



Centre for Tropical Medicine and Global Health

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Cambridge East REC
E-submission
22 June 2023

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 removes three treatment comparisons that are now completed, and updates the protocol in several places to remove redundant information or add clarifications (details of which are in the amendment tool). It also allows extension of the influenza comparisons to non-UK countries, and removes some planned collaborating countries (The Gambia, Sri Lanka and Pakistan).

We would also like to request approval to perform some additional testing of blood samples collected in RECOVERY that was not described in the ICF, although is for the same purpose as the tests that were described. We contacted you by email in April for your opinion about this testing, and you suggested submitting a non-substantial amendment, but for convenience we include it here as part of this substantial amendment. The following documents are attached:

1. RECOVERY protocol V26.0 2023-06-22 (tracked and clean)
2. RECOVERY PIS/ICF (adult) V25.0 2023-06-22 (tracked and clean)
3. RECOVERY PIS/ICF (child) V15.0 2023-06-22 (tracked and clean)
4. Justification for additional testing of blood samples collected in RECOVERY
5. Amendment tool for SA31
6. Letter confirming sponsor approval

Please let us know if you require any further information.

Yours faithfully

Professor Sir Peter W. Horby
FRCP FFPH PhD FMedSci
Chief Investigator, RECOVERY Trial
Moh Family Foundation Professor of Emerging Infectious Diseases and Global Health