

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.

13 August 2021

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

Dear Professor 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:	Substantial Amendment 19
Amendment date:	06 August 2021
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 strongly advises the study team to check that any other documents publicly available on the website are updated to reflect currently available arms, and to be clear about discontinued arms, particularly relating to children.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Completed Amendment Tool [RECOVERY SA19 Amendment Tool]	1.0	09 August 2021
Cover Letter [RECOVERY SA19 REC cover letter]	1	06 August 2021
Letter from sponsor [RECOVERY SA19 Sponsor Approval]	1.0	09 August 2021
Participant information and informed consent form [RECOVERY PIS+ICF child V9.0 2021-08-10_CLEAN]	9.0	10 August 2021
Participant information and informed consent form [RECOVERY PIS+ICF child V9.0 2021-08-10_TRACKED]	9.0	10 August 2021
Participant information sheet (PIS) [RECOVERY PIS+ICF V15.0]	15.0	06 August 2021
Participant information sheet (PIS) [RECOVERY PIS+ICF]	15.0	06 August 2021
Research protocol or project proposal [RECOVERY Protocol V17.1 2021-08-10_CLEAN_REC_edited+rhV2]	17.1	10 August 2021
Research protocol or project proposal [RECOVERY Protocol V17.1 2021-08-10_TRACKED_REC_edited+rh]	17.1	10 August 2021

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.

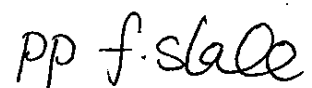
The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

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

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Attendance at Sub-Committee of the REC meeting on 11 August 2021

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
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