

Site amendment - completing and submitting

Site amendments in Research GEMS

A list of site amendments available in GEMS are listed below.

- ❖ **General amendment** impacting the department/s at participating sites.
- ❖ **Change in site investigator/s and administration contact/s** notify the research governance officer (RGO) of changes to the site investigator/s and administration contact/s.

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

The following site amendment types are to be used when ethics has been approved in another jurisdiction ([National Mutual Acceptance](#) projects).

- ❖ **Addition of a site** to generate a new site assessment form within GEMS.
- ❖ **Change in CPI/PI/Administration Contacts** notify the RGO of changes to the coordinating principal investigator (CPI), principal investigator (PI) and/or administration contacts.
- ❖ **Extension of HREC approval notification** where the managing Human Research Ethics Committee (HREC) has approved an extension to the ethics approval date.

Note: It is mandatory to provide the approved ethics document/s for these site amendments.

The following site amendments can be submitted to multiple sites in a single form:

- ❖ Change in CPI.

- ❖ Request for an extension of HREC Approval.

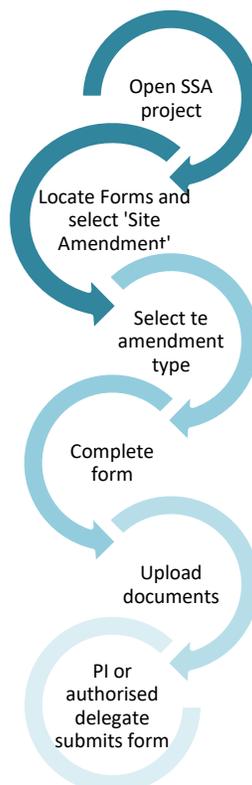
The following site amendments require individual site submissions:

- ❖ Addition of a site.
- ❖ General Amendment.
- ❖ Contract changes.
- ❖ Change in PI.
- ❖ Change in site investigator/s and/or administration contact/s.

Change in site investigator/s and administration contact/s DO NOT require ethics approval.

How does it work in GEMS?

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



The PI can give view, edit and delegate submission rights to others in completing the site amendment form. Editors can complete the form but cannot submit.

Form status

- **In Progress** Form is with the applicant for completion or when the form has been reviewed and 'More Information Required' is requested before a decision can be made.
- **Submitted** Form is with the research office.
- **Approved** Form has been reviewed and approved. An email notification will be sent to the PI and relevant team member/s.

Complete and submit the site amendment

Ensure there are no outstanding milestones before submitting an amendment.

Step 1. Locate SSA project

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



Tip: Depending on your screen size, you may see either of these icons

Click the required GEMS identifier.

Step 2. Select the site project

Select the SSA identifier and then select 'Forms'.

Step 3. Open amendment form

Click '+New form' and select 'Site Amendment'

Step 4. Project Details and Site Amendment Type

Choose the type of site amendment from the dropdown menu and complete the form.

Select Amendment Type *

The types of amendment that can be submitted to the RGO are:

- General amendment
- Addition of a site

Addition of a New Site
 CPI Change Notification
 PI Change Notification
 HREC Extension
 Change Site Investigators
 General
 Contract Changes

Ethics approved document upload

Upload the ethics approved document/s in this section. If there are no documents required, click 'Next'.

Note: It is mandatory to provide the approved ethics documents for NMA related amendments.

Uploading a new document

Click 'Add row' to add a document

Note: If you are unsure if the document already exists in GEMS, select 'Yes' and if it does not appear under Document Title then change the response to 'No' and follow the below instructions.

Upload as new version: Select 'No'

Title/ descriptor: Provide a clear document description.

*Tip: Do not use any character or symbol in the document title that you cannot use in the electronic filename i.e. #%&{ } < > * ? \$! ' + = ' " |*

Document type: Select from the dropdown list.

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

Upload file: Ensure the uploaded document filename is clear and descriptive.

Note: How you name your document in the 'Title/Descriptor' section is what the Research Office will see and how it will be listed on the approval notification e.g. 'Study protocol – v3.0 – 21.03.2022'

Click 'browse', select to find your document and then click 'open' to upload it.

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

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'.

Document Title: Select the form from the dropdown options.

Document Filename: Will preload.

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 PI or an authorised delegate can submit the amendment. Editors can save the form and notify the PI or delegate that it is now ready to submit.

For further information on sharing and permissions, [click here](#).

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

To download a copy of the site amendment and attachments, click the three dots next to the site amendment identifier and click 'Download Attachments'.

What next?

The amendment will be received by the research office managing the site project. Depending on the type of amendment e.g. HREC extension, Change in CPI, no further action is required.

Once reviewed, the PI and relevant team member/s will receive either an approval notification or a request for further information email (see User Guide [Site amendment – responding to a more information required request](#)).