

Scotland A: Adults with Incapacity only

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22 September 2020

[REDACTED]
Professor of Developmental Psychopathology
University of Cambridge
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Douglas House
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Dear [REDACTED],

Study Title: **Spectrum 10K - Common Variant Genetics of Autism and Autistic traits (GWAS).**
REC reference number: **20/SS/0080**
IRAS project ID **277521**

Thank you for your letter of 15th September 2020, responding to the Committee's request for further information on the above research, and enclosing the following revised documents:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [Spectrum 10K Poster_Parents Carers]	V1.0	27 August 2020
Other [Spectrum 10K Scotland A_REC Cover Letter_Response to Queries]	V2.0	15 September 2020
Other [Spectrum 10K Response to Queries London Queens Square REC Cover Letter]	V1.0	09 September 2020
Participant consent form [Spectrum 10K Scotland Consent Form (Welfare Attorney_Welfare Guardian_Nearest Relative)]	V2.0	05 September 2020
Participant consent form [Spectrum 10K Scotland Consent Form (Welfare Attorney_Welfare Guardian_Nearest Relative) TC]	V2.0	05 September 2020
Participant consent form [Spectrum 10K Scotland Consent (Recover Capacity)]	V1.0	05 September 2020
Participant information sheet (PIS) [Spectrum 10K Scotland PIS (Welfare Attorney_Welfare Guardian_Nearest Relative)]	V2.0	04 September 2020
Participant information sheet (PIS) [Spectrum 10K Scotland PIS (Welfare Attorney_Welfare Guardian_Nearest Relative) TC]	V2.0	04 September 2020
Participant information sheet (PIS) [Spectrum 10K Scotland PIS (Recovered Capacity)]	V1.0	04 September 2020

The further information and revised documentation has been considered on behalf of the Committee by the Chair, together with the Lead & Second Reviewers.

The Committee was satisfied with the responses to matters adequately addressed from previous letter.

However, the Committee would be grateful for a more complete response on the following points:

1. Before issuing its Final Opinion, Scotland A REC would like to see a copy of the London Queen's REC response to the applicants PO Responses.

It is the opinion of the Committee that it is not appropriate for the participant to be asked to contact the study team rather than the Independent Contact directly. The Independent Contact is supposed to be entirely independent from the study (although knowledgeable about the study). This is so the Participant has an independent person to contact regarding any concerns or issues they may have with the study, as they may feel reticent about contacting members of the study team directly.

2. The Committee therefore, would like written confirmation in a Cover Letter on headed paper, that participants will not be asked to contact the study team first and that it will be made clear in the PIS that if they have any concerns or issues regarding the study, they can contact the Independent Contact directly, with the name and contact information for the Independent Person being provided in the PIS. The Committee do not need to see the PIS documents with changes in place, only written confirmation in the Cover Letter that this has been done. The Cover Letter should also give the REC reference number, a brief description of all changes made and a list of all documents submitted.

The Committee noted that there was still highlighting throughout the clean versions of amended documents.


3. The Committee agreed that any highlighting that was not necessary (highlighting which showed changes that had been made as a result of the Committee's requests) should be removed from the clean copies and would like written confirmation in the aforementioned Cover Letter that this has been done. Again the Committee do not need to see copies of the clean documents with all unnecessary highlighting removed, only written confirmation in the Cover Letter that this has been done.

Any further revised document submitted should be given a revised version number and date.

The 60 day clock for issue of a final ethical opinion on this application will re-start when the Committee has received a response on the outstanding points.

IRAS project ID: 277521	Please quote this number on all correspondence
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Yours sincerely



Chair

Email: 

Copy to: 