REGIS

Ethics Application

QUICK REFERENCE GUIDE   FOR RESEARCH APPLICANT

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 registered your project, your Coordinating Principal Investigator (CPI) will need to complete and submit this form in REGIS.
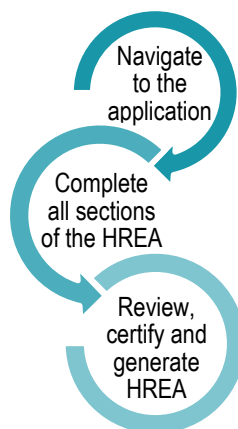
Who can access, edit and submit the application?

The person who submitted the Project Registration (if not the CPI) and the CPI have automatic access to the HREA (ETH) and can edit it. However, only the CPI can submit the application.

The CPI can give 'view' and 'edit' rights to the HREA to anyone with a REGIS account. This can be done from two places, click on the study row to expand it and select 'Invite user to register or share application' or select the 'Invite user to register or share application' button within the application, in the top right-hand corner of the screen.

Anyone with a REGIS account can have the application shared with them, they do not need to be a member of the research team.

How does it work in REGIS?

The overall process of completing the HREA in REGIS is show in the next column.

Navigate to the application

Complete all sections of the HREA

Review, certify and generate HREA

Completing the ethics application

Step 1: Navigate to the application

If you are completing directly after project registration, select the ETH identifier.

Identifier

2020/ETH00024

If completing at a later stage, from the home page select the 'Projects' icon at the top of the screen to view a list of Projects you have access to.

Select the relevant project from the list. Once in the project details, the HREA will appear with an ETH identifier and will be in the status of 'In Progress'.

Step 2: Complete all sections of the HREA

The left-hand menu shows you each section of the HREA to be completed. Several fields in the form will have been prefilled from Project Registration.

As you work your way through the application, mandatory questions and fields are marked with an *

The following details will only describe where there are system requirements to be aware of to complete the form.

Q1.9 Project Team Details:
1.9.1 – 1.9.3 will show all people added at Project Registration. If the user has completed their user profile 1.9.1-1.9.3 will be prefilled.

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

The person listed as **CPI** must have the following response in HREA (this has been prefilled).

> **1.9.4**   **MUST be the REGIS username/email**
>
> **1.9.10**   **MUST be Coordinating Principal Investigator**

PI/s – Site PI/s added at Project Registration will appear under 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 Title, Name and Surname on the previous page, 'Project Team'

1.9.5   Select Yes

AI/s or Project team members - Any other research team members that are required to be assessed by the HREC should be added here.

Updating documents uploaded at Project Registration

If any of the documents uploaded during project registration have been updated

or edited, the final version will need to be uploaded before the HREA is submitted.

Protocol: To update the Protocol with a new version click on the **x** to remove the old document

Q4.1 Attach the Project Description/Protocol to your H
- It is recommended that you use one of the templates p
- Individual attachments are limited to 10 MB in size.

File Name
x Protocol_v 1.docx

Then drag and drop or browse your local files for the new protocol.

Q4.1 Attach the Project Description/Protocol to your HI
- It is recommended that you use one of the templates pi
Description/Protocol.
- Individual attachments are limited to 10 MB in size.

x Protocol_v2 dated 12 Jan 22.docx

Other Documents: To update study wide (master) documents with a new version click on the **x** to remove the old document.

Q4.2.1 Upload attachment *

File Name	Size
x Mater PIC v1 100122.docx	18.24 kB

Then drag and drop or browse your local files for the new document.

Q4.2.1 Upload attachment *

File Name	Size
x Mater PIC v2 120122.docx	18.24 kB

Then update the description of the attachment including the version and date

Q4.2.2 Description of attachment *

Master PICF version 2 dated 12 January 2022

Add New Documents to HREA

To add a new study wide document

+ Add Another

Document Type: Select from dropdown

Document Descriptor: List exactly as you need the document to appear on the approval letter including the version and date if it exists. Usually this corresponds with the footer of the document.

Note: The document Type and Description is what the Research Office will see and how the document will appear on the approval notification.

Document Type *   Q4.2.2 Description of attachment *

Participant Infor...× ▾   Master PICF version 2 dated 12 January 2022

e.g. Participant Information Sheet Master PICF version 2 dated 12 January 2022

Upload attachment: Drag and drop or browse your local files for the new document.

Q4.3 –Q4.7 HREC
4.3-4.4 Confirm the institution and HREC/ethics review body where you will be submitting your application.

4.5 Select the Ethics Review Pathway

Low Risk review pathway is research in which the only foreseeable risk is one of discomfort. Research in which the risk for participants is more serious than discomfort is not low risk.

Greater than Low Risk review pathway Research with more than a low level of risk (as defined in paragraph 2.1.6,) must be reviewed by an HREC.

As described in the national statement on ethical conduct in human research.

If you are unsure of which review pathway should be selected, contact the reviewing Research Office to discuss.

Step 3: Review, Certify and Generate HREA.

The following sections **must be completed by the CPI**, as they are the person with overall responsibility for the research project.

Q4.7 Declaration

The person appearing here MUST be the CPI. If the CPI's name is not appearing return to 'Project Teams' and review responses.

Generate HREA Document

Selecting Generate HREA Document will submit the application to the Research Office.
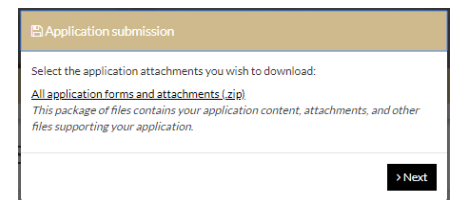
Only the CPI will have the option to submit the HREA.

Click the 'Generate HREA document' button once you are ready to submit the application.

If you are not yet ready to complete the application, you can save your progress and return to your form at another time.

Once the ethics application (HREA) has been submitted:

❖ A pop up on your screen allows you to download a .zip file of the application forms and attachments. This is useful for multi-centre studies that require document submission to other jurisdiction application portals.

🖫 Application submission

Select the application attachments you wish to download:
All application forms and attachments (.zip)
This package of files contains your application content, attachments, and other files supporting your application.

› Next

❖ The status of the application will be 'Submitted and the Research Office will proceed to assess the HREA for eligibility to be reviewed by the HREC.

❖ Any NSW Site application/s will now be created for each site listed at project registration. See *Quick Reference Guide/video: Site Application – Completing, Requesting Head of Department Support and Submitting.*