



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

26 January 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 baricitinib and anakinra to the protocol. We also wish to stop recruiting adults into the tocilizumab comparison and any participants into the convalescent plasma comparison as we have sufficient participants to answer these questions now. A full justification is enclosed.

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

Attached files:





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1. RECOVERY SA11 Amendment Tool
2. RECOVERY SA11 Sponsor Approval
3. RECOVERY Protocol V13.0 (tracked and clean)
4. RECOVERY Adult PIS V11.0 (tracked and clean)
5. RECOVERY Children PIS V8.0 (tracked and clean)
6. Baricitinib SmPC 2020-12-07
7. Anakinra SmPC 2020-05-28
8. Dexamethasone SmPC 2020-05-16
9. Justification of changes in protocol V13.0

