



# Ethics Application

QUICK REFERENCE GUIDE

FOR RESEARCH APPLICANT

## Completing an ethics application

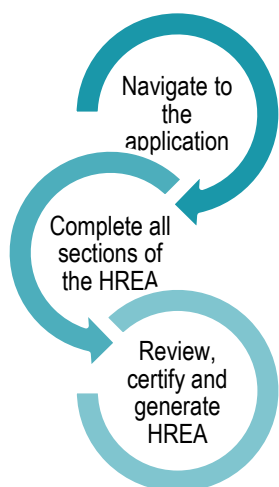
### What is an ethics application?

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), a nationwide online form developed by NHMRC and embedded into REGIS. Once you have registered your project, your Coordinating Principal Investigator (CPI) will need to complete and submit this form in REGIS.

### How does it work in REGIS?

The overall process of completing the HREA in REGIS is shown below.



### 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 and can edit it. However, only the CPI can submit the application.

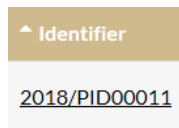
The CPI can give 'view' and 'edit' rights to the HREA to anyone with a REGIS account.

### Completing the ethics application

#### Step 1: Navigate to the application

If you are completing the HREA directly after completing the project registration, REGIS will automatically display 'Applications View' listing the ethics application within the Registered Project.

If you are accessing the HREA from the home page, select the 'Projects' icon from the top right-hand gold menu bar to view a list of Projects you have access to.



[2018/PID00011](#)

Select the relevant project from the list by clicking the hyperlinked PID under the column 'Identifier' – 'Applications view' will now display.

Once in 'Applications view' the HREA will appear in the list with the status

● In Progress and will have an identifier code that should contain the letters 'ETH', indicating it is an ethics application.

Identifier

[2018/ETH00008](#)

Click on the hyperlinked identifier code for your HREA to open the ethics application.

#### Step 2: Complete all sections of the HREA

The HREA introduction page contains REGIS specific guidance on completing the application. It is recommended you read these details before you commence. Once on the HREA introduction page, you can see all the sections that you need to complete in the left panel. As you work your way through the application, questions and fields that must be completed are marked with an \*.

Depending on your answers to some questions, further questions will reveal themselves. Your internet browser will reload while this happens.

#### Q1.1 – Q1.8 Project Overview

This section asks for high-level information about the project.

#### Q1.9 Project Team Details:

Further information about each member of the project team must be entered here.

**1.9.1 – 1.9.3** will show all people added at Project registration. If the person listed as the CPI has also been listed as a PI they will appear multiple times – **do not remove**.

The person listed as **CPI** during project registration must have the following response in HREA (this has been pre-filled).

- 1.9.10** **MUST** be Coordinating Principal Investigator.
- 1.9.11** **MUST** have Yes selected

#### Q1.10 Disclosure of Interests

Financial details and conflicts of interest should be noted in the answer to this question.

#### Q1.11 Restrictions

Add details on the publication and dissemination of data and findings from this project here.

#### Q1.12 –Q1.14 Evaluations

Add other reviews or evaluations regarding your project here.

#### Q1.15 –Q1.16 Location

Two 'Yes/No' questions are presented here about the location.

#### Q1.17 Methods

More than one research method can be selected here. For each method you select, a new section will open in the panel on the left-hand side underneath 'Method Specific'. These questions will have a number between M1.1 – M9.1.

#### Q1.18 – Q1.19 Participants

Details of participant types and groups that will be in the study are required. For each participant that you select, a new section will open in the panel on the left-hand side underneath 'Participant Specific'. These questions will have a number between P1.1–P8.3.

#### Q3.1 –Q3.18 Data and Privacy

These questions relate to privacy and security of the data. There are two tabs for completion: 'Data Characteristics' and 'Activities with Data'.

#### Q4.1 – Q4.2. Upload

The Protocol uploaded during project registration will already be attached at Q4.1.

Any other study wide documents uploaded during project registration will be attached at Q4.2

The project registration will be attached at Q4.3.

**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.

#### Updating documents uploaded at Project Registration

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


**Protocol** - to update the Protocol with a new version select 'Clear content selection'

and follow the wizard.

[Clear content selection](#)  
(KCTP\_Protocol\_REGIS.docx) [\[Open\]](#)


**Other Documents** – to update any other study wide documents 'Clear content selection' And follow the wizard.

Q4.2.1 Upload attachment\*

 [Clear content selection](#)  
(Master\_PISCF\_GeneticTesting\_v1\_1Jun18.doc) [\[Open\]](#)

then **update the description of the attachment** by changing the version number and the date if required. DO NOT change the format of description.

#### Q4.2.2 Description of attachment\*



<Document type>-<Title>-<Version>-<Date DD-MMM-YYYY>.

#### Add New Documents to HREA

To add any study wide documents, click the plus icon on the gold bar at the bottom of the screen



Select 'Upload New' and follow the wizard.

**Upload New**

Once the new document will appear in the table **enter the document description** as described above.

[Clear content selection](#)  
(Master\_PISCF\_Interventional\_REGIS.doc) [\[Open\]](#)

After HREA is submitted for the first time REIGS requires the **electronic filename to remain the same** even when a new version of the document is uploaded. **The electronic filename should NOT include any versioning or date.**

#### Q4.4 –Q4.7 HREC

Choose and confirm the institution and HREC/ethics review body where you will be submitting your application. NOTE: Q4.6 **MUST** be manually selected.

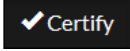
**See Step 3 below**

For further assistance if needed, contact your local research office at these links – [NSW](#) or [ACT](#).

### Step 3: Review, Certify and Generate HREA.

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

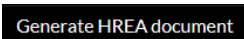
#### Declaration



Carefully read each point before clicking 'Certify'

- ❖ A Site application will also be created for each site listed at project registration if required. See *Quick Reference Guide: SSA Part 1(Completing the Application and Requesting Head of Department Support)*.

#### Generate HREA Document

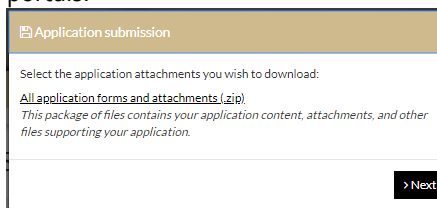


Click 'Generate HREA document'

If you are not yet ready to complete the application, you may save 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.



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

For further assistance if needed, contact your local research office at these links – [NSW](#) or [ACT](#).