

**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.**

30 April 2020

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

Dear 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 4</b>
<b>Amendment date:</b>	<b>28 April 2020</b>
<b>IRAS project ID:</b>	<b>281712</b>

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>
Annex 2: Notification of Amendment	substantial amendment 4	28 April 2020
Covering letter on headed paper		24 April 2020
Other [SmPC for methylprednisolone]		27 April 2020
Other [Data privacy notice (clean)]	1.4	24 April 2020
Other [Data privacy notice (TC)]	1.4	24 April 2020
Other [PIS Animation Storyboard]		20 April 2020
Other [RECOVERY PIS+ICF child]	1.0	24 April 2020
Other [IRAS form]		28 April 2020
Other [Sponsor approval ]		28 April 2020
Protocol [clean]	5.0	24 April 2020
Protocol [Tracked changes]	5.0	24 April 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.

### **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/>

<b>20/EE/0101:</b>	<b>Please quote this number on all correspondence</b>
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Yours sincerely

PP. 

**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*

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

**Attendance at Sub-Committee of the REC meeting on 29 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/Chair	Retired Consultant Oncologist	Yes	

**Also in attendance:**

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