

East of England - Cambridge East Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

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.

19 May 2022

Peter Horby
University of Oxford
New Richards Building, Old Road Campus, Headington
Oxford
OX3 7LG

Dear Peter Horby

Study title:	Randomised Evaluation of COVID-19 Therapy (RECOVERY)
REC reference:	20/EE/0101
Protocol number:	NDPHRECOVERY
EudraCT number:	2020-001113-21
Amendment number:	RECOVERY Substantial Amendment 27
Amendment date:	16 May 2022
IRAS project ID:	281712

The above amendment was reviewed at the meeting of the Sub-Committee held 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 Sub-Committee has approved this amendment subject to the following reassurances:

Professor Haynes has clarified that 'high flow nasal oxygen' is a recognised term for a specialised form of oxygen delivery, and will be understood without risk of confusion by local research teams. It was confirmed that participants affected by the change in steroid dose have been or will be informed by the local PIs sensitively and in keeping with their condition. A decision as to whether and how to inform in writing will be taken once further data is available.

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]	1	16 May 2022
Cover Letter [RECOVERY SA27 REC cover letter]	1	17 May 2022
Letter from sponsor [RECOVERY SA27 sponsor approval]	1	17 May 2022
Participant information sheet (PIS) [RECOVERY PIS+ICF V23.0 tracked]	23.0	13 May 2022
Participant information sheet (PIS) [RECOVERY PIS+ICF_clean]	23.0	13 May 2022
Research protocol or project proposal [RECOVERY Protocol_clean]	24.0	13 May 2022
Research protocol or project proposal [RECOVERY Protocol_tracked]	24.0	13 May 2022

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

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

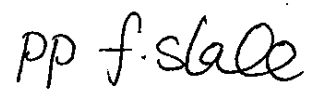
The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

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/>

Yours sincerely

A handwritten signature in black ink, appearing to read 'pp f. slae'.

Dr Alan Lamont
Chair

E-mail: CambridgeEast.REC@hra.nhs.uk

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

East of England - Cambridge East Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 19 May 2022

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Philip Bedford	Retired Study Responsible Scientist	Yes	
Mrs Victoria Hollamby	Research Governance Advisor	Yes	
Dr Alan Lamont	Retired Consultant Oncologist	Yes	Chaired the Meeting

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Faye Slade	Approvals Administrator