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), 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 show below.

Navigate to the application

Complete all sections of the HREA

Review, certify and generate HREA
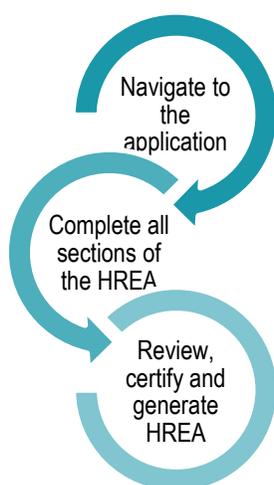
Who can access, edit and submit the application?

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.

▲ Identifier
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

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.

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

- **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

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

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

Any other study wide documents uploaded during project registration should already be attached at Q4.2.1.

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

Enter the document description in the following format
Document title_Version_Date.

For example:

Q4.2.2 Description of attachment*

Master PISCF Patient Carer Version 11.2 Date 12 June 2018

When you upload the file and have to provide a filename, please keep your electronic filenames as short as possible. Long filenames have been known to cause problems when trying to submit an application.

Also, keep in mind, HREA requires the **electronic filename to remain the same** even when a new version of the document is uploaded. As such, the electronic filename should not include any versioning or date.

Q4.3 –Q4.6 HREC

Choose and confirm the institution and HREC/ethics review body where you will be submitting your application. NOTE: Q4.5 **MUST** be manually selected.

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

✔Certify   Carefully read each point before clicking 'Certify'

Generate HREA Document

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:

❖ 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.

❖ 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).*

For technical assistance, contact
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