



Health Research Authority

East of England - Cambridge East Research Ethics Committee

2 Redman Place
London
EC20 1JQ

Tel: 02071048181

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.

04 August 2025

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:	Substantial Amendment 37
Amendment date:	30 June 2025
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.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Completed Amendment Tool [6. 281712_Substantial Amendment 37_LOCKED25July2025]	1	30 June 2025
Cover Letter [1a. RECOVERY SA37 cover letter UK REC]	1	31 July 2025
Cover Letter [1b. RECOVERY SA37 cover letter UK REC]	1	31 July 2025
Letter from sponsor [7. RECOVERY SA37 sponsor approval]	1	25 July 2025
Participant consent form [3a. RECOVERY PIS+ICF V27.0 2025-06-30 tracked]	27.0	30 June 2025
Participant consent form [3b. RECOVERY PIS+ICF V27.0 2025-06-30]	27.0	30 June 2025
Participant consent form [4a. RECOVERY PIS+ICF child V16.0 2025-06-30 tracked]	16.0	30 June 2025
Participant consent form [4b. RECOVERY PIS+ICF child V16.0 2025-06-30]	16.0	30 June 2025
Research protocol or project proposal [2a. RECOVERY Protocol V28.0 2025-06-30 tracked]	28.0	30 June 2025
Research protocol or project proposal [2b. RECOVERY Protocol V28.0 2025-06-30]	28.0	30 June 2025
Summary of product characteristics (SmPC) [5. Baloxavir marboxil SmPC V2 (EU-1-20-1500-001 2025-06-02)]	2	02 June 2025

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
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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: N/A RGEA, University of Oxford / Research Governance, Ethics and Assurance Confidentiality Advise Team

East of England - Cambridge East Research Ethics Committee

Attendance at Sub-Committee of the REC meeting held in correspondence

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	Retired Consultant Oncologist	Yes	Chair
Dr Helena Tattersall	Research Integrity Officer	Yes	Shadowing the meeting, did not contribute to the review

Also in attendance:

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