



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

6 July 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. We are applying for this amendment for the following reasons:

1. The REGEN-COV arm has been completed (and results announced). We therefore wish to remove this IMP from the protocol.
2. The COVID-19 Therapeutics Advisory Panel have advised that we add an SGLT-2 inhibitor (empagliflozin) to the trial protocol. We provide a full justification in the enclosed documents.
3. We wish to remove infliximab from the protocol for reasons explained in the enclosed justification document.

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

A handwritten signature in blue ink, appearing to read 'P. Horby', with a long horizontal flourish underneath.

Professor Sir Peter W. Horby

BSc MSc MBBS FRCP FFPH PhD
Chief Investigator, RECOVERY Trial





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Professor of Emerging Infectious Diseases and Global Health

Attached files:

1. RECOVERY Protocol V16.0 (tracked and clean)
2. RECOVERY PIS/ICF (adult) V14.0 (tracked and clean)
3. Empagliflozin SmPC
4. Letter confirming sponsor approval
5. Amendment Tool for SA17
6. Justification for SA17

