



Centre for Tropical Medicine and Global Health

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Cambridge East REC
E-submission

10 March 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. We are very grateful for your rapid review of our previous amendment, but following further discussions with the university's insurers and the MHRA we have decided we need to exclude pregnant women in the first trimester from the Paxlovid comparison.

The MHRA also requested clarification about:

- i. the eligibility assessment of and analysis of data from participants who may receive more than one trial treatment in the factorial design (now described in more detail on protocol page 1-2)
- ii. how potential interacting medications are handled by site staff (described in protocol appendix 8.2)
- iii. monitoring of participants after discharge and completion of Paxlovid course at home

We have made other modifications to the protocol which are detailed in the Amendment Tool included with this submission.

Following the approval of Substantial Amendment 24, we have also added text to the protocol and PIS to describe the collection of maternal and infant outcomes for women who were pregnant at the time of randomisation. A data flow diagram to explain this 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 V23.0 2022-03-08 (tracked and clean)
2. RECOVERY PIS/ICF (adult) V22.0 2022-03-05 (tracked and clean)
3. RECOVERY PIS/ICF (child) V14.0 2022-03-05 (tracked and clean)
4. RECOVERY Self sampling instructions V1.0 2022-03-07
5. Justification for protocol V23.0
6. Letter confirming sponsor approval
7. Amendment Tool for SA25
8. Data flow diagram for RECOVERY-UKOSS linkage