



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

30 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 substantial amendment for the above trial. The main reason for this amendment is to seek approval to add an additional randomization at study entry (main randomization part C) between aspirin and usual care alone. This is to investigate whether the 'blood thinning' effects of aspirin can reduce morbidity and mortality from thrombotic events, and its anti-inflammatory effects are also beneficial.

We have also taken this opportunity to remove unnecessary duplication from the protocol to improve clarity for the reader.

We would like to request that this amendment is a **category A** 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 SA10 Amendment Tool
2. RECOVERY SA10 Sponsor Approval
3. RECOVERY Protocol V10.0 (tracked and clean)
4. RECOVERY Adult PIS V9.0 (tracked and clean)
5. RECOVERY Children PIS V6.0 (tracked and clean)
6. Aspirin SmPC
7. Justification of aspirin dose for pregnant women V1.0 2020-10-29

