

East of England - Cambridge East Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

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.**

17 October 2022

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 29 |
| Amendment date: | 12 October 2022 |
| IRAS project ID: | 281712 |

The above amendment was reviewed at the meeting of the Sub-Committee held on 17 October 2022 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 SA29 Amendment Tool] | 1 | 12 October 2022 |
| Letter from sponsor [RECOVERY SA29 sponsor approval] | 1 | 14 October 2022 |
| Other [Sotrovimab extension memo] | 1 | 28 September 2022 |
| Other [Sotrovimab expiry extension report] | 1 | 11 August 2022 |

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: NA NA CTRGConfidentiality Advise Team

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Attendance at Sub-Committee of the REC meeting on 17 October 2022

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 | Meeting Chair |

Also in attendance:

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