



Centre for Tropical Medicine and Global Health

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Cambridge East REC
E-submission

7 December 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 removes a comparison that will complete recruitment by the time we implement this amendment (baricitinib), and allows other countries to participate in the high-dose dexamethasone and empagliflozin comparisons.

In the light of the emergence of the Omicron variant of SARS-CoV-2, we have been asked by the Department of Health and Social Care not to recruit patients with influenza pneumonia yet (but to wait for 2-3 weeks until the implications for the NHS are clearer). We have informed our sites about this and they will not approach patients with influenza pneumonia until we tell them otherwise. We do not think the PIS/ICF will confuse patients, because site staff will not approach people with influenza and already explain which treatments are available and suitable for the patient when discussing the trial. Revising the PIS/ICF (only to change it back shortly after) increases the risk of sites using the incorrect version so we would prefer not to do this.

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 V20.0 2021-12-02 (tracked and clean)
2. RECOVERY PIS/ICF (adult) V18.0 2021-11-29 (tracked and clean)
3. RECOVERY PIS/ICF (child) V12.0 2021-11-29 (tracked and clean)
4. Letter confirming sponsor approval
5. Amendment Tool for SA22