

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.**

23 November 2020

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

Dear 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 11
Amendment date:	19 November 2020
IRAS project ID:	281712

The above amendment was reviewed by the Sub-Committee 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>
Annex 2: Notification of Amendment [RECOVERY SA11 Annex 2]	1.0	19 November 2020
Completed Amendment Tool [RECOVERY SA11 Amendment Tool]	1.0	19 November 2020
Copies of materials calling attention of potential participants to the research [RECOVERY Poster]	3.0	11 November 2020
Cover Letter [RECOVERY SA11 REC cover letter]	1.0	19 November 2020
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [RECOVERY SA11 Sponsor Approval]	1.0	20 November 2020
Investigator Brochure/SmPC [REGN-COV2 IB]	4	13 November 2020
Participant information and informed consent form [RECOVERY PIS+ICF V10.1 (TC)]	10.1	21 November 2020
Research protocol or project proposal [RECOVERY Protocol V11.1 (TC)]	11.1	21 November 2020
Summary of product characteristics (SmPC) [Colchicine SmPC]	1	20 August 2019

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 be 'A. Lamont', written over a horizontal line.

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

Copy to: NA NA CTRGConfidentiality Advise Team

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Attendance at Sub-Committee of the REC meeting on 20 November 2020

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Philip Bedford	Retired Study Responsible Scientist	Yes	
Dr Alan Lamont/Chair	Retired Consultant Oncologist	Yes	
Mr Trevor McCann	Retired Strategic Development Consultant	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Joy Uzoma	Approvals Administrator