

Wales Research Ethics Committee 5
Bangor

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Please note:

This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites until the outcome of the HRA/HCRW assessment has been confirmed.

11 September 2020

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

Dear Prof 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
Amendment number:	AM10
Amendment date:	09 September 2020
IRAS project ID:	284229

The above amendment was reviewed at the meeting of the Sub-Committee held on 10 September 2020 in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

The Committee recommended that that participants are informed that staff collecting samples will be in protective equipment which may have the potential to alarm the participants neighbours and potentially disclose that participant has had a COVID-19 diagnosis.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Completed Amendment Tool [Amendment Tool for Amendment 10]	1.0	09 September 2020
Other [IRAS form]	3.0	10 September 2020
Participant consent form [FALCON Telephone Consent Form]	1.0	09 September 2020
Participant information sheet (PIS) [PIS Work Stream B]	1.0	09 September 2020
Research protocol or project proposal [FALCON Protocol (tracked)]	1.3	09 September 2020
Research protocol or project proposal [FALCON Protocol (clean)]	1.3	09 September 2020

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

Statement of compliance

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.

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
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Yours sincerely



Dr Jason Donal Walker, MB BCh BAO, FRCA
Consultant Anaesthetist
Chairman 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

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Attendance at Sub Committee meeting on 10 September 2020

Committee Members

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>	<i>Present</i>
Dr Paul G Mullins	Reader, Senior MRI Physicist (Vice-Chair)	Lay +	Yes
Dr Jason D Walker	Consultant Anaesthetist (Chairman)	Expert	Yes

In attendance

<i>Name</i>	<i>Position (or reason for attending)</i>
Mr Norbert Leon Ciumageanu	Research Approvals Officer