



**Sheffield Health
and Social Care**
NHS Foundation Trust

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Information and guidance for primary care sites on how to manage amendments to a study once it has started.

The purpose of this guide is to provide primary care staff with guidance on how to manage an amendment to a study after it has started.

1. What is an amendment?

An amendment is a change to the way a research study needs to be run after it has been given its regulatory approval(s). There are different types of amendments: Substantial amendments and non-substantial/minor amendments. It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial and to organise for it to receive the relevant approval(s).

2. What is the difference between a substantial and non-substantial amendment?

Substantial amendments usually involve:

- changes to the design or methodology of the study, or to background information likely to have a significant impact on its scientific value
- changes to the procedures undertaken by participants
- changes likely to have a significant impact on the safety or physical or mental integrity of participants, or to the risk/benefit assessment for the study.

Non-substantial amendments often comprise:

- minor changes to the protocol or other study documentation, e.g. correcting errors, updating contact points, minor clarifications
- updates of the investigator's brochure (unless there is a change to the risk/benefit assessment for the trial)

Information – Primary Care study amendments

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- changes to the chief investigator's research team.

Further amendment examples can be found here:

<https://www.hra.nhs.uk/approvals-amendments/amending-approval/examples-of-substantial-and-non-substantial-amendments/> (accessed 21/02/2023)

3. What is an amendment tool?

The amendment tool describes the amendment purpose and references the documents that have been updated. At the end of the document it explains how the amendment has been categorised. The amendment tool explains what participating sites need to do, if anything to implement the amendment.

Please see IRAS website to access the Amendment tool template.

<https://www.myresearchproject.org.uk/help/hlpamendments.aspx>

4. Which documents make up an amendment?

The amendment will always involve an amendment tool. It will also include any documents whose content have been updated. The new documents will have an updated version and date that corresponds to the date the amendment was made. These documents may include the protocol, participant information sheets, consent forms or other patient-facing documents. If the amendment has been categorised as substantial it will also include the relevant regulatory approval(s), eg HRA, MHRA.

5. What do I do when I receive an amendment tool from the study team?

When you receive an amendment tool from the study team, forward the amendment email to the Research Governance Office at Research Development Unit (RDU) at Sheffield Health and Social Care NHS Foundation Trust (SHSC) on rdu@shsc.nhs.uk. They will then carry out the governance validation checks on your behalf and send the below email (in the embedded document) to the participating sites.

Please see appendix 1 for an example of the SPC amendment email.

6. Who checks the amendment?

As soon as an amendment is released by the sponsor and received by the RDU, the governance team will carry out the governance validation checks. This is a similar but much shorter process to the initial study governance assurance letter. It involves confirming that all the documents received as part of the amendment have been approved by the HRA and have the correct version numbers and dates. When this check has been completed the RDU will advise both the study sponsor and the participating sites of this assurance.

However, ultimate acceptance of the amendment needs to be confirmed by each participating site. If you have not received an amendment email assurance from the RDU, please forward the amendment onto us. Please see below an example of the amendment assurance email that is sent to the study team, copying the participating sites, once the amendment governance validation checks have been finished.

Please see appendix 2 for an example of the SPC amendment assurance

7. Do we have to accept the amendment?

At your site you can either accept or reject the amendment. If the amendment is likely to make the study difficult to deliver you should object to it as soon as possible.

8. How long do we have to object to an amendment?

You have 35 days to raise any objection for amendment category A and B. If no objections are made, the amendment will be implemented at your site at the 35th day deadline. You may need to check your feasibility to make sure that you can still run the study after the amendment.

9. What happens if we can no longer deliver the study?

You should discuss any potential withdrawal with the study sponsor in the first instance.

10. We can accept the amendment, what do we need to do next?

Ensure all members of your local research team are aware of the changes and how that may impact on the delivery of the study at your site. Documents should be filed in the Investigator Site File (ISF) and e-ISF.

11. How do we file the amendment documents?

You should replace (supersede) previous documents and follow the version control process supplied by the sponsor. If the sponsor has not provided their instruction you can use the guidance attached below from SHSC amendment email.

12. Where can I find out more about amendments?

Further guidance can be found at:

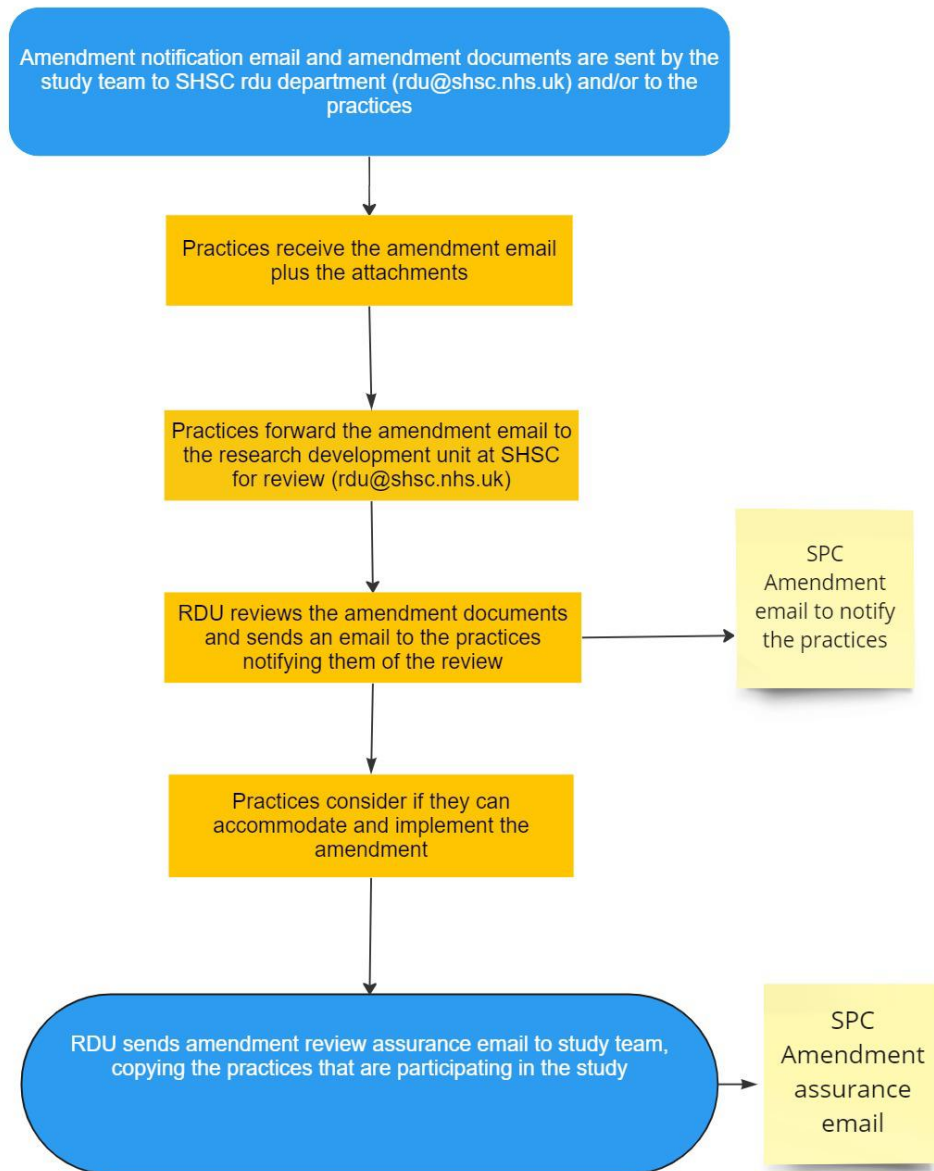
<https://www.myresearchproject.org.uk/help/hlpamendments.aspx> (accessed 11/01/2023)

13. Who do I contact if I have further questions?

For any questions, please email: rdu@shsc.nhs.uk

Amendment process flowchart

Note: SPC-Sheffield Primary Care



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Appendix 1:

Amendment email to notify the practice

To: Practice Lead/ practice research nurse/ lead research nurse/ practice manager

Subject: IRAS ID 1234 - Short title – *SAXX/NSAXX*

Amendment documents attached

Dear all,

Please find attached documents for *SAXX*. This is a category *A* amendment which means that *It affects, all participating organisations which may involve changes to activity or cost implications.]*

Please note that for category A and B amendments you have up to 35 days to decide whether you can accommodate the changes. After 35 days the amendment will be implemented if you have not made any objection.

The main purpose of this amendment is summarised below:

amendment summary from the amendment tool is copied here

If you envisage any issues in implementing the amendment, please contact the study team directly and as soon as possible.

If the sponsor has not specified what to do with the amendment documents please follow this guidance as required:

- Save copies of the attached new document versions in the correct section of the study's e-ISF

- Move previous document versions into superseded folders
- Destroy un-used paper copies of superseded paperwork
- Where required, prepare copies of new versions, eg PIS, consent, source data collection forms
- Update your version control document in the e-ISF and paper site file, use file notes as appropriate.
- Disseminate new versions to the study team within your practice as appropriate
- Update local training log, if required.
- Update Delegation log, if required.

If you have any further queries relating to the amendment please contact the study team directly.

Best wishes

< Insert signature >

Appendix 2:

Amendment assurance email to the study team

Subject: *IRAS ID 1234 - ABCD STUDY - SA01*

Dear *Mr John*

Re: Amendment to IRAS NO 1234 *The ABCD trail*

Amendment No./ Sponsor Reference: SA01

Amendment Date: 13/04/2023

REC Favourable Opinion date: 15/04/2023

Protocol version: v4

Governance review of the above amendment has been completed by Sheffield Health and Social Care NHS Foundation Trust on behalf of NHS SY-ICB (Sheffield Place).

We have advised primary care sites in Sheffield of this amendment, please liaise directly with them to ensure it is implemented.

Kind regards

< insert signature >