

## **Justification of substantial amendment for RECOVERY protocol V7.0**

We are seeking approval for the following changes:

1. Removal of hydroxychloroquine from the protocol and patient information: We have now closed recruitment to this arm as the trial showed this treatment to be ineffective. Preliminary results are in the public domain and a peer-reviewed publication is in preparation.
2. Removal of dexamethasone for adults (but not children) from the protocol and patient information: We have now closed recruitment to this arm for adults as the trial has shown this treatment to be effective so it has now been recommended by the Chief Medical Officer as standard of care in the NHS. A section (1.4) has been added to the protocol to describe this procedure. Preliminary results are in the public domain and a peer-reviewed publication is in preparation.
3. Addition of an extra question to the convalescent plasma safety data form: We wish to collect an additional item of information from participants who have been randomised between convalescent plasma and control.
4. Clarification of statistical analysis section: We wish to align the protocol with the Statistical Analysis Plan (which was published on our website on 9 June 2020).
5. Protocol change: We wish to allow patients to be randomised into the trial between convalescent plasma and control, even if none of the drug treatments in part A of the main randomisation (currently lopinavir-ritonavir and azithromycin) are both available and suitable.