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

This template email is for use by sponsors and applicants. It lets you notify participating NHS organisations in England and Wales that an amendment can be implemented. You can also use this email to notify participating NHS / HSC organisations in Northern Ireland and Scotland that an amendment can be implemented. Check the [instructions on IRAS](https://www.myresearchproject.org.uk/help/hlpamendmentsresearch.aspx#Working-with-participating-NHS/HSC-organisations-to-implement-amendments) to find out who you should send this email to.

**For category A or B amendments** – send the email once HRA and HCRW Approval (England and Wales only) or NHS / HSC Permission (Northern Ireland and Scotland only) for the amendment is in place and:

* the participating organisation has confirmed it can implement the amendment, even if this is ahead of the 35 calendar day time limit
* or the 35 calendar day time limit has passed and the participating organisation did not object
* or the 35 calendar day time limit has passed you have fixed any problems raised by the participating organisation

**For category C amendments** – send the email once all regulatory approvals for the amendment are in place and reviews completed, including and HRA and HCRW Approval (England and Wales only). If you do not need a study-wide review, you should only send the “Template email for sponsors to share category C amendment documents with participating organisations”. Do not use this template to confirm implementation as well.

You should amend text highlighted in blue before you send this email.

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**Subject: IRAS number; Amendment number and date; Implementation of Amendment**

**Attachments:**

* Confirmation of submission email
* all amended documents
* locked pdf of the amendment tool
* any applicable regulatory approvals such as REC opinion, if applicable
* HRA and HCRW Approval outcome email for the amendment (England and Wales only)

**Body of Text:**

Dear participating organisations, (or name if sending to one organisation),

I can confirm that all approvals, including HRA and HCRW Approval (organisations in England and Wales only), for the amendment to the study insert short study title have been issued. As such, the amendment **can now be implemented at your organisation.**

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 review by review bodies listed in the amendment tool**. There **were no** changes to the documents during the reviews by the relevant regulators and review bodies. I outlined the potential impacts of this amendment to you in the email detailing the categorisation.

**Option 2 - add if documents were changed during regulatory review or during review by the review bodies listed in the amendment tool.** There **were** changes to the submitted document set during the reviews by the relevant regulators and review bodies. I outlined the potential impacts of this amendment to you in the email detailing the categorisation.

If you need to discuss this amendment further please contact me.

Kind regards,

Sponsor (or representative of)