Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Professor Christopher Imray
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03 April 2020

Dear Professor Imray

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

Study title:	**The COVID-19 Vascular sERvice Study**
IRAS project ID:	**282224**
Protocol number:	**1.0**
REC reference:	**20/NW/0196**
Sponsor	**University Hospital of Coventry and Warwickshire NHS 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 **282224**. Please quote this on all correspondence.

Yours sincerely,

Michael Pate
Approvals specialist

Email: approvals@hra.nhs.uk

Copy to: *Miss Becky Haley*

List of Documents

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

Document	*Version*	*Date*
Covering letter on headed paper [Response to REC/HRA assessment]		02 April 2020
IRAS Application Form [IRAS_Form_30032020]		30 March 2020
Letter from sponsor [Sponsor letter]	1.0	27 March 2020
Letters of invitation to participant [Email invitation text]	1	02 April 2020
Organisation Information Document [Organisation Information Document]	1.2	30 March 2020
Participant consent form [Consent form - clean]	1	02 April 2020
Participant consent form [Consent form - tracked]	1	02 April 2020
Participant information sheet (PIS) [Information sheet - clean]	1	03 April 2020
Participant information sheet (PIS) [Information sheet - tracked]	1	03 April 2020
Research protocol or project proposal [Protocol]	1	02 April 2020
Schedule of Events or SoECAT [Schedule of Events - assessed]	1	03 April 2020
Summary CV for Chief Investigator (CI) [CI CV]		20 March 2018

IRAS project ID	282224

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
One site type.	Research activities should not commence at participating NHS organisations in England or Wales prior to theirformal confirmation of capacity and capability to deliver the study.	An organisation information document has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used.	No funding is being provided to participating sites by the sponsor.	Local PI.	Where arrangements are not already in place, research staff not employed by the NHS host organisation undertaking any of the research activities listed in the research application would be expected to obtain a Letter of Access based on standard DBS checks and occupational health clearance.

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. Although the GDPR transparency wording has not been used verbatim in areas of the information sheet, the wording covers everything expected on the HRA website, and has therefore been accepted, given the urgency of the research. The research team wished to retain v1 as the REC-approved documents, which is why only the dates have changed on updated documents, from the original favourable opinion with conditions REC letter.