



## 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

15 December 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 allow children with PIMS-TS (the inflammatory syndrome associated with COVID-19 in children) to be recruited into the trial even if none of the main randomization options are both suitable and available (e.g. they have already received them as usual care). Currently, such children cannot enter the trial so cannot access the second randomization between tocilizumab and control. With this amendment we propose to allow them to be recruited (but not randomized in the first randomization), but subsequently randomized between tocilizumab and control.

We would like to request that this amendment is a **category C** amendment, with sites having 3 days to review as agreed before 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.

Yours faithfully

**Professor Peter W. Horby**

BSc MSc MBBS FRCP FFPH PhD  
Chief Investigator, RECOVERY Trial  
Professor of Emerging Infectious Diseases and Global Health





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Attached files:

1. RECOVERY SA12 Amendment Tool
2. RECOVERY SA12 Sponsor Approval
3. RECOVERY Protocol V12.0 (tracked and clean)
4. RECOVERY Protocol V11.2 (tracked and clean)
5. RECOVERY Children PIS V7.0 (tracked and clean)

