**Template email for sponsors to share category C amendment documents with sites**

This is an optional email for sponsors to use to notify participating NHS organisations in England of a Category C amendment. The notification should be sent to both the research management office and local research team. For NHS/HSC organisations in Northern Ireland, Scotland and Wales, the national coordinating function will share documents with the R&D offices of their sites directly, and there is no need for the sponsor to separately notify NHS/HSC R&D offices in Scotland, Wales and Northern Ireland.

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

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; Notification of Amendment. Category C**

**Attachments:** HRA categorisation email, amendment package (including all amended documents, notice of amendment and REC opinion, if applicable and already issued); HRA Approval outcome email for the amendment (if already issued, and 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**

We have submitted an amendment to the HRA for the above referenced study. Attached is the HRA categorisation 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 to sites (e.g. new version of participant information sheet for use)**

**Option 1 - send if the categorisation email confirms HRA Approval for the amendment (i.e. all necessary approvals in place)**

When will this amendment be implemented?

This amendment has been categorised as **category C**. In line with the [UK wide policy on the handling of amendments](https://www.myresearchproject.org.uk/help/hlpamendmentsresearch.aspx), the HRA has confirmed that:

* this amendment does not impact participating NHS organisations
* this amendment has HRA Approval

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*** |
|  |  |  |
|  |  |  |

If you need to discuss this amendment please do not hesitate to contact me.

**Option 2 - send if the categorisation email indicates that HRA Approval for the amendment is pending**

When will this amendment be implemented?

This amendment has been categorised as **category C**. In line with the [UK wide policy on the handling of amendments](https://www.myresearchproject.org.uk/help/hlpamendmentsresearch.aspx), the HRA has confirmed that:

* this amendment does not impact participating NHS organisations
* HRA Approval for the amendment form is pending

As such, this amendment should **NOT** be implemented at participating organisations in England. We will further inform you once HRA Approval has been given for this amendment, and when it can be implemented. If you need to discuss this amendment please do not hesitate to contact me

**End of options**

Kind regards

Sponsor (or representative of)