



## 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

7 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 reasons for the substantial amendment are details in the Notice of Substantial Amendment, but in summary include:

1. Adding suspected SARS-CoV-2 infection to inclusion criteria (so now suspected or proven) in order to facilitate recruitment and likelihood of testing not being done, being falsely negative or introducing untoward delay in delivery of treatment.
2. Adding azithromycin as another arm in the randomization (and removing inhaled interferon- $\beta$ ) on advice of government's advisory panel.
3. Allowing use of consent by legal representative for people who lack capacity for long-term reasons (e.g. dementia).
4. Change in primary outcome to include all deaths within 28 days after randomization (not just those that occur in-hospital)
5. Modification to corticosteroid arm to allow different form of corticosteroid for pregnant women (where such alternatives are preferred by treating doctors).
6. The Statistical Analysis section has been modified to be consistent with the full Statistical Analysis Plan which is being finalized.

We would like to request that this amendment is a **category C** amendment as we do not have 35 days to wait for trusts to respond before we implement it. As we will be able to ensure the supply of azithromycin we do not think there are any local requirements that would need to be considered.

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 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. RECOVERY Protocol V3.0 2020-04-07 (clean and tracked)
3. RECOVERY PIS+ICF V3.0 2020-04-07 (clean and tracked)
4. Azithromycin Summary of Product Characteristics
5. Prednisolone Summary of Product Characteristics
6. Hydrocortisone Summary of Product Characteristics
7. Sponsor Approval of Amendment

