

RE: PRINCIPLE Trial - substantial Amendment 15

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

Tue 4/27/2021 11:15

To: Hannah Swayze <hannah.swayze@phc.ox.ac.uk>; PRINCIPLE Study <principle@phc.ox.ac.uk>

Cc: oxfordjro@mail.studyline.uk.com <oxfordjro@mail.studyline.uk.com>

 1 attachments (431 KB)

281958_SA 15_.pdf;

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 amendment as required.

Please find attached the PDF version of the signed and locked amendment tool.

Please submit this signed amendment tool, together with the tracked and clean copies of all amended documents, to the REC via the online amendment submission portal (for further guidance please refer to the HRA training video: how to complete online submission of amendments). Please make your MHRA submission, through the MHRA submission platform.

When you have received the submission confirmation, please email this, with the final documents you submitted, to the CTRG generic email address (ctrng@admin.ox.ac.uk).

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

Kind regards,

Elaine

Elaine Chick

Deputy Head | Clinical Trials and Research Governance (CTRG)

Research Services, University of Oxford

Joint Research Office

Boundary Brook House, Churchill Drive Oxford OX3 7GB

Please note I usually work Monday-Thursday only

 01865 616481

 elaine.chick@admin.ox.ac.uk

researchsupport.[admin.ox.ac.uk](https://researchsupport.admin.ox.ac.uk)

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

PID14903-A022-SP001-AC001

