London - London Bridge Research Ethics Committee
Skipton House
80 London Road

London
SE1 6LH

Telephone: 020 7104 8222
Fax:020 7104 8222

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

05 April 2019

Professor Cathy Creswell
School of Psychology and Clinical Language Sciences
University of Reading, Harry Pitt Building
Reading
RG6 6AH

Dear Professor Creswell

Study title:	**Parents' experiences of parenting a child with Obsessive Compulsive Symptoms/Disorder**
REC reference:	**19/LO/0514**
Protocol number:	**Version 1.0**
IRAS project ID:	**260035**

The Research Ethics Committee reviewed the above application at the meeting held on 27 March 2019.

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 favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact hra.studyregistration@nhs.net outlining the reasons for your request. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below. .

Conditions of the favourable opinion

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. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

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 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 documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Advertisement]	Version 1.0	25 February 2019
Covering letter on headed paper [Cover_Letter]		25 February 2019
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		25 February 2019
Interview schedules or topic guides for participants [Topic_Guide]	Version 1.0	25 February 2019
IRAS Application Form [IRAS_Form_26022019]		26 February 2019
Letter from funder [Funder_Letter]		25 February 2019
Letter from sponsor		25 February 2019
Non-validated questionnaire [Screening_Questions]	Version 1.0	25 February 2019
Other [Consent_To_Be_Contacted]	Version 1.0	25 February 2019
Other [Risk_Management_Protocol]	Version 1.0	25 February 2019
Other [Parent_Fact_Sheet]	Version 1.0	25 February 2019
Participant consent form [Participant_Study_Consent_Form]	Version 1.0	25 February 2019
Participant information sheet (PIS) [Participant_Information_Sheet]	Version 1.0	25 February 2019
Research protocol or project proposal [Research_Protocol]	Version 1.0	25 February 2019
Summary CV for Chief Investigator (CI) [Chief_Investigator_CV]		25 February 2019
Summary CV for student [Student_CV]		25 February 2019
Summary CV for supervisor (student research) [Supervisor_CV_Brynjar_Halldorsson]		25 February 2019
Summary CV for supervisor (student research) [Supervisor_CV_Cathy_Creswell]		25 February 2019
Validated questionnaire [ChOCI_Parent_Report]		

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

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

<u>Reporting requirements</u>

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 Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

19/LO/0514	**Please quote this number on all correspondence**

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

Yours sincerely
PP:

Ms Jane Smith
Chair

E-mail: nrescommittee.london-londonbridge@nhs.net

London - London Bridge Research Ethics Committee

Attendance at Committee meeting on 27 March 2019

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Ahmed Al-Nagar	Lead Pharmacist	Yes	
Dr Hilary Crowe	Student of Biomedicine at Birkbeck	No	
Mr David Gallacher	Consultant Physicist	Yes	
Miss Alice Glaser	Investigator Initiated Trials Coordinator	Yes	
Mr Nicholas Harper	Project Manager	Yes	
Dr Alex Hatziagorakis	Consultant Psychiatrist	Yes	
Ms Kate Melvin	Freelance Qualitative Researcher	Yes	
Mr Barry Moody	Retired solicitor/partner in law firm	Yes	
Bernadette Roberts	Retired Finance Manager	Yes	
Ms Jane Smith	Retired medical journal editor (BMJ)	Yes	
Miss Anna Stockwell	Early Phase Trials Coordinator	No	
Mrs Roberta Tucker	Senior Director Global Quality Assurance	Yes	
Dr Shelley Watcham	Medical Advisor	No	
Dr Ralph White	Pharmacist	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mr Connor Frost	Approvals Officer