Guidelines for the creation and submission of Human Research Ethics Applications (HREA) to the Macquarie University Forms for Research Applications system (FoRA).

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Table of Contents

Table of Contents ................................................................................................................................................... 2
INTRODUCTION .................................................................................................................................................. 3
WHO SHOULD USE THIS GUIDE? ..................................................................................................................... 3
IMPORTANT ......................................................................................................................................................... 4
PART 1: USING THE FORMS FOR RESEARCH APPLICATIONS SYSTEM (FoRA) ......................................... 5
   Logging into Fora............................................................................................................................................... 5
   Creating a New Project ...................................................................................................................................... 6
   Completing the HREA Form ............................................................................................................................. 7
   Uploading documents (Upload tab in the generate hrea document section) .................................................... 9
   HREA Form Submission Process ..................................................................................................................... 11
   Sharing a Project with Other Collaborators .................................................................................................... 14
   Adding Comments for Other Collaborators .................................................................................................... 16
   Accessing Reviewer (HREC’s) Comments ....................................................................................................... 17
   Preparing your Response to the Reviewers Comments ..................................................................................... 18
   Accessing the Approval Letter ........................................................................................................................ 19
   Requesting an Amendment to an Approved Project ...................................................................................... 20
   Completing an Amendment Request in the HREA Form ............................................................................... 21
   Submitting an Adverse Event Sub-Form ........................................................................................................ 23
   Submitting an Annual/Final Report Sub-Form .............................................................................................. 24
PART 2: CONTACTS AND MORE INFORMATION .......................................................................................... 25
   Human Research Ethics Team ........................................................................................................................ 25
   Resources and further information .................................................................................................................. 25
INTRODUCTION

This guide describes how an applicant creates, submits, and manages human research ethics applications in the human research ethics application system. This includes:

- Creating, completing, signing, and submitting an application form
- Viewing reviewer comments
- Revising an application and responding to reviewer comments
- Submitting amendments
- Submitting unexpected adverse event reports.
- Submitting annual / final reports

WHO SHOULD USE THIS GUIDE?

- Anyone who needs to submit a Human Research Ethics Application (HREA) and previously submitted via the NHMRC portal.
- Researchers whose research includes the following categories:
  - Data linkage research
  - Clinical trials (includes research using randomised trial methods, e.g., in psychology and education research)
  - Medical and health research
  - Use of human specimens.
  - Ethics oversight required for a non-research activity e.g. authorised prescriber, case study etc.
IMPORTANT

- Google Chrome is the recommended web browser. Other web browsers are not supported, and the system may not function optimally on other browsers.

- A Macquarie University OneID is required to log in and access this system. To obtain a Macquarie University Sponsored OneID please contact the ethics secretariat ethics.secretariat@mq.edu.au for access.

- Any team member can create a new project. The person who creates the application has the role of Project Owner (Chief/Primary Investigator) and the Form Owner (form creator). Please note the project owner can also be the form owner. Project/Form Owners can share the project with other team members and determine which permissions (actions) are given to other team members.

- Only Project Owners and Form Owners can action any system alerts. System alerts are messages from the system such as system updates or form updates and are displayed at the top of each application.

- Please use the form called ‘HREA’.

- The HREA form uses skip logic. Some sections and questions on the form will only be activated from the response to a previous question.

- Documents uploaded to the application form can only be in Word or pdf format.

- There are two sides to the system the Review side (for the Ethics Secretariat and Ethics Committee) and the Applicant side (for the Applicant and collaborators). Applications submitted to the Review side of the system will be locked on submission and cannot be further edited until the application is returned to the applicant by the Ethics Secretariat.
PART 1: USING THE FORMS FOR RESEARCH APPLICATIONS SYSTEM (FoRA)

LOGGING INTO FORA

Log-in to the Applicant side of FoRA via the following URL: https://ethics-and-biosafety-form.mq.edu.au/Account/Login

Username: MQ OneID
Password: MQ OneID password

Once logged in your Work Area will look like this:
The **Work Area** consists of the following features:

- **Action tiles**: Lists the actions that can be performed, e.g. creating new projects, and creating folders to organise multiple projects (applications).

- **Icons** (top of the Work Area):
  - Notifications: Contains in-system automated messages from the system on the progress of the applications in the Projects list
  - Signatures: Indicates if there are any applications that require the Chief Investigator's signature
  - Transfers: Enables the current Project Owner and Form Owner to transfer the project to another person
  - Shared: Lists who the Project Owner and Form Owner has shared the project with

- **Projects**: Displays the list of projects that you have access to.

**CREATING A NEW PROJECT**

Click on the Action tile **Create Project** in the Work Area. The following Create Project screen will appear:

![Create Project Screen](image)

Complete the **Project Title field** and for **Form** select from the drop-down list, **HREA**.
A pop up will then advise you that the form will be shared with a list of people (from the Ethics Secretariat). Tick the box to continue.

Click on the blue **Create** button.

**COMPLETING THE HREA FORM**

Once the HREA form has been created it will be displayed in the **Navigation** tab. Not all the sections of the application will be displayed at first.
To activate the other sections of the form you will need to click on the **MQ Filter Questions** section and answer all questions before clicking on the ‘**Next**’ tile to proceed to the **HREA Introduction** section. Here you will be asked to tick the **acknowledgement box**.

To see all the sections of the HREA form, click on the **Navigate** action icon.

All active sections are in blue. The inactive sections are in black and will be activated in response to your answer to a previous question (skip logic).

Work through each section of the HREA form, from **Section 1** to **Generate HREA Document**.

All responses will be automatically saved when you navigate using the Previous and Next tiles.

Use the **Previous** and **Next** arrows to move to previous or next sections of the form.

The form sections can be completed in any order. To skip a section and access the section you want to complete, click on the **Navigate** action icon to see the full list of HREA form sections.
Click on the Information icons available throughout the form and further information will be available via a pop-up (example below):

UPLOADING DOCUMENTS (UPLOAD TAB IN THE GENERATE HREA DOCUMENT SECTION)

In this section, all project documents need to be uploaded into the relevant sub-sections.
Select the specific supporting document types to be uploaded.

- Advertising material
- Case report form
- Copy of ethics approval
- Cover letter
- Curriculum vitae (CV) or resume of investigator/researcher
- Data management plans
- Drug data sheet
- Ethically defensible plans
- Evidence of Clinical Trial Notification (CTN)
- Form of indemnity
- GP/consultant information
- Institutional biosafety committee (IBC) approval
- Investigator brochure or reference safety information
- Invitation to participant
- Letter of support
- Licence for dealing with a genetically modified organism
- NSW privacy form
- Participant documentation e.g. diary, wallet card
- Participant information and consent form
- Participant information and consent form (Tracked)
- Peer review
- Protocol (Tracked)
- Questionnaire
- Radiation: letter re standard care
- Radiation: medical physicist's report
- Report forms
- Response letter
- Statistician comments
- Western Australian specific module
- Other project-related documentation

Curriculum vitae

[Upload Document]
To upload a document, click on the **Upload Document** button in one of the sub-sections. The following screen will appear (example below):

![Documents - PROTOCOL](image)

Click on the **Browse** button and select the document you wish to add to this sub-section.

Enter a **Version Date** and **Version number** and click on the **Upload** button.

Once the document is uploaded, the system will return you to the Attachments section.

After all relevant documents have been uploaded to this section proceed to the next section of the form using the **Next** arrow.

**HREA FORM SUBMISSION PROCESS**

When you reach the **Declarations** section of the form, use the tick boxes to select which team members need to sign off on the application.

![Investigator Team Declarations](image)

Once you have selected the person(s) who are required to sign off on the application, use the **Next** arrow to continue to the sign off page(s)

Click on the **electronic signature** or **upload other evidence** option then click the Sign button.
The system will do a **completeness check** to ensure that all the sections of the HREA form have been completed. Any sections that have not been completed will be presented in a list.

Click on the **blue links** to the sections that need to be completed. When all sections have been completed proceed to **Declaration** section and click on the **Sign** button again. The Sign Form will appear:
Enter your OneID as the username and your password, click on the Sign button. The following screen will appear:
All submitted projects are placed in a queue before they appear in the Review side of the system. Once the project appears in the Review side of the system, the Submission in Progress will change to Submitted.

**SHARING A PROJECT WITH OTHER COLLABORATORS**

The Project Owner and Form Owner is the role allocated to the person who creates a new project. A Project Owner and Form Owner can share a project with other team members, known as Collaborators in the system.

The Project Owner and Form Owner also choose what access permissions will be allocated to each collaborator. To share a project with another team member, click on the Action tile Share.
The following will appear:

Enter the collaborator's email address and select the access permissions for the collaborator from the list provided. Click on the Share button.

To check that the project has been shared with the collaborator access the list of collaborators via the Collaborator tab. The access permissions for each person will be displayed.
ADDING COMMENTS FOR OTHER COLLABORATORS

The HREA form enables all collaborators to communicate with each other about the responses to each section of the form.

To make comments in the form, select one of the form sections. Click on the Speech bubble at the top right of the page.

The Comments screen will appear.

Click on Add Comment. A comment box will appear.

Enter the comment in the response box and click Save. Additional comments can be added by clicking on Add Comment again.

Click on the Close button to return to the form section.
The number of comments added to that section of the form will appear in the speech bubble and will also appear in the Comments action icon.

ACCESSING REVIEWER (HREC’S) COMMENTS

After the ethics committee has reviewed the project, the Ethics Secretariat will add the reviewers’ comments to the HREA form and return the project to the Applicant side of the system.

The Review Status of the project will be Unlocked.

To access the reviewers’ comments, click on the Reviewer Comments action icon.

The Overall Reviewer Panel Comments screen will appear. This screen will list one or more reviewer comments.
The reviewer comment will also appear in a speech bubble at the top right-hand side of the relevant section. Click on the speech bubble on the left. (The speech bubble on the right contains comments on the project from team members).

Preparing your Response to the Reviewers Comments

**Your response will need to include:**

- A Word or pdf document directly addressing each of the Reviewers’ comments should be uploaded to the uploads/attachments section of the form.
- A tracked and clean copy of all revised documents uploaded the uploads/attachments section of the form.
- Amendments (changes made directly on the application) to relevant sections of the form in line with the reviewers’ comments.

To amend a response in the form, click on the section of the form you wish to change. Click on the text box/question and edit the content or change the response from the options available in the section.

Click the **Save** action icon to save the response.

When the response is ready for review, please complete the signature process in the Declaration – CI/PI/LI section of the form. From here you will be able to submit the changes for review.
ACCESSING THE APPROVAL LETTER

After the Human Research Ethics Committee has reviewed and approved your response, the Ethics Secretariat will send the approval letter to the Applicant side of the system. You will receive a notification that the application has been approved and you will receive an approval letter as an attachment via the Notifications tile in your Work Area.

Click on the attachment symbol and the attachment will appear.

Download a copy of the approval letter by clicking the **Download** button.
REQUESTING AN AMENDMENT TO AN APPROVED PROJECT

All approved applications are locked and cannot be edited. You will need to request that the project be unlocked so that an amendment can be submitted. A request to unlock the application can be made to the Ethics Secretariat via the Correspond action tile in the project or via the Correspondence tab in the project.

Click on the Correspondence tab or Correspondence tile.

Click on New Correspondence then type your request to unlock the project for amendment into the box (below) that opens and click on the Send button.

The Ethics Secretariat’s reply will appear above your message, as follows:
To see the content of the Ethics Secretariat’s reply, click on the link under the **Message** heading.

To send a new message, click on the Close button and click on New Correspondence. When the project is unlocked, the Review Status of the project will be **Unlocked**.

## COMPLETING AN AMENDMENT REQUEST IN THE HREA FORM

Select the project that you wish to amend from the list of **Projects** in the Work Area screen (after you have requested it to be unlocked).

Click on Section 1 (MQ Filter Questions) of the form and change the response to **question 0.1** to state **Amendment request** (not New Application). Click on the **Save** action icon. This action will trigger the appearance of **question 0.6 (Amendments)** where the details of the amendment request can be provided. To access question 0.6, scroll down the page to the bottom after answering question 0.1.

In question 0.6, select the type of amendment you wish to make – personnel changes, other, or both. If you select additional or removal of personnel, you will be asked to indicate whether the CI is changing before being redirected to question 0.5 to fill in or remove personnel details. See screenshot below:
If you select other project changes, the following questions will appear and **must** be answered:

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**0.6 Indicate the nature of the change you are making to the project**

- ☐ Addition or removal of personnel
- ☑ Other project changes

**0.6.1 Is the chief investigator changing?**

- ☐ Yes
- ☑ No

*Please update the researcher profile in question 0.5, and the chief investigator faculty in question 0.3.1 (applicable only for the Chief Investigator), and the Project Team section (applicable for both the Chief Investigator or other personnel) of this form.*

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Applicants then complete the form by answering all questions and by clicking the **Next** button to move through the form. The sign-off process for an amendment involves the CI sign off in the declaration section.

When the amendment is approved, the system will send you an email notifying you that the amendment has been approved. This will also appear in the Notifications tile.
SUBMITTING AN ADVERSE EVENT SUB-FORM

The Adverse Event Form is a sub-form of the main form. Click on the **Create Sub-form** action tile in the project.

Select the **HREA ADVERSE EVENTS v.1.0** from the drop-down selection

A pop up will then advise you that the form will be shared with a list of people (from the Ethics Secretariat). Tick the confirmation box to continue.

Click on the **Create** button. The Adverse Event Sub-form will appear in the Project Tree at the top of the Work Area and the form will appear in the Navigation tab.

Not all the sections of the Sub-form will be displayed at first.

To activate the rest of the sections of the form click into section **0.3 Acknowledgement** and tick the acknowledgement box. The information will be automatically saved.

The system will auto-populate details of the personnel listed in the main form into section **1.1** of the Adverse Event Report sub-form.

Complete all section of the form. Sign-off on the form in section **5.3**, before clicking submit.
SUBMITTING AN ANNUAL/FINAL REPORT SUB-FORM

The Annual/Final Report is a sub-form of the main form. Click on the Create Sub-form action icon in the project. Select the HREA ANNUAL/FINAL REPORT v.1.0 from the Drop-down options.

A pop up will then advise you that the form will be shared with a list of people (from the Ethics Secretariat). Tick the confirmation box to continue.

Click on the Create button.

The Annual/Final Report sub-form will appear in the Project Tree at the top of the Work Area and the form will appear in the Navigation tab.

Not all the sections of the Sub-form will be displayed at first.

To activate other sections of the form, click into section 0.3 Acknowledgement and tick the acknowledgement box. The information will be automatically saved.

Click on Question 1.1 in Section 1 to select the type of report that you wish to submit, i.e. Annual Report or Final Report. This triggers sections relevant to the type of form chosen, i.e. section 2.1 for an Annual Report or section 3.1 for a Final report. Please see the screenshot below.

![1.1 Report Details](image)

The system will auto-populate details of the personnel listed in the main form into section 1.1 of the Annual/Final report sub-form.

Complete all section of the form. Sign-off on the form in section 5.3, before clicking submit.
PART 2: CONTACTS AND MORE INFORMATION

HUMAN RESEARCH ETHICS TEAM

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RESOURCES AND FURTHER INFORMATION

For access to the National Statement for the Ethical Conduct in Human Research click this link

For further information, resources, templates, and important dates please go to the MQ Human Ethics Website

For more guides and FAQ's visit the MQ Human Ethics Wiki

For submitting a HASS Ethics application go to the Human Research Management System