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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

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05 November 2020

Professor Richard Body
Professor, Emergency Medicine
The University of Manchester
Emergency Department
Manchester Royal Infirmary
Oxford Road, 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/SS/0115
Protocol number: Not applicable
IRAS project ID: 289109

The Research Ethics Committee reviewed the above application at the meeting held on 29 October 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.

Adults with Incapacity (Scotland) Act 2000

I confirm that the Committee has approved this research project for the purposes of the Adults with Incapacity (Scotland) Act 2000. The Committee is satisfied that the requirements of section 51 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.

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

Chair-Dr Ian Zealley
Vice-Chair-Dr Mary=Joan MacLeod

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/>

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

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 haven't 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. We are

also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at: <https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/>

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:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper [Cover letter]		15 October 2020
GP/consultant information sheets or letters [FALOCN GP Letter]	1.1	20 May 2020
IRAS Application Form [IRAS_Form_14102020]		14 October 2020
Other [Wales REC 5 Favorable Opinion Letter]		04 June 2020
Participant consent form [FALCON Participant ICF]	1.3	14 July 2020
Participant consent form [FALCON Participant Regained]	1.0	09 October 2020

Capacity ICF (Scotland)]		
Participant consent form [Personal Legal Representative Consent Form]	1.0	15 October 2020
Participant information sheet (PIS) [FALCON PIS]	1.2	14 July 2020
Participant information sheet (PIS) [FALCON PIS Regained Capacity (Scotland)]	1.0	08 October 2020
Participant information sheet (PIS) [Personal Legal Representative Information Sheet]	1.0	15 October 2020
Research protocol or project proposal [FALCON Protocol]	1.4	16 October 2020
Summary CV for Chief Investigator (CI) [Chief Investigator CV]		14 October 2020

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: 289109 Please quote this number on all correspondence

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

Yours sincerely



Dr Ian Zealley
Chair

E-mail: Manx.Neill@nhslothian.scot.nhs.uk

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

“After ethical review – guidance for researchers” [SL-AR2 for other studies]

Copy to: *Ms Emma Columbine*
Lead Nation: England: approvals@hra.nhs.uk

Scotland A: Adults with Incapacity only

Attendance at Committee meeting on 29 October 2020

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mr Graham Ayres	Solicitor	Yes	
Dr Jill Bradshaw	Senior Lecturer in Intellectual and Developmental Disability	No	
Dr Laura Doull	Clinical Brain Sciences Project Manager	Yes	
Dr Jessica MacLaren	Registered Nurse-Lecturer in Mental Health	No	
Dr Mary-Joan Macleod	Clinical Pharmacologist/Consultant Physician	No	
Mrs Joanne Mair	Researcher	Yes	
Professor Brian McKinstry	Retired GP/Director Scottish Health Research Register	Yes	
Dr Anthony Pottage	Retired Physician/Clinical Pharmacologist	Yes	
Dr Lindsay Ramage	Head Of Research Governance	No	
Dr Jacqueline Stephen	Trial Statistician	Yes	
Dr Charles Wallis	Consultant in Anaesthesia & Intensive Care	Yes	
Dr Hester Ward	Public Health Consultant	Yes	
Mr Robert Wyllie	COVID-19 Clinical Guidance Cell Secretariat, Chief Medical Officer's Directorate	Yes	
Dr Ian Zealley	Consultant In Department Of Radiology	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Manx Neill	Scotland A/B REC Manager
Dr Helen Newbery	Scientific Officer
Mrs Sriparna Pal	Administrative Assistant-Scotland A REC

Written comments received from:

<i>Name</i>	<i>Position</i>
Dr Jessica MacLaren	Registered Nurse-Lecturer in Mental Health