

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.

08 April 2020

Peter Horby
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: SA02
Amendment date:
IRAS project ID: 281712

The above amendment was reviewed on 07 April 2020 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>
Cover Letter		07 April 2020

Investigator Brochure/SmPC [Azithromycin SmPC]		25 September 2019
Investigator Brochure/SmPC [Hydrocortisone SmPC]		02 November 2018
Investigator Brochure/SmPC [Prednisolone SmPC]		18 February 2020
IRAS Application Form [for SA2]		07 April 2020
Letter from sponsor		07 April 2020
Other [Email correspondence with the REC Chair]		08 April 2020
Participant information and informed consent form [Tracked changes]	3	07 April 2020
Participant information and informed consent form	3	07 April 2020
Research protocol or project proposal [Tracked changes]	3	07 April 2020
Research protocol or project proposal	3	07 April 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.

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/>

20/EE/0101:	Please quote this number on all correspondence
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Yours sincerely



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 CTRG*

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Attendance at Sub-Committee of the REC meeting on 07 April 2020

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Alan Lamont (Chair)	Retired Consultant Oncologist	Yes	
Dr Derek Prater	Pharmacist	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Tad Jones	Approvals Officer