

**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.**

27 January 2021

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

Dear Professor 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 13</b>
<b>Amendment date:</b>	<b>26 January 2021</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>
Completed Amendment Tool [Amendment Tool SA13]	1.0	26 January 2021
Cover Letter [REC Cover Letter]	1	26 January 2021
Letter from sponsor [RECOVERY SA13 Sponsor Approval]	1	26 January 2021
Other [RECOVERY SA13 Justification of changes]	1.0	26 January 2021
Participant information sheet (PIS) [RECOVERY PIS+ICF (tracked)]	11.0	26 January 2021
Participant information sheet (PIS) [RECOVERY PIS+ICF]	11.0	26 January 2021
Participant information sheet (PIS) [RECOVERY PIS+ICF child]	8.0	26 January 2021
Participant information sheet (PIS) [RECOVERY PIS+ICF child (tracked)]	8.0	26 January 2021
Research protocol or project proposal [RECOVERY Protocol]	13.0	26 January 2021
Research protocol or project proposal [RECOVERY Protocol (tracked)]	13.0	26 January 2021
Summary of product characteristics (SmPC) [Baricitinib SmPC]	1.0	07 December 2020
Summary of product characteristics (SmPC) [Anakinra SmPC]	1.0	28 May 2020
Summary of product characteristics (SmPC) [Dexamethasone SmPC]	1.0	01 May 2018

## **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**

Yours sincerely

A handwritten signature in black ink, appearing to be 'V. Hollamby', written in a cursive style.

**Victoria Hollamby**  
**Vice 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 CTRGConfidentiality Advise Team*

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**Attendance at Sub-Committee of the REC meeting on 27 January 2021**

**Committee Members:**

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mrs Victoria Hollamby/Chair	Research Governance Advisor	Yes	
Dr Derek Prater	Pharmacist	Yes	

**Also in attendance:**

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