



Centre for Tropical Medicine and Global Health

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Cambridge East REC
E-submission

13 November 2021

Dear Dr Lamont

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 authorisation of a substantial amendment for the above trial. This amendment adds patients with influenza pneumonia to the protocol. It is anticipated that there will be a major influenza season this year which could lead to several thousand deaths, but little is known about treatments to reduce mortality from this among hospitalized patients. As described in the enclosed justification, RECOVERY is ideally positioned to address this important public health question.

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 Sir Peter W. Horby

BSc MSc MBBS FRCP FFPH PhD
Chief Investigator, RECOVERY Trial
Professor of Emerging Infectious Diseases and Global Health

Attached files:

1. RECOVERY Protocol V11.0 2021-11-12 (tracked and clean)
2. RECOVERY PIS/ICF (adult) V17.0 2021-11-12 (tracked and clean)
3. RECOVERY PIS/ICF (child) V11.0 2021-11-12
4. Justification for RECOVERY Protocol V19.0
5. SmPCs for oseltamivir and baloxavir
6. UK Teratology Information Service advice for use of baloxavir in pregnancy
7. Letter confirming sponsor approval
8. Amendment Tool for SA21