**Template email for sponsors to share category A or B amendment documents with sites – where regulatory approvals are outstanding**

This is an optional email for sponsors to use to notify participating NHS organisations in England that are affected by a Category A or B 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 A and B amendments, and is intended to be sent as soon as the categorisation email is issued to the sponsor.

**In England, the 35 calendar day clock starts from the date that participating organisations (**[**NHS R&D Office**](http://www.rdforum.nhs.uk/content/contact-details/)**,** [**LCRN**](https://www.nihr.ac.uk/nihr-in-your-area/local-clinical-research-networks.htm) **(where applicable) as well as the local research team) are notified of the amendment by the sponsor.**

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

**Please note:** this is for use where HRA Approval (and potentially other regulatory approvals) are outstanding at categorisation. Sponsors should check the categorisation email for the HRA Approval status – **use this email if the categorisation email HRA Approval status is pending.**

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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 insert option A or B**

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

**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 for the above referenced study. Attached is the categorisation email together with the amendment package. Please read the documents carefully as these provide information on how this amendment should be implemented, as well as what the amendment entails.

When will this amendment be implemented?

This amendment has been categorised as **category** **INSERT A or B END**. In line with the HRA categorisation email and [UK wide policy on the handling of amendments](https://www.myresearchproject.org.uk/help/hlpamendmentsresearch.aspx), your site has 35 calendar days from the date of this notification to raise an objection about the amendment. If we do not hear from you by **insert date**, we will assume that the amendment may be implemented at your site, once regulatory approvals are in place. If you need more time to consider the amendment please contact us prior to the 35 day deadline and we will assist with any queries you may have. If you are able to notify us ahead of this date that you are able to accommodate this amendment it will enable us to potentially implement sooner.

What is the impact on research activities at sites?

**Insert if no impact on research activities.** This amendment does not impact the research activities undertaken at participating NHS organisations.

**Insert if there is an impact on the research activities.** This amendment impacts the research activities undertaken at NHS organisations. The main changes for attention are **user to summarise the important changes to research activities that NHS organisations may need to consider, for example changes in procedures, patient visits, additional tests, changes affecting support departments (list not exhaustive).**

Is there any impact on funding/agreements?

**Insert if no impact on funding and/or agreements.** This amendment **does not impact** the funding/agreement that have previously been agreed.

**Insert if there is an impact on funding/agreement.** This amendment **impacts** the funding/agreement that have previously been agreed. **User to provide information on the changes, and how these are to be discussed/agreed.**

What is the HRA Approval status of the amendment?

Please note that this amendment is currently outstanding regulatory approvals. These documents are being provided to you for your information and review at this stage; they should **NOT** be implemented until all approvals are received. We will further inform you when HRA Approval for the amendment is issued, and it can be implemented.

If you need to discuss the impact of the amendment at your site please do not hesitate to contact me.

Kind regards

Sponsor (or representative of)