Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

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10 June 2020

Dear Professor Hobbs

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

Study title:	**Expanding national RAPid community Test evaluation capacity fOR COVID-19**
IRAS project ID:	**284320**
Protocol number:	**1.0**
REC reference:	**20/NW/0282**
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 **284320**. Please quote this on all correspondence.

Yours sincerely,

Michael Pate
Approvals specialist

Email: approvals@hra.nhs.uk

Copy to: *Dr Brian Nicholson – University of Oxford*

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 [Template agreement]		02 June 2020
Copies of advertisement materials for research participants [Advert poster]	Version 1.1	05 June 2020
Covering letter on headed paper [Provisional outcome response]	Version 1	06 June 2020
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor insurance]		29 July 2019
Interview schedules or topic guides for participants [Patient facing ecrf questions]	Version 1	01 June 2020
IRAS Application Form [IRAS_Form_02062020]		02 June 2020
Letter from funder [Funding confirmation]		15 May 2020
Letter from sponsor [Sponsor letter]		02 June 2020
Letters of invitation to participant [Invite text]	Version 1.1	05 June 2020
MHRA Notice of No Objection Letter (Medical Devices) and relevant correspondence [Letter re MHRA process]		08 June 2020
Organisation Information Document [Organisation Information Document]		02 June 2020
Participant consent form [Assent form]	1.0	01 June 2020
Participant consent form [Parent consent form]	1.0	01 June 2020
Participant consent form [Adult consent form]	1.0	01 June 2020
Participant information sheet (PIS) [Adult PIS]	1.0	01 June 2020
Participant information sheet (PIS) [6-9yrs PIS]	Version 1.1	05 June 2020
Participant information sheet (PIS) [PIS Gillick]	1.0	05 June 2020
Participant information sheet (PIS) [10-15yrs PIS]	1.1	05 June 2020
Participant information sheet (PIS) [10-15yrs PIS]	Version 1.1	05 June 2020
Participant information sheet (PIS) [<6yrs PIS]	Version 1.1	05 June 2020
Research protocol or project proposal [RAPTOR Protocol]	Version 1.1	08 June 2020
Sample diary card/patient card [Symptom diary]	1.0	01 June 2020
Sample diary card/patient card [Symptom diary - mobile]	1.0	08 June 2020
Schedule of Events or SoECAT [SoECAT]	1.0	20 May 2020
Summary CV for Chief Investigator (CI) [CI CV]		02 June 2020

IRAS project ID	284320

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
All sites will be conducting the same activities. Therefore, one site type.	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.	An organisation information document has been submitted and the sponsor is intending to use a separate site agreement The sponsor is using a bespoke agreement. The HRA and HCRW take no position on the acceptability of these changes. Participating NHS organisations should now determine its	It is noted this this study has requested inclusion on the CRN portfolio but does not incur Excess Treatment Costs. You have provided an AcoRD Specialist authorised SoECAT.	A local PI is expected at sites.	It is expected that the principles of the HR Good Practice Pack are followed for researchers working in primary care. Researchers are advised to follow the processes of the local primary care management function

		acceptability and liaise with the sponsor to confirm the content of the agreement.			

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 been put forward for adoption to the NIHR Portfolio.