



FoRA - HREA APPLICANT GUIDE

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

Version Date: June 2021 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

HREA APPLICANT GUIDE



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

FoRA Review Work Area Contacts Help Log in

MACQUARIE
University

**Forms for Research Applications
(FoRA) Review**

Log in

Domain
mqauth.uni.mq.edu.au

User Name
mq20120048

Password
.....

Log in

Once logged in your **Work Area** will look like this:

Ethics, Biosafety & other Apps Work Area Contacts Help Ms Fran Thorp (fran.thorp@mq.edu.au)

Actions
Create Folder Delete Folder Create Project Delete Project Duplicate Project Transfer

Work Area

Notifications 296 Signatures 0 Transfers 0 Shared 4797

Icons

Project

Action Tiles


Projects

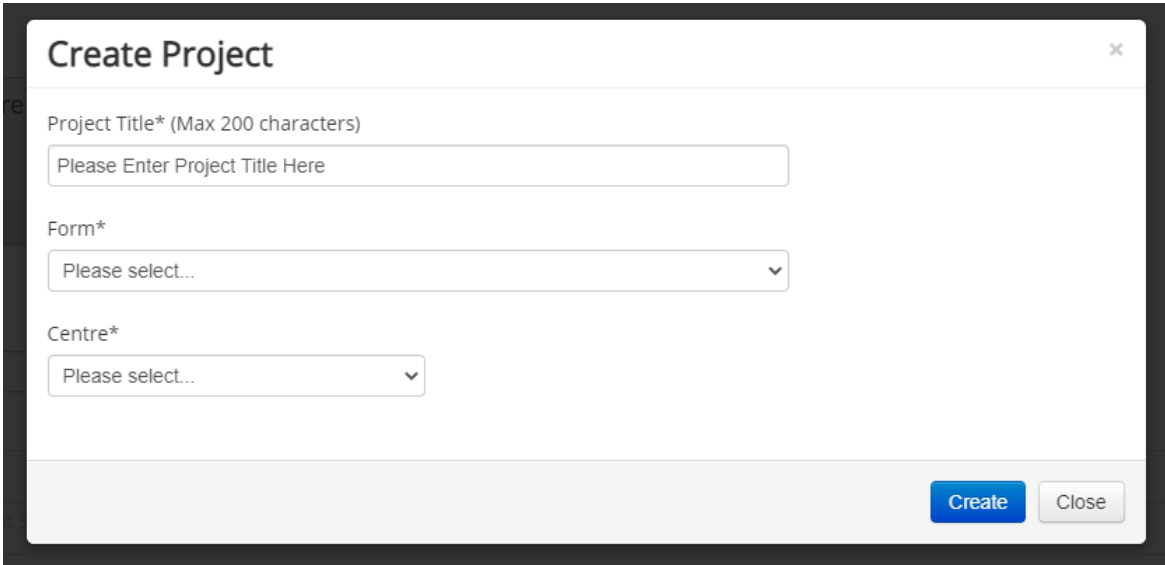
Project Title	Project ID	Owner	Date Created	Date Modified	Transfer Status
October 2020 test	9201	Ms Fran Thorp	08/10/2020 15:19	08/10/2020 15:47	
Test application for Peter Barrett	9114	Ms Fran Thorp	10/09/2020 14:04	10/09/2020 14:09	
Test EAEP 21 July 2020	7923	Ms Fran Thorp	21/07/2020 15:26	21/07/2020 16:20	
De-identified data test	6798	Ms Fran Thorp	01/06/2020 10:03	01/06/2020 10:27	
HEAF test	6774	Ms Fran Thorp	25/05/2020 12:00	25/05/2020 12:01	
Guidelines 2	6736	Ms Fran Thorp	13/05/2020 15:25	13/05/2020 15:26	
Guidelines 1	6735	Ms Fran Thorp	13/05/2020 14:25	14/05/2020 10:46	
DMP test - Fran Thorp	6603	Ms Fran Thorp	31/03/2020 16:47	31/03/2020 17:01	
HREA test - Fran Thorp	6600	Ms Fran Thorp	31/03/2020 16:07	31/03/2020 16:24	
EAEP test - Fran Thorp	6594	Ms Fran Thorp	31/03/2020 09:46	31/03/2020 15:43	
10 March FT form	6551	Ms Fran Thorp	10/03/2020 16:36	04/06/2020 11:37	
HREA MRES Application	6529	Ms Fran Thorp	10/03/2020 15:11	10/03/2020 15:11	
Test Hons	6469	Ms Fran Thorp	27/02/2020 12:35	24/09/2020 10:40	
PHS ethics training application	6406	Ms Fran Thorp	17/02/2020 13:26	17/02/2020 13:46	
Fran's Testing of Low and High Workflows in HREMS	6372	Ms Fran Thorp	10/02/2020 14:59	10/02/2020 15:17	

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:



The screenshot shows a 'Create Project' dialog box with the following fields:

- Project Title* (Max 200 characters):** A text input field with the placeholder text 'Please Enter Project Title Here'.
- Form*:** A dropdown menu with the placeholder text 'Please select...'.
- Centre*:** A dropdown menu with the placeholder text 'Please select...'.

At the bottom right of the dialog, there are two buttons: a blue 'Create' button and a grey 'Close' button.

Complete the **Project Title field** and for **Form** select from the drop-down list, **HREA**.

Create Project

Project Title* (Max 200 characters)
Please Enter Project Title Here

Form*
HREA

This form will automatically be shared with:

- Jennifer Rowland [Human Ethics Secretariat]
- Fran Thorp [Human Ethics Secretariat]
- Dione Pham [Human Ethics Secretariat]
- Alex Carey-White [Human Ethics Secretariat]

Please tick to confirm you are happy to continue*

Create Close

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.

HREA Applicant Guide Project 9517

Project Tree

- HREA Applicant Guide Project
 - HREA

Action Required	Status	Review Reference	Date Modified
Yes	Not Submitted	N/A	28/01/2021 11:28

Navigation Documents Signatures Collaborators Submissions Correspondence Centre History

HREA Show Inactive Sections

Section


Section 1
HREA Introduction

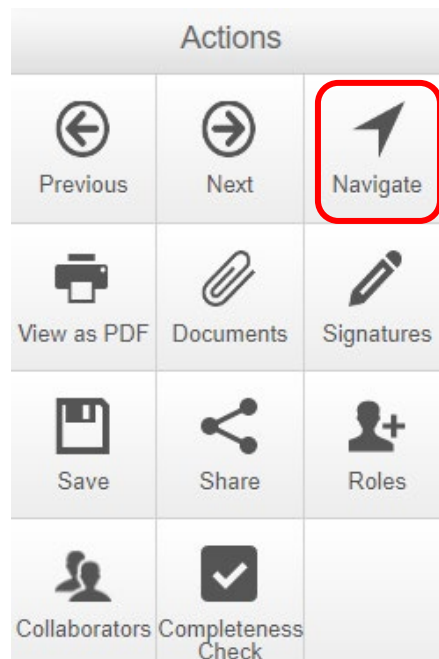
Questions

- MQ Filter Questions
- Introduction HREC Directory

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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).



HREA




Section	Questions
Section 1	MQ Filter Questions
HREA Introduction	Introduction HREC Directory
Project Overview	Project Overview
Project Team	Project Team
Disclosure of Interest	Disclosure of Interests
Restrictions	Restrictions
Evaluations	Evaluations
Location	Location
Methods	Methods
Participants	Participants
Risk	Risk - General Risk - Dependent or unequal relationships
Benefit	Benefit
Data and Privacy	Data Characteristics Activities with Data
Generate HREA document	Generate HREA document Upload HREC Declaration Declaration - CI/CPI/Lead Investigator Declaration - PI Declaration - AI/Investigator Declaration - Other Generate HREA document

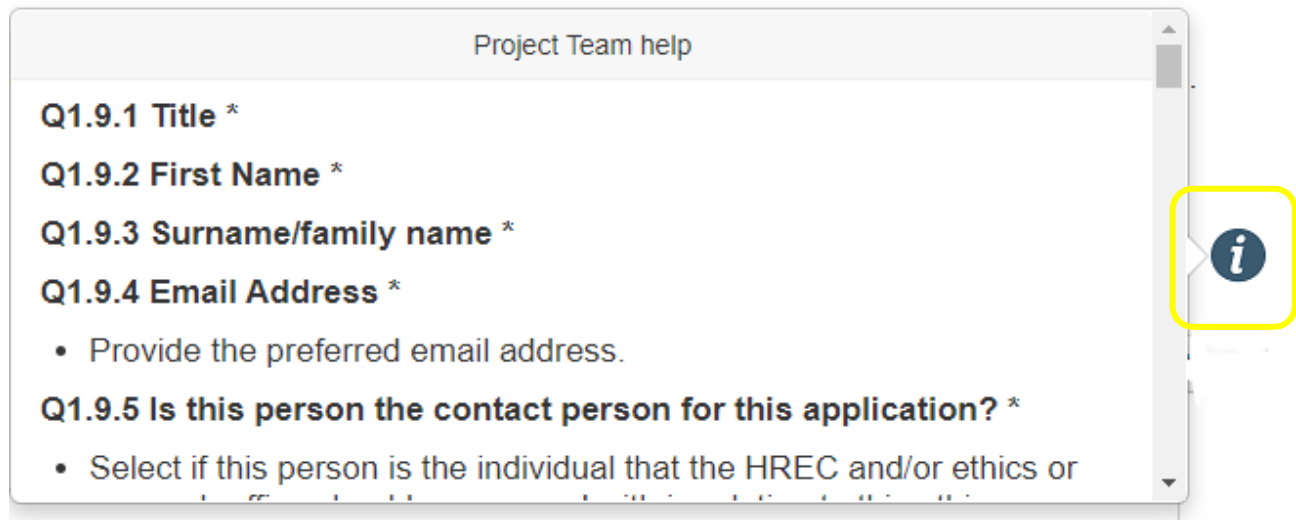
Work through each section of the HREA form, from **Section 1** to **Generate HREA Document**.

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 GENRATE HREA DOCUMENT SECTION)

In this section, all project documents need to be uploaded into the relevant sub-sections.

Attachments

Q4.1 Attach the [Project Description/Protocol](#) to your HREA. *

- It is recommended that you use one of the templates provided in the HREA for your [Project Description/Protocol](#).
- Individual attachments are limited to 10 MB in size.

[Upload Document](#)

Q4.2 Are there any other relevant documents associated with conducting your research project?

- This may include attachment of:
 - participant information and consent forms,
 - questionnaires,
 - report forms,
 - advertising materials,
 - data management plans (see National Statement Chapter 3.1),
 - ethically defensible plans for the communication of research findings or results to participants (see National Statement Chapters 3.1, 3.2 and 3.3, as appropriate, for guidance on the content of ethically defensible plans),
 - authorisations, approvals, letters of support or other clearances, and/or
 - other project-related documentation specific to your institution and/or jurisdiction.
- Consult with your institution's research/ethics office for advice on the necessary documentation.

Yes

No

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

Please attach your PROTOCOL here:

Document Name	Version Date	Version
<input type="button" value="Browse"/>	<input type="text"/>	<input type="text"/>

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


This declaration must be completed by each of the researchers/investigators or, where applicable, one member on behalf of the research team.

- Consult your institution's policy for guidance on whether all members must sign this application or whether one member can sign on behalf of the research team.
- You can upload evidence of the other researchers/investigators' agreement to this declaration (e.g. a PDF of an email).
- You can have researchers/investigators sign this application after it is completed and printed (i.e. a 'wet ink' signature).
- You can use the request signature feature to have other researchers/investigators complete their declaration within this application.
- **You must identify which researchers/investigators will be providing evidence or wet ink signatures. Upload any supporting documents and enter the relevant details for those researchers/investigators before requesting electronic signatures/electronically signing the application as this will lock the form.**

Indicate which members must sign this application

- Chief Investigator/Researcher
- Coordinating Principal Investigator/Researcher
- Lead Investigator/Researcher
- Principal Investigator
- Associate/Assistant/Sub-/Co-Investigator/Researcher
- Investigator/Researcher
- Other

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.

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.

Chief Investigator/Researcher i

I, (insert name)

certify that:

- All information in this application and supporting documentation is correct and as complete as possible;
- I have read and addressed in this application the requirements of the National Statement and any other relevant guidelines;
- I have familiarised myself with, considered and addressed in this application any relevant legislation, regulations, research guidelines and organisational policies;
- All relevant financial and non-financial interests of the project team have been disclosed; and
- In the capacity of a supervisor, as applicable, I have reviewed this application and I will provide appropriate supervision to the student(s) in accordance with the arrangements specified in this application and those associated with the student's educational program.

Q4.7 How will the Chief Investigator/Researcher agree to these terms?

- You can use the ERM 'request/sign' function to electronically sign this application.
- Select 'Upload other evidence' to upload and attach other evidence, such as an email.
- Select 'Sign after printing' if you intend to sign the HREA after it is printed (i.e. 'wet ink' signature).

Electronic signature (in place of HREA 'sign on screen')
 Upload other evidence
 Wet ink sign after printing

Electronic signature

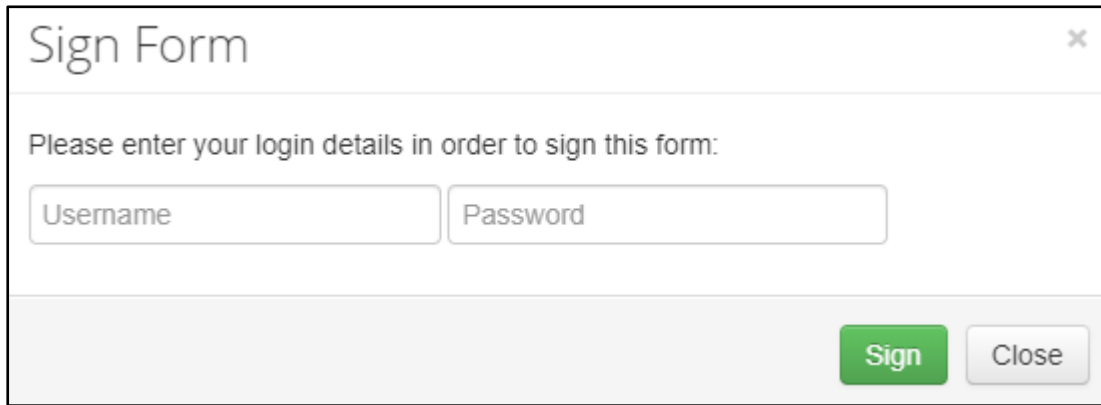
The system will do a **completeness check** to ensure that all the sections of the HREA form have been completed. Any sections that have not been completed will be presented in a list.

Completeness Check

Incomplete: Please complete the following questions

- [0.3.1 State the Project Grant Reference Number/s](#)
- [0.3.2 Please state the funding body](#)
- [HREA Full Project Title](#)
- [Q1.2](#)
- [Q1.3](#)
- [Q1.4](#)
- [Q1.7 When do you anticipate starting the research project? *](#)
- [Q1.8 What is the anticipated duration of the research project? *](#)
- [Q1.9.1 Title](#)
- [Q1.9.2 First Name](#)
- [Q1.9.3 Surname](#)
- [Q1.9.4 Email](#)
- [Q1.9.5 Is this person the contact person for this application?](#)
- [Q1.9.6 Is this person a student on this project?](#)
- [Q1.9.7 Institutional affiliation and position.](#)
- [Q1.9.10 Contact Type](#)
- [Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?](#)

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:



Sign Form

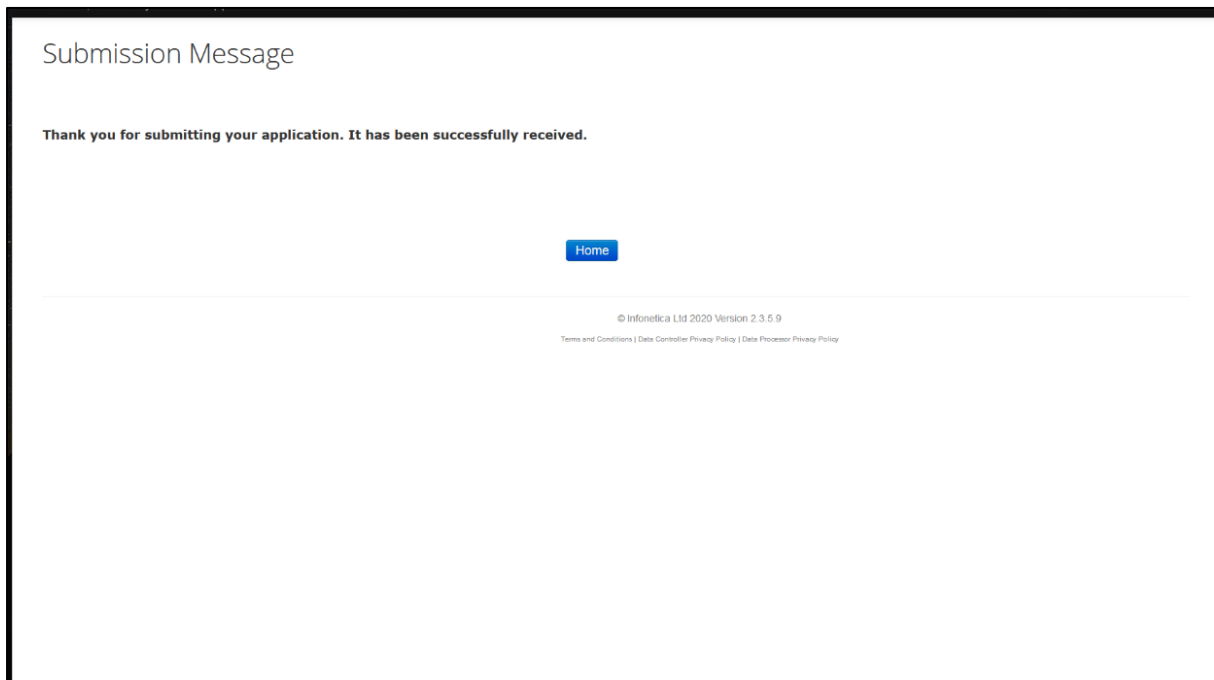
Please enter your login details in order to sign this form:

Username Password

Sign Close

The image shows a dialog box titled "Sign Form" with a close button (X) in the top right corner. Below the title bar, there is a text prompt: "Please enter your login details in order to sign this form:". Underneath this prompt are two input fields: "Username" and "Password". At the bottom right of the dialog box, there are two buttons: a green "Sign" button and a grey "Close" button.

Enter your OneID as the username and your password, click on the Sign button.
The following screen will appear:



Submission Message

Thank you for submitting your application. It has been successfully received.

Home

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The image shows a screen titled "Submission Message". The main text reads: "Thank you for submitting your application. It has been successfully received." Below this text is a blue button labeled "Home". At the bottom of the screen, there is a footer containing the copyright information: "© Infonetica Ltd 2020 Version 2.3.5.9" and links for "Terms and Conditions | Data Controller Privacy Policy | Data Processor Privacy Policy".

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**.

The screenshot shows the 'HREA Applicant Guide Project' interface. At the top right, the project ID '9517' is displayed. Below the project tree, a table lists project details. The 'Status' column is highlighted with a yellow box, showing 'Submission in progress'. The table also includes columns for 'Action Required', 'Review Reference', and 'Date Modified'. Below the table is a navigation bar with tabs for 'Navigation', 'Documents', 'Signatures', 'Collaborators', 'Submissions', 'Correspondence', 'Centre', and 'History'. The main content area is titled 'HREA' and contains a list of sections and questions, such as 'MQ Filter Questions', 'Introduction', 'HREC Directory', 'Project Overview', 'Project Team', 'Disclosure of Interests', 'Restrictions', 'Evaluations', 'Location', 'Methods', 'Participants', and 'Risk'.








Action Required	Status	Review Reference	Date Modified
No	Submission in progress	N/A	02/02/2021 11:36

SHARING A PROJECT WITH OTHER COLLABORATORS

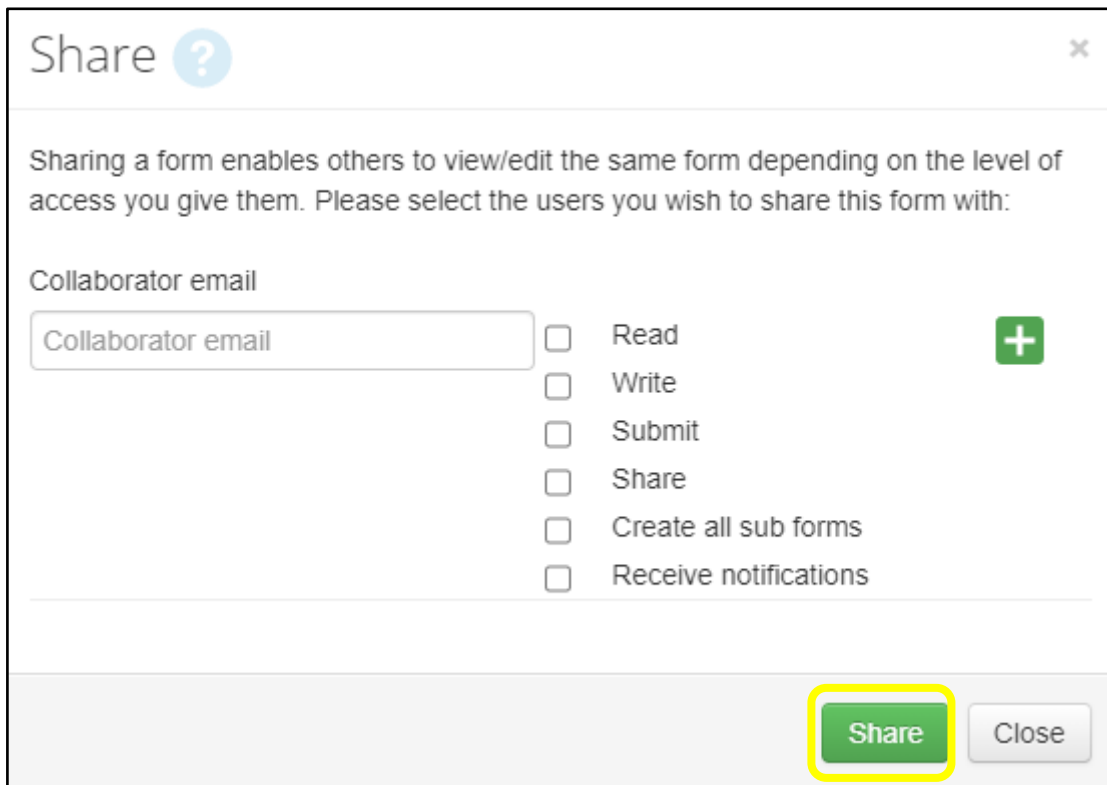
The **Project Owner and Form Owner** is the role allocated to the person who creates a new project. A Project Owner and Form Owner can share a project with other team members, known as **Collaborators** in the system.

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 screenshot shows the 'Actions' menu with several options. The 'Share' icon, which is a share symbol (three nodes connected by lines), is highlighted with a yellow box. Other icons include a project tree, a plus sign, a person with a plus sign, a printer, an envelope, and a download arrow.

Actions		
 Project	 Create Subform	 Share
 Roles	 View as PDF	 Correspond
 Import Xml		

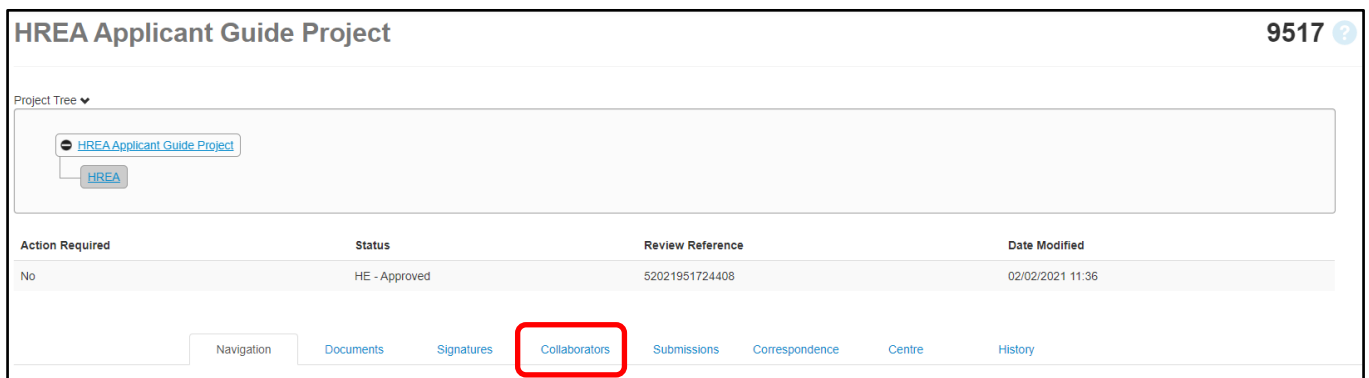
The following will appear:



A dialog box titled "Share" with a question mark icon and a close button. The text inside reads: "Sharing a form enables others to view/edit the same form depending on the level of access you give them. Please select the users you wish to share this form with:". Below this is a section labeled "Collaborator email" with an input field containing "Collaborator email". To the right of the input field is a list of permissions, each with a checkbox: "Read", "Write", "Submit", "Share", "Create all sub forms", and "Receive notifications". A green plus sign icon is to the right of the "Read" checkbox. At the bottom right of the dialog, there is a green "Share" button (highlighted with a yellow border) and a grey "Close" button.

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.




The interface shows the "HREA Applicant Guide Project" with a project ID of "9517". Below the project name is a "Project Tree" showing a folder structure with "HREA Applicant Guide Project" and "HREA". A table displays project details:

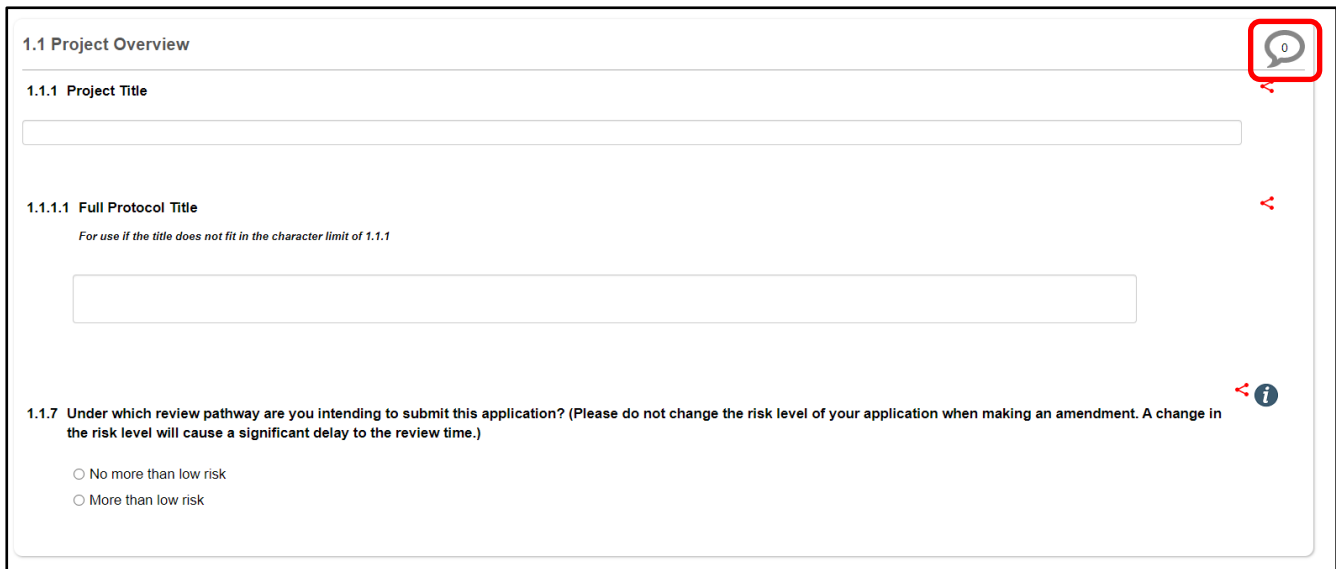
Action Required	Status	Review Reference	Date Modified
No	HE - Approved	52021951724408	02/02/2021 11:36

At the bottom, there is a navigation bar with tabs: "Navigation", "Documents", "Signatures", "Collaborators" (highlighted with a red border), "Submissions", "Correspondence", "Centre", and "History".

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 screenshot shows a form section titled "1.1 Project Overview". It contains several sub-sections: "1.1.1 Project Title" with a text input field, "1.1.1.1 Full Protocol Title" with a text input field and a note "For use if the title does not fit in the character limit of 1.1.1", and "1.1.7 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.)" with two radio button options: "No more than low risk" and "More than low risk". A speech bubble icon with the number "0" is highlighted with a red box in the top right corner of the form section.

The **Comments** screen will appear.



The screenshot shows a "Comments" window with a title bar that says "Comments +Add Comment". Below the title bar is a yellow message box that reads "Note: No comments have yet been added to this application. (Not visible to reviewers)". There is a "Close" button in the bottom right corner.

Click on **Add Comment**. A comment box will appear.

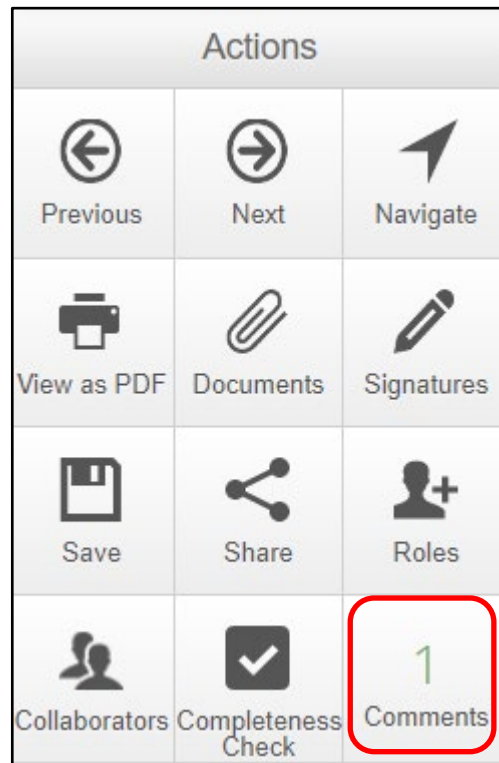


The screenshot shows the "Comments" window with a comment box. The comment box is highlighted with a red box. Below the comment box are "Save" and "Cancel" buttons. The "Save" button is highlighted with a red box. To the right of the comment box is a table with columns "Date Added" and "Owner". The table has one row with "Now" and "You". There is a "Close" button in the bottom right corner.

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.

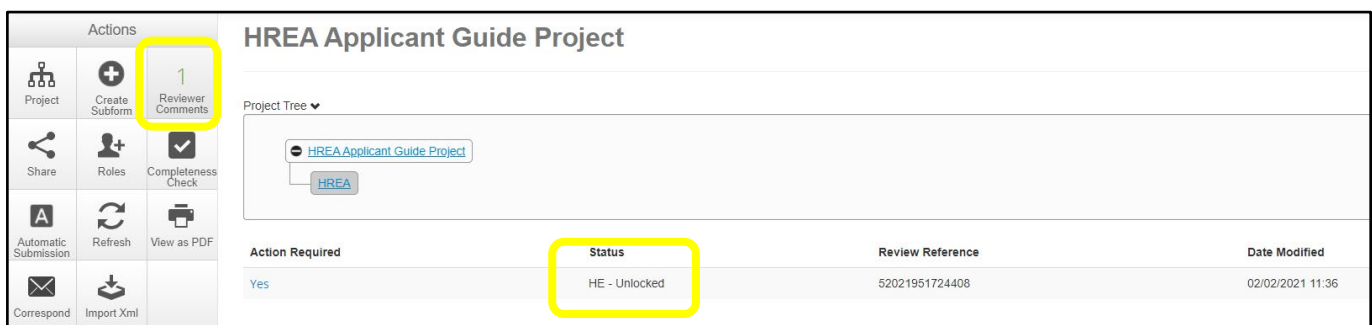


ACCESSING REVIEWER (HREC'S) COMMENTS

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.

Overall Reviewer Panel Comments			
Title	Comment	Date Added	Submission
Q1.1 What is the Project Title (as presented in the Project Description/Protocol)? *	Test comment	05/02/2021 at 10:57 AM	Latest Submission

Show Previous Comments

Close

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).

HREA

Project Overview

Q1.1 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.

Reviewers Comments

1

0

Collaborators Comments

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.

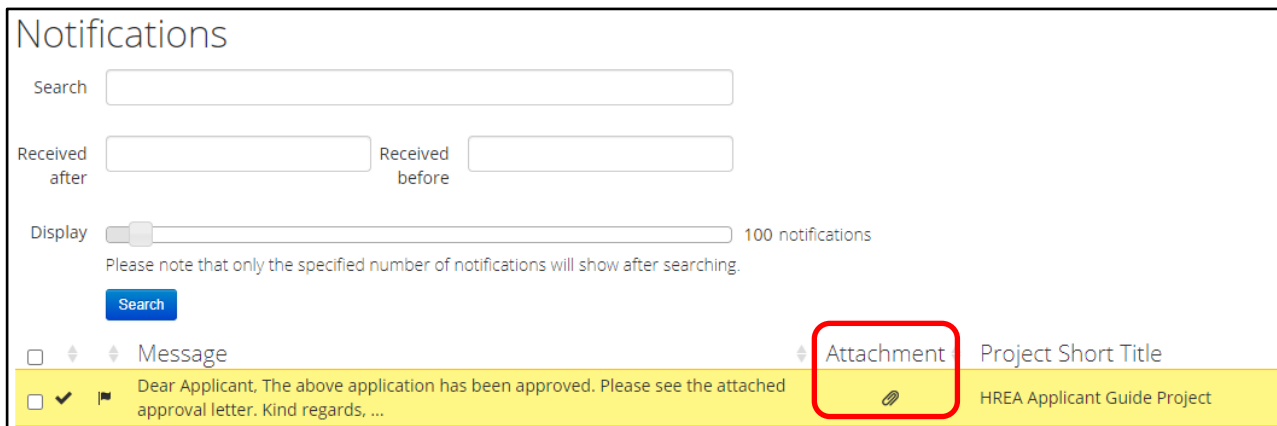
To amend a response in the form, click on the section of the form you wish to change. Click on the text box/question and edit the content or change the response from the options available in the section.

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.

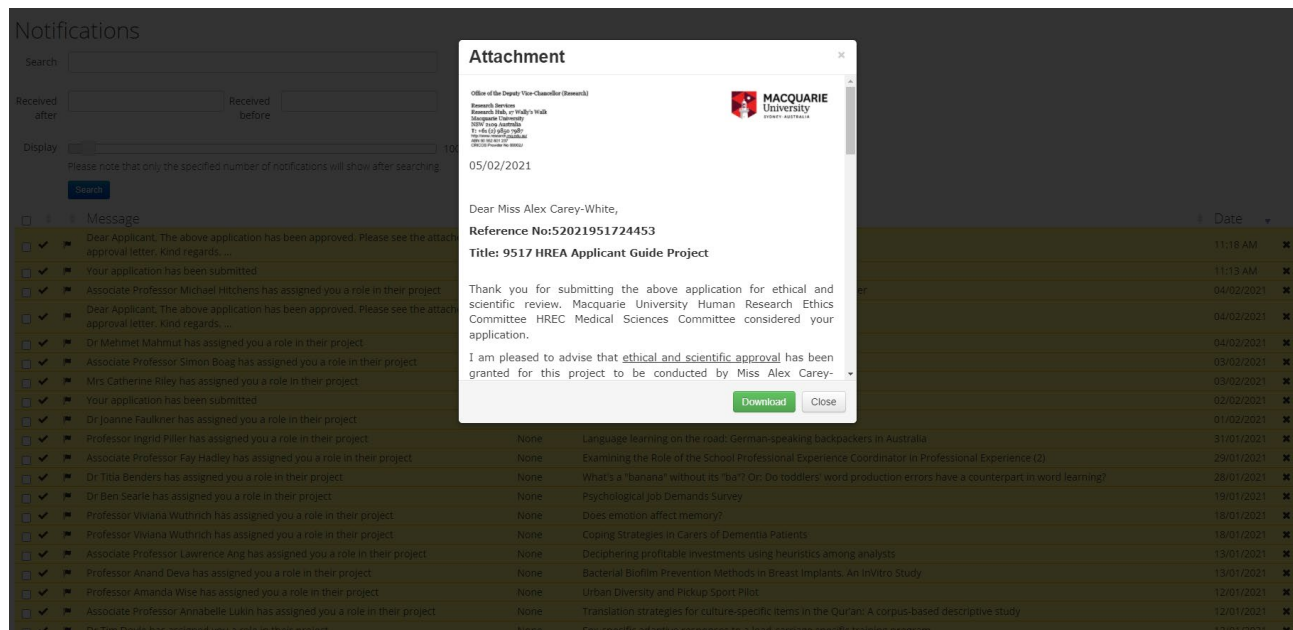
ACCESSING THE APPROVAL LETTER

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.



The screenshot shows the 'Notifications' section of a system. At the top, there is a search bar and filters for 'Received after' and 'Received before'. A 'Display' slider is set to 100 notifications. Below these is a 'Search' button. The notification list has columns for 'Message', 'Attachment', and 'Project Short Title'. The first notification is highlighted in yellow and contains the text: 'Dear Applicant, The above application has been approved. Please see the attached approval letter. Kind regards, ...'. The 'Attachment' column for this notification shows a document icon, which is circled in red.

Click on the attachment symbol and the attachment will appear.




The screenshot shows the 'Notifications' interface with an 'Attachment' modal window open. The modal window displays the following information:

- Attachment**
- Office of the Deputy Vice-Chancellor (Research)
- Research Services
Research Hub, 170 Wally's Walk
Sydney, New South Wales
2008
T: +61 2 9517 2445
E: ethics@mq.edu.au
www.mq.edu.au/research
- MACQUARIE University
HUMAN RESEARCH ETHICS
- 05/02/2021
- Dear Miss Alex Carey-White,
- Reference No:52021951724453**
- Title: 9517 HREA Applicant Guide Project**
- Thank you for submitting the above application for ethical and scientific review. Macquarie University Human Research Ethics Committee HREC Medical Sciences Committee considered your application.
- I am pleased to advise that ethical and scientific approval has been granted for this project to be conducted by Miss Alex Carey-
- Download** **Close**

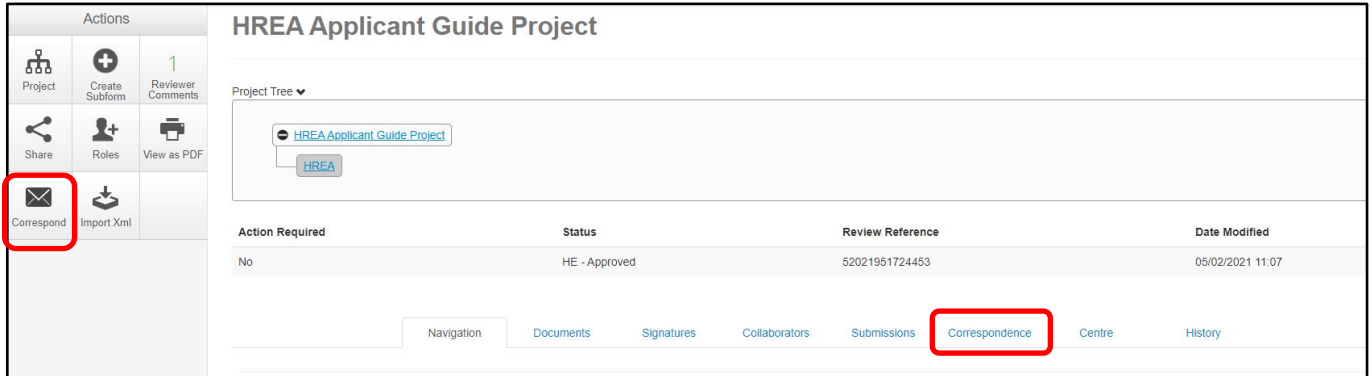
The background shows a list of notifications with columns for 'Message', 'Attachment', and 'Date'. The first notification is highlighted in yellow and contains the text: 'Dear Applicant, The above application has been approved. Please see the attached approval letter. Kind regards, ...'. The 'Attachment' column for this notification shows a document icon, which is circled in red.

Download a copy of the approval letter by clicking the **Download** button.

REQUESTING AN AMENDMENT TO AN APPROVED PROJECT

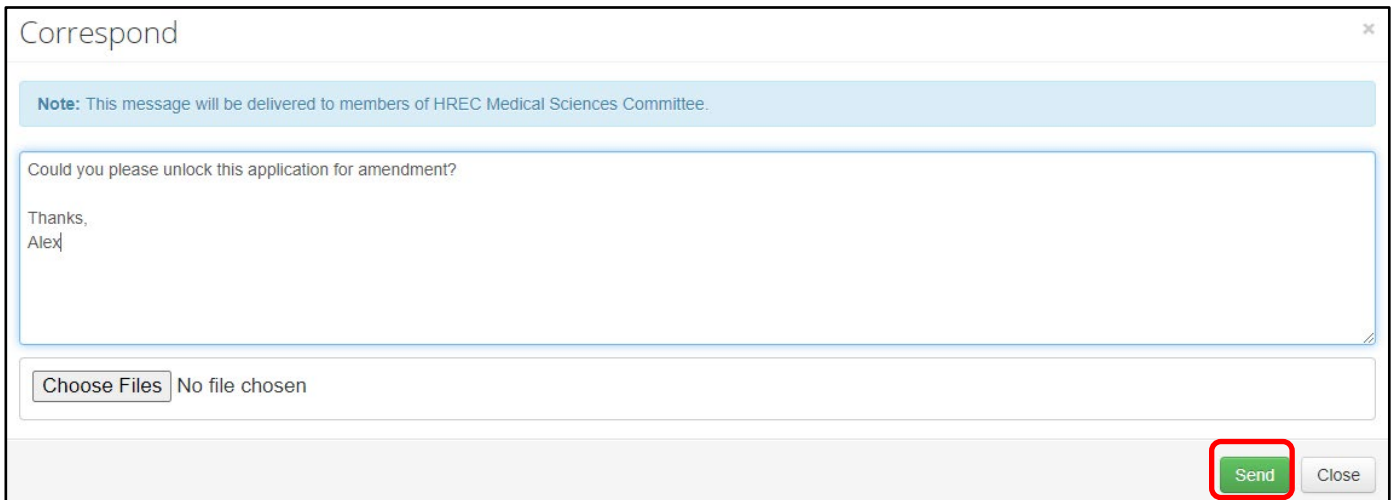
All approved applications are locked and cannot be edited. You will need to request that the project be unlocked so that an amendment can be submitted. A request to unlock the application can be made to the Ethics Secretariat via the **Correspond**  action tile in the project or via the **Correspondence**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

Click on the Correspondence tab or Correspondence tile.



The screenshot shows the 'HREA Applicant Guide Project' interface. On the left, the 'Actions' sidebar includes a 'Correspond' button with an envelope icon, which is highlighted with a red box. The main area shows a 'Project Tree' with 'HREA Applicant Guide Project' and 'HREA' sub-items. Below this is a table with columns: Action Required, Status, Review Reference, and Date Modified. The table contains one row: 'No', 'HE - Approved', '52021951724453', and '05/02/2021 11:07'. At the bottom, a navigation bar includes tabs for 'Navigation', 'Documents', 'Signatures', 'Collaborators', 'Submissions', 'Correspondence' (highlighted with a red box), 'Centre', and 'History'.

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 screenshot shows the 'Correspond' dialog box. At the top, there is a note: 'Note: This message will be delivered to members of HREC Medical Sciences Committee.' Below this is a text input area containing the message: 'Could you please unlock this application for amendment?' followed by 'Thanks, Alex'. At the bottom left, there is a 'Choose Files' button and the text 'No file chosen'. At the bottom right, there is a green 'Send' button (highlighted with a red box) and a 'Close' button.

The Ethics Secretariat's reply will appear above your message, as follows:

Action Required	Status	Review Reference	Date Modified
Yes	HE - Unlocked	52021951724453	05/02/2021 11:07

Navigation Documents Signatures Collaborators Submissions Correspondence Centre History

Correspondence + New Correspondence

Search correspondence...

User	Date	Message
Review user	05/02/2021	Hi there, The application is now unlocked. Kind regard...
Miss Alex Carey-White	05/02/2021	Could you please unlock this application for amendment? T...

Showing 1 to 2 of 2 entries

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.

Actions

Previous Next Navigate

View as PDF Documents Signatures

Save Share Roles

Collaborators Completeness Check Reviewer Comments

HREA

9517 Version: v1..r1

Filter Questions 0

0.1 Please identify the purpose of this application

New application

Amendment request

0.2 Project Title (Short Version)

HREA Applicant Guide Project

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:

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.

If you select other project changes, the following questions will appear and **must** be answered:


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


- Addition or removal of personnel
- Other project changes

0.6.2 Please explain the changes that are intended and the rationale for making these changes 

0.6.3 Are there any inconveniences or risks arising from the proposed changes? 


- Yes
- No

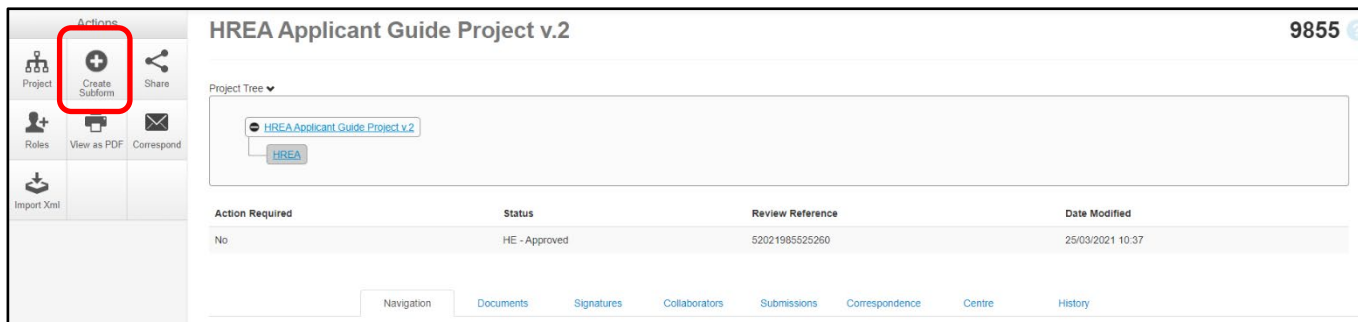
0.6.4 Please list all clean and tracked copies of amended documents and why they were changed 

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.

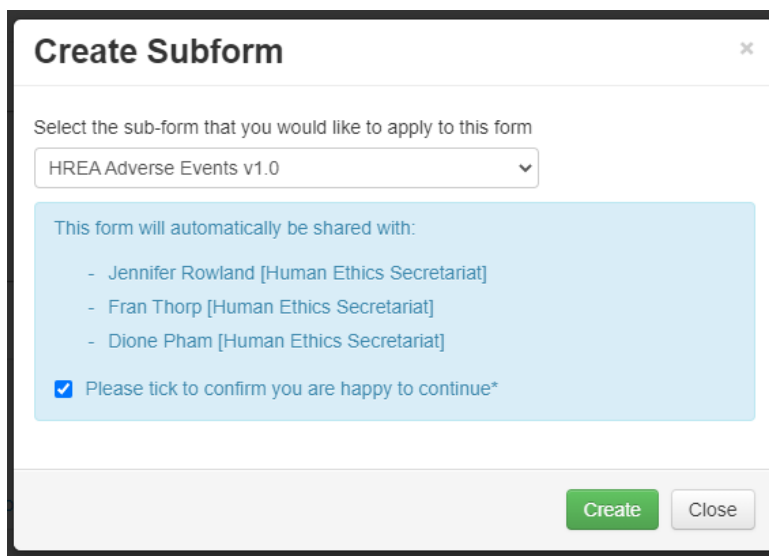
SUBMITTING AN ADVERSE EVENT SUB-FORM

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.

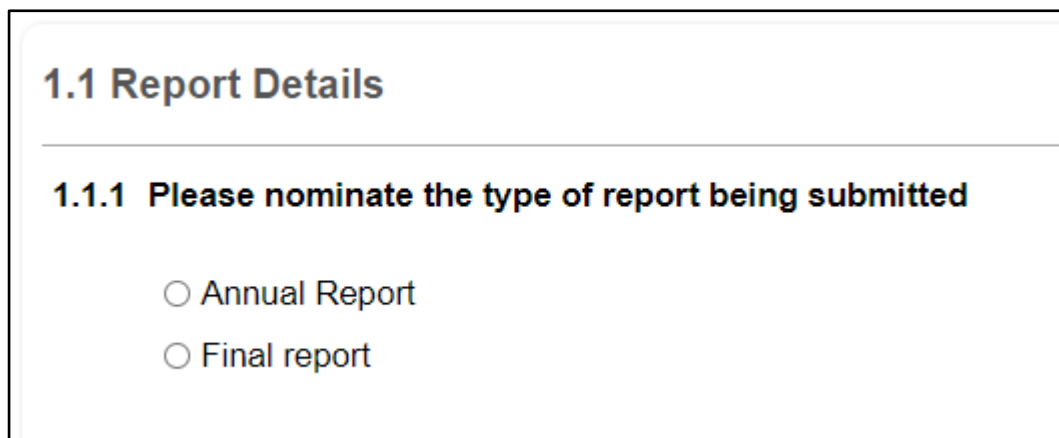
Click on the **Create** button.

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

1.1.1 Please nominate the type of report being submitted

Annual Report

Final report

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

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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-2007-updated-2018>

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 a HASS Ethics application go to the Human Research Management System

<https://ethics-and-biosafety-form.mq.edu.au/Account/Login?ReturnUrl=/Account/Login?ReturnUrl=%2FHome%2FIndex>

