

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.

16 April 2020

Peter Horby
1st Floor, Boundary Brook House
Churchill Drive
Headington, Oxford
OX3 7GB

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:	SA3
Amendment date:	14 April 2020
IRAS project ID:	281712

The above amendment was 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>
Annex 2: Notification of Amendment [RECOVERY SA3 Amendment Form 2020-04-14.pdf]	SA3	14 April 2020
Cover Letter [RECOVERY SA3 REC cover letter.pdf]		
Letter from sponsor [RECOVERY SA3 Sponsor approval 2020-04-14.pdf]		14 April 2020
Participant information and informed consent form [RECOVERY PIS+ICF V4.1 2020-04-16 TRACKED.docx]	4.1	16 April 2020
Participant information sheet (PIS) [RECOVERY_Legal Representative PIS V1.1 2020-04-08 TRACKED.docx]	1.1	08 April 2020
Participant information sheet (PIS) [RECOVERY_Legal Representative PIS V1.1 2020-04-08.pdf]	1.1	08 April 2020
Research protocol or project proposal [RECOVERY Protocol V4.0 2020-04-14.pdf]	4.0	14 April 2020
Research protocol or project proposal [RECOVERY Protocol V4.0 2020-04-14 TRACKED.docx]	4.0	14 April 2020
Summary of product characteristics (SmPC) [Tocilizumab SmPC.pdf]		

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.

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
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Yours sincerely

A handwritten signature in black ink, appearing to read 'PP/LA/GW'.

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

East of England - Cambridge East Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 16 April 2020

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	