Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Miss Eilidh Grant
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University of Sussex
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Email: approvals@hra.nhs.uk
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12 April 2023

Dear Miss Grant

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

Study title:	**Understanding the clinician and service user experience of Cognitive Behavioural Therapy (CBT) for Obsessive-Compulsive Disorder (OCD) and the factors which influence treatment outcomes: a qualitative study.**
IRAS project ID:	**317280**
REC reference:	**23/PR/0176**
Sponsor	**University of Sussex**

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 **317280**. Please quote this on all correspondence.

Yours sincerely,
Carolyn Halliwell

Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Dr Anthony Walsh*

List of Documents

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

Document	*Version*	*Date*
Copies of materials calling attention of potential participants to the research [Materials calling attention to potential ps]	1	15 February 2023
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		01 August 2022
Interview schedules or topic guides for participants [Interview and focus group schedules]	1	15 February 2023
IRAS Application Form [IRAS_Form_10022023]		10 February 2023
Letter from funder [Eilidh Grant funding letter]		10 May 2021
Letter from sponsor		23 January 2023
Letters of invitation to participant [Letters of invitation to participants]	2	31 March 2023
Non-validated questionnaire [Questionnaires]	1	15 February 2023
Other [Debrief materials]	1	15 February 2023
Other [Template PIC agreement]		
Other [Email reminder and demographics survey link for FGs and Interviews]	1	15 February 2023
Other [REC response letter]	1	31 March 2023
Participant consent form [Consent forms]	1	15 February 2023
Participant information sheet (PIS) [PIS_ServiceUserFGandInterviews]	2	04 April 2023
Participant information sheet (PIS) [PIS_ServiceUserQualtrics]	2	04 April 2023
Participant information sheet (PIS) [PIS_Clinicians]	2	04 April 2023
Research protocol or project proposal [NHS research protocol]	3	31 March 2023
Summary CV for Chief Investigator (CI) [Eilidh Grant CV]		
Summary CV for supervisor (student research) [Supervisor CVs]		

IRAS project ID	317280

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
The single NHS organisation involved in this study will act as a participant identification centre (PIC).	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.	The sponsor has provided the appropriate model non-commercial PIC agreement that it intends to use as a contract between participating organisations and NHS organisations acting as their Participant Identification Centres (PICs).	Study funding arrangements are detailed in A65 of the IRAS form.	The Chief Investigator may be responsible for all research activities performed at participating NHS organisations.	All research activities will be undertaken remotely and, therefore, it is not expected that any additional HR arrangements will be necessary.

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 that they do not intend to apply for inclusion on the NIHR CRN Portfolio.