Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Dr Lisa Newington
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Email: HCRW.approvals@wales.nhs.uk

04 August 2021

Dear Dr Newington,

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

Study title:	**Interview study to explore participants' views of taking part in healthcare research**
IRAS project ID:	**298078**
Protocol number:	**N/A**
REC reference:	**21/WA/0229**
Sponsor	**Imperial College London**

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 **298078**. Please quote this on all correspondence.

Yours sincerely,

Mair Davidson
Approvals Specialist

Email: HCRW.approvals@wales.nhs.uk

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 [Model agreement PICs]	1.0	24 May 2021
Copies of materials calling attention of potential participants to the research [Flyer]	1.0	02 June 2021
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor insurance]	1.0	05 August 2020
Interview schedules or topic guides for participants [Interview schedule]	1.0	06 April 2021
IRAS Application Form [IRAS_Form_28062021]		28 June 2021
Letter from funder [Grant award letter]	1.0	29 April 2021
Letter from sponsor [Sponsor letter]	1.0	23 June 2021
Letters of invitation to participant [Invitation text]	1.0	11 May 2021
Non-validated questionnaire [Screening questions]	1.0	06 April 2021
Other [Responses to REC review]	1.0	12 July 2021
Participant consent form [Consent form]	1.0	09 June 2021
Participant information sheet (PIS) [Participant information sheet]	1.0	17 June 2021
Referee's report or other scientific critique report [Peer review certificate]	1.0	03 June 2021
Referee's report or other scientific critique report [Responses to peer reviewers]	1.0	16 March 2021
Research protocol or project proposal [Study Protocol]	1.0	02 June 2021
Summary CV for Chief Investigator (CI) [CV]	1.0	28 June 2021

IRAS project ID	298078

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 NHS orgainsations in this study will be Participant Identification Centres. Their activity is clearly described in the accompanying documentation.	PIC activities should not commence until a PIC Agreement is in place. HRA and HCRW recommend use of the standard Participating NHS Organisation to PIC agreement available here.	HRA and HCRW recommend use of the standard Participating NHS Organisation to PIC agreement, available here. The sponsor has provided the appropriate model agreement for use.	There will be no funding provided to Participant Identification Centres by the sponsor.	Neither a PI nor Local Collaborator should be in place at Participant Identification Centres.	Participant identification will be conducted by locally employed staff; therefore, no Letters of Access nor Honorary Research Contracts are expected.

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.
This study has not been put forward for adoption to the NIHR Portfolio.