



# Health Research Authority

## East of England - Cambridge East Research Ethics Committee

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**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.**

03 November 2023

Prof Peter Horby  
Professor of Emerging Infectious Diseases  
University of Oxford  
New Richards Building  
Old Road Campus  
Headington, Oxford  
OX3 7LG

Dear Prof Horby

<b>Study title:</b>	<b>Randomised Evaluation of COVID-19 Therapy (RECOVERY)</b>
<b>REC reference:</b>	<b>20/EE/0101</b>
<b>Protocol number:</b>	<b>NDPHRECOVERY</b>
<b>EudraCT number:</b>	<b>2020-001113-21</b>
<b>Amendment number:</b>	<b>Substantial Amendment 33</b>
<b>Amendment date:</b>	<b>13 September 2023</b>
<b>IRAS project ID:</b>	<b>281712</b>

The above amendment was reviewed at the meeting of the Sub-Committee held on 03 November 2023 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.

## Recommendations

The Committee recommends:

1. additional clarification is needed to pre-empt possible confusion about eligibility, particularly in the training that site staff will receive regarding the community-acquired pneumonia training module, to include-
  - a. Reasons for exclusion of people with suspected TB and Pneumocystis infection (including the change in terminology, meaning PJP is the same as PCP)
  - b. Clarification that the protocol eligibility currently requires planned antibiotic treatment for inclusion in the CAP comparison (so patients with fungal infection are not eligible).
  - c. Clarification that the protocol currently states that all treatments remain at the discretion of the clinician acting in the patient's best interest (so that, for example if Mycoplasma infection was diagnosed and steroids were considered indicated after randomisation, these should be given regardless of trial treatment allocation).
2. The protocol should in due course be updated, for example at the time of the next amendment, to update the text to be the definitive source document for the conduct of the study in the light of the above.

## Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Completed Amendment Tool [281712_Substantial Amendment 33]	1	13 September 2023
Cover Letter [RECOVERY SA33 REC cover letter]	1	23 October 2023
Letter from sponsor [RECOVERY SA33 sponsor approval]	1	26 October 2023
Other [Justification for RECOVERY Protocol V27]	1	13 September 2023
Participant consent form [RECOVERY PIS+ICF V26.0 2023-09-13 TRACKED]	26.0	13 September 2023
Participant consent form [RECOVERY PIS+ICF V26.0 2023-09-13]	26.0	13 September 2023
Research protocol or project proposal [RECOVERY Protocol V27.0 2023-09-13 TRACKED]	27.0	13 September 2023
Research protocol or project proposal [RECOVERY Protocol V27.0 2023-09-13]	27.0	13 September 2023

## 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](mailto:CambridgeEast.REC@hra.nhs.uk)

*Enclosures: List of names and professions of members who took part in the review*

Copy to: CTRGConfidentiality Advise Team

**East of England - Cambridge East Research Ethics Committee**

**Attendance at Sub-Committee of the REC meeting on 03 November 2023**

**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 – meeting Chair

**Also in attendance:**

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