

Completing and submitting an ethics amendment

The following amendment types must be submitted using Research GEMS.

General amendments affecting the conduct, design or methodology of a project and includes changes to:

- Information previously given in the Human Research Ethics Application (HREA).
- Study protocol.
- Information sheet/s and consent form/s for participants or any other supporting documentation for the study.

Request for an extension of Human Research Ethics Committee (HREC) Approval to extend the project beyond the original period granted by the HREC.

Note: For extension requests of over 12 months you should contact the research office first to seek advice.

Addition of a site and update the study details of the additional site/s and investigator/s. SA sites will have a site specific assessment (SSA) application form generated in GEMS.

Change to CPI/PI/administration contact notification to the HREC of changes to the Coordinating Principal Investigator (CPI), site Principal Investigator/s (PI) and/or remove/add administration contacts.

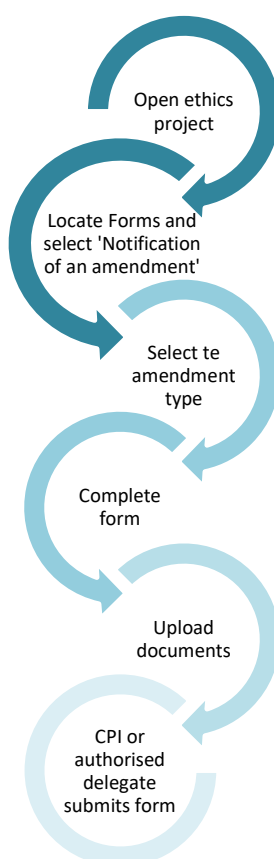
Tip: Ethics projects can have up to two admin. contacts as delegates. You may need to remove an admin. delegate before adding another admin. delegate.

If the CPI is not the person submitting the form then upon submission, an email will be sent to the CPI to approve any users added with submit permission.

How does it work in GEMS?

The CPI can give view, edit and submit rights to team members when completing the amendment form. Editors can complete the form but cannot submit.

The amendment form can be saved at any time and completed later. A saved amendment is active for 365 days.



Form status

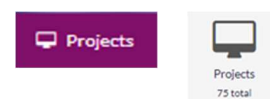
- **Submitted** Form is with the research office.

- **Information Required** Form is with the applicant for completion or editing.
- **Information Provided** Form has been resubmitted with requested information.
- **Approved** Form has been reviewed and approved. An email notification will be sent to the CPI and relevant project team members.

Complete and submit the amendment

Step 1. Locate the ethics project

If the project is not visible in the 'Top 5 projects' section, select 'Projects' to see all.



Click the title of the Project.

Step 2. Select the ethics project

Only an approved study can have an amendment created.

Click the ethics identifier from the table at the bottom of the 'Applications' tab.

IDENTIFIER	STATUS
2022/HRE00046	● Approved

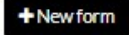
Step 3. Find the Forms page

Click on the 'Forms' tab within the top banner of the ethics project.



Step 4. Create a new form

Click the '+New Form' button from the top right corner of the page.



Step 5. Complete the amendment form

Respond to the mandatory COVID-19 question/s (see [COVID-19 Data Collection – Applicant Guidance](#))

Select the type of amendment and provide a response to all questions.

Under **Study type** A warning will appear 'Is this study type correct?', ensure it is correct before proceeding.

If it is incorrect you will need to contact the research office.

Clinical trial studies will have clinical trial specific questions.

Document Upload: If there are **no documents required** skip this section and move to Declaration.

Uploading a new document

A new document is a document that does not yet exist in GEMS.

Note: Unsure if the document already exists in GEMS? Select 'Yes.' If it does not appear in the Document Title/Descriptor drop down change the response to 'No' and follow the below instructions.

Uploading a new version document select 'No'

Document Title/Descriptor: Provide a clear and descriptive document description.

Document Type: Select from the dropdown.

Version and Date: Version and date of the document (normally listed in footer).

This information will give the file a GEMS title.

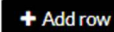
Note: How you name your document in the 'Document Title/Descriptor' section is what the research office will see and how it will be listed on the approval notification. See below example.

Document descriptor - your name for the file *

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Click 'Browse, choose the file and then 'open'.

To add more new documents, select the 'Add row' icon.



Uploading a new version of a document: A new version of an approved document is used when the document is already located in GEMS. If you are uploading an updated version of an **approved document** select 'yes'.

Upload as a new version *

Yes No

Document Title/Descriptor: Select the form from the dropdown options.

Document Type: Will preload.

Document Version and Date: Provide the new version and date of the document (normally listed in footer).

Click 'Browse, choose the file and then 'open'.

The document filename will appear next to the title/descriptor.

Step 5. Declaration

The CPI or authorised delegate with submit permission can submit the amendment form. Editors can save the form and notify the CPI or authorised delegate that it is ready to submit.

Once submitted the status of the form will be 'Submitted'. Each amendment form is given a

unique identifier number.

Click the three dots next to the title and select 'Download attachments' to download a copy of the amendment form and any attached documents.



What next?

The amendment will be received by the research office managing the ethics project.

Once reviewed you will receive either an approval notification or a request for further information (see User Guide [Ethics amendment - responding to an information request](#)).

Upon approval, it is the researcher's responsibility to advise the Research Governance Officers of the approved ethics amendments that relate to the site authorisations.

What needs to be submitted to the RGO in GEMS?

The following site amendments need to be submitted via GEMS:

- ❖ General amendments.

The following site amendments are submitted directly to the RGO and do not need ethics approval:

- ❖ Changing site investigators and administration contacts.
- ❖ Contract changes.

For more information about site amendments, see User Guide [Site amendment – completing and submitting](#).