



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

Forms for Research Applications

June 2021



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.
- PLEASE NOTE the HREA form is developed and managed by the NHMRC and can therefore not be changed.

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://fora-form.mq.edu.au/Account/Login>

Username: MQ OneID

Password: MQ OneID password

The screenshot shows the login page for the Macquarie University Ethics, Biosafety & other Applications system. The page has a header with the university logo and the title 'Ethics, Biosafety & other Applications'. Below the title is a 'Log in' form with fields for 'Domain*' (pre-filled with 'mqauth.unimq.edu.au'), 'User Name*', and 'Password*'. A 'Log in' button is at the bottom of the form. The footer contains copyright information for Infonetica Ltd 2020 and links to Terms and Conditions, Data Controller Privacy Policy, and Data Processor Privacy Policy.

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


The screenshot shows the 'Work Area' dashboard. On the left, there is a sidebar with 'Actions' and 'Project' sections. The 'Actions' section contains icons for 'Create Folder', 'Delete Folder', 'Create Project' (highlighted with a red box), 'Write Project', 'Duplicate Project', and 'Transfer Project'. The 'Project' section contains a 'Create Project' icon. The main area of the dashboard is titled 'Work Area' and contains four summary cards: 'Notifications' (296), 'Signatures' (0), 'Transfers' (0), and 'Shared' (4797). Below these cards is a 'Projects' table with columns for Project Title, Project ID, Owner, Date Created, Date Modified, and Transfer Status. The table lists various projects, including 'October 2020 test', 'Test application for Peter Barrett', 'Test EAEF 21 July 2020', 'De-identified data test', 'HEAF test', 'Guidelines 2', 'Guidelines 1', 'DMP test - Fran Thorp', 'HREA test - Fran Thorp', 'EAEF test - Fran Thorp', '10 March FT form', 'HREA MRES Application', 'Test Hons', 'FHS ethics training application', and 'Fran's Testing of Low and High Workflows in HREMS'. Annotations include a yellow box around the 'Create Project' icon in the Actions section, a yellow box around the 'Project' section, and a yellow box around the 'Projects' table. Arrows point from the text 'Action Tiles' to the Actions section, 'Icons' to the Project section, and 'Project' to the Projects table.

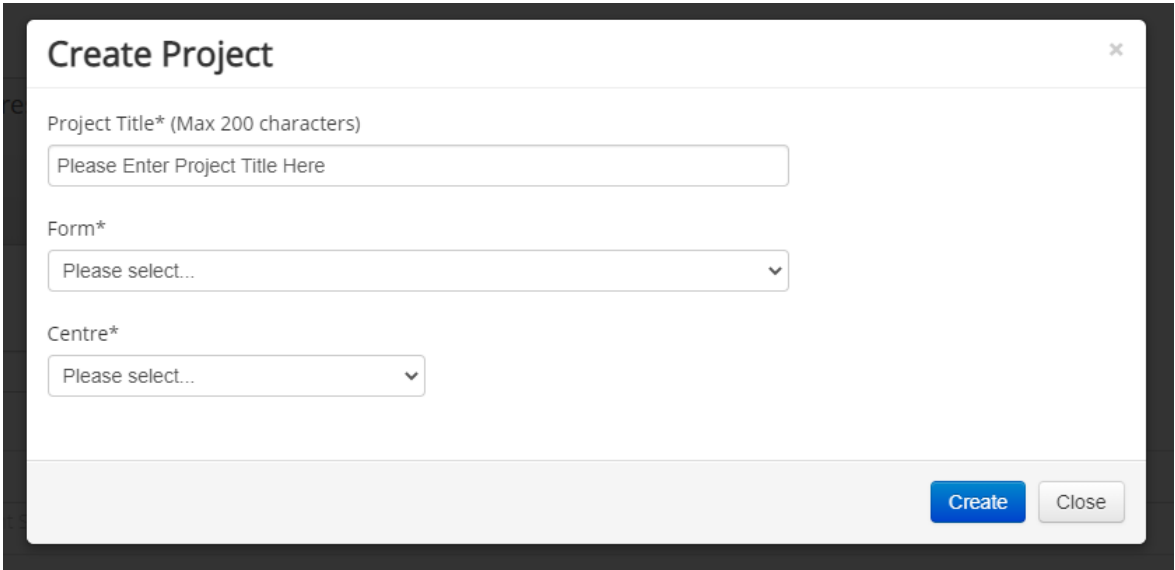
Project Title	Project ID	Owner	Date Created	Date Modified	Transfer Status
October 2020 test	9201	Ms Fran Thorp	08/10/2020 15:19	08/10/2020 15:47	
Test application for Peter Barrett	9114	Ms Fran Thorp	10/09/2020 14:04	10/09/2020 14:09	
Test EAEF 21 July 2020	7923	Ms Fran Thorp	21/07/2020 15:26	21/07/2020 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	
EAEF test - Fran Thorp	6594	Ms Fran Thorp	31/03/2020 09:46	31/03/2020 15:43	
10 March FT form	6531	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	
FHS 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:

A screenshot of a web form titled "Create Project" with a close button (X) in the top right corner. The form contains three required fields: "Project Title* (Max 200 characters)" with a text input field containing the placeholder "Please Enter Project Title Here"; "Form*" with a dropdown menu showing "Please select..."; and "Centre*" with a dropdown menu showing "Please select...". At the bottom right of the form are two buttons: a blue "Create" button and a grey "Close" button.

Create Project

Project Title* (Max 200 characters)

Please Enter Project Title Here

Form*

Please select...

Centre*

Please select...

Create Close

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.

Actions

Project

Share

Roles

Completeness Check

Automatic Submission

Refresh

View as PDF

Correspond

Import Xml

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

Section

Section 1

HREA Introduction

Questions

MQ Filter Questions


Introduction

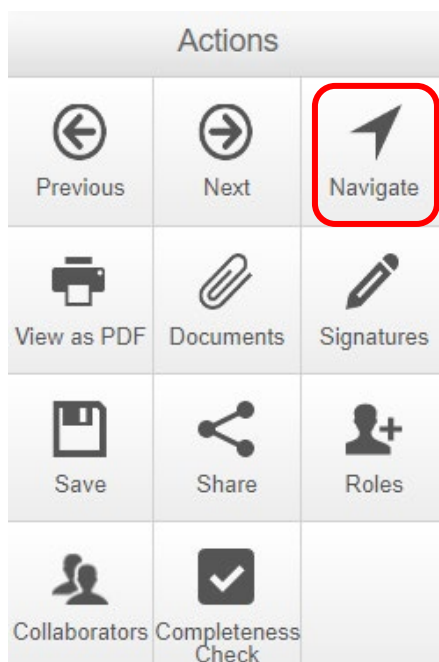
HREC Directory

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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
Section 1
HREA Introduction
Project Overview
Project Team
Disclosure of Interest
Restrictions
Evaluations
Location
Methods
Participants
Risk
Benefit
Data and Privacy
Generate HREA document

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

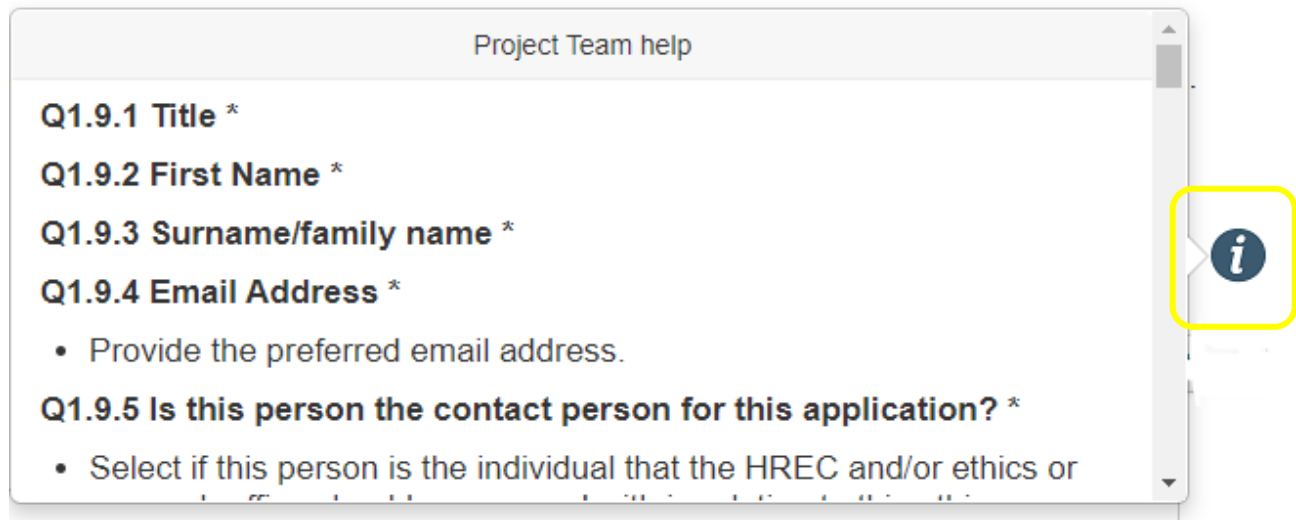
Work through each section of the HREA form, from **Section 1** to **Generate HREA Document**.

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. Please note that individual attachments are limited to 10MB in size and the cumulative size for all attachments must not exceed 95MB

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.

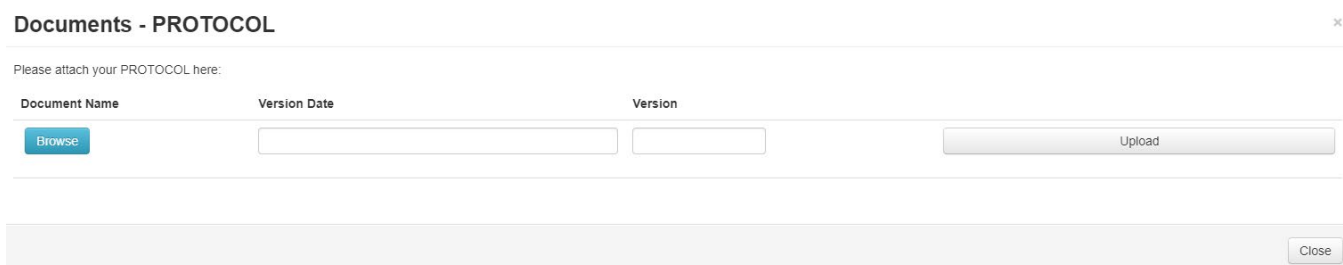
- ☐ Advertising material
- ☐ Case report form
- ☐ Copy of ethics approval
- ☐ Cover letter
- ☐ Curriculum vitae (CV) or resume of investigator/researcher
- ☐ Data management plans
- ☐ Drug data sheet
- ☐ Ethically defensible plans
- ☐ Evidence of Clinical Trial Notification (CTN)
- ☐ Form of indemnity
- ☐ 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

Please limit your CV to 2 pages and ensure you include skills, training, experience, competency, and qualifications relevant to the research activity. Please include if CI to a PhD research project supervisory experience and qualifications.


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



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

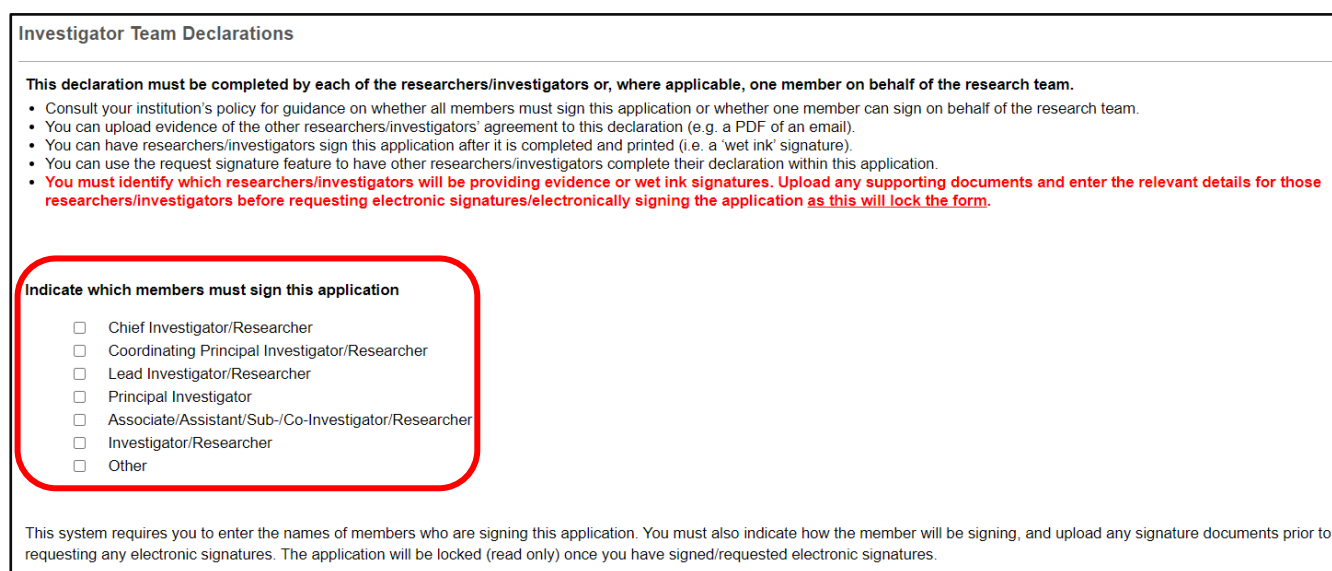
Enter a **Version Date** and **Version number** and click on the **Upload** button.

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, (insert name)

PLEASE ENTER NAME HERE

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

Request Signature

Sign

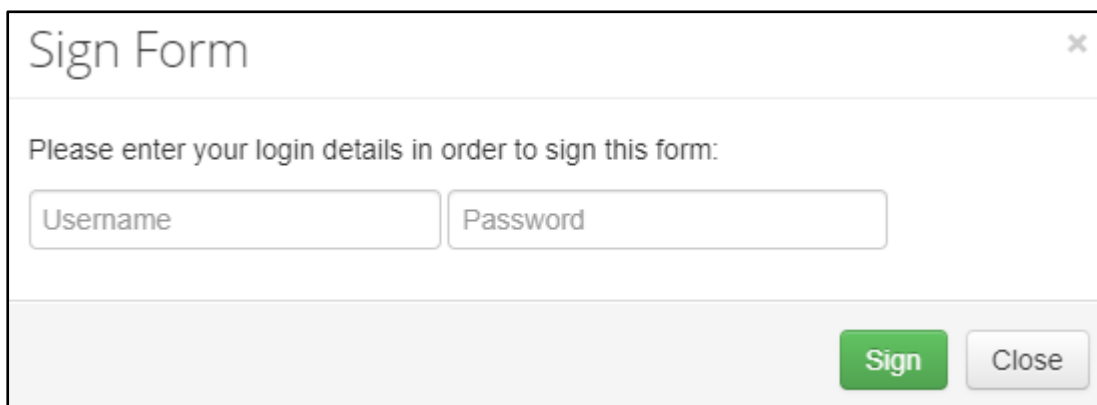
The system will do a **completeness check** to ensure that all the sections of the HREA form have been completed. Any sections that have not been completed will be presented in a list.

Completeness Check

Incomplete: Please complete the following questions

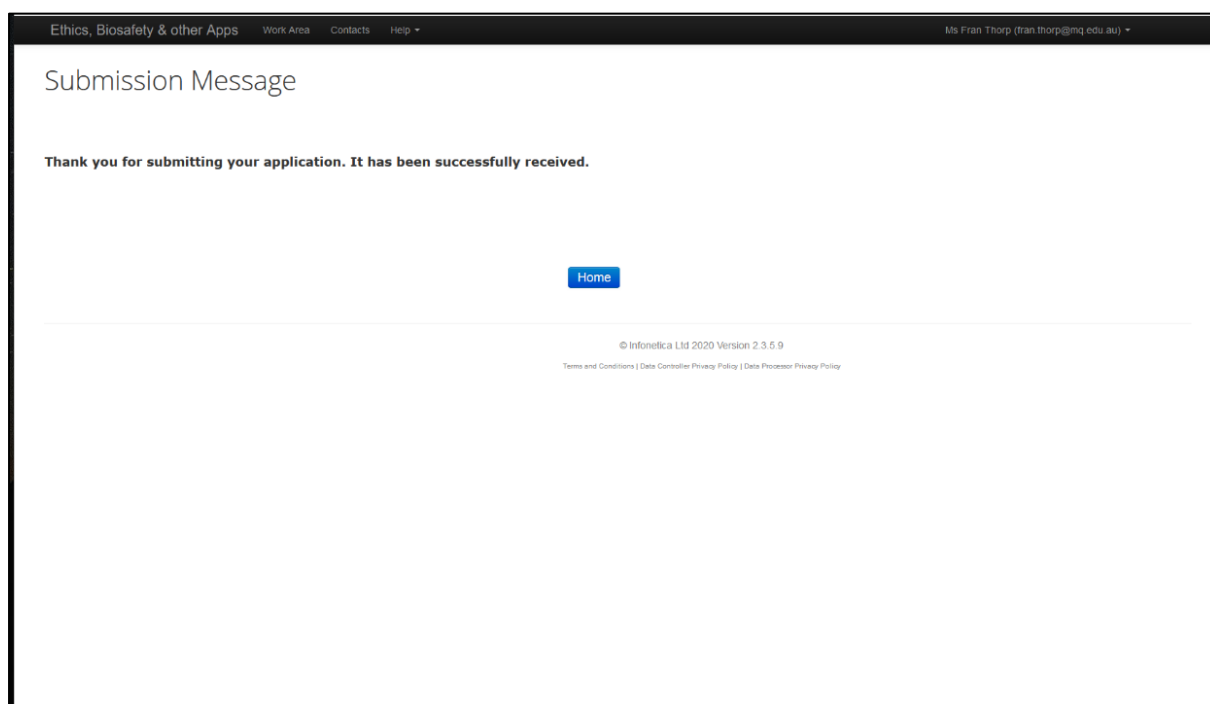
- 0.3.1 State the Project Grant Reference Number/s
- 0.3.2 Please state the funding body
- HREA Full Project Title
- Q1.2
- Q1.3
- Q1.4
- Q1.7 When do you anticipate starting the research project? *
- Q1.8 What is the anticipated duration of the research project? *
- Q1.9.1 Title
- Q1.9.2 First Name
- 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:



A dialog box titled "Sign Form" with a close button (X) in the top right corner. The main text reads "Please enter your login details in order to sign this form:". Below this text are two input fields: "Username" and "Password". At the bottom right of the dialog 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:



A screenshot of a web application interface. The top navigation bar includes links for "Ethics, Biosafety & other Apps", "Work Area", "Contacts", and "Help". The user's name and email, "Ms Fran Thorp (fran.thorp@mq.edu.au)", are displayed in the top right. The main content area is titled "Submission Message" and contains the text "Thank you for submitting your application. It has been successfully received." Below this text is a blue "Home" button. At the bottom of the page, there is a footer with the copyright notice "© Infonetica Ltd 2020 Version 2.3.5.9" and links for "Terms and Conditions", "Data Controller Privacy Policy", and "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**.

HREA Applicant Guide Project 9517 ?

Project Tree ▼

- HREA Applicant Guide Project
 - HREA

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

Navigation Documents Signatures Collaborators Submissions Correspondence Centre History


HREA ☐ Show Inactive Sections

Section








- Section 1
 - HREA Introduction
 - MQ Filter Questions
 - Introduction HREC Directory
 - Project Overview
 - Project Overview
 - Project Team
 - Project Team
 - Disclosure of Interests
 - Disclosure of Interests
 - Restrictions
 - Restrictions
 - Evaluations
 - Evaluations
 - Location
 - Location
 - Methods
 - Methods
 - Participants
 - Participants
 - Risk
 - Risk - General
 - Risk - Dependent or unequal relationships

SHARING A PROJECT WITH OTHER COLLABORATORS

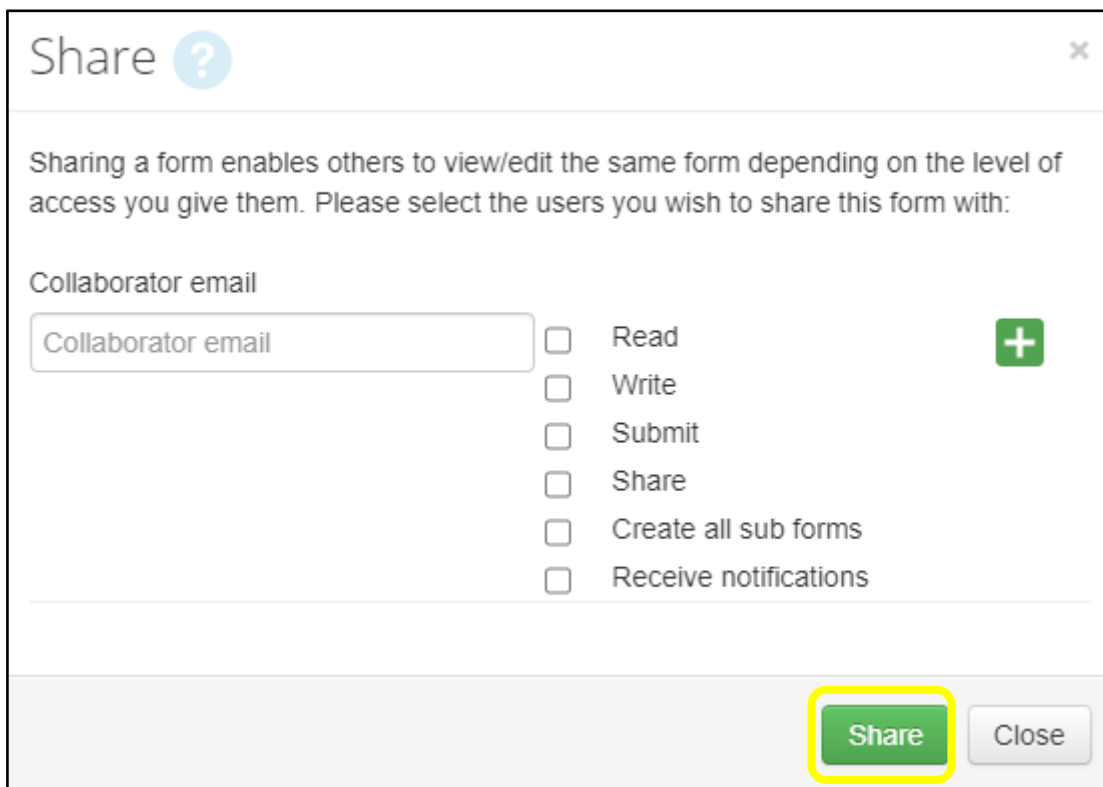
The **Project Owner and Form Owner** is the role allocated to the person who creates a new project. A Project Owner and Form Owner can share a project with other team members, known as **Collaborators** in the system.

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**.

Actions

 Project	 Create Subform	 Share
 Roles	 View as PDF	 Correspond
 Import Xml		

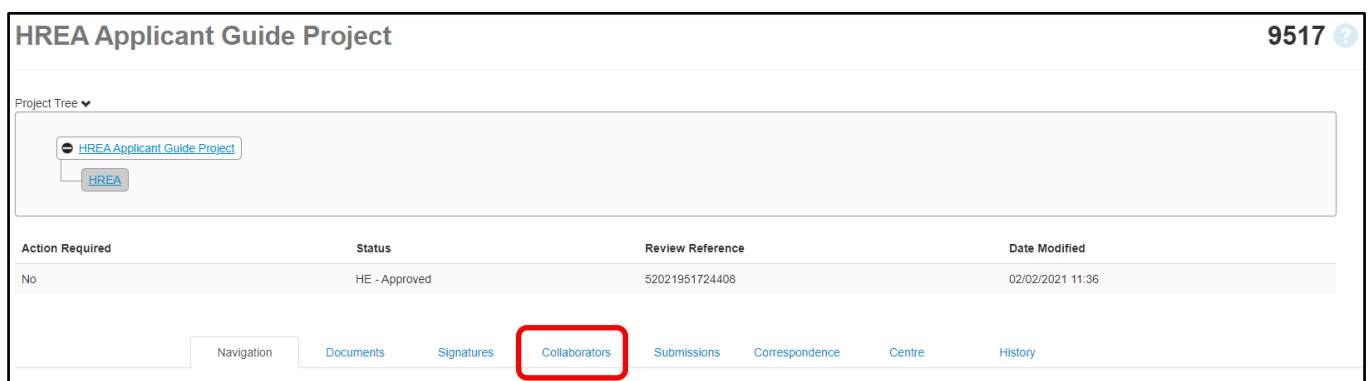
The following will appear:



A 'Share' dialog box with a title bar containing the word 'Share' and a question mark icon. The main text 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 titled 'Collaborator email' with a text input field labeled 'Collaborator email'. To the right of the input field is a list of permissions, each with an unchecked checkbox: 'Read', 'Write', 'Submit', 'Share', 'Create all sub forms', and 'Receive notifications'. A green plus icon is to the right of the 'Read' checkbox. At the bottom right, there is a green 'Share' button (highlighted with a yellow rectangle) 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 for the 'HREA Applicant Guide Project' shows a project tree on the left with 'HREA Applicant Guide Project' and 'HREA' sub-items. Below the tree is a table with the following data:

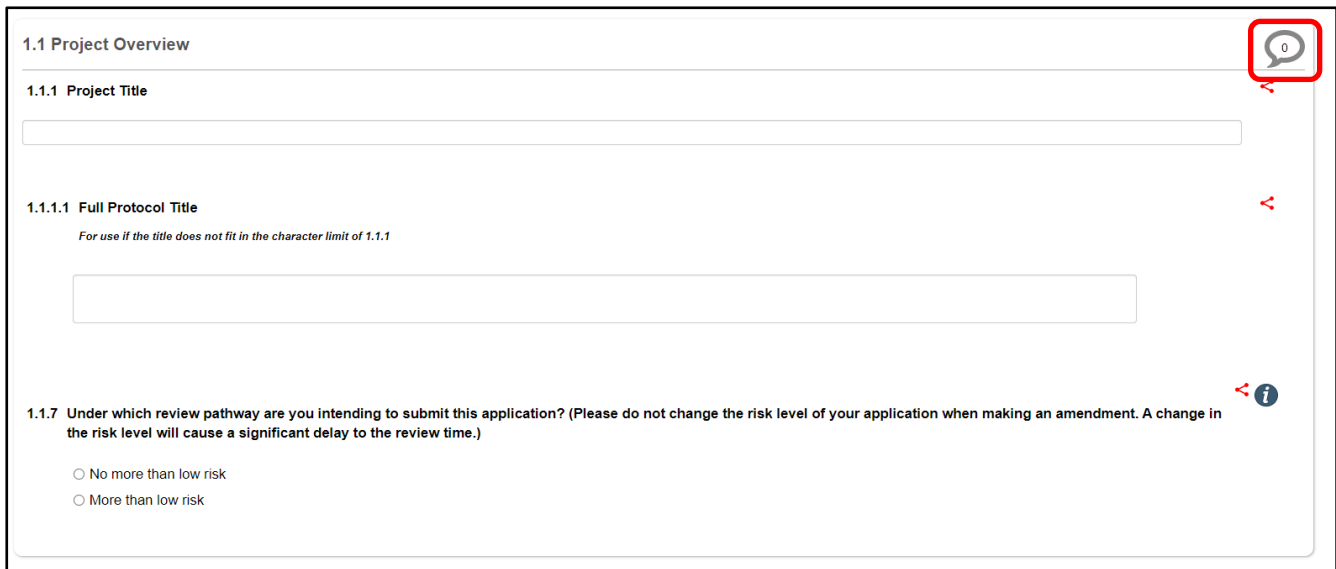
Action Required	Status	Review Reference	Date Modified
No	HE - Approved	52021951724408	02/02/2021 11:36

At the bottom, there is a navigation bar with tabs: 'Navigation', 'Documents', 'Signatures', 'Collaborators' (highlighted with a red rectangle), '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.



1.1 Project Overview

1.1.1 Project Title

1.1.1.1 Full Protocol Title

For use if the title does not fit in the character limit of 1.1.1

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.)

☐ No more than low risk

☐ More than low risk

The **Comments** screen will appear.

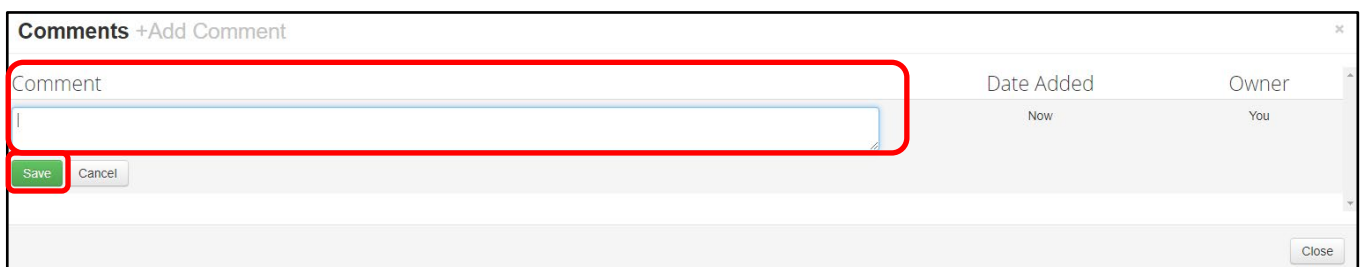


Comments +Add Comment

Note: No comments have yet been added to this application. (Not visible to reviewers)

Close

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



Comments +Add Comment

Comment

Date Added

Owner

Now

You

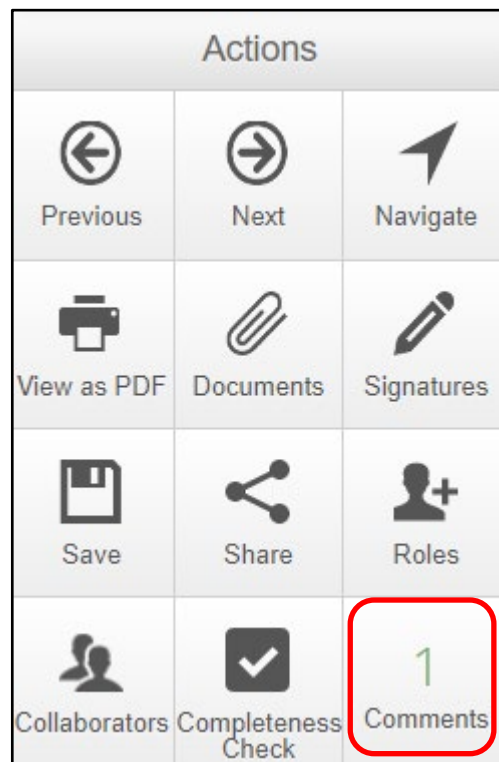
Save Cancel

Close

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.

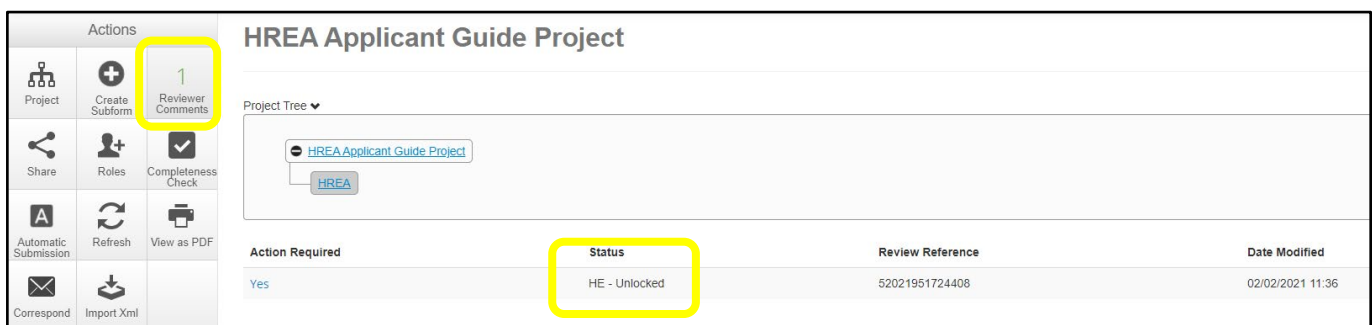


ACCESSING REVIEWER (HREC'S) COMMENTS

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)? *		05/02/2021 at 10:57 AM	Latest Submission
Test comment			

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

Collaborators Comments

Preparing your Response to the Reveiwers Coments

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.

Notifications

Search

Received after Received before

Display 100 notifications

Please note that only the specified number of notifications will show after searching.

<input type="checkbox"/>			Message		Attachment	Project Short Title
<input type="checkbox"/>			Dear Applicant, The above application has been approved. Please see the attached approval letter. Kind regards, ...			HREA Applicant Guide Project

Click on the attachment symbol and the attachment will appear.

Search

Received after

Received before

Display

Please note that only the specified number of notifications will show after searching.

Search

Message

✓

Dear Applicant, The above application has been approved. Please see the attached approval letter. Kind regards. ...

✓

Your application has been submitted

✓

Associate Professor Michael Hitchens has assigned you a role in their project

✓

Dear Applicant, The above application has been approved. Please see the attached approval letter. Kind regards. ...

✓

Dr Mehmet Mahmut has assigned you a role in their project

✓

Associate Professor Simon Boag has assigned you a role in their project

✓

Mrs Catherine Riley has assigned you a role in their project

✓

Your application has been submitted

✓

Dr Joanne Faulkner has assigned you a role in their project

✓

Professor Ingrid Piller has assigned you a role in their project

✓

Associate Professor Kay Hadley has assigned you a role in their project

✓

Dr Tilla Benders has assigned you a role in their project

✓

Dr Ben Searle has assigned you a role in their project

✓

Professor Viviana Wutrich has assigned you a role in their project

✓

Professor Viviana Wutrich has assigned you a role in their project

✓

Associate Professor Lawrence Ang has assigned you a role in their project

✓

Professor Anand Deva has assigned you a role in their project

✓

Professor Amanda Wise has assigned you a role in their project

✓

Associate Professor Annabelle Lukin has assigned you a role in their project

✓

Dr Tessa Davis has assigned you a role in their project

Attachment

Office of the Deputy Vice-Chancellor (Research)

Research Services

Research Hub, c/- Miller's Walk

Macquarie University


1517 HWA Avenue

T: +61 (0) 2 9514 2400

F: +61 (0) 2 9514 2400

www.mq.edu.au/research

0800 00 00 00 (toll free)



05/02/2021

Dear Miss Alex Carey-White,

Reference No:5021951724453

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

None

Language learning on the road: German-speaking backpackers in Australia

None

Examining the Role of the School Professional Experience Coordinator in Professional Experience (2)

None

What's a "banana" without its "ba"? Or: Do toddlers' word production errors have a counterpart in word learning?

None

Psychological job Demands Survey

None

Does emotion affect memory?

None

Coping Strategies in Carers of Dementia Patients

None

Deciphering profitable investments using heuristics among analysts

None

Bacterial Biofilm Prevention Methods in Breast Implants. An In vitro Study

None

Urban Diversity and Pickup Sports Pilot

None


Translation strategies for culture-specific items in the Quran: A corpus-based descriptive study

None

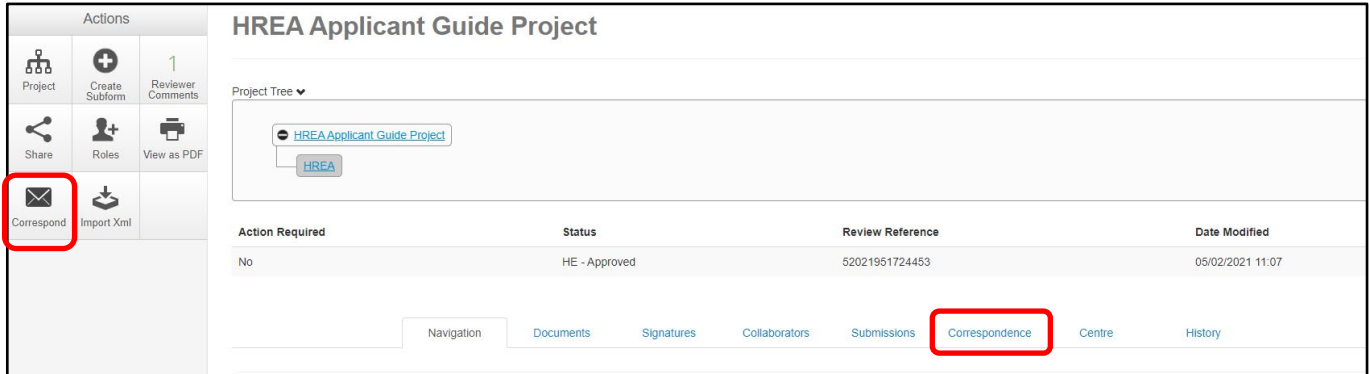
Can specific safety or compliance standards be used to predict business performance?

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.



HREA Applicant Guide Project

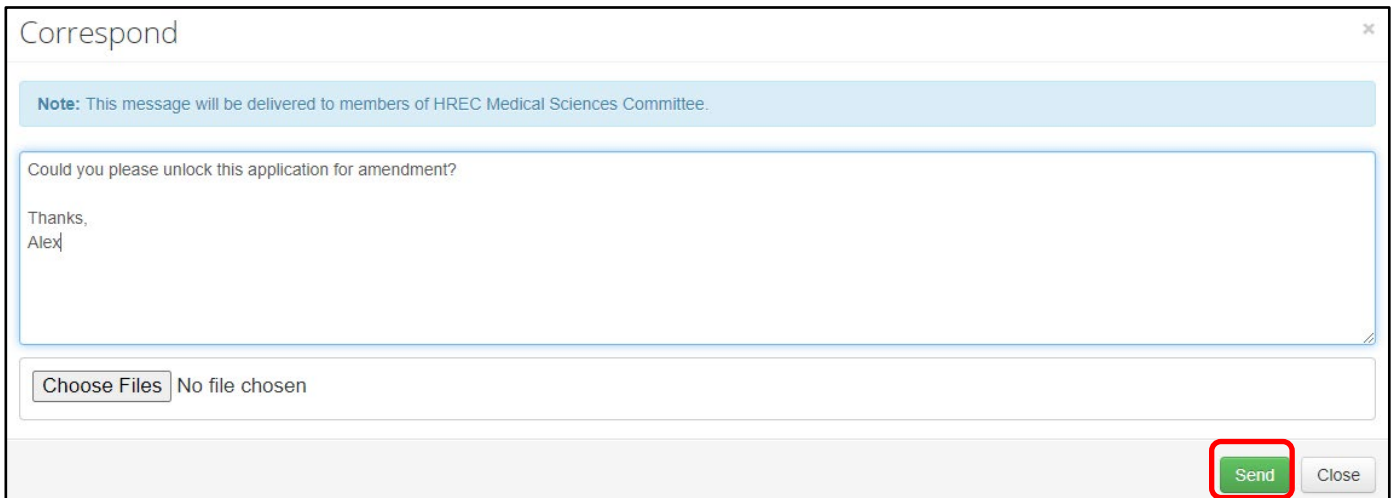
Project Tree ▼

- HREA Applicant Guide Project
 - HREA

Action Required	Status	Review Reference	Date Modified
No	HE - Approved	52021951724453	05/02/2021 11:07

Navigation | Documents | Signatures | Collaborators | Submissions | **Correspondence** | Centre | 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.



Correspond

Note: This message will be delivered to members of HREC Medical Sciences Committee.

Could you please unlock this application for amendment?

Thanks,
Alex

Choose Files No file chosen

Send Close

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: v1.1

Filter Questions

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

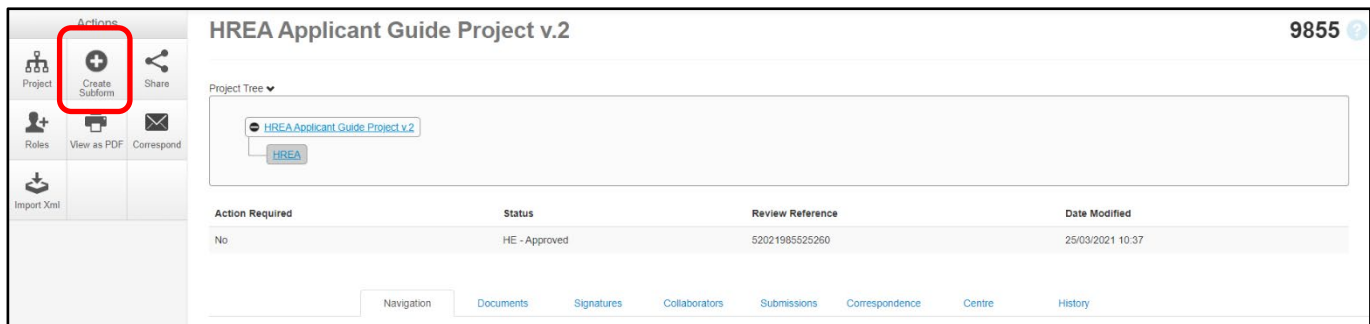
0.6.4 Please list all clean and tracked copies of amended documents and why they were changed 

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.

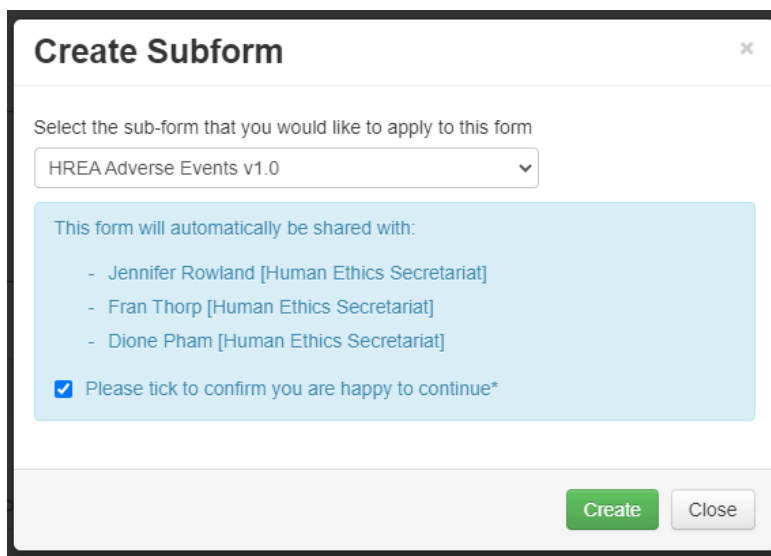
SUBMITTING AN ADVERSE EVENT SUB-FORM

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.

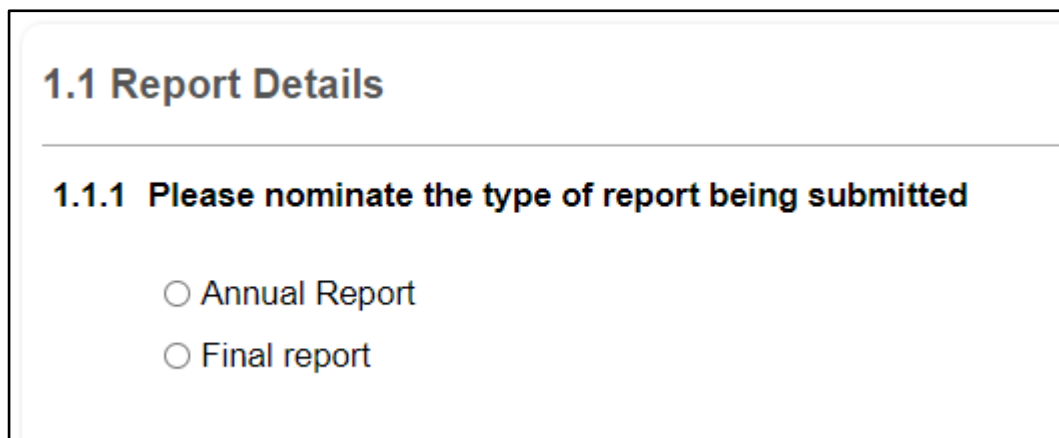
Click on the **Create** button.

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


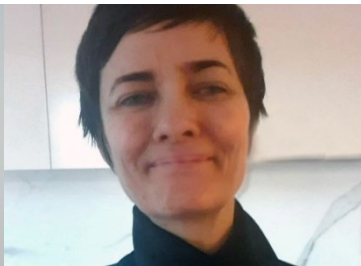


☐ Final report

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

HUMAN RESEARCH ETHICS TEAM

			
Dr Karolyn White	Jennifer Rowland	Fran Thorp	Alex Carey-White
Director, Research Ethics, and Integrity	Human Research Ethics Manager & Secretariat to Medical Sciences HREC	Secretariat to the Humanities and Social Science HREC	BETA and CTU Ethics Officer
Karolyn.white@mq.edu.au 02 9850 7854	jennifer.rowland@mq.edu.au 02 9850 4194	fran.thorp@mq.edu.au 02 9850 7850	Alex.carey-white@mq.edu.au 02 9850 4490

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>

the 1990s, the incidence of *S. flexneri* has increased in the United Kingdom [10]. In the United States, *S. flexneri* has been reported to be the most common serotype of *Shigella* isolated from children with shigellosis [11]. In the United Kingdom, *S. flexneri* has been reported to be the most common serotype of *Shigella* isolated from children with shigellosis [12].

The purpose of this study was to determine the prevalence of *S. flexneri* in children with shigellosis in the United Kingdom. The study was conducted in the United Kingdom, where the incidence of shigellosis is high. The study was conducted in the United Kingdom, where the incidence of shigellosis is high. The study was conducted in the United Kingdom, where the incidence of shigellosis is high.

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