



## 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

Cambridge East REC  
E-submission

23 March 2020

Dear Sir or Madam

**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 an expedited authorisation of a substantial amendment for the above trial. The reasons for the substantial amendment are details in the Notice of Substantial Amendment, but in summary include:

1. Addition of hydroxychloroquine as a randomization arm: Hydroxychloroquine has been tested in many previous viral diseases and is recommended by the World Health Organisation for testing in COVID-19. The UK Department of Health has now secured a large supply so it is feasible to include this in the RECOVERY trial protocol
2. Removal of requirement for PCR confirmation of SARS-CoV-2 infection for inclusion: Other rapid diagnostic tests are being developed so we do not wish to limit the trial to one particular type of test.
3. Removal of severe depressive illness as a contraindication to interferon: this problem occurs with long-term systemic therapy and is very unlikely to occur with a short course of topical treatment.
4. We have now created our trial website ([www.recoverytrial.net](http://www.recoverytrial.net)) and wish to inform the committee of this.
5. A number of administrative details and typographical errors have been updated/corrected in this version of the protocol.

We would like to request that this amendment is a **category C** amendment as we do not have 35 days to wait for trusts to respond before we implement it. As we will be able to ensure the supply of hydroxychloroquine we do not think there are any local requirements that would need to be considered.

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





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**Professor Peter W. Horby**

BSc MSc MBBS FRCP FFPH PhD

Chief Investigator, RECOVERY Trial

Professor of Emerging Infectious Diseases and Global Health

Attached files:

1. Cover letter
2. RECOVERY Protocol V2.0 2020-03-23 (clean and tracked)
3. RECOVERY PIS+ICF V2.0 2020-03-23 (clean and tracked)
4. Hydroxychloroquine Summary of Product Characteristics
5. Sponsor Approval of Amendment

