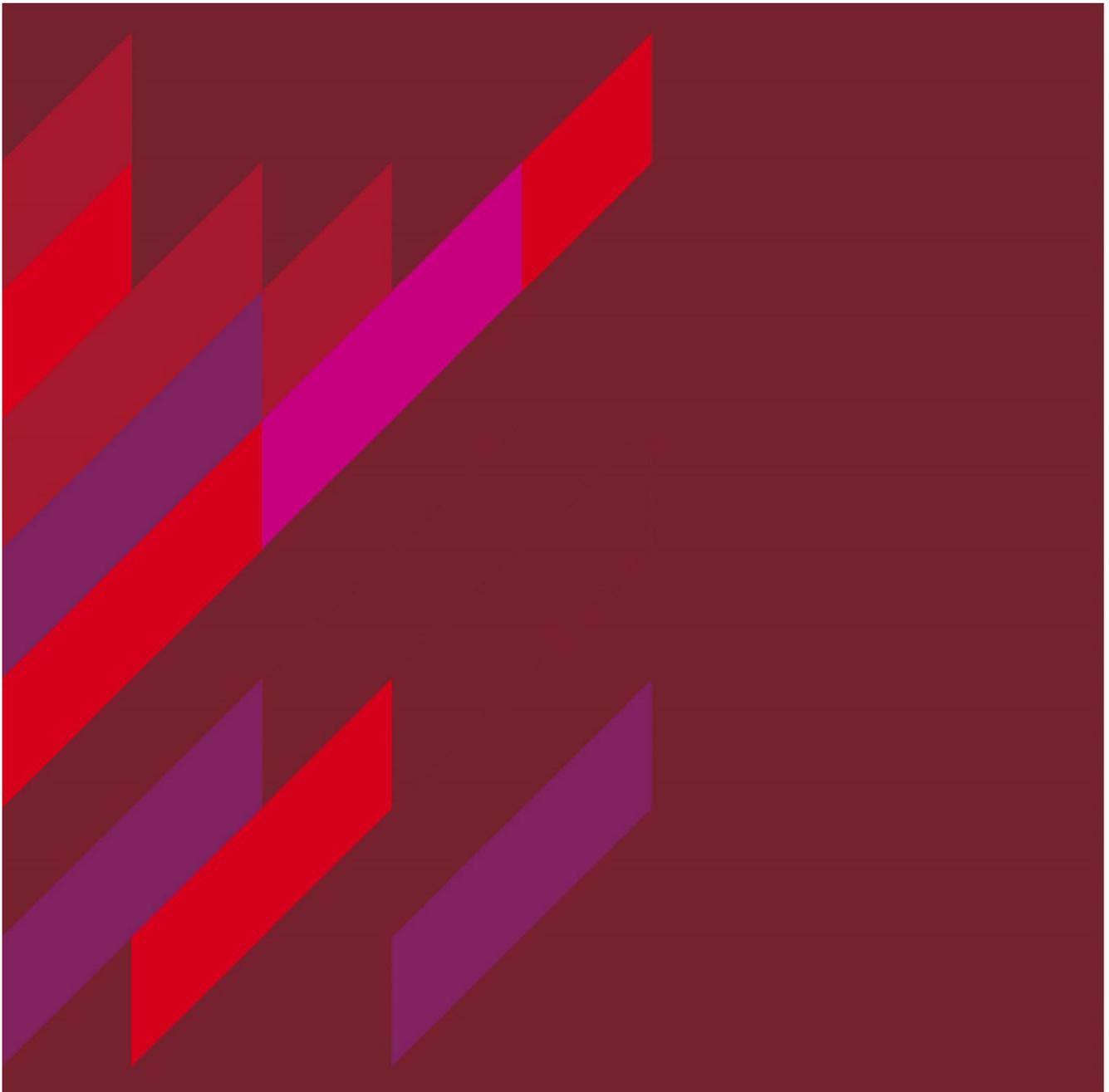# FoRA: RISK ASSESSMENT
APPLICANT GUIDE

Information and hints to help you complete the essential elements of the Risk Assessment (RA) section of the Human Research Ethics Application (HREA) in the Macquarie University Forms for Research Applications system (FoRA)

Version Date: *June 2024 V1*

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For additional help:

For technical support, contact OneHelp:
+61 2 9850-HELP (4357)
help@mq.edu.au

For Human Research Ethics support,
contact ethics.secretariat@mq.edu.au

RA APPLICANT GUIDE

Forms for Research Applications   June 2024

INTRODUCTION

The *National Statement on Ethical Conduct in Human Research (2023)* has been updated. One of the most significant changes is the new requirement that all human research must be reviewed for risk. This now includes research considered exempt from ethical review. To streamline this new process and create a one-stop form for all human research, the new Risk Assessment form AND the Data Management Plan have been integrated into the HREA (Human Research Ethics Application) form.

The Risk Assessment Section has two purposes:

1.   To help researchers determine the **level of risk** of their research project
2.   To provide a pathway for research that may be considered **Exempt** from ethics review

The Risk Assessment (RA) questions are organized into **5 sections** to identify any foreseeable risks, discomfort, or specific types of data associated with the research. Upon completing a section, if your project is determined to be "Low Risk" or "Greater than Low Risk," you will receive a pop-up statement informing you of the assessed risk level. In such cases, you will not need to complete the remaining RA sections and will be directed to the main HREA and integrated Data Management Plan (DMP) form for completion. If no determination is made, you will proceed to the next RA section. You will only complete all five sections if your answers indicate that your project is "Minimal Risk" and likely exempt from ethics review.

This guide focuses exclusively on the **Risk Assessment/Exempt Section,** which serves as the pre-filter questions to the HREA. It describes how an applicant creates, submits, and manages an application in FoRA, including:

- Creating, completing, signing, and submitting an application form

- Viewing reviewer comments

- Revising an application and responding to reviewer comments
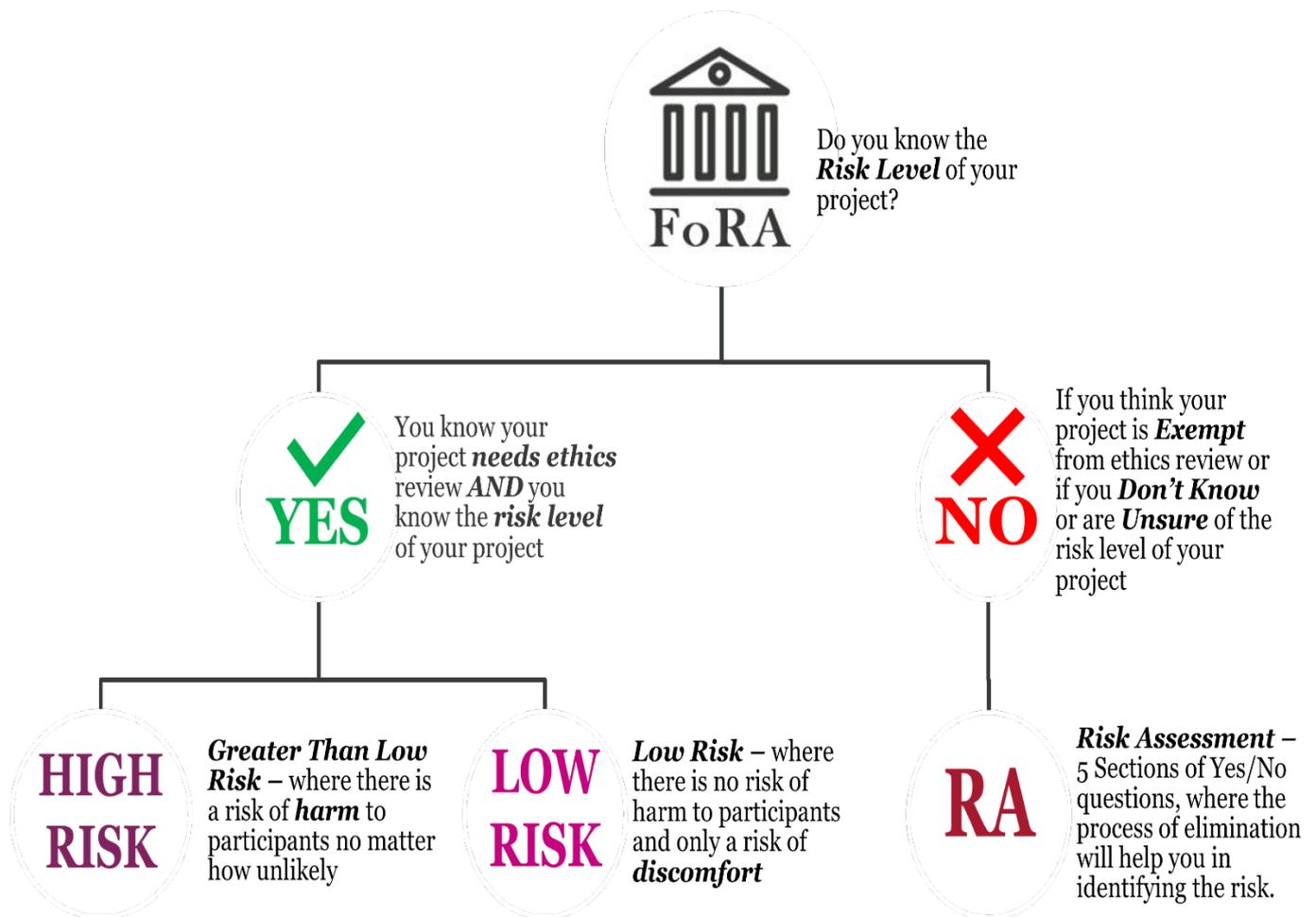
For how to submit a **HREA application** go here for guide

For how to submit the **DMP Section of the HREA** go here for guide.

WHO SHOULD USE THIS GUIDE?

1. Anyone who is either *unsure* or *does not know* the **RISK LEVEL** of their research project
2. Anyone who believes their research is **EXEMPT** from ethics review

Use the below flow diagram to help you decide which pathway is appropriate for your research project. If your research is either "Low Risk" or "Greater than Low Risk" please refer to the [**FoRA Applicant Guide-HREA**](#) go here for guide for how to submit.

Do you know the *Risk Level* of your project?

YES — You know your project *needs ethics review AND* you know the *risk level* of your project

NO — If you think your project is *Exempt* from ethics review or if you *Don't Know* or are *Unsure* of the risk level of your project

HIGH RISK — *Greater Than Low Risk* – where there is a risk of *harm* to participants no matter how unlikely

LOW RISK — *Low Risk* – where there is no risk of harm to participants and only a risk of *discomfort*

RA — *Risk Assessment* – 5 Sections of Yes/No questions, where the process of elimination will help you in identifying the risk.

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 Risk Assessment form is integrated as pre filter questions to the HREA

- The RA filter questions sections of 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 PLATFORM (FoRA)

LOGGING INTO FORA

Log-in to the Applicant side of FoRA via the following URL: https://fora-form.mq.edu.au/

Username: MQ OneID

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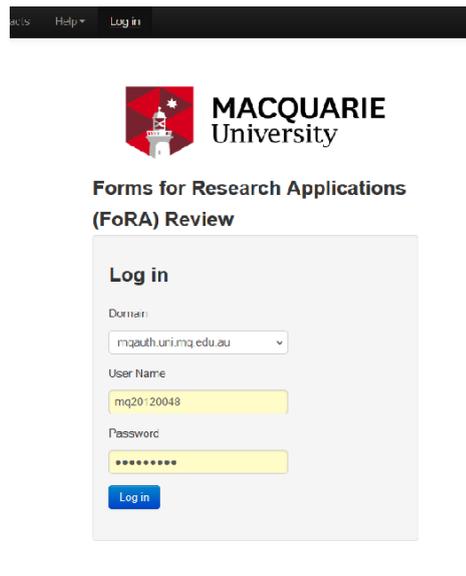
Once logged in your **Work Area** will look like this:
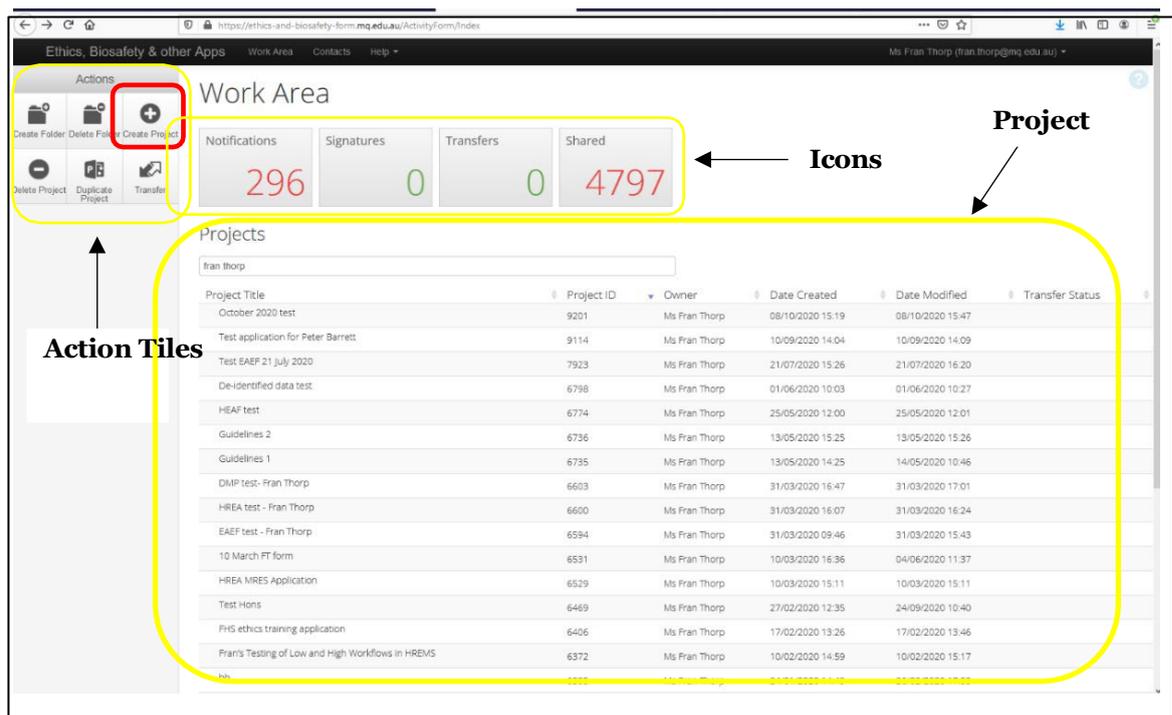
The **Work Area** consists of the following features:

- **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:
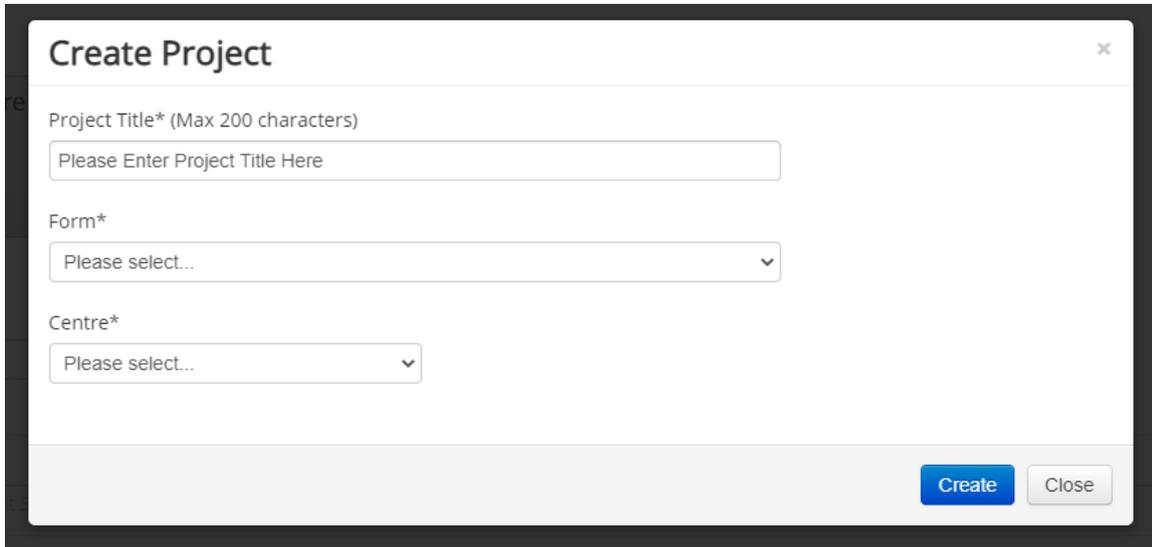
Complete the **Project Title** field and for **Form** select from the drop-down list, Human Ethics Applications **HREA**
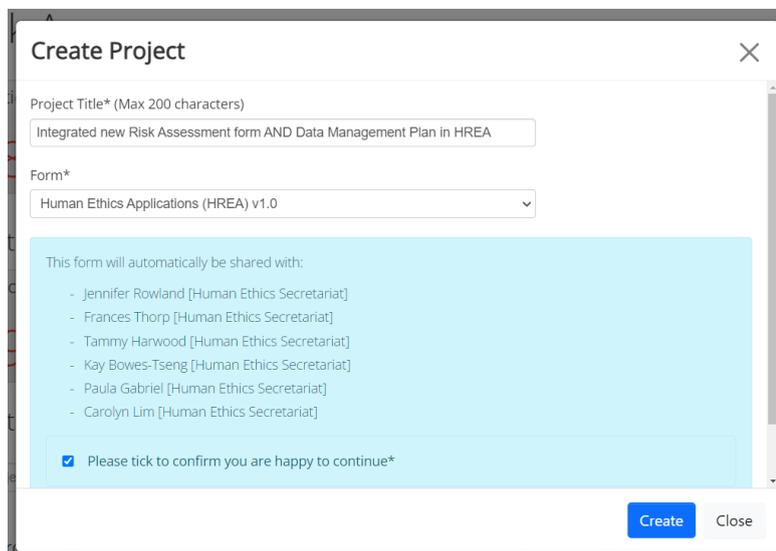
A pop up will advise you that the form will be shared with a list of people (all members of the Ethics Secretariat Team).

Tick the confirmation box.

Click on the blue **Create** button.

COMPLETING THE MQ FILTER QUESTION SECTION

Once the form has been created it will be displayed in the **Navigation** tab. Not all the sections of the application will be displayed at first, as some sections are inactive.

The inactive sections are in black and will be activated in response to your answer to a previous question (skip logic). The blue sections contain links and will open if clicked on.

To activate the other sections of the form, click on **MQ Filter Questions** and complete the **Application Purpose**.

If this is a new application, then select **New application** and **complete the Project Title field.**

Search and add the **Chief Investigator (CI)** for the project.

Note: There should be only one Chief Investigator (CI) listed on the project. The CI must be a continuing MQ staff member, Students cannot be a CI. For student projects, the CI must be the Macquarie University primary supervisor and the students should be listed as Co-Investigators.

The Chief Investigator (CI) can only be added by clicking in the **Search User** text box, and searching for using the Chief Investigators name and MQ email address.

Select the relevant Chief Investigators email address and their information will automatically populate for you.

After completing this section, click **'Next Page'** or the ⊘→ icon in the Action Tile section
Next

This unlocks the inactive **MQ Risk Review Questions** to complete.
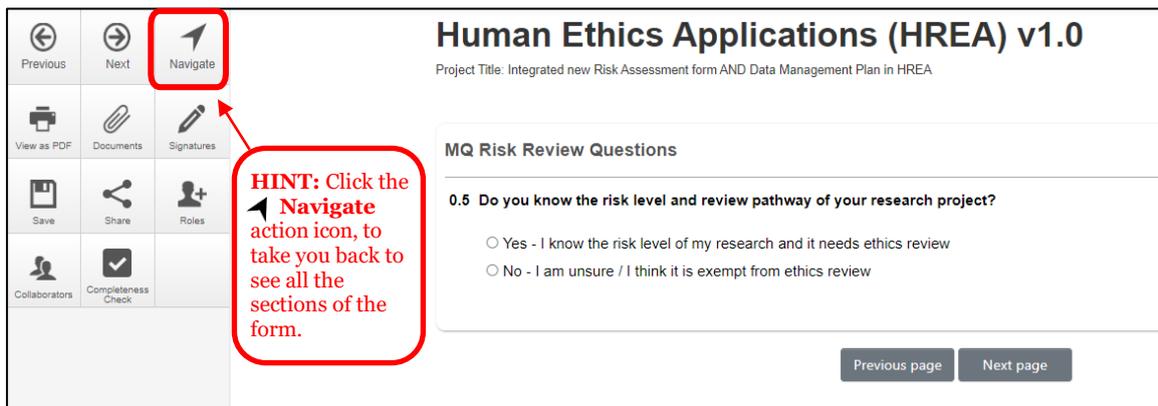
The **MQ Risk Assessment Section** will evaluate whether the research involves foreseeable harms, even if unlikely, vulnerable groups, or specific topics as outlined in the National Statement. It will also consider any foreseeable "discomforts" to participants. This assessment will help determine the level of risk for your project.

The first question you will be asked in the MQ Risk Review Questions is: **Do you know the risk level and review pathway of your project?**

If you know the level of risk (***Low Risk*** or ***Greater than Low Risk***) for your project, select **"Yes – I know the risk level of my research and it needs ethics review"**.

At this stage, you no longer need to complete the remaining Risk Assessment Sections. You will be directed to the **MQ Ethics Review Filter Questions**. Since you have indicated you know the risk pathway, choose one of the two options provided:

1. Low Risk

2. Greater than Low Risk

Select the appropriate risk review pathway for your project and click

'Next Page' to continue to the **MQ Ethics Review Filter Questions.**

MQ Ethics Review Filter Questions

0.6 Under which review pathway are you intending to submit this application? (Please do not change the risk level of your application when making an amendment. A change in the risk level will cause a significant delay to the review time).

○ Low Risk
○ Greater than Low Risk

If you are continuing on the "**Know my Risk**" pathway please refer to the **FoRA Applicant Guide-HREA** On how to submit a HREA

COMPLETING THE MQ RISK ASSESSMENT FILTER SECTION

If you are unsure of the risk level of or believe it may be exempt from ethics review, select **"No"**. The system will provide further information about the risk assessment section.

- If you are **unsure** or **don't know** the risk level or you think your research is **Exempt** from ethics review: **select No**.
  - You will be taken into the first set of Risk Assessment question sections.

The **MQ Risk Assessment Questions** section is divided into three steps: RA, RB, and RC. Based on the responses to these questions, some sections may not be relevant or necessary to complete.

Click "**Next**".

The **MQ Risk Review Questions** are primarily **"Yes"** or **"No"** selections or single preference selection from a list of choices. If you are not sure of your response the best practice is to err on the side of caution and identify a higher level of risk if it's a 'close call'. Please note: If your response

opens a text box, please provide the required information.

The risk assessment section will provide real time advice based on your responses to the questions. Risk assessment advice will be displayed at the bottom of the screen in red for you to follow.

If there are no pop-up instructions, **click 'Next'** and continue to complete the next section until you are provided advice on which risk pathway to use.

The last step in the risk assessment form will identify if your study requires an ethics review, or if it is 'exempt'.

Depending on your response to the questions in **RC. Assessment of Risk** section, it may trigger further questions to be answered, advise you to submit a low-risk ethics application, or a possible exemption from ethical review.

If an exemption is suggested, and you agree to this assessment, the system will provide advice in red on screen. This will trigger new questions to unlock which you will need to complete. If it has been determined your project is Exempt from ethics review you MUST upload a copy of your protocol or project description or it will be returned to you before it is reviewed.

To upload the project description, click on the **Upload Document** button.
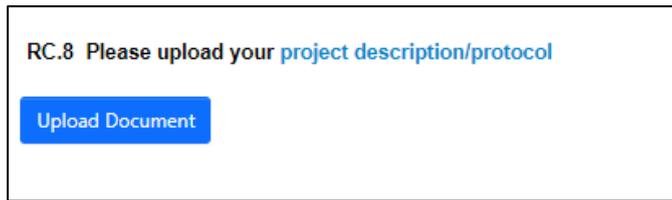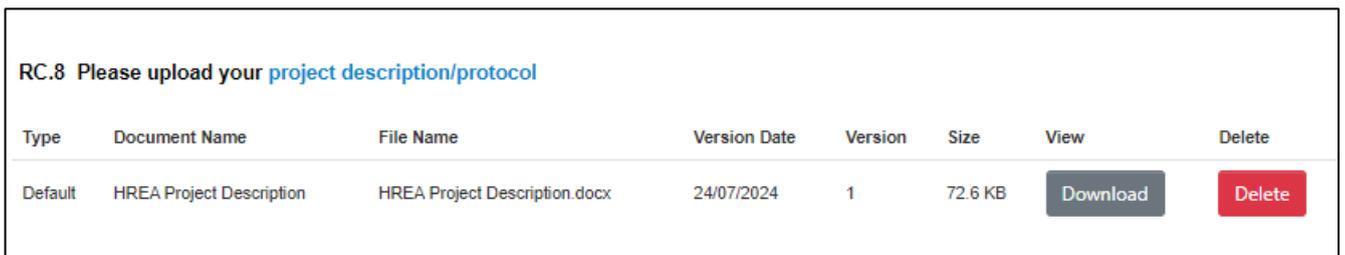

The following screen will appear (example below):

Click on the **Browse** button and select the project description/protocol.

Enter a **Version Date** and **Version number** and click on the **Upload** button.
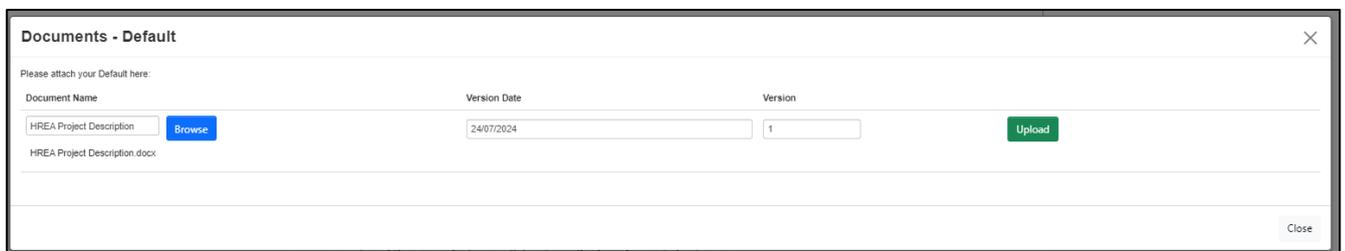
Once the document is uploaded, the system will return you to the same screen where you can see the uploaded project description.

Select the tick box **'I agree'** and click **'Next'**

Please complete Questions RC.6 and RC.7, and upload your project description and submit for review.

RC.6 What is the Project Title (as presented in the Project Description/Protocol)? Minimise the use of acronyms where possible. Please keep the total number of characters below 2000 * with same link out as per the HREA

RC.7 Provide a summary of the research project in non-technical language. * This summary should provide the reviewers with an overview of the research aims, participants, methods and expected outcomes.

RC.8 Please upload your project description/protocol

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Default	HREA Project Description	HREA Project Description.docx	23/07/2024	1	72.6 KB	Download	Delete

RC.9 Declaration - This declaration must be completed by the Chief Investigator

You can upload evidence of the Chief Investigators' agreement to this declaration (e.g. a PDF of an email).

You can use the request signature feature to have the Chief Investigator complete their declaration within this application.

Upload any supporting documents and enter the relevant details before requesting electronic signatures/electronically signing the application as this will lock the form.

This system requires you to enter the names of members who are signing this application. You must also indicate how the member will be signing, and upload any signature documents prior to requesting any electronic signatures. The application will be locked (read only) once you have signed/requested electronic signatures."

☑ I agree

Previous page   Next page

RISK ASSESSMENT FORM SUBMISSION PROCESS

When you reach the Declaration section of the form, the CI will need to sign off here.

If you are the CI, select digital signature or upload other evidence option then click the Sign button.
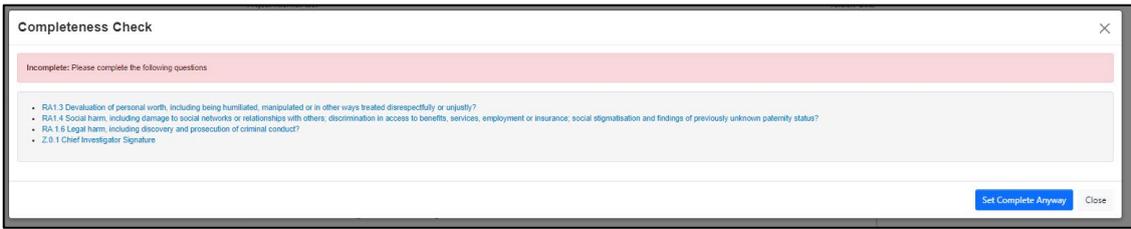
If you are not the CI, click **'Request signature'**.

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 go to the sections that need to be completed.
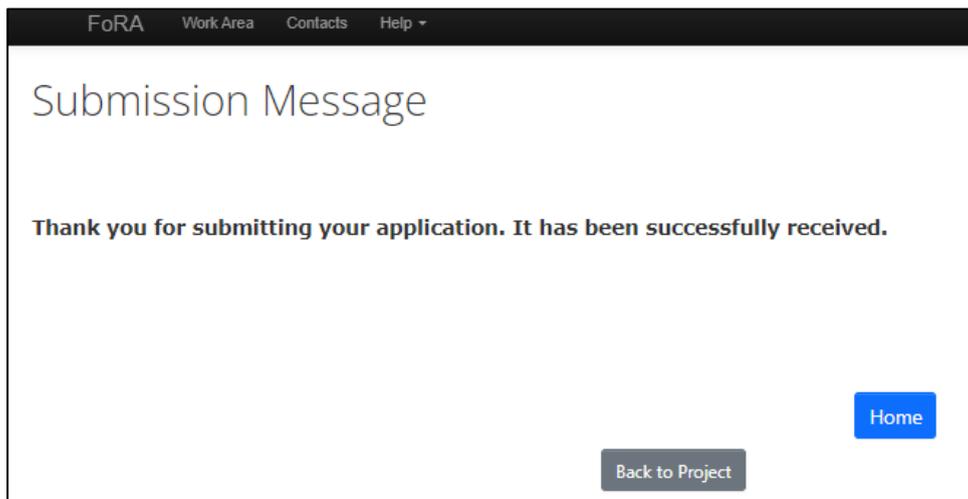
When all sections have been completed proceed to **Declaration** section and click on the blue **Sign** button again. The Sign Form will appear:
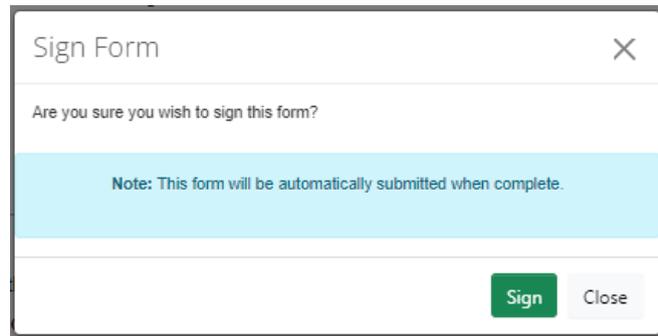
Click on the green '**Sign'** button.

The following submission screen will appear:

All submitted projects are placed in a queue before they appear in the **Review** side of the system. You can see if any action is required on the form, and the status of the submission

Once the project appears in the **Review** side of the system, the **Submission in Progress** will change to **Submitted**.
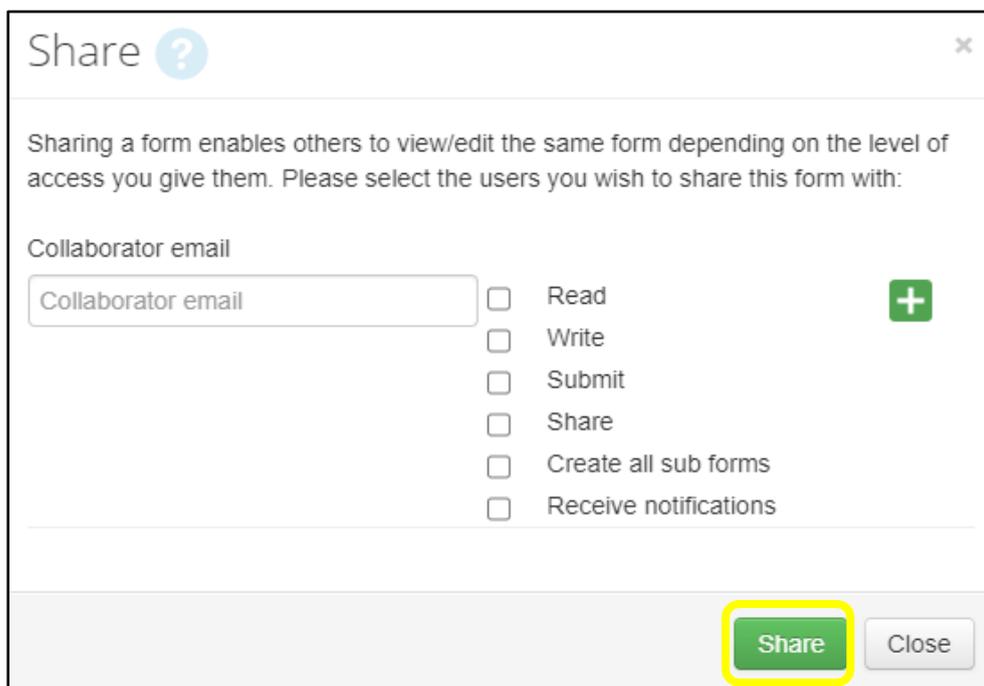
SHARING A PROJECT WITH OTHER COLLABORATORS

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**.
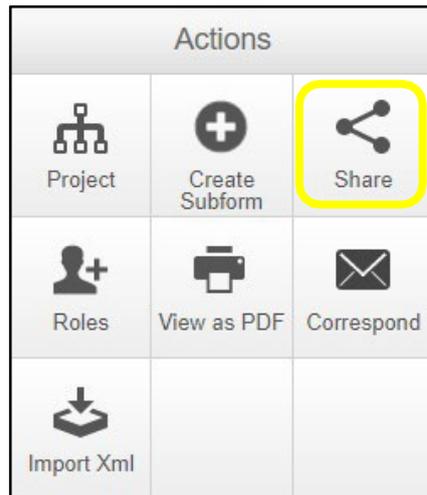
The following will appear:

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 integrated 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.
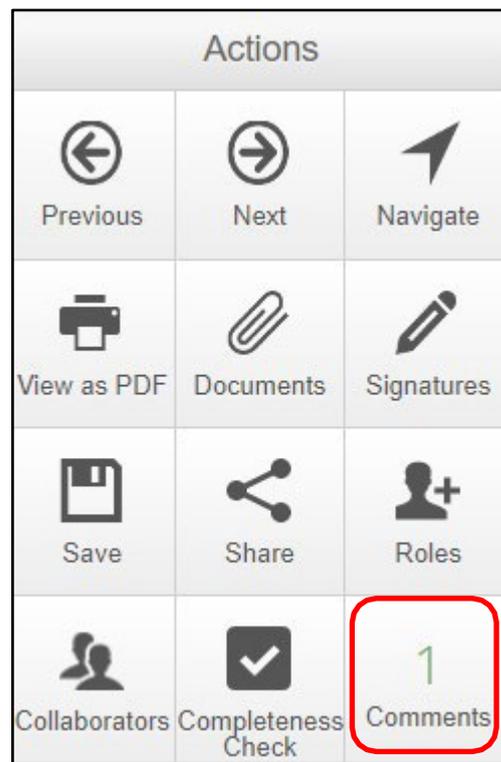
ACCESSING REVIEWER COMMENTS

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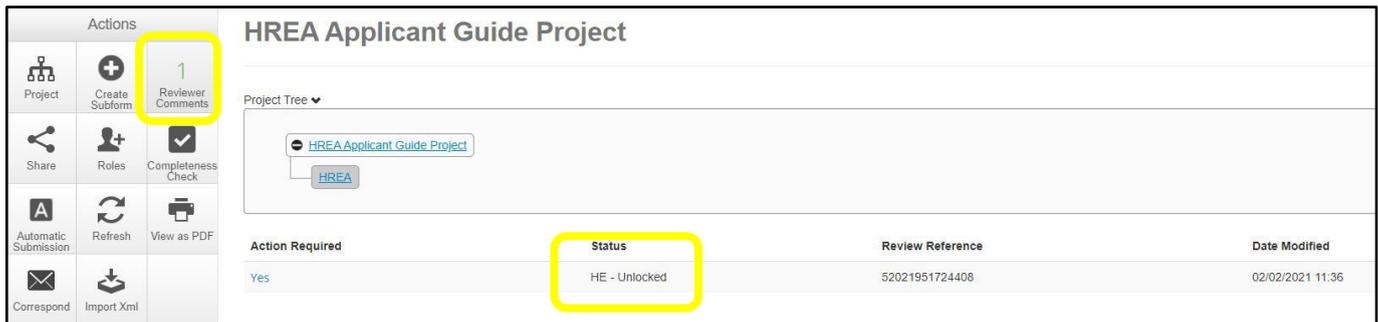
The **Overall Reviewer Panel Comments** screen will appear. This screen will list one or more reviewer comments.
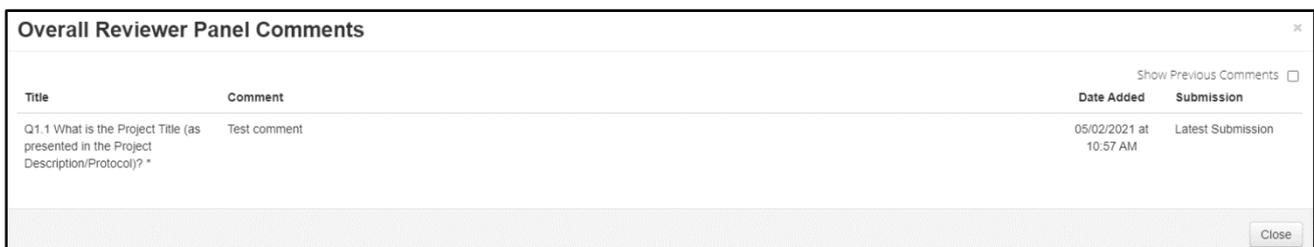
The reviewer comment will also appear in a speech bubble at the top right-hand side of the relevant section. Click on the speech bubble on the left. (The speech bubble on the right contains comments on the project from team members).

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 your project has been assessed for risk and found to be Exempt from ethics review, FoRA will generate an 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.

Exempt and Risk Assessment Workflow

I DON'T KNOW OR AM UNSURE OF PROJECTS RISK LEVEL?

You will be taken into the first set of the *5 RA Question Sections.* Answer each *Section in Order and Follow the Directions*

Completed all *5 Sections* of the *RA*; indicates your project may qualify as *"minimal risk"* and *exempt* from ethics review

Submit Application with a *Project Description/ Protocol* for *Risk Review.*

Project is *reviewed for Risk* and you are *notified via the system.* There are *1 of 3 outcomes*

Please Note your answers may trigger a pop-up statement identifying your project as "*Low Risk*" or "*Greater than Low Risk*" you will not need to complete the rest of the RA sections and will be directed to the *HREA and DMP*

You may be asked to *supply more information*

Based on the *risk level* refer either to the *Low-Risk* or *Greater than Low Risk Workflows*

①

② Your research may be reviewed as *more* than *"minimal risk"* and a full *HREA* and *DMP* needs to be submitted

③ Your research has been reviewed as **"Minimal Risk"** and **Exempt** from ethics review, and *no further reporting* is required to Ethics

PART 2: CONTACTS AND MORE INFORMATION

HUMAN RESEARCH ETHICS TEAM

Jennifer Rowland	Fran Thorp	Tammy Harwood	Kay Bowes-Tseng	Paula Gabriel	Carolyn Lim
Human Research Ethics Manager & Secretariat to MDS HREC	Human Research Ethics Coordinator & Secretariat to HASS HREC	Human Research Ethics Coordinator	Human Research Ethics Officer	Human Research Ethics Administrator	Human Research Ethics Administrator
jennifer.Rowland @mq.edu.au 02 9850 4194	fran.thorp @mq.edu.au 02 9850 7850	tammy.harwood @mq.edu.au 02 9850 4490	kay.bowes-Tseng @mq.edu.au 02 9850 4197	Paula.Gabriel @mq.edu.au 02 9850 4459	Carolyn.lim @mq.edu.au 02 9850 4459

RESOURCES AND FURTHER INFORMATION

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

https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023

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

https://www.mq.edu.au/research/ethics-integrity-and-policies/ethics/human-ethics

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

https://wiki.mq.edu.au/login.action?os_destination=%2Fpages%2Fviewpage.action%3FpageId%3D271189535

For submitting an application go to the FoRA

https://fora-form.mq.edu.au/ActivityForm/Index