



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

19 November 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 colchicine to the main randomization (part A) of this trial. This is to investigate whether its anti-inflammatory effects are beneficial. We also wish to stop recruiting participants to the azithromycin comparison as we have sufficient participants to answer this question now.

We have also taken this opportunity to submit a revised version of the trial poster, and the new version of the REGN-COV2 Investigators' Brochure.

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 SA11 Amendment Tool
2. RECOVERY SA11 Sponsor Approval
3. RECOVERY Protocol V11.0 (tracked and clean)
4. RECOVERY Adult PIS V10.0 (tracked and clean)
5. Colchicine SmPC 2019-08-20
6. RECOVERY Poster V3.0 2020-11-11
7. REGN-COV2 Investigators' Brochure V4.0

