

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.

17 November 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 21
Amendment date:	12 November 2021
IRAS project ID:	281712

The above amendment was reviewed at the meeting of the Committee held on 16 November 2021.

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 [RECOVERY SA21 Amendment Tool]	1	12 November 2021
Cover Letter [RECOVERY SA21 REC cover letter]	1	13 November 2021
Letter from sponsor [RECOVERY SA21 Sponsor approval]	1	12 November 2021

Other [Justification for RECOVERY Protocol V19]	1	11 November 2021
Participant information and informed consent form [RECOVERY PIS+ICF child V11.1 2021-11-17]	11.1	17 November 2021
Participant information and informed consent form [RECOVERY PIS+ICF V17.1 2021-11-17]	17.1	17 November 2021
Participant information and informed consent form [RECOVERY PIS+ICF child V11.1 2021-11-17_TRACKED]	11.1	17 November 2021
Participant information and informed consent form [RECOVERY PIS+ICF V17.1 2021-11-17_TRACKED]	17.1	17 November 2021
Referee's report or other scientific critique report [UKTIS scientific evidence]	1	09 September 2021
Research protocol or project proposal [RECOVERY Protocol V19.1 2021-11-16_TRACKED]	19.1	16 November 2021
Research protocol or project proposal [RECOVERY Protocol V19.1 2021-11-16]	19.1	16 November 2021
Summary of product characteristics (SmPC) [Baloxavir SmPC]	1	26 August 2021
Summary of product characteristics (SmPC) [Oseltamivir SmPC]	1	25 May 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.

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

Copy to: *CTRG Confidentiality Advise Team*

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Attendance at Committee meeting on 16 November 2021

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Philip Bedford	Retired Study Responsible Scientist	Yes	
Dr Helen Burns (BIS 08/07/2021 - 07/01/2022)	Retired GP	No	
Dr Alan Calverd	Scientific Consultant	Yes	
Mr John Chandler	Former Chief Executive PSP Association	Yes	
Mr Edward Gibbes	Freelance journalist	Yes	
Mrs Helen Hall	Research Grants Advisor	Yes	
Dr Fay Hartley	Pharmacist	Yes	
Dr Sinead Healy	Research Governance Facilitator	Yes	
Mrs Victoria Hollamby	Research Governance Advisor	No	
Dr Alan Lamont	Retired Consultant Oncologist	Yes	Chaired the Meeting
Mr Trevor McCann	Retired Strategic Development Consultant	No	
Mrs Sophie McKenny (née Newton)	Hearing Implant Research Nurse	Yes	
Dr Derek Prater	Pharmacist	Yes	
Dr Wendi Qian	Senior Statistician	No	
Dr Jessica Santos	Global Compliance & Quality Director	No	
Dr Joyce Whittington	Psychologist	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Dr Stephanie Clutterbuck	Approvals Officer
Laura Greenfield	Approvals Specialist