

From: Elaine Chick elaine.chick@admin.ox.ac.uk

To: Jared Robinson <jared.robinson@phc.ox.ac.uk>; PRINCIPLE Study <principle@phc.ox.ac.uk>; oxfordjro@mail.studyline.uk.com

Date: 20/07/2021

Subject: PRINCIPLE Trial - substantial Amendment 16

Dear Jared

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 (ctrig@admin.ox.ac.uk).

Please send a copy of the approval letter(s) to the CTRG generic email address (ctrig@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

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Please note I usually work Monday-Thursday only

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PID14903-A024-SP001-AC001