



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

13 October 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 non-substantial amendment for the above trial. The reason for this amendment is to seek approval to send participants a letter to inform them about the results to date in the RECOVERY trial and to allow them to sign-up to receive future newsletters electronically.

These newsletters will be distributed by NHS Digital and equivalent bodies in the devolved nations (as part of the NHS DigiTrials initiative). These bodies will do a vital status check prior to mailing to avoid sending these letters to deceased participants. We have sought feedback from the Nuffield Department of Population Health's Public Advisory Panel and from the NHS DigiTrials Co-development Panel and the text has been modified accordingly. We have two letters: one for adult participants and one for the parents or guardians of children who have participated. The public panels have recommended that in future newsletters we consider writing directly to children and to the relatives of deceased participants.

As discussed with the chair of the REC, future newsletters would be similar in style and content and we propose to inform the REC when future newsletters have been sent but would not seek approval for each one.

We would like to request that this amendment is a **category C** amendment.

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. RECOVERY SA09 Amendment Tool
2. RECOVERY Participant Letter (Adults) V1.0 2020-10-11
3. RECOVERY Participant Letters (Parents) V1.0 2020-10-11
4. RECOVERY SA09 Sponsor Approval

