NHS
Health Research Authority

London - Fulham Research Ethics Committee
Barlow House
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Manchester
M1 3DZ

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

21 August 2018

Dr Gerome Breen
Reader
King's College London
Social, Genetic and Developmental Psychiatry Centre
De Crespigny Park
London
SE5 8AF

Dear Dr Breen

Study title:	**NIHR Mental Health BioResource for Depression and Anxiety**
REC reference:	**18/LO/1218**
Protocol number:	**N/A**
IRAS project ID:	**245339**

Thank you for your letter of 14th August 2018 responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further

information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will

be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Animation storyboard]		14 August 2018
Copies of advertisement materials for research participants [Social media footage - script]	1	25 June 2018
Copies of advertisement materials for research participants [Six week Facebook social media plan]	1	08 August 2018
Copies of advertisement materials for research participants [Six week Twitter social media plan]	1	08 August 2018
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [KCL Insurances]		15 June 2018
IRAS Application Form [IRAS_Form_18062018]		18 June 2018
IRAS Application Form XML file [IRAS_Form_18062018]		18 June 2018
IRAS Checklist XML [Checklist_14082018]		14 August 2018
Letter from funder [NIHR Funding Award]		10 April 2018
Letter from sponsor [SLaM R&D Confirmation of Sponsorship]		15 June 2018
Letter from statistician [Statistician Review Letter]		25 May 2018
Non-validated questionnaire [Optional Follow-Up Questionnaire]	1.1	05 June 2018
Non-validated questionnaire [Optional Follow-Up Questionnaire]	1.1	05 June 2018
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Non-validated questionnaire [Optional Follow-Up Questionnaire]	1.1	05 June 2018
Non-validated questionnaire [Optional Follow-Up Questionnaire]	1.1	05 June 2018
Non-validated questionnaire [Sign-Up Questionnaire with highlighted changes]	1.2	30 July 2018
Non-validated questionnaire [Sign-Up Questionnaire]	1.2	30 July 2018
Non-validated questionnaire [Optional Follow-Up Questionnaire]	1.1	13 August 2018

Other [PR Campaign Key Messages]	1.1	12 June 2018
Other [Saliva Instructions Flyer 04]	1.1	04 June 2018
Other [GLAD Request Callback Phone Script]	1.1	15 June 2018
Other [Appendices]	1.1	12 June 2018
Other [Maudsley Data/Sample Access Request Form]	1.1	04 June 2018
Other [NIHR Access Request Form]	1.1	05 June 2018
Other [Data/Recontact Access Protocol]	1.1	04 June 2018
Other [PR Campaign Key Messages]	1.1	12 June 2018
Other [Website Screenshots]	1.2	13 August 2018
Other [AWS Solution for Website]	1	02 July 2018
Other [About GLAD page text]	1	09 August 2018
Other [Introductory page for PIS]	1	13 August 2018
Other [Cover letter - Response to REC provisional opinion]		13 August 2018
Participant consent form [GLAD Consent Form]	1.2	30 July 2018
Participant information sheet (PIS) [GLAD PIS]	1.2	30 July 2018
Participant information sheet (PIS) [GLAD PIS with tracked changes]	1.2	30 July 2018
Research protocol or project proposal [GLAD Protocol]	1.1	04 June 2018
Summary CV for Chief Investigator (CI) [G Breen CV]		15 June 2018
Validated questionnaire [Optional Follow-Up Questionnaire]		15 June 2018
Validated questionnaire [Optional Follow-Up Questionnaire]		15 June 2018
Validated questionnaire [Optional Follow-Up Questionnaire]		15 June 2018
Validated questionnaire [Optional Follow-Up Questionnaire]		15 June 2018
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Validated questionnaire [Optional Follow-Up Questionnaire]		

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

18/LO/1218	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

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The Rev'd Nigel Griffin (Chair)
Chair

Email:nrescommittee.london-fulham@nhs.net

Enclosures: "After ethical review – guidance for researchers" *[SL-AR2]*

Copy to: *Professor Reza Razavi,*
Ms Jennifer Liebscher, South London and the Maudsley NHS Foundation Trust