DATA SHARING AGREEMENT

This DATA SHARING AGREEMENT (this "Agreement") is effective as of January 21, 2014 (the "Effective Date") between Jon Jureidini, PhD ("Researcher"), located at University of Adelaide, Adelaide, AU and GlaxoSmithKline Research and Development Ltd, with offices at 980 Great West Road, Brentford, Middlesex, TW8 9GS ("GSK").

BACKGROUND

GSK and its affiliates develop, manufacture, distribute, and sell pharmaceutical and healthcare products. Researcher desires access to certain data collected by GSK in order to conduct certain analyses as further described below. GSK and Researcher intend to establish this Agreement with respect to Researcher's access to GSK data.

DEFINITIONS

"GSK Confidential Information" means all information (including, without limitation, patient-level data, anonymised Case Report Forms, research specifications or Protocols, reports, specifications, computer programs or models and related documentation, know-how, trade secrets, or business or research plans) of GSK or GSK's affiliates that are provided to Researcher in connection with this Agreement.

"New Intellectual Property" means all discoveries, developments, inventions (whether patentable or not), improvements, methods of use or delivery , know-how or trade secrets which are made by Researcher in connection with the use of GSK Confidential Information under this Agreement.

"Analytical Tools" includes but is not limited to any methodology, statistical methods, formulae or other methods or tools used by Researcher in conducting the Analysis.

"GSK Uses" means any and all uses of or related to a compound which is owned or Controlled by GSK on or after the effective date, including the compound(s) which was used to generate the patient level data, which would otherwise be an infringement of any New Intellectual Property. For the avoidance of doubt, a related use includes, but is not limited to a diagnostic test applicable to a disease treated by the compound or the class to which it belongs.

1. DATA SHARING

(a) GSK and Researcher agree that GSK will provide the Researcher with access to patient level data (and anonymised Case Report Forms) from the GSK-sponsored clinical studies listed in Exhibit A for the sole purpose of analysis according to Researcher's approved research plan (the "Analysis") attached as Exhibit B and for no other purpose. Researcher agrees that data provided by GSK are GSK Confidential Information. GSK makes no representations or warranties regarding the suitability of the data provided to Researcher for the Analysis.

(b) Researcher agrees that it will only use GSK Confidential Information for the approved Analysis and associated obligations and will not download or transfer the GSK

Confidential Information from the GSK access system for either the approved use or other uses.

(c) Researcher agrees to provide access and reasonable assistance to GSK to utilize and implement any Analytical Tools for the sole purpose of reproducing the Analysis.

(d) Researcher agrees that it will inform GSK immediately (and will also inform any regulatory authority) of any safety concerns identified as part of the Analysis. Researcher agrees that GSK may take action regarding such safety concerns, including informing regulatory authorities or healthcare providers, or otherwise making the safety concern public, even in advance of publication of the Analysis by Researcher.

(e) Researcher agrees to comply with any additional requirements identified by the Independent Review Panel which approved the Analysis plan, listed in Exhibit C.

2. CONFIDENTIALITY

(a) GSK Confidential Information and all tangible expressions, in any media, of GSK Confidential Information are the sole property of GSK. Researcher agrees not to use GSK Confidential Information for any purposes other than the purpose(s) described in this Agreement. Researcher agrees not to disclose GSK Confidential Information to third parties except as necessary for the purpose(s) described in this Agreement and under an agreement by the third party (with the exception of regulatory authorities notified of Analysis results) to be bound by the obligations of this Section. Researcher shall safeguard GSK Confidential Information with the same standard of care that is used with Researcher's confidential information, but in no event less than reasonable care. At any time upon the request of GSK, all tangible expressions, in any media, of GSK Confidential Information in Researcher's possession shall be delivered to GSK, or at GSK's option, destroyed.

(b) The obligations of confidentiality and limited use under this Section shall not extend to any information:

(i) which is or becomes publicly available, except through breach of this Agreement;

(ii) which Researcher can demonstrate that it possessed prior to, or developed independently from, disclosure under this Agreement;

(iii) which Researcher receives from a third party which is not legally prohibited from disclosing such information; or

(iv) which Researcher is required by law to disclose, provided that GSK is notified of any such requirement with sufficient time to seek a protective order or other modifications to the requirement.

(c) The obligations of this Section shall survive this Agreement for a period of fifteen (15) years after the Effective Date.

3. INTELLECTUAL PROPERTY

(a) Researcher will notify GSK, promptly and in writing, of any New Intellectual Property. Researcher hereby grants to GSK and to GSK's Affiliates a perpetual, non-exclusive, royalty-free, worldwide license for GSK Uses with right to sublicense (with an exclusive option, to be exercised within one hundred eighty (180) days from notice of the New Intellectual Property to negotiate in good faith an exclusive, fee-bearing, worldwide license with right to sublicense for GSK Uses) to all New Intellectual Property which Researcher may have or obtain, each without additional consideration from GSK. Researcher will provide reasonable assistance to GSK, upon commercially reasonable terms that are at least as favorable to GSK as the terms agreed with any other licensee for such assistance, to facilitate GSK in fully utilizing any New Intellectual Property for GSK Uses.

(b) If GSK exercises its option to negotiate an exclusive license for GSK Uses, GSK and Researcher will exclusively negotiate in good faith, for up to one hundred eighty (180) days or such mutually agreeable longer period, regarding commercially reasonable terms for an exclusive, worldwide, fee-bearing license, including the right to sublicense, for GSK and GSK's Affiliates to make, have made, use, sell or otherwise dispose of the subject matter of the New Intellectual Property or products incorporating the subject matter of the New Intellectual Property for GSK Uses. In the event that GSK does not exercise its option to negotiate an exclusive license, or in the event Researcher and GSK fail to agree to commercially reasonable exclusive license terms following good faith negotiation, Researcher may negotiate further non-exclusive license terms with third parties for GSK Uses. The Researcher may negotiate license terms with third parties for non-GSK Uses. Any such terms shall be consistent with the non-exclusive license granted to GSK in section 3(a) above. Should any terms be agreed with a third party in accordance with this section, then for five (5) years after the effective date, Researcher will notify GSK, within thirty (30) days of the effective date of any such agreement, of the identity of the third party.

(c) Researcher agrees to obtain written agreements with Researcher employees, agents, and subcontractors which assign, without additional consideration, all rights, title and interests in New Intellectual Property to Researcher for subsequent licensing to GSK. The obligations of this Section shall survive termination of this Agreement.

4. PUBLICATION

Researcher agrees to post a summary of the Analysis plan on a publicly-available internet register or website prior to conducting the Analysis, and to post summary results of the Analysis on the same publicly-available internet register or website within one year of completing the Analysis. Researcher also agrees to submit the results of the Analysis for publication in the peer-reviewed literature (a "Publication") in a timely and complete manner as described in the Publication plan attached as Exhibit D, with such Publication appropriately disclosing the strengths and weaknesses of the Analysis methodology. Researcher shall submit to GSK a copy of the summary results of the Analysis at the time of posting the summary results as well as a copy of any proposed Publication within five (5) days of submission to a scientific congress or journal. Additionally, Researcher shall provide GSK with a reference citation upon publication. In the event GSK submits Analysis results to regulatory authorities with the potential to impact product labelling, Researcher agree that GSK may post a summary of the Analysis results on

GSK's Clinical Trial Register. Researcher agrees, following publication, to provide other researchers with additional details of the Analysis on request and to provide access and reasonable assistance to those other researchers to utilize and implement any Analytical Tools for the sole purpose of reproducing the Analysis.

Notwithstanding Section 2, in the event that the Researcher believes that the Analysis demonstrates that information related to efficacy or other effects in any of the treatment arms has been inaccurately entered into, or omitted from, the Clinical Study Report published on GSK's website, the Researcher may document such inaccuracies or omissions and deposit a spreadsheet of the corrected data with a journal as part of a publication agreement for the results of the Analysis in the peer- reviewed literature, provided that at all times the Researcher continues to comply with its data privacy obligations under Section 7(d).

The obligations of this Section shall survive termination of this Agreement.

5. INDEPENDENT CONTRACTOR

The relationship of the parties is that of independent contractors. Neither party is the partner, joint venturer, or agent of the other and neither party has authority to make any statement, representation, commitment, or action of any kind which purports to bind the other without the other's prior written authorization.

6. ASSIGNMENT

GSK may assign its rights and duties under this Agreement without Researcher's consent. Any assignment by Researcher is valid only upon the prior written consent of GSK. To the extent permitted above, this Agreement shall be binding upon and inure to the benefit of the parties and their permitted successors and assigns.

7. REPRESENTATIONS AND WARRANTIES

(a) Researcher represents and warrants that it does not have, and will not enter into, any legal or contractual obligations that would prevent it from complying with its obligations under this Agreement, including without limitation, the obligations of Section 3.

(b) Researcher represents and warrants that it has the authority to bind to the terms of this Agreement any individual proposed by Researcher to have access to GSK data, and that the term "Researcher" shall apply to all such individuals.

(c) Researcher represents and warrants that it will obtain any regulatory or ethics approvals necessary to conduct the Analysis.

(d) Researcher acknowledges the importance of data privacy of individuals to whom accessed data may relate, and commits to comply with all applicable data privacy legislation, not to attempt to identify subjects, and not to combine accessed data with other sources of data that would lead to the identification of any individual.

8. GOVERNING LAW; VENUE

This Agreement shall be governed by and interpreted in accordance with the laws of England and Wales.

9. ENTIRE AGREEMENT

This Agreement represents the entire and integrated agreement between the parties and supersedes all prior negotiations, representations or agreements, either written or oral, regarding its subject matter.

GlaxoSmithKline:		**Researcher:**	
By:	[signature]	By:	
Name:	RUSSELL BROOKS	Name:	
Title:	VP, LEGAL OPERATIONS	Title:	
Date:	21st January 2014	Date:	

Attachments:

Exhibit A – Clinical Trial Listing
Exhibit B – Analysis Plan
Exhibit C – Independent Review Panel Requirements
Exhibit D – Publication Plan

Exhibit A – Clinical Trial Listing

29060/329, "A Multi-center, Double-blind, Placebo-Controlled Study of Paroxetine and Imipramine in Adolescents with Unipolar Major Depression"

Exhibit B – Analysis Plan

Statistical analysis plan is identical to that proposed in PROTOCOL NUMBER 29060/329 dated 12 June 1993

Criteria for Efficacy

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.

1.2 Secondary efficacy variables

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

- Depression items in K –SAD-P
- 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.

2 Statistical Methods

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

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 tor 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.

3 Efficacy Analysis

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.

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 at 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.

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 processing of the SAS system. The ordinal scales which have very few levels (such as the Severity of Illness) will also be analyzed using non parametric methodology so that the results are consistent across modes of analysis.

Dichotomous variables such as response (based on HAMO 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.

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.

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.

4 Safety Analysis

4.1 patients Valid for Clinical Safety & Tolerability

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

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 at 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.

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.

Exhibit C – Independent Review Panel Requirements

None specified

Exhibit D – Publication Plan

The report of our analysis will be submitted to BMJ.