

AMENDMENTS

- An amendment is any change to be made to a research study that has already been approved.
- Changes can include the addition of a new site, an extension of dates to a research study, changing the number of participants, typographical changes, or amending the study design and procedures.
- Amendments must always be reviewed by the Sponsor Representative before submission for other approvals and implementation.

Types of amendment

The approvals needed for an amendment depends on the classification. There are two classifications of amendment:

- Non substantial amendments
- Substantial amendments

NHS approved studies



- Submit a copy of the amendment tool and all documents that are changing to your Sponsor Representative, quoting the AC number.
- All amended documents should have the changes clearly highlighted and be version-controlled.

Amendment tool

- The tool can be accessed via IRAS for your project.
- It categorises the amendment and provides tailored guidance on how to submit. It will identify the bodies the amendment should be sent to based on the changes being made to the study.
- The tool also provides detailed information about the amendment to participating sites.

Sponsor review

- Your Sponsor Representative will review the amendment, authorise and lock the amendment tool and send you an amendment classification email with the locked amendment tool attached.
- At this stage, the amendment can be submitted.
- A new login and password will be needed for the new part of IRAS to submit amendments.
- Once logged in, input the IRAS ID and other study information. Some of this can be copied from the tool, and documents can be uploaded, including a pdf copy of the tool.
- The system will email a confirmation that the amendment has been submitted.

Read the [amendment tool and full guidance](#) about the new process for handling amendments.

Watch a training video for [online submission of amendments](#).

EMREC approved studies

- Submit a summary of changes and all documents that are changing to your Sponsor Representative, quoting the AC number.
- All amended documents should have the changes clearly highlighted and be version-controlled.
- Your Sponsor Representative will review the amendment, and send you an email confirming they approve the changes.
- The amendment can then be submitted to EMREC.

What next?

- Ensure you receive all the correct approvals before implementing an amendment. Remember this will be dependent on the classification of the amendment and the study type.