

## Jared Robinson

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**From:** berkshire.rec@hra.nhs.uk <noreply@harp.org.uk>  
**Sent:** 12 August 2021 10:07  
**To:** Christopher Butler; CTRG Sponsorship Correspondence; PRINCIPLE Study  
**Cc:** berkshire.rec@hra.nhs.uk  
**Subject:** IRAS Project ID 281958. Regulatory Approvals Outstanding for HRA Assessment of Amendment

**Categories:** Becky

Dear Prof Butler,

<b>IRAS Project ID:</b>	<b>281958</b>
<b>Short Study Title:</b>	<b>PRINCIPLE [COVID-19] [UPH]</b>
<b>Amendment No./ Sponsor Ref:</b>	<b>Substantial Amendment 17</b>
<b>Amendment Date</b>	<b>24 July 2021</b>
<b>Amendment Type:</b>	<b>Substantial CTIMP - for review</b>

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:

<b>Other regulatory approvals and authorisations</b>	The Confidentiality Advisory Group will share the outcome of their amendment review with the Approvals Specialist when available.
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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](mailto:E.amendments@hra.nhs.uk)

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