



Centre for Tropical Medicine and Global Health

Nuffield Department of Medicine
Nuffield Department of Medicine Research Building
University of Oxford
Old Road Campus, Roosevelt Drive
Headington
OXFORD
OX3 7FZ

Cambridge East REC
E-submission

14 May 2020

Dear Sir or Madam

Trial: Randomised evaluation of Covid-19 therapy (RECOVERY)
EudraCT: 2020-001113-21
IRAS: 281712
REC ref: 20/EE/0101

Please find enclosed an application for an expedited authorisation of a substantial amendment for the above trial. The main reason for this amendment is to seek approval:

1. To include convalescent plasma as a treatment in the trial. This is being collected by NHS Blood and Transplant who are responsible for collection, quality control and delivery to sites. As described in the protocol it will be offered in a "factorial" design with the main randomization. Patients are free to opt out of this intervention and we have changed the PIS/ICF to include an option to do this.

We would like to request that this amendment is a **category A** amendment with agreement from trusts requested within 3 working days (as previously discussed with HRA).

I believe all the necessary documentation required for this submission is attached and look forward to hearing the outcome.





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Please let us know if you require any further information.

Yours faithfully

A handwritten signature in blue ink, appearing to read 'Peter Horby', with a long horizontal flourish underneath.

Professor Peter W. Horby

BSc MSc MBBS FRCP FFPH PhD

Chief Investigator, RECOVERY Trial

Professor of Emerging Infectious Diseases and Global Health

Attached files:

1. Cover letter
2. Notification of Amendment form
3. RECOVERY Protocol V6.0 2020-05-12 (clean and tracked)
4. RECOVERY PIS+ICF V5.0 2020-05-11 (clean and tracked)
5. RECOVERY PIS+ICF (children) V2.0 2020-05-11 (clean and tracked)
6. Sponsor Approval of Amendment

