

IRAS Project ID 281958. Regulatory Approvals Outstanding for HRA Assessment of Amendment

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Mon 04/10/2021 16:44

To: Christopher Butler <christopher.butler@phc.ox.ac.uk>; CTRG Sponsorship Correspondence <ctr@admin.ox.ac.uk>; PRINCIPLE Study <principle@phc.ox.ac.uk>

Cc: berkshire.rec@hra.nhs.uk <berkshire.rec@hra.nhs.uk>

Dear Prof Butler,

IRAS Project ID:	281958
Short Study Title:	PRINCIPLE [COVID-19] [UPH]
Amendment No./ Sponsor Ref:	Substantial Amendment 18
Amendment Date	24 August 2021
Amendment Type:	Substantial CTIMP - for review

HRA assessment of this amendment is ongoing. The following regulatory approvals are outstanding for this amendment and these will need to be in place before HRA assessment of this amendment can be completed:

CTIMPS - Acceptance of Amendment to Clinical Trials Authorisation (CTA)	The MHRA will not share the acceptance of amendment to the CTA for this amendment with the HRA. You should send a copy of the acceptance of amendment to the CTA to the HRA when available.
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Where the table above indicates that you should send regulatory approvals to the HRA, these should be sent to the REC (if the REC is in England or Wales) or amendments@hra.nhs.uk (if the REC is in Northern Ireland or Scotland) as soon they are available to avoid delays in HRA assessment of this amendment.

If there are any conditions attached to any regulatory approvals, these will need to be considered by the Approval Specialist before assessment of the amendment can be completed.

If any regulatory approvals are based on an amended request (e.g. the regulator requested changes to the original amendment submission before approving it), details about what has been changed should be provided to the Approval Specialist before assessment of the amendment can be completed.

You should not implement this amendment at participating NHS organisations in England until HRA Approval for the amendment has been issued and the conditions detailed in the categorisation email issued previously have been met.

Please do not hesitate to contact me if you require further information.

Kind regards

Mr Philip Evans

Health Research Authority

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E. amendments@hra.nhs.uk

W. www.hra.nhs.uk

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