



Health Research Authority

East of England - Cambridge East Research Ethics Committee

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London
EC20 1JQ

Tel: 02071048181
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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 in England until the outcome of the HRA assessment has been confirmed.

26 May 2023

Prof Peter Horby
Professor of Emerging Infectious Diseases
University of Oxford
New Richards Building
Old Road Campus
Headington, Oxford
OX3 7LG

Dear Prof 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 30
Amendment date:	05 May 2023
IRAS project ID:	281712

The above amendment was reviewed at the meeting of the Sub-Committee held on 26 May 2023 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.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Completed Amendment Tool [RECOVERY SA30 amendment tool]	1	05 May 2023
Cover Letter [RECOVERY SA30 cover letter]	1	05 May 2023
Other [RECOVERY SA30 Sponsor approval]	1	16 May 2023
Other [Technical memo]	1	07 April 2023
Other [Stability report]	1	07 April 2023
Other [Comparability report]	1	07 April 2023

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/>

IRAS Project ID - 281712:

Please quote this number on all correspondence

Yours sincerely

Dr Alan Lamont
Chair
Pp. Laura Fairman
Approvals Administrator

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

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

Copy to: CTRG Confidentiality Advise Team

East of England - Cambridge East Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 26 May 2023

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	Chair

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Laura Fairman	Approvals Administrator - minutes