**Template email for sponsors to share category C amendment documents with participating NHS/HSC organisations**

This email template is for use by sponsors or applicants. It allows you to share amendments with participating NHS/HSC organisations. Send this email when you receive confirmation you have submitted your amendment. Check the [instructions on IRAS](https://www.myresearchproject.org.uk/help/hlpamendmentsresearch.aspx#Sharing-amendments-with-participating-NHS/HSC-organisations) to find out who you should send this email to.

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

**Subject: IRAS number; Amendment number and date; Notification of Amendment. Category C**

**Attachments:**

* confirmation of submission email
* all amended documents
* locked pdf of the amendment tool
* any applicable regulatory approvals such as REC opinion or MHRA notice of no objection, if already issued
* HRA and HCRW Approval outcome email for the amendment (if applicable and already issued; participating NHS organisations in England and Wales only. You can share the amendment with NHS organisations before you receive HRA and HCRW Approval. Share the approval email with participating organisations in England and Wales when it is available)

**Body of Text:**

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

I have submitted an amendment for the study Short Study Title; IRAS Number. Attached is the confirmation of submission email together with the amendment package. Please read the documents carefully.

What does the amendment relate to?

**User to add a brief summary of the amendment and any changes (for example, new version of participant information sheet for use)**.

**Option 1 - send if the submission email confirms it is non-notifiable with no study wide review required**

When will this amendment be implemented?

This is a **category C** amendment.. The amendment tool confirms that this amendment:

* does not impact participating NHS/HSC organisations
* is a non-notifiable amendment and does not need study wide review
* does not need national coordinating function review (include for participating organisations in Northern Ireland and Scotland only)
* does not need HRA & HCRW Approval (include for participating organisations in England and Wales only)

This is in line with the UK wide policy on the handling of amendments. As such, this amendment will be **implemented immediately**.

What are the approved documents?

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

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

**Option 2 - send if you need HRA and HCRW Approval (England and Wales) and / or national coordinating function review (Northern Ireland and Scotland)**

When will this amendment be implemented?

This is a **category C** amendment. The amendment tool confirms that this amendment:

* does not impact participating NHS/HSC organisations
* needs HRA & HCRW Approval in place before the amendment is implemented (include for participating organisations in England and Wales only)
* needs national coordinating function review to be completed before the amendment is implemented (include for participating organisations in Northern Ireland and Scotland only)

This is in line with the UK wide policy on the handling of amendments.

Include for participating organisations in England and Wales when HRA and HCRW Approval is not yet in place: As such, do **NOT** implement this amendment. We will share the confirmation of HRA & HCRW Approval with you when it is available. You can then implement the amendment.

Include for participating organisations in England and Wales when HRA and HCRW Approval is in place: Confirmation of HRA and HCRW Approval has been received. As such, this amendment will be **implemented immediately**.

Include for participating organisations in Northern Ireland and Scotland: You can implement this amendment as soon as any reviews listed in the amendment tool are completed.

**End of options**

If you need to discuss this amendment please contact me.

Kind regards,

Sponsor (or representative of)