Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Ariennir gan Lywodraeth Cymru
Funded by Welsh Government

Health and Care Research Wales Support and Delivery Centre
Canolfan Cefnogi a Chyflenwi Ymchwil Iechyd a Gofal Cymru

Castlebridge 4
15-19 Cowbridge Road East
Cardiff, CF11 9AB

Telephone: 02920 230457
Email: Wales.REC5@wales.nhs.uk
Website : www.hra.nhs.uk
gov.wales/healthandcareresearch

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 and Wales until you receive HRA and HCRW Approval

27 May 2020

Professor Richard Body
Professor, Emergency Medicine
The University of Manchester
Emergency Department,
Manchester Royal Infirmary
Oxford Rd, Manchester
M13 9WL

Dear Professor Body,

Study title:	**Facilitating Accelerated CLinical evaluation Of Novel diagnostic tests for COVID-19 (FALCON C-19)**
REC reference:	**20/WA/0169**
Protocol number:	**Not applicable**
IRAS project ID:	**284229**

The Research Ethics Committee reviewed the above application at the meeting held on 27 May 2020. Thank you for attending 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.

Mental Capacity Act 2005 (England and Wales)

I confirm that the Committee has approved this research project for the purposes of the Mental Capacity Act 2005 (England and Wales). The Committee is satisfied that the requirements of section 31 of the Act will be met in relation to research carried out as part of this project on, or in relation to, a person who lacks capacity to consent to taking part in the project.

Mental Capacity Act (Northern Ireland) 2016

The Committee approved this research project for the purposes of the Mental Capacity Act (Northern Ireland) 2016. The Committee is satisfied that the requirements of Part 8 of the Act will be met in relation to research carried out as part of this project on, or in relation to, a person who lacks capacity to consent to taking part in the project

Conditions of the favourable opinion

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

Number	Condition
1	The Committee noted that a participant in this study will have the option to withdraw in order to take part in an interventional trial - if this would have an impact on the results of the study, or the well-being and safety of the participant; the Committee requested that this is clarified in all the Information Sheets in paragraph “Can I end my participation early?”
2	The Committee noted the intent to retain samples for a period of 5 years and use them in future research, but requested that the information relating to DNA analysis is clarified: the Information Sheets need to mention that future studies may need the sample for DNA analysis (as the Consent Form requests explicit permission for this)
3	Similarly, the intent to extract data for the secondary outcome measures from the medical record is described in the Information Sheets, but explicit consent needs to be requested in the Consent Form/Consultee Declaration Form.
4	The Committee noted that the protocol stipulates in section 6.3 that patients who have been included in the study based on Consultee Declaration (whilst they lacked the capacity to consent) should be given information about the study when they regain capacity and Consent should be sought. To this end, the existing Participant Information Sheet should be tailored to create a new Information sheet, reflecting what has happened to the participant and explain their option to consent to take part of withdraw from the study. The new Information Sheet for patients regaining capacity should be submitted to the REC, for the completion of the record. The existing Consent Form (as amended following the conditions above) is suitable and can be used to obtain consent.
5	The Committee noted that the Information Sheet for Consultees is aimed exclusively at Personal Consultees and needs to be amended to enable a Nominated Consultee to be informed and provide a Declaration.
6	It was also noted that the section headers in the Consultee Information Sheet are the same as in the Participant Information Sheet and inadvertently refer to the Consultee’s data, samples, involvement in the study, etc. – this will need to be amended to ensure it refers to the participant.

7	The introduction paragraph states “we are inviting all people over 18 years of age” and paragraph “Who is eligible to participate?” states “Anyone 18 years or older” - this will need to be rectified for accuracy, preferably keeping ‘aged 18 or older’ as a criterion.
8	The Committee also requested that a number of inaccuracies in the Consultee Declaration Form be amended, such as references to ‘researcher taking consent’ (where the Consultee is providing a declaration not consent), the Consultee being referred to as ‘participant’s representative’ and requests are made to ‘obtain written *consent* from the participant’s consultee’.
9	In addition, the Consultee Declaration Form omits a number paragraphs included in the Patient Consent Form (such as retention and future use of samples and data, informing the GP, etc) – and the Committee requested that this is amended to ensure it includes all pertinent information that the Consultee is required to advise on.
10	The Committee noted that the study intends to retain participants who lose capacity during the study, and accepted the explanation given during the meeting that participants who lose capacity after being discharged from hospital will not be followed-up, however, the team would like to retain in the study and collect samples from patients who consented to take part but subsequently deteriorated and lost capacity whilst in critical care; in this case consent would not be enduring and the team would approach a Consultee to seek a Declaration to allow the patient’s continued participation. This process should be clarified in section 6.3 (Recruitment) of the Protocol.

The Committee also made the following recommendation:

Number	Recommendation
1	The Committee noted that the IRAS application form lists (filter page question 3 and A71-2) that potentially all UK countries would be involved in the study - albeit the answer to question A 72 (research sites) only lists sites in England. The Committee recommended that the research team notes that if sites in Scotland are to be included in the study an application for ethical review will have to be submitted to Scotland A REC, as per the provisions of the ‘Adults with Incapacity (Scotland) Act, 2000’. This is not a condition of the ethical opinion, it is a recommendation only that the study team notes this legal requirement.

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).

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering letter on headed paper [Cover letter]	1.0	21 May 2020
GP/consultant information sheets or letters [GP letter]	1.1	20 May 2020
Initial Assessment for REC		26 May 2020
IRAS Application Form [IRAS_Form_26052020]		26 May 2020
Organisation Information Document	1.0	
Other [284229 20-WA-0169 DOCUMENT PACK]		
Participant consent form [ICF]	1.0	20 May 2020
Participant consent form [Consultee telephone declaration]	1.0	20 May 2020
Participant information sheet (PIS) [PIS]	1.0	20 May 2020
Participant information sheet (PIS) [Consultee information sheet]	1.0	20 May 2020
Research protocol or project proposal [Protocol]	1.0	20 May 2020
Schedule of Events or SoECAT [Validated]	1.0	27 May 2020
Summary CV for Chief Investigator (CI) [Chief Investigator CV]	1	21 May 2020

Membership of the Committee

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

No declarations of interest were made in relation to this application.

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: 284229	**Please quote this number on all correspondence**

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

Yours sincerely

Dr Jason Donal Walker, MB BCh BAO, FRCA
Consultant Anaesthetist
Chair, Wales REC 5

E-mail: WalesREC5@wales.nhs.uk

Enclosures:	List of names and professions of members who were present at the meeting and those who submitted written comments
Copy to:	Ms Emma Columbine, research.sponsor@mft.nhs.uk
	Lead Nation England: approvals@hra.nhs.uk

Attendance at ad-hoc (Expedite Review) Committee meeting on 27 May 2020

Committee Members:

Name	*Profession*	*Present*
Dr Swapna Alexander	Consultant Physician	Yes
Dr Kathryn Ann Clarke	Head of Patient Safety	Yes
Mr Haydn Cullen-Jones	Retired Teacher	Yes
Professor Iolo J. Doull	Consultant Respiratory Paediatrician	Yes
Dr Jamie Duckers	Consultant Respiratory Physician	Yes
Dr Gail Holland	Trials Unit Manager	Yes
Mr Roger S Laidlaw	Deprivation of Liberty Safeguards Coordinator	Yes
Mr Eliezer Lichtenstein	Manual Therapist	Yes
Mr John E Owen	Retired Psychiatric Social Worker	Yes
Mr Vishwanath Puranik	Consultant ENT Surgeon	Yes
Dr Victoria Shepherd	Critical Care Nurse	Yes
Dr Bapuji Rao Velagapudi	Consultant Psychiatrist	Yes
Dr Jason Donal Walker	Consultant Anaesthetist (Chair)	Yes
Dr Anthony David White	Consultant Physician	Yes

Also in attendance:

Name	*Position (or reason for attending)*
Mr Gurmel Bhachu	Approvals Specialist
Mr Norbert Leon Ciumageanu	Approvals Officer
Dr Rossela Roberts	Approvals Operations Manager