# Completing an ethics application

What is an ethics application?

Ethical review is a key process to assess all research involving humans against ethical and scientific principles set out by the National Health and Medical Research Council (NHMRC).

As a result, all human research applicants must complete a Human Research Ethics Application (HREA). Once you have , your Coordinating Principal Investigator (CPI) or an authorised delegate will need to complete and submit this form in Research GEMS.

How does it work in Research GEMS?

The overall process of completing the HREA in GEMS is shown here.
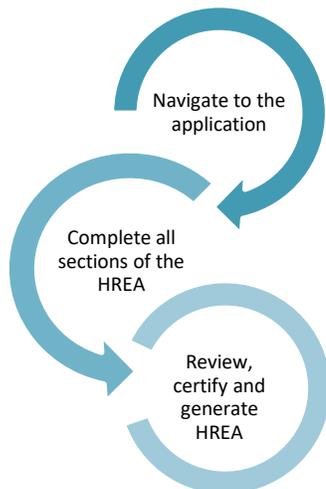
Who can view, edit and submit the application?

The CPI and any administration contacts nominated in the project registration are given automatic access to the HREA.

The HREA can be shared with view, edit and submit access to assist in the management of the application.

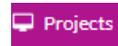*For further information on sharing and permissions, click here.*

Completing an ethics application

Step 1. Navigate to the application

Directly after project registration, select the HREA via its identifier.

Alternatively, from the GEMS home page, select the 'Projects' icon to view a list of projects you have access to.

Step 2. Complete all sections of the HREA

The introduction page contains important information, and all relevant sections are listed on the left hand side panel. Mandatory questions and fields are marked with an asterisk * and must be completed before submission.

Some information provided in the project registration will appear in the HREA.

The following details describe system requirements to be aware of in completing the rest of the form.

Project Team tab

Q1.9.1 – 1.9.3 will show all people added at project registration. A total of ten team members can be added here.

CPI – will be the first person in the table. If this person is also a site Principal Investigator (PI) they will appear multiple times – **do not remove.**

PI – Site PI/s added at project registration will appear after the CPI.

Administration contact - If you would like to add an administration contact to the ethics application who is not already listed in the table, add another line with their details.

Associate Investigator/s or project team members - Any other research team members that are required to be assessed by the Human Research Ethics Committee (HREC) should be added here.

Project Team Details tab

The person listed as CPI must have the following responses in the HREA (these will be prefilled):

❖ Q1.9.10 MUST be Coordinating Principal Investigator.
❖ Q1.9.11 MUST have 'Yes' selected.

Administration contacts should consider the following responses:

❖ Q1.9.5 Select Yes.
Q1.9.11 Up to two Administration Contacts may be given approval to Submit on behalf of the CPI.

For further information on sharing and permissions, click here.

Updating documents uploaded at Project Registration

Hint: Before updating or uploading new documents; If any of the documents have the document version or date in the electronic filename REMOVE from the file name BEFORE you upload into the HREA.

If any of the documents uploaded during project registration have been updated/edited they will need to be replaced before the HREA is submitted.

Update the description of the attachment by changing the version number and the date if required. DO NOT change the naming format of the description.
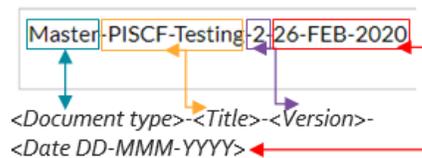
Add new documents to HREA

To add any study wide documents, click "add row."

Select 'browse' and follow the wizard.

Enter the document description as described previous.

After the HREA is submitted for the first time, GEMS requires the electronic filename to remain the same even when a new version of the document is uploaded.

For further information on file naming conventions, [click here.](#)

Remove documents from the HREA

To remove any documents from the HREA, click the X symbol to the left of the File Name to delete the document.

HREC tab

Confirm the institution and HREC/ethics review body where you will be submitting your application.

Step 3. Review, certify and generate HREA

The following sections must be completed by the CPI or an [authorised delegate](#). The CPI remains the person with overall responsibility for the research project.

Declaration tab

The person/s appearing here will be the CPI and/or an [authorised delegate](#). If the name/s are not appearing correctly, return to "Project Teams" and review the responses.

Generate HREA document

Generate refers to the submission of the application to the nominated research office. Only the CPI or an [authorised delegate](#) will be able to submit the HREA.

Person/s with edit access can save the form and notify the CPI or an [authorised delegate](#) that the application is ready to submit.

Click 'Generate HREA document.'

If you are not yet ready to submit the application, you can save and return to your HREA at another time.

Once the HREA has been submitted, a pop-up message will appear on your screen allowing you to download a .zip file of the application form and attachments. This is useful for multi-centre studies that require the submission of documents via other systems other than Research GEMS.
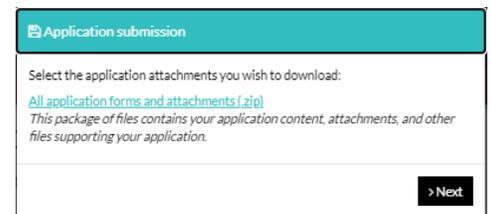
The status of the application will now appear as 'Submitted'.

What next?

Once the HREA has been submitted, your application will be assessed by the research office for eligibility to be reviewed by the HREC.

If you have any questions, contact the relevant research office of the ethics application.

Note: Any South Australian based Site Specific Assessment (SSA) application/s will not be authorised until the HREA is approved by the reviewing HREC.