

Glasgow Clinical Trials Unit Guideline

Guideline number	Guideline 59.013B	Version	1.0
Title	Creation Of A Project Amendment		

Amendment requests can be submitted either in the body of an email or as an attachment. Try to encourage researchers to use the Notification of Amendment form, Form 59.013B, so you have a formal record of the request in the project folder.

On receipt of application for a project amendment:

On receipt of application open the Safe Haven Projects Register database - Open the Forms Section of the database and update the following:

All mandatory fields are highlighted on the forms in bold text – make sure they are all filled in or future queries will make no sense.

Maintain A Project: 01 – Amend a Project:

- Create a new record for the project by entering the project number
- The Amendment ID will be auto-generated when you create the record
- Set amendment type
- Set date of application for amendment (Amendment Request Date)
- Select the amendment reason

If the amendment is non-substantial you can approve this yourself, as long as there is proof of the request and reason for it.

If the amendment is substantial, it must be submitted to the LPAC group for approval.

When approved;

Maintain A Project: 01 – Amend a Project:

- Set approval date

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Guideline signatories

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Document history

Version	Date	Description
1.0		First Release

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