



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

24 April 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 to recruit children into the trial. This has been discussed with an expert advisory group of paediatricians and neonatologists who have drafted the relevant sections of the protocol and the child-specific information. They also received input from a number of Young People's Groups who reviewed the information materials.

We are also seeking approval of an animation of the participant information sheet that we hope could be used to introduce the trial to potential participants.

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.

Please let us know if you require any further information.





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Yours faithfully

A handwritten signature in blue ink, appearing to read 'P. Horby', with a long horizontal flourish at the bottom.

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. Updated IRAS form
4. RECOVERY Protocol V5.0 2020-04-24 (clean and tracked)
5. RECOVERY PIS+ICF child V1.0 2020-04-24
6. Participant Privacy Notice V1.4 2020-04-24 (clean and tracked)
7. RECOVERY PIS Animation Storyboard 2020-04-20
8. SmPC for methylprednisolone
9. Sponsor Approval of Amendment

