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Department of Psychological Medicine
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North Adelaide, 5006
Australia

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James Shannon
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Brentford, Middlesex TW8 9GS
United Kingdom

Dear Dr Shannon

Thank you for your letter dated 19 November 2013. In that letter you said that you would prepare an agreement under which our team could gain access to CRFs, but we have not heard from your staff.

In the meantime, we have reviewed your existing data sharing agreement. We think that the agreement is vague in many places, with some ambiguity between data and GSK confidential information, and no clear definition of data. Our understanding of data based on the UK precedent is the actual clinical records, though we are not seeking access to these.

We see the clearest guidance as coming from the following:
"Researcher is permitted to publish the underlying data and the results of the analysis of the data, as long Researcher complies with paragraph 7(d) of the Data Sharing Agreement, and does not identify or disclose the identities of the research subjects."

We suggest the following in relation to our access to the CRFs:

1. We agree not to share CRFs with third parties.
2. We will not to attempt to identify any records.
3. In the event that the CRFs reveal information related to efficacy or other effects in any of the treatment arms that has been
   - inaccurately entered into GSK's CSR we have been working from or
   - not entered into the CSR

   we will enter this information into our spreadsheets of corrected data.
4. If a journal such as BMJ were to invite us to deposit these spreadsheets with them as part of a publication agreement which many journals do, we would envisage depositing them as requested.

Does this fit with your understanding of what GSK's agreement entails? Given that you have a good deal of knowledge about what we are doing, it would be

helpful if you could advise of any points where you anticipate GSK's interests and ours might conflict.

Also I just wanted to follow up on a question from my previous letter that you did not answer. What was GSK's follow-up of patients who were in Study 329? For instance, were those who became suicidal or violent on Paxil subsequently advised of the possible role of the drug in their dangerous and distressing feelings/actions and counselled that it may be better for them to avoid SSRIs in future?

Yours sincerely

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