

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.

14 July 2020

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

Dear 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 7
Amendment date:	03 July 2020
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.

Recommendation

1) please correct the drafting error as highlighted-
RECOVERY PIS ICF Child.... There is a typo on page 5:

WHAT YOU SHOULD KNOW ABOUT THIS RESEARCH STUDY: 1) Why is this research being done?
Paragraph 3. The RECOVERY trial has recently shown that dexamethasone, a steroid medicine, can be used to treat adults with COVID-19 who need oxygen. There are several other medicines which may turn out to be helpful (or possibly harmful) when added to the usual standard of care. We are learning more about the condition called PIMS-TS all the time, as this condition has only been recently **identified. don't** know yet if specific treatments that might be useful in active COVID-19 infection might also be helpful in children with PIMS-TS. This study aims to find out whether any of these additional treatments are of any help for COVID-19 in children or the illness linked to previous COVID-19.

2) Please confirm the GP will be informed about the advice not to administer live vaccines for three months after immunoglobulin

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Annex 2: Notification of Amendment [Annex 2]	1	09 July 2020
Completed Amendment Tool [Amendment Tool]	1	09 July 2020
Covering letter on headed paper [RECOVERY SA7 REC cover letter]	1	09 July 2020
Other [Letter of support paediatric RECOVERY]	1	04 July 2020
Other [Justification of changes]	1	08 July 2020
Other [MHRA Approval Letter]		13 July 2020
Participant information sheet (PIS) [RECOVERY PIS+ICF child]	4.0	08 July 2020
Participant information sheet (PIS) [RECOVERY PIS+ICF Tracked]	7.0	08 July 2020
Participant information sheet (PIS) [RECOVERY PIS+ICF]	7.0	08 July 2020
Participant information sheet (PIS) [RECOVERY PIS+ICF child tracked]	4.0	08 July 2020
Referee's report or other scientific critique report [Letter of support]	1	04 July 2020
Research protocol or project proposal [RECOVERY Protocol]	8.0	08 July 2020
Research protocol or project proposal [RECOVERY Protocol tracked]	8.0	08 July 2020
Summary of product characteristics (SmPC) [Privigen SmPC]	1	09 July 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/>

20/EE/0101:	Please quote this number on all correspondence
--------------------	-------------------------------------------------------

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: NA NA CTRG Confidentiality Advise Team

East of England - Cambridge East Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 10 July 2020

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Alan Lamont/Chair	Retired Consultant Oncologist	Yes	
Miss Sophie Newton	Hearing Implant Research Nurse	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Joy Uzoma	