Processing site amendments
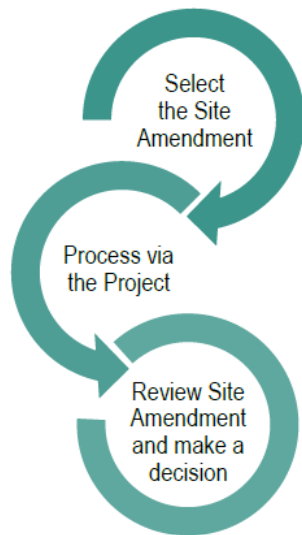
The following diagram is an overview of processing a Site Amendment in Research GEMS

Select the Site Amendment

Process via the Project

Review Site Amendment and make a decision

Note: This user guide assumes you have already set up your homepage tiles. See user guide – Setting up home page tiles

Understanding the types of Site Amendments and how they act in the system

When Ethics is in GEMS, the following approved amendments will be automatically shared with the Research Governance Office:

❖ Change to CPI – no RGO action is required. Contact details are automatically updated.
❖ Request for an Extension of HREC – no RGO action is required. Expiry date is automatically updated
❖ Change to PI – RGO review is required
❖ Addition of a New Site (Automatically creates a SA Site Application (SSA) for completion)

The following Site Amendments are submitted directly to the RGO through the Site more information form in GEMS. Ethics approval is required before the RGO can finalise;

❖ Site General Amendment

The following Site Amendments are submitted directly to the RGO via GEMS and do not need Ethics approval.

❖ Changing Site Investigators and Administration Contact
❖ Contract Changes

Processing a Site Amendment

Step 1
Select the site amendment for review and processing from the Decision homepage tile.

Step 2
You will be taken to 'Decisions' in the Site Project (post-approval).

Step 3
Download the form and attachments using the download icon. A temporary .zip file will download.

Note: Where Ethics is from an external HREC the ethics approved documents will be included as an attachment to the form.

Review the amendment form and documents, as per your local Research Office policy.

For Site General Amendments When Ethics is in GEMS, the ethics amendment form ID has been included on the Site General Amendment form.

Ethics Form ID	29977

Note to Research Office: Locate the related Ethics approved documents by typing form ID to search filter of the Related documents section.

The Research Office can search the Site Project's 'Related Documents' using the Ethics Form ID i.e. 29977, for the ethics approved amendment documents. See below example.
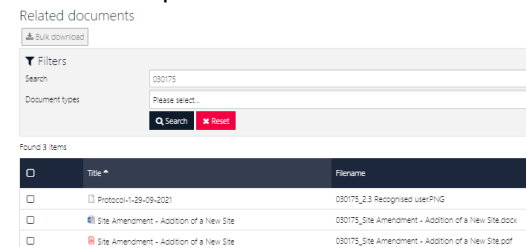
Step 4 Select 'Edit' on the right-hand side of the screen and click the 'Edit' icon on the decision row.

For Site General Amendments

Use the 'Select Documents' icon to choose the documents related to that amendment. Most recently submitted documents are identifiable by the * next to the System Version number. You can also use the Form ID which appears in the 'Filename' i.e. 030047
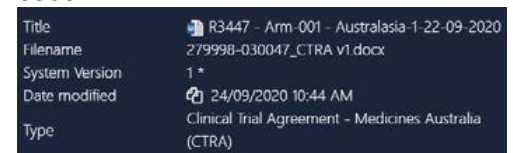
Click the tick at the bottom of the page and click 'Save' on the right-hand side of the screen.

Step 5
In the 'User' section, a list of users will prefill if your Research Office has Research Governance Officers listed in the system. If your name appears progress to step 6.

If there are no users, you will need to manually add yourself. Click the three dots at the end of the 'User' cell to

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search for the person who will or has made the decision.

Search for the user by typing in their first name, last name or email address.

Click on the checkbox next to the user and then on the 'Add user/s' tick icon at the bottom of the panel. This is the person who has been delegated authority to undertake review of Governance business i.e. Research Governance Officer (RGO).

Click 'Save' within the wizard.

Step 6
Select the 'View user decision' icon next to the form you are processing to access the user decision.

Step 7
Click on the available user decision and the management panel will appear.

Step 8
Click on 'Choose' to select the decision:
- ❖ Accepted
- ❖ Rejected
- ❖ More information required

When 'More information required' is selected, add a reason in the 'Comments' section and it will pull into the email template. Once comments have been added, click 'Save'.

Step 9
Click on the 'Send email' icon which has generated, triggering the email wizard to appear. The email template will load

based off your decision, edit as required.
You can reload the email template by
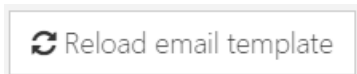
clicking the 'Reload email template' button. This will revert the email back to the original template, removing any information manually added. If you navigate away from the page, any information added manually will save.

Click 'send'. The tick next to the 'Type' of amendment indicates that an email has been sent.