



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 February 2021

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 early phase assessment of dimethyl fumarate to the protocol. A full justification is enclosed.

We would like to request that this amendment is **category A**, as per the amendment tool.

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. Clinical Trial Protocol V14.0 (tracked and clean)
2. Notification of Substantial Amendment form, Annex 2 form
3. RECOVERY PIS/ICF (adult) V12.0 (tracked and clean)
4. Justification of changes for protocol V14.0
5. Dimethyl fumarate SmPC
6. Sponsor approval

