NHS
Health Research Authority

North West - Liverpool Central Research Ethics Committee

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Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

02 April 2020

Professor Christopher Imray
University Hospital Coventry and Warwickshire
Clifford Bridge Road
Coventry
CV2 2DX

Dear Professor Imray

Study title:	**The COVID-19 Vascular sERvice Study**
REC reference:	**20/NW/0196**
Protocol number:	**1.0**
IRAS project ID:	**282224**

The Research Ethics Committee reviewed the above application at the meeting held on 01 April 2020. Thank you for asking Mr Athanasios Saratzis to attend by teleconference to discuss the application.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Action required by the applicant;

Number	Condition	Response from the applicant
1.	The Committee were unclear what participants would be asked to do from the statement 'if you take part in the study you agree to follow the instructions given to you by the study doctor' in section 1.4 of the Participant Information Sheet. Following clarification from the applicant, members asked for this statement to be removed and the document updated to reflect that participants would be following the normal NHS care pathway during the Covid-19 pandemic and would not be asked to do anything specific in relation to the study.	

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Registration is a legal requirement for clinical trials of investigational medicinal products (CTIMPs), except for phase I trials in healthy volunteers (these must still register as a condition of the REC favourable opinion).

Registration should take place as early as possible and within six weeks of recruiting the first research participant at the latest. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

As set out in the UK Policy Framework, research sponsors are responsible for making information about research publicly available before it starts e.g. by registering the research project on a publicly accessible register. Further guidance on registration is available at:

https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

You should notify the REC of the registration details. We routinely audit applications for compliance with these conditions.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC Sites

The favourable opinion applies to all NHS/HSC sites taking part in the study taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland)being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Initial Assessment for REC		30 March 2020

IRAS Application Form [IRAS_Form_30032020]		30 March 2020
Letter from sponsor [Sponsor letter]	1.0	27 March 2020
Participant consent form [Consent form]	1.0	27 March 2020
Participant information sheet (PIS) [PIS]	1.0	27 March 2020
Research protocol or project proposal [Protocol]	1.0	27 March 2020
Summary CV for Chief Investigator (CI) [CI CV]		20 March 2018

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high-quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

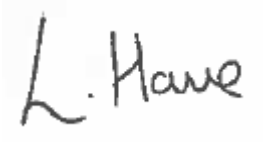
HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 282224 **Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely



Laura Howe
Approvals Officer

On behalf of

Mr Paul Mooney
Chair

E-mail: liverpoolcentral.rec@hra.nhs.uk

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

Copy to: Miss Becky Haley

North West - Liverpool Central Research Ethics Committee

Attendance at Committee meeting on 01 April 2020

Committee Members:

Name	*Profession*	*Present*	*Notes*
Miss Hannah Allsop	Senior Pharmacist	No	
Ms Davara Lee Bennett	PhD Student in Public Health and Policy	Yes	
Miss Fiona Brailsford	Research Coordinator	Yes	
Ms Erika Brennan	Clinical Trials Manager	No	
Professor Murthy Burra	Consultant Anaesthetist	No	
Mr Waiel Elzamzami	Healthcare Scientist	No	
Mrs Helen Hind	Clinical Samples Manager	Yes	
Mr Richard Hovey	Business Analyst	Yes	
Miss Karen Knowles	Transfusion Laboratory Manager	No	
Mr Alan McGarrity	Retired Police Inspector	Yes	
Mr Paul Mooney	Deputy Director of Pharmacy - Operations	Yes	
Ms Pamela Parry	Senior Primary Care Research Nurse	No	
Miss Joanne Skellern	Lecturer in learning disabilities	Yes	
Mrs Ann Williams	Commissioning and Contract Manager	Yes	