**Template email for sponsors to share category A or B amendment documents with participating NHS/HSC organisations – where regulatory approvals are outstanding**

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. Be aware that the 35 calendar day clock to implement the amendment starts:

* when you send the amendment to participating organisations in England or Wales
* when you send the amendment to the participating organisation in Scotland or Northern Ireland in a single site study
* when you submit the amendment in IRAS for participating organisations in Scotland and Northern Ireland in multi-centre studies

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**Subject: IRAS number;** **Amendment number and date; Notification of Amendment Category insert option A or B**

**Attachments:**

* confirmation of submission email
* all amended documents
* locked pdf of the amendment tool
* any applicable available regulatory approvals such as REC opinion or MHRA notice of no objection

**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 and amendment tool carefully. These provide information about how you should implement this amendment, as well as what the amendment entails.

What is the impact on research activities at participating organisations?

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

**Insert if there is an impact on the research activities.** This amendment impacts the research activities at NHS/HSC organisations. Further details are provided in the attached documents. The main changes for attention have been summarised in the table below: **state the important changes to research activities that NHS/HSC organisations may need to consider. It is important that you are clear about the changes. There are examples to help you understand how to complete the table with information your participating organisations need. The examples are not exhaustive, and you may need to add more detail for some changes. Remove the examples before you send the email. Add more lines if you need them.**

|  |  |
| --- | --- |
| **Describe the Change** | **If you know the support departments/teams this impacts, state them** |
| A new study drug is being added, drug X. Participants receive the drug to the same schedule as previously described in the protocol. I have attached an updated pharmacy manual with details of how Drug X should be managed by pharmacy. | Local research team and pharmacy departments. |
| New safety information which means that consent must be re-sought from all participants | Don’t know – please help us to disseminate this appropriately |
| 2 new blood tests per participant | Local research team, laboratory teams |
| An additional test is being done to tissue samples | Laboratory or pathology teams |
| Adding a new study arm, arm Y. | All departments |
| Removing 1 interview per participant | Local research team |
| Changing 2 echo scans to be MUGA scans instead | Radiation departments |
| The participant information sheet has been updated. You do not need to re-seek consent from current participants. All potential participants should be given this new participant information sheet. | Local research team |
| The investigator’s brochure has been updated | Pharmacy department |
| The principal investigator is changing from Dr A to Research Nurse B. | Local research team |

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 we have already agreed.

**Insert if there is an impact on funding/agreement.** This amendment **impacts** the funding/agreement that we agreed before. **Provide information on the changes, and how you want to discuss/agree them.**

What is the regulatory approval status of the amendment?

Please note that this amendment is currently outstanding regulatory approvals. These documents are being provided to you to support any arrangements that you need to make before you implement the amendment. Do **NOT** implement the amendment until all you receive all approvals from me. This includes HRA & HCRW Approval (insert for organisations in England and Wales only). We will then tell you when the amendment can be implemented.

When will this amendment be implemented?

This amendment is a **category** **INSERT A or B** (as stated in the amendment tool) amendment. You have 35 calendar days to identify any issues affecting your capacity or capability to implement the amendment. This is in line with the [UK wide policy on the handling of amendments](https://www.myresearchproject.org.uk/help/hlpamendmentsresearch.aspx).

If I do not hear from you by **insert date of 35 calendar day target in line with guidance on page 1**, I will assume that your organisation can implement the amendment. This is conditional on relevant approvals being in place and reviews being completed.

If you need more time to consider the amendment or identify any issues, please contact me before the 35-day deadline. I will assist with any queries you may have.

If you can accommodate the amendment before this date please tell me. It might help us to implement the amendment sooner.

If you need to discuss the impact of the amendment at your organisation please contact me.

Kind regards,

Sponsor (or representative of)