

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.

12 July 2021

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: RECOVERY SA18
Amendment date: 06 July 2021
IRAS project ID: 281712

The above amendment was reviewed 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>
Completed Amendment Tool [281712_Substantial Amendment 18]	1	05 July 2021
Cover Letter [RECOVERY SA18 REC cover letter]	1	06 July 2021
Letter from sponsor [RECOVERY SA18 Sponsor Approval]	1	06 July 2021
Other [RECOVERY SA18 Justification of changes]	1	05 July 2021
Participant information sheet (PIS) [RECOVERY PIS+ICF V14.0 2021-06-30]	14.0	30 June 2021

Participant information sheet (PIS) [RECOVERY PIS+ICF V14.0 2021-06-30_TRACKED]	14.0	30 June 2021
Research protocol or project proposal [RECOVERY Protocol V16.1 2021-07-08 (CLEAN)]	16.1	08 July 2021
Research protocol or project proposal [RECOVERY Protocol V16.1 2021-07-08_TRACKED]	16.1	05 July 2021
Summary of product characteristics (SmPC) [Empagliflozin SmPC V1.0 2020-10-22]	1	22 October 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.

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

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

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

*Copy to: Peter Horby, University of Oxford
NA NA CTRGConfidentiality Advise Team*

East of England - Cambridge East Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 07 July 2021

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mrs Victoria Hollamby	Research Governance Advisor	Yes	
Dr Alan Lamont		Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Chelsea Phillips	Approvals Administrator