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).

The process is facilitated by the completion of a Human Research Ethics Application (HREA), a nationwide online ethics application form developed by NHMRC and embedded into REGIS. It is the first application generated and completed in REGIS after Project Registration.

The NSW Office for Health and Medical Research (OHMR) provides additional information and guidance for HREA completion on their website.

How does it work in REGIS?

You, as the Research Applicant, will need to:

❖ Create a profile in REGIS – see Quick Reference Guide: Creating a REGIS User Account
❖ Register the project – see Quick Reference Guide: Creating Project Registration.

After registering the project, REGIS will:

❖ Create a project reference number called a Project Identifier (PID)
❖ Automatically generate the HREA in Project View (if prior approval is not already obtained) for your completion.

Anyone on the project team assigned to the project in Project Registration can contribute to the HREA. However only the Coordinating Principal Investigator (CPI) can submit the application.

The HREA, once submitted, is assessed by the Research Office to ensure the application is eligible for review. Then, it is reviewed by a NSW or ACT public health Human Research Ethics Committee (HREC). These administrative and review processes also occur within REGIS.

What information is needed?

You should have the following information ready to complete and submit your ethics application:

❖ Your REGIS username and password
❖ Full knowledge and detailed information about the application
❖ Project documentation uploaded at the point of Project Registration – see User Reference Guide: Creating a Project Registration.

How to complete the ethics application in REGIS?

REMEMBER! You can save your ethics application at any time for completion later.

Step 1
Opening the Ethics Application.
When you log in to REGIS, your home page will have a top right gold menu bar with some icons.

Click the ‘Projects’ icon to take you to Project View.

A list of projects will appear in a table. All your projects will have a PID – Project Identifier.

Click the hyperlink PID under the column ‘Identifier’ to see the details of your project.

Your project title should appear at the top of the screen. Click Applications on the left section panel. This is where you can access all your applications (for both ethics and site governance).
As you have registered your project, your HREA will have automatically generated and will appear in the list as ‘in progress’. The HREA will have an identifier code that should contain the letters ‘ETH’, indicating it is an ethics application.

Click on the hyperlink identifier code for your HREA to open the application for completion.

**Step 2**

**Introduction**

You are now 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 form, questions and fields that must be completed before you can submit the application are marked with an asterisk (*).

Navigate through the project using either the left panel or the following on screen buttons:

- Click to download and Preview the application.
- Click to Save the application.
- Click to go to Next page
- Click to go to Previous page

**Step 3**

Work your way through each section of the application. Depending on your answers to some questions, further questions will reveal themselves. Your internet browser will reload while this happens.

*Note: You don’t have to go through the application sections in sequential order. Finished sections will be denoted by a green check mark against the section completed. Similarly, unfinished sections will be denoted by a red cross against those sections requiring completion.*

**Step 4**

**Project Overview Q1.1 – Q1.8**

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

**Step 5**

**Project Team Details: Q1.9**

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

**Step 6**

**Disclosure of Interests Q1.10**

Financial details & conflicts of interest should be noted in this question.

**Step 7**

**Restrictions Q1.11**

Details on the publication and dissemination of data & findings from this project are added here.

**Step 8**

**Evaluations Q1.12 – Q1.14**

You are asked here to add other reviews or evaluations regarding your project.

**Step 9**

**Location Q1.15 – Q1.16**

Two “Yes / No” questions are presented here about location.

**Step 10**

**Methods Q1.17**

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

**Step 11**

**Participants Q1.18 – Q1.19**

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 participant specific questions will contain a number between P1.1 – P8.3.

**Step 12**

**Data and Privacy Q3.1 – Q3.18**

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

**Step 13**

**Upload Q4.1 – Q4.2**

Attach any relevant documents associated with the research project in these questions.

**Step 14**

**HREC Q4.3 – Q4.6**

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

**Step 15**

**Declaration**

It must be completed by the CPI, as the person with overall responsibility for the research project.

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:**

- The research office of the selected HREC will manage the application and approval process. They will assess the eligibility of the application. All eligible applications will then be submitted to the HREC for review. If you have any questions throughout this process, you should contact the research office.

- If you are also intending to conduct your project at locations, facilities or services in NSW, SSA/s will be generated within REGIS at submission of the HREA – See Quick Reference Guide: Completing a Site Specific Assessment.

For technical assistance, contact

**REGIS HELP DESK**

support.f1solutions.com.au

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