Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

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21 May 2024

Dear Ms Burton

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**What are the experiences of maternity care and mental health care for women with Obsessive Compulsive Disorder during pregnancy and postpartum? a descriptive study with survey and qualitative interviews**
IRAS project ID:	**317220**
Protocol number:	**PID17677**
REC reference:	**24/ES/0027**
Sponsor	**University of Oxford**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report

(including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

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

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **317220**. Please quote this on all correspondence.

Yours sincerely,

Andrea Bell

Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *RGEA*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Contract/Study Agreement template [mNC_PIC_Hollie Burton_Perinatal OCD care experience study_ Oxford_Draft]		04 April 2024
Copies of materials calling attention of potential participants to the research [HB_socialmediaadvert_perinatalOCD_v1.1_100524]	1.1	10 May 2024
Copies of materials calling attention of potential participants to the research [HB_socialmediaadvert_perinatalOCD_v1.0 270324]	1.0	27 March 2024
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [2023-2024 UoO CT Insurance Policy Summary]	n/a	26 July 2023
Interview schedules or topic guides for participants [HB_interviewschedule_perinatalOCD & YBOCS]	1.0	12 March 2024
IRAS Application Form [IRAS_Form_27032024]		27 March 2024
IRAS Application Form [IRAS_Form_17052024]		17 May 2024
Letter from funder [Burton H - Confirmation of study and funding letter Nov 2023]	n/a	07 November 2023
Letter from sponsor [Signed sponsor letter H BURTON PID17677]		12 March 2024
Non-validated questionnaire [HB_Maternitysurvey_perinatalOCD & OCI-R]	1.0	12 March 2024
Other [Supervisor CV - CCarson_2 page CV_Nov22]		17 November 2022
Other [Supervisor CV - PSalkovskis_2page CV]		
Other [HB_distressprotocol_v1.0_250324]	1.0	25 March 2024
Other [HB_Paulcollegueemail_v1.0]	1.0	25 March 2024
Other [Response to validation under consideration]		27 March 2024
Other [HB_responsetoREC_v1_150524]	1.0	15 May 2024
Other [Researcher correspondence re provisional opinion action point]		
Participant consent form [HB_consent_survey_perinatalOCD_v1.1 150524]	1.1	15 May 2024

Participant consent form [HB_consent_interview_perinatalOCD_v1.1 150524]	1.1	15 May 2024
Participant information sheet (PIS) [HB_Participantinformation_survey_perinatalOCD_v1.1_100524]	1.1	10 May 2024
Participant information sheet (PIS) [HB_Participantinformation_interview_perinatalOCD_v1.1_100524]	1.1	10 May 2024
Research protocol or project proposal [HB_protocol_perinatalOCD_V1.0_270324]	1.0	27 March 2024
Response to Request for Further Information [Response to request]		
Summary CV for Chief Investigator (CI) [H Burton CV March 2024]	1.0	13 March 2024
Summary CV for student [H Burton CV March 2024]		
Summary CV for supervisor (student research) [UKRI CV-and-List-of-OutputsAlderdice2023]	1.0	13 March 2024

IRAS project ID	317220

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
Activities at NHS organisations will involve PIC activity only, including the identification of participants, database searches and the provision of study documentation.	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study in accordance with the contracting expectations detailed. Due to the nature of the activities involved, organisations will be expected to provide that confirmation to the sponsor: • Within 35 days of receipt of the local information pack • After HRA/HCRW Approval has been issued. If the organisation is not	The sponsor has provided the appropriate model PIC agreement that it intends to use as a subcontract between participating organisations and NHS organisations acting as their Participant Identification Centres (PICs).	Sponsor is not providing funding to PICs.	The Chief Investigator will be responsible for all study activities performed at PICs.	Where an external individual will be conducting any of the research activities that will be undertaken at this site type then they would be expected to hold a Letter of Access. This should be issued be on the basis of a Research Passport (if university employed) or an NHS-to-NHS confirmation of pre-engagement checks letter (if NHS employed). These should confirm Occupational Health Clearance. These should confirm standard DBS checks.

	able to formally confirm capacity and capability within this timeframe, they must inform the sponsor of this and provide a justification. If the sponsor is not satisfied with the justification, then the sponsor may escalate to the National Coordinating Function where the participating NHS organisation is located.				

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.
The applicant has indicated they do not intend to apply for inclusion on the NIHR CRN Portfolio.