



Centre for Tropical Medicine and Global Health

Nuffield Department of Medicine
Nuffield Department of Medicine Research Building
University of Oxford
Old Road Campus, Roosevelt Drive
Headington
OXFORD
OX3 7FZ

Clinical Trials Unit
Medicines Healthcare Regulatory Agency
E-submission

13 March 2020

Cambridge East REC
E-submission

13 March 2020

Dear Sir or Madam

Trial: Randomised evaluation of Covid-19 therapy (RECOVERY)
EudraCT: 2020-001113-21
IRAS: 281712

Please find enclosed an application for an expedited authorisation of a clinical trial investigating the treatment of COVID-19. This trial will operate at a large number of hospitals in the UK and compare the safety and efficacy of four different treatments:

1. Standard care;
2. Lopinavir/ritonavir;
3. Interferon β 1a;
4. Dexamethasone

The trial is designed to be very streamlined so as to cause minimal impact on the clinical service which is likely to be operating under extreme pressure as the number of cases of COVID-19 increase over the coming weeks.

Only essential data will be collected (using bespoke IT systems). It is intended that all investigational medicinal products will be prescribed by the treating clinicians and will be stored, labelled and accounted for as per routine care, with no additional trial-specific requirements to minimise the impact on clinical services.

The trial is funded by a grant to the University of Oxford from UK Research and Innovation/National Institute for Health Research (NIHR) and by core funding provided by NIHR Oxford Biomedical Research Centre, the Wellcome Trust, the Bill and Melinda Gates Foundation, Health Data Research UK, and the Medical Research Council Population Health Research Unit, and NIHR Clinical Trials Unit Support Funding.





Centre for Tropical Medicine and Global Health

Nuffield Department of Medicine
Nuffield Department of Medicine Research Building
University of Oxford
Old Road Campus, Roosevelt Drive
Headington
OXFORD
OX3 7FZ

At present Oxford is the only site listed in Part C of the application form. It is anticipated that there will be around 120 sites, however confirmation of their participation is not available at this stage. Details of the sites will be provided in due course.

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

A handwritten signature in blue ink, appearing to read 'Peter Horby', with a long horizontal flourish at the end.

Professor Peter W. Horby

BSc MSc MBBS FRCP FFPH PhD

Chief Investigator, RECOVERY Trial

Professor of Emerging Infectious Diseases and Global Health

