



Centre for Tropical Medicine and Global Health

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Cambridge East REC
E-submission

25 January 2022

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. A full justification of this amendment is enclosed.

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 V22.0 2022-01-19 (tracked and clean)
2. RECOVERY PIS/ICF (adult) V20.0 2022-01-17 (tracked and clean)
3. SmPC for Paxlovid
4. Letter confirming sponsor approval
5. Amendment Tool for SA24
6. Justification for amendment
7. UK Teratology Information Service Paxlovid opinion