

RE: PRINCIPLE Substantial Amendment 5 EudraCT: 2020-001209-22

Elaine Chick <elaine.chick@admin.ox.ac.uk>

Wed 5/20/2020 08:54

To: Hannah Swayze <hannah.swayze@phc.ox.ac.uk>

Cc: rpm@oxfordjro.org <rpm@oxfordjro.org>

Dear Hannah

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 amendments as required.

- Email documents to the REC that originally reviewed the study. The REC will review the amendments and categorise it. If necessary, they will transfer the amendments internally to HRA for them to review as well.
 - If the amendment does not require HRA review, the REC will state this in their categorisation letter.
 - 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 (ctrig@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 (ctrig@admin.ox.ac.uk) once you have received them. Please do not implement your amendments until all approvals are in place.

Best wishes

Elaine



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PID14903-A005-SP001-AC001