**Template email for sponsors to confirm implementation of an amendment**

This is an optional email for sponsors to use to notify participating NHS organisations in England that an amendment can be implemented. The notification should be sent to both the research management office and local research team, as well as the LCRN for studies included on the NIHR portfolio.

**For category A&B amendments** – this should be sent once all regulatory approvals are in place and HRA Approval for the amendment has been issued, and when the 35 calendar time limit has passed. This may be used ahead of the 35 calendar time limit if (a) HRA Approval for the amendment has been issued and (b) the site has confirmed it can implement the amendment.

**For category C amendments** – this should be sent once all regulatory approvals are in place and HRA Approval for the amendment has been issued. Where HRA Approval for the amendment was confirmed in the categorisation email the use should send the “Template email for sponsors to share category C amendment documents with sites” only.

The use of this template email will ensure clear and consistent communication between the sponsor and participating NHS organisations in England about implementation of amendments, and is intended to be sent as soon as the amendment can be implemented.

Text that is highlighted in red should be amended by the sponsor as appropriate prior to issue of the email.

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**From:** Sponsor (or representative)

**To:** Site research management function and local research team and, where applicable LCRN, (this template can be used to email multiple sites in one email, or one site individually).

**Subject: IRAS Number; Implementation of Amendment**

**Attachments:** HRA categorisation email, amendment package (including all approved amended documents, notice of amendment and REC opinion where applicable); HRA Approval of the amendment email (if confirmed separate to the categorisation email)

**Body of Text:**

Dear participating organisation/s, (name if sending to one site),

**RE: IRAS Number; Short Study Title; Amendment Reference**

Further to my previous email, I can now confirm that all approvals, including HRA Approval, for this amendment have been issued. As such, the amendment **can now be implemented at your site.**

What are the approved documents?

The table below details the final set of documents approved for this amendment.

|  |  |  |
| --- | --- | --- |
| ***Document*** | ***Version Number*** | ***Date*** |
|  |  |  |
|  |  |  |

**Option 1 - add if no changes to documents during regulatory review**. Please note there were no changes to the documents as a result of the regulatory review(s).

**Option 2 - add if documents were changes during regulatory review.** Please note there were changes to the submitted document set as a result of regulatory review(s).

The potential impacts of this amendment to research sites were outlined in the initial document set provided to you with the categorisation email. If you need to discuss this amendment further please do not hesitate to contact me

Kind regards

Sponsor (or representative of)