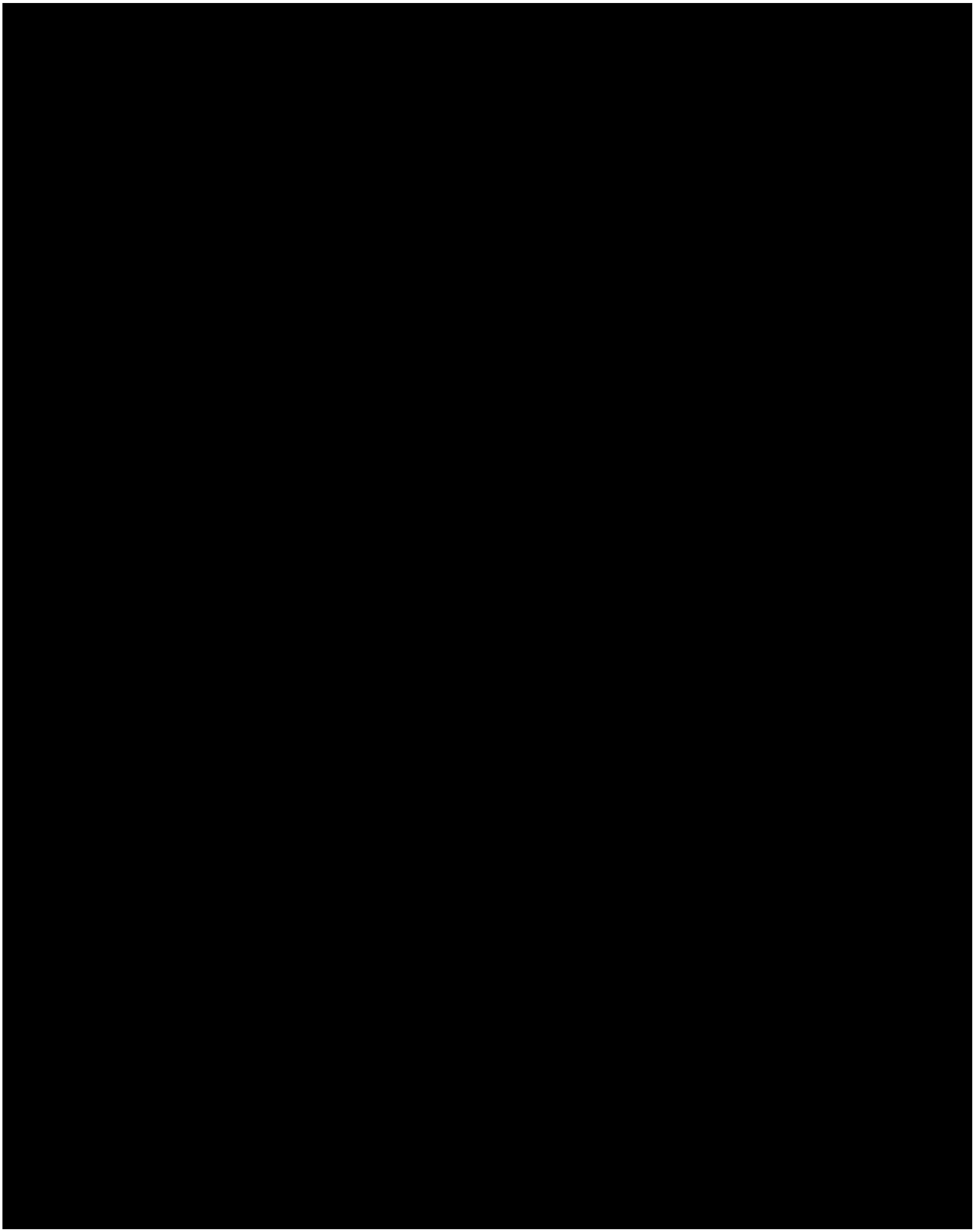

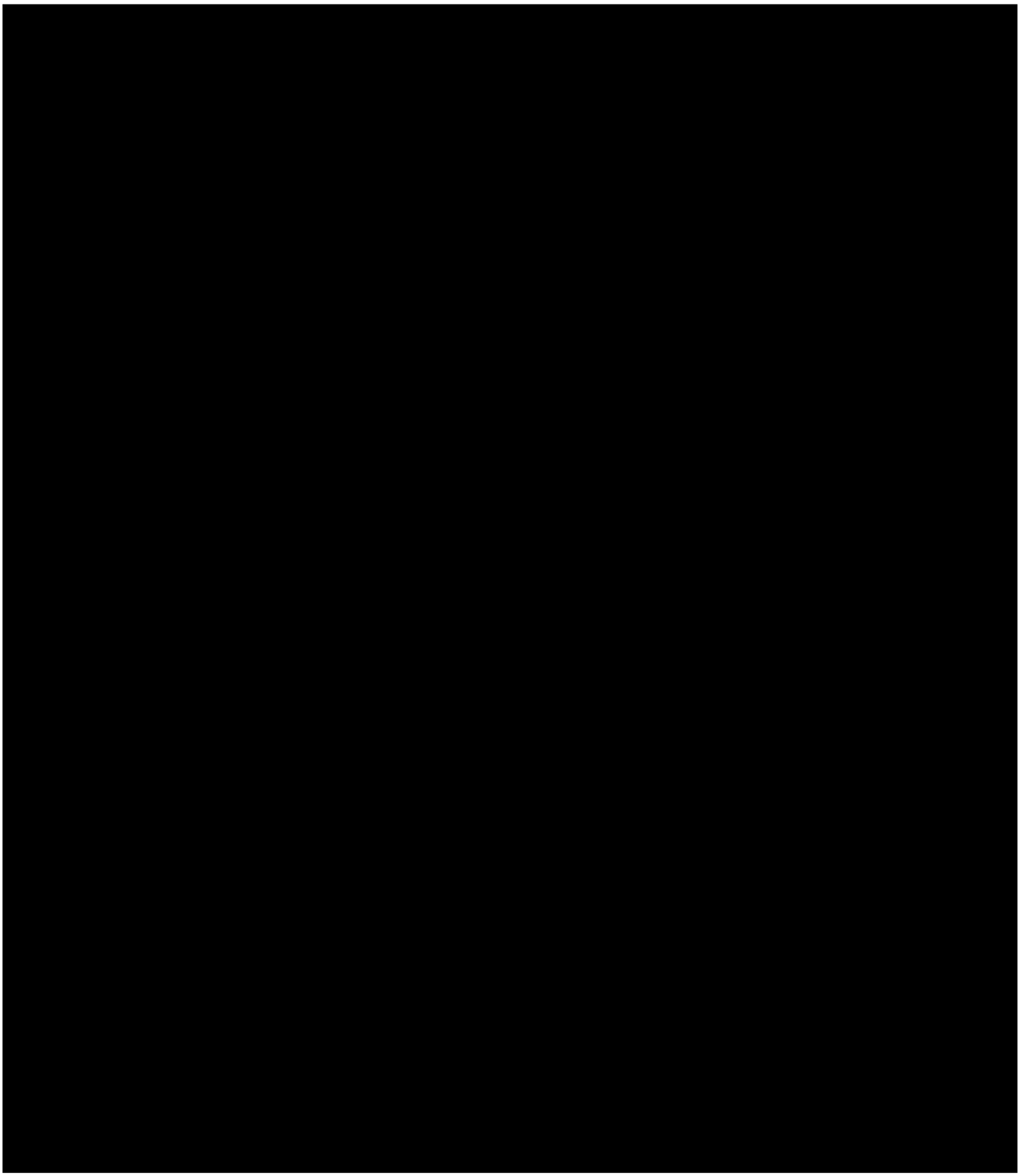

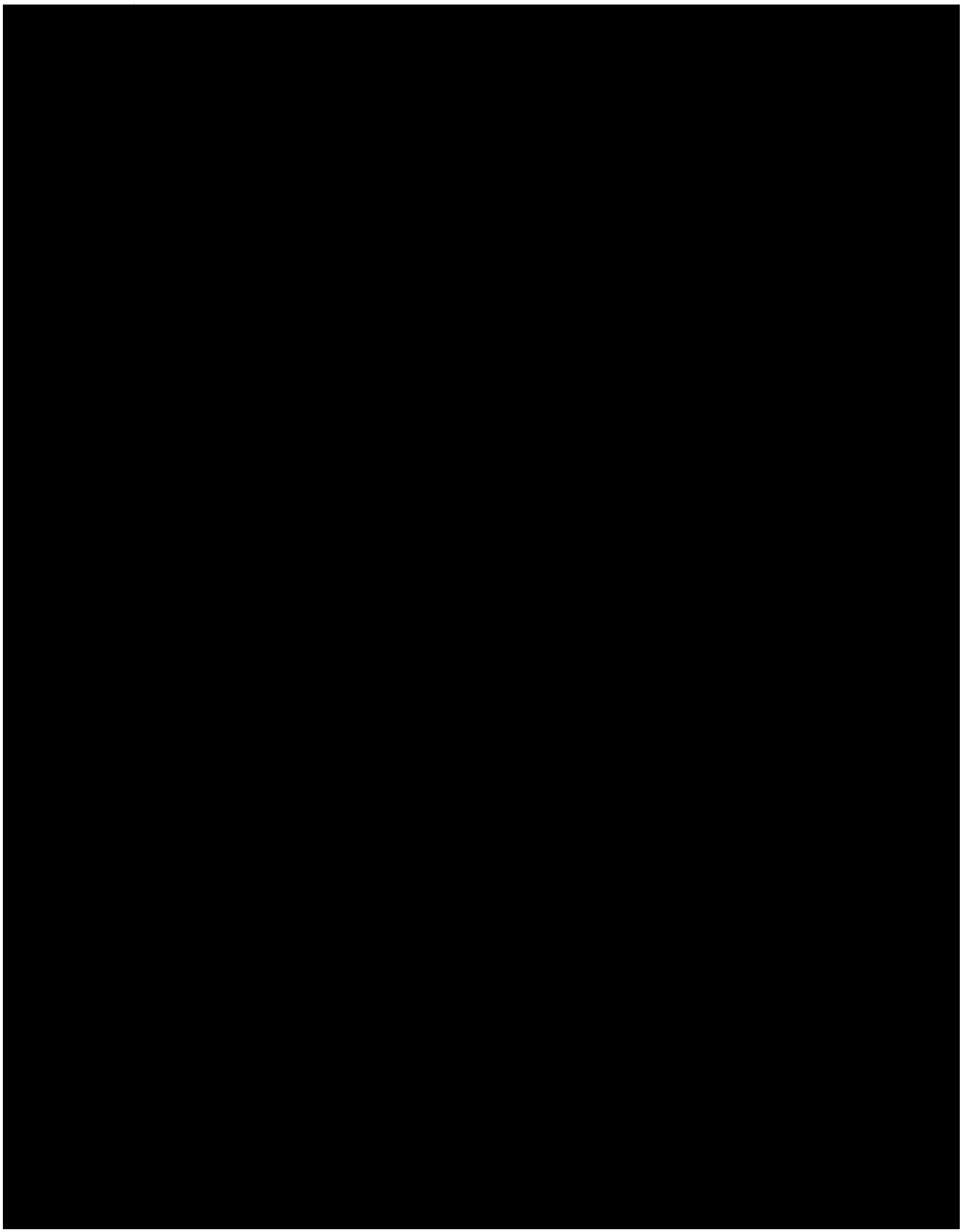

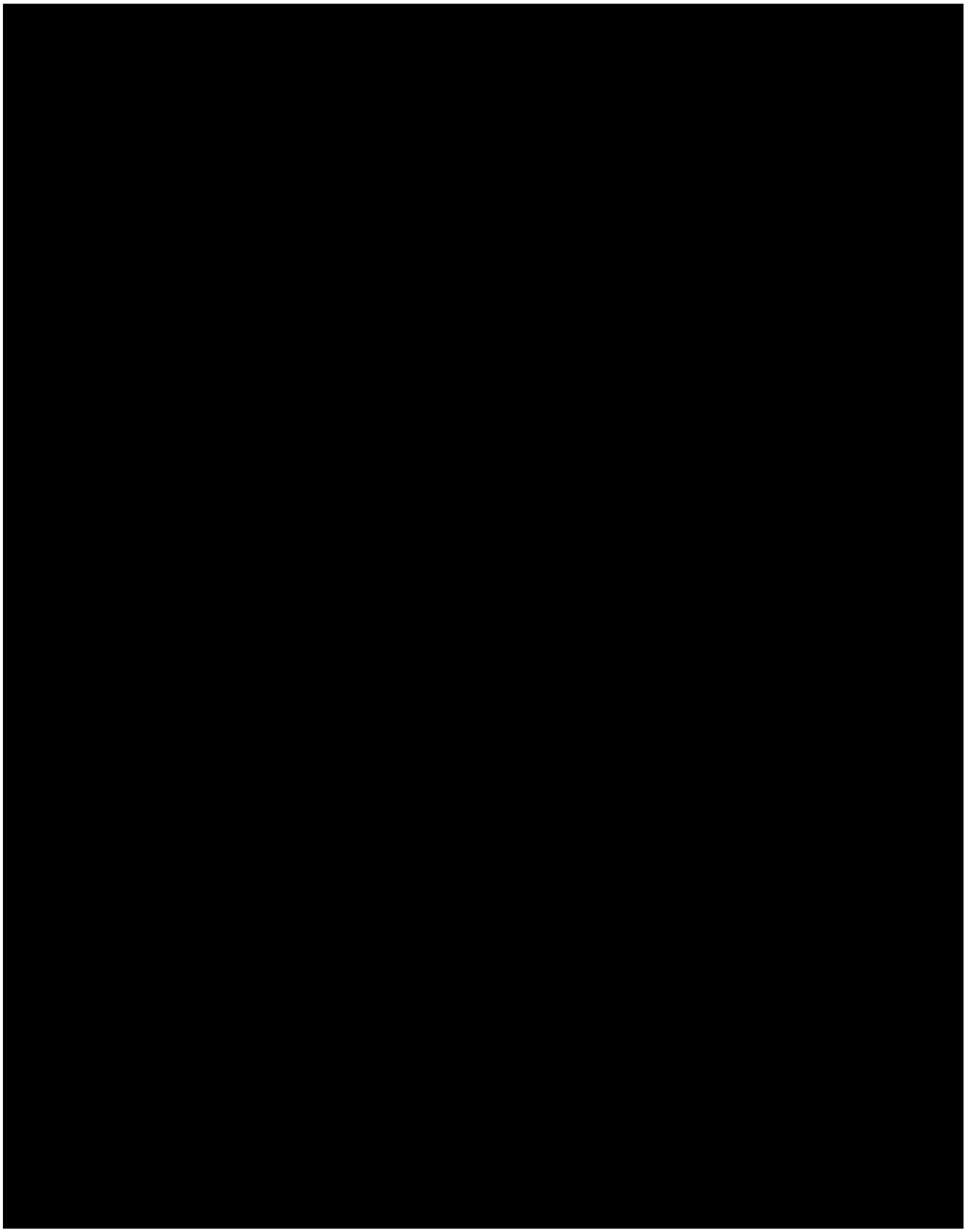

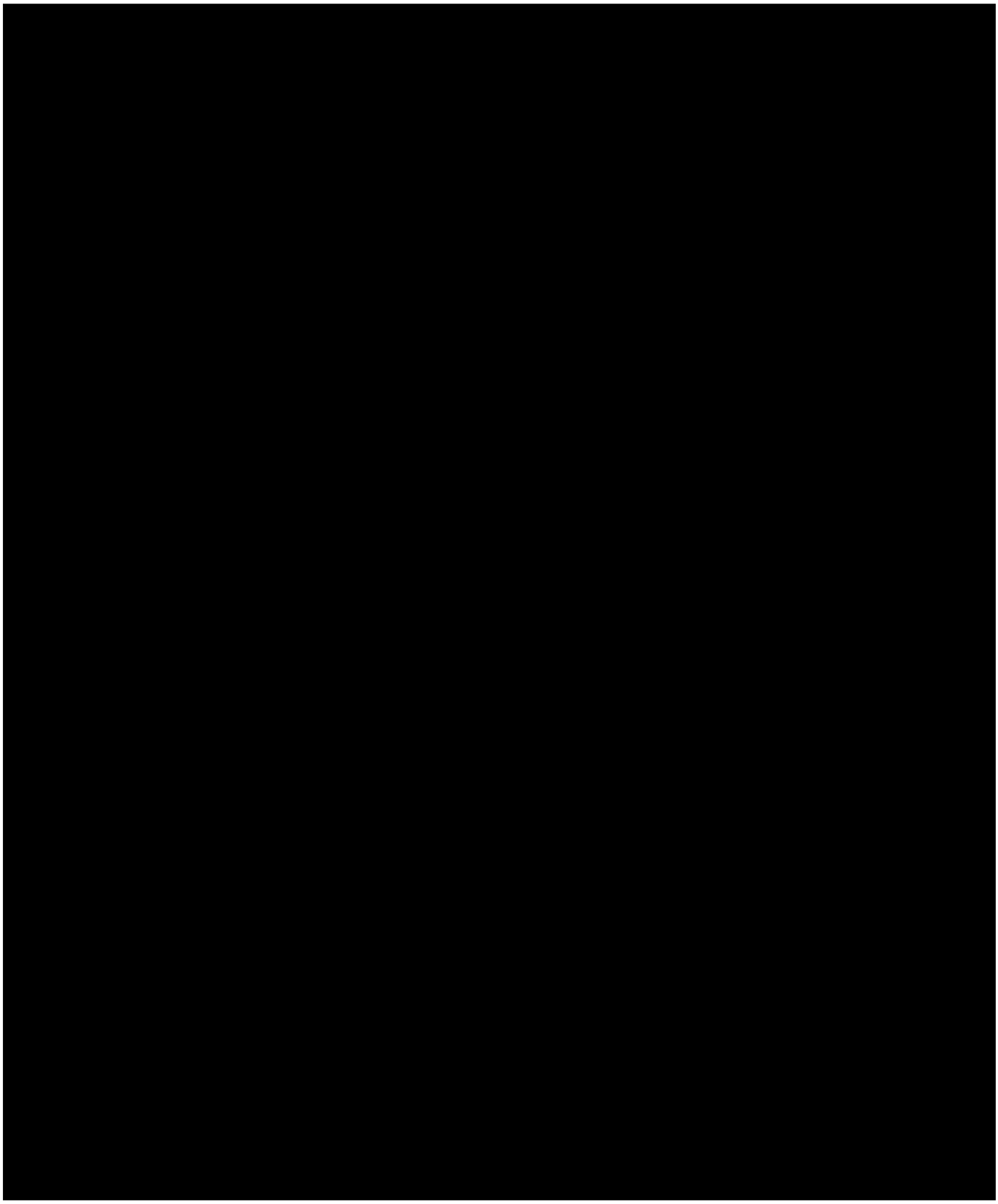

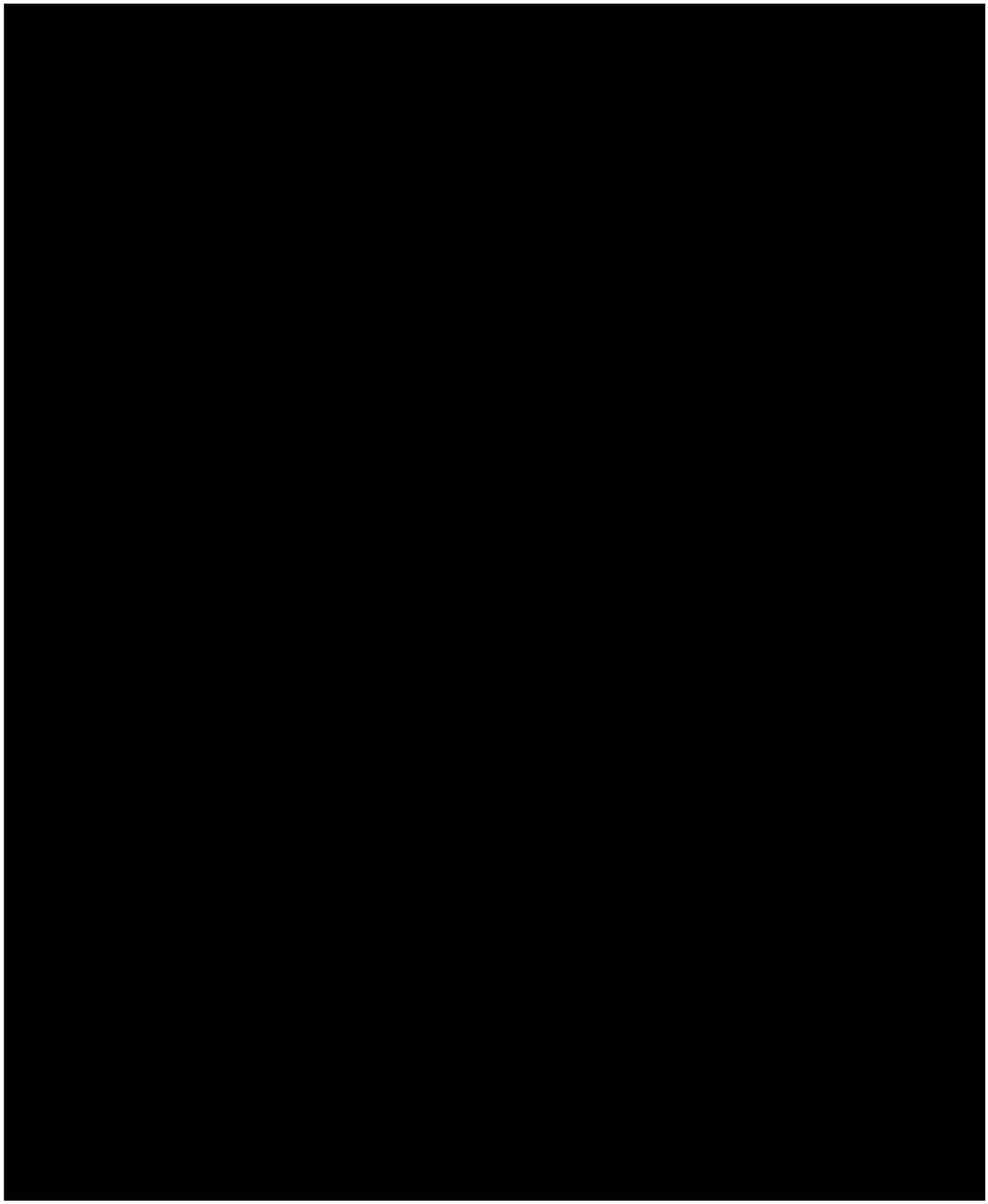

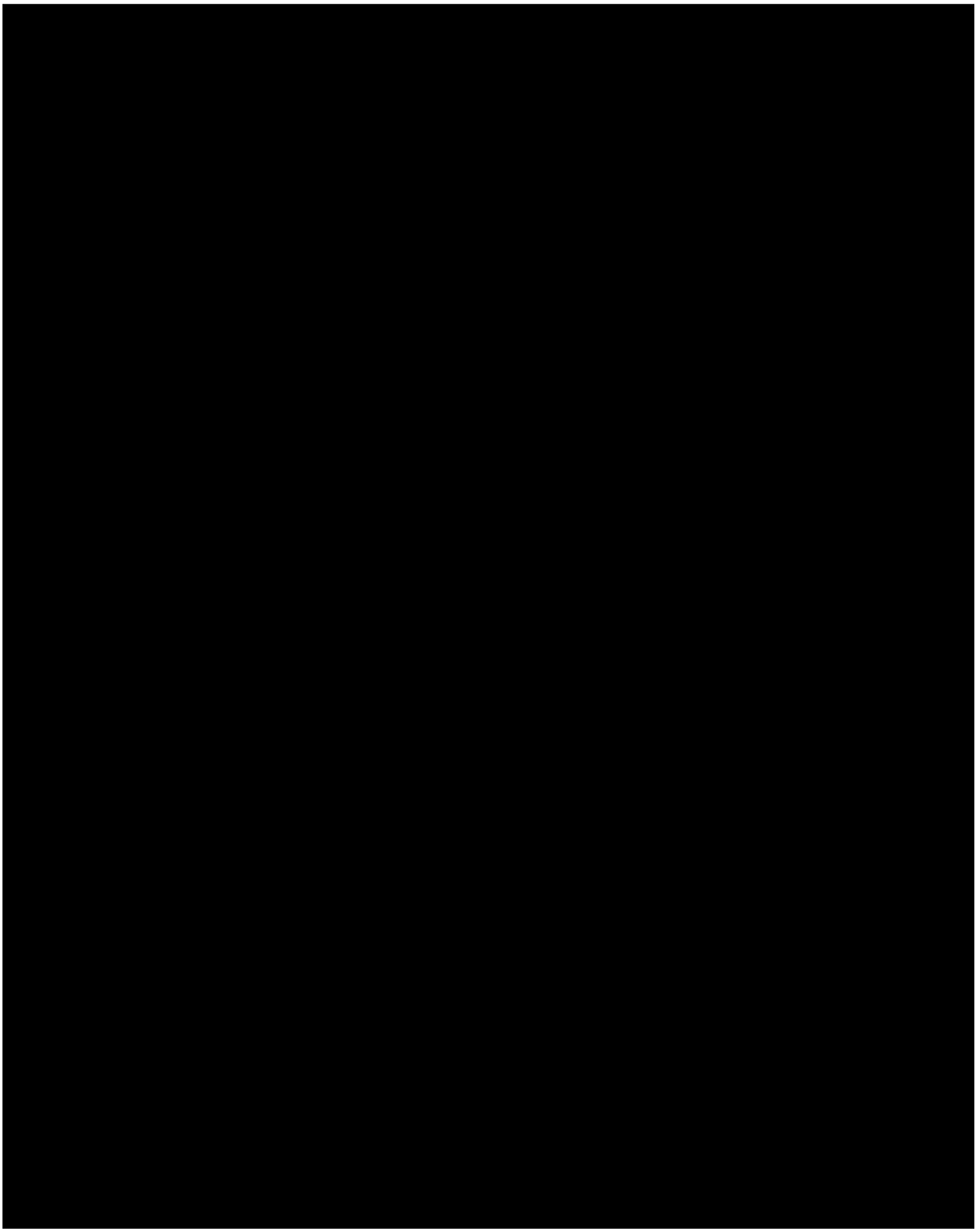

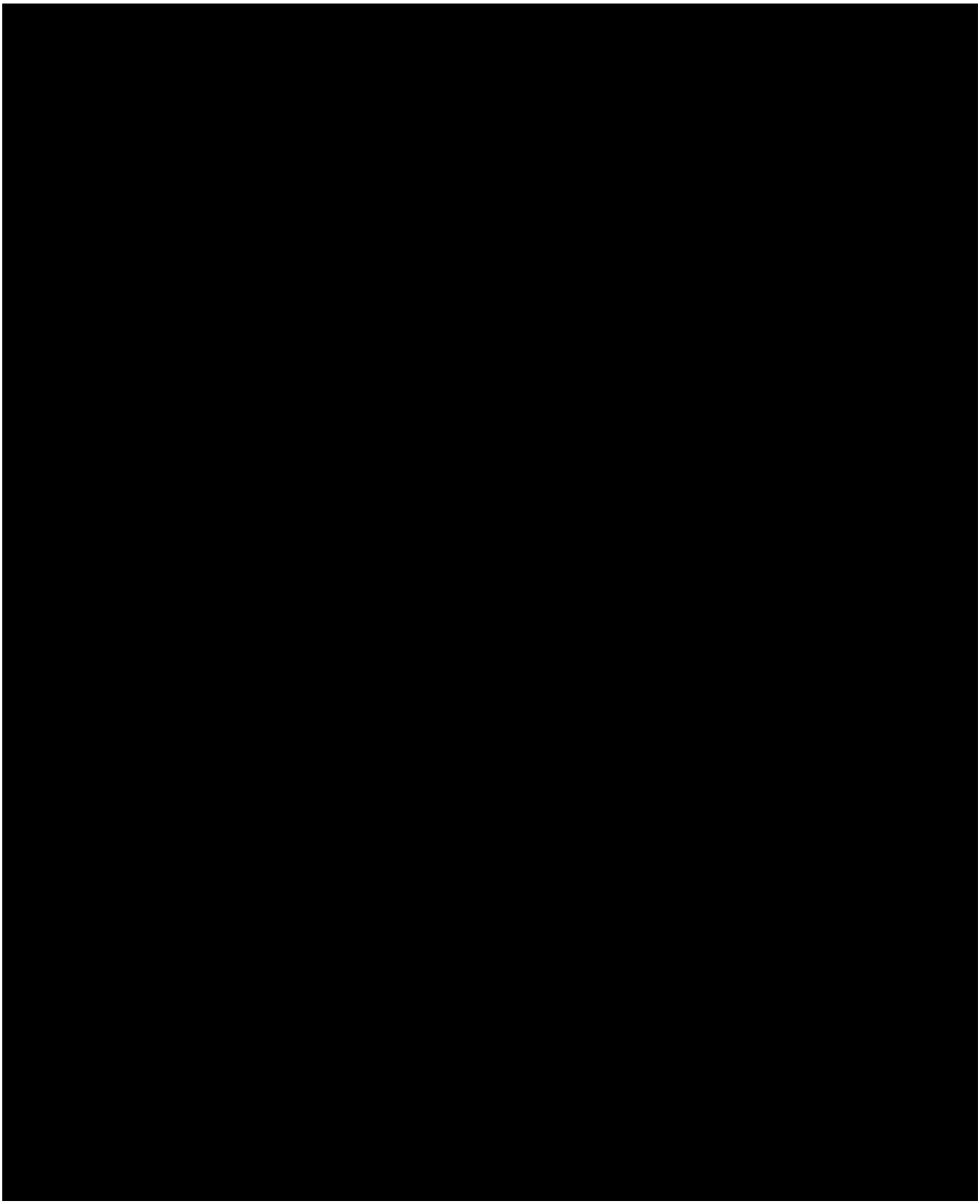

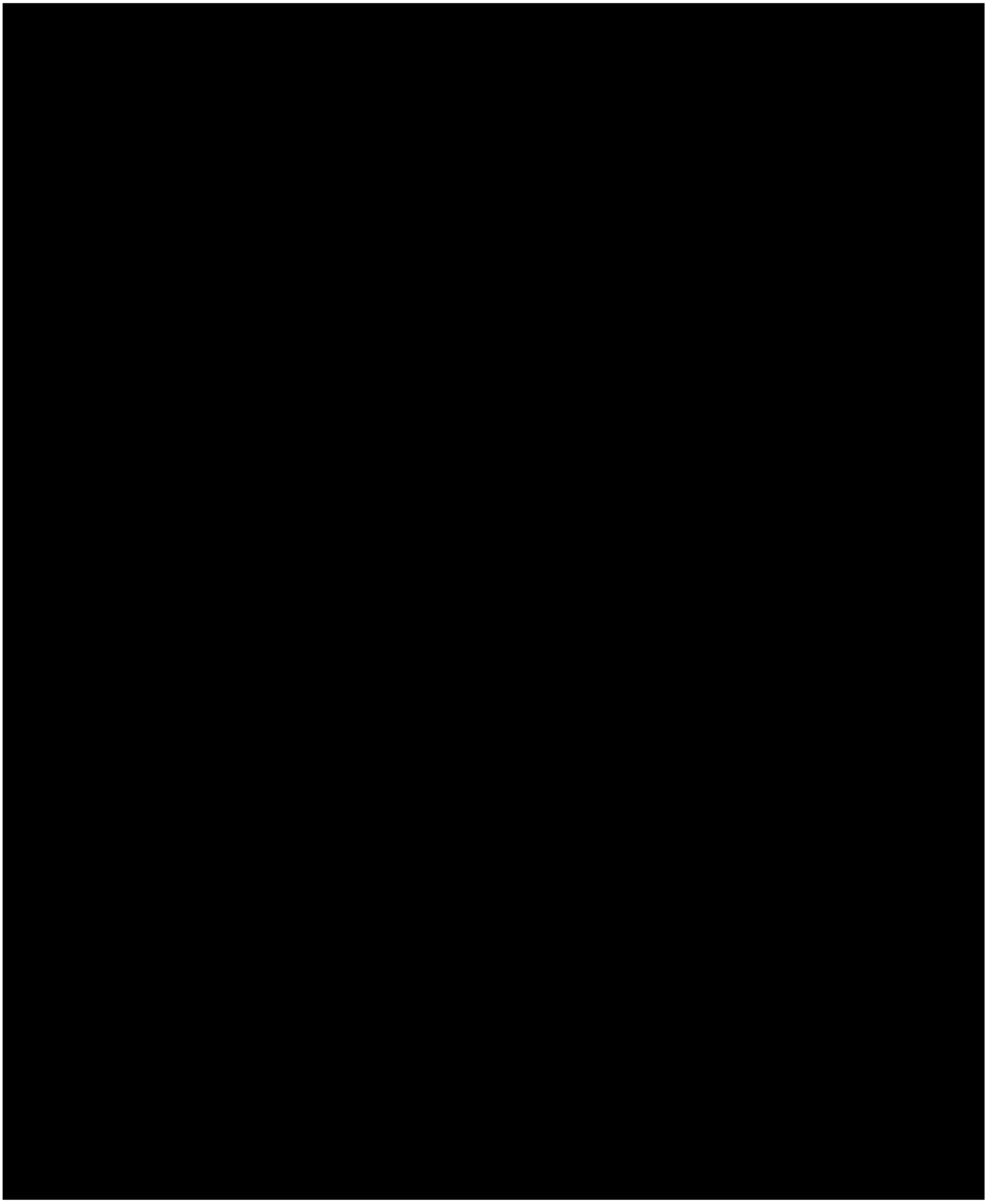

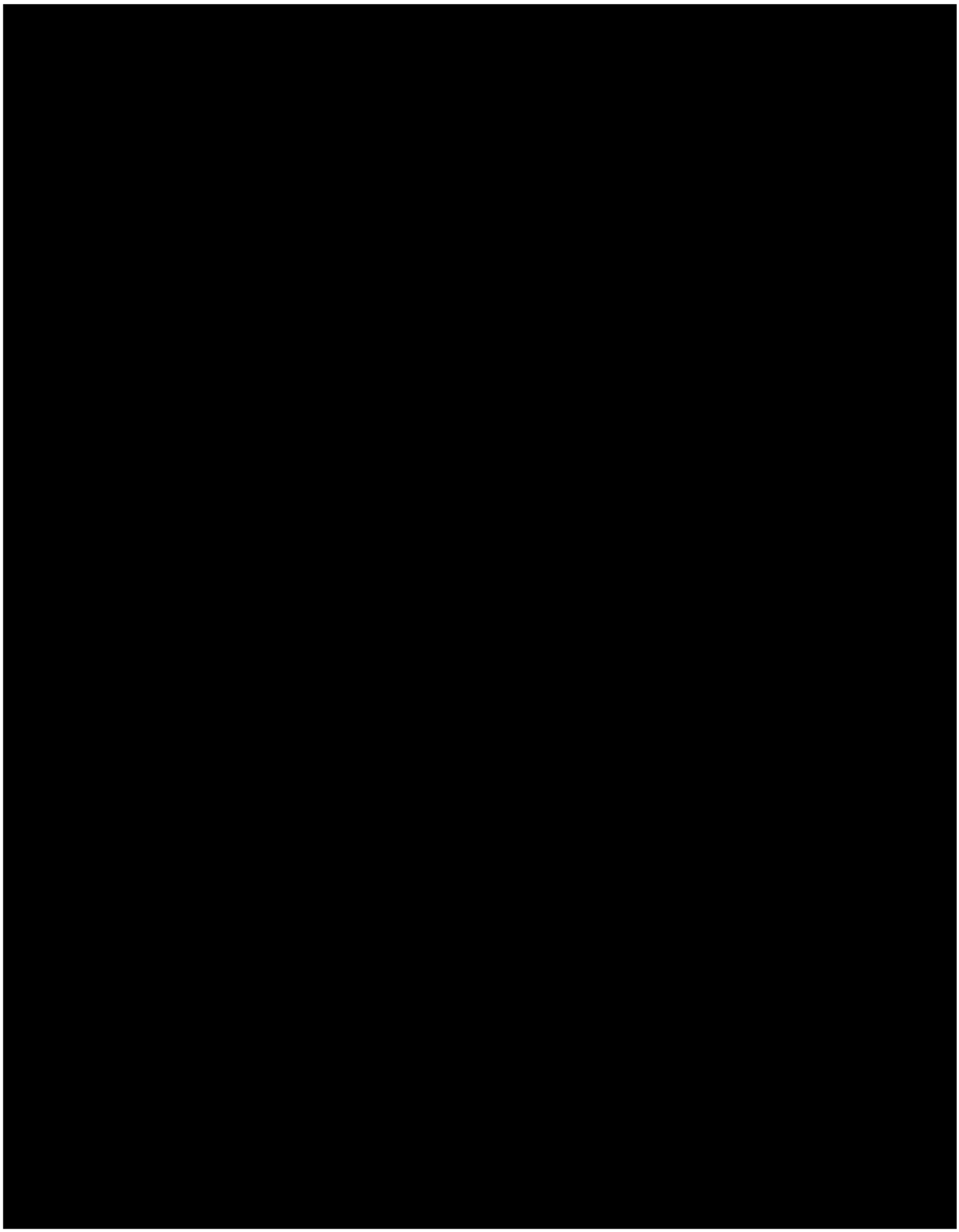

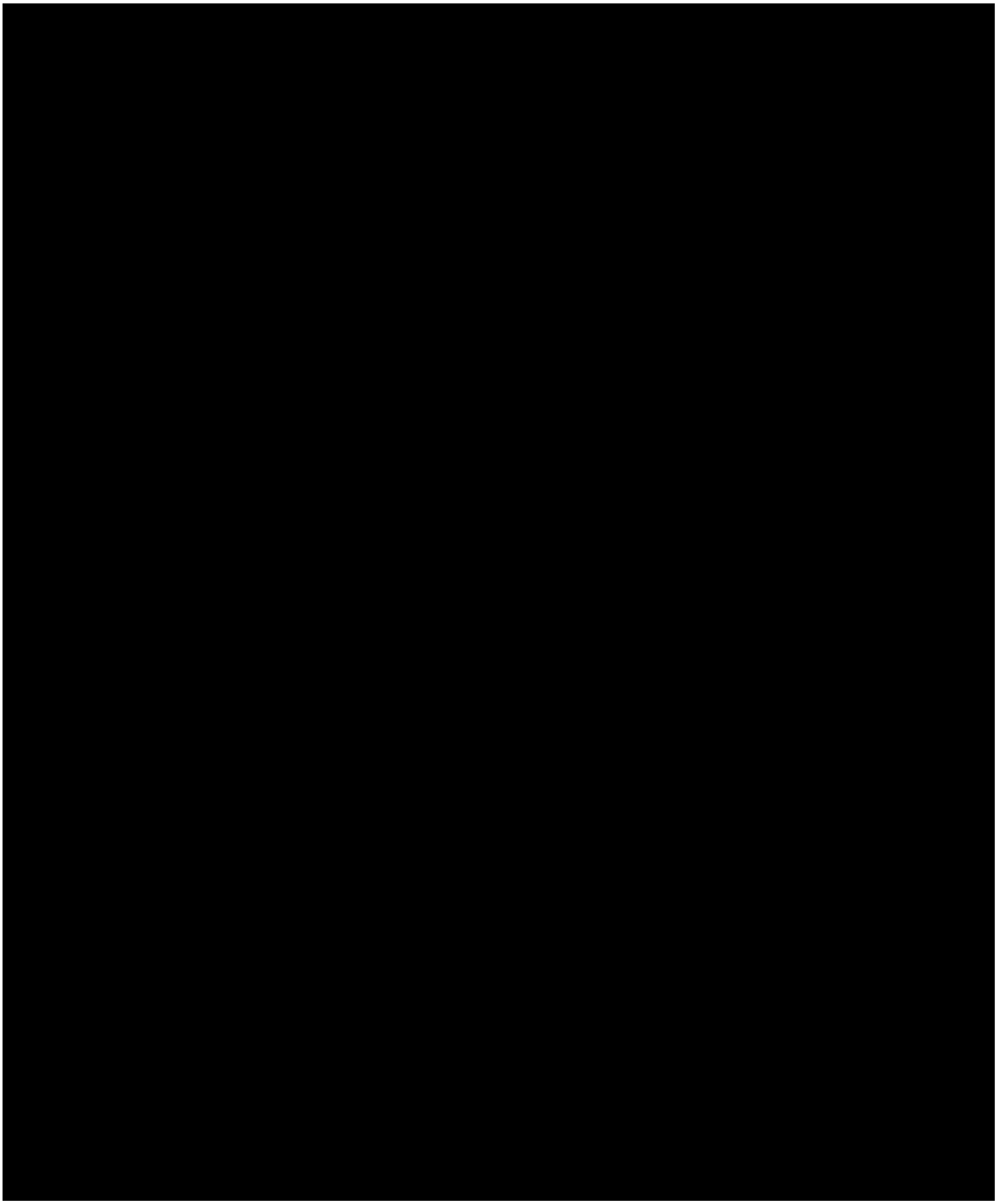

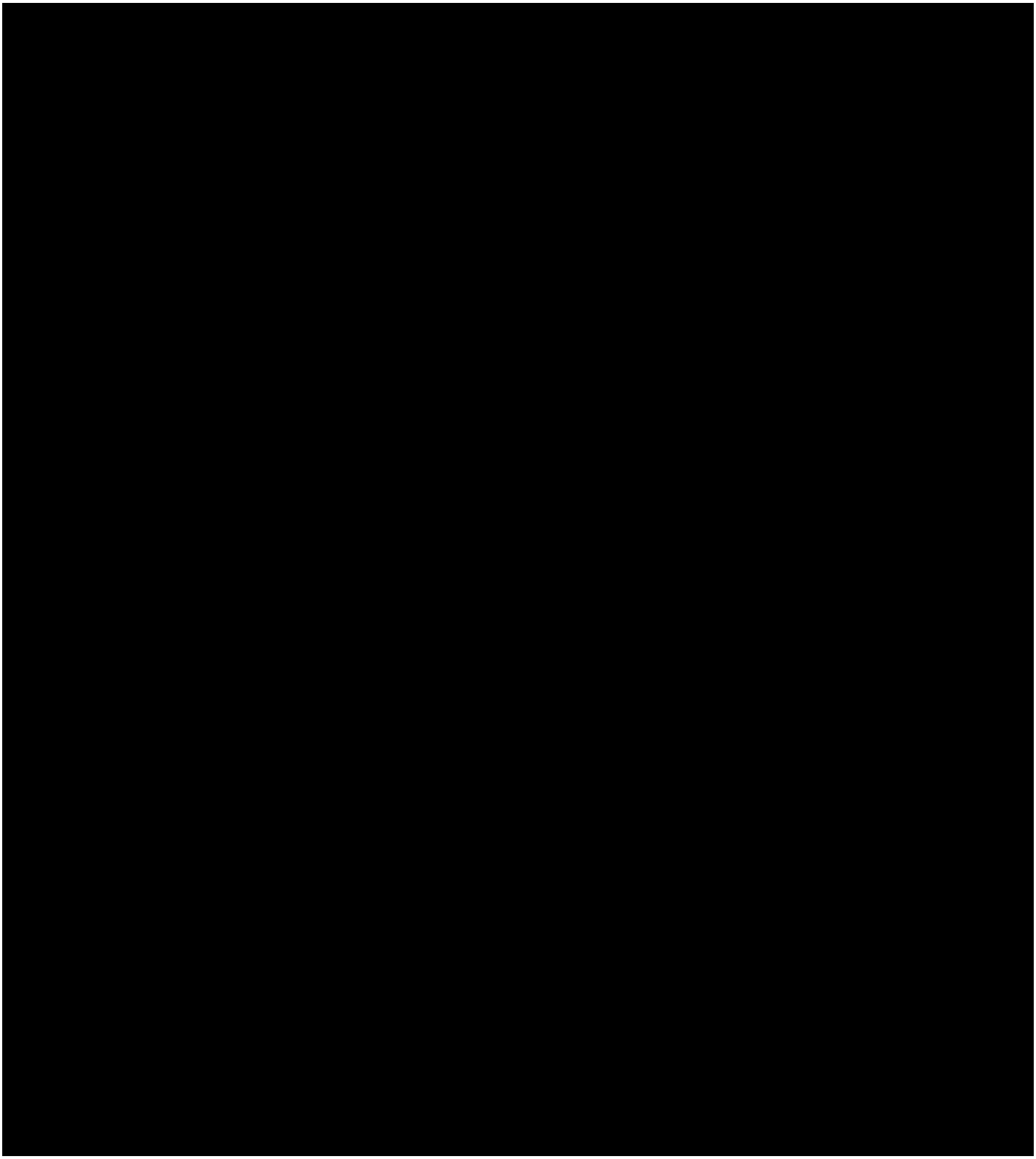

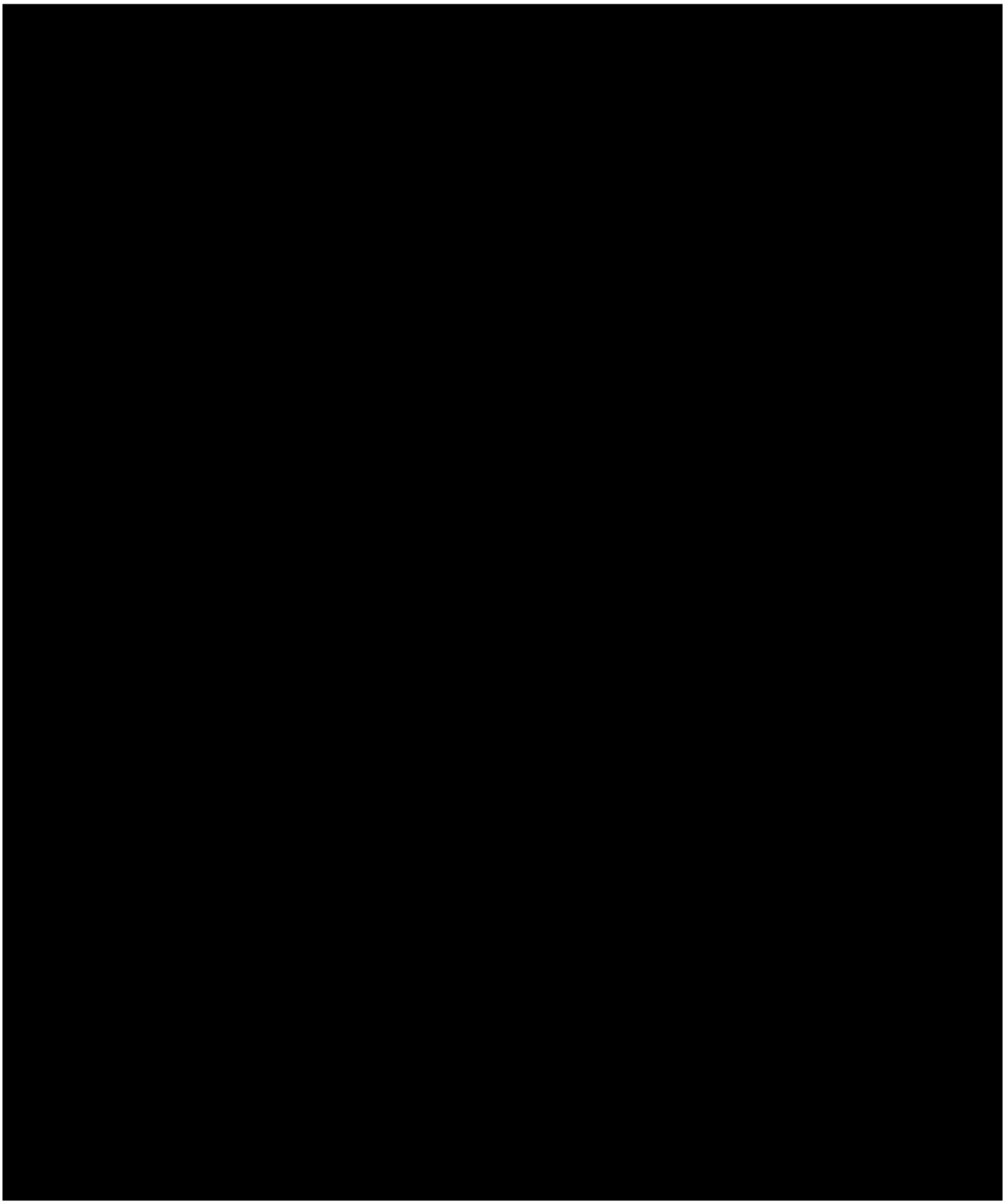

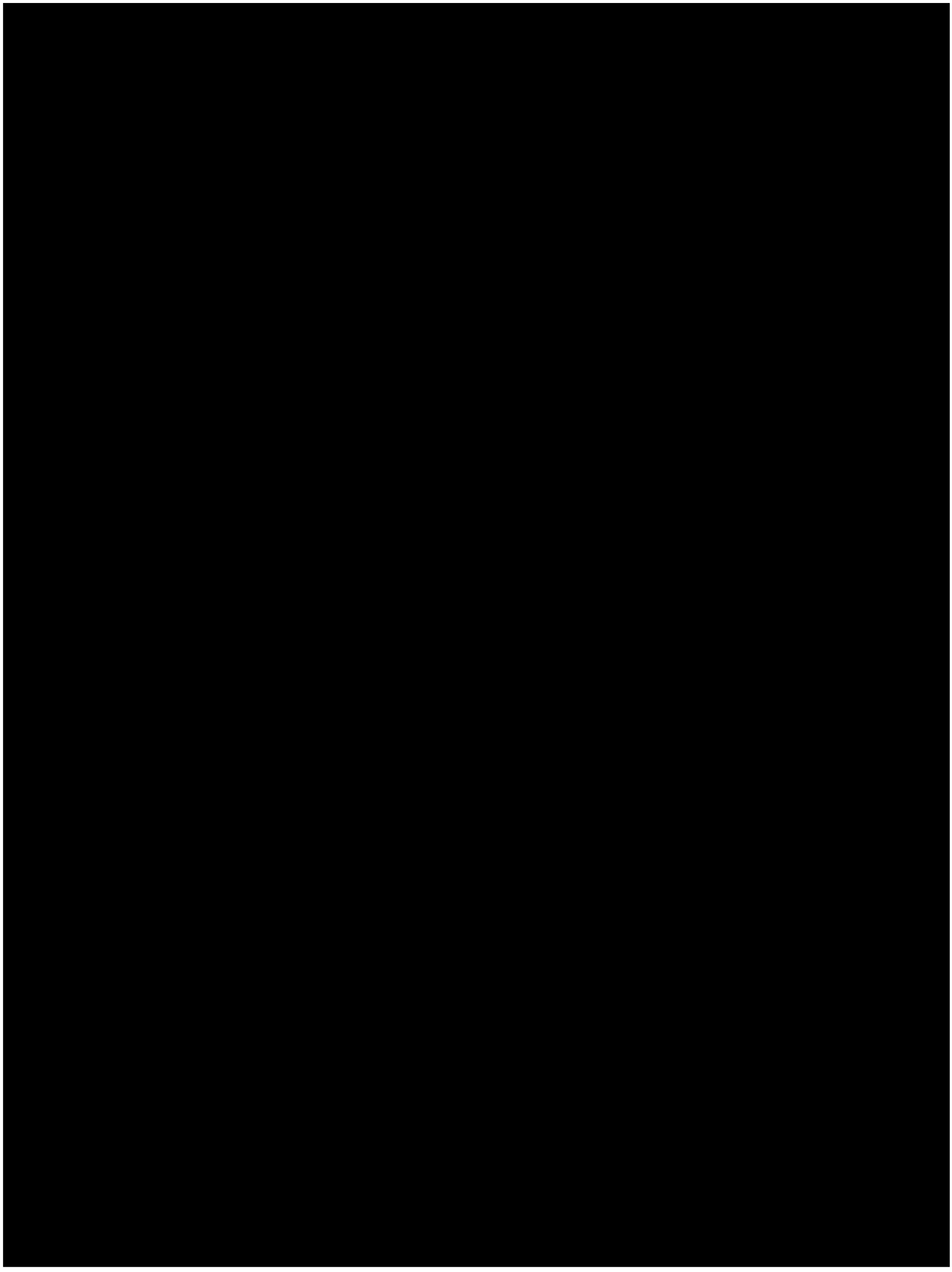

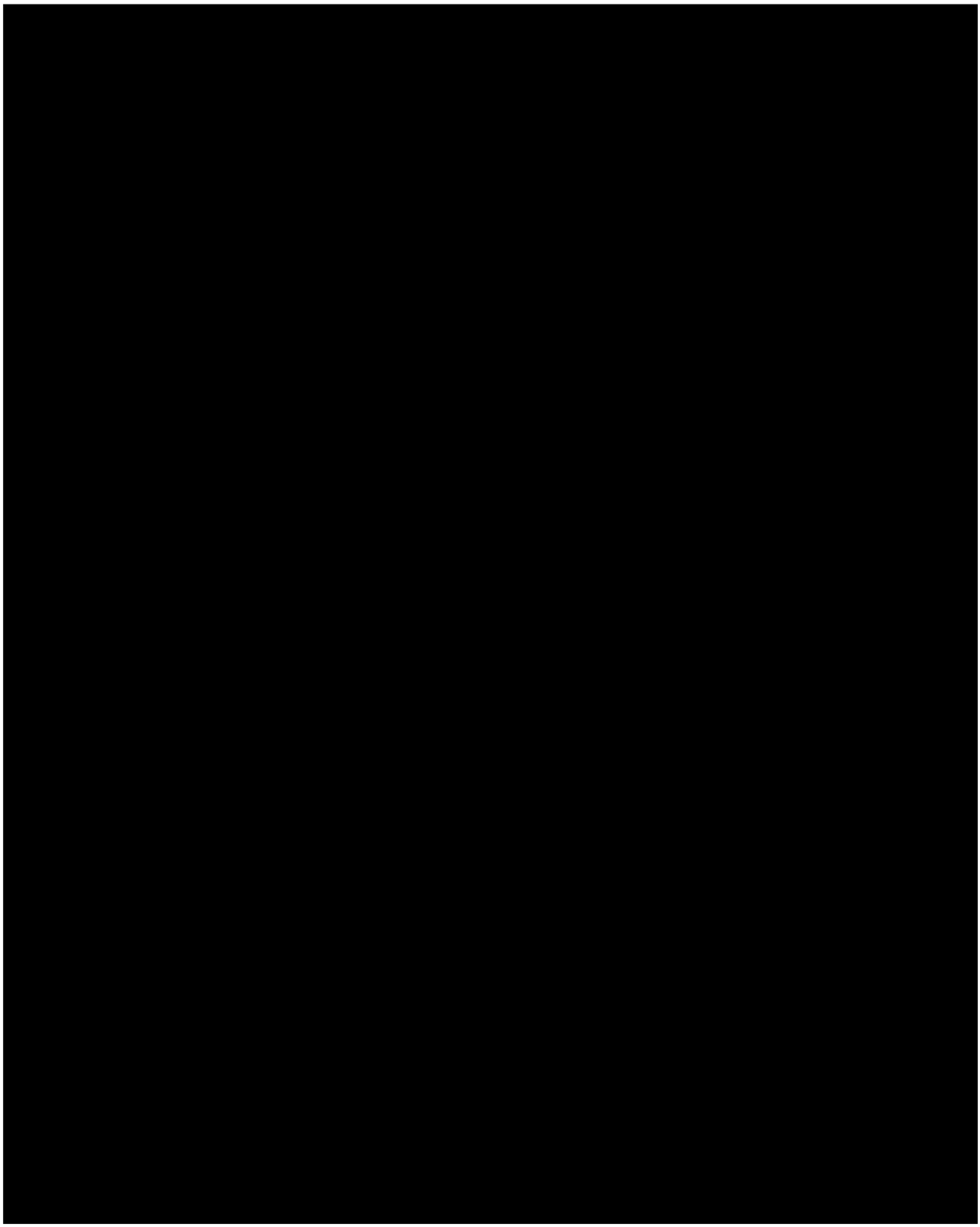

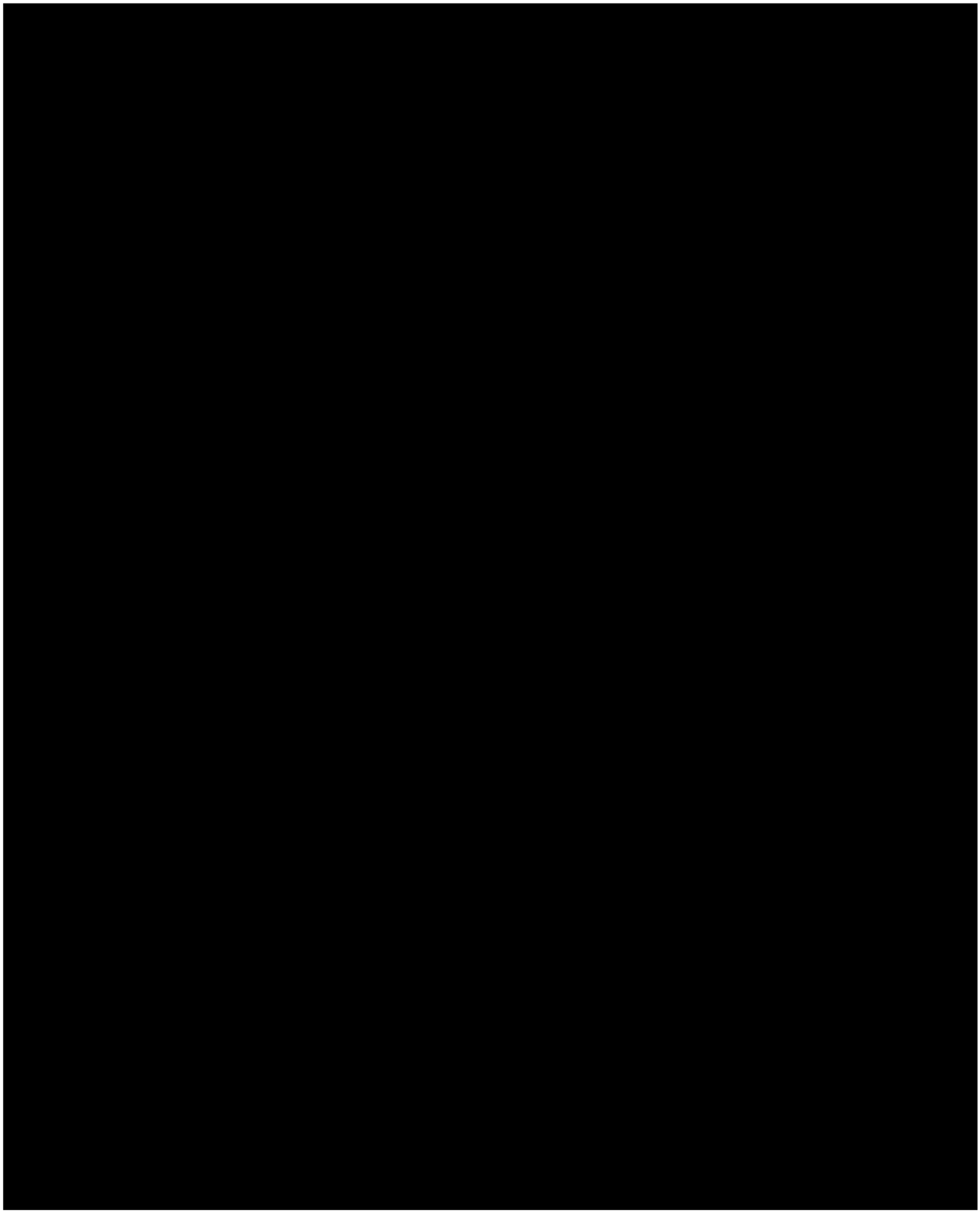

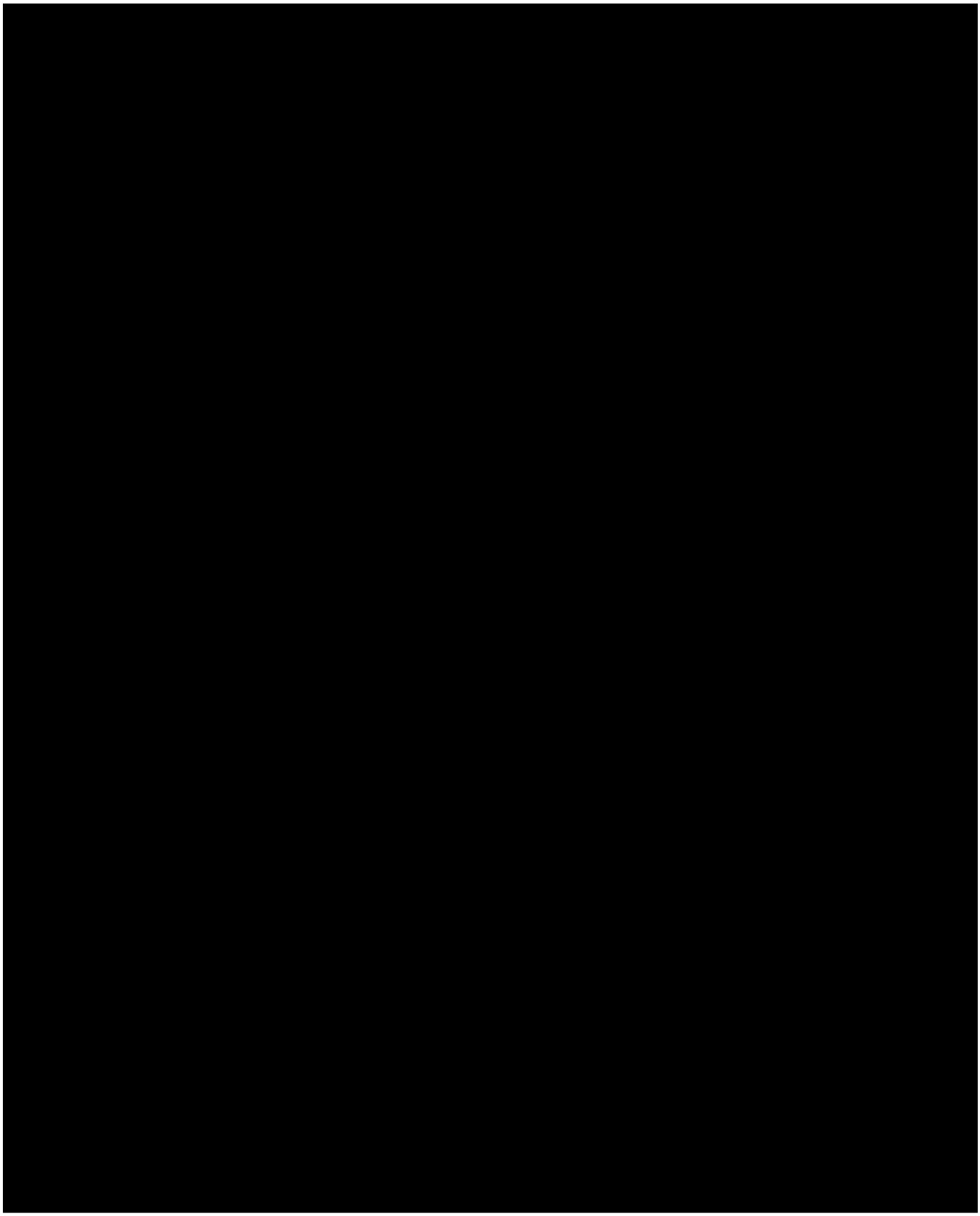

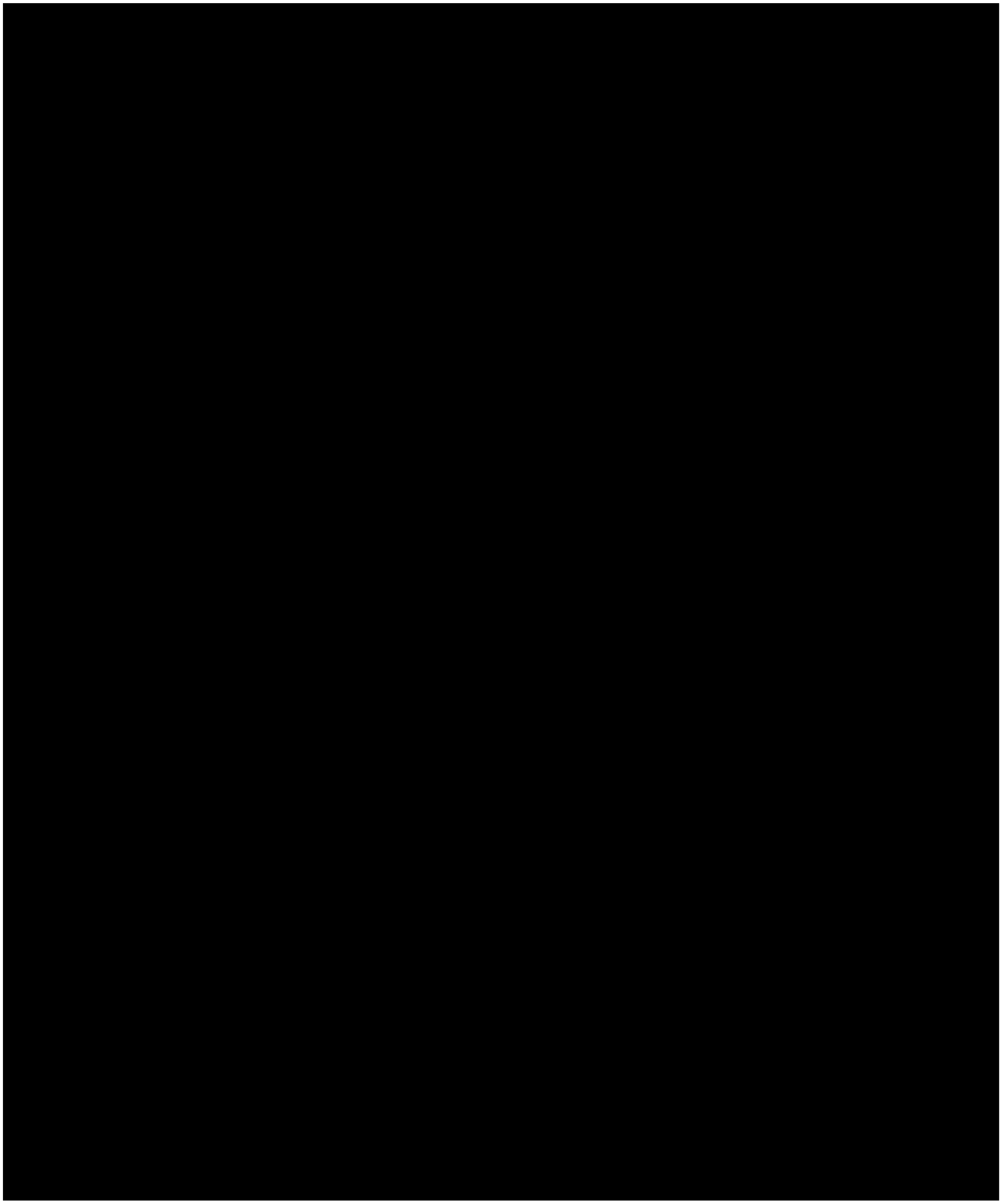

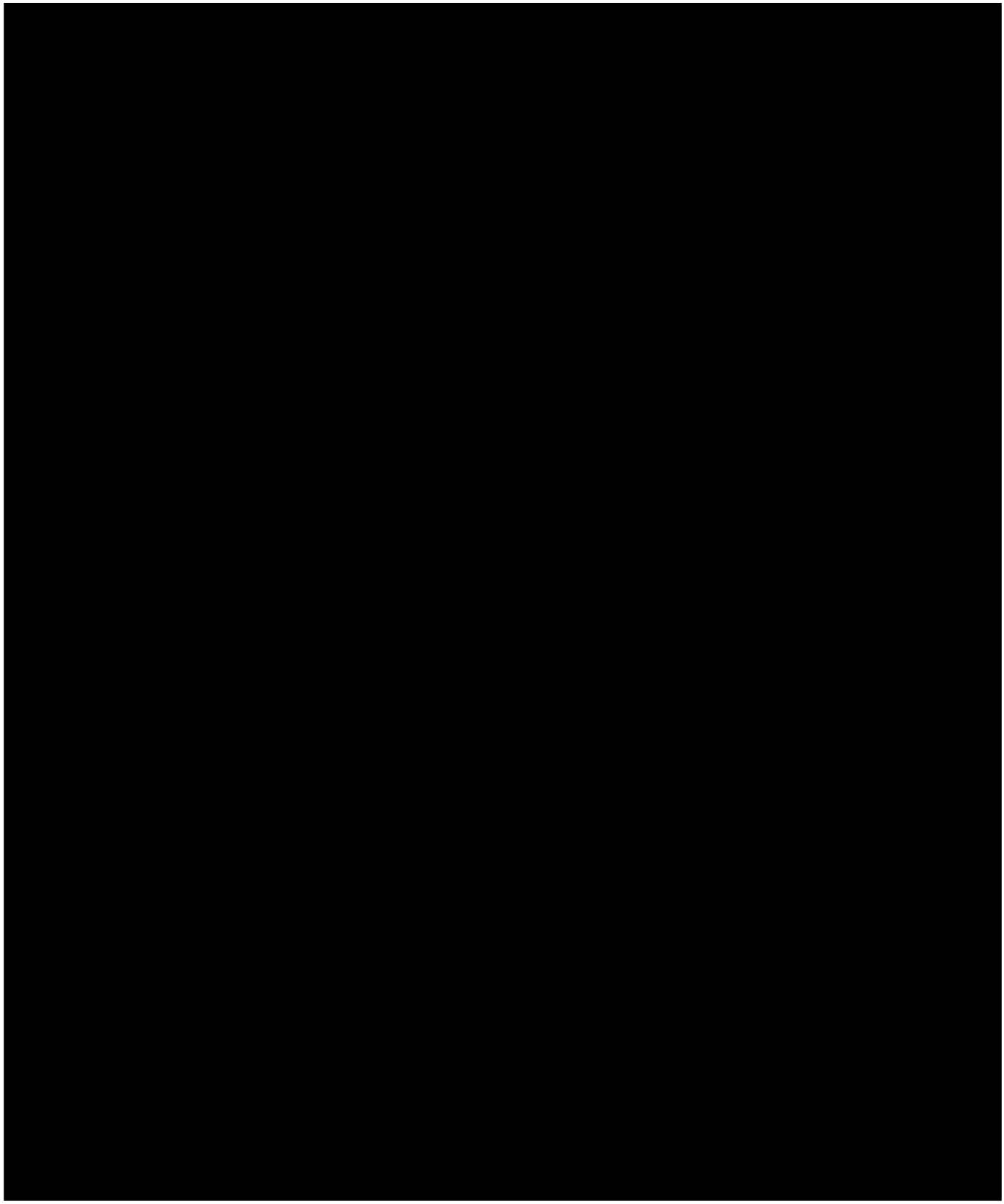

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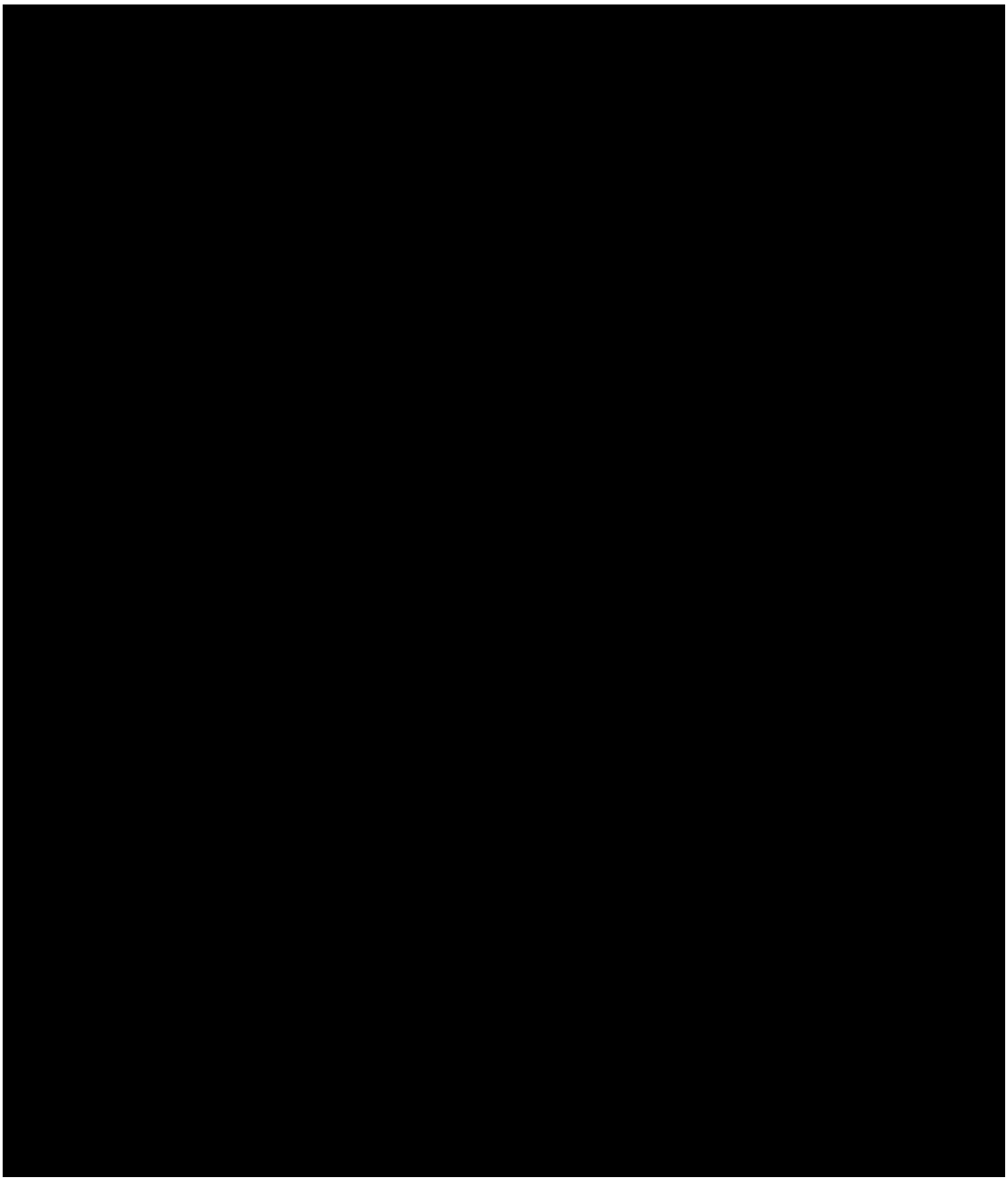
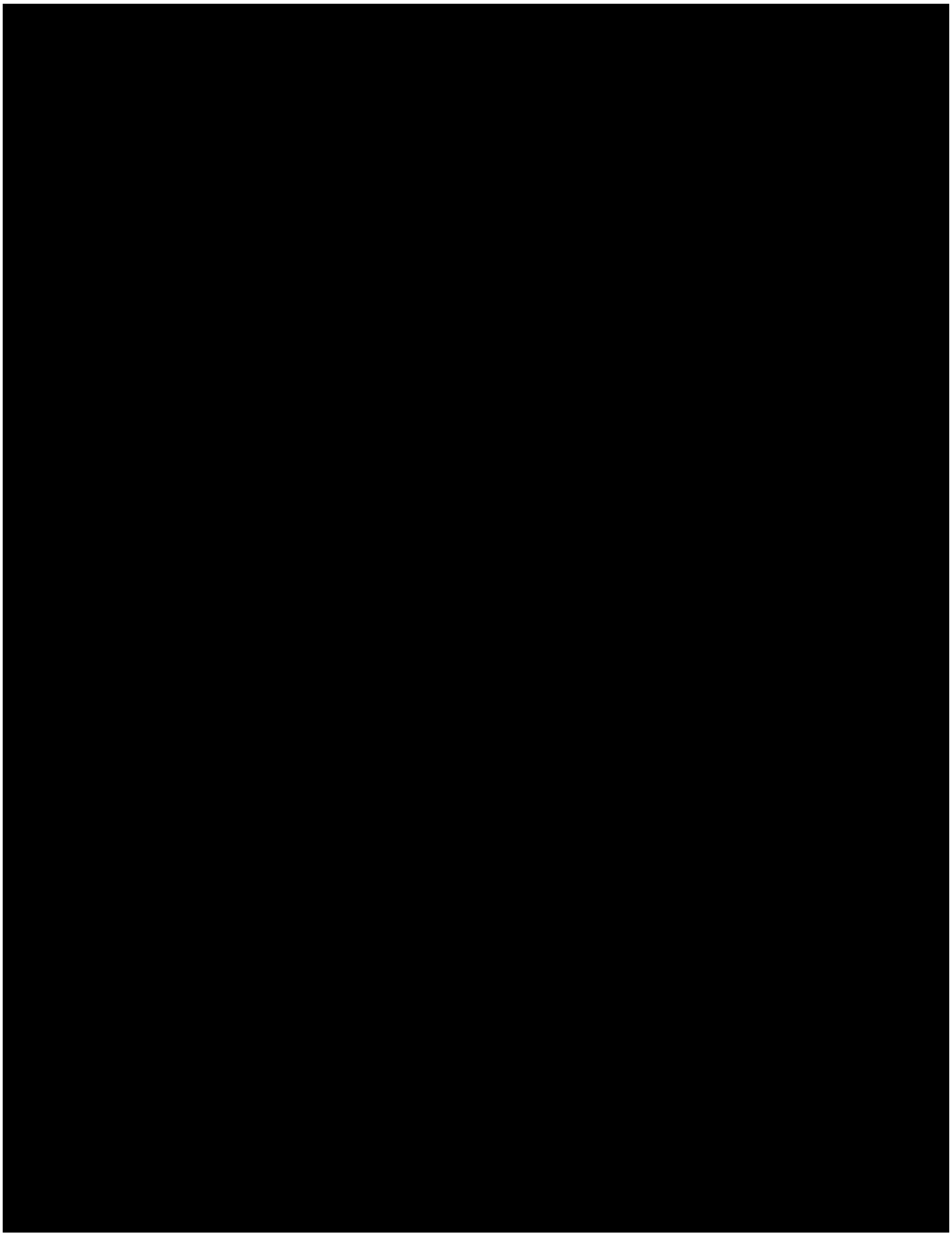
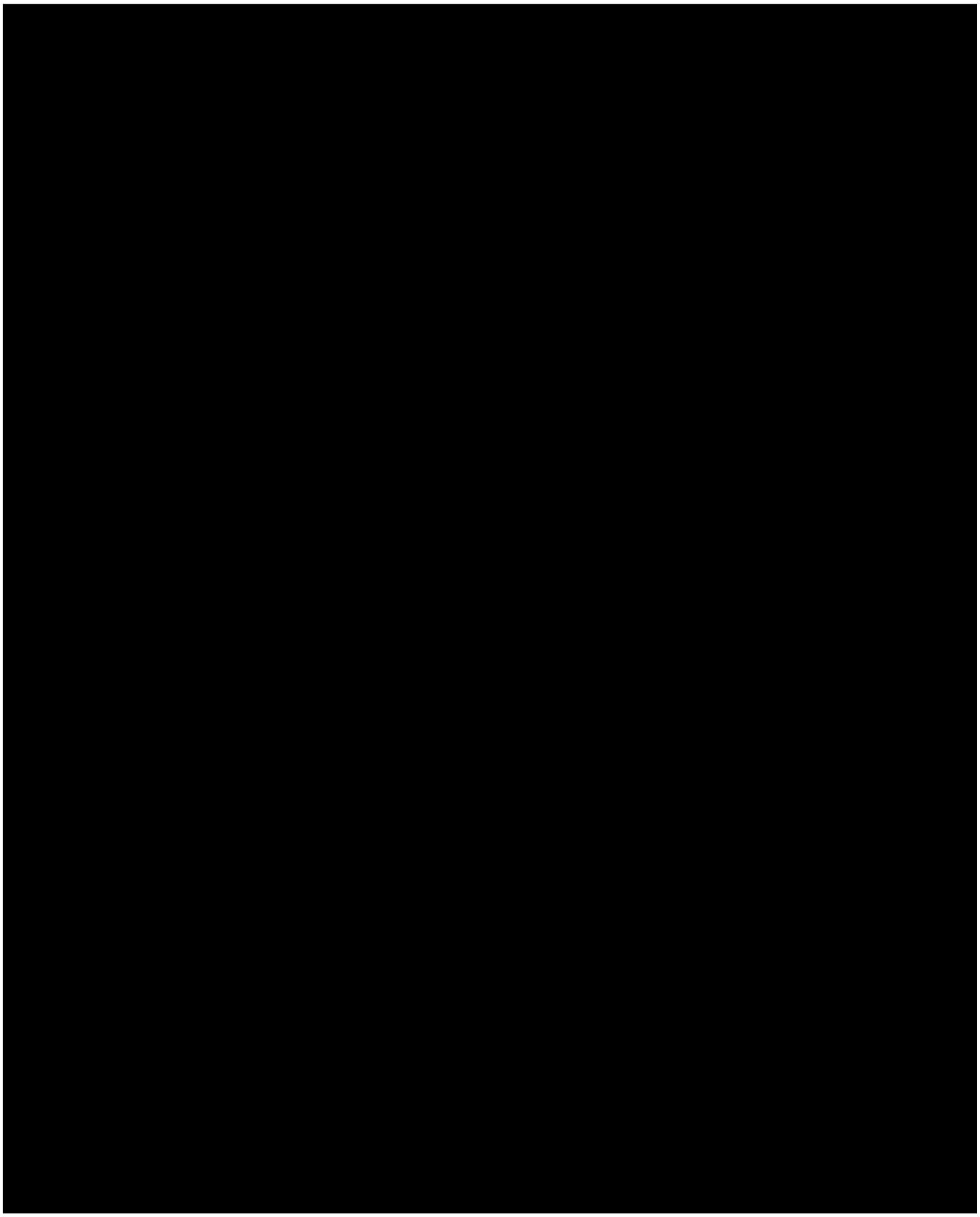
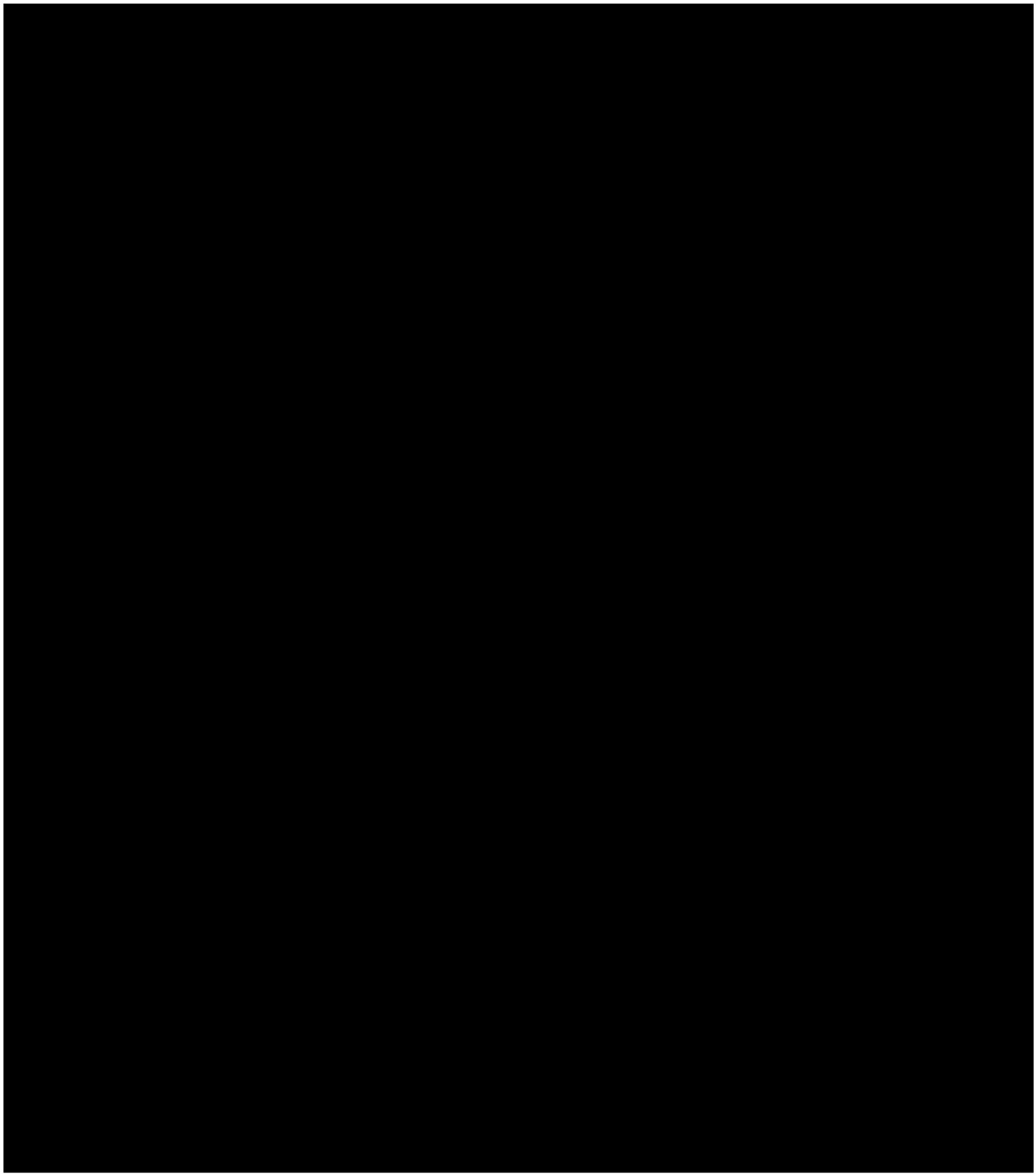
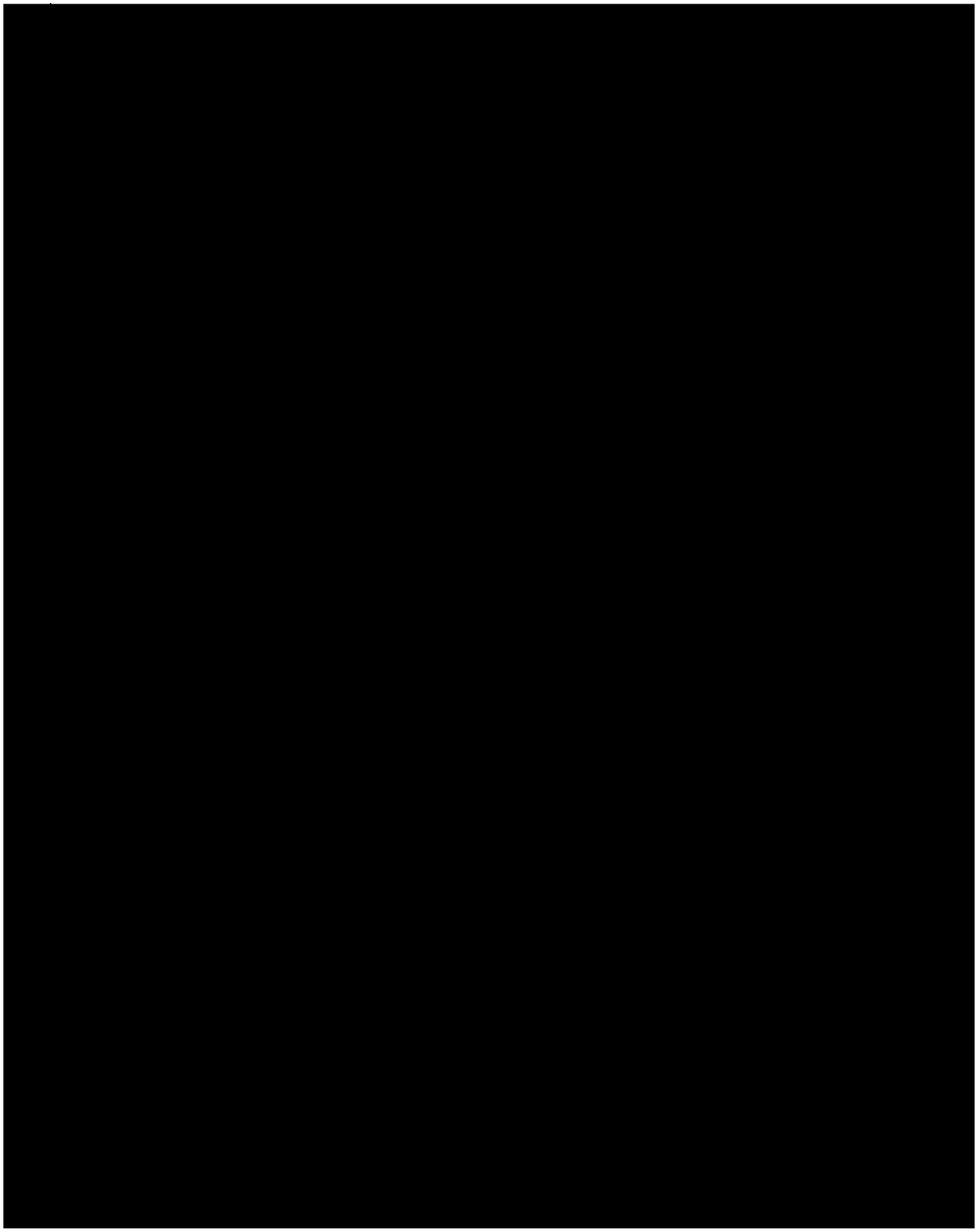
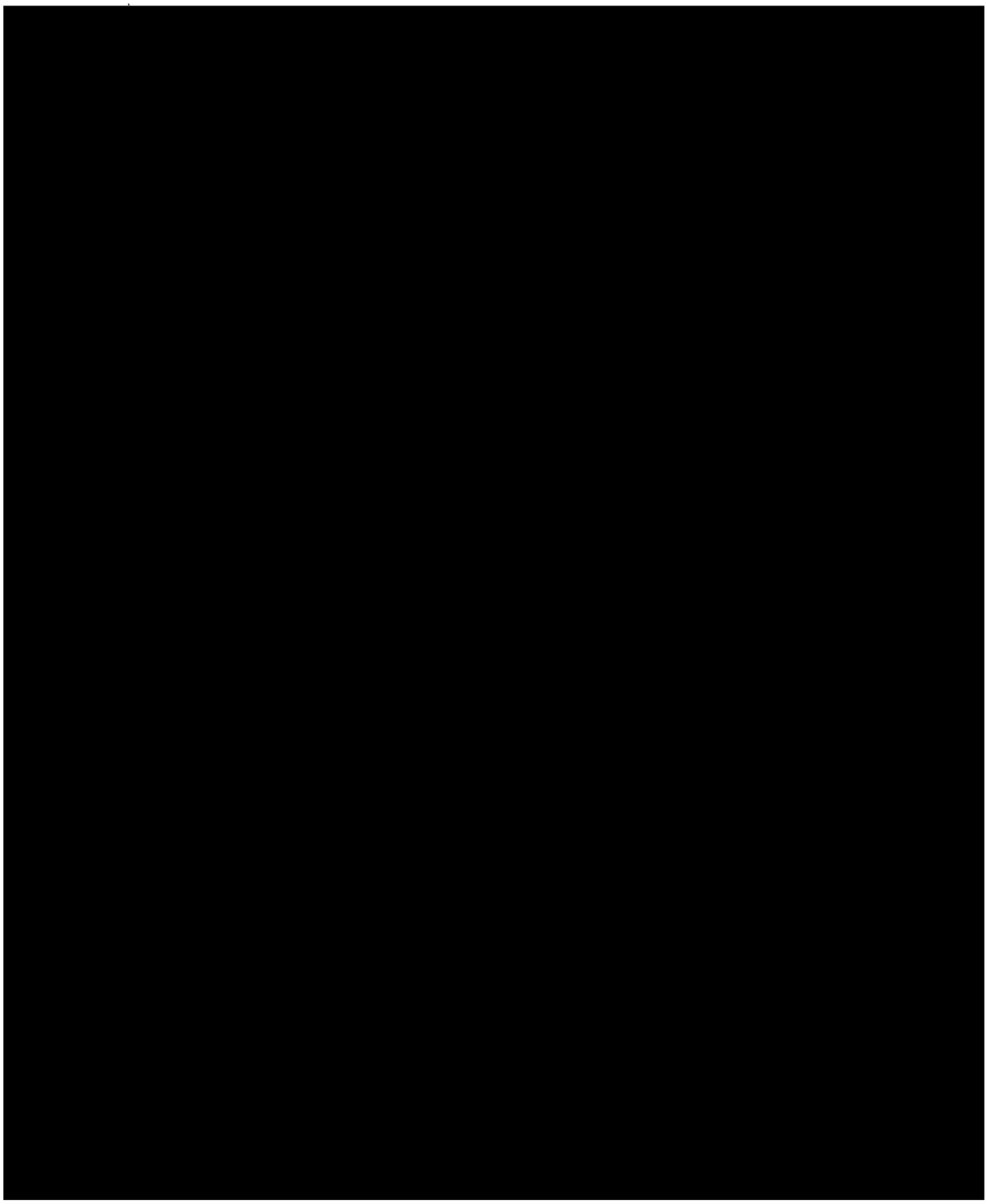


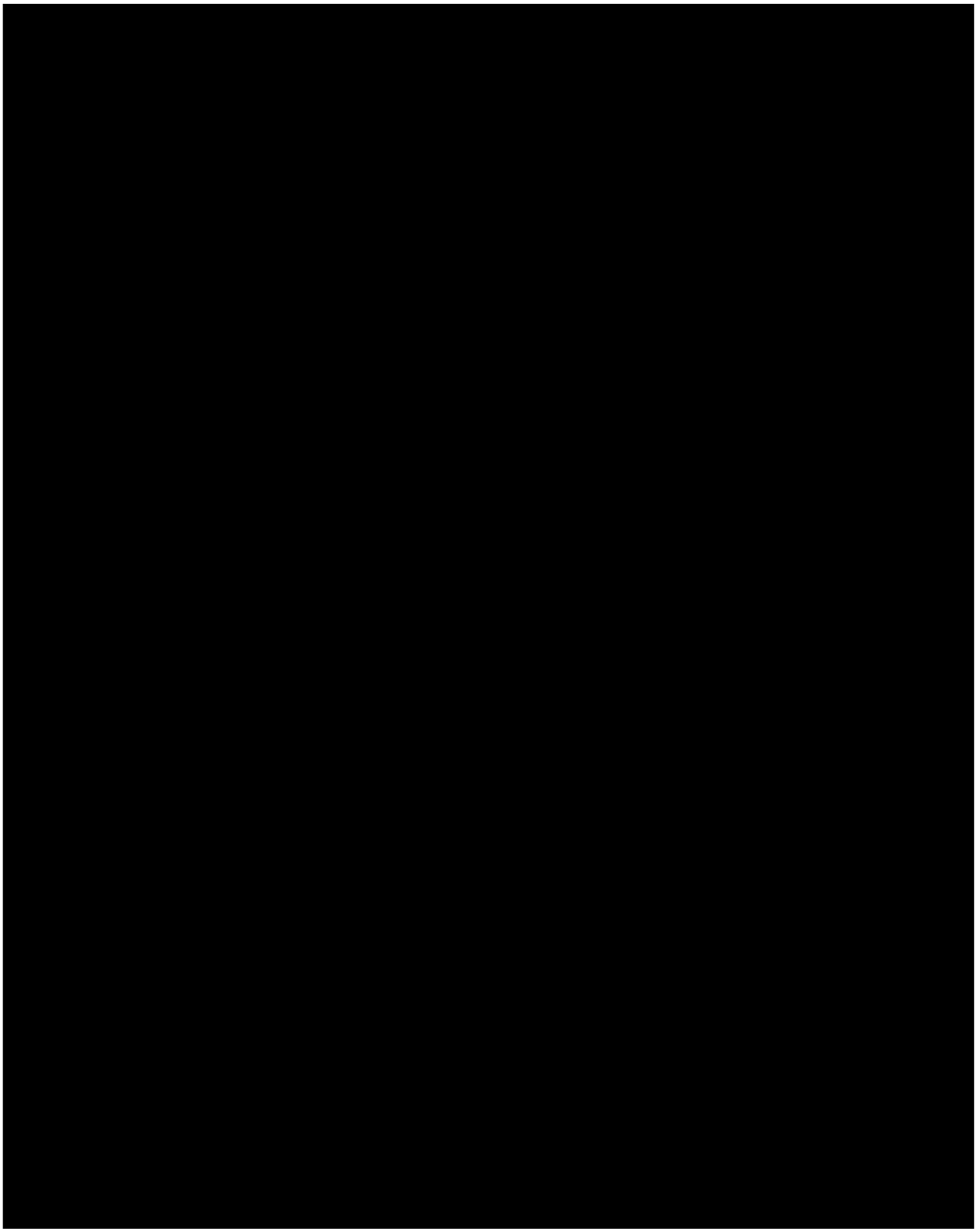


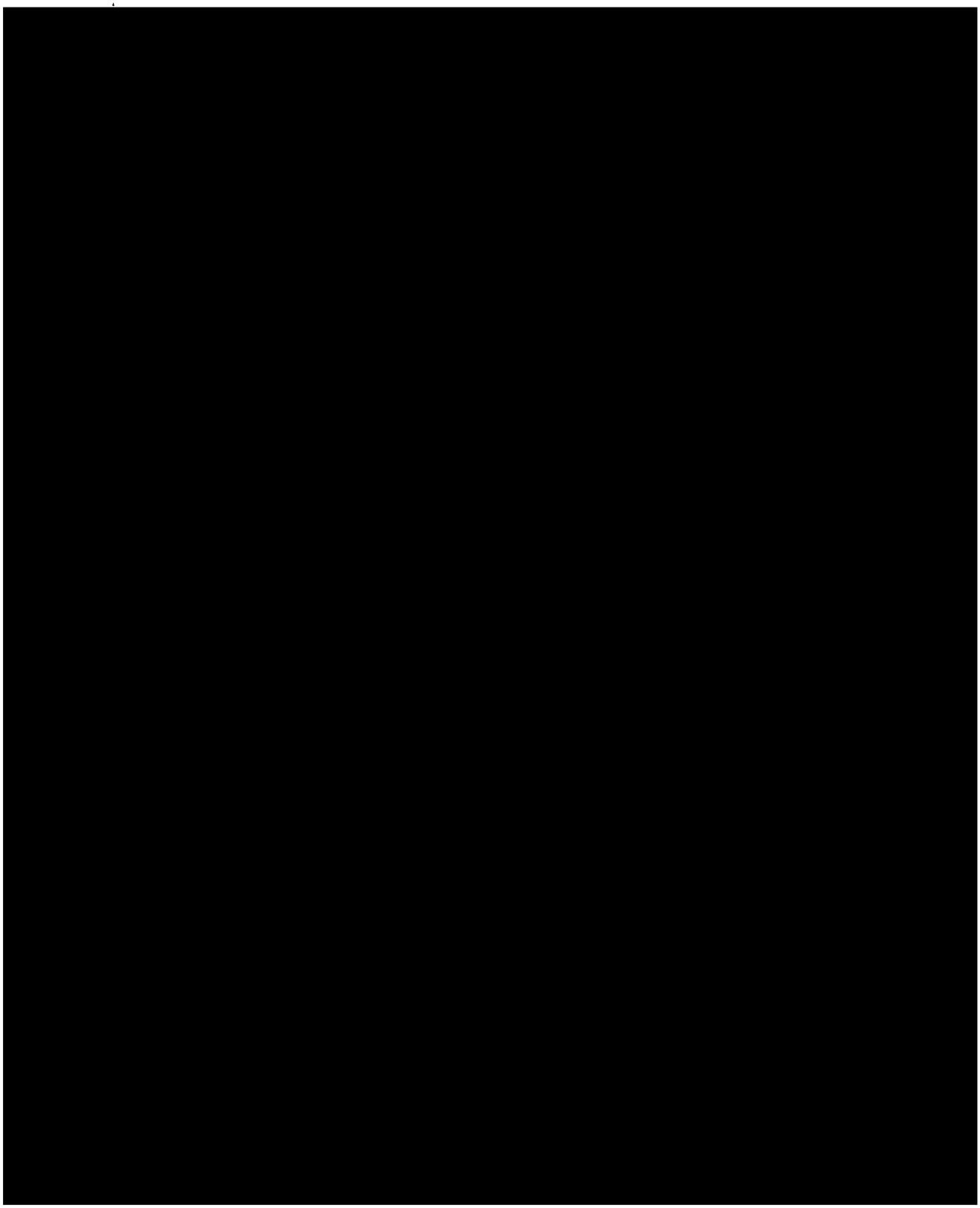


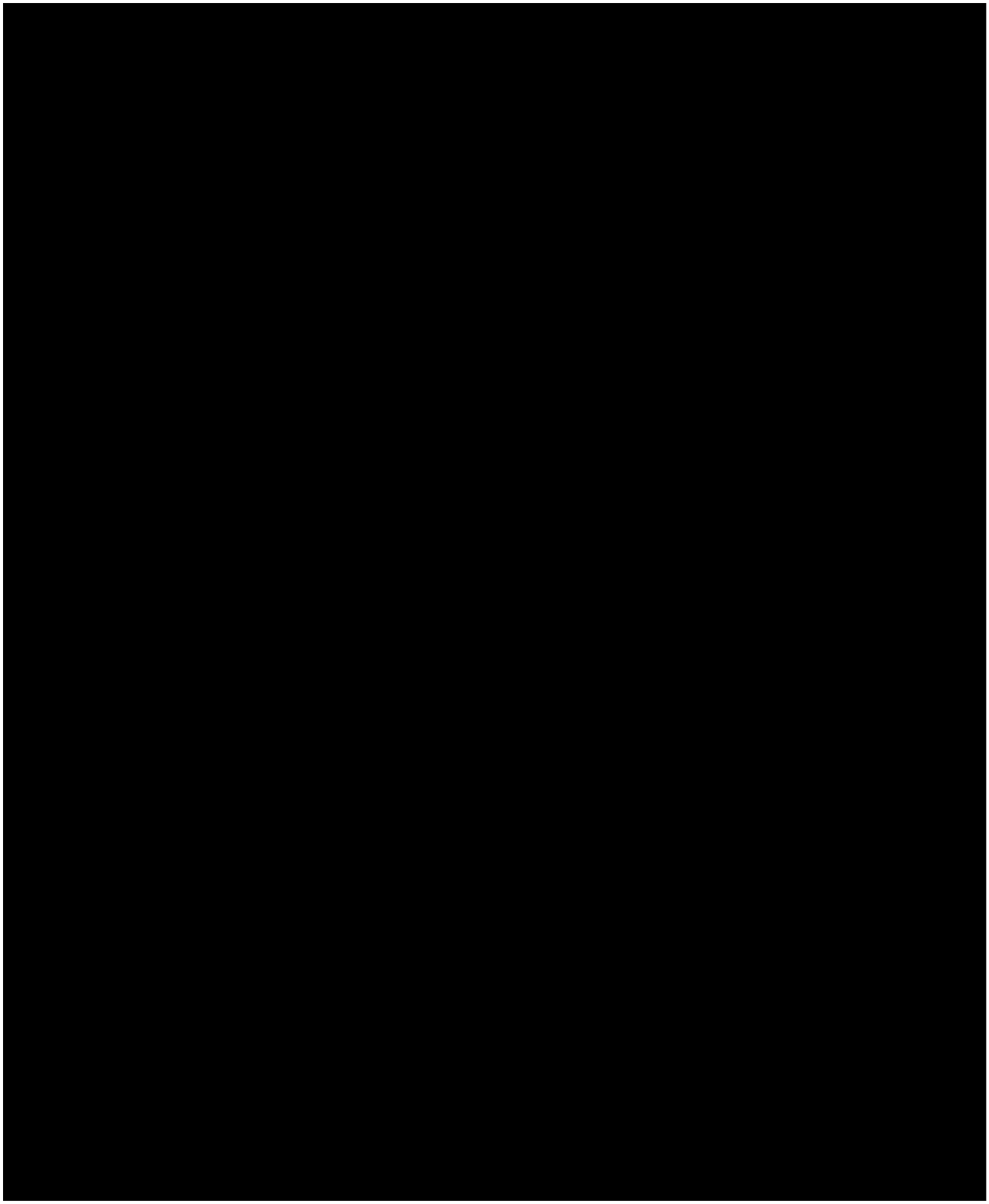


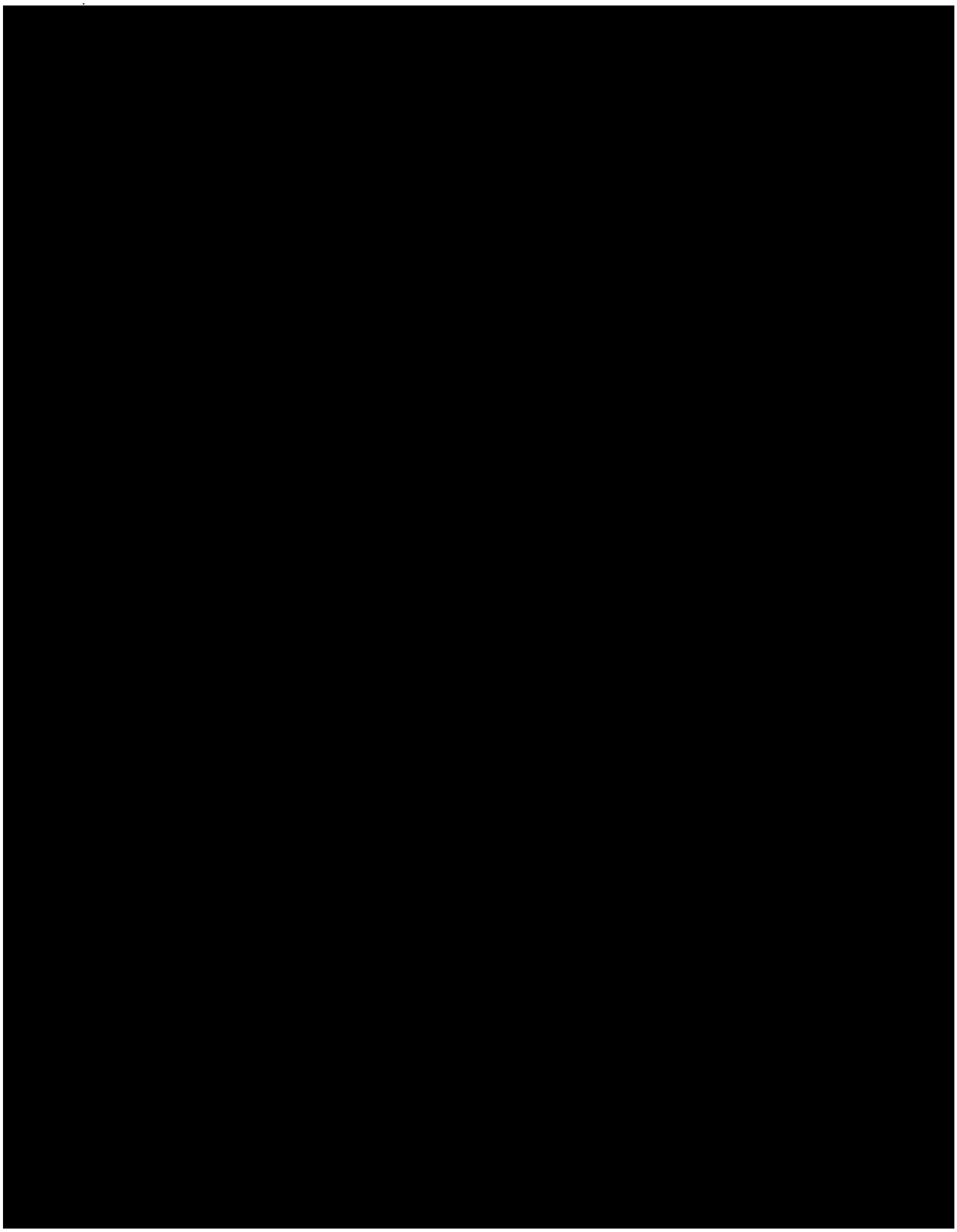


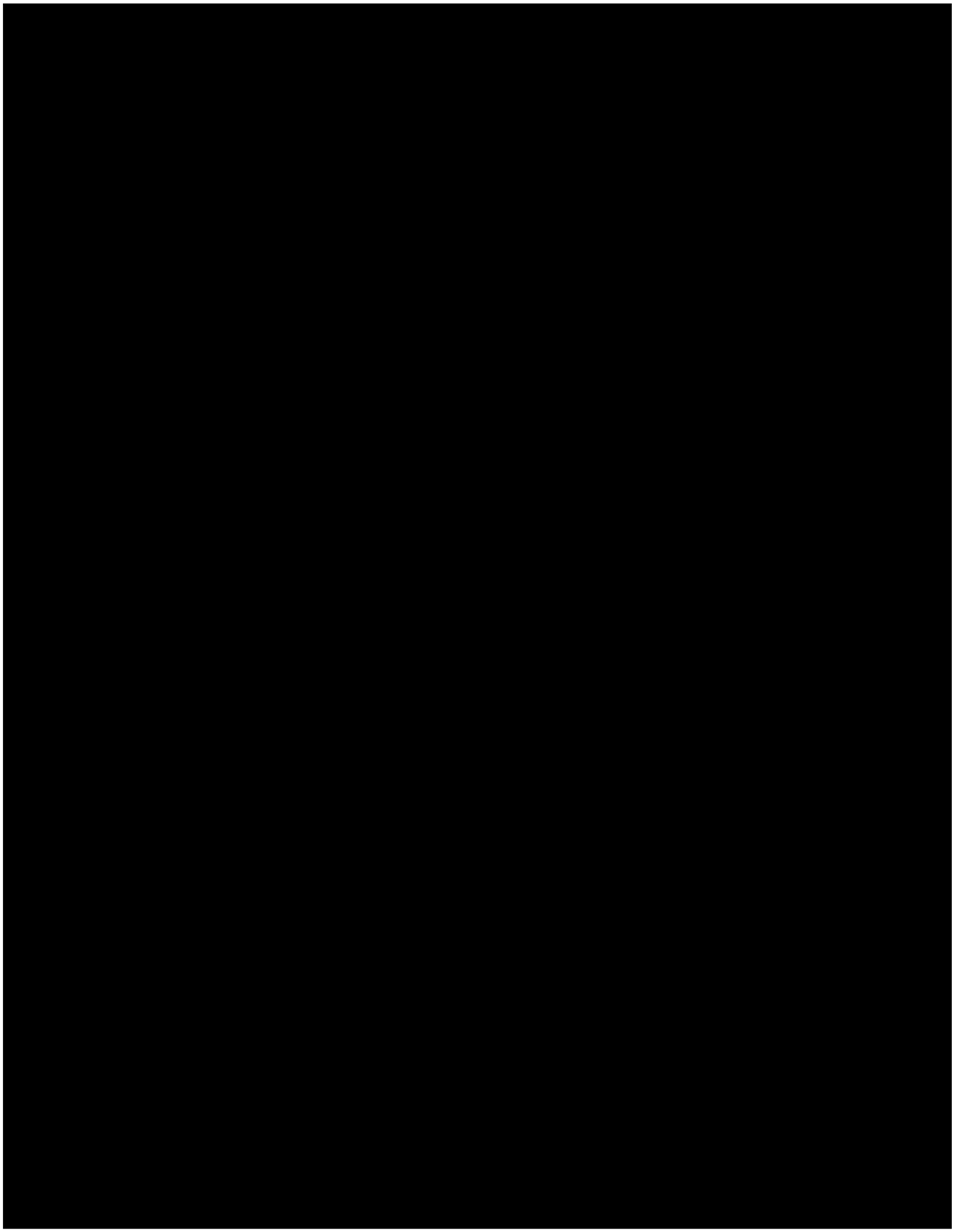


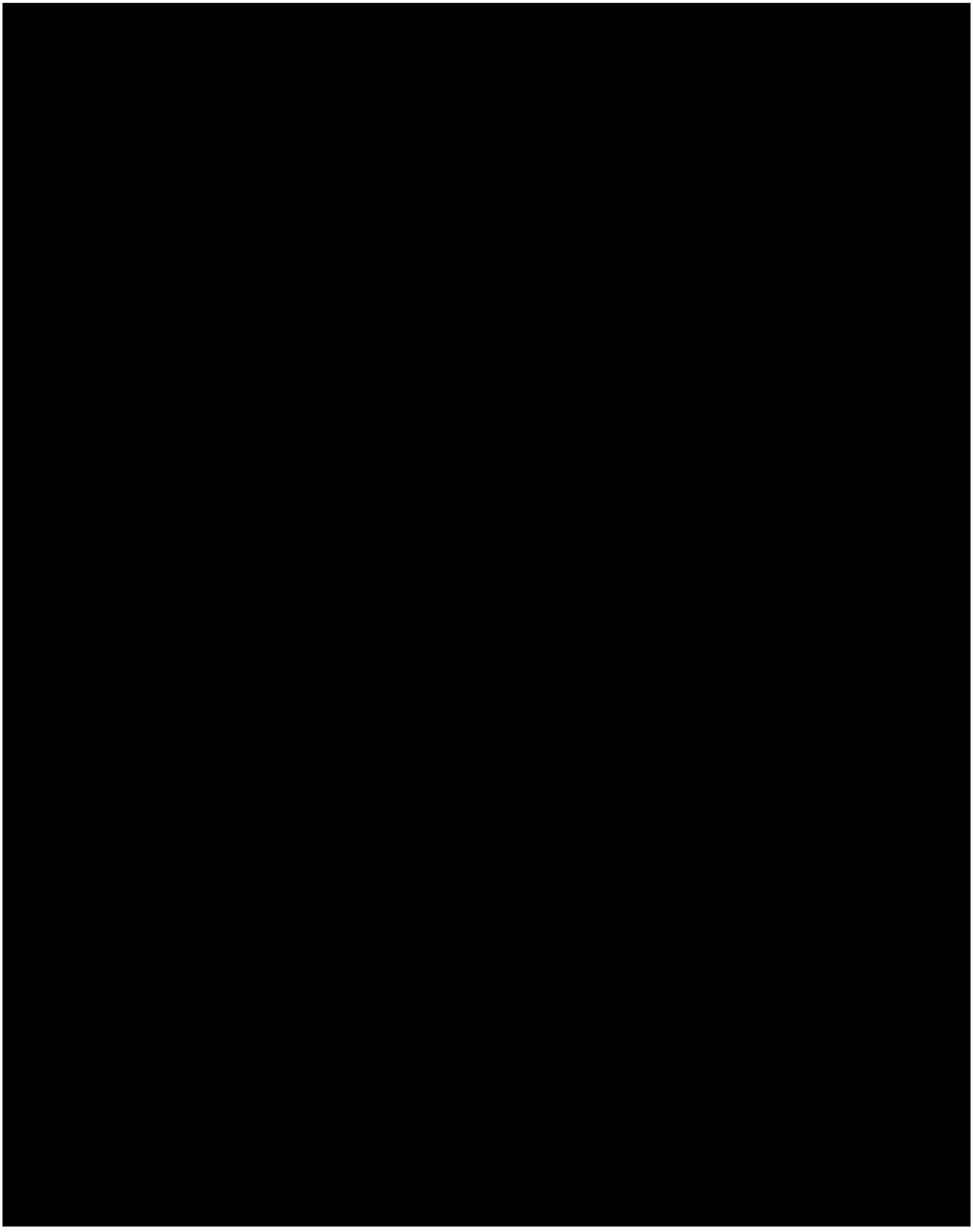


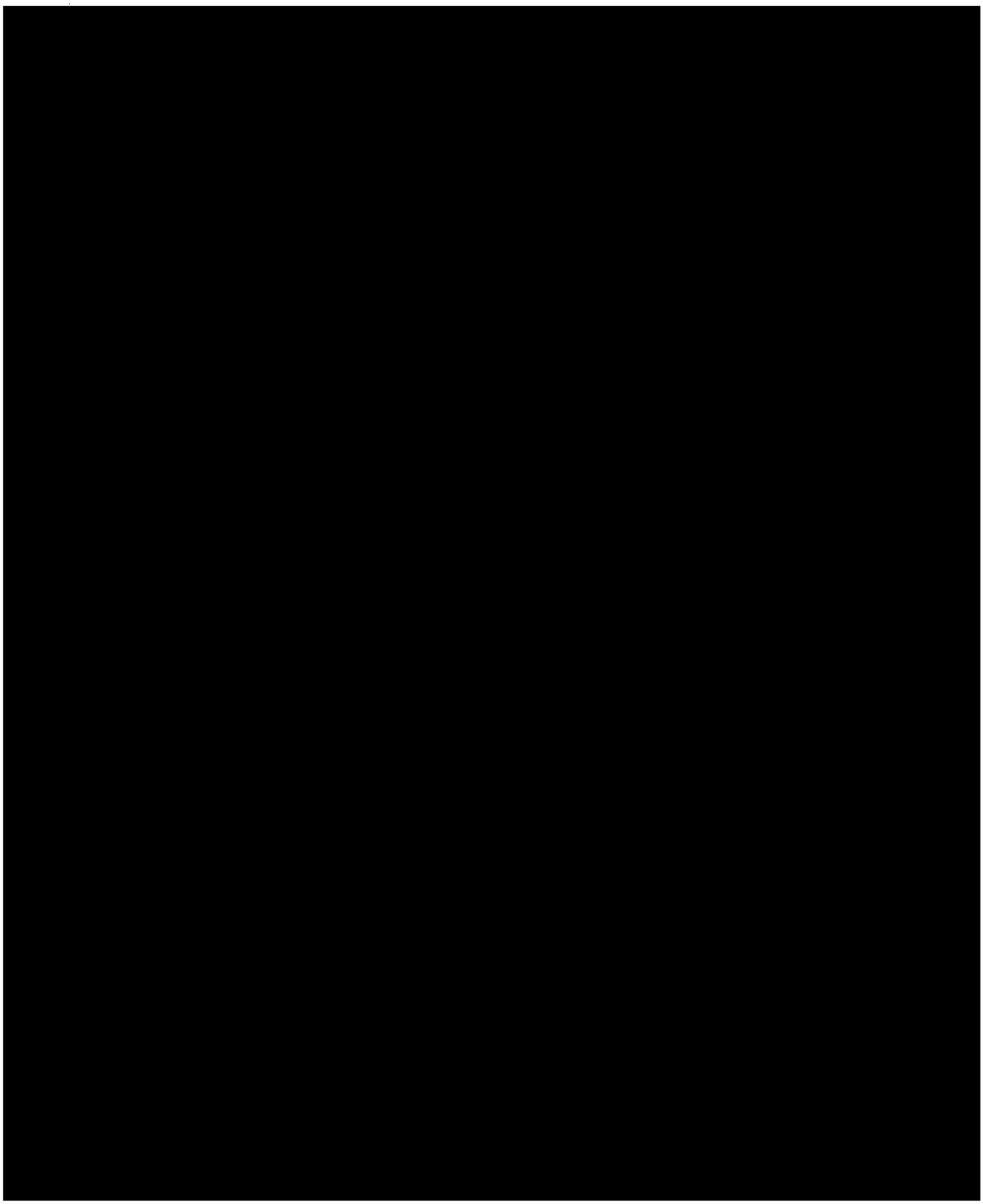


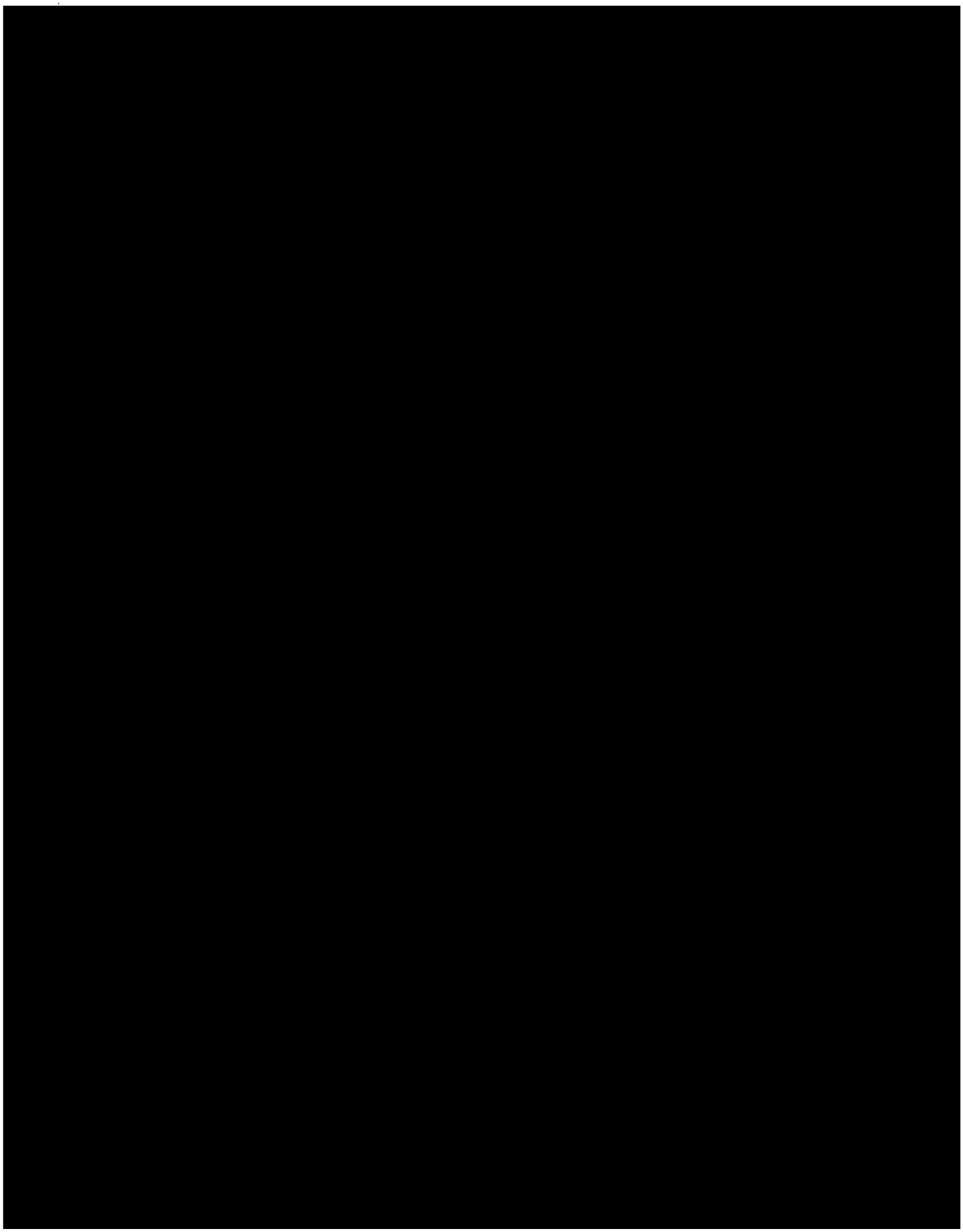


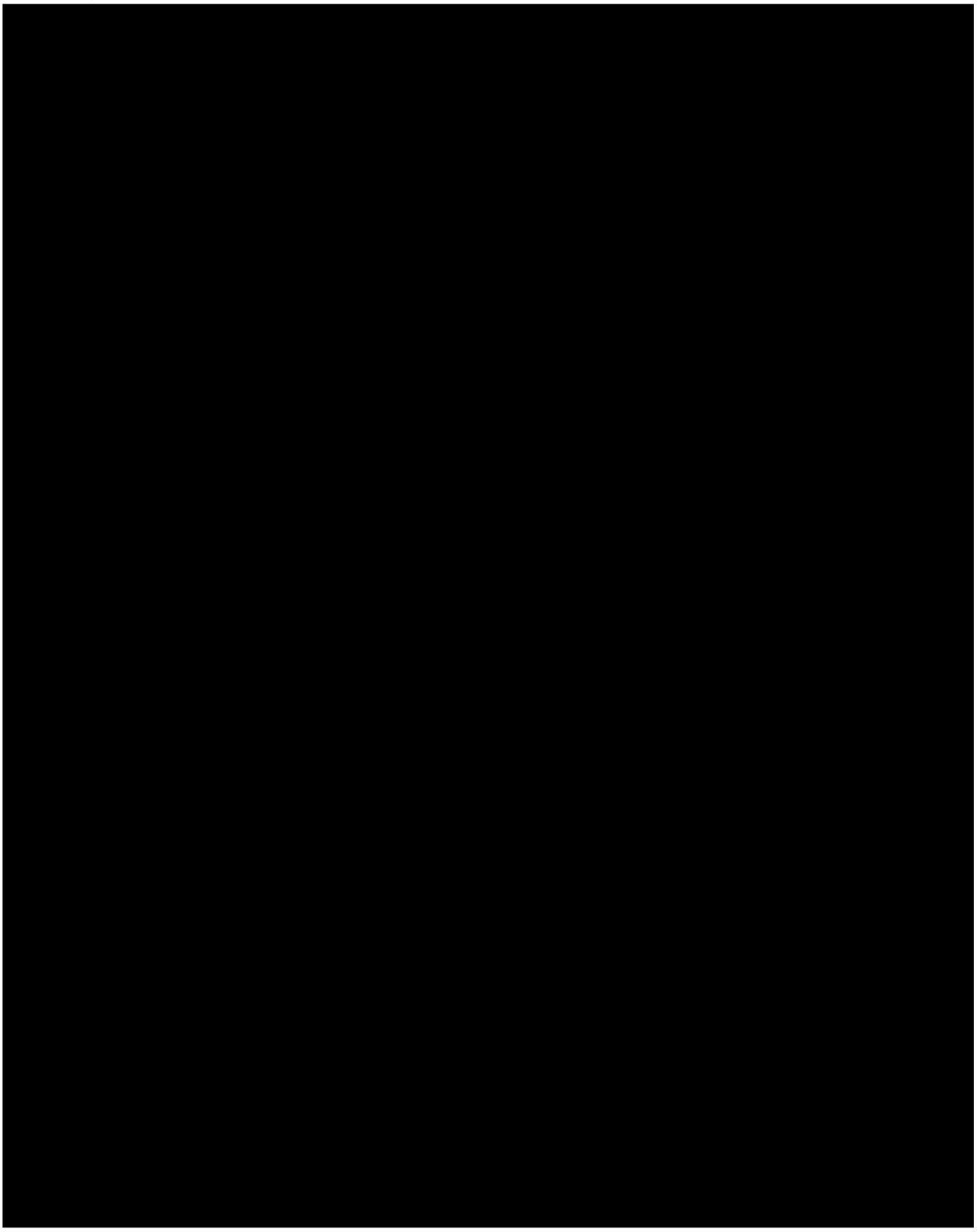


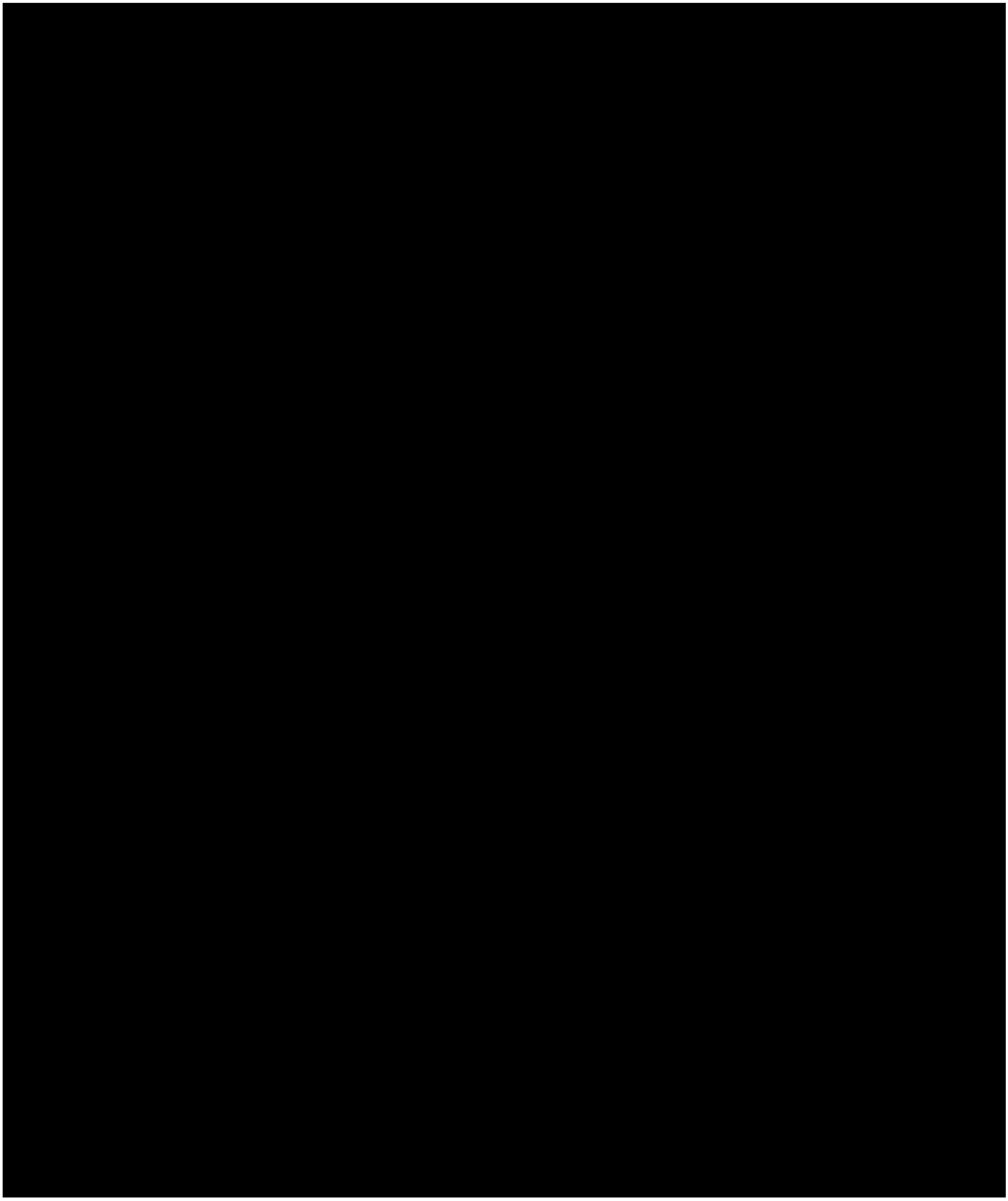


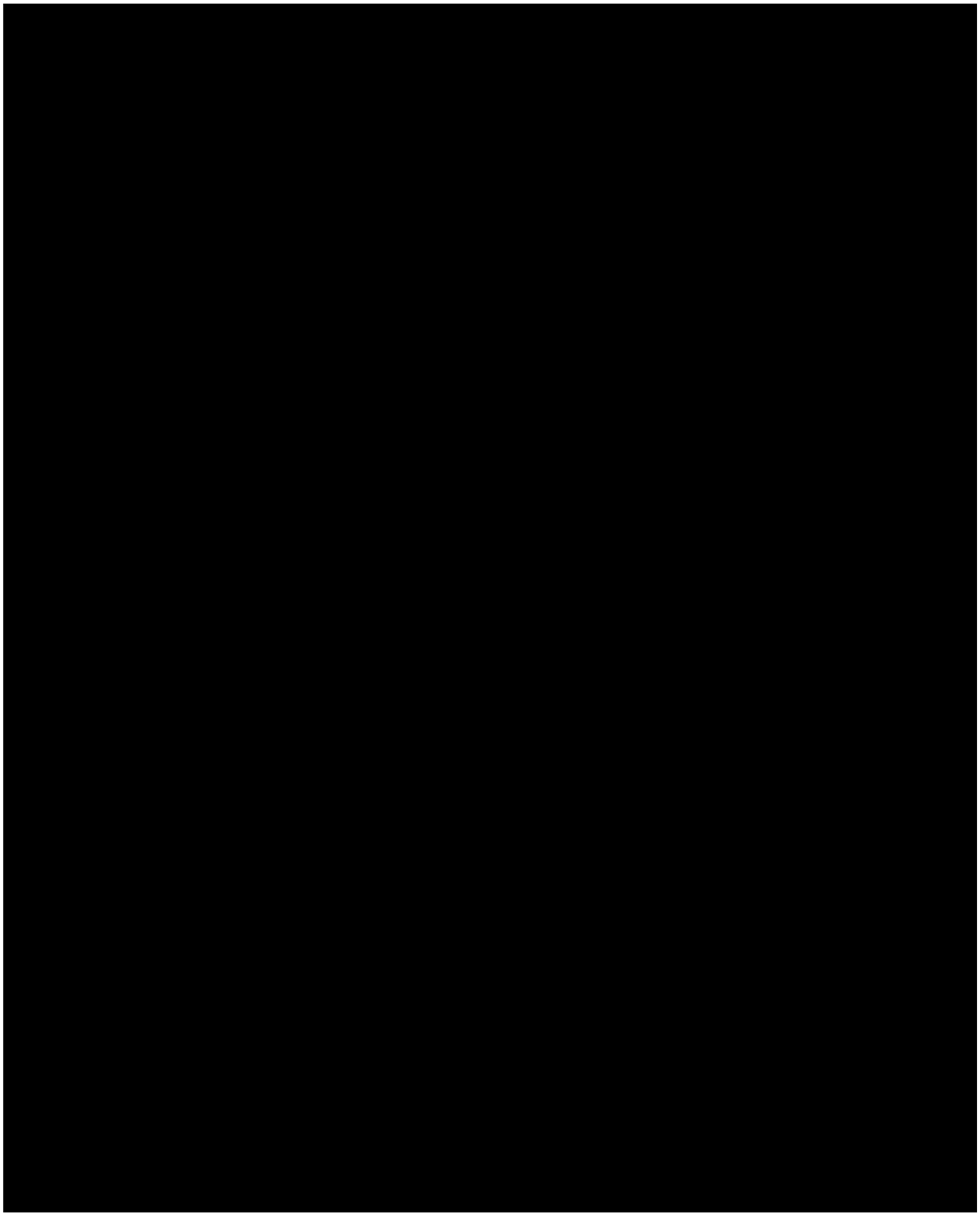


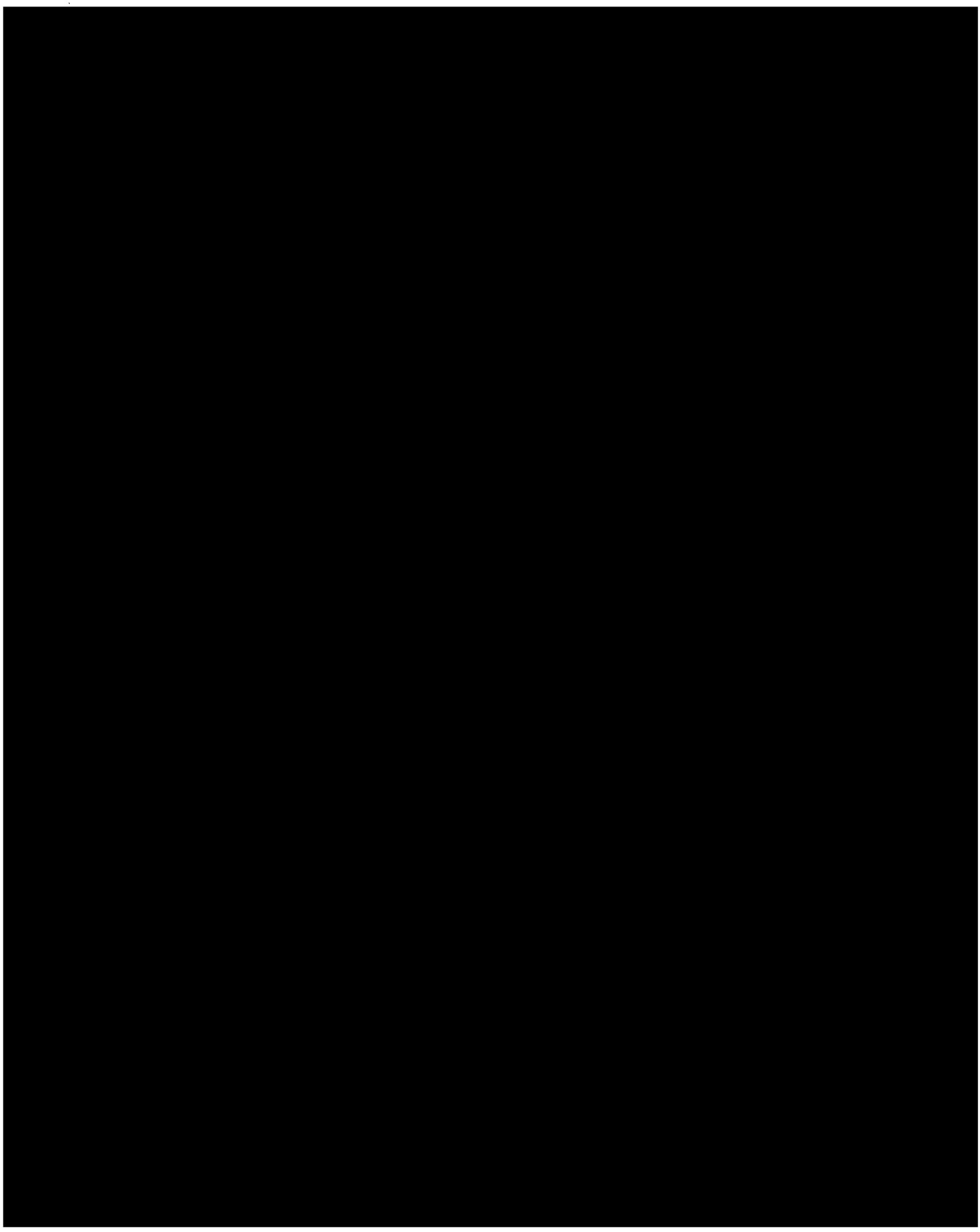


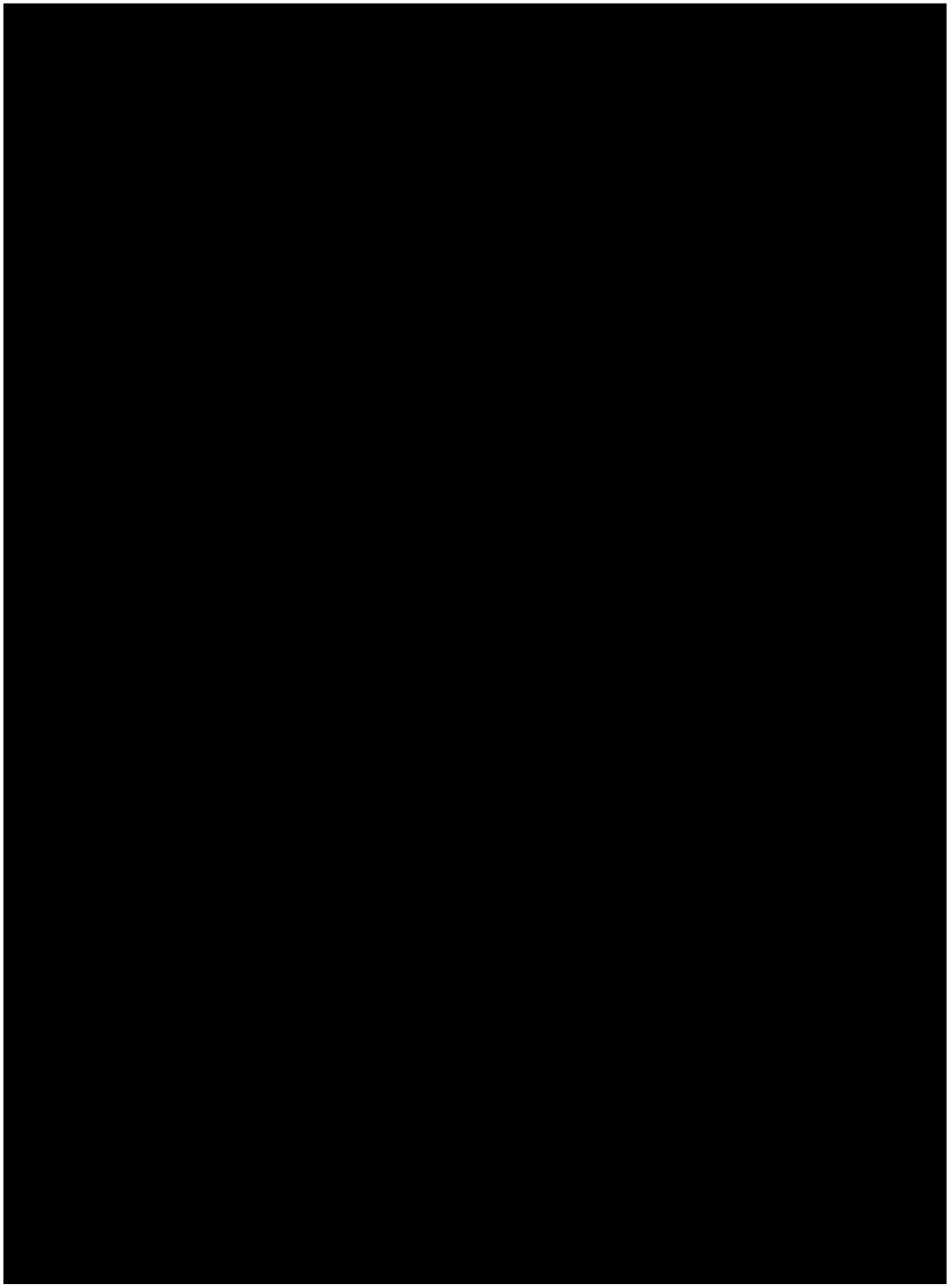


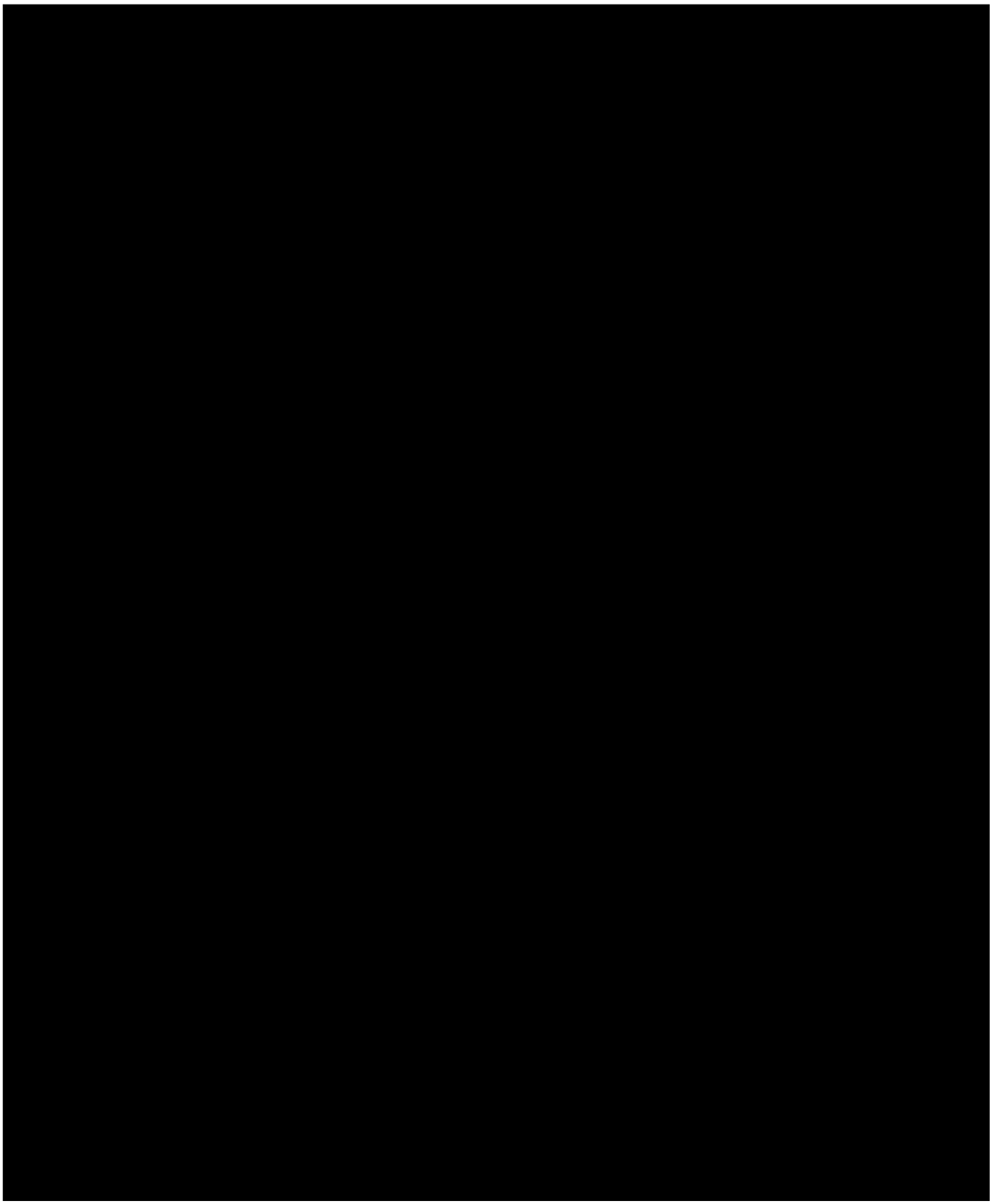


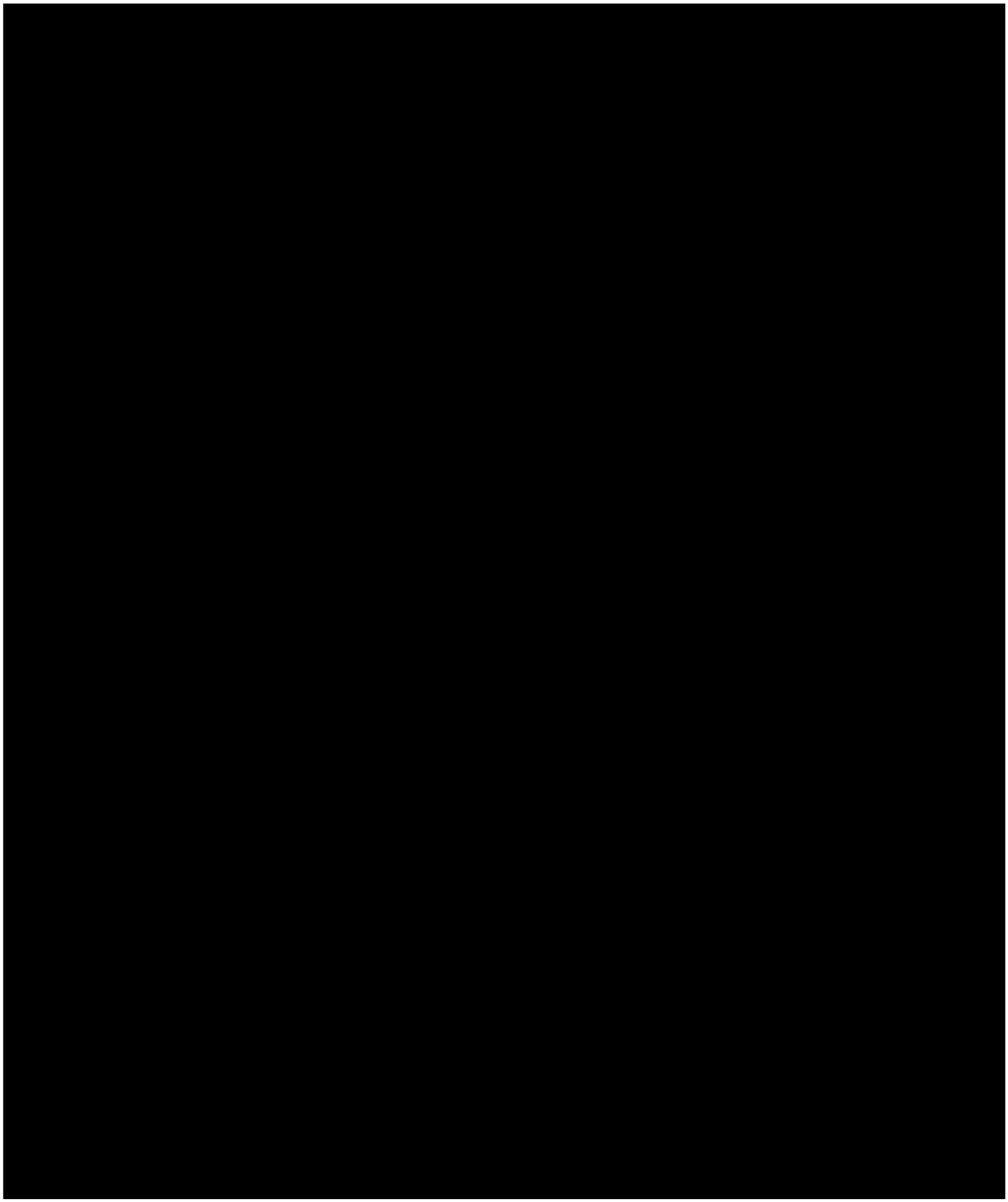


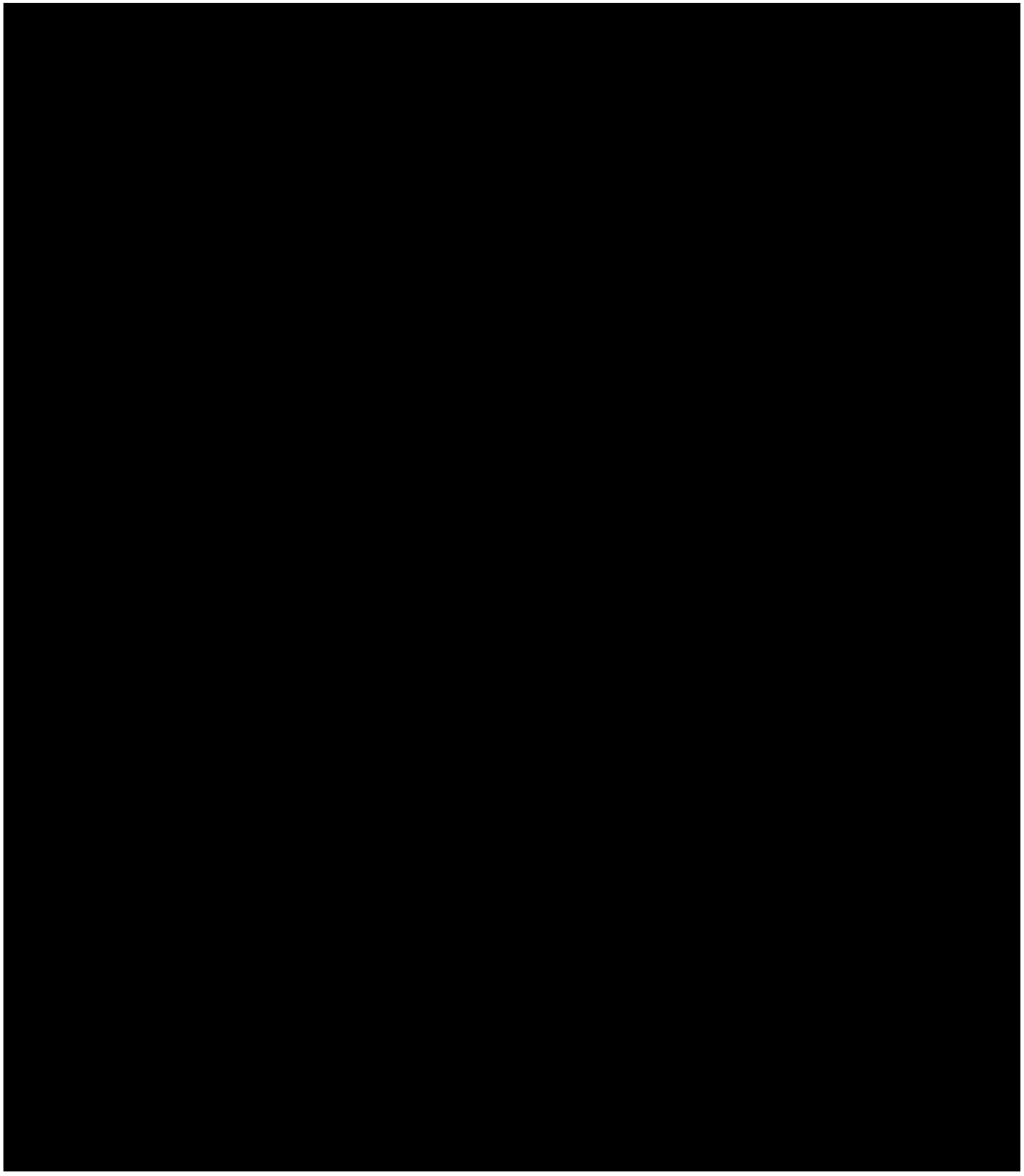


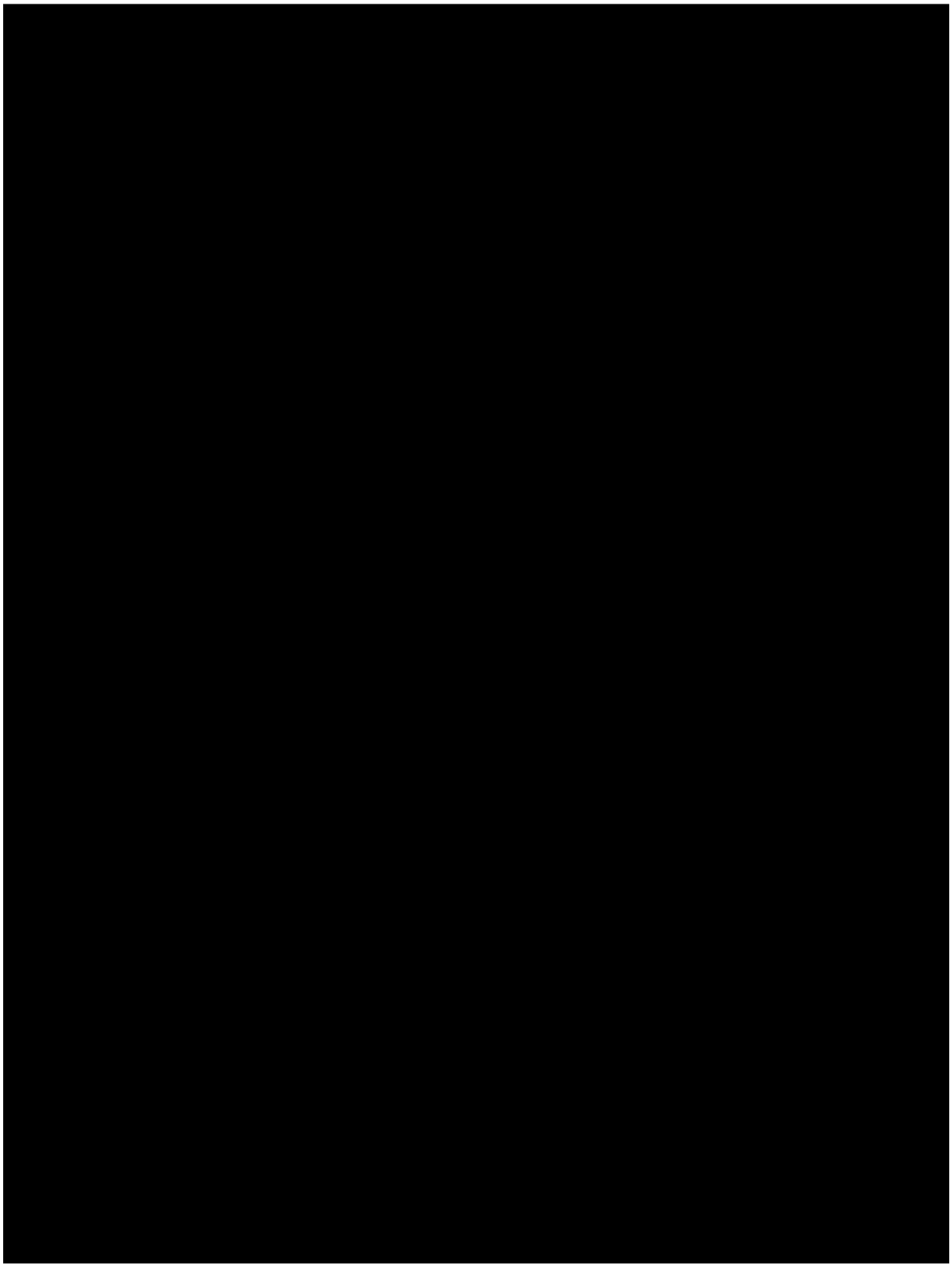


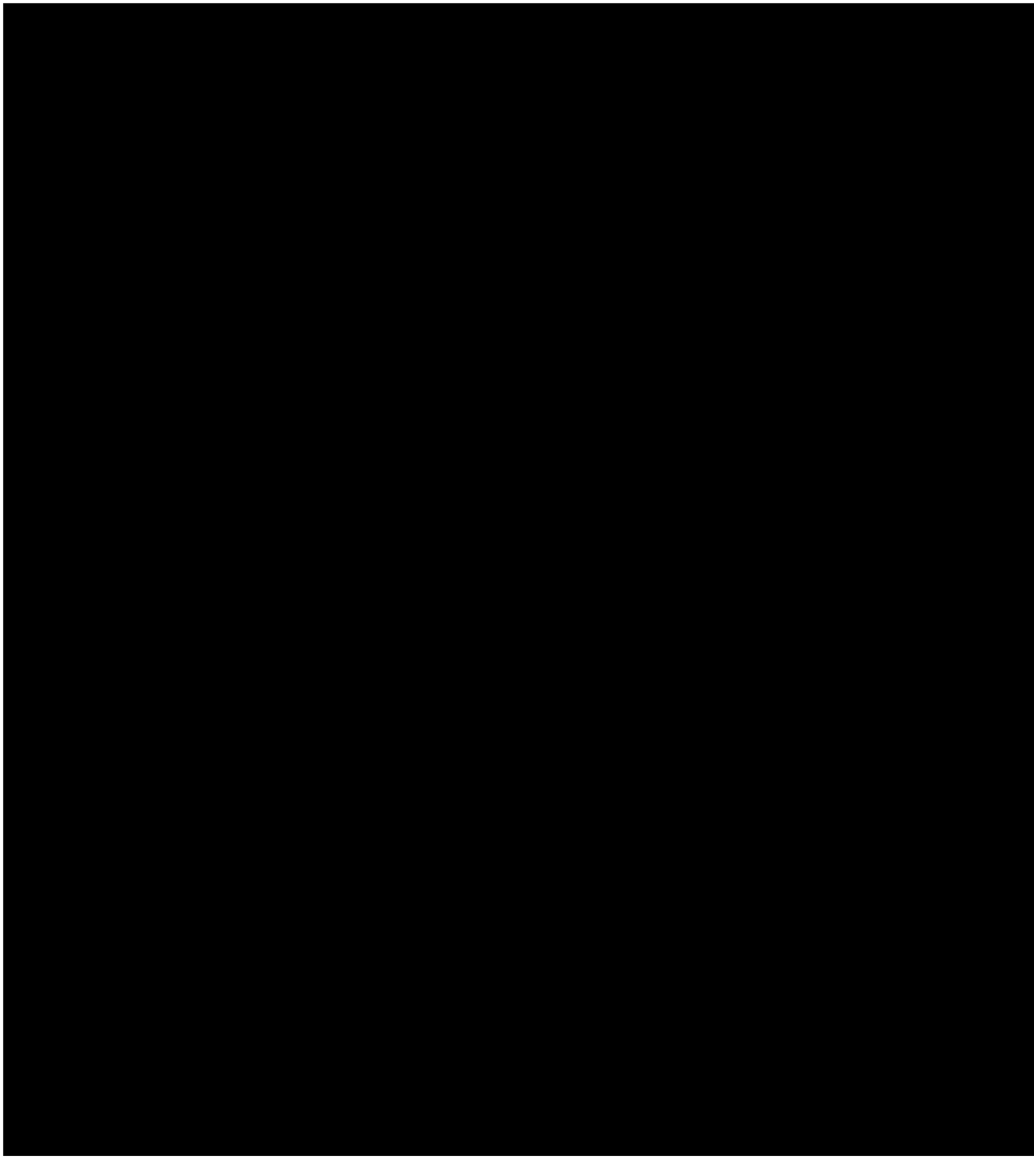


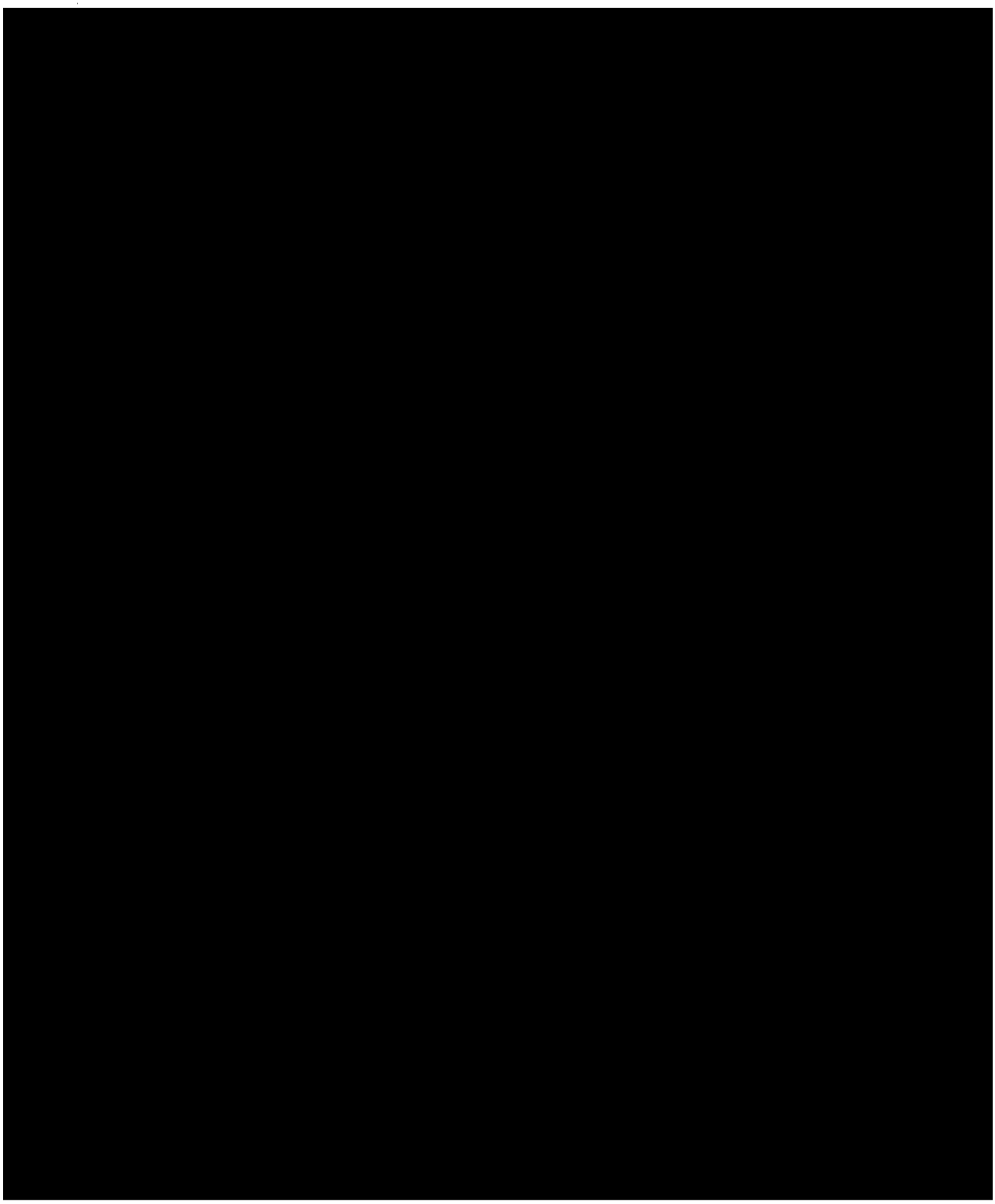


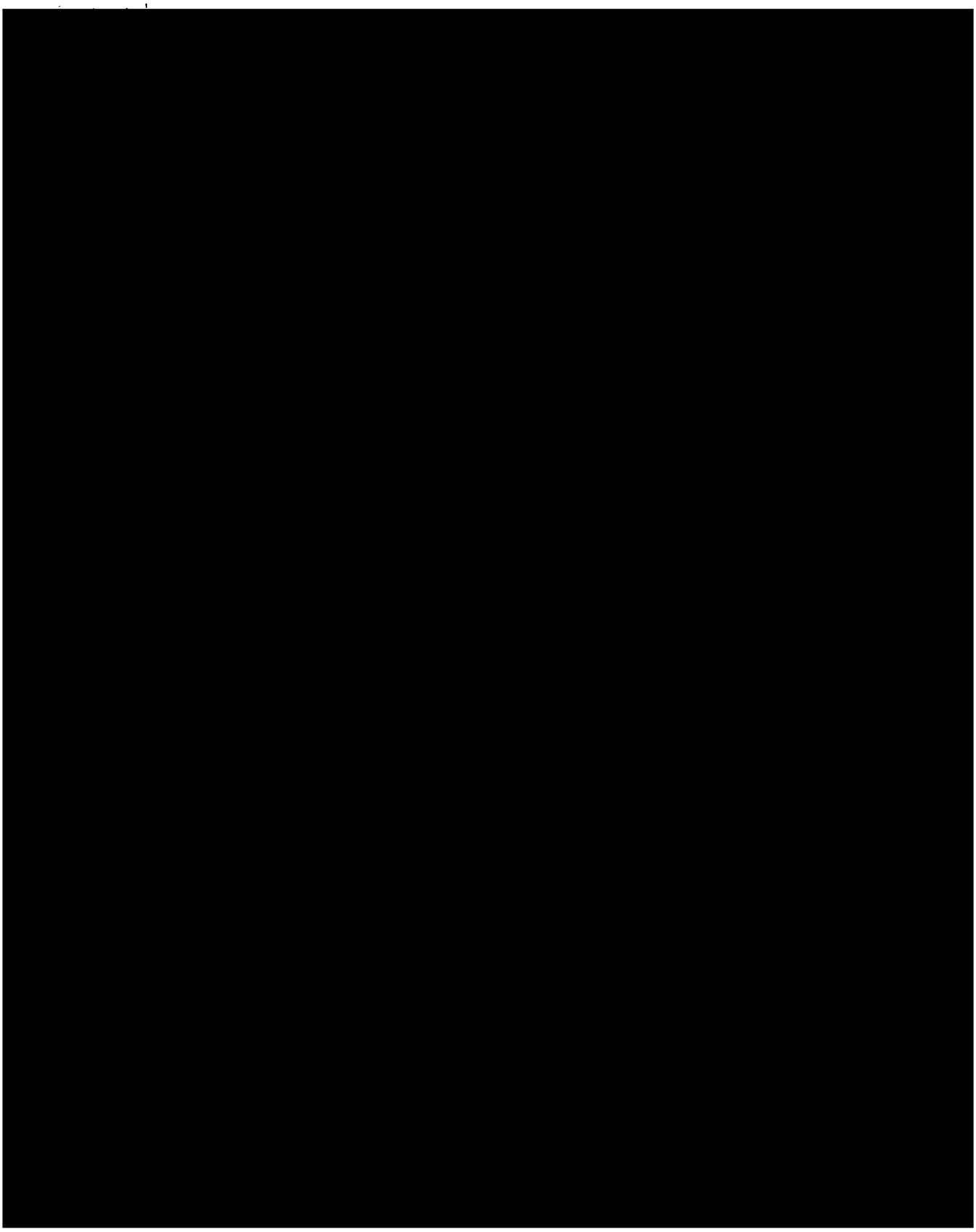


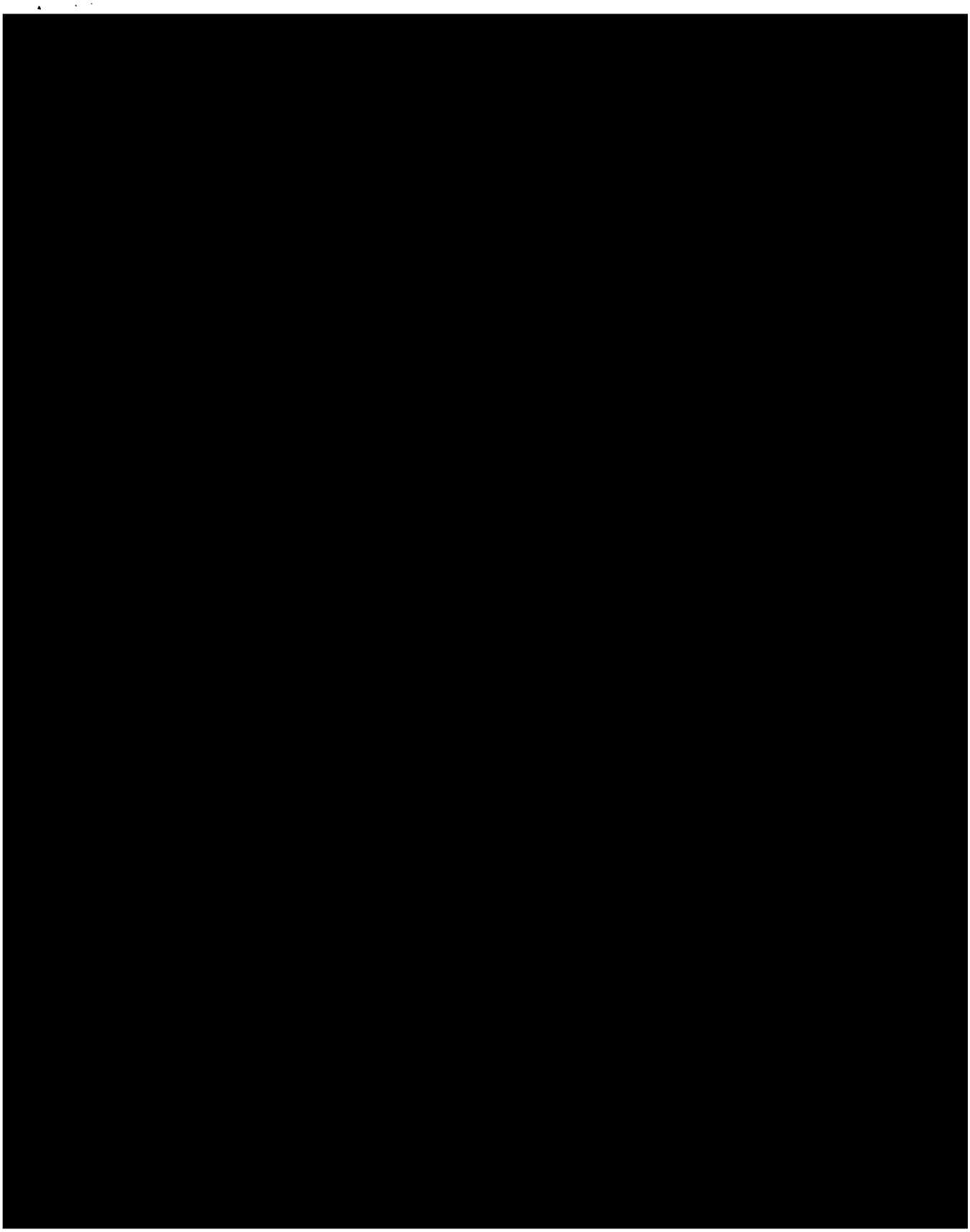




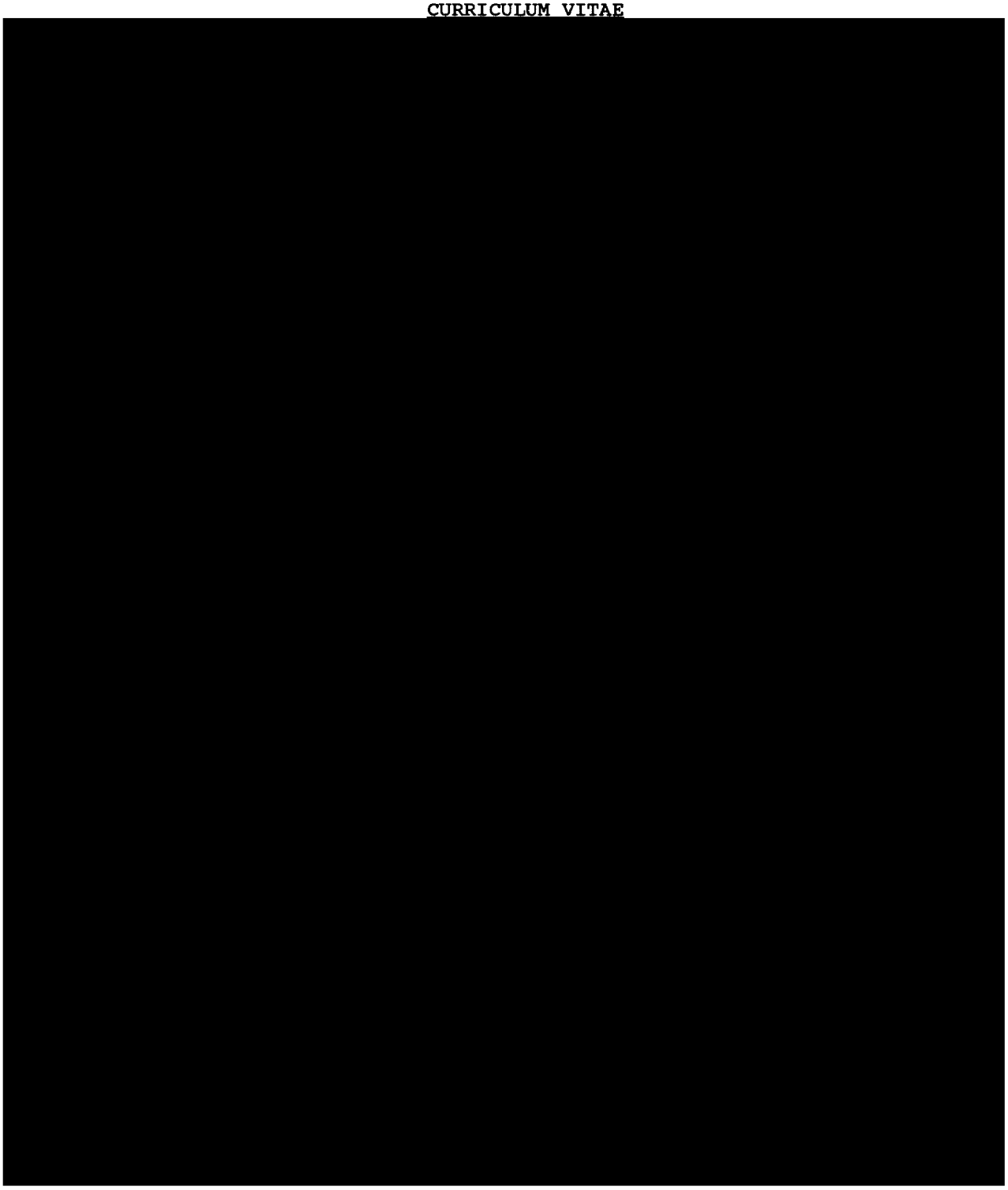


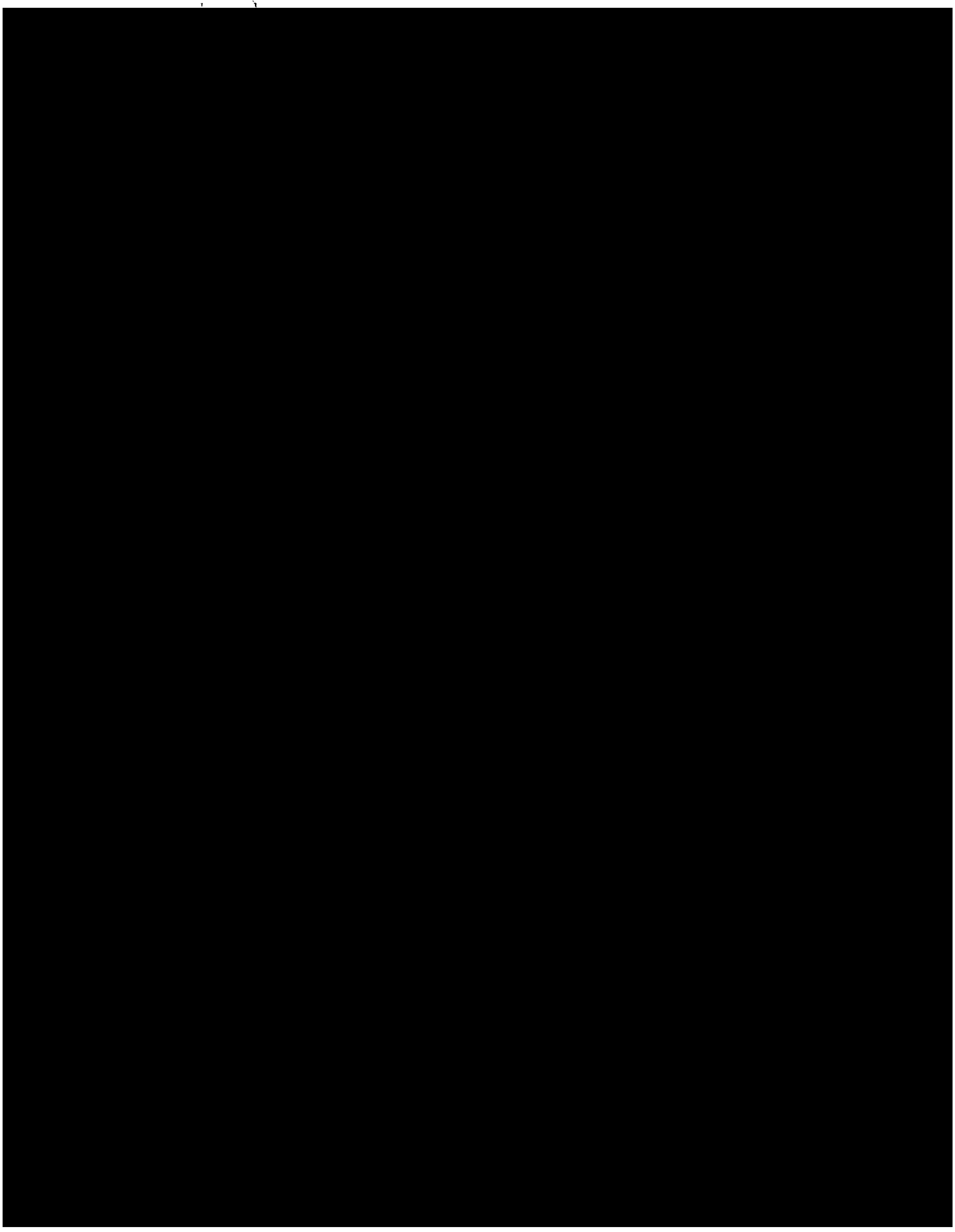


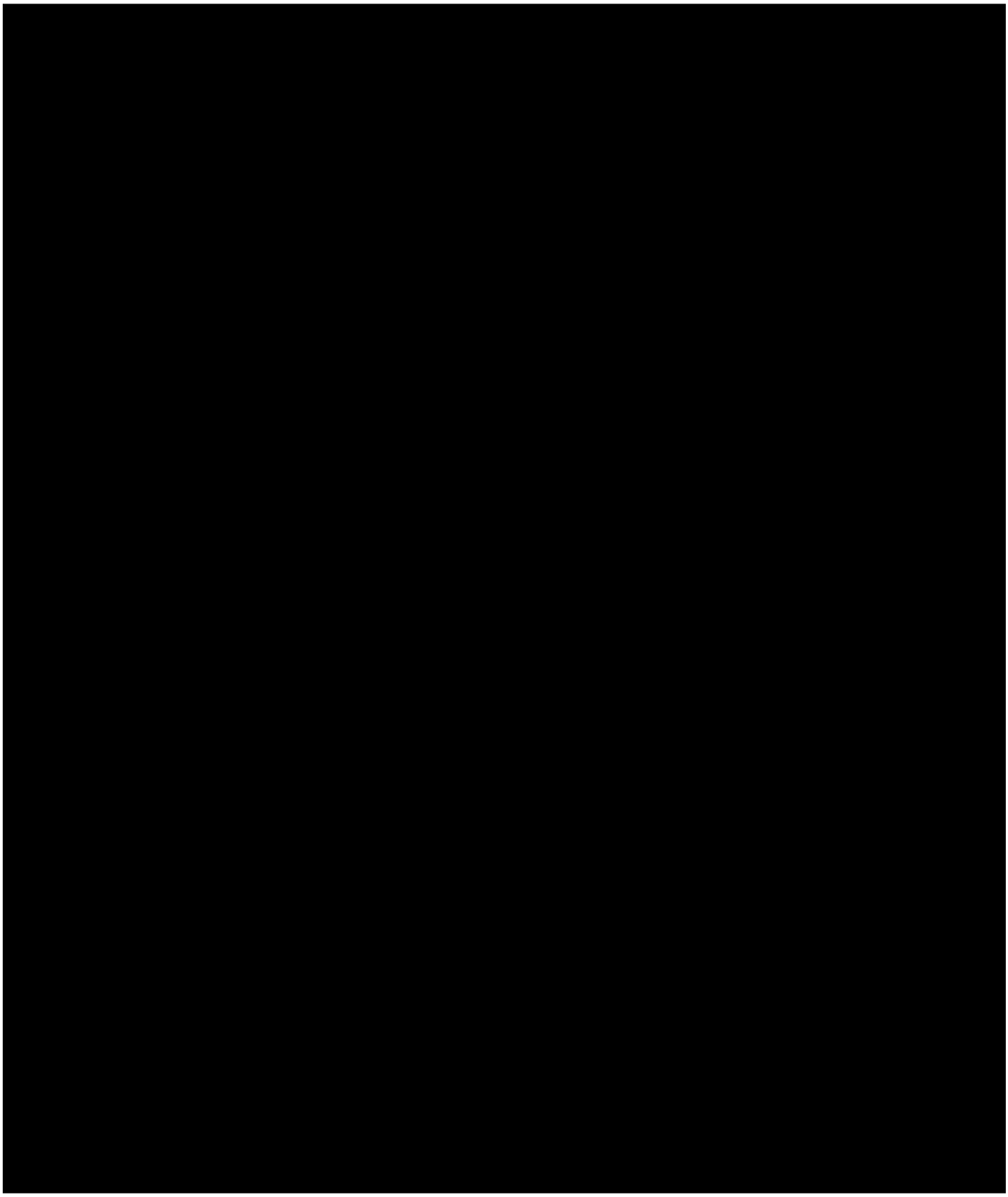


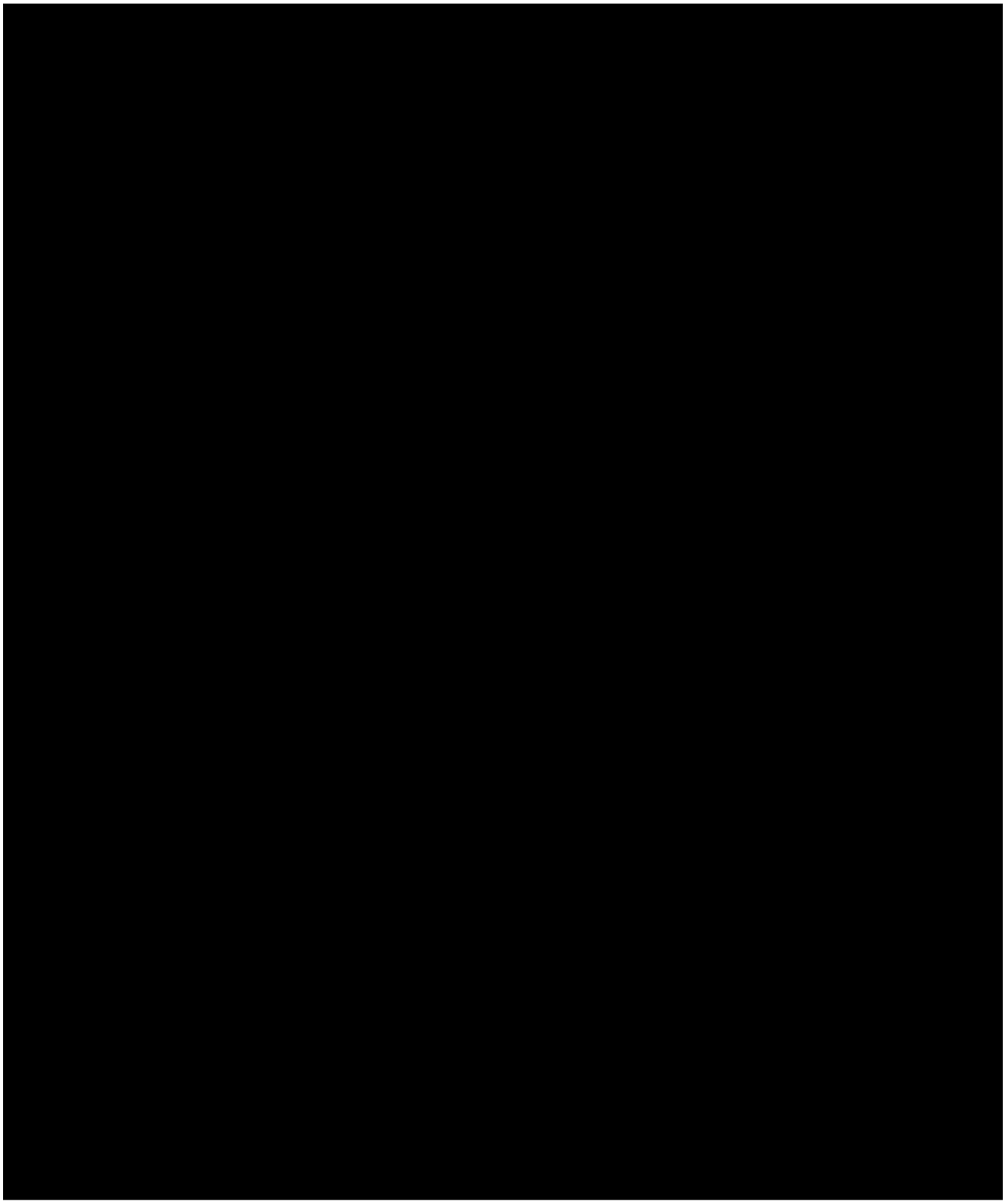


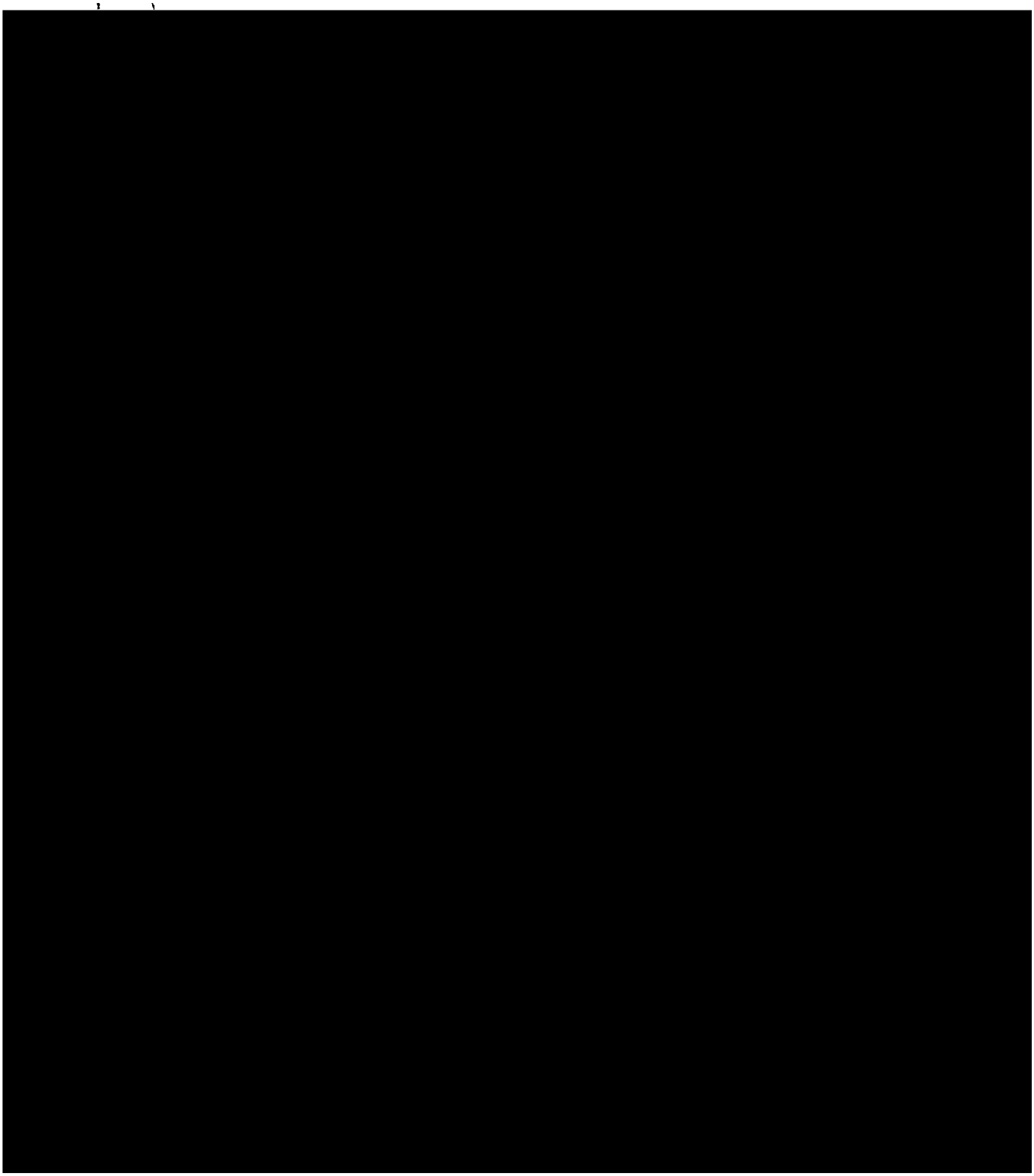
CURRICULUM VITAE

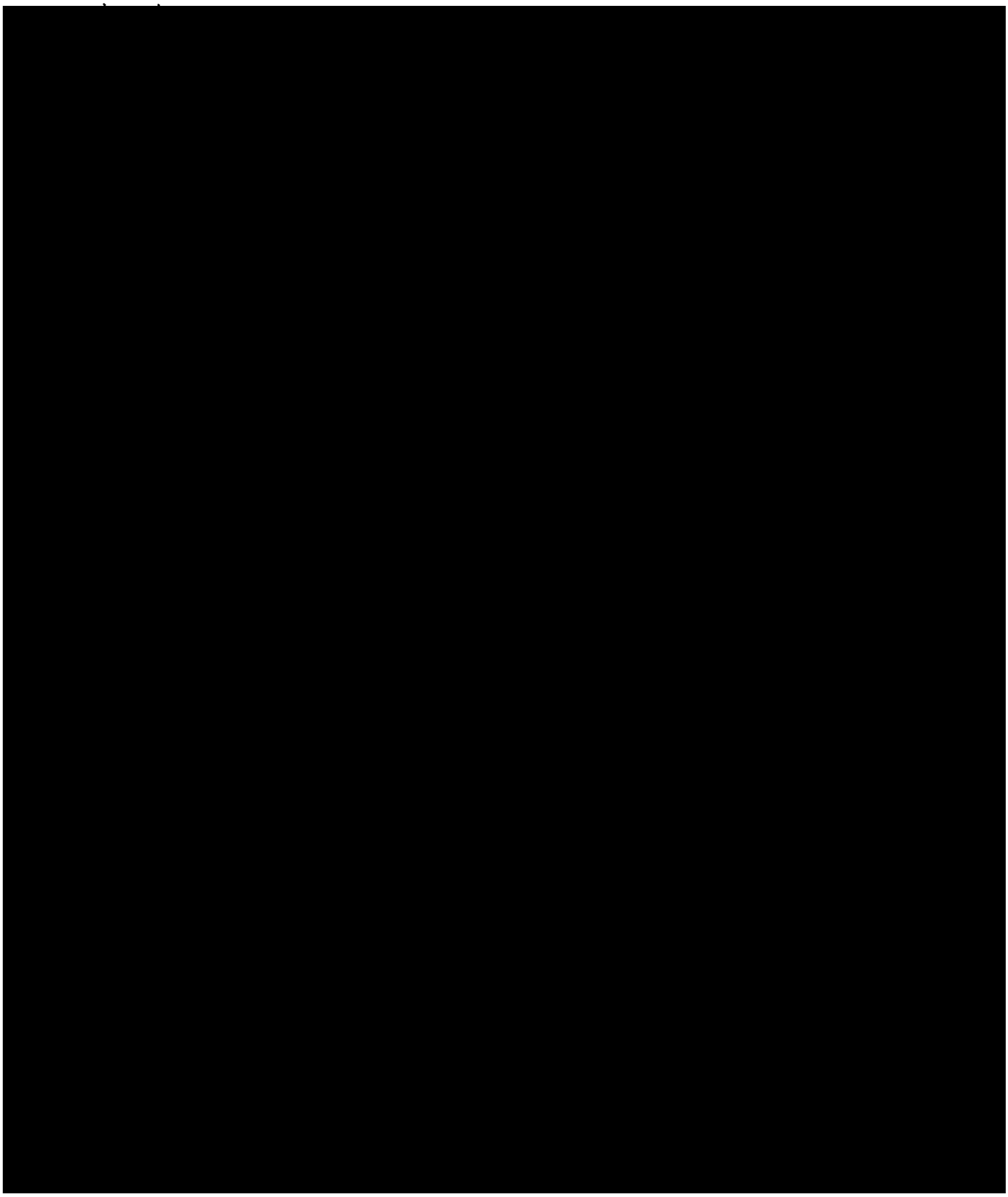


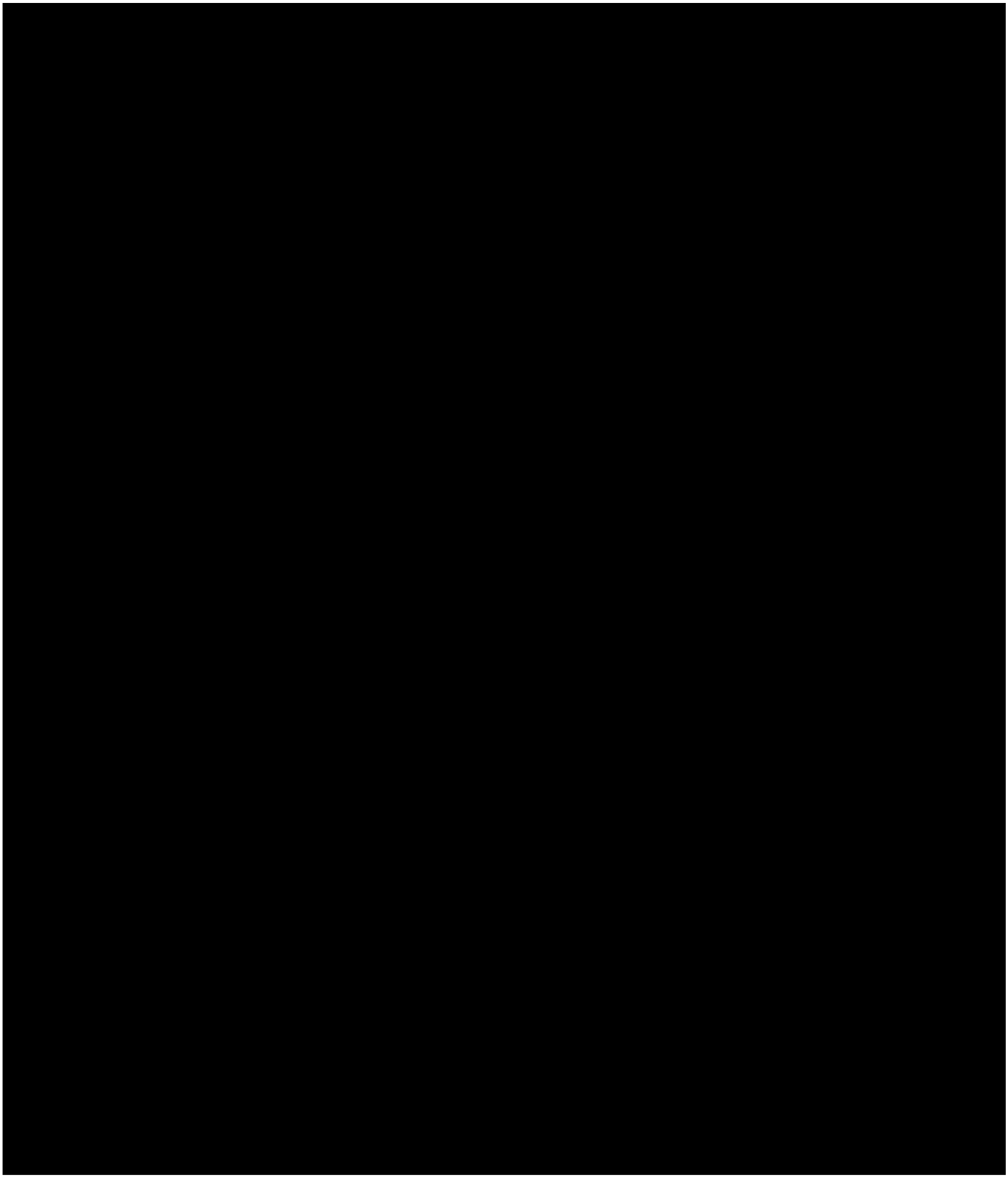


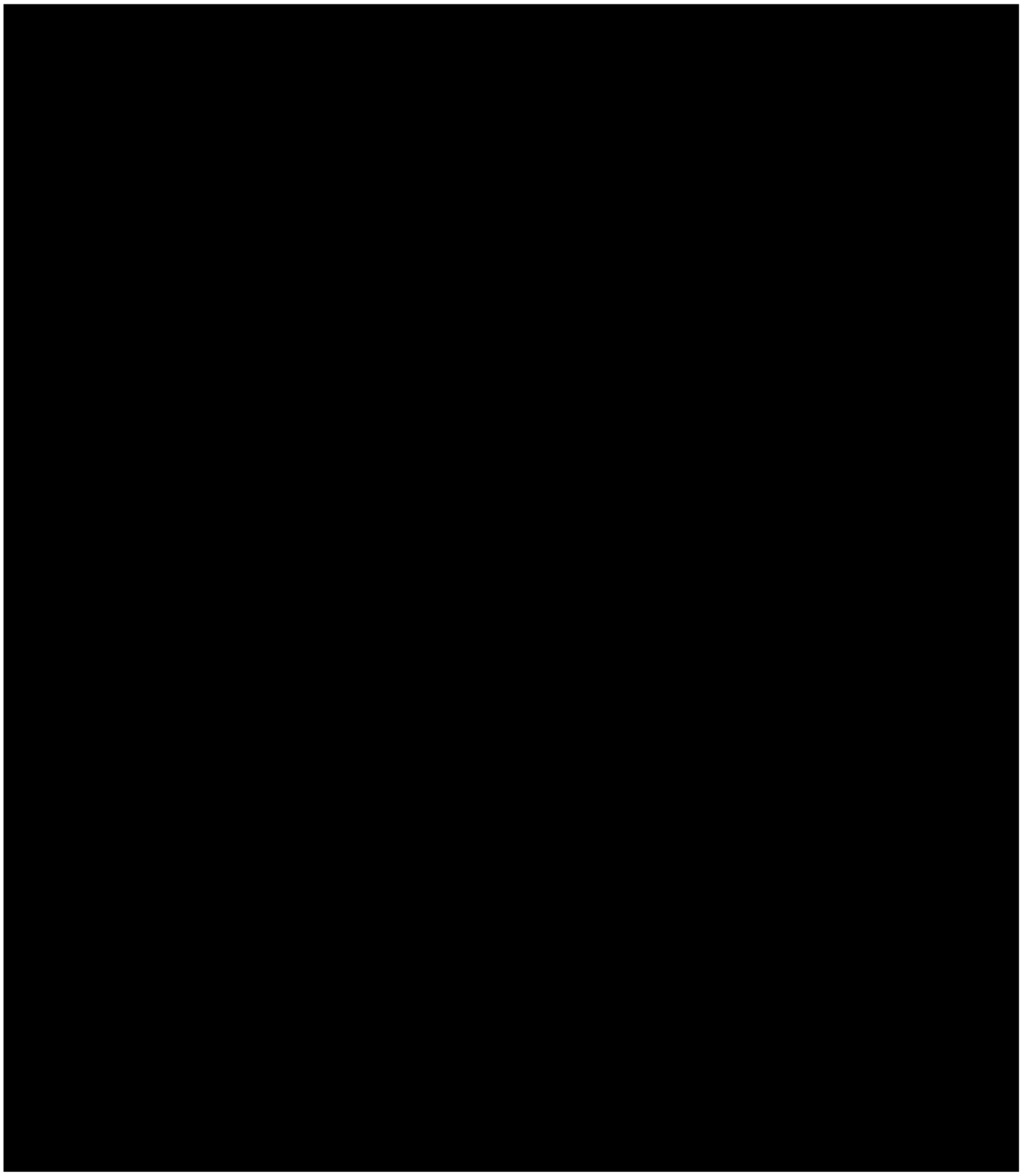


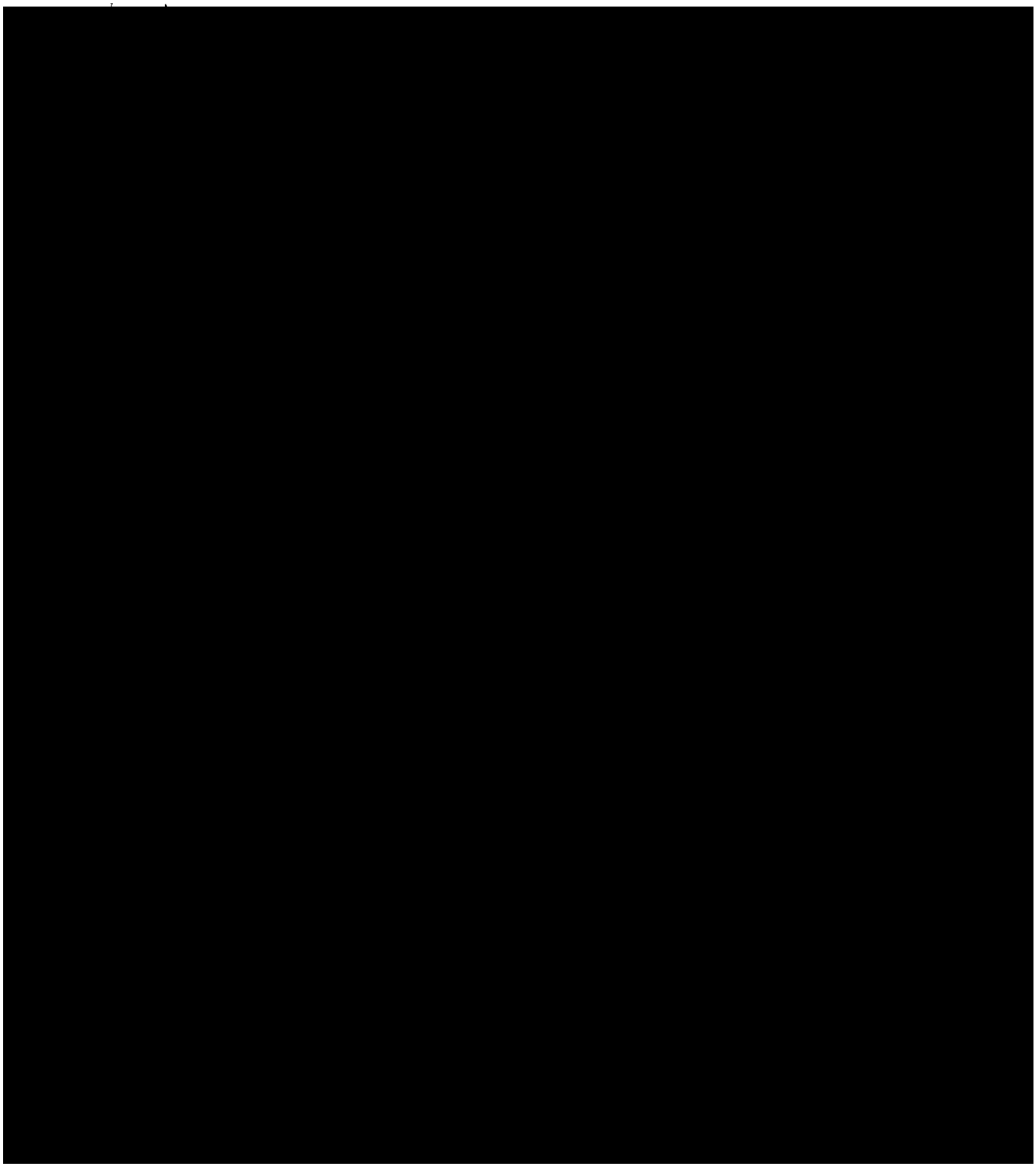


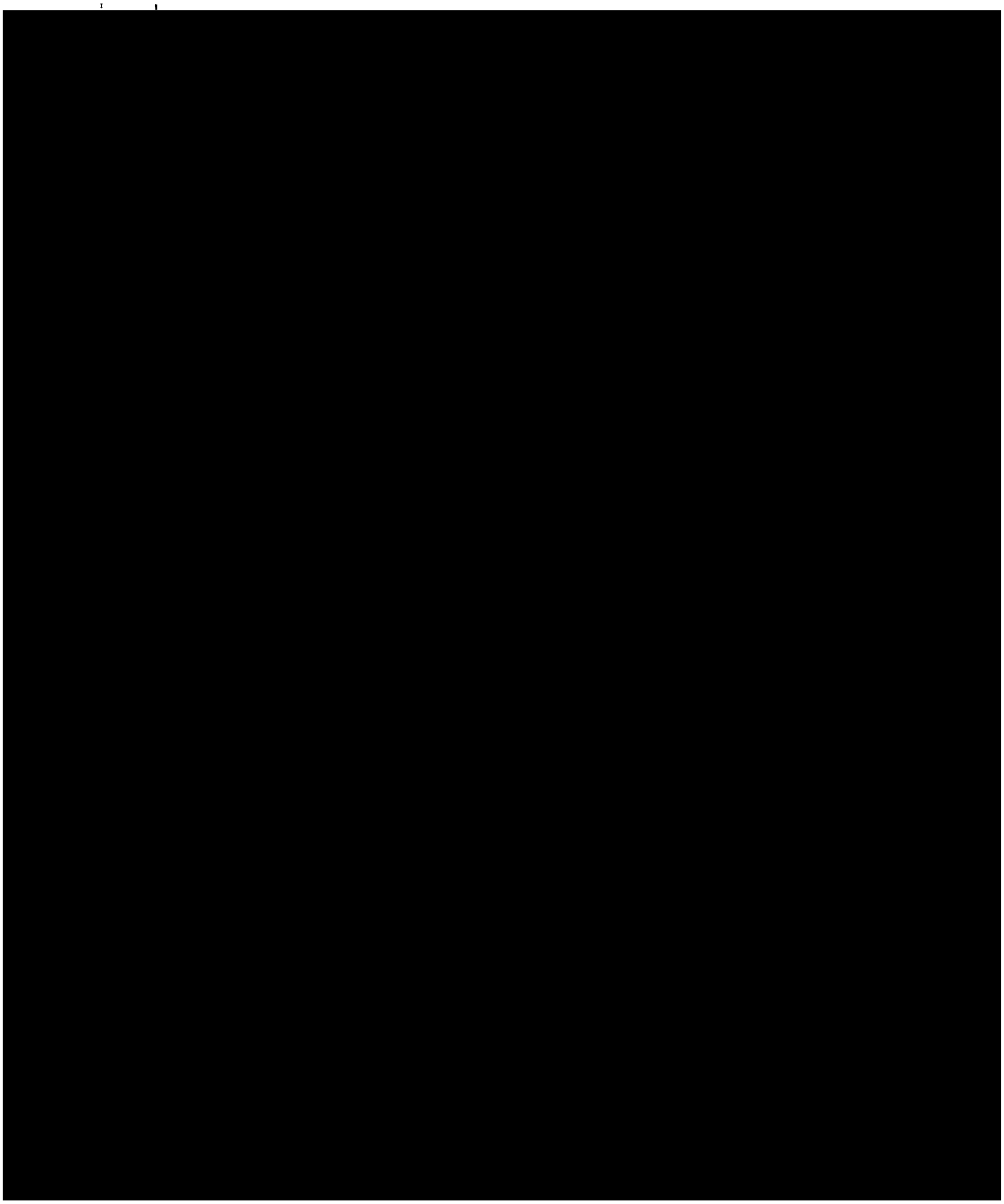


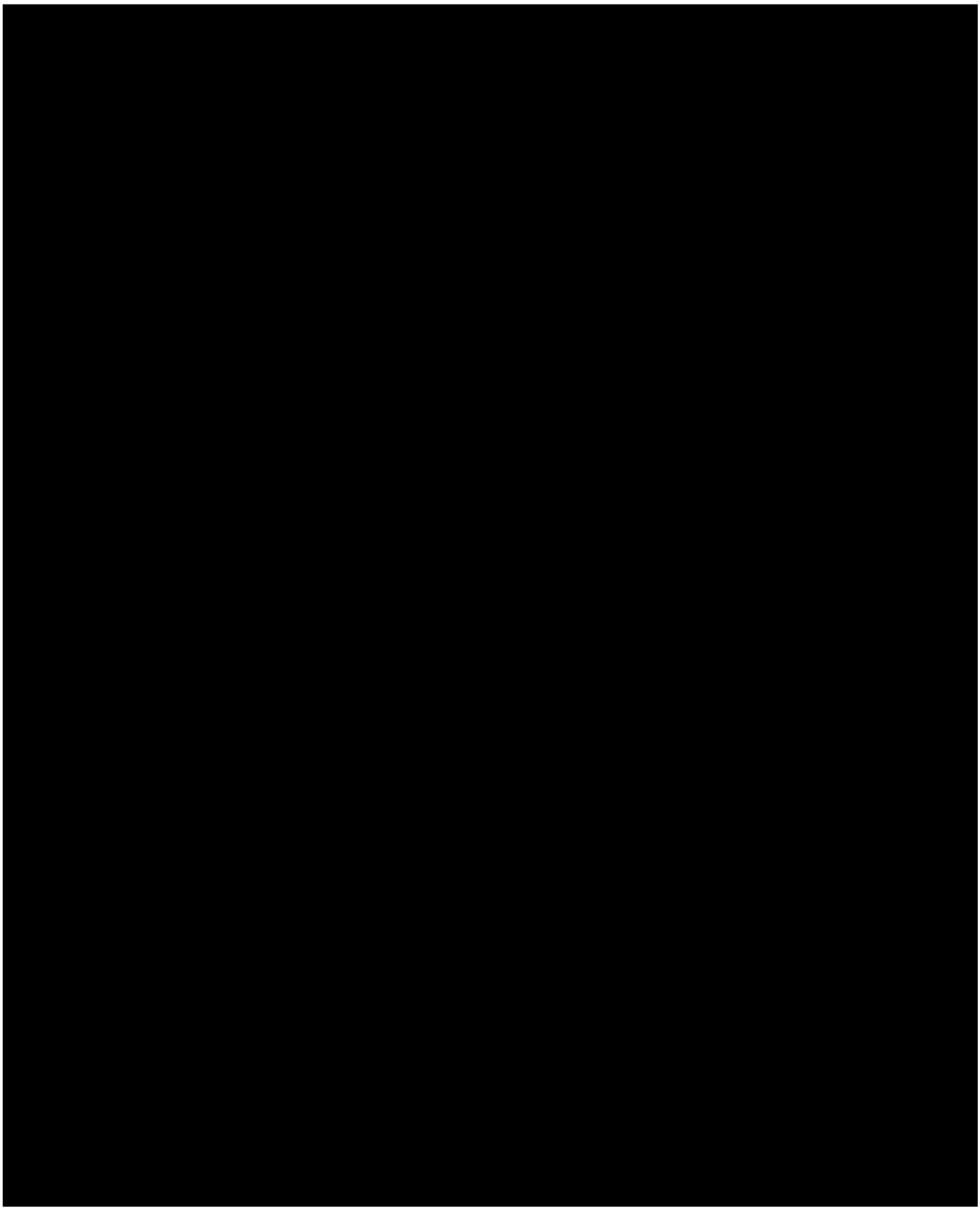


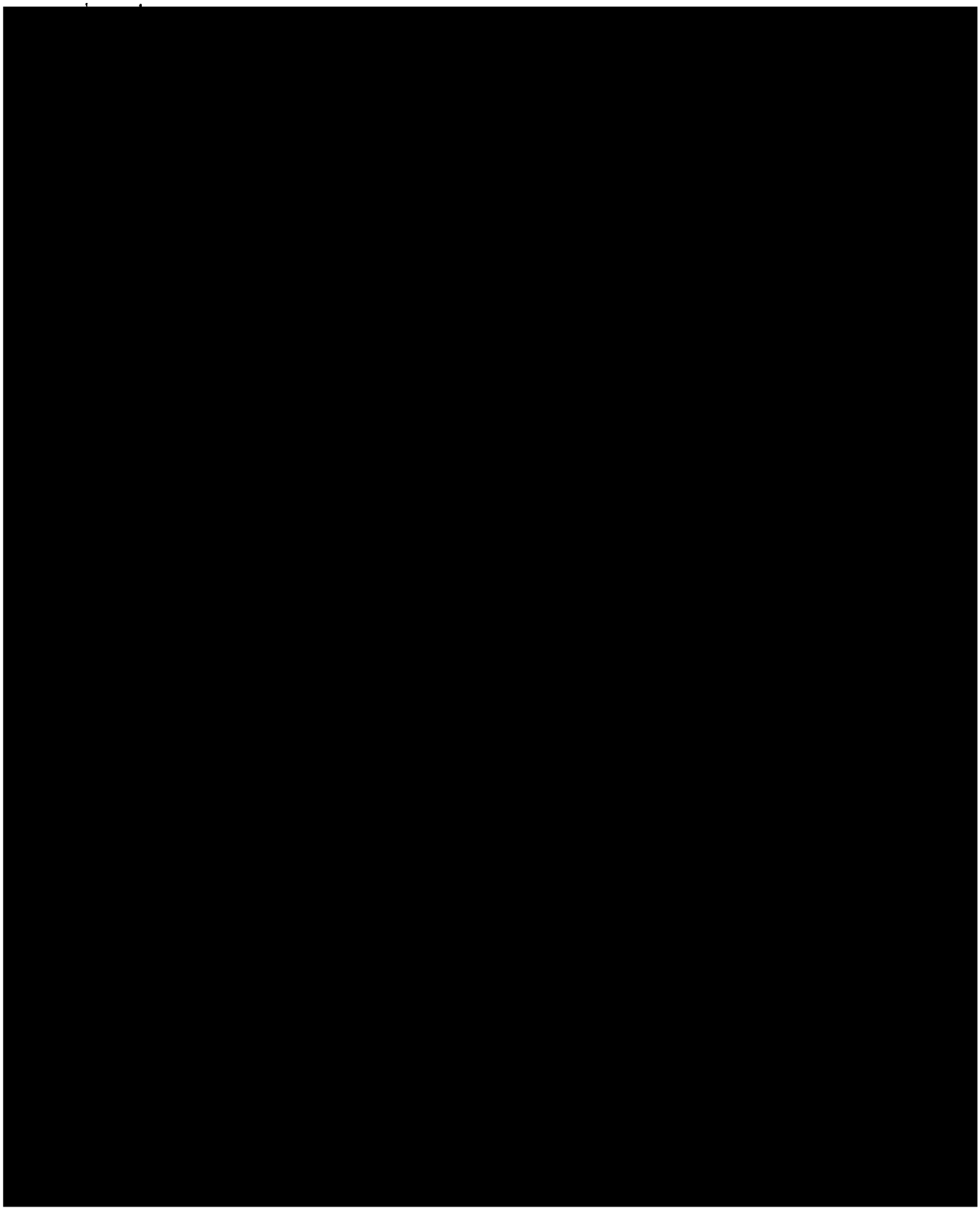


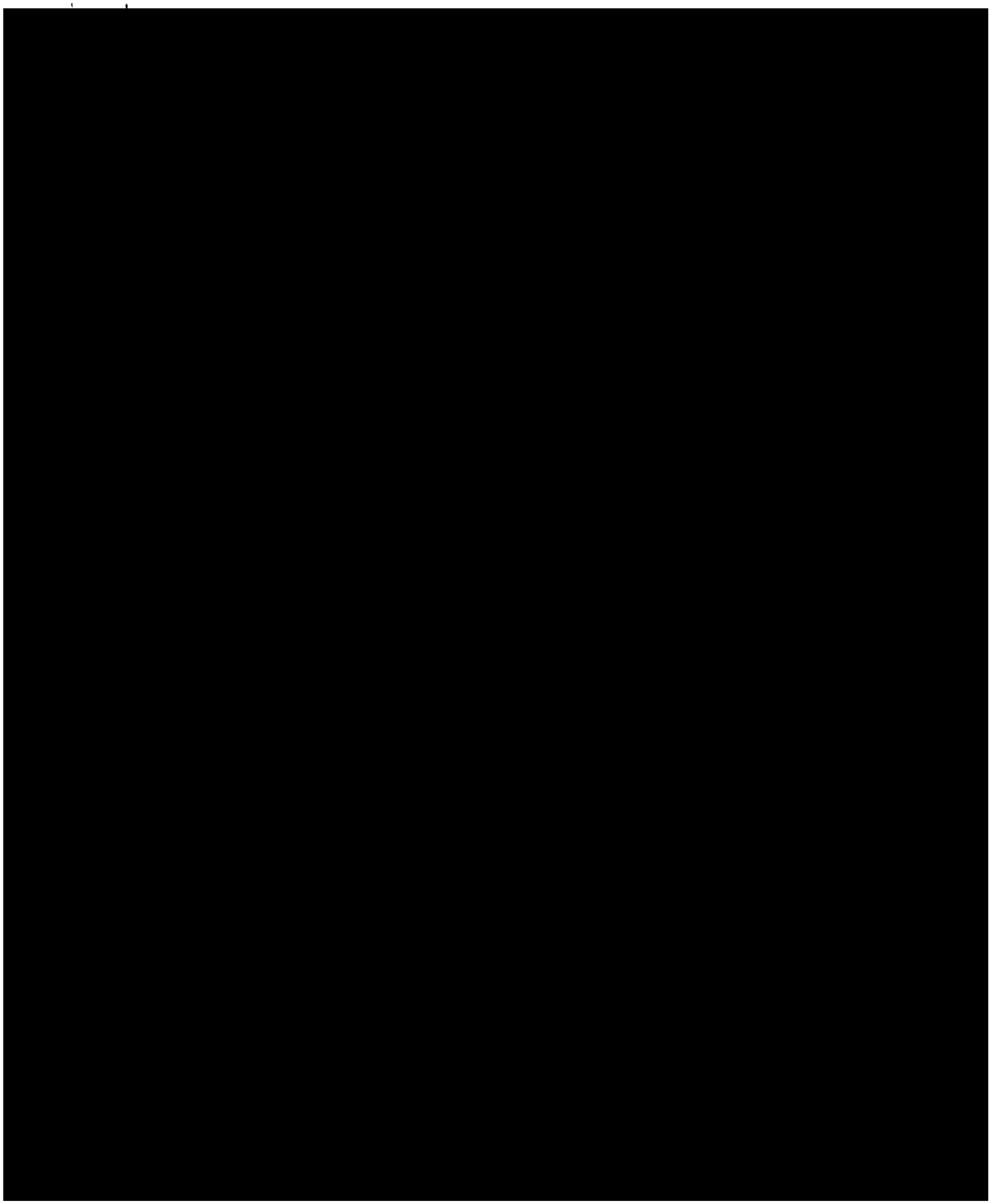


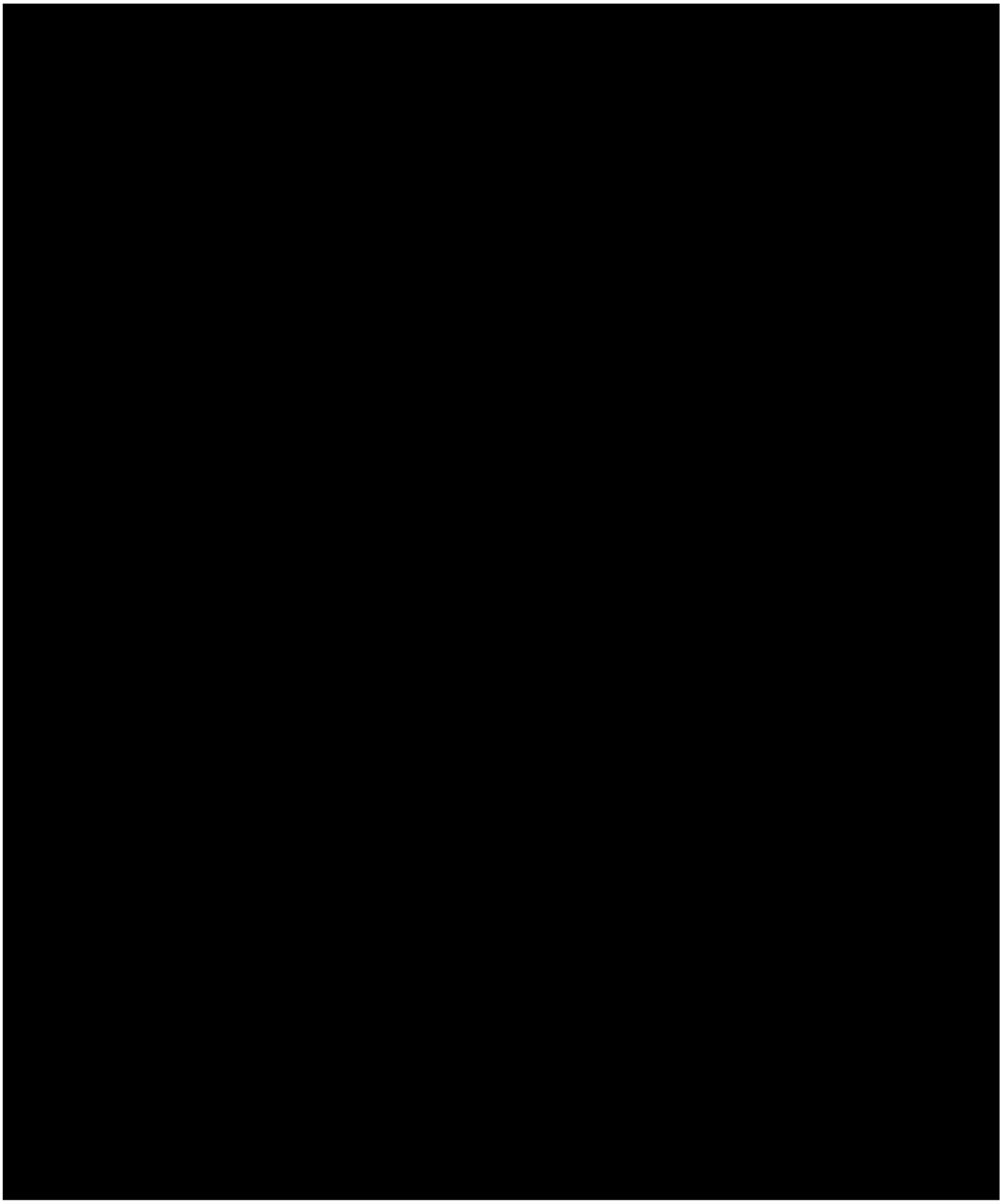


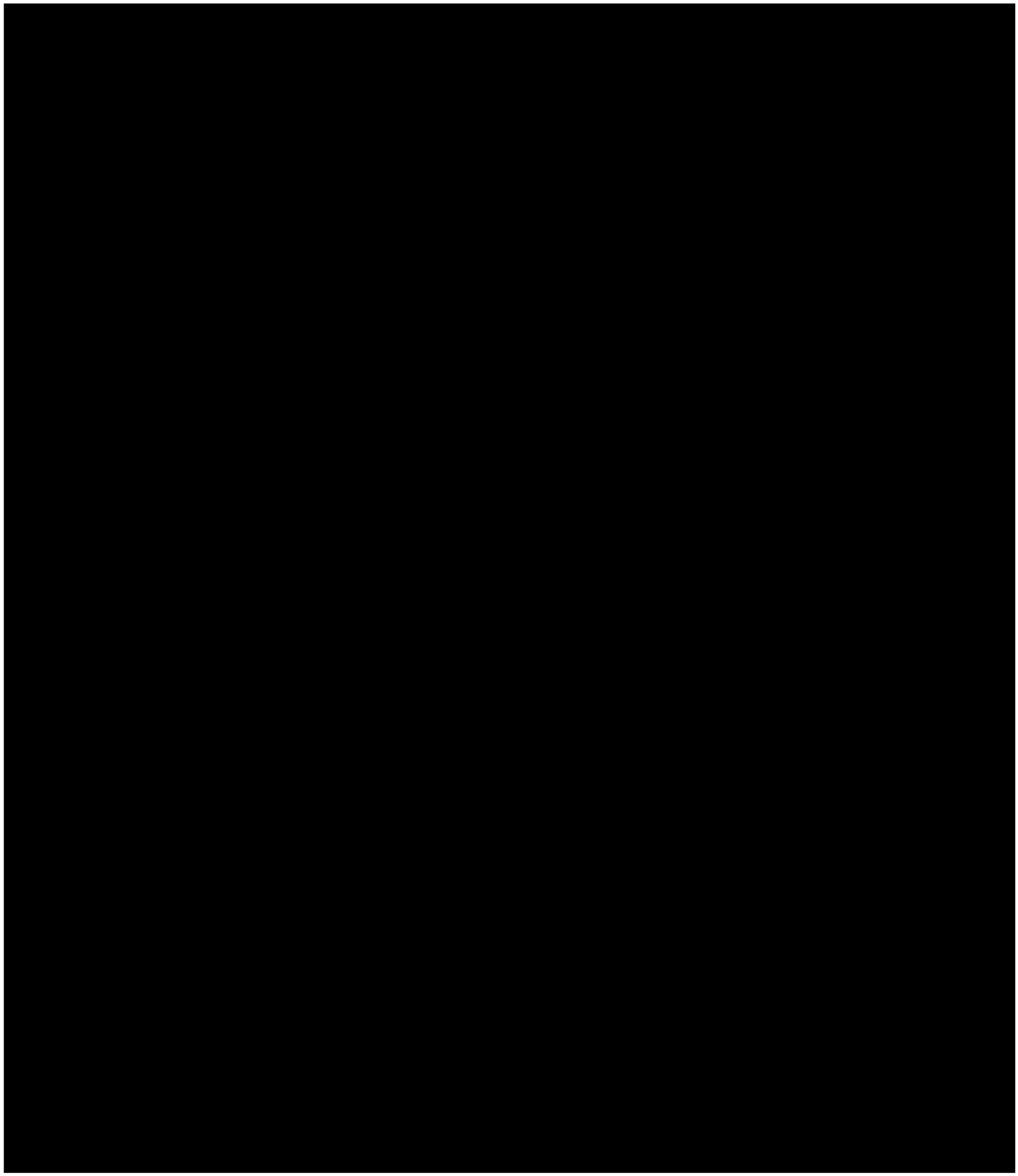


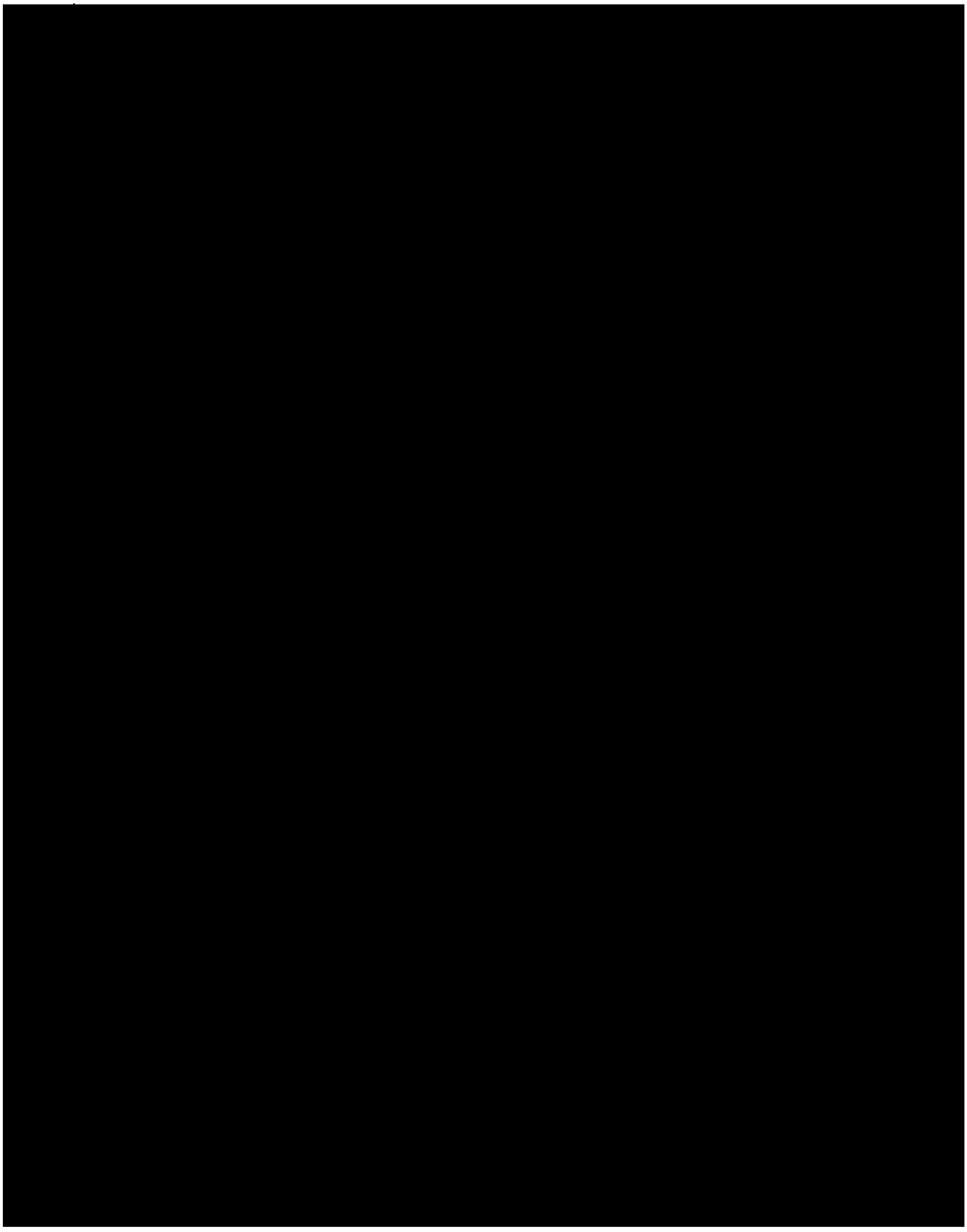


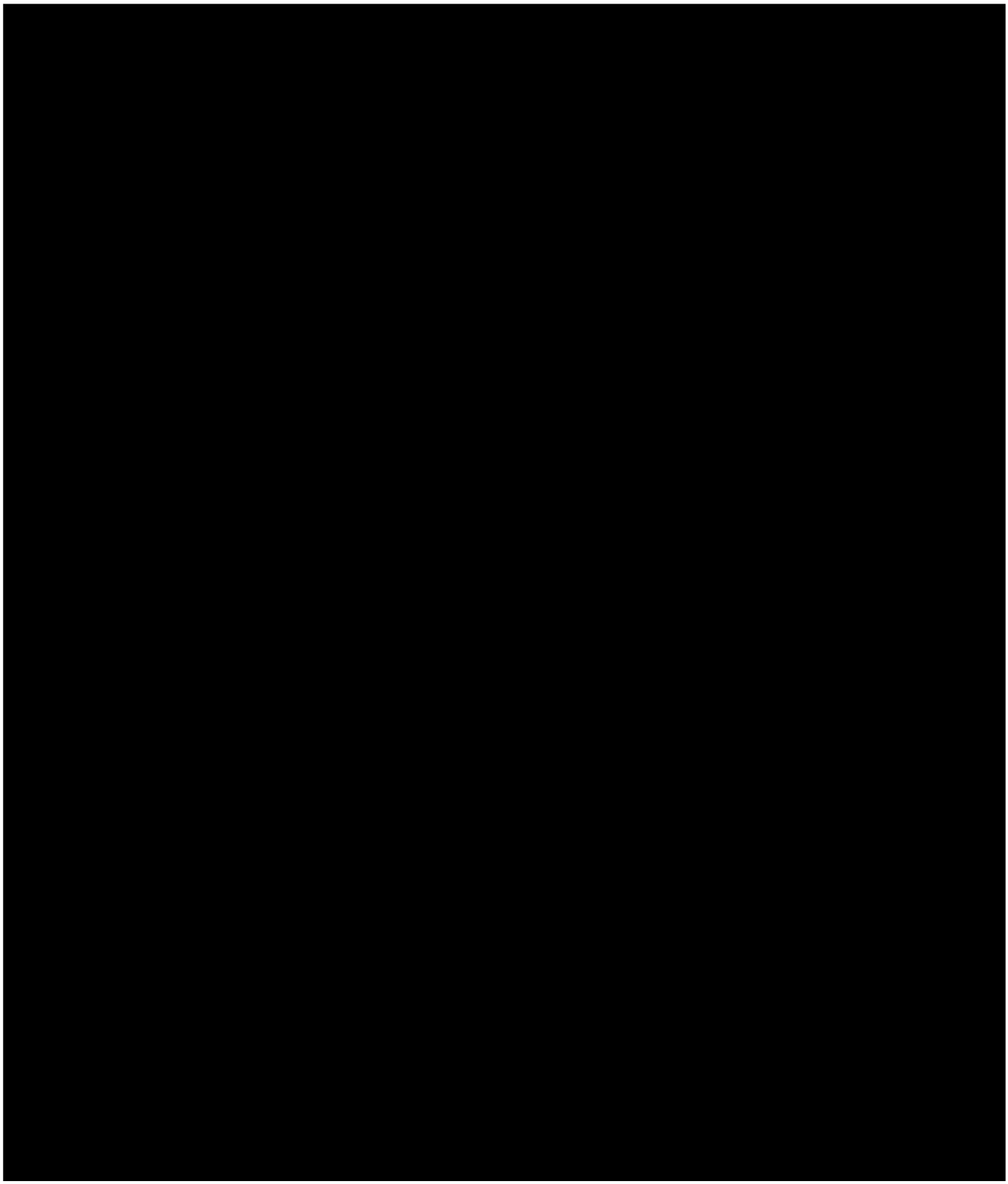


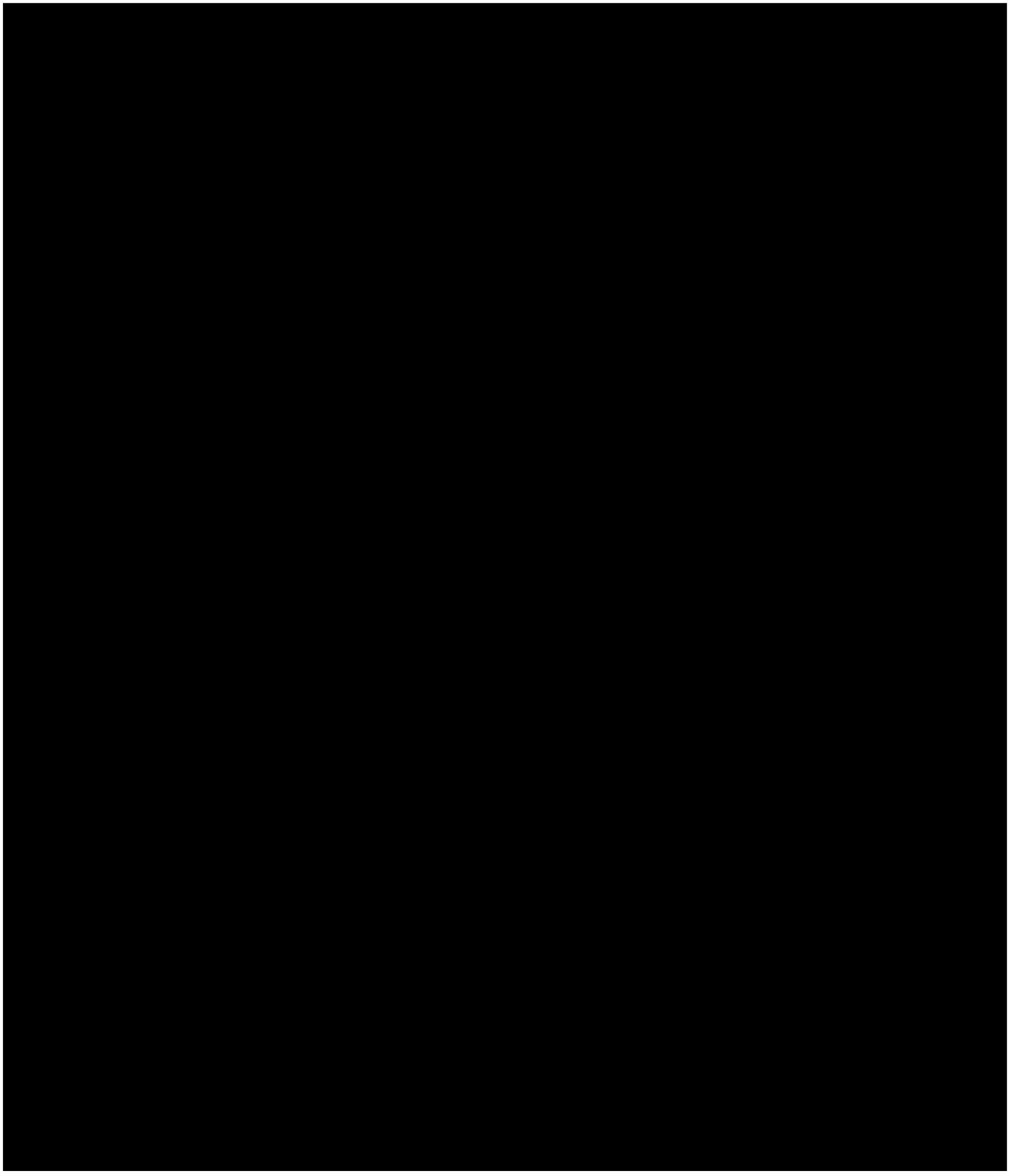


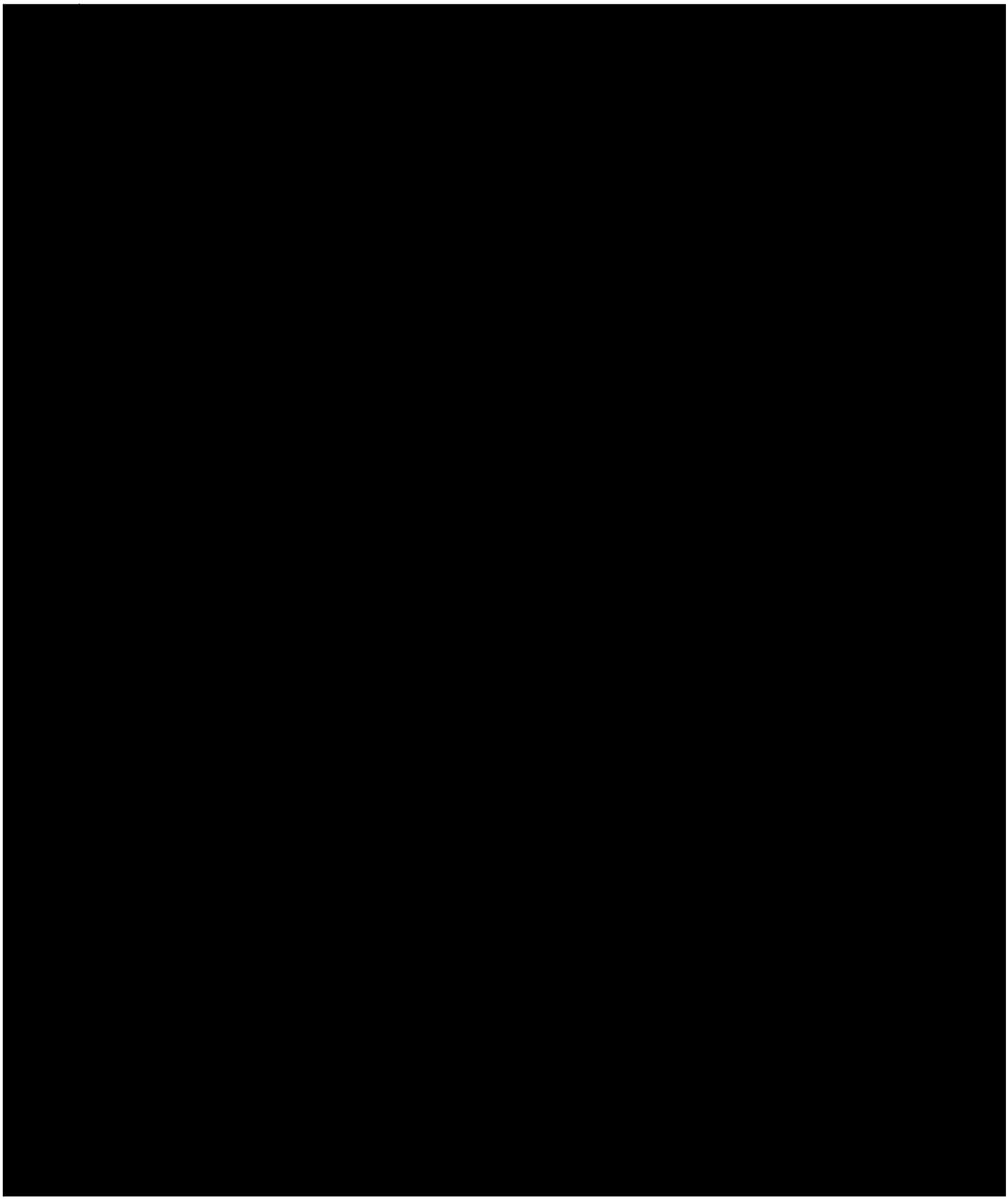


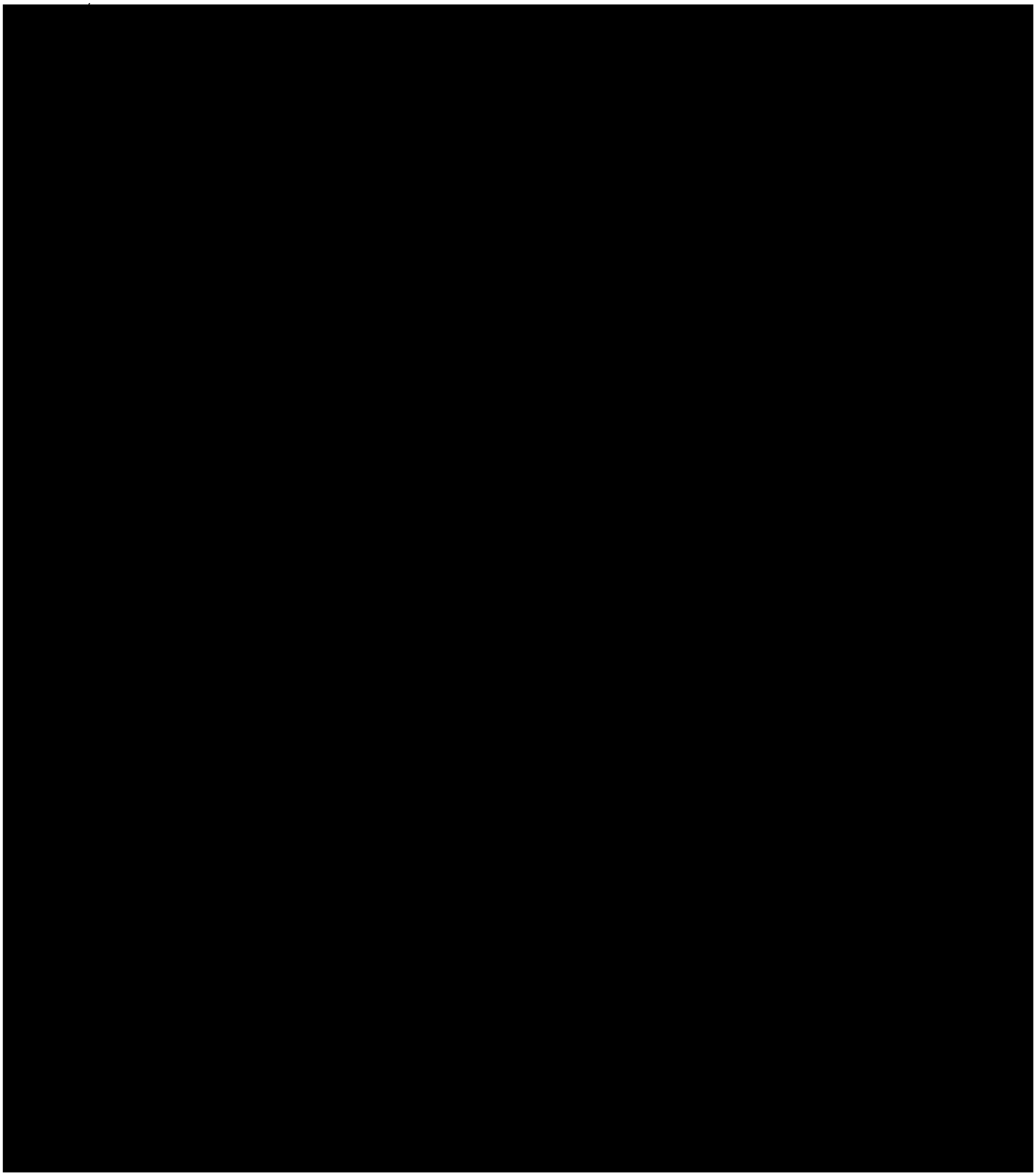


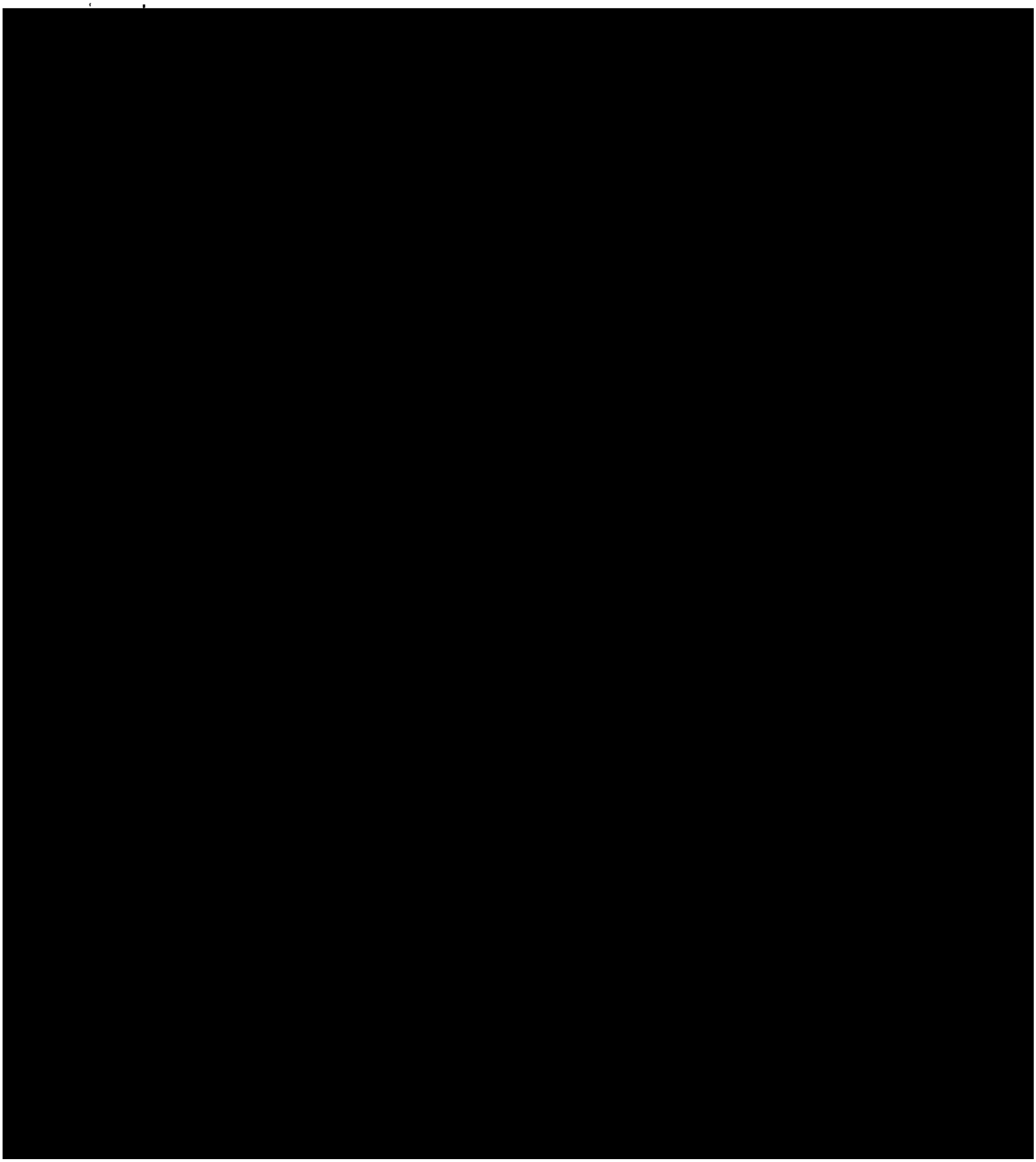


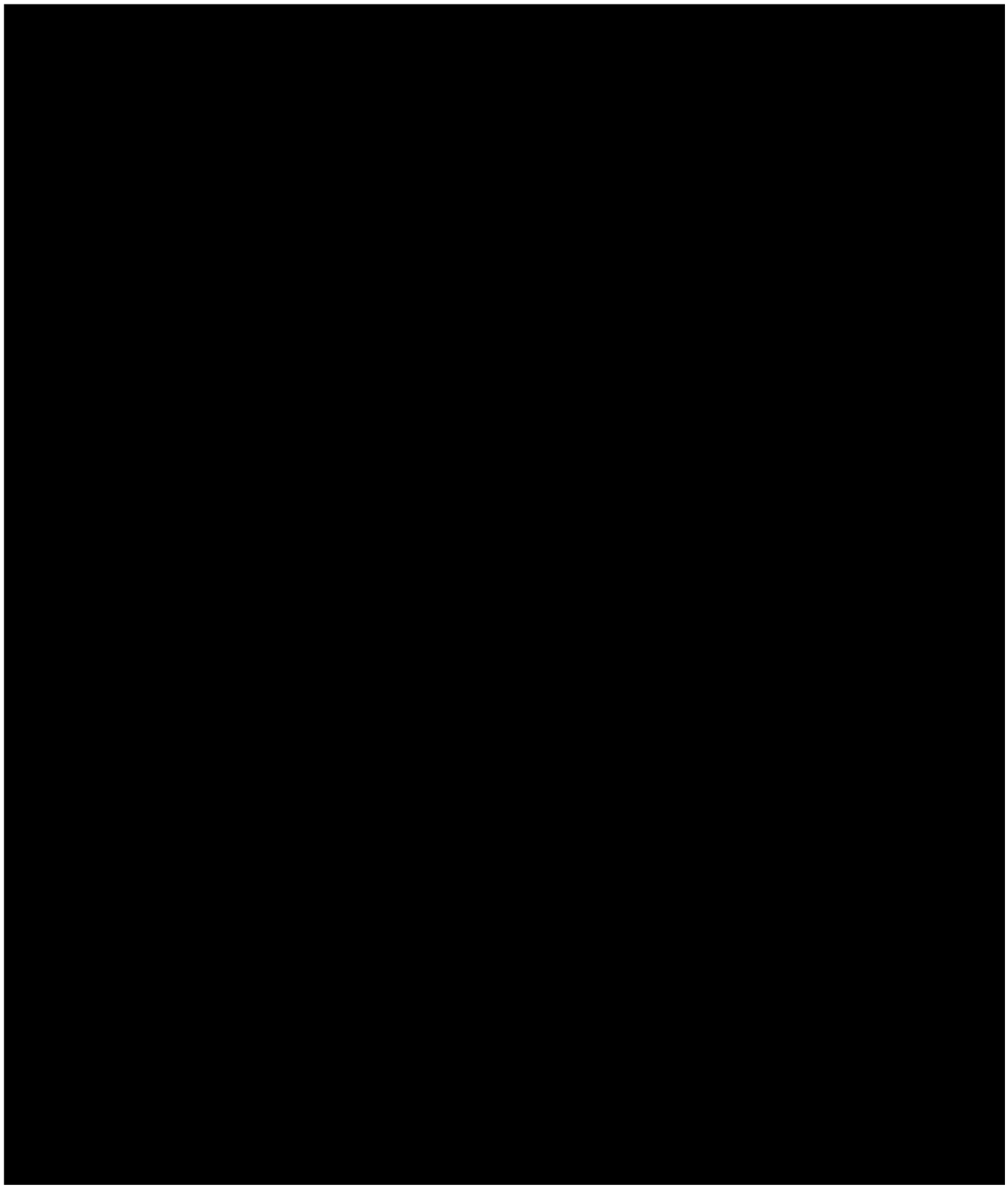


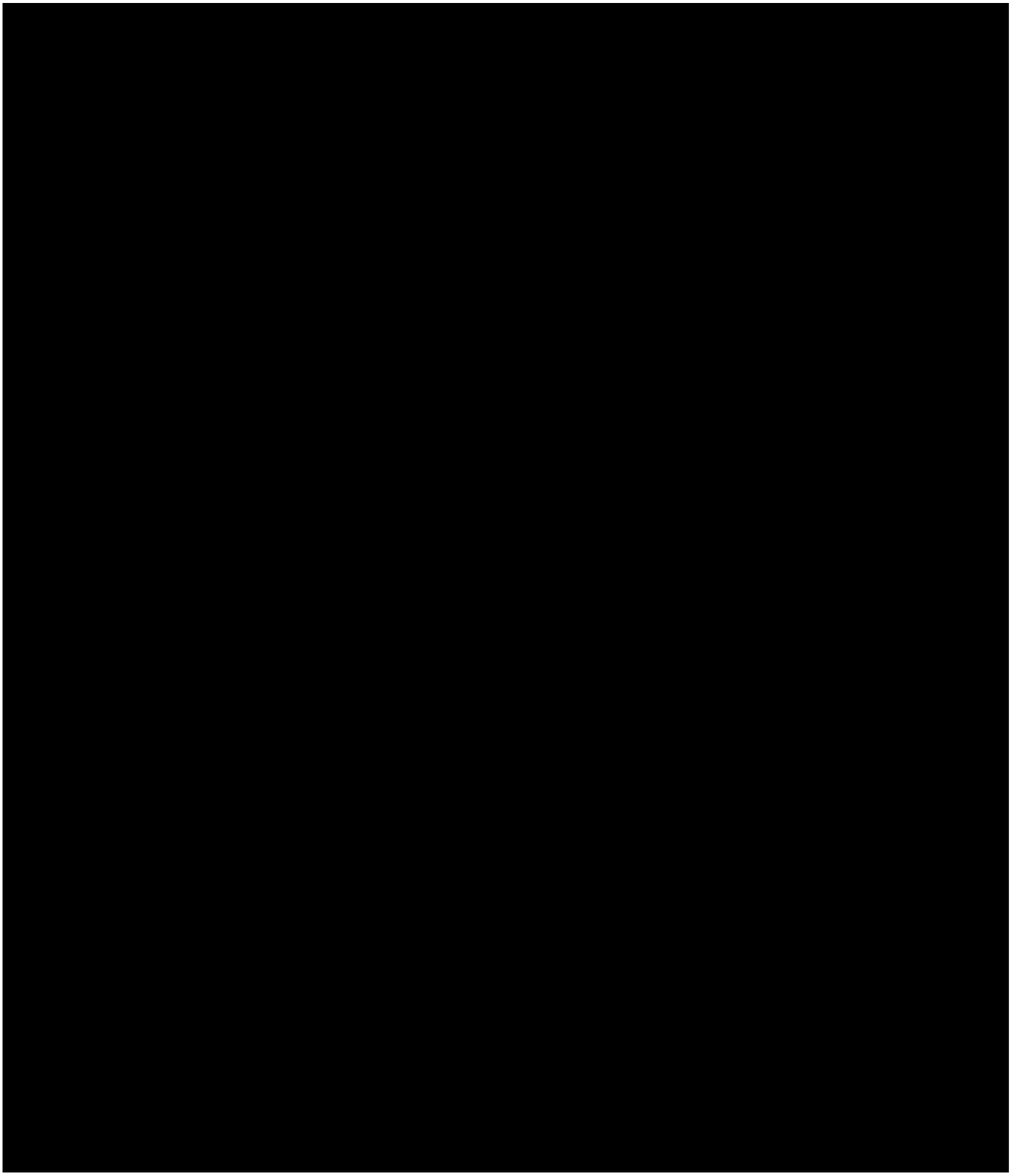


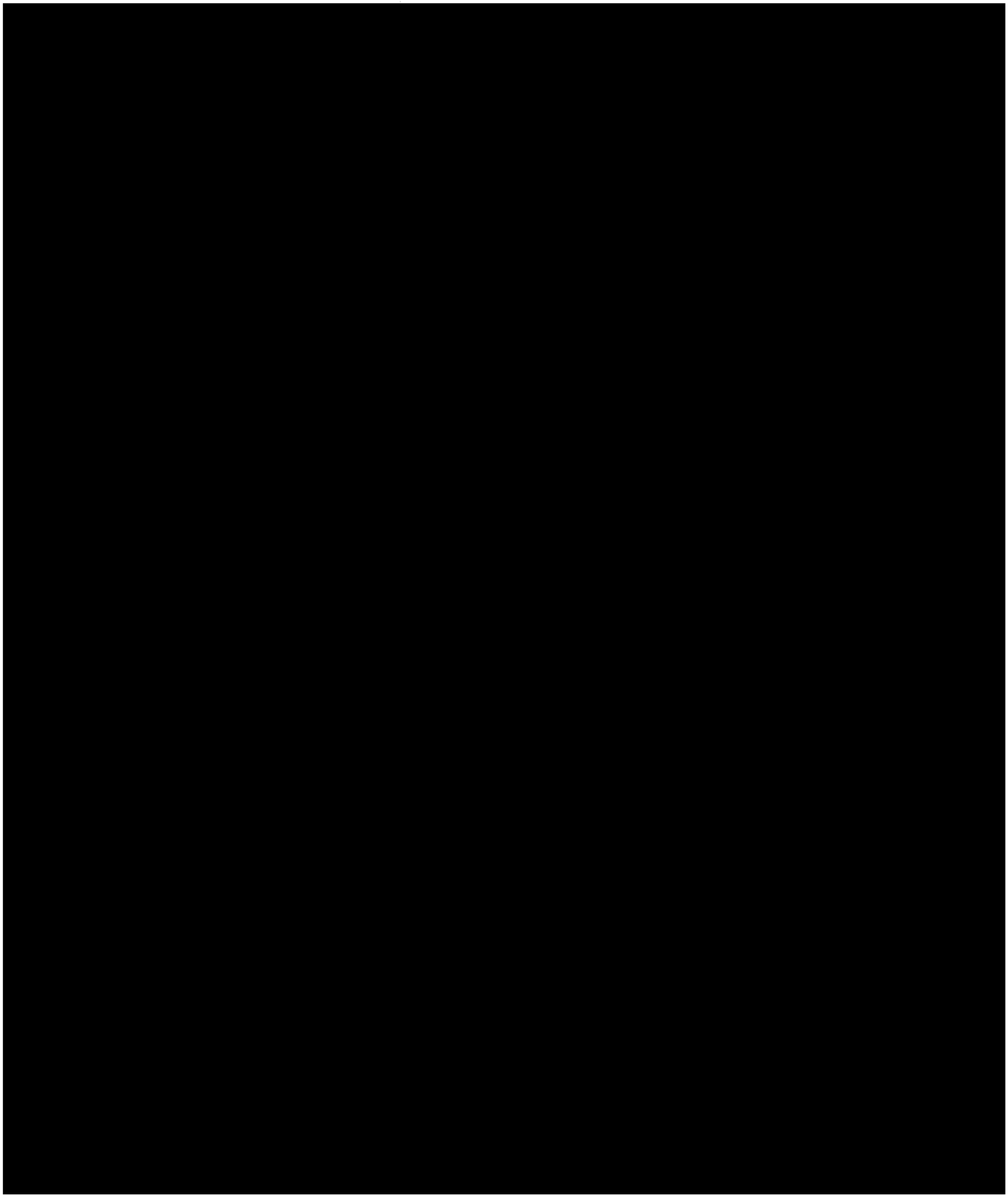


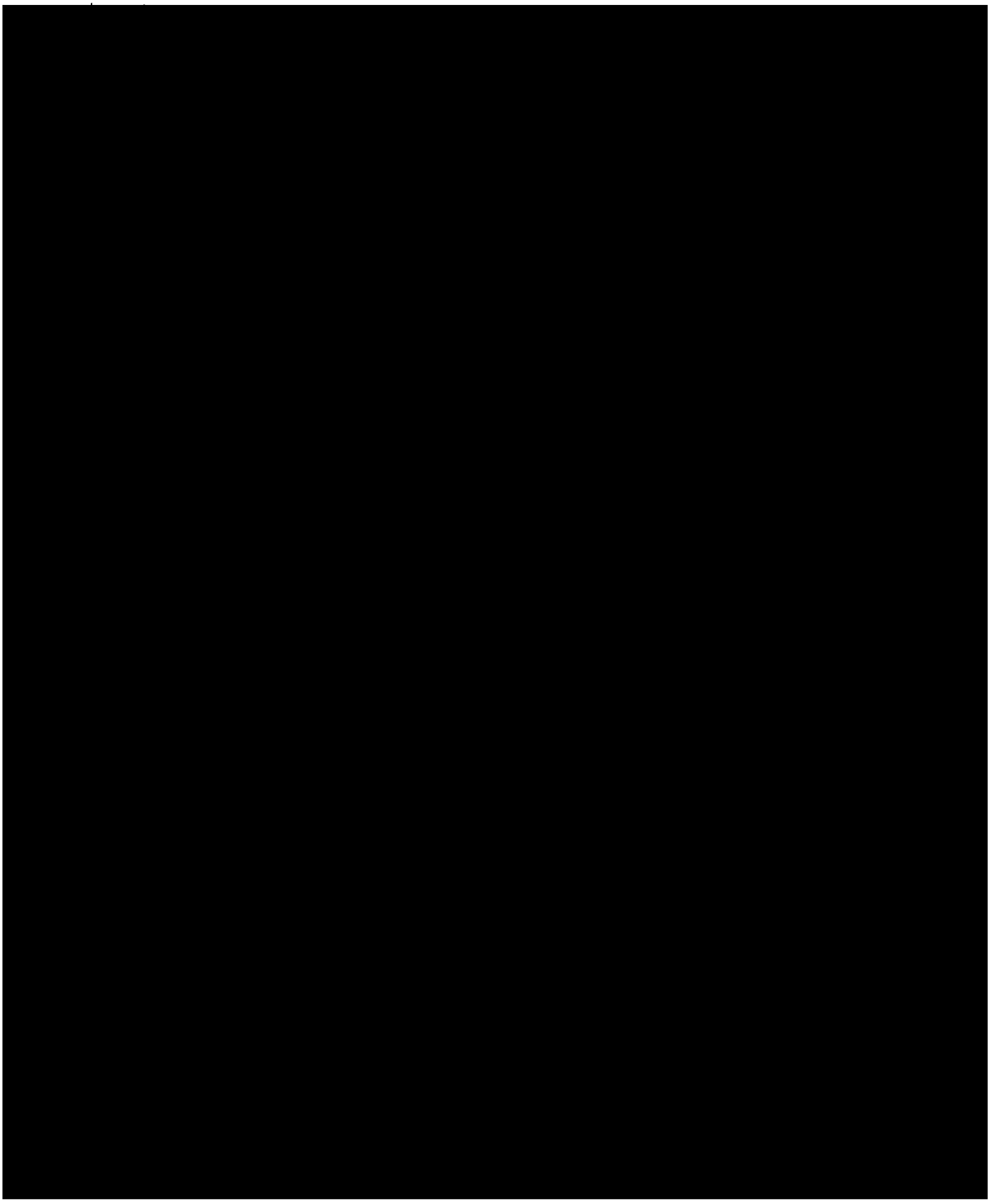


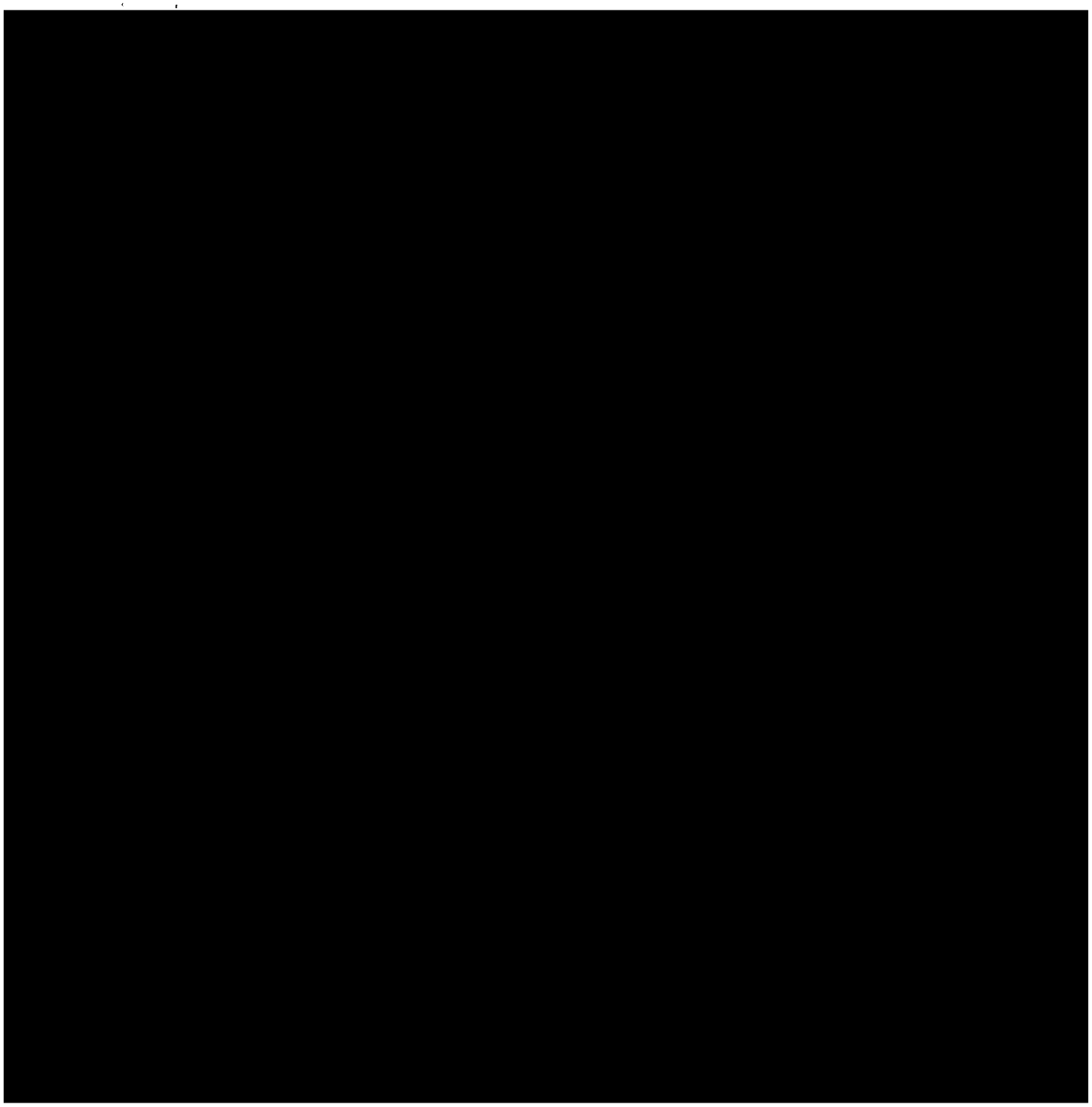


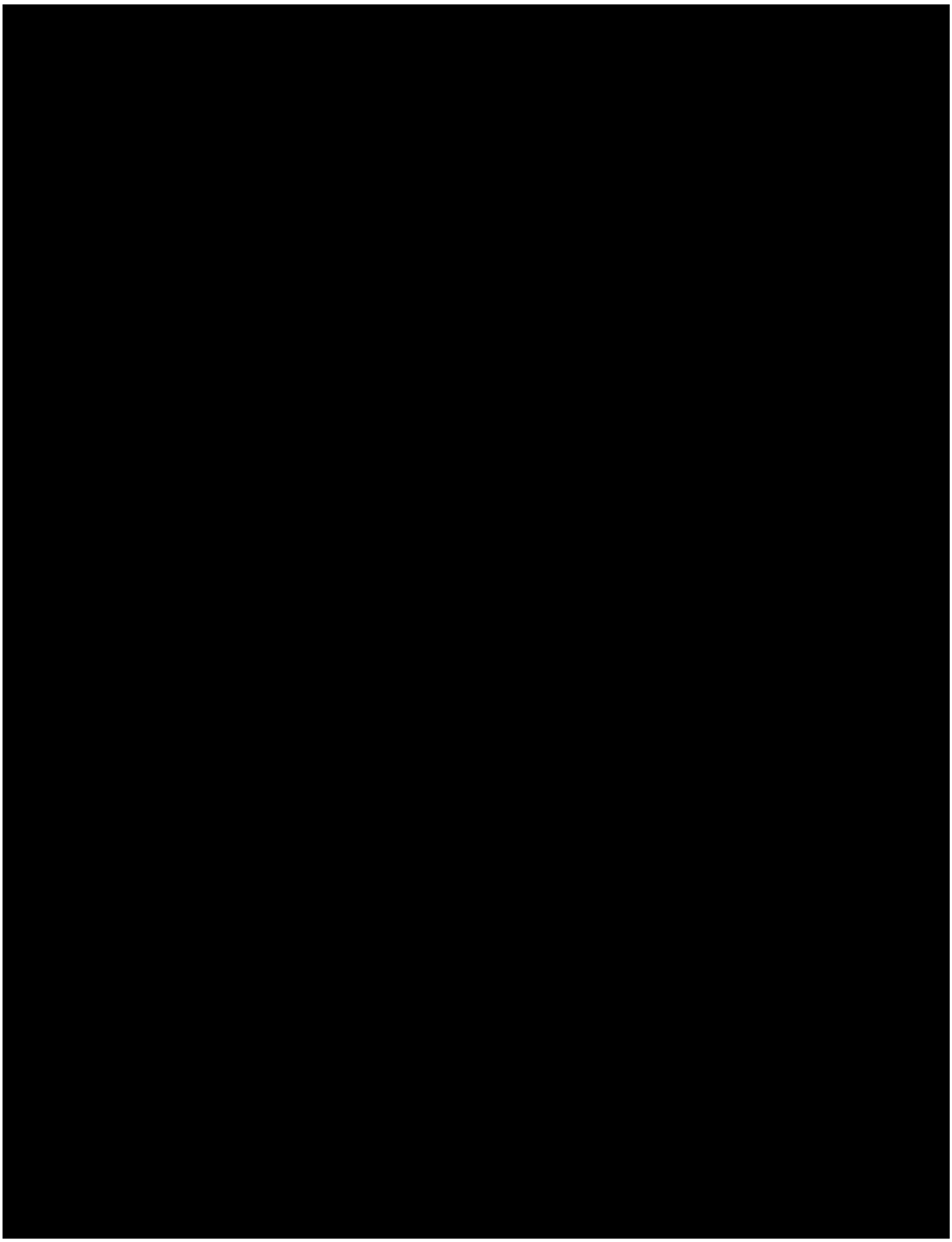


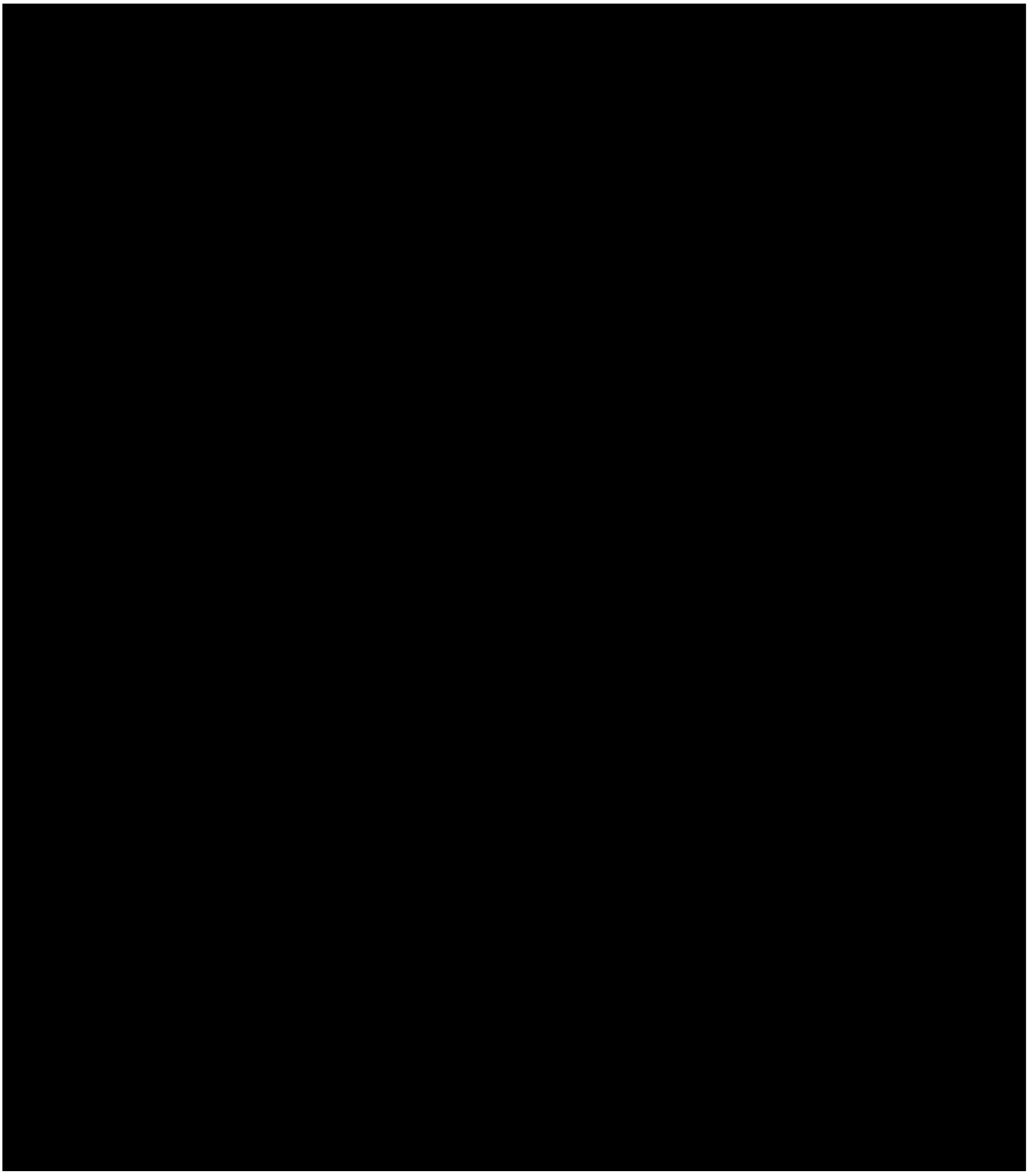


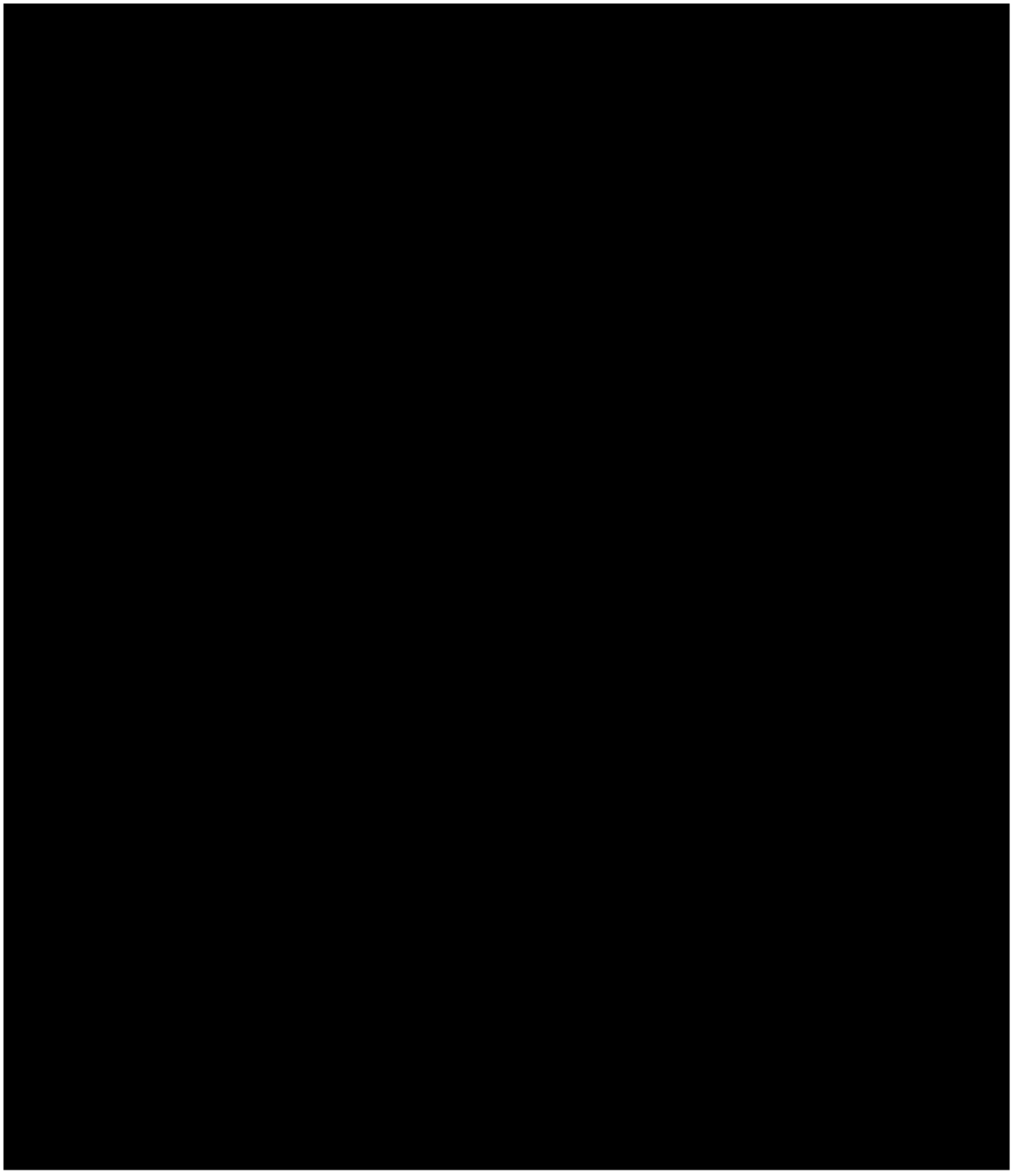


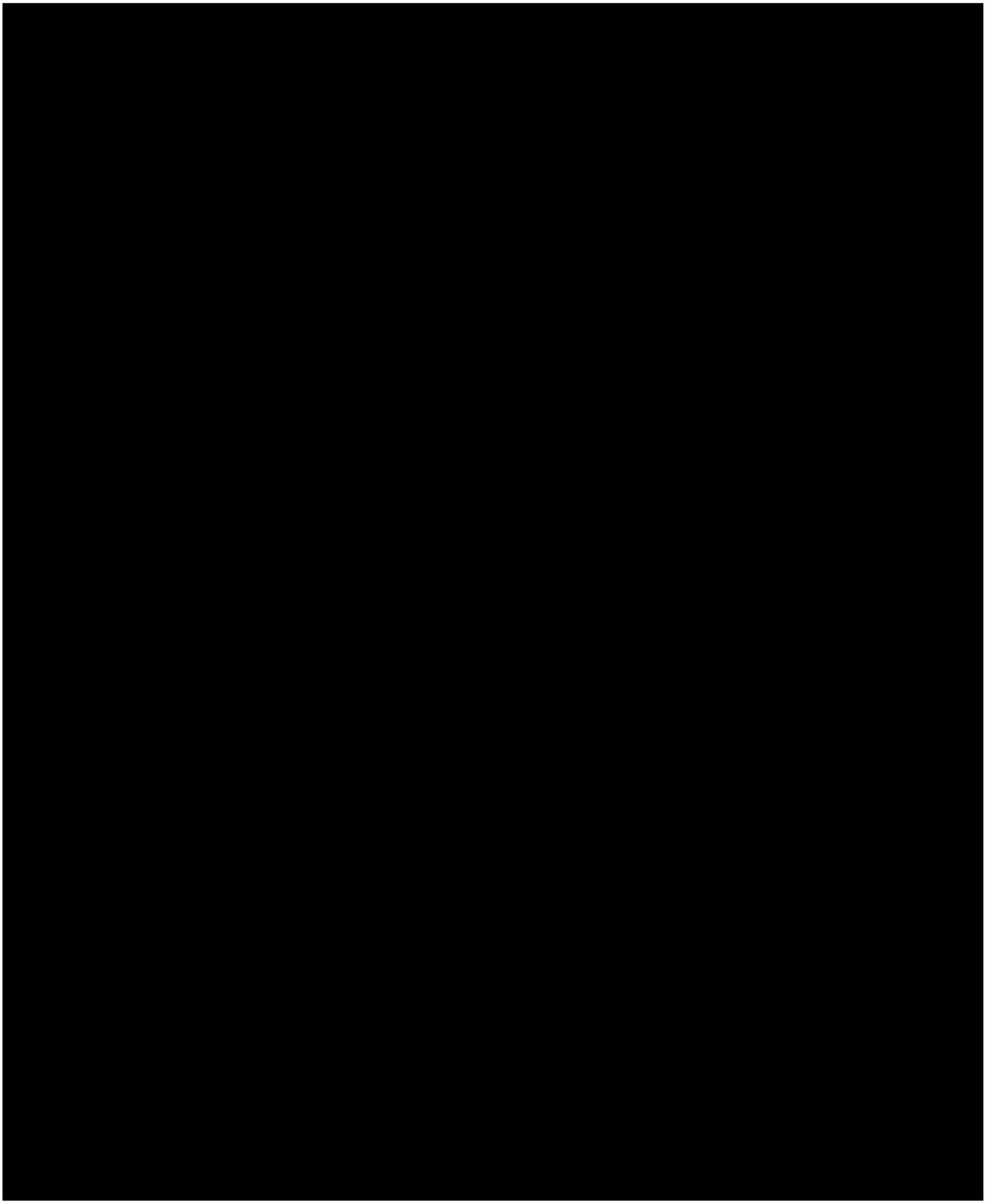


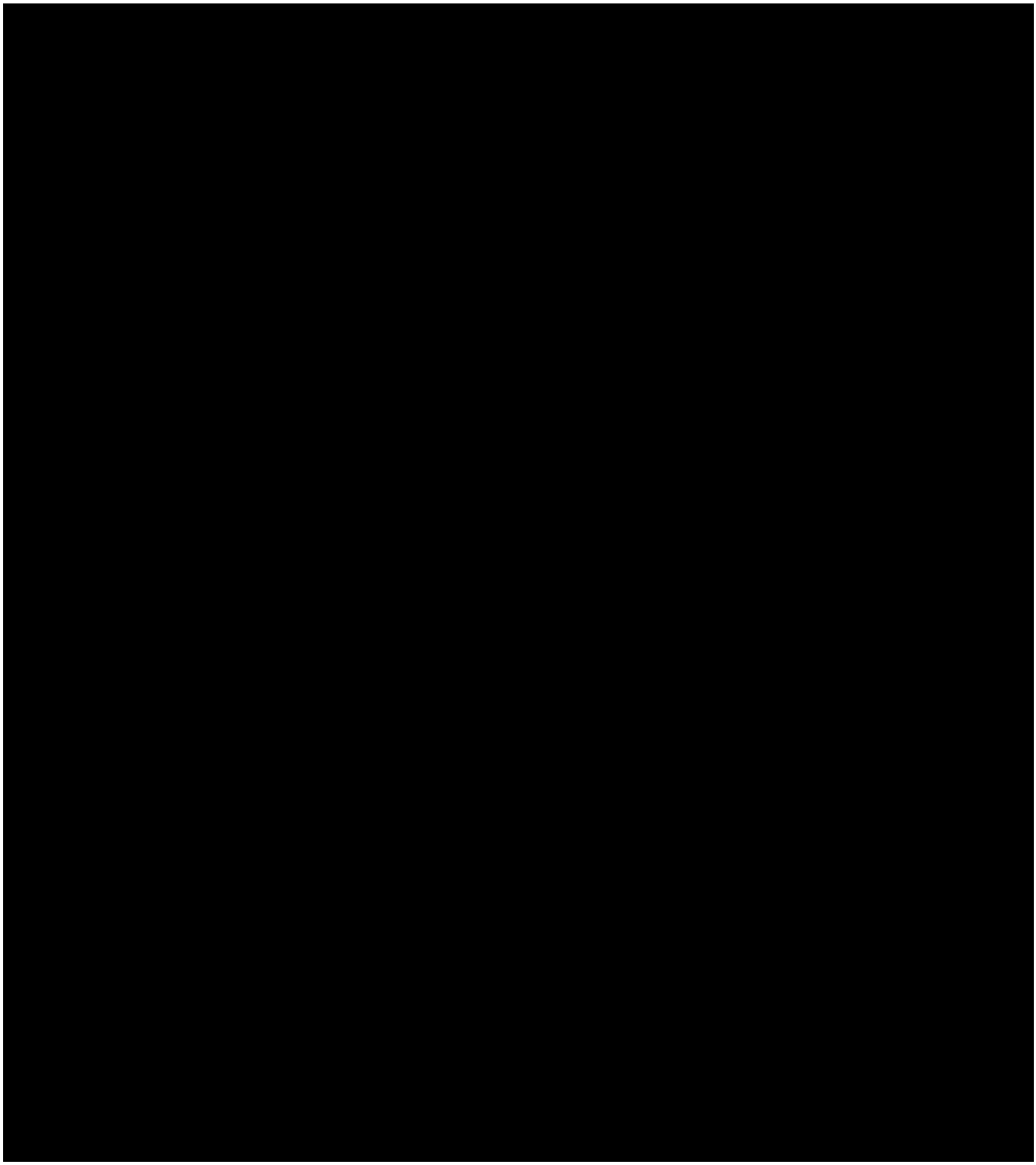


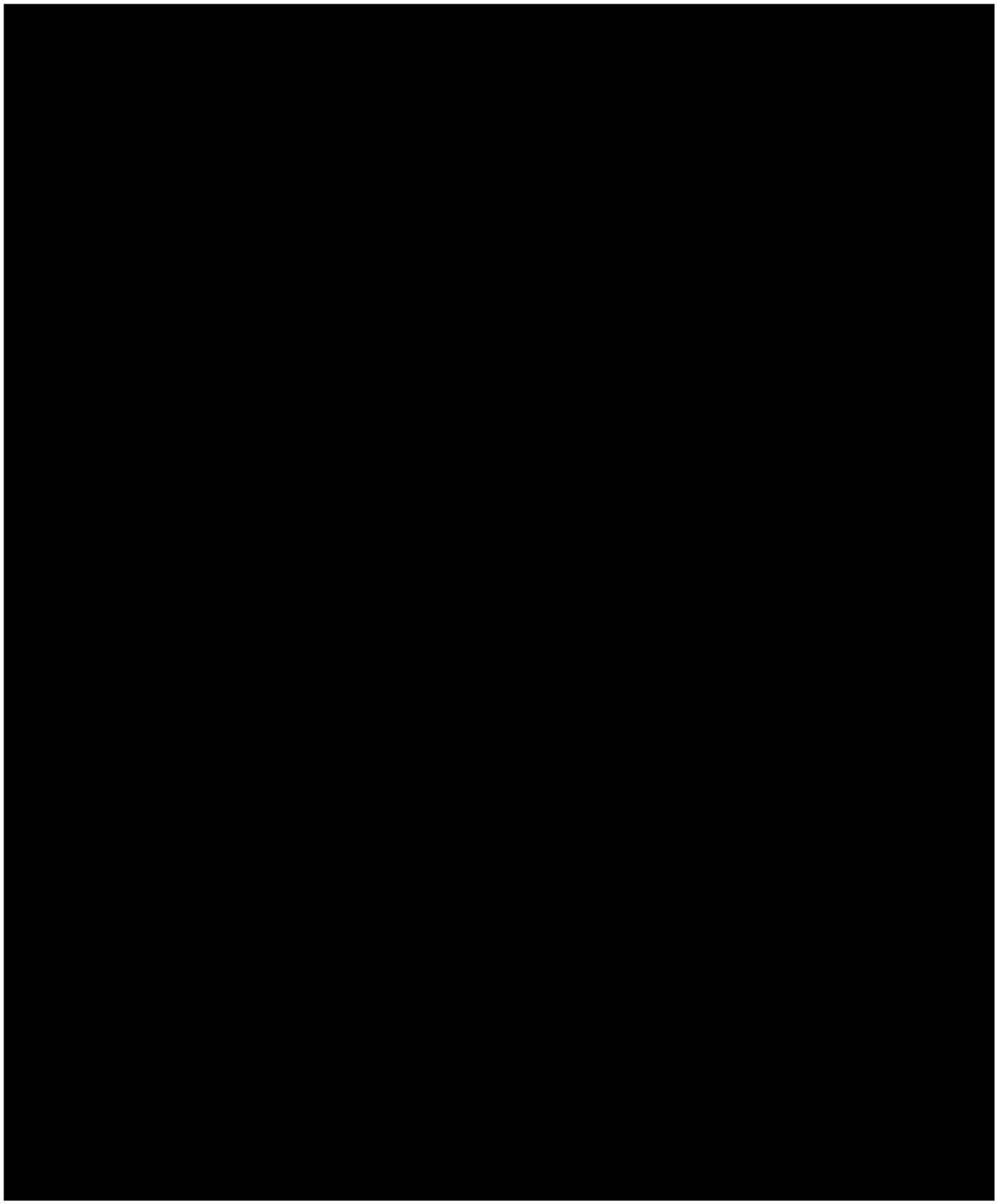


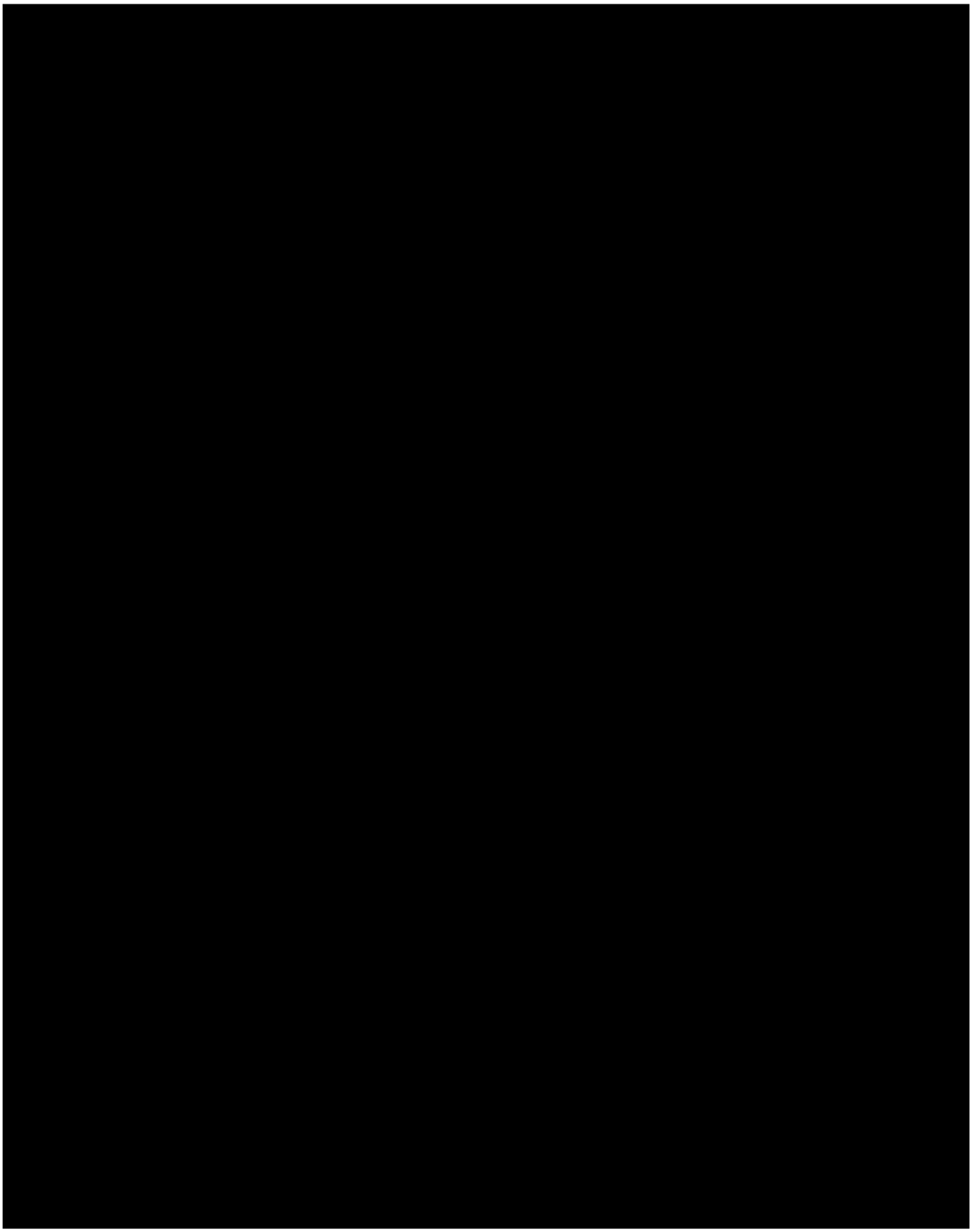


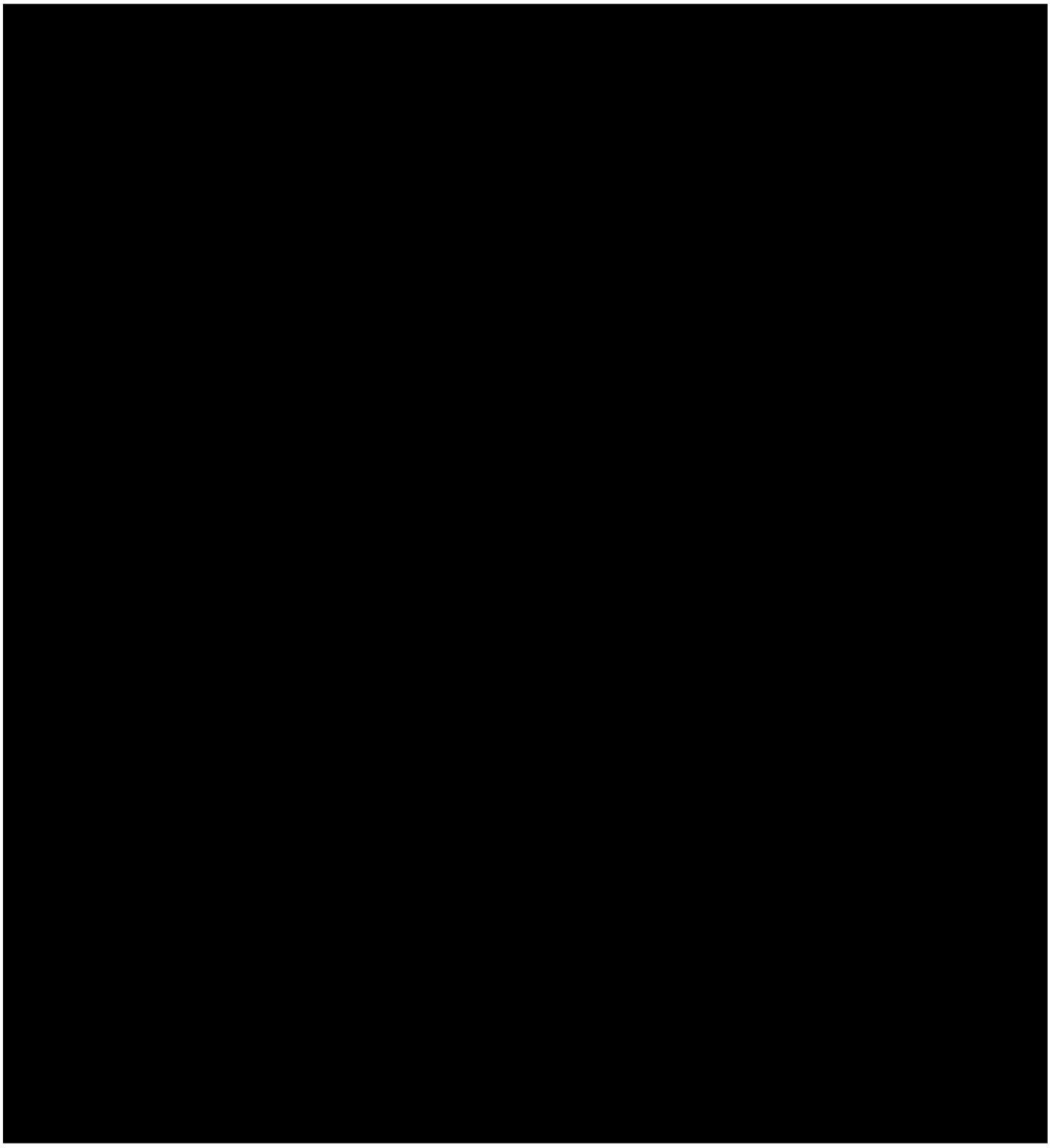


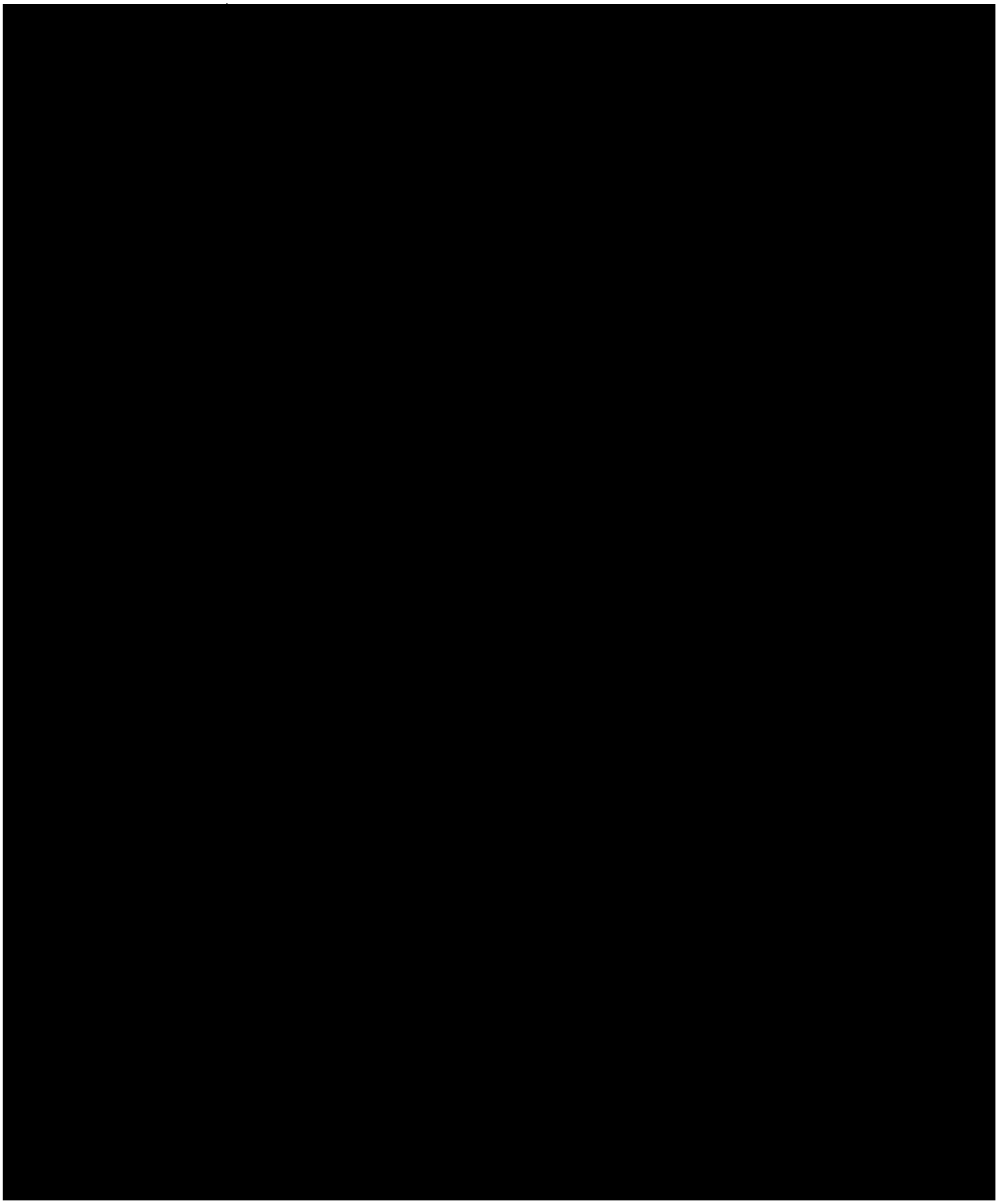


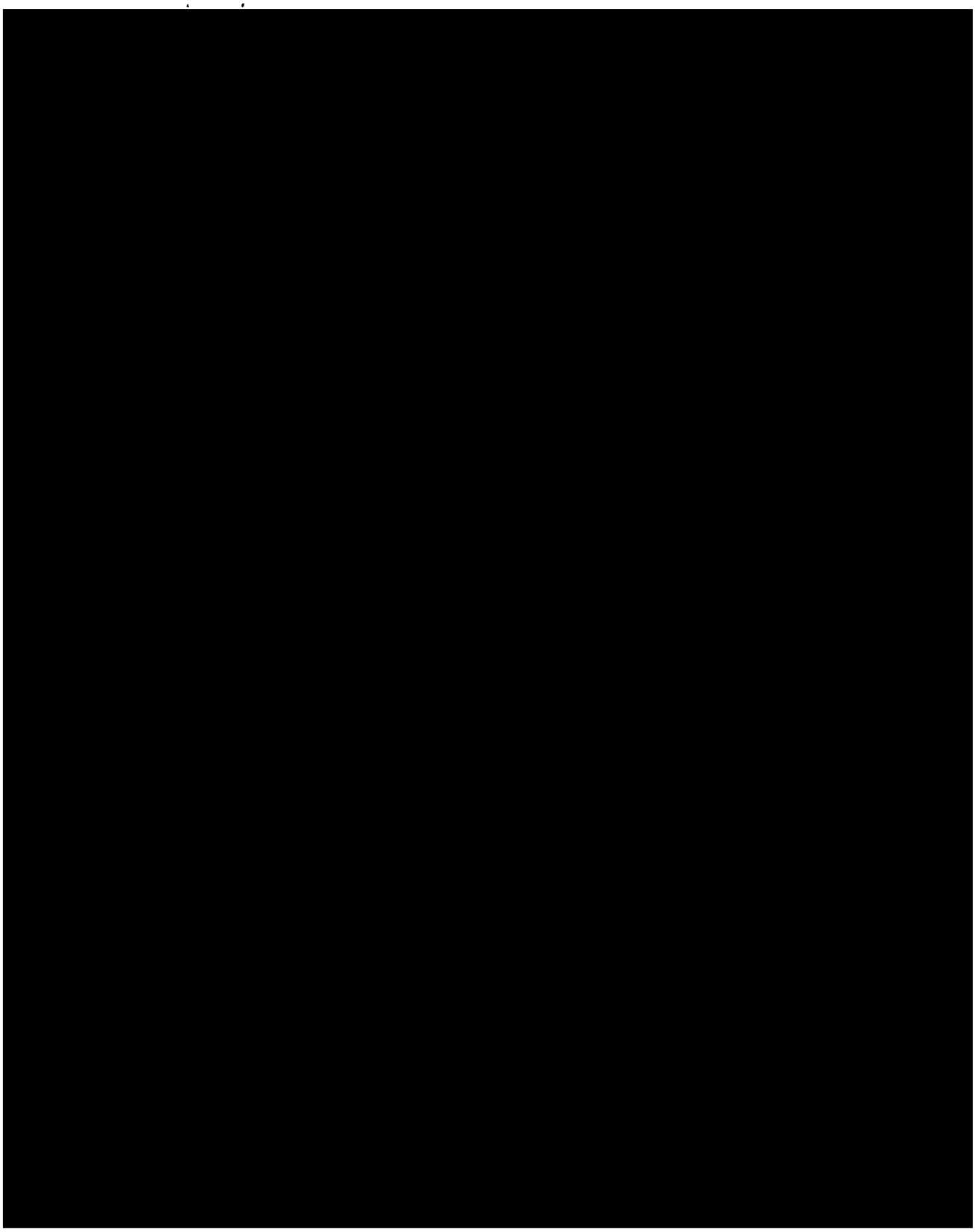


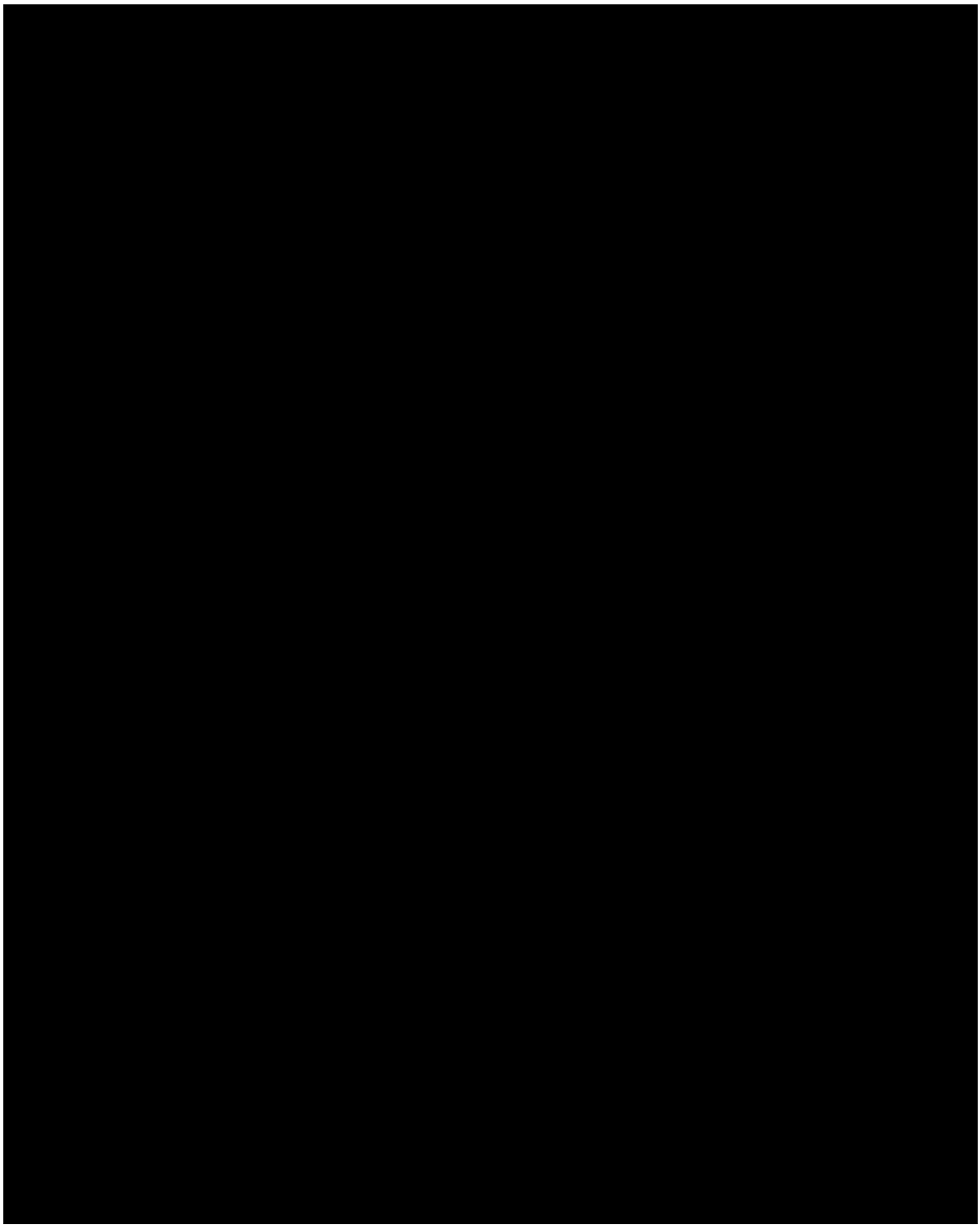


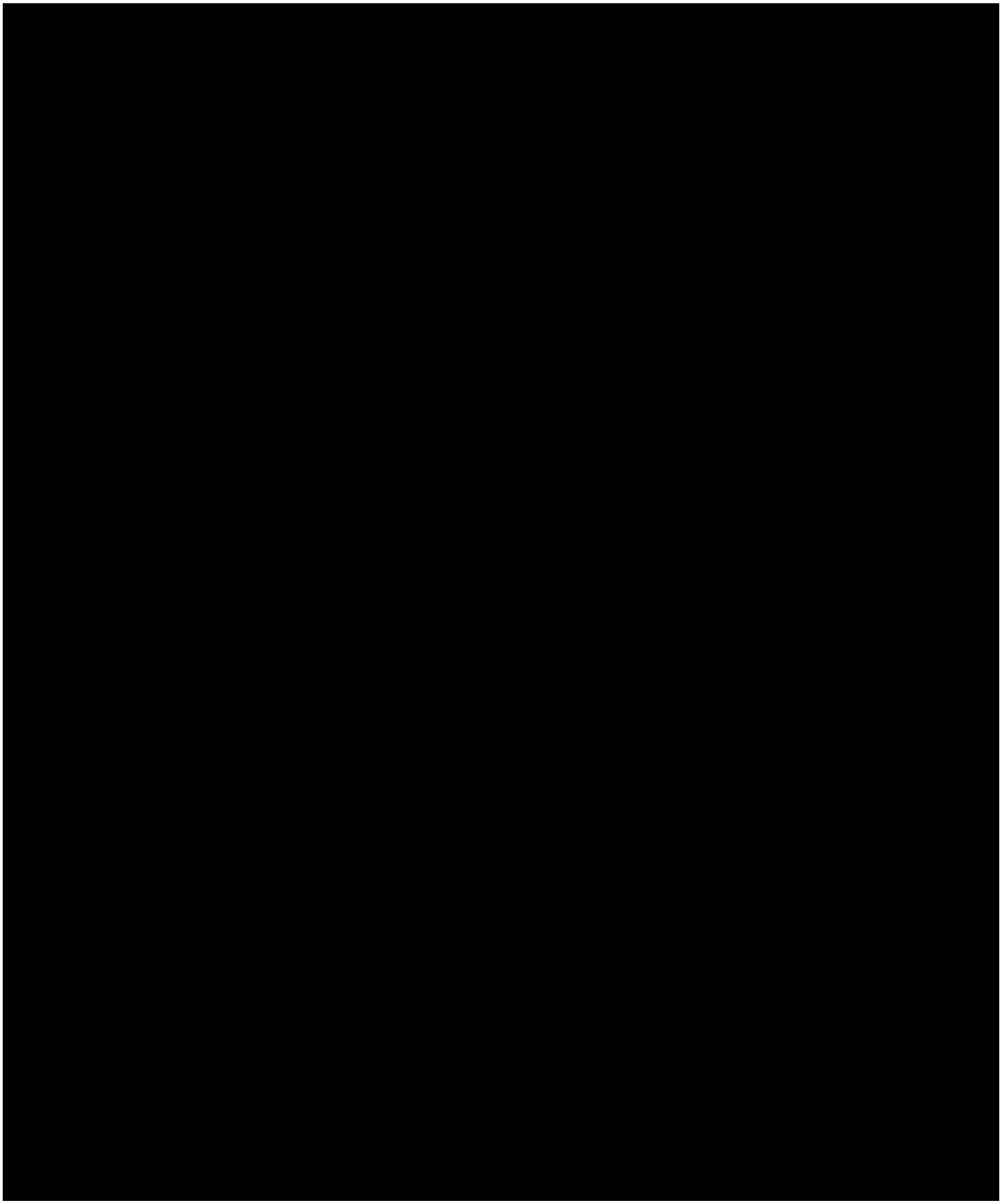


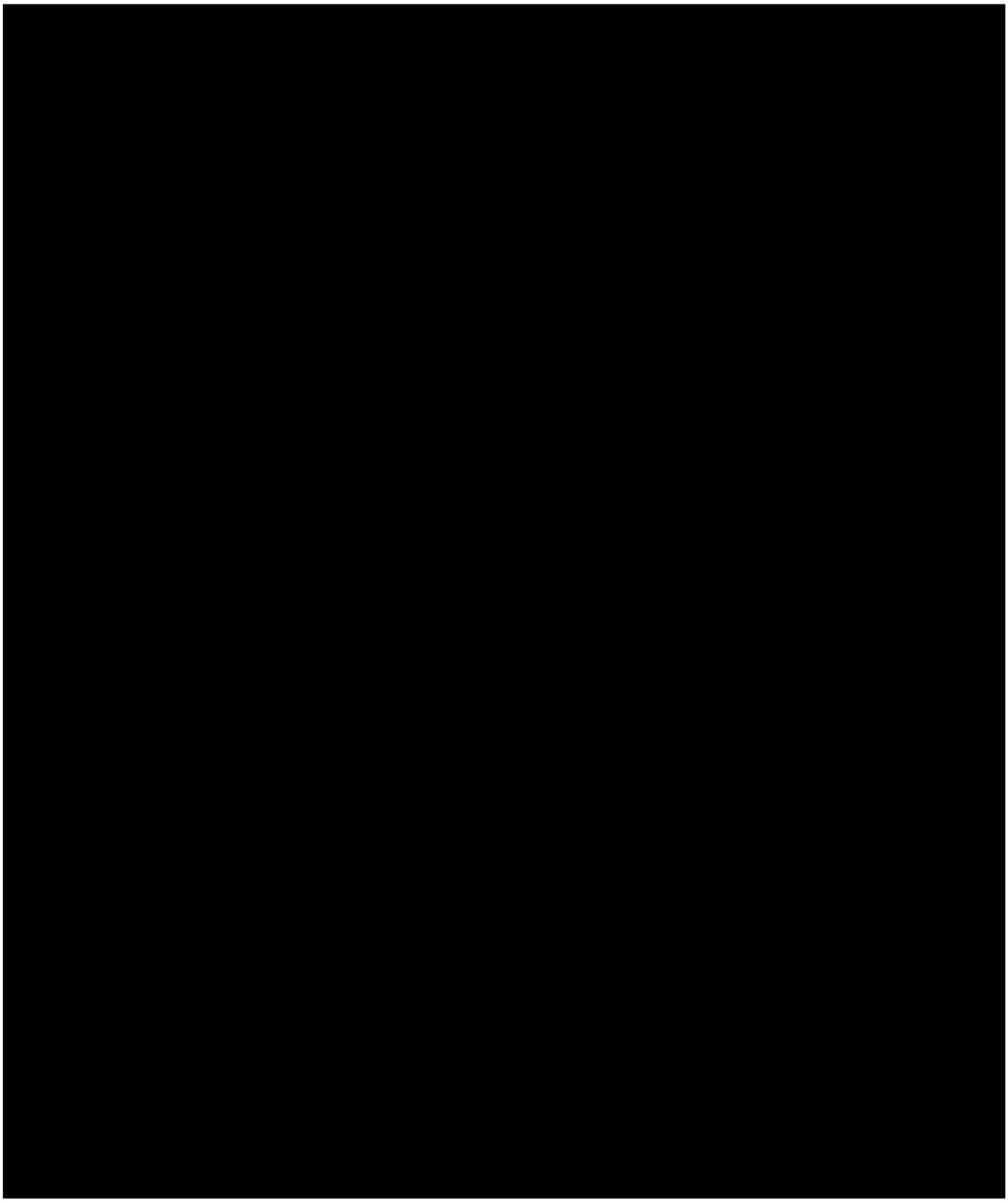


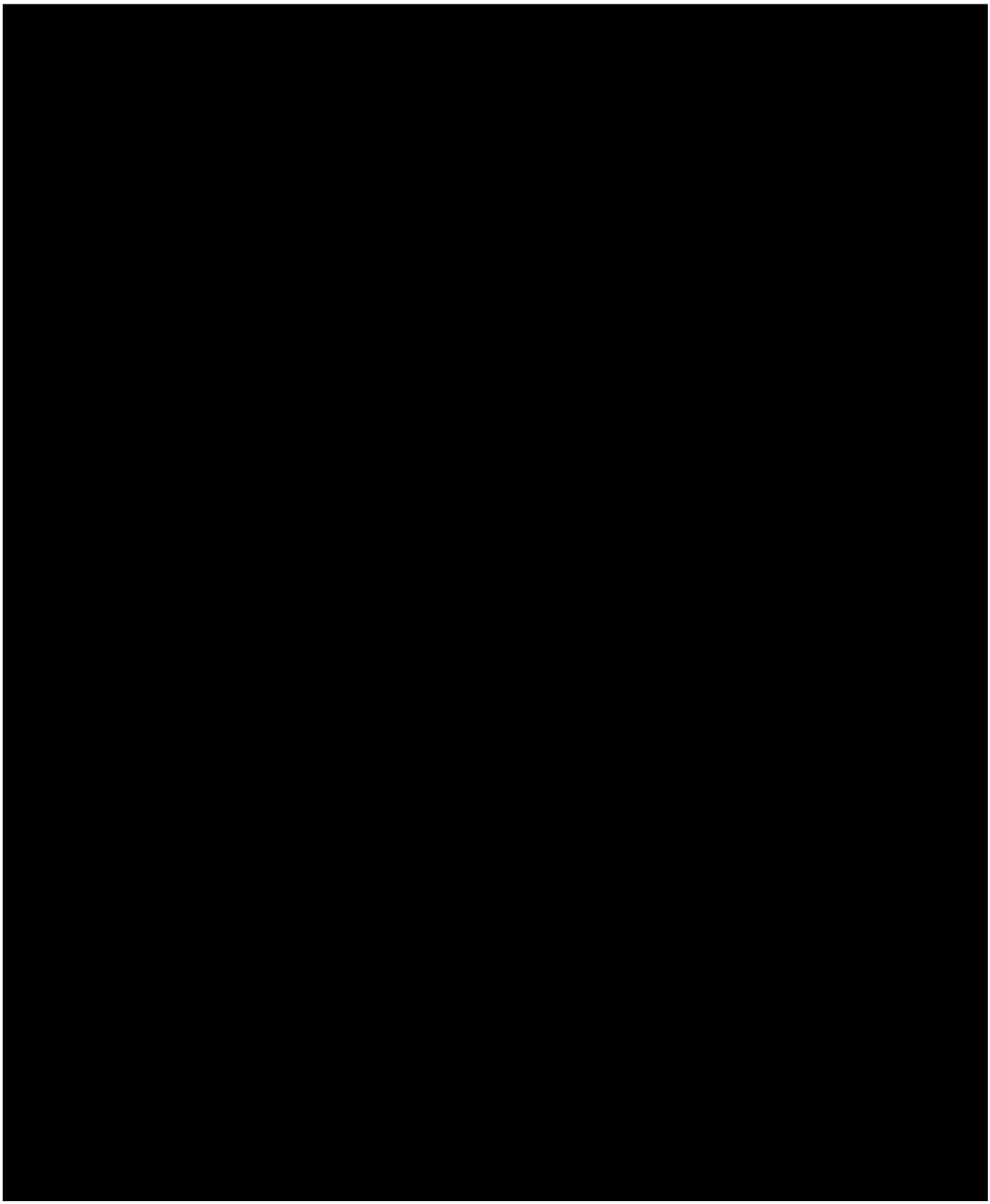


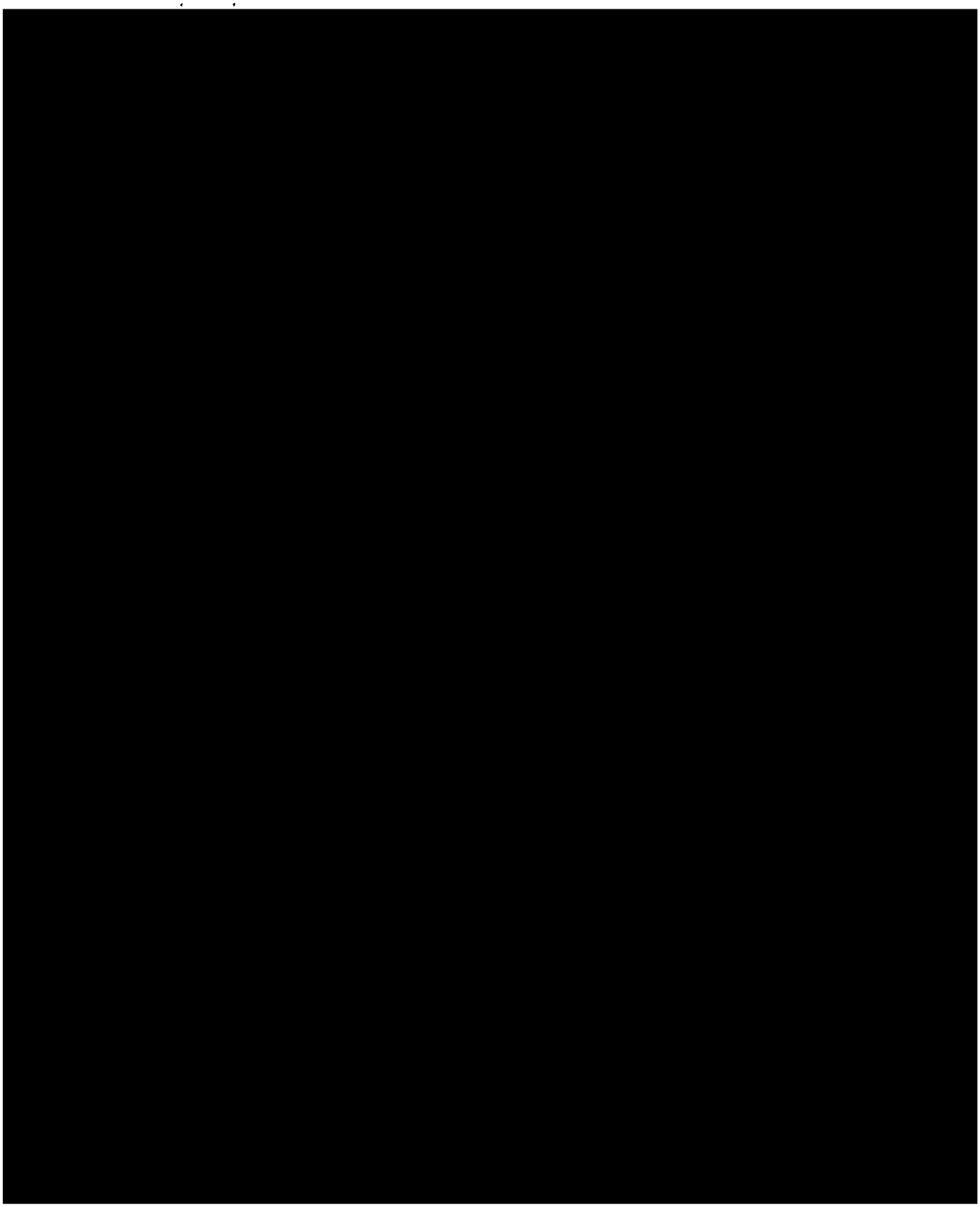


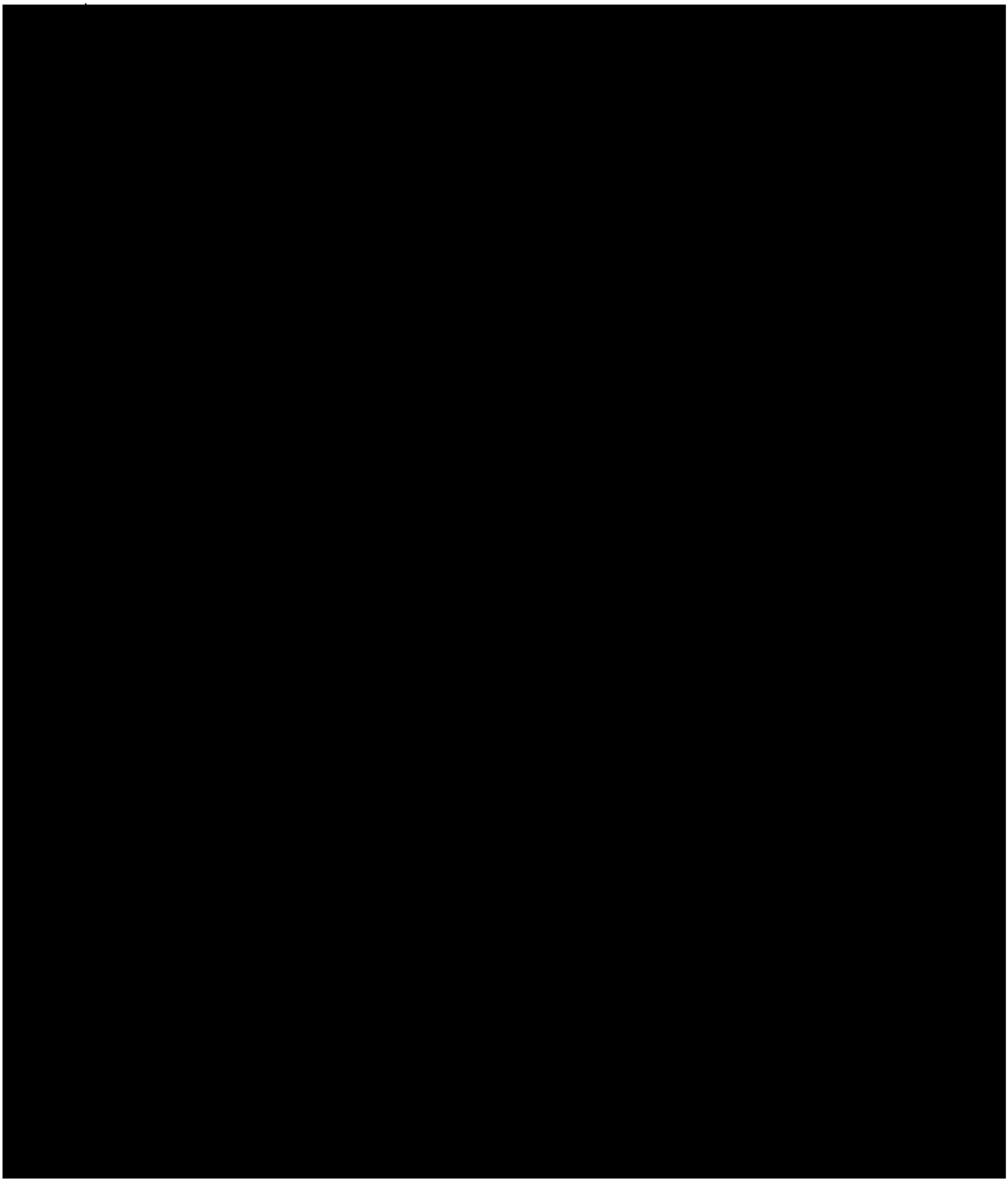


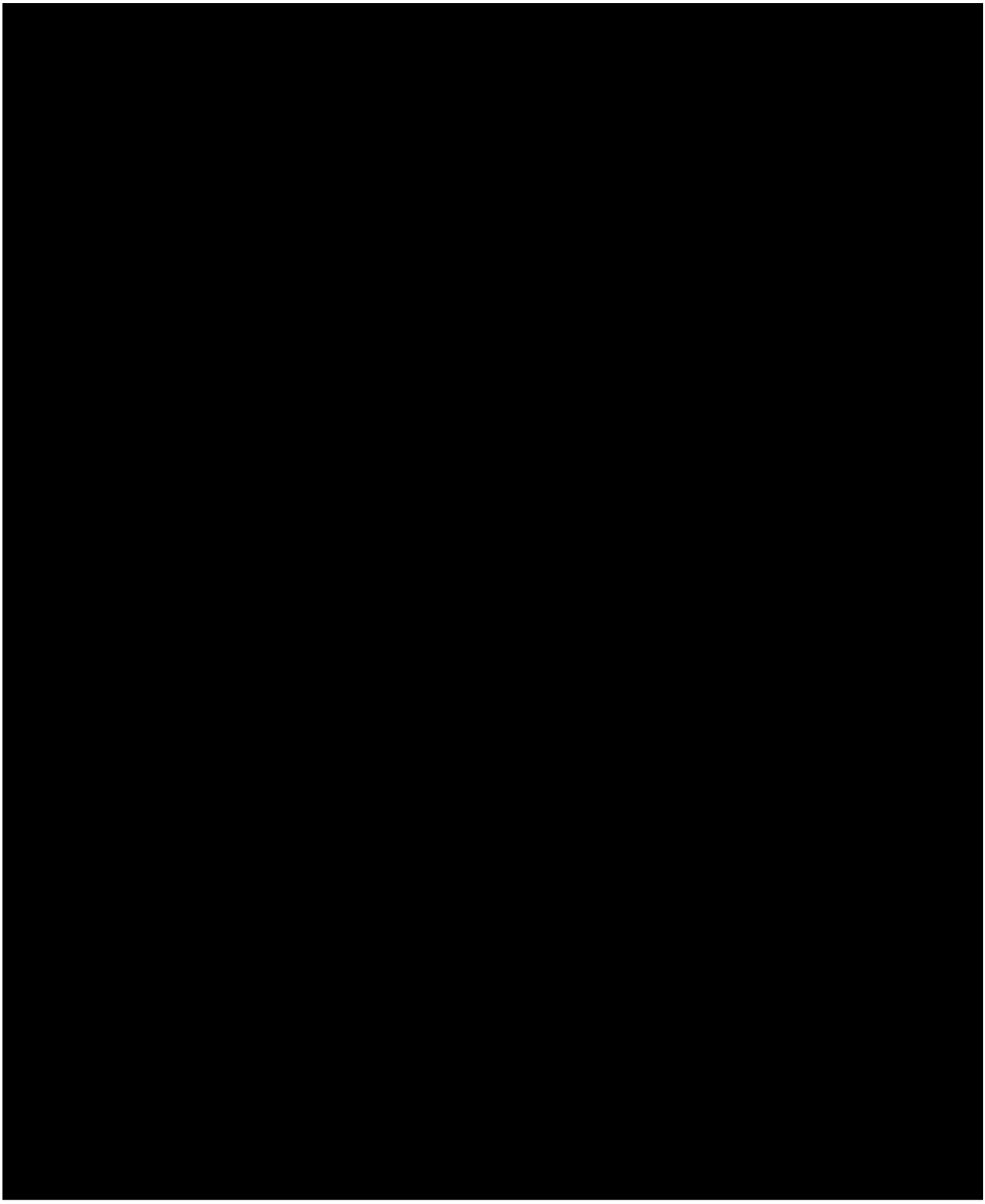


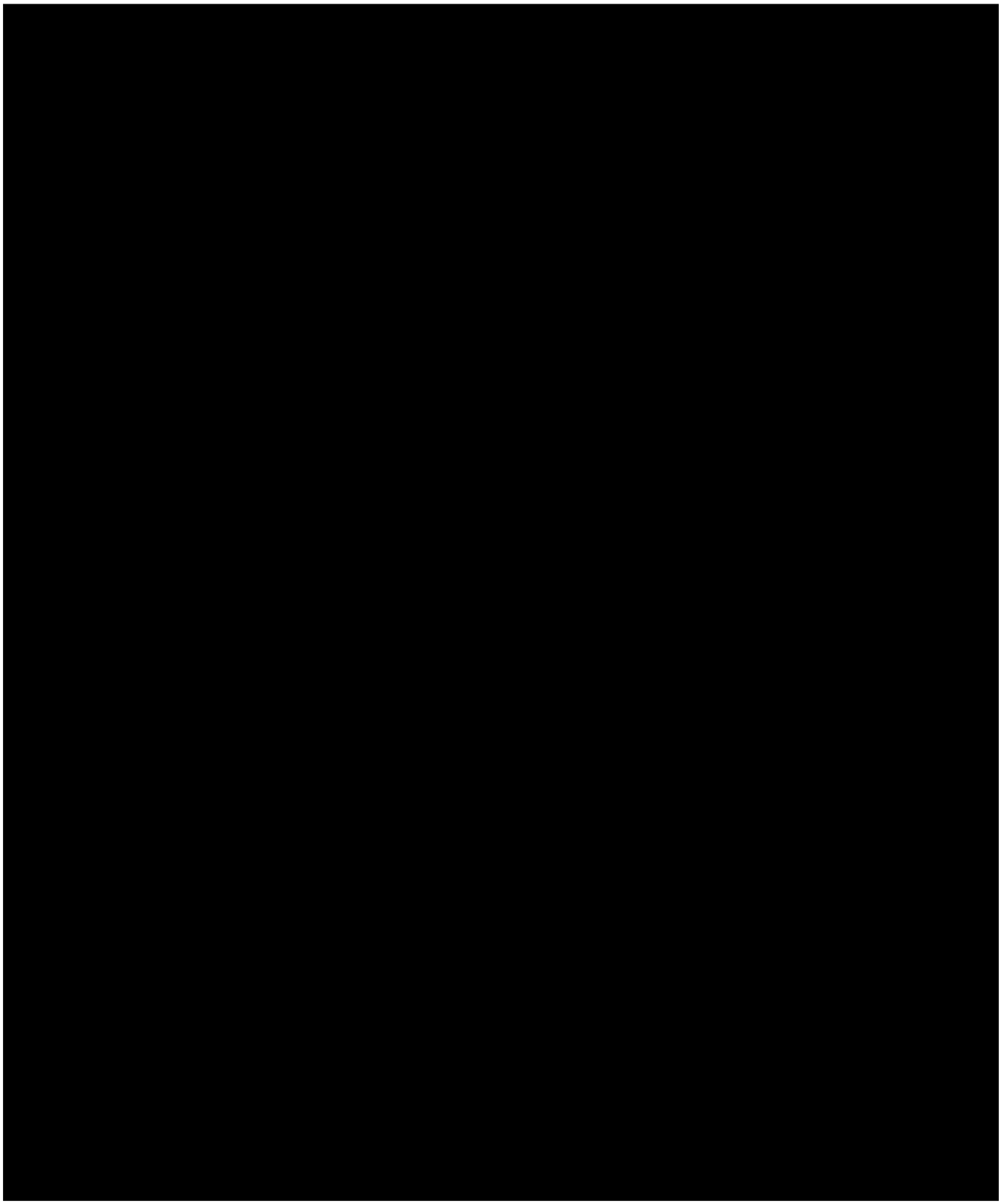


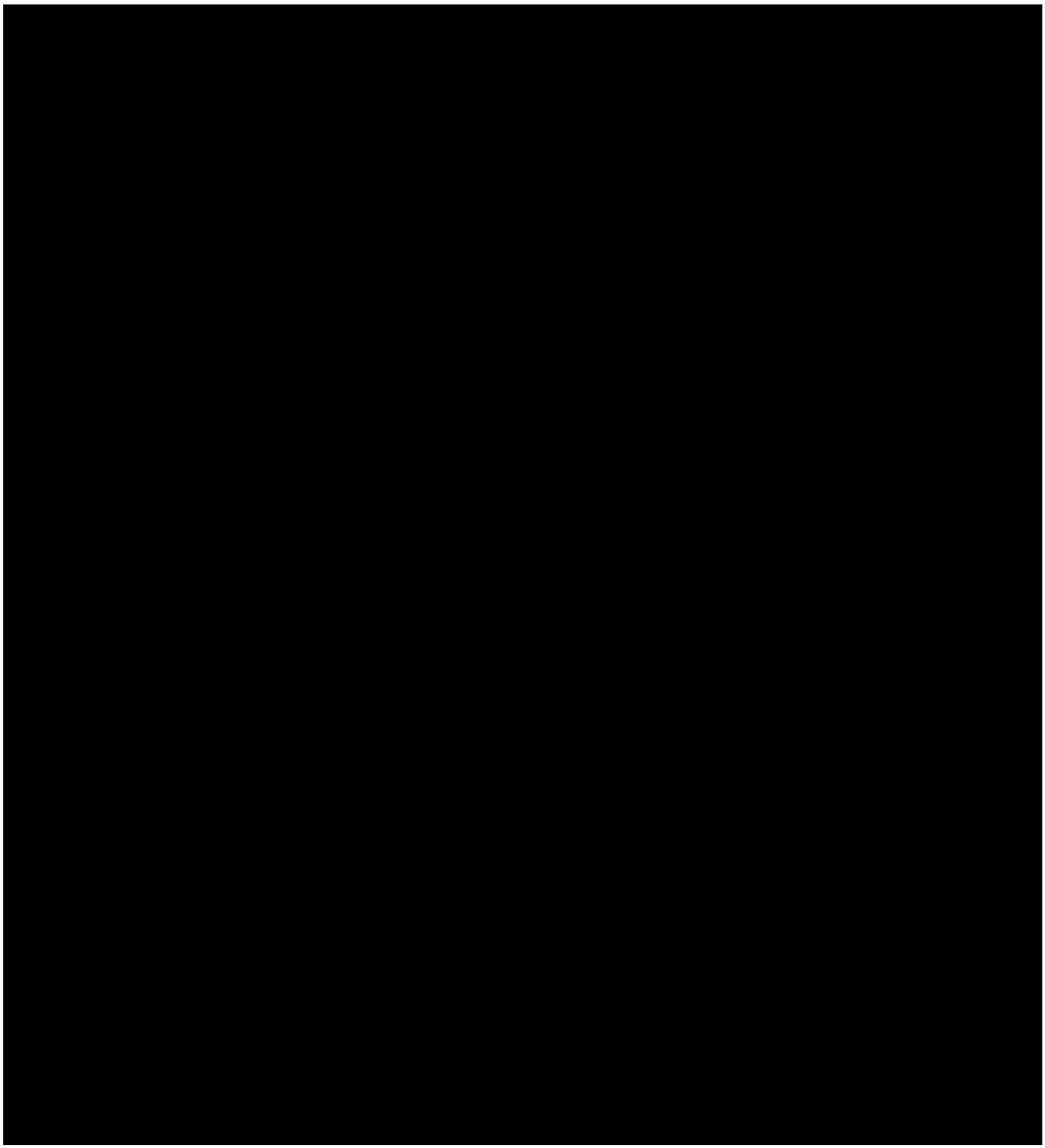


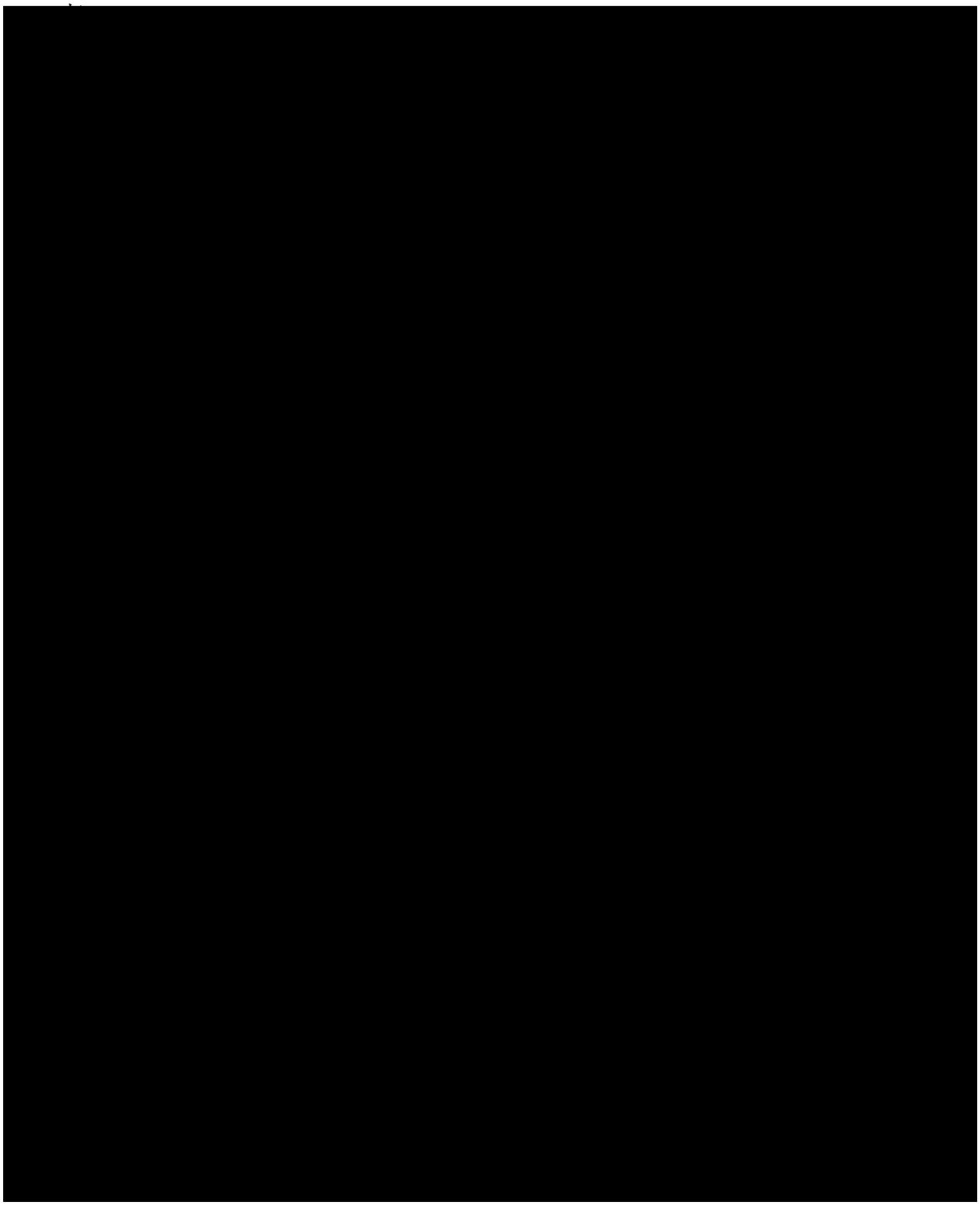












Randomisation Code

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PROJECT - 29060 PROTOCOL - 329I
Coding Memo Creator - OAKESR8
Date Printed: August 12, 1993 Date Created: August 12, 1993
Seed: 8570387 Block Size: 6

TREATMENT GROUP - PLACEBO
Interval Number 1 Named PHASE 1
Drug: PLACEBO

00001	00005	00010	00012	00016	00018
00020	00024	00027	00028	00031	00033
00037	00042	00047	00048	00049	00053
00059	00060	00062	00064	00069	00071
00074	00078	00080	00084	00085	00086
00094	00095	00097	00101	00107	00108
00111	00114	00115	00120	00123	00125
00128	00129	00135	00136	00141	00144
00148	00150	00155	00156	00158	00162
00164	00168	00169	00174	00176	00177
00183	00184	00189	00191	00197	00198
00200	00202	00207	00210	00213	00216
00217	00218	00224	00225	00229	00232
00237	00238	00241	00246	00251	00252
00253	00254	00259	00263	00266	00267
00274	00276	00277	00282	00285	00287
00291	00293	00296	00298	00302	00306
00311	00312	00315	00316	00320	00323
00327	00330	00331	00334	00337	00342
00343	00345	00349	00353	00357	00359

TREATMENT GROUP - IMIPRAMINE PO
Interval Number 1 Named PHASE 1
Drug: PO IMIPRAMINE

00003	00006	00007	00009	00013	00014
00022	00023	00026	00030	00035	00036
00040	00041	00044	00045	00050	00054
00056	00057	00061	00066	00067	00070
00073	00076	00079	00082	00088	00090
00092	00093	00098	00100	00103	00104
00110	00113	00117	00118	00122	00126
00127	00132	00134	00137	00139	00143
00146	00149	00153	00154	00159	00161
00163	00166	00171	00172	00175	00180
00185	00186	00187	00192	00194	00195
00199	00203	00208	00209	00211	00215
00219	00221	00223	00227	00230	00233
00236	00239	00243	00244	00247	00249
00255	00256	00262	00264	00269	00270
00272	00273	00279	00281	00284	00286
00289	00290	00295	00297	00301	00305
00307	00308	00314	00317	00321	00322
00325	00326	00332	00335	00339	00341
00346	00347	00351	00352	00356	00360

TREATMENT GROUP - PAROXETINE PO
Interval Number 1 Named PHASE 1
Drug: PO PAROXETINE

CODING MEMO Page - 1
PROJECT - 29060 PROTOCOL - 329II
Coding Memo Creator - OAKESR8
Date Printed: August 12, 1993 Date Created: August 12, 1993
Seed: 4108925 Block Size: 8

TREATMENT GROUP - PLACEBO
Interval Number 1 Named PHASE 2
Drug: PLACEBO

00003	00007	00009	00016	00018	00020
00026	00029	00038	00039	00043	00046
00050	00055	00058	00063	00065	00066
00077	00080	00083	00087	00090	00096
00098	00101	00107	00111	00115	00117
00122	00126	00129	00135	00139	00141
00145	00146	00156	00160	00161	00165
00175	00176	00177	00182	00185	00186

TREATMENT GROUP - IMIPRAMINE PO
Interval Number 1 Named PHASE 2
Drug: PO IMIPRAMINE

00001	00006	00008	00013	00014	00015
00017	00019	00022	00027	00028	00032
00035	00036	00037	00045	00047	00048
00049	00052	00053	00059	00061	00062
00067	00069	00072	00074	00076	00078
00082	00084	00085	00089	00092	00094
00097	00099	00103	00105	00106	00112
00114	00116	00120	00121	00125	00128
00131	00133	00134	00138	00140	00142
00147	00150	00151	00153	00154	00158
00166	00167	00168	00171	00173	00174
00178	00183	00184	00188	00189	00191

TREATMENT GROUP - PAROXETINE PO
Interval Number 1 Named PHASE 2
Drug: PO PAROXETINE

00002	00004	00005	00010	00011	00012
00021	00023	00024	00025	00030	00031
00033	00034	00040	00041	00042	00044
00051	00054	00056	00057	00060	00064
00068	00070	00071	00073	00075	00079
00081	00086	00088	00091	00093	00095
00100	00102	00104	00108	00109	00110
00113	00118	00119	00123	00124	00127
00130	00132	00136	00137	00143	00144
00148	00149	00152	00155	00157	00159
00162	00163	00164	00169	00170	00172
00179	00180	00181	00187	00190	00192

CODING MEMO Page - 2
PROJECT - 29060 PROTOCOL - 329I
Coding Memo Creator - OAKESR8
Date Printed: August 12, 1993 Date Created: August 12, 1993
Seed: 8570387 Block Size: 6

TREATMENT GROUP - PAROXETINE PO (CONT.)

00002	00004	00008	00011	00015	00017
00019	00021	00025	00029	00032	00034
00038	00039	00043	00046	00051	00052
00055	00058	00063	00065	00068	00072
00075	00077	00081	00083	00087	00089
00091	00096	00099	00102	00105	00106
00109	00112	00116	00119	00121	00124
00130	00131	00133	00138	00140	00142
00145	00147	00151	00152	00157	00160
00165	00167	00170	00173	00178	00179
00181	00182	00188	00190	00193	00196
00201	00204	00205	00206	00212	00214
00220	00222	00226	00228	00231	00234
00235	00240	00242	00245	00248	00250
00257	00258	00260	00261	00265	00268
00271	00275	00278	00280	00283	00288
00292	00294	00299	00300	00303	00304
00309	00310	00313	00318	00319	00324
00328	00329	00333	00336	00338	00340
00344	00348	00350	00354	00355	00358

Certificates of Analysis

SmithKline Beecham
Pharmaceuticals

Drug Product Certificate of Analysis

Product:	Overencapsulated Paxil Tablets		
Batch Number:	U95085	**Formula Code:**	AM
Date of Manufacture:	08-May-1995	**Strength:**	10 mg
Sample Log Number:	9500258	**Use-by Date:**	31-Jul-1999

Test	Result
General Appearance	Passes Bluish green opaque Supro B capsules containing a yellow capsule shaped, film coated tablet.
Identification (HPLC)	Passes
Assay - Paroxetine (HPLC)	100.8% LC (n=2)
Dissolution (HPLC)	Avg = 99% dissolved (n=6) L = 93% H = 102% RSD% = 3.2

This product conforms with Product Specification CPSC/PDSU 0203/01.

This product was manufactured and tested in accordance with current Good Manufacturing Practice.

Approved by [redacted] on 01 Jul 1999
Quality Assurance Date

COPY

SmithKline Beecham Pharmaceuticals
Pharmaceutical Technologies

Drug Product Certificate of Analysis

Certificate of Analysis:	PDRU 0500
Product:	Overencapsulated Paxil Tablets
Strength:	10 mg
Formula:	N/A
Lot Number:	U-93127
Date of Overencapsulation:	27-Jul-93
Request Log Number:	9300697

Test	Specification	Results
General Appearance	Bluish green opaque Supro B capsules containing a yellow capsule shaped, film coated tablet.	Passes
Identification (HPLC)	The retention time of the major peak in the sample preparation corresponds with that of the standard preparation as obtained in the assay.	Passes
Assay - Paroxetine (HPLC)	90.0 - 110.0% of claim	99.0% (n=2)
Dissolution (UV)	Not less than 80% (Q) in 60 minutes or Overencapsulated tablet average must not be less than 90% of the tablet average and the commercial tablet must comply with USP of not less than 80% (Q) in 60 minutes	95% (n=6) Low=91% High=99% RSD%=3.2

This product conforms with Product Specification CPSC/PDSU 0203/01

Approved by: [redacted] Date: 09 DEC 93

Prepared by: [redacted]

SmithKline Beecham
Pharmaceuticals

Drug Product Certificate of Analysis

Product:	Overencapsulated Paxil Tablets		
Batch Number:	U95086	**Formula Code:**	AN
Date of Manufacture:	08-May-1995	**Strength:**	20 mg
Sample Log Number:	9500257	**Use-by Date:**	31-Jul-1999

Test	Result
General Appearance	Passes Bluish green opaque Supro B capsules containing a pink capsule shaped, film coated tablet.
Identification (HPLC)	Passes
Assay - Paroxetine (HPLC)	101.7% LC (n=2)
Dissolution (HPLC)	Avg = 102% dissolved (n=6) L = 96% H = 108% RSD% = 4.5

This product conforms with Product Specification CPSC/PDSU 0204/01.

This product was manufactured and tested in accordance with current Good Manufacturing Practice.

Approved by [redacted] on 01 Jul 1997
Quality Assurance Date

COPY

SmithKline Beecham Pharmaceuticals
Pharmaceutical Technologies

Drug Product Certificate of Analysis

Certificate of Analysis:	PDRU 0501
Product:	Overencapsulated Paxil Tablets
Strength:	20 mg
Formula:	N/A
Lot Number:	U-93128
Date of Overencapsulation:	03-Aug-93
Request Log Number:	9300696

Test	Specification	Results
General Appearance	Bluish green opaque Supro B capsules containing a pink capsule shaped, bisected film coated tablet.	Passes
Identification (HPLC)	The retention time of the major peak in the sample preparation corresponds with that of the standard preparation as obtained in the assay.	Passes
Assay - Paroxetine (HPLC)	90.0 - 110.0% of claim	100.4% (n=2)
Dissolution (UV)	Not less than 80% (Q) in 60 minutes or Overencapsulated tablet average must not be less than 90% of the tablet average and the commercial tablet must comply with USP of not less than 80% (Q) in 60 minutes	96% (n=6) Low=89% High=102% RSD%=4.7

This product conforms with Product Specification CPSC/PDSU 0204/01

Approved by: [redacted] Date: 09 DEC 93

Prepared by: [redacted]

COPY

SmithKline Beecham
Pharmaceuticals

Drug Product Certificate of Analysis

Product:	Overencapsulated Placebo for Paxil Tablets, 20 mg		
Batch Number:	U95084	**Formula Code:**	ER
Date of Manufacture:	02-May-1995	**Strength:**	placebo
Sample Log Number:	9500256	**Use-by Date:**	31-Jul-1999

Test	Specification
General Appearance	Passes Bluish green opaque Supro B capsules containing a pink capsule shaped, bisected film coated tablet.
Paroxetine Content (HPLC)	Passes Absence of Active

This product conforms with Product Specification CPSC/PDSU 0207/01.

This product was manufactured and tested in accordance with current Good Manufacturing Practice.

Approved by [redacted] on 01 Jul 1997
Quality Assurance Date

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SmithKline Beecham Pharmaceuticals
Pharmaceutical Technologies

Drug Product Certificate of Analysis

Certificate of Analysis:	PDRU 0497
Product:	Overencapsulated Placebo for Paxil Tablets, 20 mg
Strength:	Placebo
Formula:	N/A
Lot Number:	U-93126
Date of Overencapsulation:	21-Jul-93
Request Log Number:	9300634

Test	Specification	Results
General Appearance	Bluish green opaque Supro B capsules containing a pink capsule shaped, bisected film coated tablet.	Passes
Paroxetine Content (HPLC)	Absence of Active	Passes

This product conforms with Product Specification CPSC/PDSU 0207/01

Approved by: [redacted] Date: 09 DEC 93

Prepared by: [redacted]

COPY

SmithKline Beecham Pharmaceuticals

Pharmaceutical Technologies

Drug Product Analytical Report

Analytical Report:	PDRU 0915
Product:	Overencapsulated Imipramine HCl Tablets
Strength:	50 mg
Formula:	AA
Lot Number:	U 9 5 1 2 1
Date of Overencapsulation:	07-Jun-95
Commercial Lot Number:	22763 (Biocraft Laboratories)
Use by Date:	01-Feb-98
Request Log Number:	9 5 0 0 2 9 8

Test	Specification	Results
General Appearance	Bluish green opaque Supro B capsules containing a round green film coated tablet debossed with BL on one side and 21 on the other side.	Passes
Identification (UV)	The ultraviolet spectrum for the sample closely matches that of the standard similarly prepared in the Assay or dissolution procedure for Imipramine HCl tablets.	Passes
Assay - Imipramine HCl (UV)	93.0 - 107.0% of claim	101.9% (n=2)
Dissolution (UV)	Not less than 75% (Q) in 45 minutes or Overencapsulated tablet average must not be less than 90% of the tablet average and the commercial tablet must comply with USP of not less than 75% (Q) in 45 minutes	Avg = 100% (n=6) L = 83% H = 106% RSD% = 8.5

This product conforms with Product Specification CPSC/PDSU 0209/01.

Approved by: [redacted] Date: 27 JUL 95

Prepared by: CAG

LNB Reference: SLM-24857 pp. 22-27.

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SmithKline Beecham Pharmaceuticals
Pharmaceutical Technologies

Drug Product Certificate of Analysis

Certificate of Analysis:	PDRU 0499
Product:	Overencapsulated Imipramine Hydrochloride USP Tablets
Strength:	50 mg
Formula:	commercial
Lot Number:	U-93135
Date of Overencapsulation:	30-Jun-1993
Request Log Number:	9300596

Test	Specification	Results
General Appearance	Bluish green opaque Supro B capsules containing a round green film coated tablet debossed with BL on one side and 21 on the other side.	Passes
Identification (UV)	The ultraviolet spectrum for the sample closely matches that of the standard similarly prepared in the Assay or dissolution procedure for Imipramine HCl tablets.	Passes
Assay - Imipramine HCl (UV)	93.0 - 107.0% of claim	100.5% (n=2)
Dissolution (UV)	Not less than 75% (Q) in 45 minutes or Overencapsulated tablet average must not be less than 90% of the commercial tablet average and the commercial tablet must comply with USP of not less than 75% (Q) in 45 minutes	102% (n=6) Low=100% High=104%

This product conforms with Product Specification CPSC/PDSU 0209/01

Approved by: [redacted] Date: 07 DEC 93

Prepared by:

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SB

SmithKline Beecham Pharmaceuticals
Pharmaceutical Technologies

Drug Product Certificate of Analysis

Certificate of Analysis:	PDRU 0498
Product:	Overencapsulated Imipramine Hydrochloride USP Tablets
Strength:	50 mg
Formula:	commercial
Lot Number:	U-93139
Date of Overencapsulation:	16-Aug-93
Request Log Number:	9300695

Test	Specification	Results
General Appearance	Bluish green opaque Supro B capsules containing a round green film coated tablet debossed with BL on one side and 21 on the other side.	Passes
Identification (UV)	The ultraviolet spectrum for the sample closely matches that of the standard similarly prepared in the Assay or dissolution procedure for Imipramine HCl tablets.	Passes
Assay - Imipramine HCl (UV)	93.0 - 107.0% of claim	100.3% (n=2)
Dissolution (UV)	Not less than 75% (Q) in 45 minutes or Overencapsulated tablet average must not be less than 90% of the commercial tablet average and the commercial tablet must comply with USP of not less than 75% (Q) in 45 minutes	102% (n=6) Low=101% High=103%

This product conforms with Product Specification CPSC/PDSU 0209/01

Approved by: [redacted] Date: 09 DEC 93

Prepared by: [redacted]

COPY

SmithKline Beecham
Pharmaceuticals

Drug Product Certificate of Analysis

Product:	Overencapsulated Placebo for Imipramine Tablets		
Batch Number:	U 9 5 0 8 7	**Formula Code:**	BF
Date of Manufacture:	11-May-1995	**Strength:**	placebo
Sample Log Number:	9 5 0 0 2 6 8	**Use-by Date:**	30-Apr-1998

Test	Specification
General Appearance	Passes Bluish green opaque Supro B capsules containing a round green film coated tablet debossed with RL on one side and 71 on the other side.
Imipramine Content (UV)	Passes Absence of Active

This product conforms with Product Specification CPSC/PDSU 0210/01.

This product was manufactured and tested in accordance with current Good Manufacturing Practice.

Approved by [redacted] on 01 Jul 1997
Quality Assurance Date

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SmithKline Beecham Pharmaceuticals
Pharmaceutical Technologies

Drug Product Certificate of Analysis

Certificate of Analysis:	PDRU 0493
Product:	Overencapsulated Placebo for Imipramine HCl Tablets, 50 mg
Strength:	Placebo
Formula:	N/A
Lot Number:	U-93178
Date of Overencapsulation:	07-Sep-93
Request Log Number:	9300771

Test	Specification	Results
General Appearance	Bluish green opaque Supro B capsules containing a round green film coated tablet debossed with RL on one side and 71 on the other side.	Passes
Imipramine Content (UV)	Absence of Active as per dissolution procedure for Imipraimine HCl tablets.	Passes

This product conforms with Product Specification CPSC/PDSU 0210/01

Approved by: [redacted] Date: 06 DEC 93

Prepared by:

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Statistical Report

Confidential

SmithKline Beecham

Paroxetine

BRL-029060

Statistical Report

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SB Document Number: BRL-029060/RSD-100V2V/1

Statistical TOC

Statistical List of Tables

Statistical List of Figures

1 Introduction

The purpose of this appendix is to describe the statistical methodology used to analyze results presented in the clinical report. Summaries for the clinical report were provided for the double-blind acute and continuation phases. The focus of this appendix will be on methodology for the acute phase. Analysis for the continuation phase was performed similarly as the acute phase. All model testing was performed on acute phase data.

The primary efficacy parameters of consideration were HAMD Total (17 item) mean change from baseline at endpoint, K-SADS-L Depression subscale mean change from baseline at endpoint and percentage of responders at endpoint, where response was defined as a HAMD total score less than or equal to 8 or a decrease from baseline in HAMD total score of 50% or greater. Endpoint of the acute phase was defined as the last observation carried forward to week 8.

The following results from the acute phase endpoint (last observation carried forward) statistical analyses are presented for the primary efficacy parameters: parametric ANOVA tables from analysis of variance of mean change from baseline for full and reduced models, and p-values for responders at endpoint, patients in remission at endpoint, patients with sustained response, and patients withdrawing due to lack of efficacy.

Covariate analyses which were performed to determine the importance of prognostic variables in predicting a patients' response at endpoint and to determine the effect of various covariates on the HAMD Total and K-SADS-L Depression subscale at endpoint are also presented.

1.1 Patient Populations

The primary population of interest was the Intent-to-Treat (ITT) population. The acute phase was of primary interest in this study. Two hundred seventy-five (275) patients were included in acute phase of the ITT population. Only 271 randomized patients having at least one post-dose assessment during the acute phase were included in the efficacy analyses and only this subset of patients was included in calculations of baseline scores presented in acute phase efficacy tables. One hundred ninety (190) patients completed the acute phase of the study. Of these 190 patients, 125 patients entered the continuation phase. One hundred eighteen (118) patients had at least one efficacy assessment during the

continuation phase and only this subset of patients was included in continuation phase tables.

Also of interest was the Per Protocol population for the acute phase. This population does not include patients having significant protocol violations during the acute phase as specified by the inclusion/exclusion criteria of the protocol. There were 30 patients determined to be protocol violators during the acute phase. Since more than 5% of the ITT patients were protocol violators, the primary efficacy variables were analyzed for the per protocol population, as well as for the intent-to-treat population. Protocol violators were identified prior to the breaking of the blind. No patients were identified with significant protocol violations during the continuation phase. The acute phase protocol violators and reason for violation are provided in Table 1.

Table 1 Summary of Patients Identified as Acute Phase Protocol Violators and Reason for Violation

Has C-GAS score □ 60 at screening:			
329.002.00099	329.002.00241	329.002.00323	329.005.00006
329.005.00012	329.005.00109	329.005.00112	329.005.00116
329.005.00335	329.005.00336	329.006.00037	329.006.00038
329.006.00041	329.006.00042	329.008.00273	329.012.00227
Is non-compliant:			
329.003.00075	329.003.00092	329.003.00093	329.003.00248
329.003.00292	329.003.00314	329.008.00157	329.009.00131
329.009.00199			
Received prohibited concomitant medication(s):			
329.005.00002			
Does not meet age requirement:			
329.007.00140			
Has severe or uncontrolled medical condition(s):			
329.009.00203			
Has received prohibited medication(s) prior to screening and/or baseline:			
329.007.00311			
Has no previous episodes of major depression as specified in the protocol:			
329.009.00237			

2 Statistical Methodology

2.1 Efficacy Variables at Baseline

The general linear model procedure, PROC GLM, in SAS version 6.08 was used to analyze data at baseline to demonstrate comparability. A model with effects for treatment and investigator was used. If the treatment effect was found to be significant ($p \leq 0.05$), then the baseline score was included in the model. SAS type III sums of squares were used.

2.2 Change from Baseline

The calculation of change from baseline (change = score - baseline score) required a baseline value. Therefore, if a patient was missing a baseline evaluation for a variable, the screening visit evaluation was used, if available. If no screening or baseline data were available for a patient, then treatment period data for that patient were not included in the analysis of change from baseline. Means presented in the study report summary tables are least squares (adjusted) means.

The change from baseline of efficacy variables, was analyzed by the general linear models procedure, PROC GLM, in SAS version 6.08 for each of the treatment groups. SAS type III sums of squares were used.

Comparisons between paroxetine and placebo and between imipramine and placebo were made using the CONTRAST statement. Treatment comparisons were made at a significance level of 0.05.

The statistical model was determined by analyzing data at endpoint. A full model was tested using effects for treatment, investigator, and treatment by investigator interaction. If the interaction was not found to be significant ($p > 0.10$), then a reduced model was used in the analyses including effects for treatment and investigator.

Data were analyzed at each week of the acute phase using the statistical model determined from the endpoint analysis (last observation carried forward to week 8).

The primary efficacy parameters analyzed were HAMD Total (17 item) and K-SADS-L Depression subscale. The K-SADS-L Depression subscale was

computed by summing the scores from the following 9 items: 2, 20, 34, 42, 44, 56, 83, 85, and 109

The mean change from baseline for the following secondary efficacy parameters was analyzed: HAMD depressed mood item (item 1), HAMD anxiety/somatization subfactor (items 10, 11, 12, 13, 15, 17), HAMD sleep subfactor (items 4, 5, 6), HAMD cognitive disturbance subfactor (items 2, 3, 9), HAMD retardation subfactor (items 1, 7, 8, 14), self perception profile (SPP) score, autonomous functioning checklist total (AFC) score, AFC self/family care subscore (items 1-22), AFC management subscore (items 23-42), AFC recreational activity subscore (items 43-58), AFC social/vocational activities subscore (items 59-78), sickness impact profile (SIP) score, SIP present health subscore, SIP present quality of life subscore, SIP sleep/rest subscore (section A), SIP home maintenance subscore (section B), SIP social interaction subscore (section C), SIP alertness behavior subscore (section D), SIP communication subscore (section E) and SIP recreational pastimes subscore (section F) were analyzed in the same manner as the primary change from baseline variables. Variables were analyzed at weekly intervals and at endpoint.

The mean CGI Global Improvement score was analyzed at weekly intervals and at endpoint using the same methodology as that used for mean change from baseline.

2.3 Percent Responders

The percent of responders was analyzed using the categorical modeling procedure, PROC CATMOD, in SAS version 6.08. Response was defined as a HAMD total score less than or equal to 8 or a decrease from baseline in HAMD total score of 50% or greater. Patients were classified as being a responder or non-responder. The proportion of responders was then compared among the treatments. A generalized logit model with maximum likelihood parameter estimations was used.

Comparisons between paroxetine and placebo and between imipramine and placebo were made using the CONTRAST statement with a significance level of 0.05

The statistical model was determined by analyzing data at endpoint. A full model was tested using effects for treatment, investigator, and treatment by investigator interaction. If the interaction was not found to be significant ($p \square 0.10$), then a

reduced model was used in the analyses only including effects for treatment and investigator.

The following secondary variables were analyzed similarly as percent of patients responding: percent of patients withdrawing due to lack of efficacy and percent of patients in remission at weekly intervals and at endpoint. Remission was defined as HAMD total score less than or equal to 8.

2.4 Survival Analysis

Survival analysis was performed for the time to sustained response, defined as response lasting until endpoint of the acute phase. The Cox proportional hazards modeling procedure, PROC PHREG, of SAS version 6.08 was used. Patients who did not achieve sustained respond were censored.

A test of the validity of the proportional hazards model was first considered using a time-dependent variable in the model. If the time-dependent variable was significant (p□0.05), then the hazard ratio changes with time and the proportional hazards model assumption is invalid. If the assumptions were met, the survival analysis was performed comparing treatment groups.

The failure time was considered to be on a continuous scale, thus the default option (*Breslow*) for the handling of ties was used.

2.5 Covariate Analyses

Exploratory analyses were done to determine the effect of various covariates on percentage of responders at endpoint of the acute phase and the mean HAMD Total and K-SADS-L Depression subscale at endpoint of the acute phase. Response was defined as HAMD Total score less than or equal to 8 or a 50% or greater decrease from baseline in HAMD Total. The ten covariates of interest included the following: AFC at endpoint, SPP at endpoint, SIP at endpoint, atypical depression (yes, no), melancholic/ endogenous subtype of depression (yes, no), current anxiety disorder (yes, no), current comorbid disorder other than major depressive disorder (yes, no), age at first onset of depression, number of episodes of major depressive disorder, and family history of major depressive disorder (yes, no).

For responders at endpoint of the acute phase, an analysis via logistic regression was performed for each variable of interest using a model with an effect for the variable. PROC LOGISTIC of the SAS system was used.

For mean HAMD and K-SADS-L at endpoint of the acute phase, an analysis of variance was performed for each covariate via the General Linear Models procedure, PROC GLM of SAS, using type III sums of squares. Each analysis used a model including effects for treatment, covariate, and treatment by covariate interaction.

3 Summary of Statistical Results

All patients randomized with data from at least one post dose assessment were included in the intent-to-treat efficacy analyses. Endpoint was used to determine the statistical model.

3.1 Efficacy Variables at Baseline

No significant differences at baseline were observed.

3.2 Change from Baseline Model Verification

The full model at endpoint was tested. The treatment-by-investigator interaction was found to be nonsignificant for all variables except the HAMD Retardation subscale. All nonsignificant interactions were removed from the model for analysis at all timepoints. For these analyses, a reduced model with effects for treatment and investigator was used.

ANOVA tables are included below which show the results of the full model with interaction and the reduced model without interaction at endpoint for mean change from baseline for the primary efficacy variables.

The treatment-by-investigator interaction p-values at endpoint from the analysis of variance (ANOVA) are provided in Table 2 for each efficacy parameter.

Table 2 Treatment-by-Investigator ANOVA P-values for Efficacy Parameters

Variable	Treatment-by-Investigator P-value
HAMD Total	0.811
K-SADS-L Depression	0.965
HAMD Depressed Mood	
HAMD Anxiety/Somatization	0.706
HAMD Sleep Disturbance	0.796
HAMD Cognitive Disturbance	0.990
HAMD Retardation	0.042
SPP Total	0.962
AFC Total	0.499
AFC Self/Family Care	0.646
AFC Management	0.324
AFC Recreational Activity	0.831
AFC Social/Vocational Activities	0.435
SIP Total	0.939
SIP Present Health	0.180
SIP Present Quality of Life	0.505
SIP Sleep/Rest	0.807
SIP Home Maintenance	0.902
SIP Social Interaction	0.763
SIP Alertness Behavior	0.980
SIP Communication	0.899
SIP Recreational Pastimes	0.765

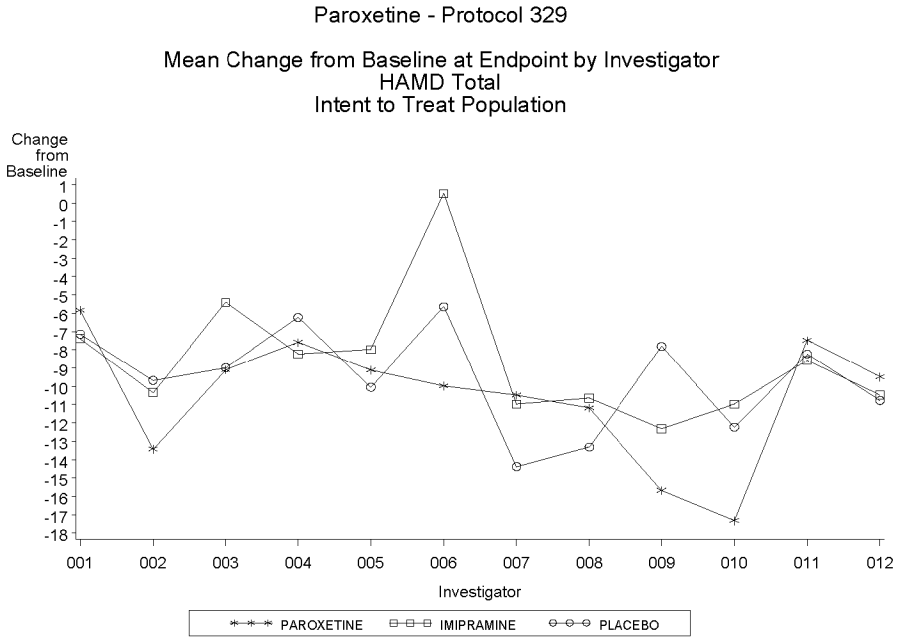
3.2.1 HAMD Total (17 items)

Analysis of the mean change from baseline of the HAMD total yielded no statistically significant treatment by investigator interaction (p=0.811). The baseline treatment effect was also not significant (p=0.220). A reduced model without interaction was used for this analysis. For the calculation of the HAMD score, individual missing results were not replaced. The missing items were allowed for by calculating the total as (S/n)x N, where S was the score recorded for n items and N was the number of items which should have been present.

Table 3 ANOVA Table for HAMD Total Mean Change from Baseline at Endpoint

Analysis of Variance of Improvement from Baseline at Endpoint						
HAMD Total (17 items)						
Intent-to-Treat Population						
		Degrees of	Sum of			Root
	Source	Freedom	Squares	F Value	P-value	MSE
Full Model	Treatment	2	120.82	1.12	0.329	
	Investigator	11	1145.48	1.93	0.037	
	Treat. by Inv.	22	863.59	0.73	0.811	
	Error	235	12712.23			7.35
Reduced Model	Treatment	2	181.44	1.72	0.182	
	Investigator	11	1090.83	1.88	0.043	
	Error	257	13575.82			7.27
Type III Sum of Squares are presented for treatment, investigator, and treatment by investigator effects.						

Figure 1 Plot of Treatment-by-Investigator HAMD Total Mean Change from Baseline at Endpoint



3.2.2 K-SADS-L Depression Subscale

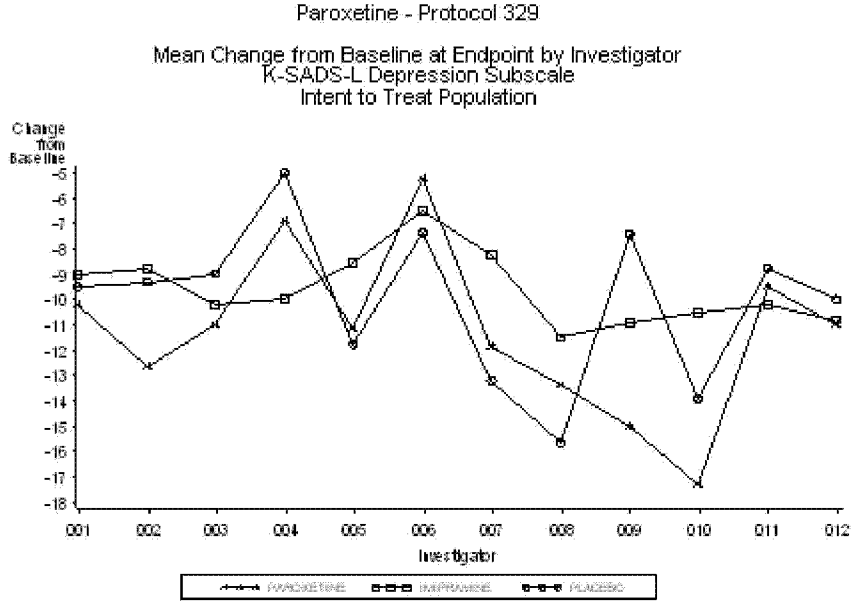
Analysis of the mean change from baseline of the K-SADS-L total yielded no statistically significant treatment by investigator interaction (p=0.965). The baseline treatment effect was also not significant (p=0.164). A reduced model without interaction was used for this analysis. For the calculation of the

K-SADS-L depression subscale, individual missing results were not replaced. The missing items were allowed for by calculating the total as (S/n)x N, where S was the score recorded for n items and N was the number of items which should have been present.

Table 4 ANOVA Table for K-SADS-L Depression Subscale Mean Change from Baseline at Endpoint

Analysis of Variance of Improvement from Baseline at Endpoint						
K-SADS-L Depression Subscale						
Intent-to-Treat Population						
		Degrees of	Sum of			Root
	Source	Freedom	Squares	F Value	P-value	MSE
Full Model	Treatment	2	87.53	0.79	0.455	
	Investigator	11	542.13	0.89	0.551	
	Treat. by Inv.	22	630.97	0.52	0.965	
	Error	220	12183.12			7.44
Reduced Model	Treatment	2	245.82	2.32	0.100	
	Investigator	11	583.23	1.00	0.446	
	Error	242	12814.09			7.28
Type III Sum of Squares are presented for treatment, investigator, and treatment by investigator effects.						

Figure 2 Plot of Treatment-by-Investigator K-SADS-L Depression Subscale Mean Change from Baseline at Endpoint



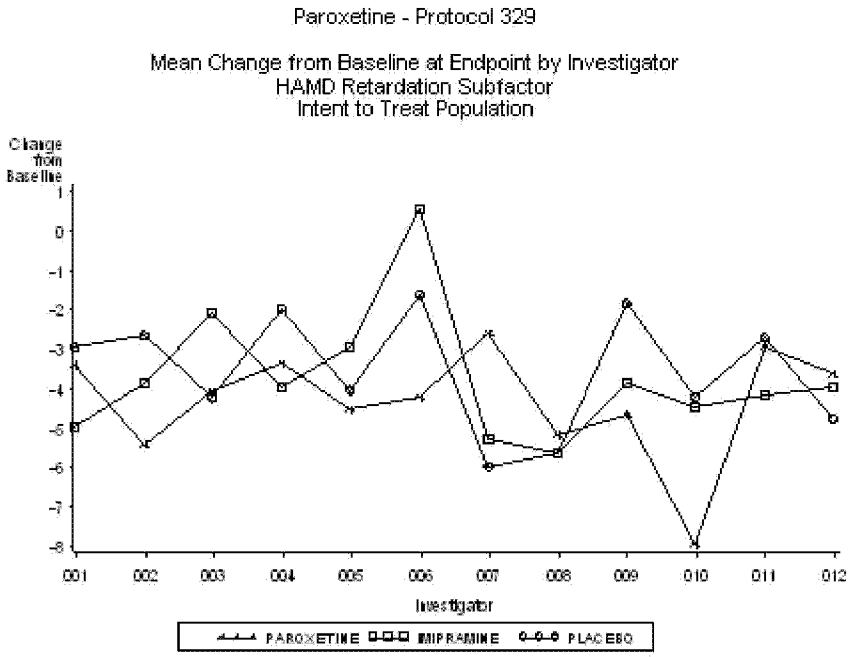
3.2.3 HAMD Retardation Subfactor

The HAMD retardation subfactor was found to have a significant treatment-by-investigator interaction (p=0.042) at endpoint. Treatment by investigator means were plotted. Centers 006, 010, and 007 were investigated for their effect on the interaction. When center 007 was removed, the interaction effect was nonsignificant (p=0.205). There was no reason to believe that the results observed at any center were not accurate. Therefore, the retardation subscale was analyzed with a full model including effects for treatment, investigator, and treatment-by-investigator interaction.

Table 5 ANOVA Table for HAMD Retardation Subfactor Mean Change from Baseline at Endpoint

Analysis of Variance of Improvement from Baseline at Endpoint						
HAMD Retardation Subfactor						
Intent-to-Treat Population						
		Degrees of	Sum of			Root
	Source	Freedom	Squares	F Value	P-value	MSE
Full Model	Treatment	2	20.89	1.46	0.234	
	Investigator	11	129.34	1.65	0.087	
	Treat. by Inv.	22	255.09	1.62	0.042	
	Error	235	1677.65			2.67
Type III Sum of Squares are presented for treatment, investigator, and treatment by investigator effects.						

Figure 3 Plot of Treatment-by-Investigator HAMD Retardation Subfactor Mean Change from Baseline at Endpoint



3.3 Percent Response Model Verification

The percent of patients responding, as defined by HAMD total score less than or equal to 8 or a decrease from baseline in HAMD total score of 50% or greater was analyzed using categorical modeling methods on a model including treatment and investigator effects.

Due to the small treatment-by-investigator cells by response for some sites, no test of the interaction effect could be made.

3.4 Survival Analysis

Survival analysis was performed for the time to sustained response, defined as response lasting until endpoint of the acute phase. Response was defined as a HAMD total score less than or equal to 8 or a decrease from baseline in HAMD total score of 50% or greater. Patients were classified as being a responder or non-responder. Nonresponders were considered as censored values.

Survival analysis was performed for time to sustained response during the acute phase. The test for the model assumptions included effects for treatment and a

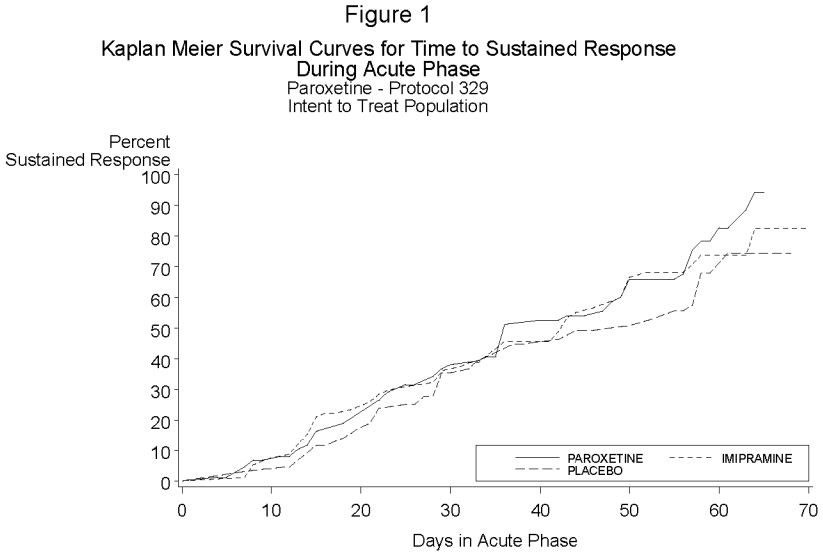
time-dependent variable, *treatment x log(# of days)*. Two treatment effects were included: paroxetine relative to placebo and imipramine relative to placebo. Two time-dependent variables were included similarly. This tests were not significant (p=0.180 and 0.066), thus we conclude that there is no evidence of an increasing or decreasing trend over time in the hazard ratio. Since the model assumptions were met, the analysis was done using a model with the treatment effect.

The results are presented in Table 6. When comparing each active drug to placebo, no significant treatment effect was observed. A plot of the Kaplan Meier curves is also provided below.

Table 6 Survival Analysis of Sustained Response During the Acute Phase

	Par vs Pla	Imp vs Pla
P-value	0.095	0.222
Risk Ratio	1.383	1.273
95% C. I.	(0.946, 2.022)	(0.864, 1.877)

Figure 4 Kaplan Meier Survival Curves for Time to Sustained Response During Acute Phase



3.5 Per Protocol Analyses

An analysis of mean change from baseline in HAMD Total and K-SADS-L Depression subscale at endpoint of the acute phase was performed for the per protocol population.

Similarly to the ITT analyses, the full model at endpoint was tested. The treatment-by-investigator interaction was found to be nonsignificant for both variable. Therefore, for these analyses, a reduced model with effects for treatment and investigator was used.

ANOVA tables are included below which show the results of the full model with interaction and the reduced model without interaction for each variable.

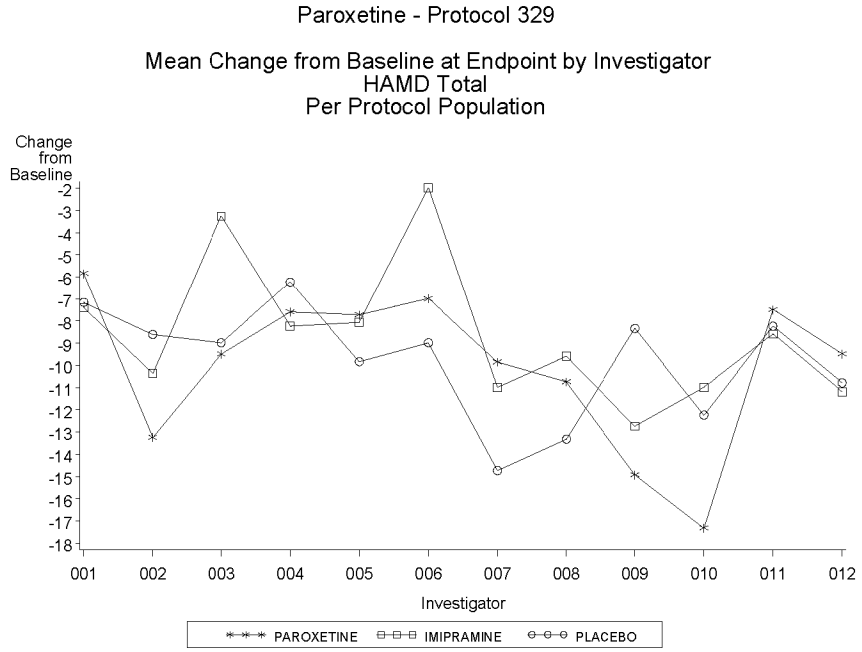
3.5.1 HAMD Total (17 items)

Analysis of the mean change from baseline of the HAMD total yielded no statistically significant treatment by investigator interaction (p=0.850). The baseline treatment effect was also not significant (p=0.290). A reduced model without interaction was used for this analysis.

Table 7 ANOVA Table for HAMD Total Mean Change from Baseline at Endpoint Per Protocol Population

Analysis of Variance of Improvement from Baseline at Endpoint						
HAMD Total (17 items)						
Per Protocol Population						
		Degrees of	Sum of			Root
	Source	Freedom	Squares	F Value	P-value	MSE
Full Model	Treatment	2	58.73	0.52	0.593	
	Investigator	11	1014.54	1.65	0.088	
	Treat. by Inv.	22	845.99	0.69	0.850	
	Error	205	11479.00			7.48
Reduced Model	Treatment	2	77.29	0.71	0.492	
	Investigator	11	1041.82	1.74	0.065	
	Error	227	12324.98			7.36
Type III Sum of Squares are presented for treatment, investigator, and treatment by investigator effects.						

Figure 5 Plot of Treatment-by-Investigator HAMD Total Mean Change from Baseline at Endpoint Per Protocol Population



3.5.2 K-SADS-L Depression Subscale

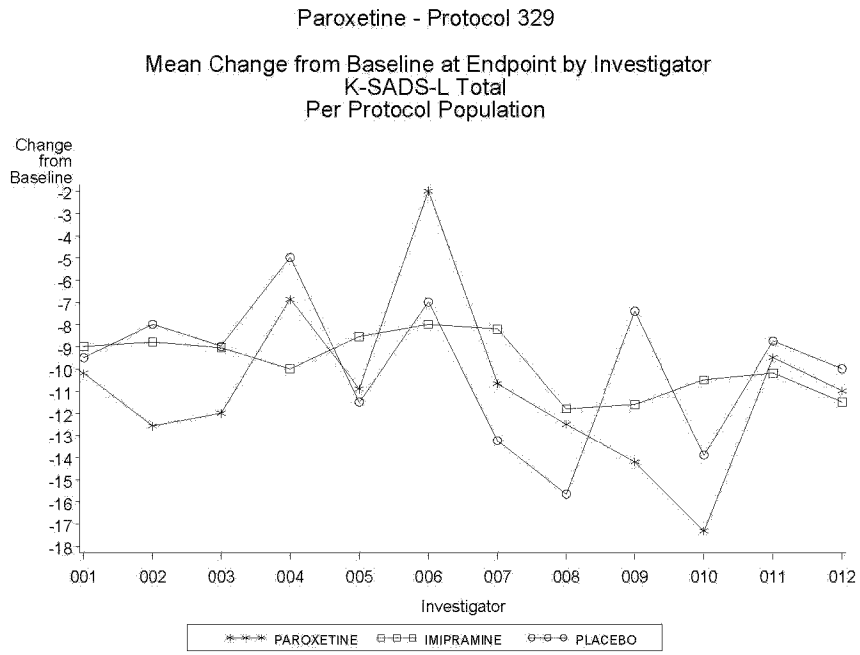
Analysis of the mean change from baseline of the K-SADS-L total yielded no statistically significant treatment by investigator interaction (p=0.975). The

baseline treatment effect was also not significant (p=0.247). A reduced model without interaction was used for this analysis.

Table 8 ANOVA Table for K-SADS-L Depression Subscale Mean Change from Baseline at Endpoint Per Protocol Population

Analysis of Variance of Improvement from Baseline at Endpoint						
K-SADS-L Depression Subscale						
Per Protocol Population						
		Degrees of	Sum of			Root
	Source	Freedom	Squares	F Value	P-value	MSE
Full Model	Treatment	2	32.77	0.28	0.754	
	Investigator	11	468.09	0.73	0.705	
	Treat. by Inv.	22	622.15	0.49	0.975	
	Error	192	11137.08			7.62
Reduced Model	Treatment	2	185.68	1.69	0.187	
	Investigator	11	619.86	1.03	0.425	
	Error	214	11759.23			4.41
Type III Sum of Squares are presented for treatment, investigator, and treatment by investigator effects.						

Figure 6 Plot of Treatment-by-Investigator K-SADS-L Depression Subscale Mean Change from Baseline at Endpoint Per Protocol Population



3.6 Covariate Analyses

3.6.1 Percentage of Responders

The effect of covariates was evaluated using response as defined by the HAMD Total. Logistic analyses were performed for each covariate with a model including effects for treatment, covariate, and treatment-by-covariate interaction. For categorical covariates, analyses were done via the Categorical Modeling (CATMOD) procedure of the SAS system. For continuous covariates (AFC, SPP, SIP, age at first onset, and number of episodes), analyses were done via the Logistic (LOGISTIC) procedure of the SAS system. Given below are the p-values at endpoint for treatment, covariate, and treatment-by-covariate interaction effects (Table 13.28.1). The number and percentage of responders are also presented for each covariate (Table 13.28.2). Tests of interactions were made at the 0.10 level of significance and tests of overall treatment effects were made at the 0.05 level of significance. Due to the small number of patients without a family history of depression (5-paroxetine, 4-imipramine, 3-placebo), categorical analyses were not performed for this covariate.

To determine the overall treatment effect for logistic analysis of continuous covariates, an indicator variable denoting paroxetine versus placebo and imipramine versus placebo were included as effects. For the interaction effect, each of the treatment comparison indicators was multiplied by the covariate to obtained two interaction effects. The overall interaction p-value was obtained by taking the difference in the log likelihood and degrees of freedom from models with and without the interactions terms and obtaining the p-value from the Chi-Square distribution. The overall treatment effect was obtained in a similar manner by comparing the model without the interaction terms to a model containing only the covariate.

A significant treatment-by-covariate interaction was found for AFC, SIP, age at first onset, and number of episodes. The overall treatment effect was not significant except for the SIP covariate. The overall treatment p-value for each covariate was consistent with the model with no covariate (Table 13.28.1) with the exception of SIP. The significant atypical depression effect should be interpreted as the patients with atypical depression showed more response. The significant melancholic/endogenous subtype effect should be interpreted as the patients not classified as this subtype showed more response.

Table 13.28.1 Summary of Covariate Analysis for Percentage of Responders at Endpoint

Protocol 329

Covariate	Treatment P-value	Covariate P-value	Treatment-by-Covariate P-value
None	0.275	-	-
AFC[2]	0.257	0.101	0.001
SPP[2]	0.129	0.003	0.717
excluding interaction	0.129	□0.001	
SIP[2]	0.050	□0.001	0.082
Atypical Depression[1]	0.356	0.023	0.503
excluding interaction	0.564	0.017	
Melancholic/Endogenous Subtype[1]	0.413	0.025	0.797
excluding interaction	0.339	0.027	
Current Anxiety Disorder[1]	0.116	0.208	0.114
excluding interaction	0.442	0.068	
Current Comorbid Disorder[1]	0.227	0.440	0.436
excluding interaction	0.352	0.387	
Age at First Onset of Depression[2]	0.337	0.932	0.034
Number of Major Depressive Episodes[2]	0.352	0.028	0.010

[1] Categorical analysis via logistic analysis (CATMOD) with a model including effects for treatment, covariate, treatment-by-covariate interaction, and study.

[2] Analysis via logistic regression (LOGISTIC) with a model including effects for treatment, covariate, treatment-by-covariate interaction, and study

Table 13.28.2 Summary of Response at Endpoint by Covariate

Covariate		Paroxetine			Imipramine			Placebo		
		n	N	%	n	N	%	n	N	%
None		60	90	66.7	55	94	58.5	48	87	55.2
AFC		48	60	80.0	41	57	71.9	41	62	66.1
SIP		51	63	81.0	42	60	70.0	41	66	62.1
SPP		50	62	80.7	42	60	70.0	41	66	62.1
Atypical Depression	Yes	19	22	86.4	10	15	66.7	6	8	75.0
	No	40	67	59.7	44	77	57.1	42	78	53.9
Melancholic/Endogenous Subtype of Depression	Yes	18	33	54.6	17	33	51.5	17	35	48.6
	No	41	56	73.2	37	60	61.7	31	51	60.8
Current Anxiety Disorder	Yes	9	12	75.0	7	21	33.3	10	21	47.6
	No	50	77	64.9	47	72	65.3	38	65	58.5
Current Comorbid Disorder	Yes	21	30	70.0	20	37	54.1	16	34	47.1
	No	38	59	64.4	34	56	60.7	32	52	61.5
Age at Onset of Depression		59	89	66.3	54	93	58.1	48	86	55.8
Number of Episodes of Major Depressive Disorder		59	89	66.3	54	93	58.1	48	86	55.8
Family History of Major Depressive Disorder	Yes	51	77	66.2	51	84	60.7	44	83	53.0
	No	3	5	60.0	2	4	50.0	3	3	100.0

3.6.2 HAMD Total

An analysis of variance was performed for each covariate with a model including effects for treatment, covariate, and treatment-by-covariate interaction. Analyses were done via the General Linear Models (GLM) procedure of the SAS system. Provided below are the p-values at endpoint for each effect from the type III sums of squares for treatment, covariate, and treatment-by-covariate interaction effects (Table 13.29.1). The sample size, least square means, and standard errors from the analysis of variance are also presented for each covariate (Table 13.29.2). Tests of interactions were made at the 0.10 level of significance and tests of overall treatment effects were made at the 0.05 level of significance.

As shown in Table 13.29.1, there were two treatment-by-covariate interaction with a p-value □ 0.10. A significant interaction was observed in analyses with the covariate of AFC at endpoint and number of episodes. The significant AFC at endpoint and number of depressive episodes covariates can be interpreted as a significant linear relationship with magnitude of the covariate and magnitude of the HAMD Total at endpoint. The significant atypical depression effect should be interpreted as the patients without atypical depression showed greater improvement. The significant melancholic/ endogenous subtype effect should be interpreted as the patients classified as this subtype showed greater improvement. The significant current anxiety disorder effect should be interpreted as the patients having current anxiety disorder in general showed greater improvement.

Table 13.29.1 Summary of Covariate Analysis for HAMD Total at Endpoint

Protocol 329

Covariate	Treatment P-value	Covariate P-value	Treatment-by-Covariate P-value
None	0.290	-	-
AFC	0.019	0.017	0.013
SPP excluding interaction	0.860 0.327	□0.001 □0.001	0.627
SIP excluding interaction	0.114 0.088	□0.001 □0.001	0.272
Atypical Depression excluding interaction	0.266 0.497	0.010 0.036	0.458
Melancholic/Endogenous Subtype excluding interaction	0.427 0.325	0.014 0.014	0.761
Current Anxiety Disorder excluding interaction	0.094 0.420	0.104 0.040	0.103
Current Comorbid Disorder excluding interaction	0.134 0.333	0.200 0.191	0.107
Age at First Onset of Depression excluding interaction	0.797 0.306	0.229 0.255	0.810
Number of Major Depressive Episodes	0.063	□0.001	0.018
Family History of Major Depressive Disorder excluding interaction	0.897 0.255	0.120 0.160	0.590

Analysis of variance (GLM) with a model including effect for treatment, covariate, treatment-by-covariate interaction, and study.

Table 13.29.2 Summary of HAMD Total at Endpoint by Covariate

Covariate		Paroxetine			Imipramine			Placebo		
		n	mean	s.e.	n	mean	s.e.	n	mean	s.e.
None		90	8.47	0.76	94	9.34	0.75	87	10.18	0.78
AFC		60	6.41	0.82	57	7.46	0.84	62	8.10	0.80
SIP		63	6.42	0.63	60	8.24	0.66	66	7.44	0.63
SPP		62	6.70	0.74	60	7.59	0.75	66	8.26	0.72
Atypical Depression	Yes	22	5.32	1.54	15	8.13	1.86	8	9.50	2.56
	No	67	9.46	0.88	77	9.58	0.82	78	10.21	0.82
Melancholic/Endogenous Subtype of Depression	Yes	33	10.45	1.26	33	10.48	1.26	35	11.26	1.22
	No	56	7.25	0.96	60	8.80	0.93	51	9.37	1.01
Current Anxiety Disorder	Yes	12	7.17	2.08	21	13.00	1.57	21	11.90	1.57
	No	77	8.64	0.82	72	8.35	0.85	65	9.57	0.89
Current Comorbid Disorder	Yes	30	7.60	1.32	37	10.13	1.19	34	12.29	1.24
	No	59	8.86	0.94	56	8.91	0.97	52	8.73	1.00
Age at Onset of Depression		88	8.48	0.78	93	9.39	0.76	86	10.21	0.79
Number of Episodes of Major Depressive Disorder		89	8.62	0.75	93	9.38	0.73	86	10.08	0.76
Family History of Major Depressive Disorder	Yes	77	8.40	0.82	84	9.13	0.79	83	10.43	0.79
	No	5	6.60	3.22	4	7.50	3.61	3	3.67	4.16

3.6.3 KSADS Total

An analysis of variance was also performed for each covariate with a model including effects for treatment, covariate, and treatment-by-covariate interaction. Analyses were done via the General Linear Models (GLM) procedure of the SAS system. Provided below are the p-values at endpoint for each effect from the type III sums of squares for treatment, covariate, and treatment-by-covariate interaction effects (Table 13.30.1). The sample size, least square means, and standard errors from the analysis of variance are also presented for each covariate (Table 13.30.2). Tests of interactions were made at the 0.10 level of significance and tests of overall treatment effects were made at the 0.05 level of significance.

As shown in Table 13.30.1, there were two treatment-by-covariate interaction with a p-value □ 0.10. A significant interaction was observed in analyses with the covariate of current comorbidity and number of episodes. The significant AFC at endpoint, SPP at endpoint, SIP at endpoint, and number of depressive episodes covariates can be interpreted as a significant linear relationship with magnitude of the covariate and magnitude of the K-SADS-L depressive subscale at endpoint. The significant atypical depression effect should be interpreted as the patients without atypical depression showed greater improvement. The significant melancholic/ endogenous subtype effect should be interpreted as the patients classified as this subtype showed greater improvement.

Table 13.30.1 Summary of Covariate Analysis for KSAD Total at Endpoint

Protocol 329

Covariate	Treatment P-value	Covariate P-value	Treatment-by-Covariate P-value
None	0.058	-	-
AFC excluding interaction	0.212 0.168	0.004 0.006	0.261
SPP excluding interaction	0.670 0.227	□0.001 □0.001	0.359
SIP excluding interaction	0.382 0.097	□0.001 □0.001	0.825
Atypical Depression excluding interaction	0.096 0.182	0.107 0.026	0.452
Melancholic/Endogenous Subtype excluding interaction	0.112 0.092	0.002 0.002	0.833
Current Anxiety Disorder excluding interaction	0.019 0.098	0.540 0.264	0.183
Current Comorbid Disorder	0.014	0.725	0.050
Age at First Onset of Depression excluding interaction	0.580 0.073	0.143 0.153	0.810
Number of Major Depressive Episodes	0.055	0.001	0.010
Family History of Major Depressive Disorder excluding interaction	0.949 0.054	0.104 0.143	0.640

Analysis of variance (GLM) with a model including effect for treatment, covariate, treatment-by-covariate interaction, and study.

Table 13.30.2 Summary of KSAD Total at Endpoint by Covariate

Covariate		Paroxetine			Imipramine			Placebo		
		n	mean	s.e.	n	mean	s.e.	n	mean	s.e.
None		83	16.75	0.85	89	18.00	0.82	85	19.59	0.84
AFC		60	15.39	0.92	57	16.74	0.94	62	17.74	0.91
SIP		63	15.56	0.71	60	17.58	0.75	66	17.08	0.71
SPP		62	15.90	0.84	60	16.72	0.85	66	17.94	0.82
Atypical Depression	Yes	22	13.68	1.64	14	15.43	2.06	7	19.86	2.91
	No	60	17.83	0.99	73	18.51	0.90	77	19.48	0.88
Melancholic/Endogenous Subtype of Depression	Yes	29	18.62	1.42	32	20.50	1.35	35	20.94	1.29
	No	53	15.68	1.05	56	16.63	1.02	49	18.49	1.09
Current Anxiety Disorder	Yes	10	14.3	2.44	19	19.58	1.77	21	21.86	1.68
	No	72	17.06	0.91	69	17.61	0.93	63	18.73	0.97
Current Comorbid Disorder	Yes	25	14.68	1.54	35	17.74	1.06	33	21.48	1.34
	No	57	17.61	1.02	53	18.49	1.30	51	18.24	1.08
Age at Onset of Depression		81	16.80	0.86	88	17.98	0.83	84	19.60	0.85
Number of Episodes of Major Depressive Disorder		82	16.89	0.84	88	18.04	0.81	84	19.45	0.82
Family History of Major Depressive Disorder	Yes	71	16.67	0.93	81	18.16	0.87	81	19.90	0.87
	No	5	15.60	3.49	3	13.33	4.50	3	13.67	4.50

3.7 Confidence Intervals for Efficacy Results at Week 8

The following table provides results for the mean change from baseline in depression related scales and in % responders including the 95% confidence intervals for the treatment difference between active drug and placebo at Week 8 of the observed cases (OC) and last observation carried forward (LOCF) datasets.

Mean Change from Baseline in HAM-D Total Score, Depression Item, K-SADS-L Depression Subgroup, K-SADS-L Depression Item, Mean CGI Score, and Percent of Patients Meeting Definition of Responder or Remission

Week 8, ITT Population

	Paroxetine	Imipramine	Placebo	95% Confidence Intervals Paroxetine vs Placebo	Imipramine vs Placebo
Mean Change in HAM-D Total (SEM)					
Wk 8 LOCF	-10.7 □ 0.81	-8.9 □ 0.81	-9.1 □ 0.83	(-3.92, 0.62)	(-2.09, 2.45)
Wk 8 OC	-12.2 □ 0.88	-10.6 □ 0.97	-10.5 □ 0.88	(-4.11, 0.77)	(-2.65, 2.49)
Mean Change HAM-D Depression Item (SEM)					
Wk 8 LOCF	-2.00 □ 0.14	-1.62 □ 0.14	-1.33 □ 0.14	(-1.06, -0.28)	(-0.68, 0.10)
Wk 8 OC	-2.21 □ 0.17	-1.76 □ 0.18	-1.54 □ 0.17	(-1.14, -0.20)	(-0.71, 0.27)
Mean Change in K-SADS-L 9-Item Depression Subscore (SEM)					
Wk 8 LOCF	-11.7 □ 0.84	-9.6 □ 0.83	-9.6 □ 0.83	(-4.40, 0.22)	(-2.28, 2.32)
Wk 8 OC	-12.0 □ 0.93	-10.7 □ 1.02	-10.8 □ 0.93	(-3.74, 1.42)	(-2.52, 2.90)
Mean Change in K-SADS-L Depression Item (SEM)					
Wk 8 LOCF	-2.20 □ 0.18	-1.77 □ 0.18	-1.73 □ 0.19	(-0.97, 0.03)	(-0.54, 0.46)
Wk 8 OC	-2.35 □ 0.20	-2.05 □ 0.22	-1.93 □ 0.20	(-0.97, 0.13)	(-0.70, 0.46)
Mean Clinical Global Improvement Score (SEM)					
Wk 8 LOCF	2.4 □ 0.16	2.7 □ 0.15	2.7 □ 0.16	(-0.80, 0.08)	(-0.46, 0.40)
Wk 8 OC	1.9 □ 0.15	2.2 □ 0.17	2.4 □ 0.16	(-0.88, -0.02)	(-0.66, 0.26)
% Responders (50% □ HAM-D Total or a Score □8)					
Wk 8 LOCF	67% (60/90)	59% (55/94)	55% (48/87)	(-2.8, 25.7)	(-11.1, 17.7)
Wk 8 OC	81% (54/67)	73% (41/56)	65% (43/66)	(0.5, 30.3)	(-8.3, 24.3)
% Responders (CGI Rating of "Very Much Improved" or "Much Improved")					
Wk 8 LOCF	66% (59/90)	52% (49/94)	48% (42/87)	(2.9, 31.7)	(-10.6, 18.4)
Wk 8 OC	79% (53/67)	68% (38/56)	61% (40/66)	(3.2, 33.8)	(-9.7, 24.3)
% Remission (HAM-D Score □ 8)					
Wk 8 LOCF	63% (57/90)	50% (47/94)	46% (40/87)	(2.8, 31.8)	(-10.6, 18.6)
Wk 8 OC	76% (51/67)	64% (36/56)	58% (38/66)	(2.8, 34.2)	(-10.6, 24.0)

Audited Investigator Sites

Confidential

SmithKline Beecham

Paroxetine

BRL-029060

List of Audited Investigator Sites

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SB Document Number: BRL-029060/RSD-100V2W/1

Audited Investigator Sites

Worldwide Regulatory Compliance-GCP is an independent function within SmithKline Beecham with responsibility for assuring Company management that clinical trials are organised, performed and reported in compliance with Company protocols and working practices and the requirements of national and international GCP (Good Clinical Practice) guidelines. This is achieved through a combination of study specific audits of investigator sites and audits, at regular intervals, of SmithKline Beecham systems for data handling, reporting and archiving.

Details of the selection of investigators for audit, and the methods of performing and reporting the audits are documented in WRC SOPs.

List of Audited Investigators

Study Number:

Centre No	Investigator	Site Address	Country	Audit Date
005	[redacted]	University of Pittsburgh, Pittsburgh, PA.	USA	16-Sep-97 - 17-Sep-97
009		UT Southwestern at Dallas, TX.	USA	30-July-97 - 1-Aug-97