

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.

20 December 2021

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

Dear Peter 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 23 |
| Amendment date: | 17 December 2021 |
| 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.

The Sub-Committee had the following comments:

The Sub-Committee noted a typographical error in the new protocol text 2.8.1.1 'resistance makers' should be 'markers'. This can be addressed in a future amendment.

Approved documents

The documents reviewed and approved at the meeting were:

| <i>Document</i> | <i>Version</i> | <i>Date</i> |
|---|----------------|------------------|
| Completed Amendment Tool [Amendment Tool] | 1 | 17 December 2021 |
| Cover Letter [RECOVERY SA23 Justification of changes] | 1 | 17 December 2021 |
| Cover Letter [RECOVERY SA23 REC cover letter] | 1 | 17 December 2021 |
| Letter from sponsor [RECOVERY SA23 sponsors approval] | 1 | 17 December 2021 |
| Other [RECOVERY SAP v3.1] | 3.1 | 29 October 2021 |
| Participant information and informed consent form [RECOVERY PIS+ICF V19.1] | 19.1 | 19 December 2021 |
| Participant information and informed consent form [RECOVERY PIS+ICF V19.1 2021-12-19_TRACKED] | 19.1 | 19 December 2021 |
| Participant information and informed consent form [RECOVERY PIS+ICF child V13.1] | 13.1 | 19 December 2021 |
| Participant information and informed consent form [RECOVERY PIS+ICF child V13.1 2021-12-19_TRACKED] | 13.1 | 19 December 2021 |
| Research protocol or project proposal [RECOVERY Protocol v21.1 Tracked Changes] | 21.1 | 19 December 2021 |
| Research protocol or project proposal [RECOVERY Protocol v21.1] | 21.1 | 19 December 2021 |
| Summary of product characteristics (SmPC) [Molnupiravir SmPC] | 1 | 05 November 2021 |
| Summary of product characteristics (SmPC) [Sotrovimab SmPC] | 1 | 01 December 2021 |

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.

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/>

Please quote this number on all correspondence

pp f. slide

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

Copy to: CTRG Confidentiality Advise Team

East of England - Cambridge East Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 17 December 2021

Committee Members:

| <i>Name</i> | <i>Profession</i> | <i>Present</i> | <i>Notes</i> |
|------------------|---|----------------|---------------------|
| Mr John Chandler | Former Chief Executive PSP Association | Yes | |
| Dr Alan Lamont | Retired Consultant Oncologist | Yes | Chaired the Meeting |

Also in attendance:

| <i>Name</i> | <i>Position (or reason for attending)</i> |
|-----------------|---|
| Miss Faye Slade | Approvals Administrator |