

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

The Old Chapel  
Royal Standard Place  
Nottingham  
NG1 6FS

15 September 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 8  
**Amendment date:** 10 September 2020  
**IRAS project ID:** 281712

Thank you for submitting the above amendment, which was received on 15 September 2020. I can confirm that this is a valid notice of a substantial amendment and will be reviewed by the Sub-Committee of the REC at its next meeting.

**Documents received**

The documents to be reviewed are as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Annex 2: Notification of Amendment [Annex 2]	1.0	15 September 2020
Completed Amendment Tool [Amendment Tool]	1.0	15 September 2020
Cover Letter [RECOVERY SA8 REC cover letter]	1.0	15 September 2020
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [RECOVERY SA8 Sponsor Approval]	1.0	15 September 2020
Investigator Brochure/SmPC [Investigators' Brochure REGN10933+REGN10987]	3	26 June 2020
Other [Safety Summary for RECOVERY Study]	1.0	27 August 2020
Other [REGN10933+REGN10987-dose rationale for RECOVERY study]	1.0	10 September 2020

Other [RECOVERY - Data privacy notice V2.0 2020-09-11_TRACKED]	2.0	11 September 2020
Other [RECOVERY SA8 Justification of changes V1.0 2020-09-15]	1.0	15 September 2020
Other [RECOVERY - Data privacy notice V2.0 2020-09-11]	2.0	11 September 2020
Participant information sheet (PIS) [RECOVERY PIS+ICF child]	5.0	10 September 2020
Participant information sheet (PIS) [RECOVERY PIS+ICF V8.0 2020-09-10]	8.0	10 September 2020
Participant information sheet (PIS) [RECOVERY PIS+ICF child V5.0 2020-09-10_TRACKED]	5.0	10 September 2020
Participant information sheet (PIS) [RECOVERY PIS+ICF V8.0 2020-09-10_TRACKED]	8.0	10 September 2020
Research protocol or project proposal [RECOVERY Protocol V9.0 2020-09-10_TRACKED]	9.0	10 September 2020
Research protocol or project proposal [RECOVERY Protocol V9.0 2020-09-10_CLEAN]	9.0	10 September 2020

### Notification of the Committee's decision

The Committee will issue an ethical opinion on the amendment within a maximum of 35 days from the date of receipt.

### R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval for the research.

### 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>IRAS Project ID:281712:</b>	<b>Please quote this number on all correspondence</b>
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Yours sincerely



**Joy Uzoma**

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Copy to: NA NA CTRG