



Health Research Authority

London - Brighton & Sussex Research Ethics Committee

Health Research Authority
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London
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Tel: 0207 104 8241

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

01 June 2020

Mr Scott Regan
Warwick Clinical Trials Unit
University of Warwick, Gibbet Hill Campus
Coventry
CV4 7AL

Dear Mr Regan

Study title:	Ventilation Strategies in COVID-19; CPAP, High-flow, and standard care
REC reference:	20/HRA/1696
Protocol number:	26/19-20
Amendment number:	SA 03
Amendment date:	01 June 2020
IRAS project ID:	282338

The above amendment was reviewed at the meeting of the Sub-Committee held on 01 June 2020.

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 Sub Committee recommended that the font size in the Easy Read information sheet is reduced slightly as currently it is an unnecessarily extensive eleven pages of length.**

Approved Documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [ERUK-recovery-rs-v3a(print)_v1.0 29.05.20.]	v1.0	29 May 2020
Copies of advertisement materials for research participants [ERUK-recovery-rs-v3a(screen)_v1.0 29.05.20.]	v1.0	29 May 2020
Notice of Amendment (non-CTIMP) [SA03 01.06.2020.]	SA 03	01 June 2020
Other [RECOVERY RS Consent Form Consultee v3.0 29.05.20_tracked changes.]	v3.0	29 May 2020
Other [RECOVERY RS Consultee Cover Letter V2.0 29.05.2020_tracked changes.]	v2.0	29 May 2020
Participant information sheet (PIS) [RECOVERY RS Patient Information Sheet v4 29-05-20_tracked changes.]	v4	29 May 2020
Participant information sheet (PIS) [RECOVERY RS PIS on Commencement v2.0 29-05-20_tracked changes.]	v2.0	29 May 2020
Participant information sheet (PIS) [RECOVERY RS Short Patient Information Sheet v4 29-05-20_tracked.]	v4	29 May 2020
Participant information sheet (PIS) [RECOVERY RS Short PIS on Commencement v2.0 29-05-20_tracked changes.]	v2.0	29 May 2020
Research protocol or project proposal [RECOVERY RS Protocol v4.0 29.05.20_changes.]	v4.0	29 May 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/>

20/HRA/1696:	Please quote this number on all correspondence
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Yours sincerely

A handwritten signature in black ink, appearing to read 'SW', with a small dot above the 'W'.

PP
Dr Simon Walton
Chair

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

Enclosures: List of names and professions of members who took part in the review

Copy to: Professor Gavin Perkins, University of Warwick Confidentiality Advise Team

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Attendance at Sub-Committee of the REC meeting on 01 June 2020

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr John Bull (Vice Chair)	Consultant Physician (retired)	Yes	
Mr Maurice Marchant	Public Health Information Specialist (retired)	Yes	

Also in Attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Charlotte Ferris	Approvals Officer
Dr Keith Haylock	Approvals Administrator