

Email: approvals@hra.nhs.uk

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

28 January 2021
Reissued 2 February 2021

Dear Professor Horby

<p>Confirmation of Continued HRA Approval following Urgent Safety Measure</p>
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Study title:	Randomised Evaluation of COVID-19 Therapy (RECOVERY)
IRAS project ID:	281712
EudraCT number:	2020-001113-21
Protocol number:	NDPHRECOVERY
REC reference:	20/EE/0101
Amendment number:	17 (your ref SA14)
Amendment date:	28th January 2021
Amendment Category	C
Sponsor:	University of Oxford

Thank you for notifying the HRA of the above substantial amendment.

The HRA acknowledges that this falls within the category of an Urgent Safety Measure as described in version 7.4 of the Standard Operating Procedures for Research Ethics Committees.

The Clinical Trials Regulations provide that the sponsor or the Chief Investigator, or the local Principal Investigator at a trial site, may take appropriate urgent safety measures in order to protect the subjects of a CTIMP against any immediate hazard to their health or safety.

Following an assessment of the documentation, I can confirm **continued HRA Approval** for this application.

The documents assessed as part of this urgent safety measure are listed in *Appendix A*.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please email the HRA at approvals@hra.nhs.uk. Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>.

Your IRAS project ID is **281712**. Please quote this on all correspondence.

Yours sincerely

Catherine Adams
Approvals Manager

Email: approvals@hra.nhs.uk

Copy to: *OUHFT Research and Development Dept, Oxford Radcliffe Hospitals NHS
Foundation Trust
Richard Haynes, University of Oxford
NA NA CTRG*

Appendix A - List of Documents

The document set assessed as part of the amendment is below.

<i>Document</i>	<i>Version</i>	<i>Date</i>
Completed Amendment Tool [RECOVERY SA14 Amendment Tool]	1.0	27 January 2021
Cover Letter [RECOVERY SA14 REC cover letter]	1	28 January 2021
Letter from sponsor [RECOVERY SA14 Sponsor Approval]	1	28 January 2021
Other [RECOVERY Vaccine letter safety-report-form]	1	27 January 2021
Other [RECOVERY Vaccination letter]	1.0	27 January 2021

