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27 April 2020

Dear Professor Rathod

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

Study title:	**Psychological impact of COVID- 19- pandemic and experience: An international survey.**
IRAS project ID:	**282858**
REC reference:	**20/HRA/1934**
Sponsor	**Southern Health NHS Foundation Trust**

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 **282858**. Please quote this on all correspondence.

Yours sincerely,

Rekha Keshvara

Approvals Manager

Email: approvals@hra.nhs.uk

Copy to: *Mrs Penny Bartlett*

List of Documents

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

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Newsletter advert text]	V1	17 April 2020
IRAS Application Form [IRAS_Form_17042020]		17 April 2020
IRAS Application Form XML file [IRAS_Form_17042020]		17 April 2020
IRAS Checklist XML [Checklist_21042020]		21 April 2020
Letter from funder [Funding letter]		
Letter from funder		20 April 2020
Letter from sponsor [Sponsor letter]		
Letters of invitation to participant [Letter advert]	V1	17 April 2020
Non-validated questionnaire [Questionnaire]	V1.7	21 April 2020
Organisation Information Document		
Other [Social media adverts]	V1	17 April 2020
Other [Email advert]	V1	17 April 2020
Other [Questionnaire - TRACKED]	V1.7	21 April 2020
Other [Protocol - TRACKED]	V1.5	20 April 2020
Other [PIS- TRACKED]	V2	20 April 2020
Other [Peer Review 1]		
Other [Peer Review 2]		
Other [Peer review 2 - Questionnaire comments]		
Other [Peer Review 3]		
Participant information sheet (PIS) [Participant Information Sheet]	V2	20 April 2020
Research protocol or project proposal [Protocol]	V1.5	20 April 2020
Schedule of Events or SoECAT	2	17 April 2020
Summary CV for Chief Investigator (CI) [CI CV]		

IRAS project ID	282858

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
There is one type of participating NHS organisation; activities will be the same at all organisations.	Organisations will not be required to formally confirm capacity and capability, and research procedures may begin 35 days after provision of the local information pack, provided the following conditions are met. You have contacted participating NHS organisations (see below for details) HRA and HCRW Approval has been issued. The NHS organisation has not provided a reason as to why they cannot	An Organisation Information Document has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used.	As per the Organisation Information Document, there are no funds being provided to the sites by the sponsor.	The study is limited to participants completing an online questionnaire and therefore, a Local Collaborator or Principal Investigator is not expected for the study.	The study is limited to participants completing an online questionnaire and therefore, HR good practice arrangements are not expected for the trial.

	participate. The NHS organisation has not requested additional time to confirm. You may start the research prior to the above deadline if HRA and HCRW Approval has been issued and the site positively confirms that the research may proceed. You may now provide the local information pack for your study to your participating NHS organisations in England and/or Wales. If you have not already started to provide the local information packs to participating NHS organisations in Northern Ireland and/or Scotland please do so when you are ready. A current list of R&D contacts is accessible at				

	the NHS RD Forum website and these contacts MUST be used for this purpose. The password to access the R&D contact list is Redhouse1.				

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 intend to apply for inclusion on the NIHR CRN Portfolio.