30.06.2017

Amendment Categorisation and Implementation Information

Dear Dr Moonesinghe,

Thank you for submitting an amendment to your project.

If you have participating NHS/HSC organisations in any other UK nations that are affected by this amendment we will forward the information to the relevant national coordinating function(s).

Please note that you may only implement changes described in the amendment notice.

What Happens Next?

Information Specific to Participating NHS Organisations in England

1. **This email also constitutes HRA Approval for the amendment**, and you should not expect anything further from the HRA.
2. You may implement this amendment immediately.
3. You should ensure that participating NHS organisations in England are informed of this amendment. In doing so, you should include the NHS R&D Office, LCRN (where applicable) as well as the local research team.
4. Participating NHS organisations in England should prepare to implement this amendment, where expected.

Information Specific to Participating NHS/HSC Organisations in Northern Ireland, Scotland and/or Wales

1. **You may implement this amendment immediately**
2. You do not need to inform the R&D offices, as we have separately made it available via their national coordinating functions.
3. Participating NHS/HSC organisations should prepare to implement this amendment, where expected.

IRAS Project ID:	215928
Short Study Title:	Perioperative Quality Improvement Programme: Patient Study
Date complete amendment submission received:	08/12/2017
Amendment No./ Sponsor Ref:	Additional of new sites & PIS update - 07/12/2017
Amendment Date:	07 December 2017
Amendment Type:	Non-substantial
Outcome of HRA Assessment	**This email also constitutes HRA Approval for the amendment,** and you should not expect anything further from the HRA.
For NHS/HSC R&D Office information	
Amendment Category	**C**

Information relating to the addition of new sites

This amendment also adds new participating NHS/HSC organisations to the study.

If your study is supported by a research network, please contact the network as early as possible to help support set up of the new site(s).

The 35 day implementation date does not apply to the new sites. Please set up new sites as detailed below (as processes change from time to time, we recommend that you refer to the most up to date guidance about site set up, found within IRAS).

For new sites in Northern Ireland, Scotland and/or Wales only:	Please start to set up your new sites. Sites may not open until NHS/HSC management permission is in place.
For new sites in England only:	For studies which already have HRA Approval: **This email also constitutes HRA Approval for the amendment, and you should not expect anything further from the HRA**. Please start to set up your new sites. Sites may not open until the site has confirmed capacity and capability (where applicable). For studies which do not yet have HRA Approval: **HRA Approval is pending and you will receive confirmation of HRA Approval.** You can start the process of setting up the new site but cannot open the study at the site until HRA Approval is in place and the site has confirmed capacity and capability (where applicable).

If you have any questions relating to the wider HRA approval process, please direct these to hra.approval@nhs.net.

If you have any questions relating this amendment in one of the devolved administrations, please direct these to the relevant national coordinating function.

Additional information on the management of amendments can be found in the IRAS guidance.

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

Kind regards

Mr Ali Hussain
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