

Richard Haynes

From: Heather House <heather.house@admin.ox.ac.uk>
Sent: 15 May 2020 11:33
To: Richard Haynes
Cc: rpm@oxfordjro.org; CTRG Sponsorship Correspondence; Joseph Butchinsky
Subject: Randomised Evaluation of COVID-19 Therapy (RECOVERY), Substantial Amendment 5.0, PID14892, REC Ref 20/EE/0101

Dear Richard,

I can confirm that the above referenced substantial amendment has been reviewed in CTRG and we are happy for it to be submitted to the relevant organisations for approval. This email can be forwarded as confirmation of sponsor approval for the amendment as required.

In order to ensure validation of your submission by the REC, send them both tracked and clean copies of all amended documents.

- Email documents to the REC that originally reviewed the study. The REC will review the amendment and categorise it. If necessary, they will transfer the amendment internally to HRA for them to review as well.
 - o If the amendment does not require HRA review, the REC will state this in their categorisation letter.
 - o If it is sent on to the HRA, the HRA will advise you when you can send final REC and HRA approved documents to your local sites.
- Copy in CTRG generic email address (ctr@admin.ox.ac.uk) so the sponsor has final documents and is included in subsequent correspondence

Please make your MHRA submission, through the Common European Submission Platform (CESP).

Please send a copy of the approval letters to the CTRG generic email address (ctr@admin.ox.ac.uk) once you have received them. Please do not implement your amendment until all approvals are in place.

Kind regards,
Heather

PID14892-A006-SP001-AC001

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In line with University policy, Research Services are working remotely. Please email and leave a contact number if necessary. We will maintain operational continuity as far as possible and appreciate your patience in this challenging period.

Guidance (FAQs) for Clinical Research during the COVID-19 national emergency can be found on:
<https://researchsupport.admin.ox.ac.uk/ctrq>