



FoRA - EAEF APPLICANT GUIDE

Guidelines for creating an Externally Approved Ethics Form (EAEF) into 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



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 annual / final reports
- Submitting unexpected adverse event reports.



WHO SHOULD USE THIS GUIDE?

- This form is for research that has had prior review by another NHMRC registered Human Research Ethics Committee (HREC).
- Researchers who need to submit an EAEF are those who are undertaking research that has had NHMRC HREC approval obtained elsewhere, and research activities will occur at Macquarie University or Macquarie University Hospital.



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 'Externally Approved Ethics Form' (EAEF)
- The EAEF 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.
- All EAEF submissions must be signed by the nominated Chief Investigator only.
- 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 in this guide:
 - yellow highlights/boxes are to draw attention to an area on the screen.
 - red highlights/boxes indicate action required, i.e. click highlighted button.

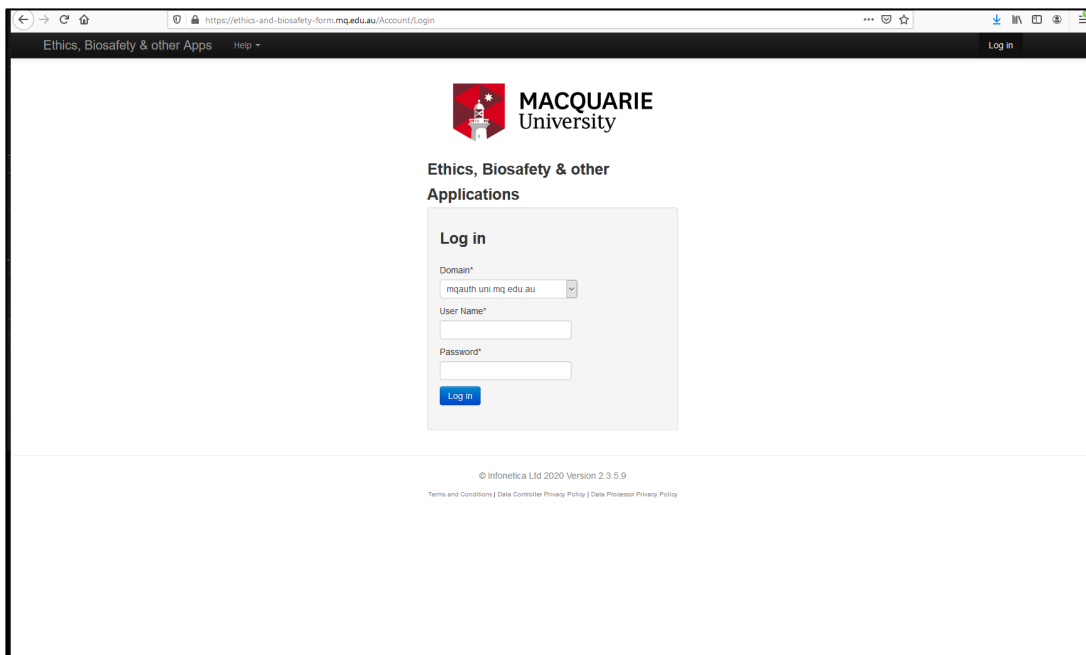
LOGGING INTO THE FORMS FOR RESEARCH APPLICATIONS SYSTEM (FoRA)

Log-in to the Applicant side of FoRA via the following URL:

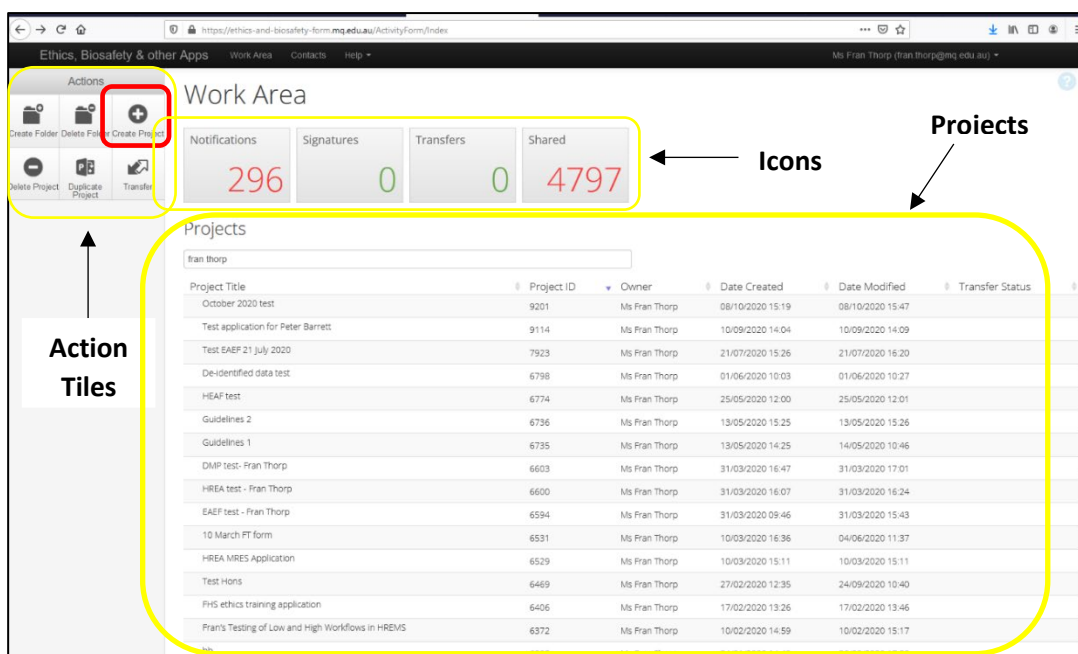
<https://fora-form.mq.edu.au/Account/Login>

Username: MQ OneID/Student ID

Password: OneID/Student ID password



The **Work Area** will look like this:



The **Work Area** consists of the following features:

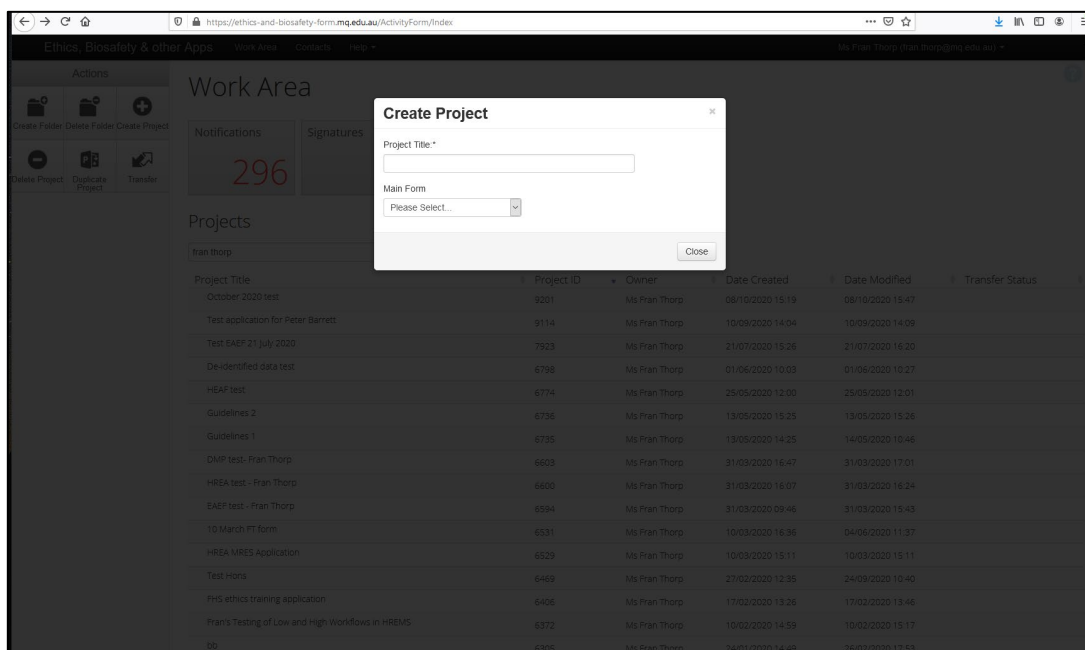
- **Action icons:** Lists the actions that can be performed, e.g. creating new projects, and creating folders to organise multiple projects (applications).
- **Tiles:** (top of the Work Area):

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 icon **Create Project in the Work Area**. The following **Create Project** screen will appear:



Complete the **Project Title** field and select the **Externally Approved Ethics Form (EAEF) V1.0** from the drop-down list.

Create Project

Project Title* (Max 200 characters)
28 Jan 2021 EAEF

Form*
Externally Approved Ethics Form (EAEF) v1.0

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 **Create** button.

COMPLETING THE EAEF

Once the EAEF has been created it will be displayed in the **Navigation** tab.

https://ethics-and-biosafety-form.mq.edu.au/Project/Index/17850

Ethics, Biosafety & other Apps Work Area Contacts Help

Beta Test Mode Ms Fran Thorp (fran.thorp@mq.edu.au)

28 Jan 2021 EAEF 9515

Project Tree

- 28 Jan 2021 EAEF
 - Externally Approved Ethics Form (EAEF) v1.0

Action Required	Status	Review Reference	Date Modified
Yes	Not Submitted	N/A	28/01/2021 11:19

Navigation Documents Signatures Collaborators Submissions Correspondence Centre History

Externally Approved Ethics Form (EAEF) v1.0

Section

- 0 Instructions
- 1 Project Title
- 2 Investigators & Research Personnel
- 3 Funding & Support
- 4 Prior Ethical Approval
- 5 Nature of Research
- 6 Participant Information & Consent
- 7 Privacy & Confidentiality
- 8 Declaration by Chief Investigator

Questions

- 0.1 Instructions
- 1.1 Project Title
- 2.1 Investigators & Research Personnel
- 3.1 Funding & Support
- 4.1 Prior Ethical Approval
- 5.1 Nature of Research
- 6.1 Participant Information & Consent
- 7.1 Privacy & Confidentiality
- 8.1 Declaration by Chief Investigator

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Terms and Conditions | Data Controller Privacy Policy | Data Processor Privacy Policy

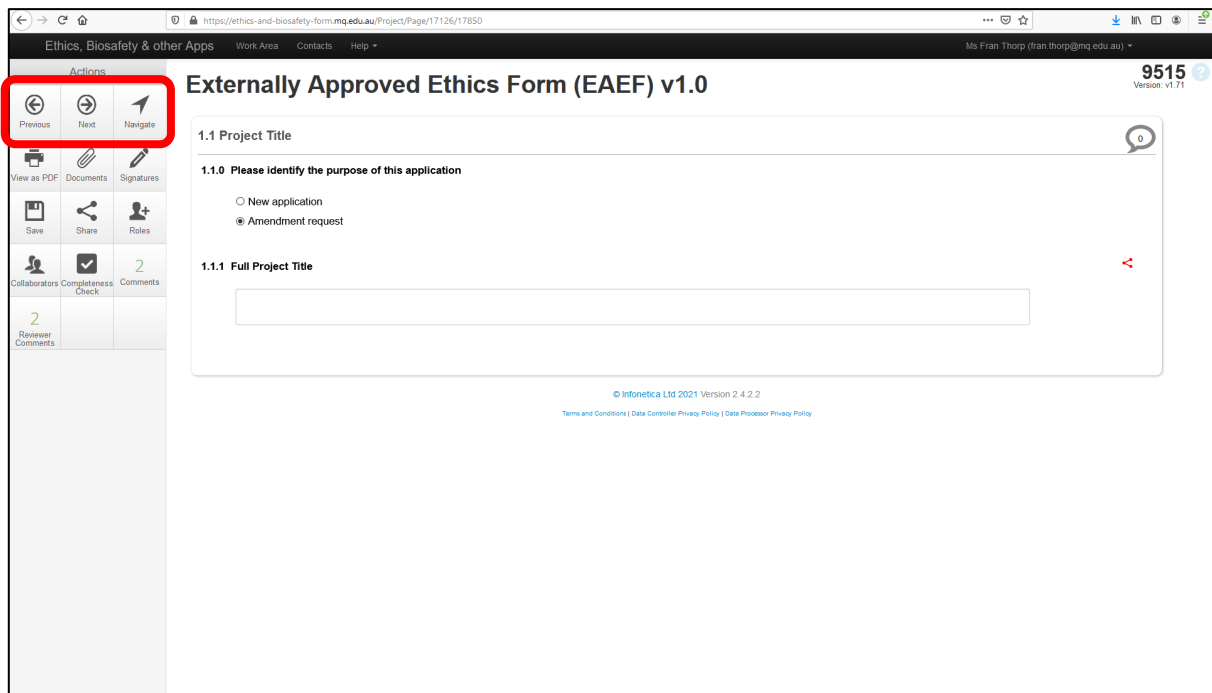
Work through each section of the EAEF form from **section 0.1 to section 9.1**.

(N.B. **Section 8.1** is the Amendment section, which will be hidden from view and will only be activated after an application is approved.)

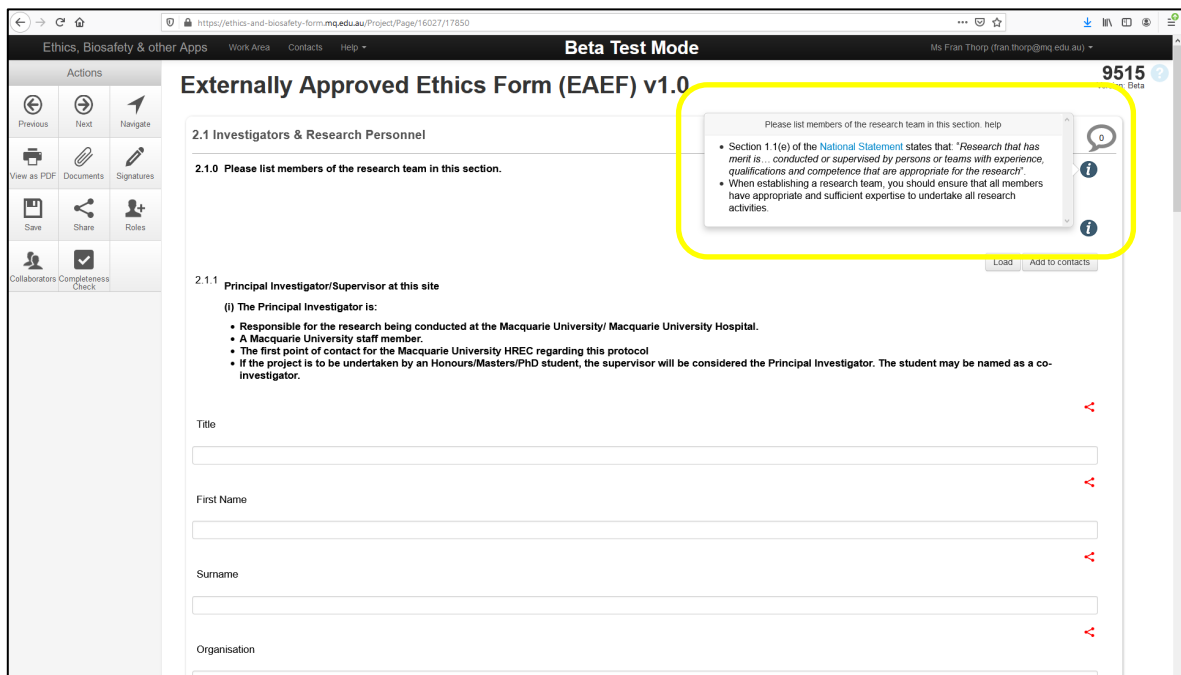
All responses will be automatically saved.

Use the **Previous** and **Next action icons** 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 complete list of EAEF form sections.

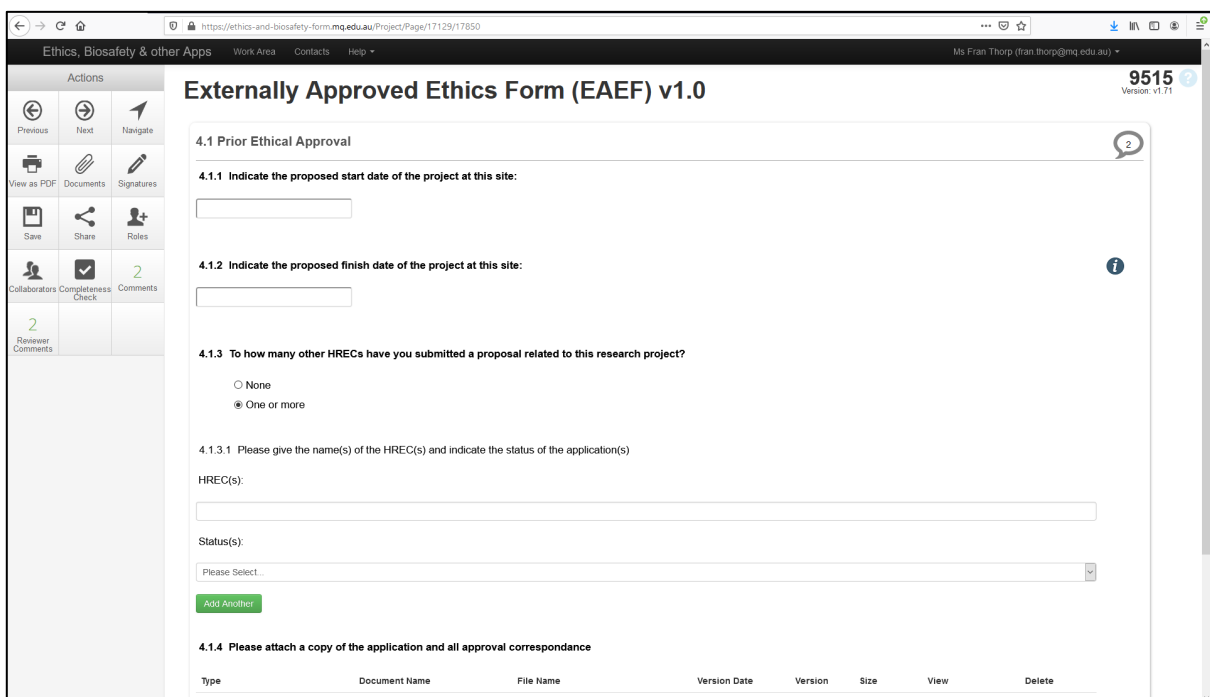


Click on the **Information icons** available throughout the form. Further information will be available via a pop-up (example below):

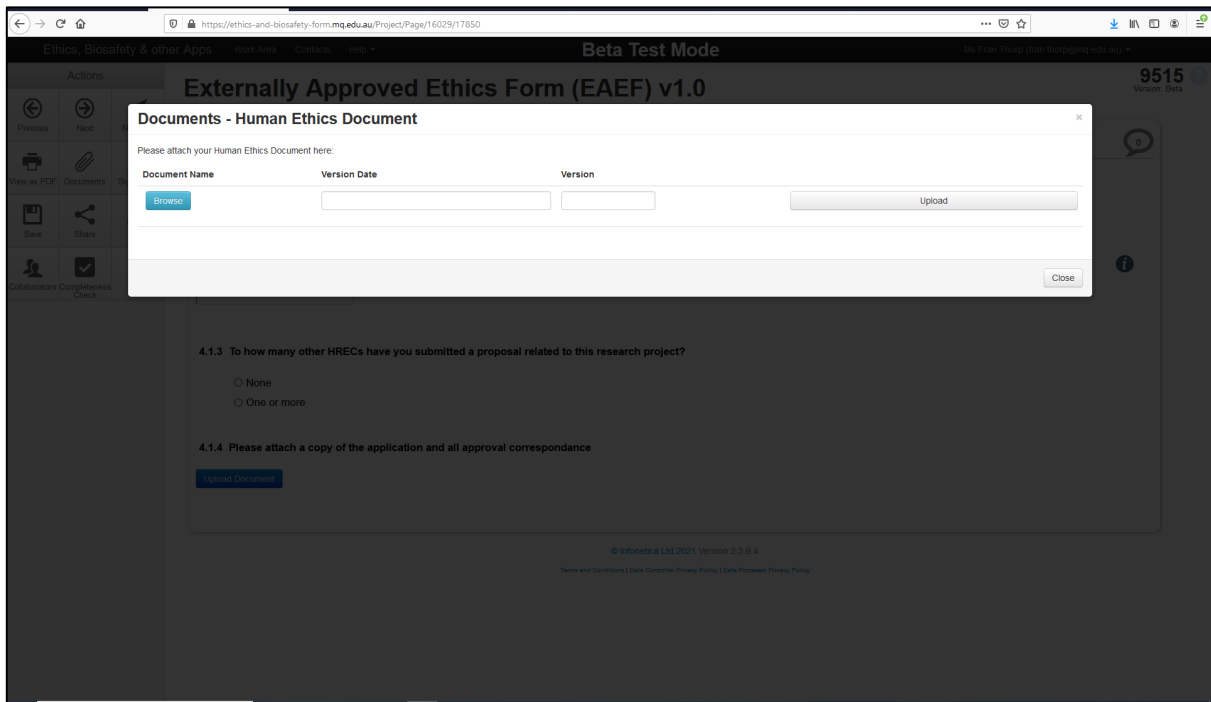


UPLOADING THE APPROVED APPLICATION AND ALL APPROVAL CORRESPONDENCE TO THE EAEF: SECTION 4.1

Question 4.1.4 in Section 4.1 enables applicants to upload the documents related to the approved project.



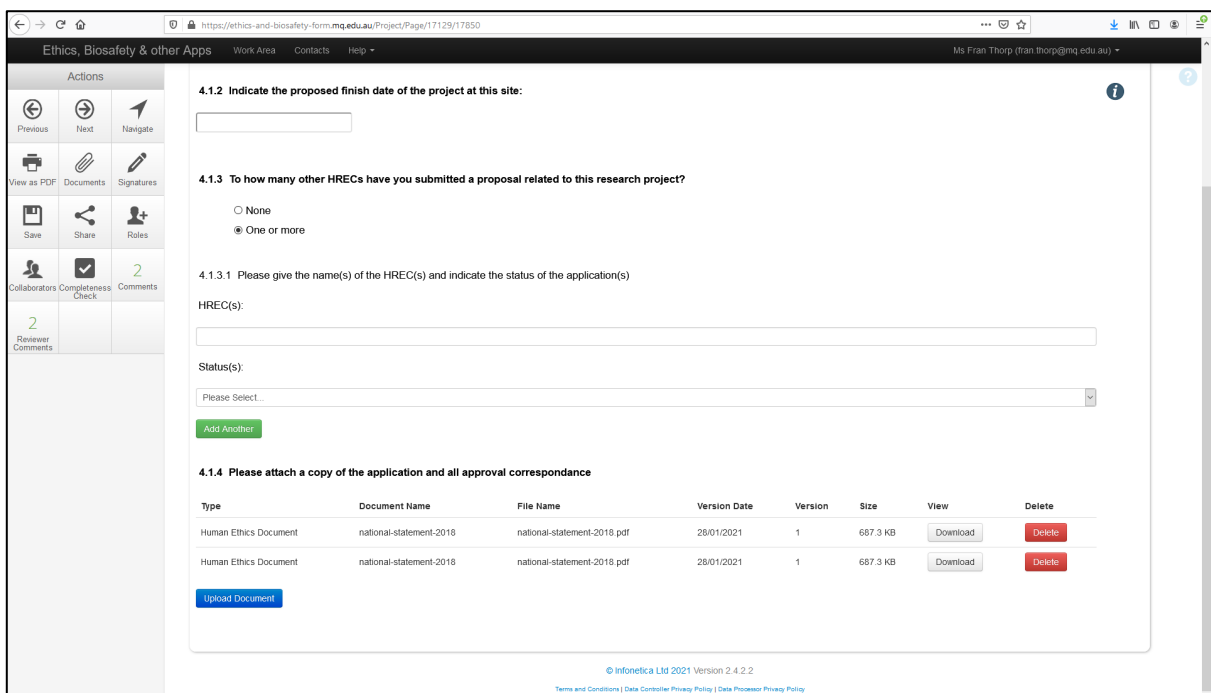
To upload a document, click on the **Upload Document** button in Q4.1.4. The following screen will appear (example below):



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 section 4.1. The uploaded document will appear below Q4.1.4.

To upload another document, click on the **Upload Document** button under the list of uploaded documents and repeat the above actions.



UPLOADING A DATA MANAGEMENT PLAN – SECTION 7.1

Upload the Data Management Plan to Q7.1.2.1.5 by clicking on the **Upload Document** button. 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.

The screenshot shows the 'Externally Approved Ethics Form (EAEF) v1.0' interface. The left sidebar contains navigation and action buttons. The main content area is titled '7.1 Privacy & Confidentiality' and includes sections 7.1.1 through 7.1.4. Section 7.1.2.1.5 'Alternatively, upload your DMP as an attachment' features a table with one entry:

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
DMP - General Documents	Data Management Plan	Data Management Plan.docx	28/01/2021	1	11.6 KB	Download	Delete

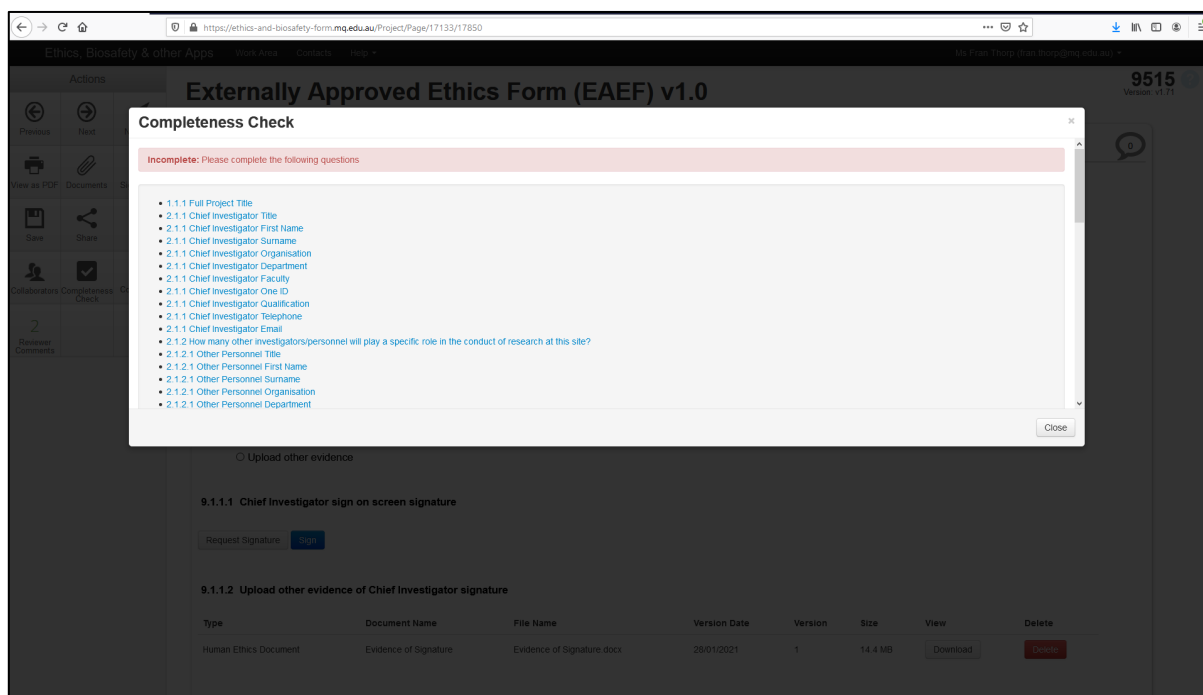
SIGNING AND SUBMITTING THE EAEF – SECTION 8.1

When you reach **section 9.1**, click on the **Sign on screen** option then click the **Sign** button.

The screenshot shows the 'Externally Approved Ethics Form (EAEF) v1.0' interface at section 9.1. The main content area is titled '9.1 Declaration by Chief Investigator' and includes section 9.1.1 'Declaration by Chief Investigator'. It contains a list of bullet points regarding the declaration and a 'How do I agree to these terms?' section with radio buttons for 'Sign on screen' (selected) and 'Upload other evidence'. Below this is a 'Request Signature' button and a 'Sign' button. Section 9.1.1.2 'Upload other evidence of Chief Investigator signature' features a table with one entry:

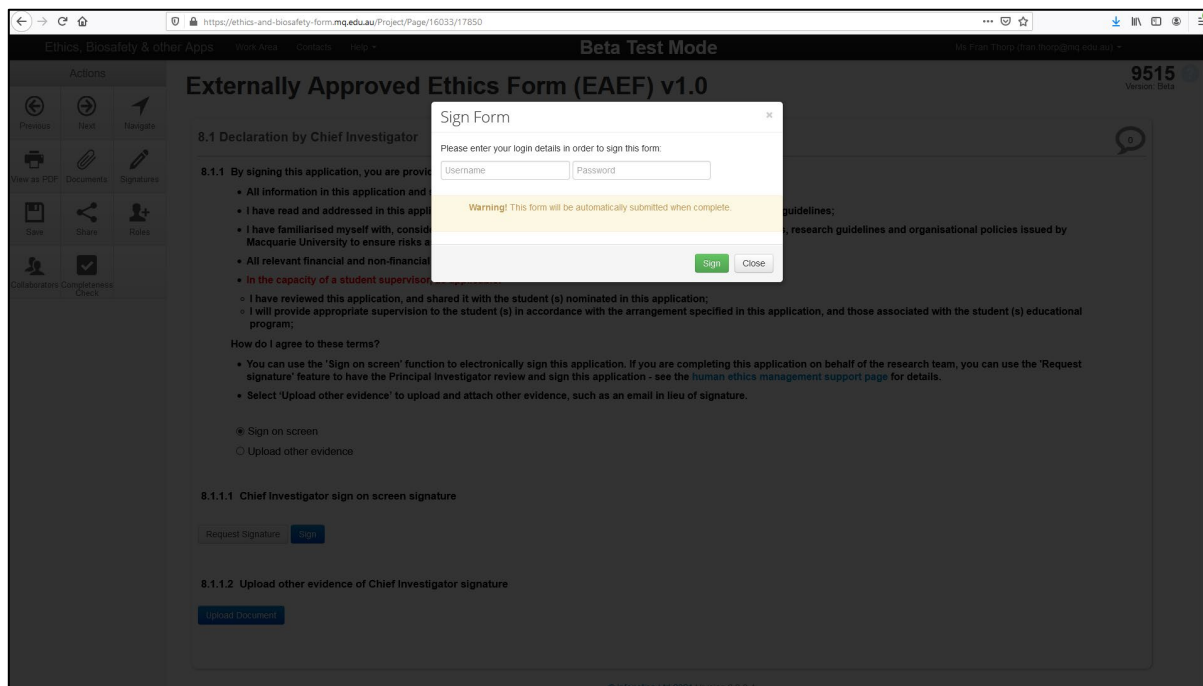
Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Human Ethics Document	Evidence of Signature	Evidence of Signature.docx	28/01/2021	1	14.4 MB	Download	Delete

The system will do a **completeness check** to ensure that all the sections of the EAEF form have been completed.

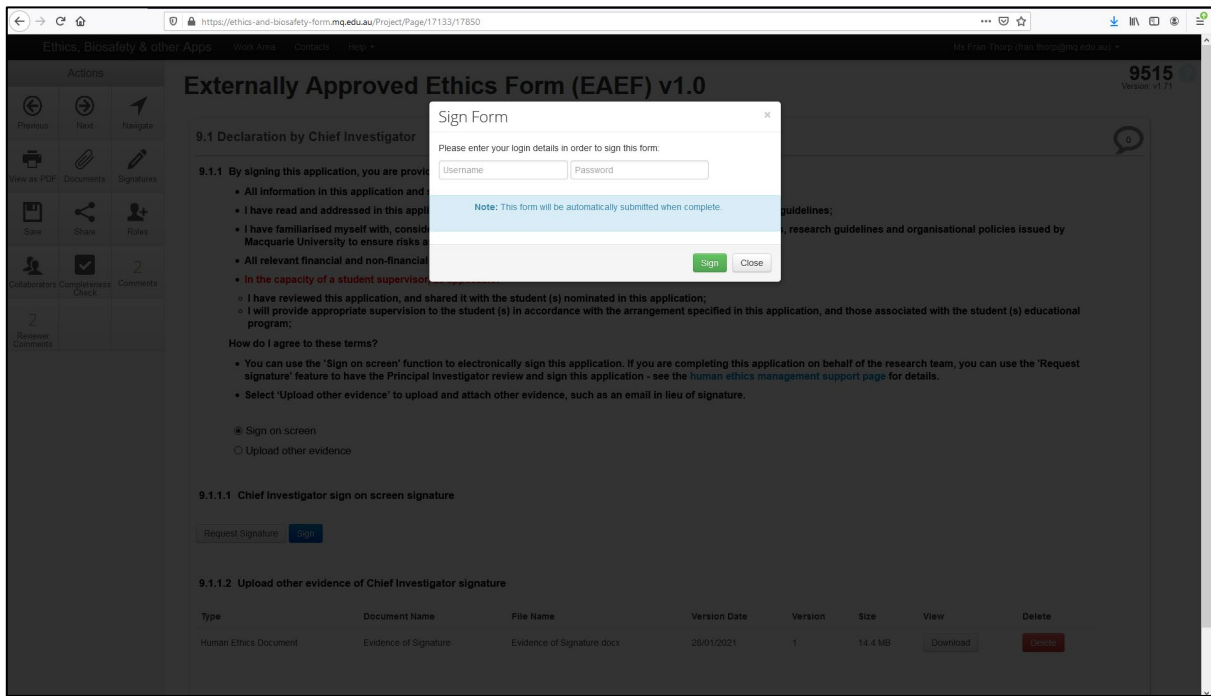


Click on the blue links of the sections that need to be completed. When all sections have been completed proceed to **section 9.1** and click on the Sign button again.

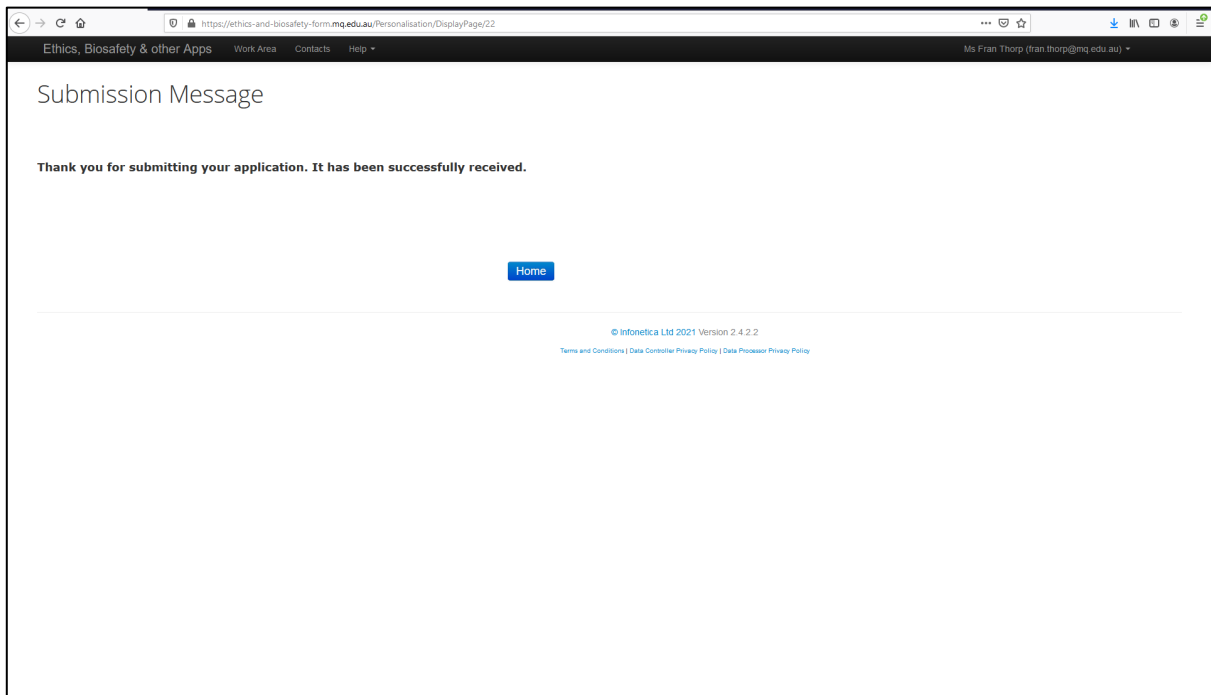
The Sign Form will appear:



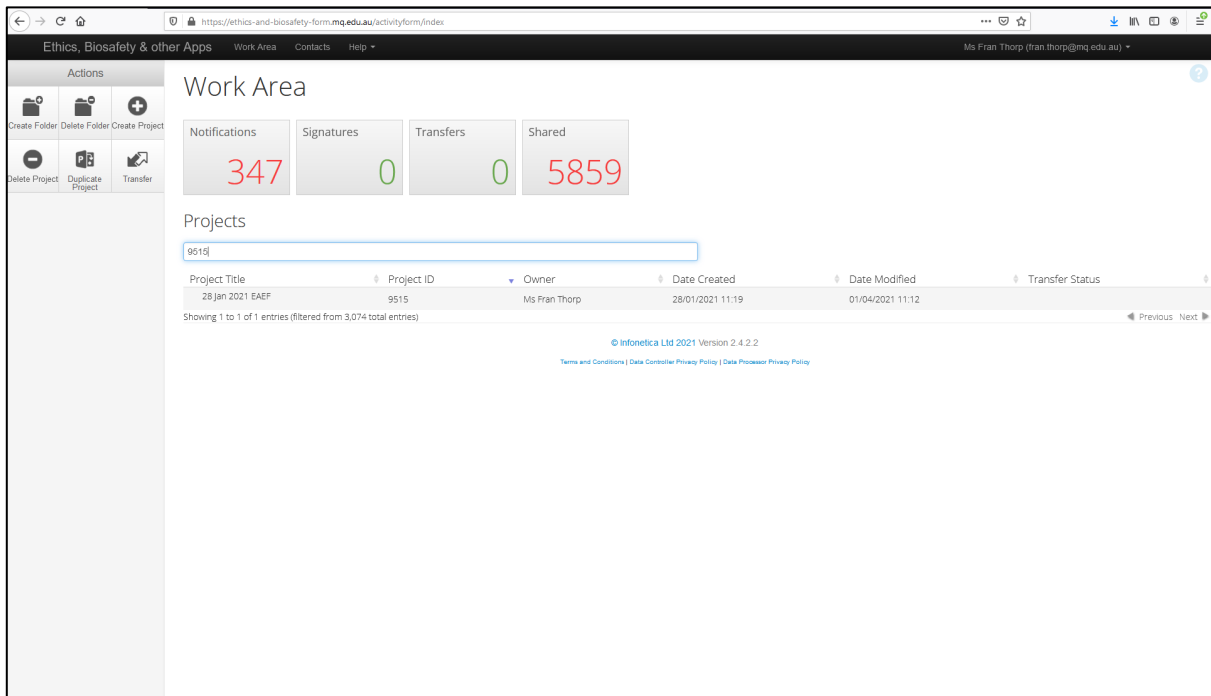
Enter your Sponsored OneID and Password and click on the Sign button.



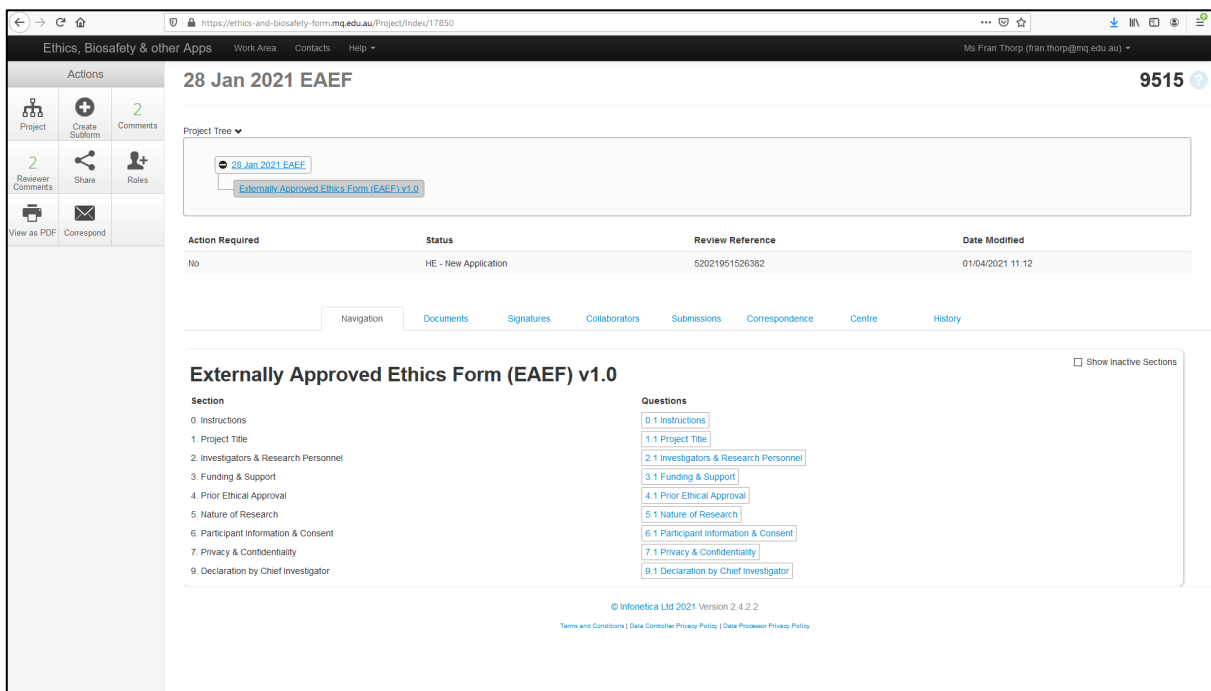
The following screen will appear:



Click on the **Home** button to return to the Work Area. The submitted project will be listed under the **Projects** heading.



To access the project, click on the project name. The status of the submitted application will change from **'Not Submitted'** to **'New Application'**.

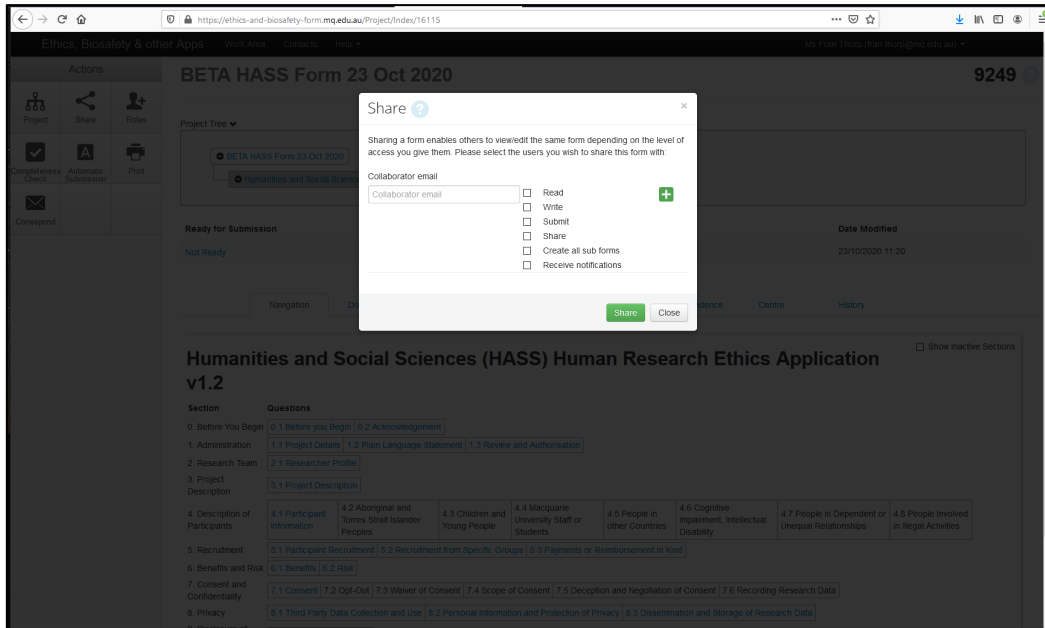


SHARING A PROJECT WITH OTHER COLLABORATORS

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 selects what access permissions will be allocated to each collaborator. To share a project with another team member, click on the Action icon **Share**.

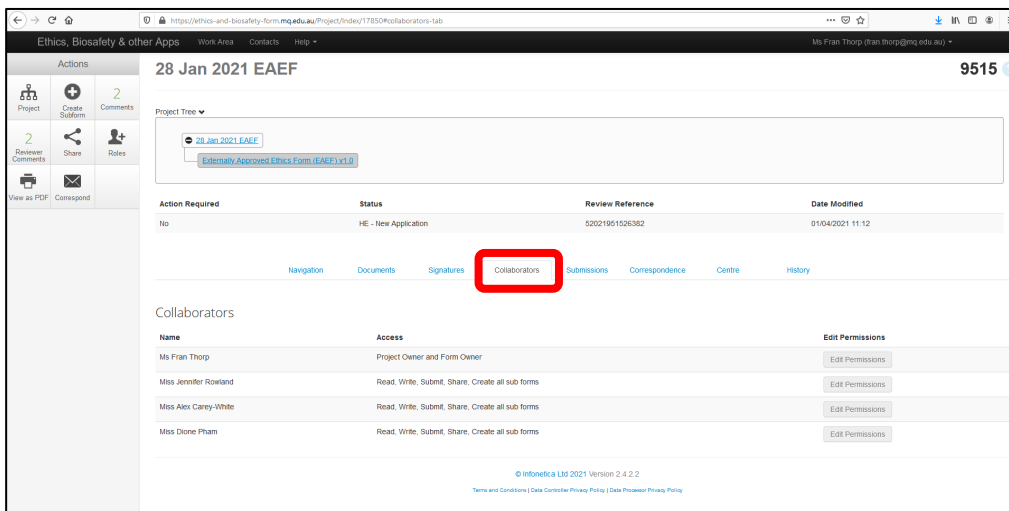
The following will appear:



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

Click on the **Share** button.

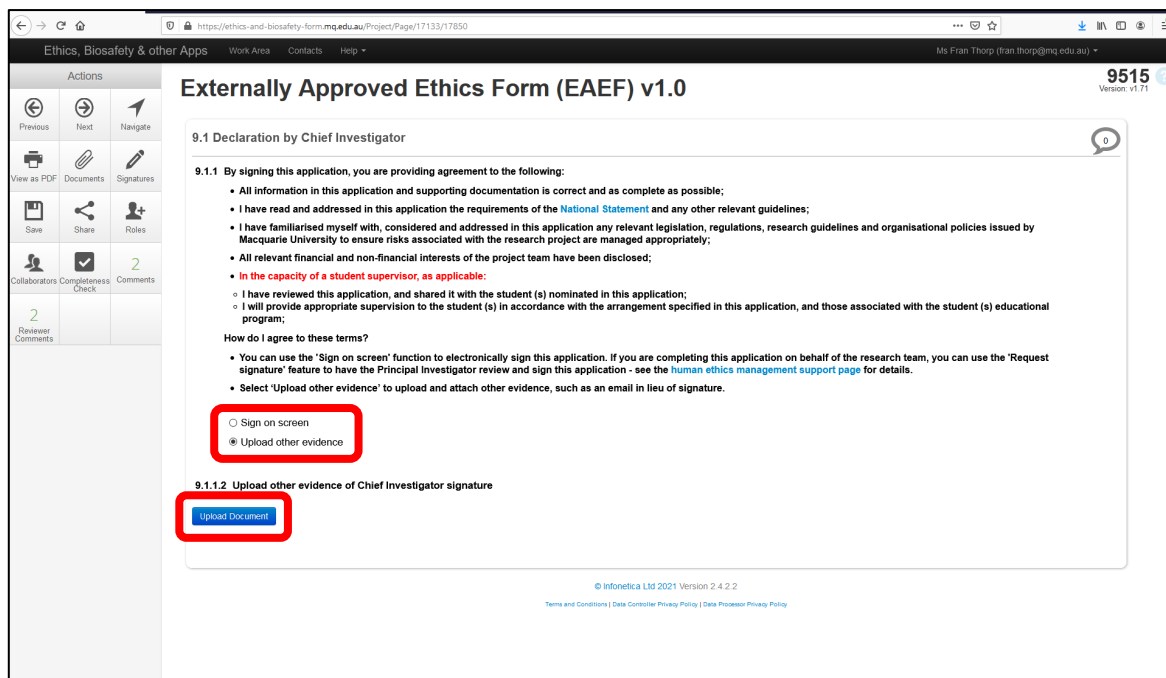
To check that the project has been shared with the collaborator access the list of collaborators via the **Collaborator** tab. The access permissions for each person will be displayed. All people listed under the Collaborators heading will have access to the application.



SUBMITTING AN EAEF WITH EVIDENCE OF CHIEF INVESTIGATOR SIGNATURE – SECTION 8.1

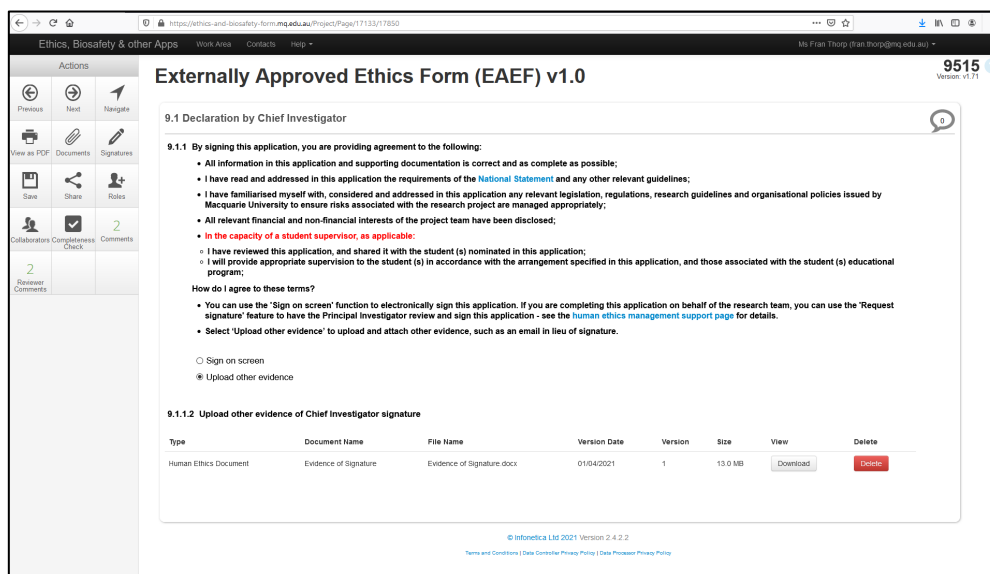
If a Chief Investigator is unable to sign and submit the project, **Section 8.1** enables other personnel to submit the application on their behalf. The Chief Investigator must first provide a document indicating that they have read the application and support its submission.

The person submitting the application on the Chief Investigator's behalf first needs to click on the **Upload other evidence** option in **Q8.1.1**.



Click on the **Upload Document** button. Click on the **Browse** button and select the evidence of signature document. Enter a **Version Date** and **Version** number and click on the **Upload** button.

Click the **Upload** button to upload evidence of the Chief Investigator's signature.

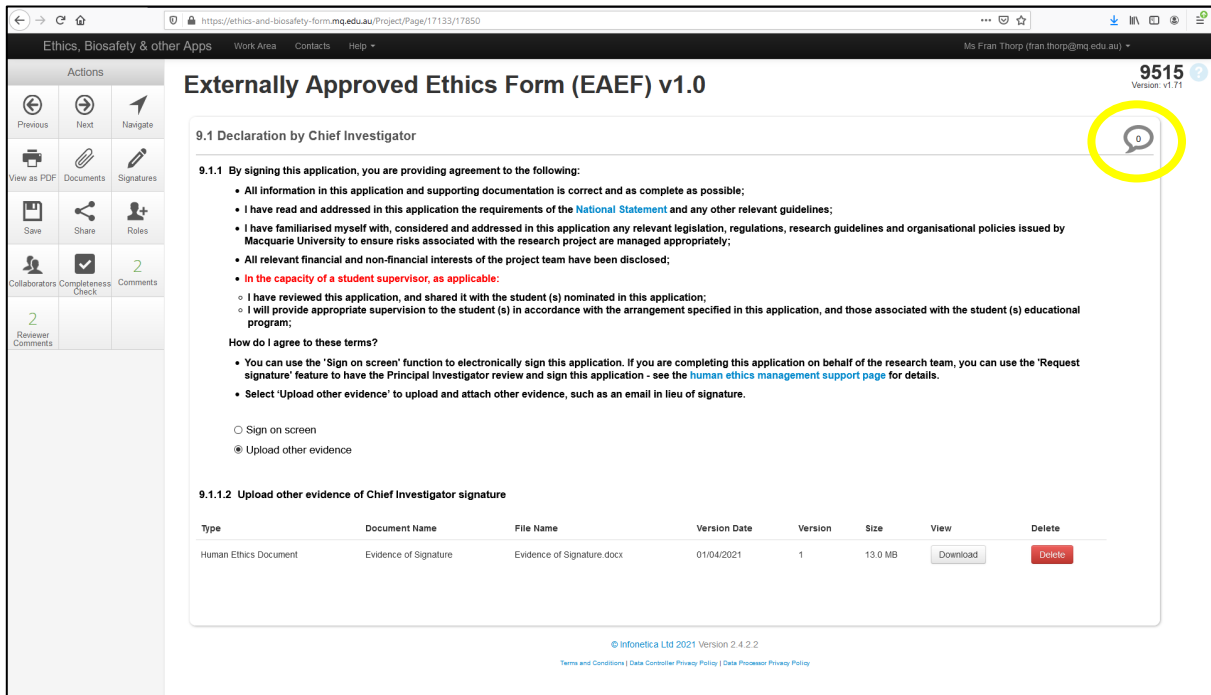


ADDING COMMENTS TO THE EAEF FORM FOR OTHER COLLABORATORS

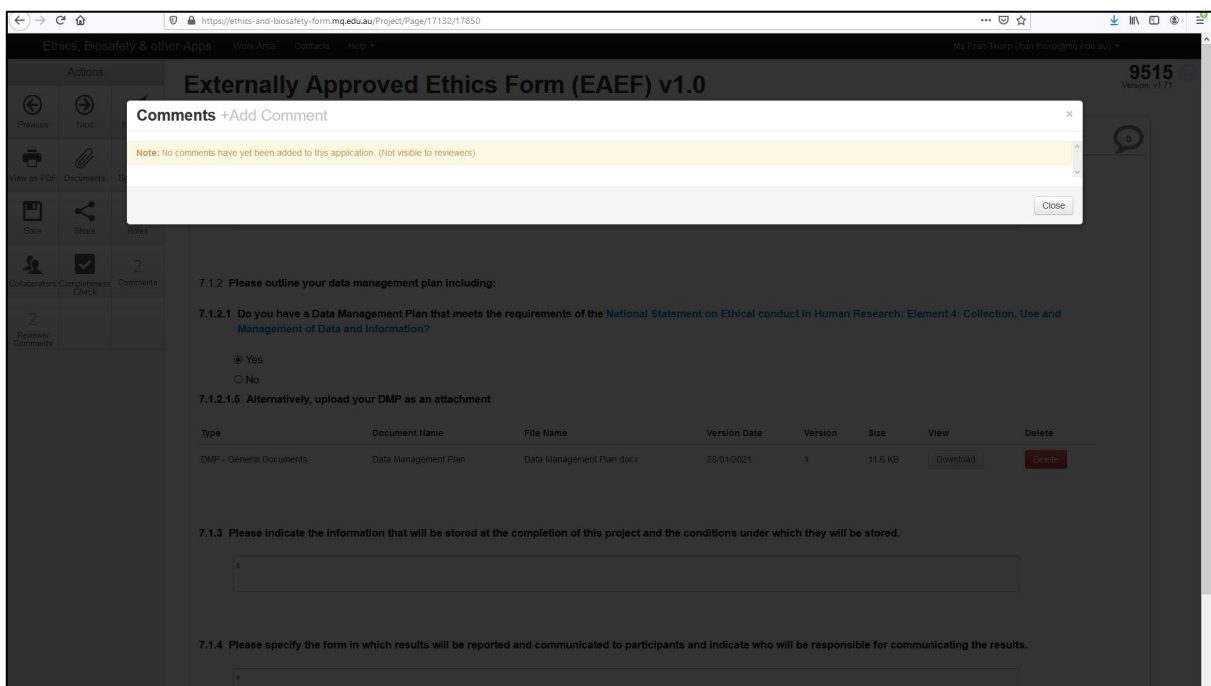
The EAEF form enables all collaborators to communicate with each other about the responses to each section of the form.

To make comments in the form, select one of the form sections.

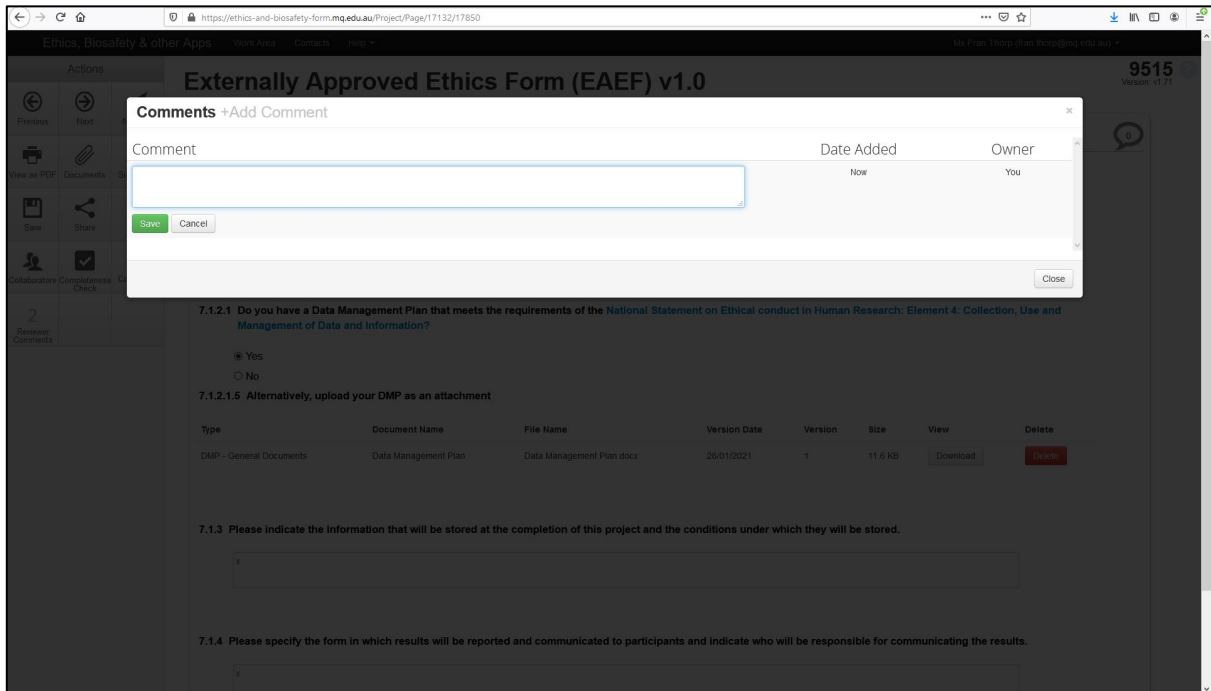
Click on the speech bubble at the top right of the page.



The **Comments** screen will appear.



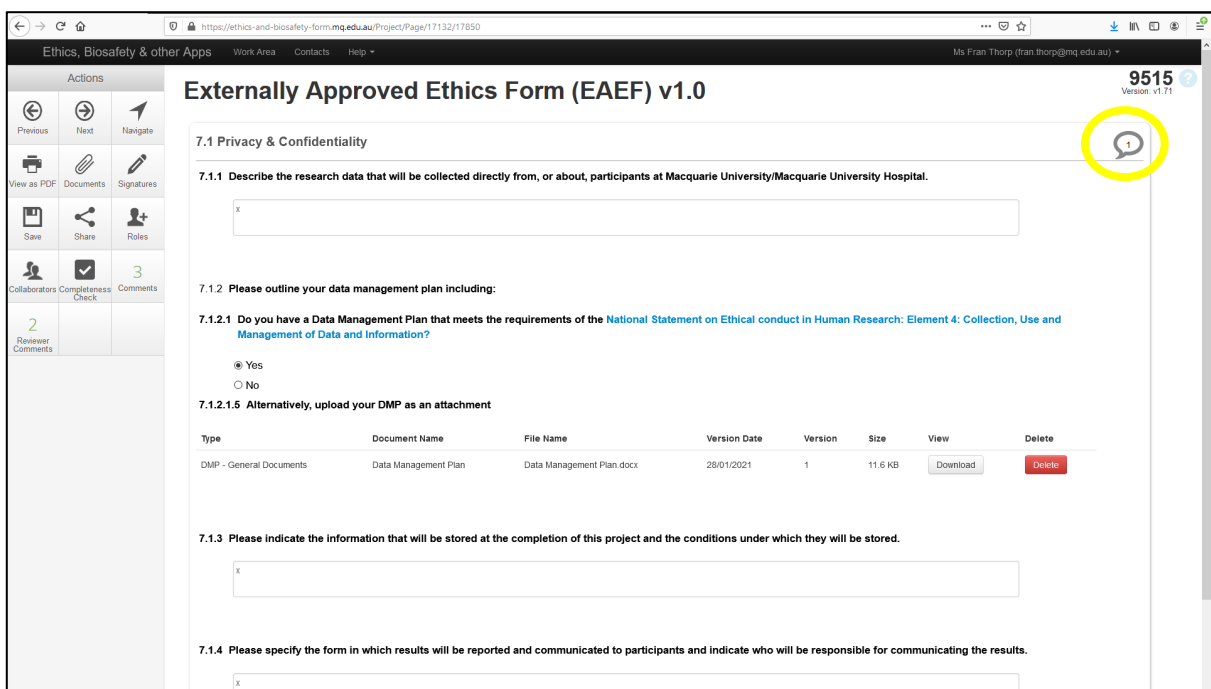
Click on **Add Comment**. A comment box will appear.



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. The number of comments will also appear in the **Comments** action icon.

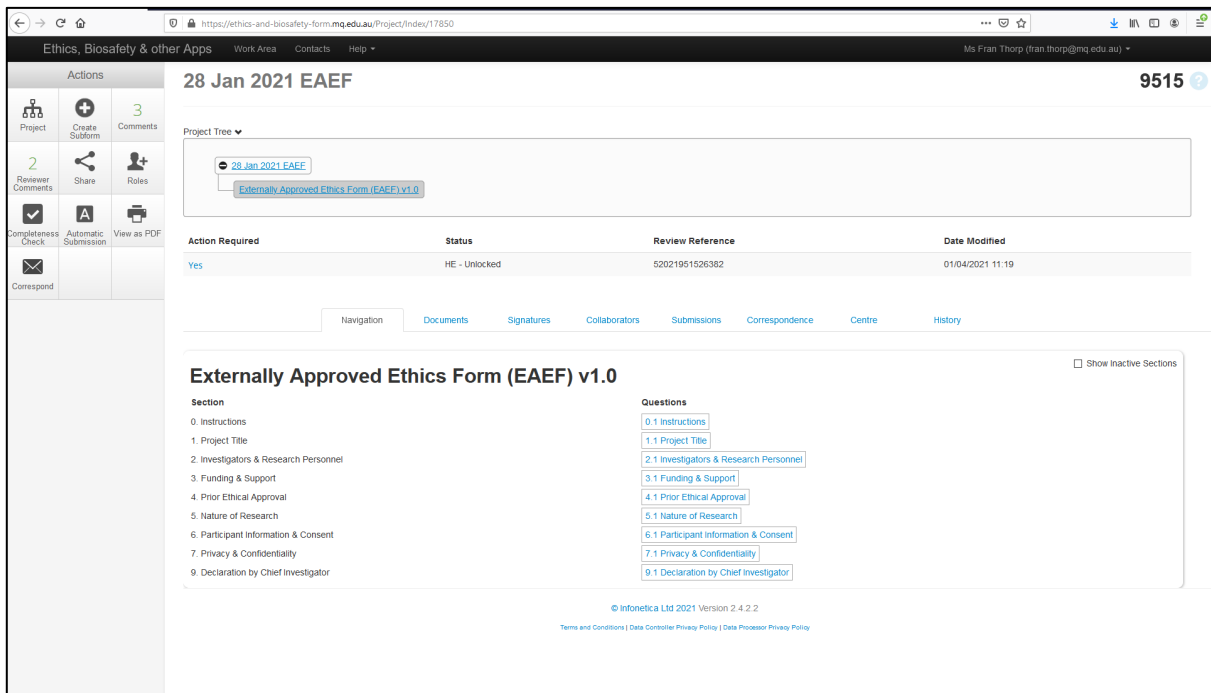


ACCESSING REVIEWER COMMENTS

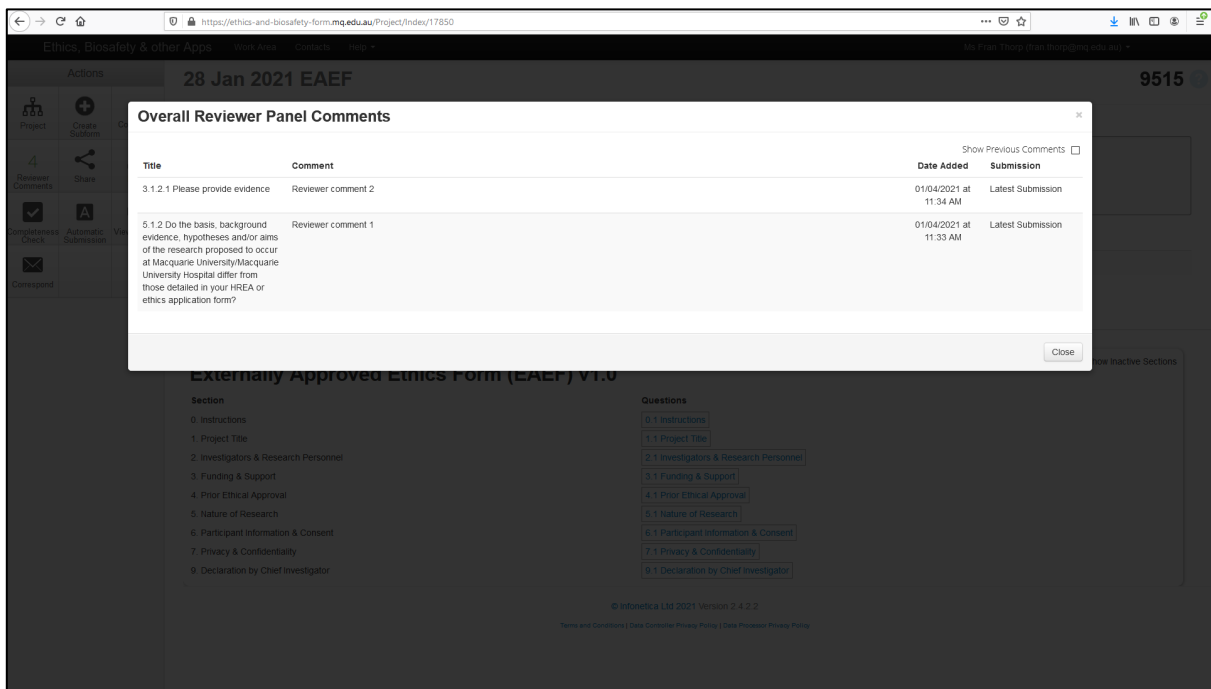
After the ethics committee has reviewed the project, the Ethics Secretariat will add the reviewers' comments to the EAEF and return the project to the Applicant side of the system.

The Status of the project will be **Unlocked**.

To access the reviewers' comments, click on the **Review 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 one of the two speech bubbles visible at the top right-hand side of the relevant section. Click on the speech bubble on the left. (The speech bubble on the right shows comments on the project from team members.)

PREPARING YOUR RESPONSE TO THE REVIEWERS' COMMENTS

Your response will need to include:

- A Word or pdf document directly addressing each of the Reviewers' comments, which should be uploaded to section 4.1.4 of the form. The committee's feedback should be cut and pasted into this document and the direct response written directly underneath it or presented in tabular format.
- A tracked and clean copy of all revised documents uploaded to section 4.1.4 in the form.
- Updates to relevant sections of the form in line with the reviewers' comments.

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

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

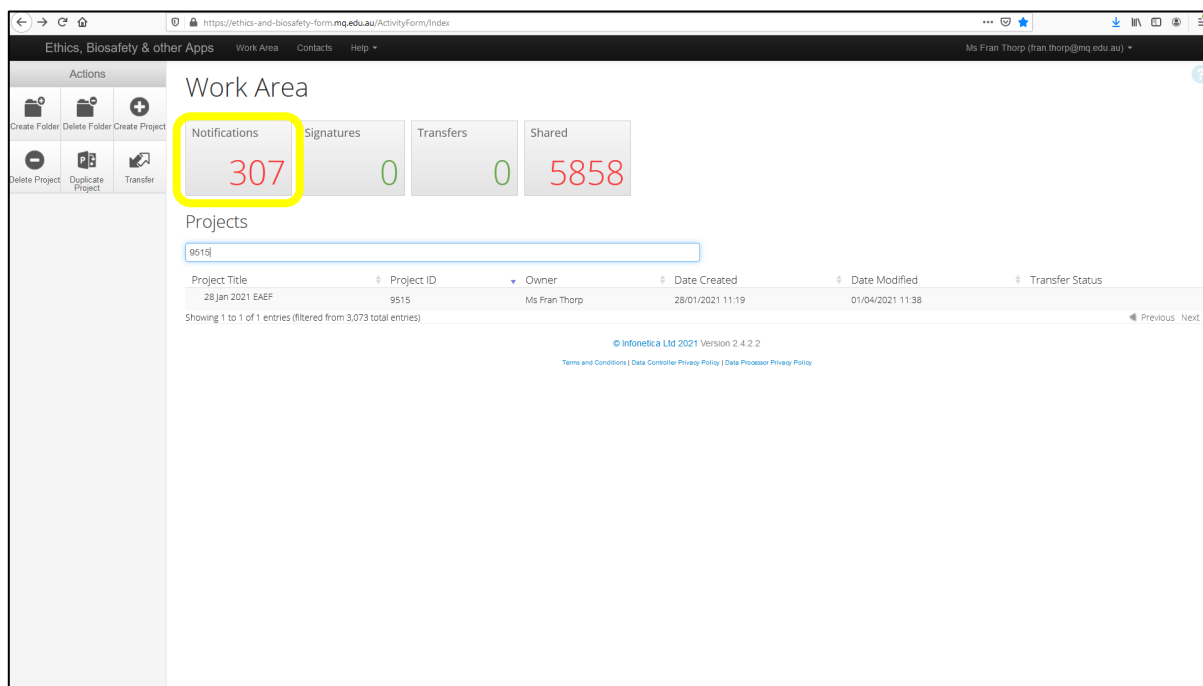
When the EAEF is ready for review, proceed to **section 9.1**.

As you have already completed the signature process for the initial submission, you only need to click on the **Sign** button in **section 9.1.1.1**. Complete the signature process as for your initial submission.

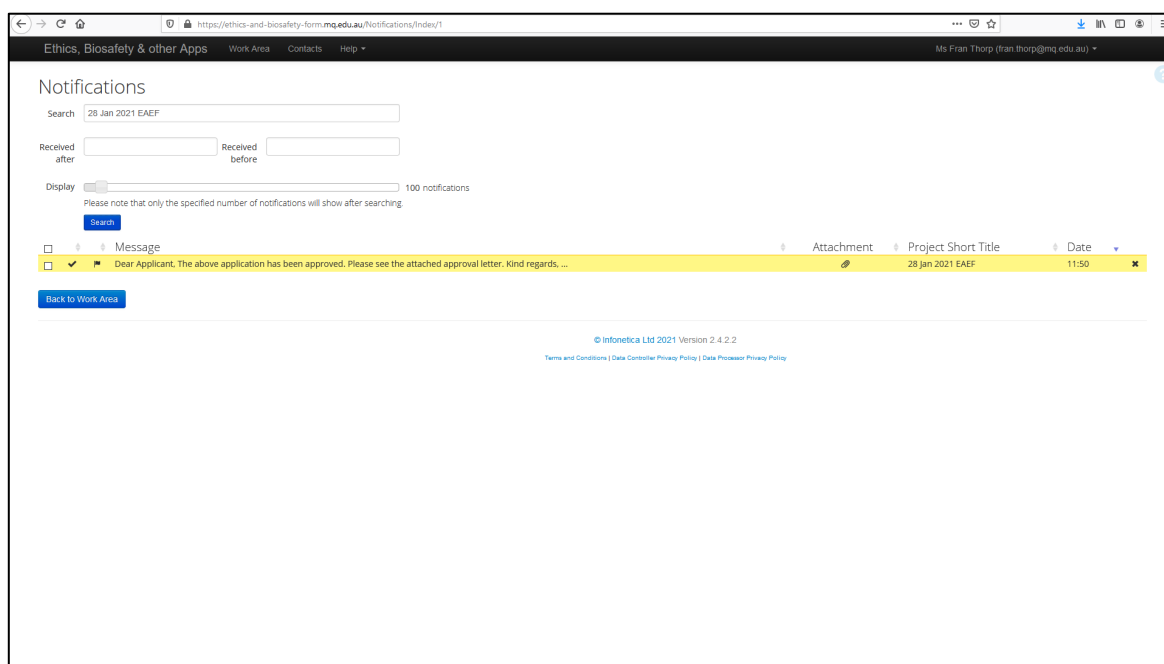
ACCESSING THE APPROVAL LETTER

After the reviewers have 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 an approval letter as an attachment via the Notifications tile in your Work Area.

The Notifications tile is in your Work Area.

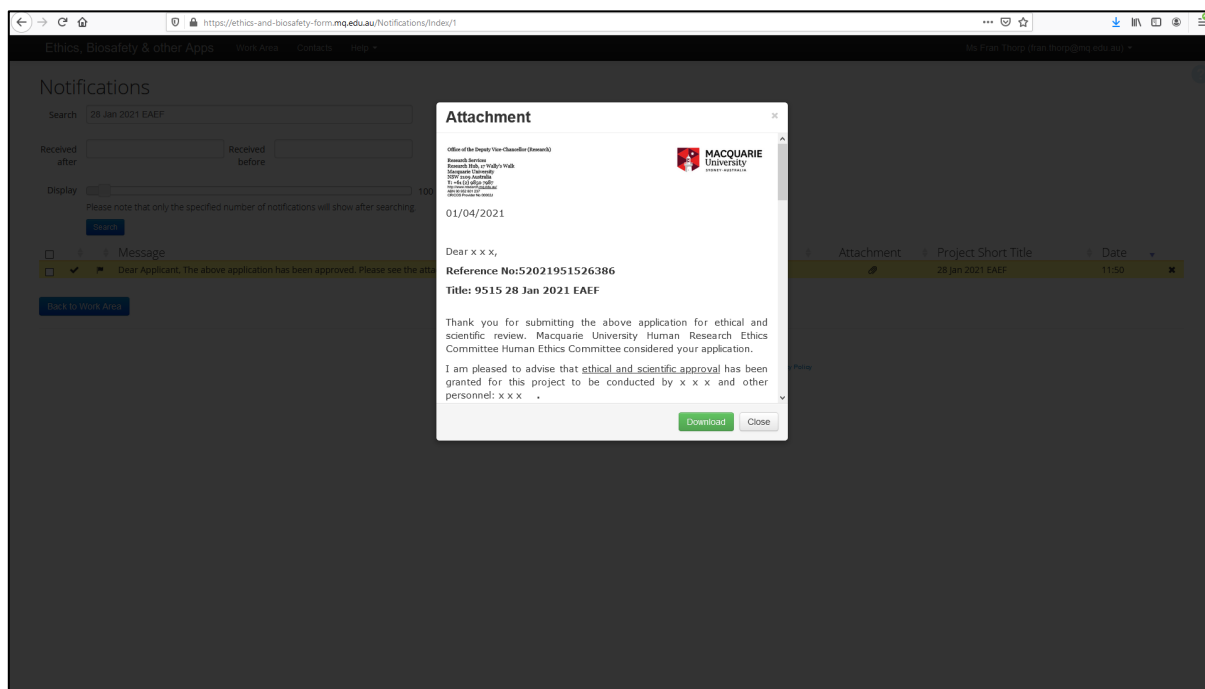


Click on the tile and enter the title of the project in the **Search** box and click the **Search** button to find all notifications relating to that project. The approval letter will be attached to a notification.



Click on the attachment symbol and the attachment will appear.

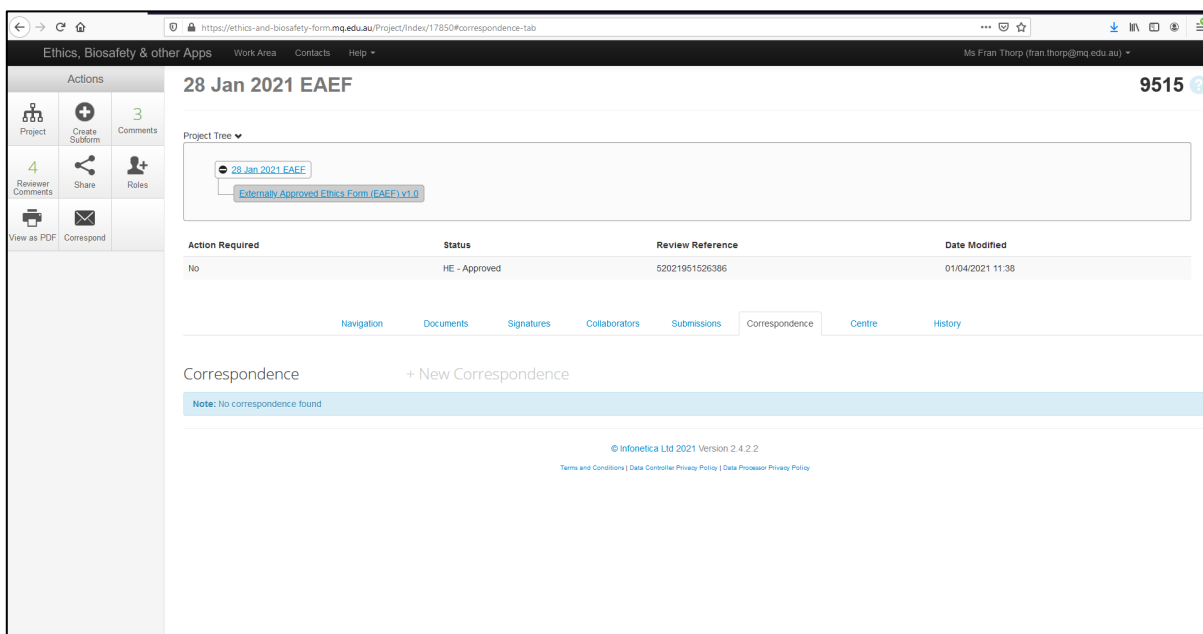
Download a copy of the approval letter by clicking the **Download** button.



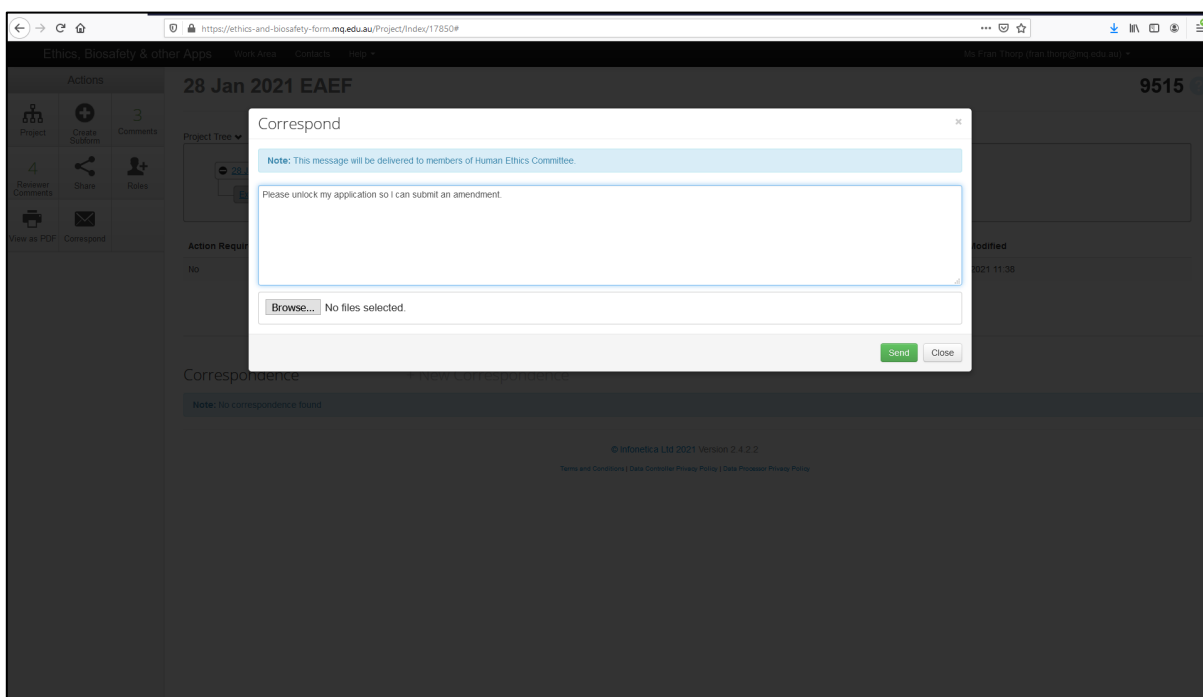
REQUESTING AN AMENDMENT TO AN APPROVED PROJECT

All approved applications are locked and cannot be edited. The ethics administrator will unlock the application for you on request via the **Correspondence** tab or by clicking on the **Correspondence** action icon in the application.

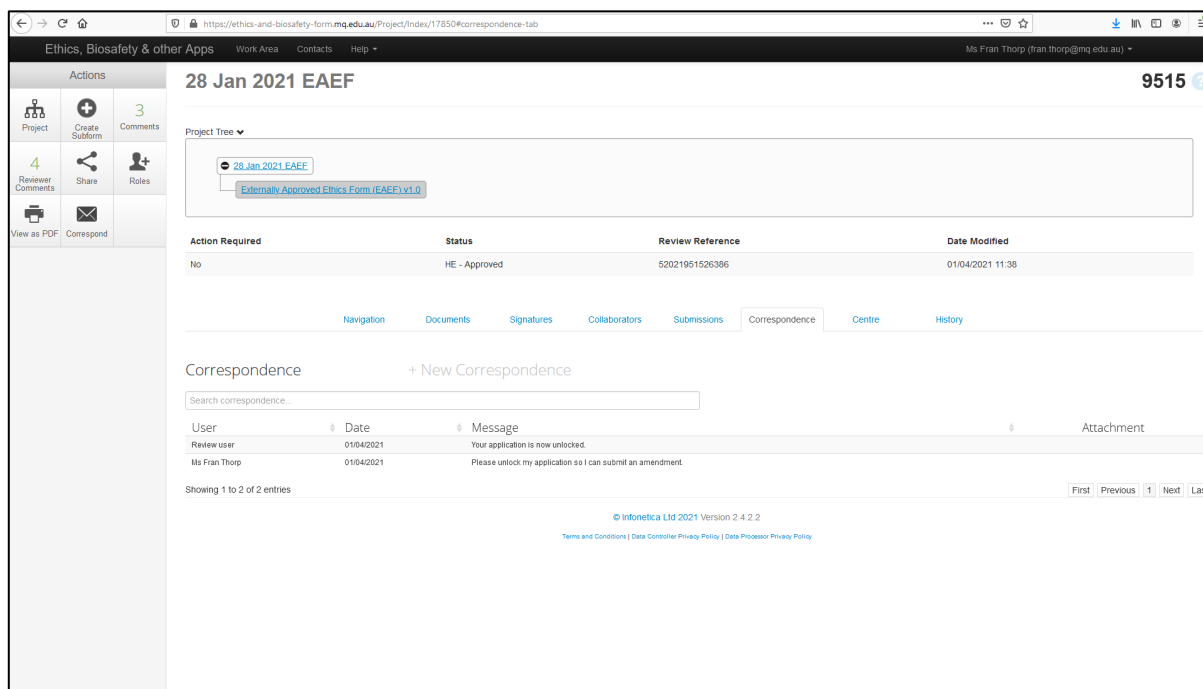
Click on the Correspondence tab.



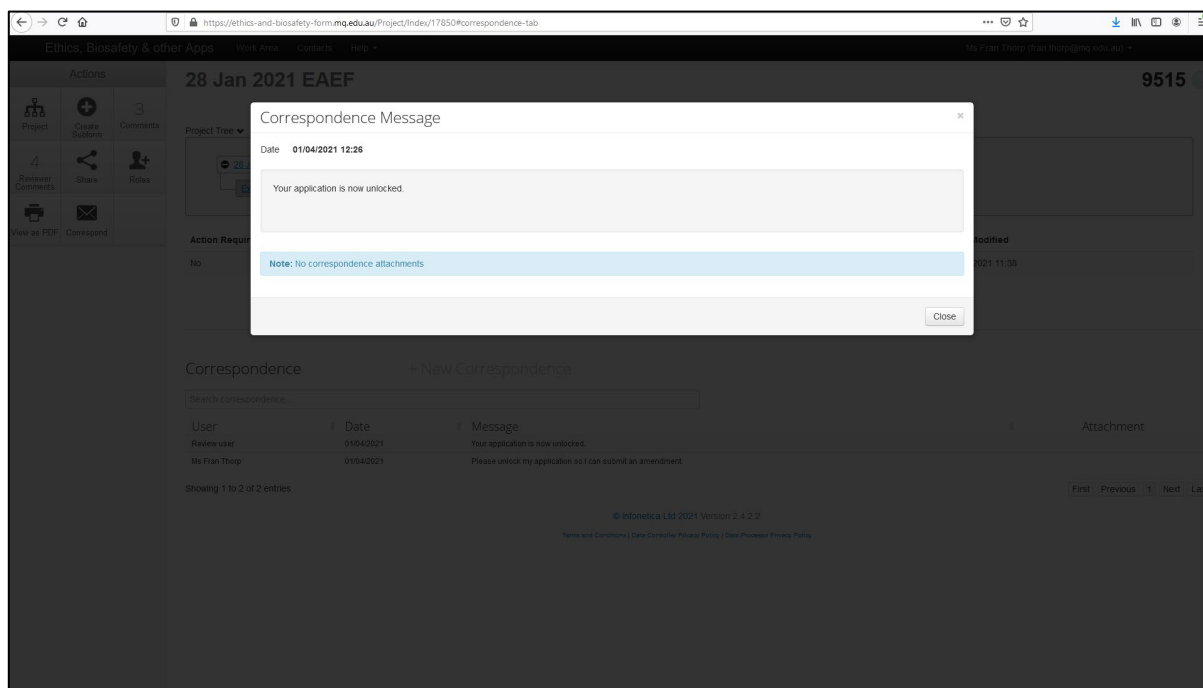
Click on New Correspondence.



Type your request to unlock the project for amendment into the box and click on the **Send** button.
The Ethics Administrator's reply will appear above your message, as follows:



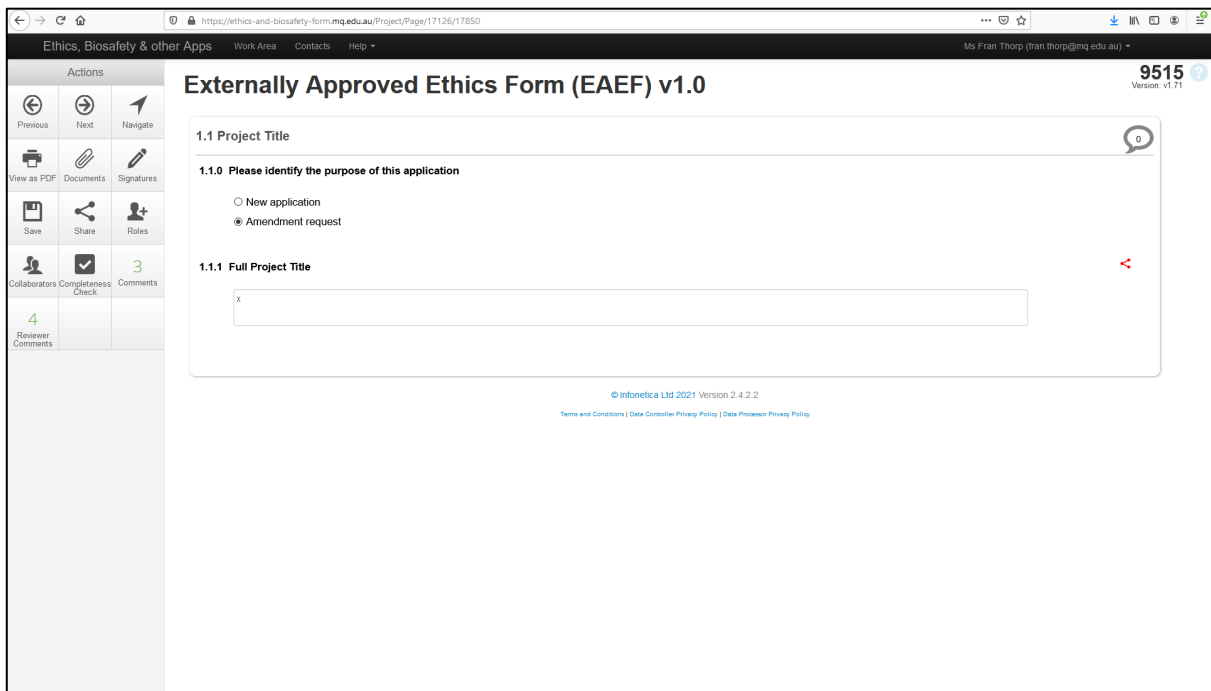
To see the full content of the Ethics Secretariat's reply, click on the link under the **Message** heading.



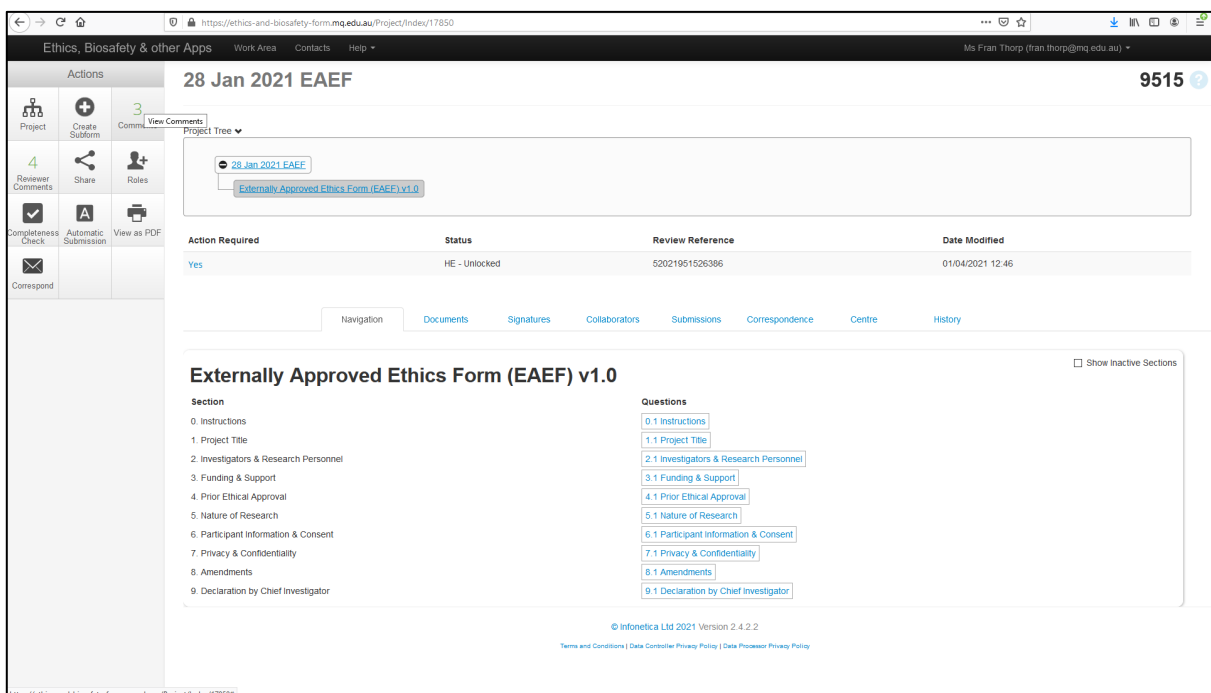
To send a new message, click on the **Close** button and click on **New Correspondence**.
When the project is unlocked, the Review Status of the project will be **Unlocked**.

COMPLETING AN AMENDMENT REQUEST IN THE EAEF

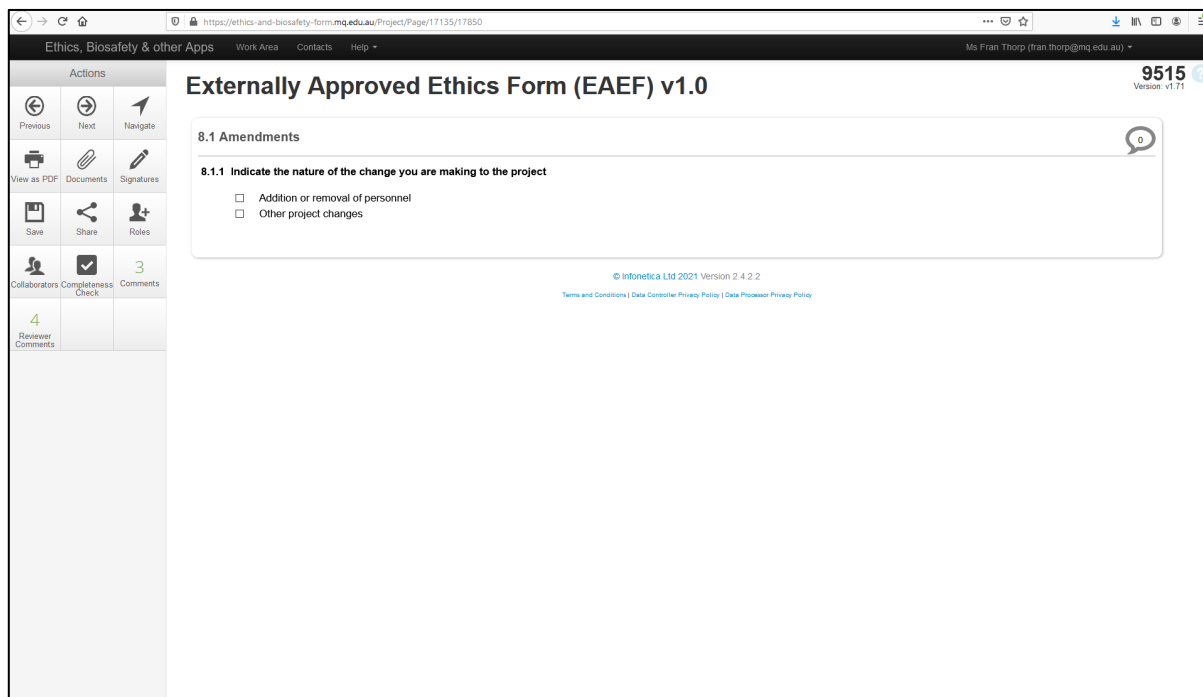
Select the project that you wish to amend. Click on section **1.1 Project Title**. Click on the Amendment request option in **question 1.1.0**. Click on the Save action icon.



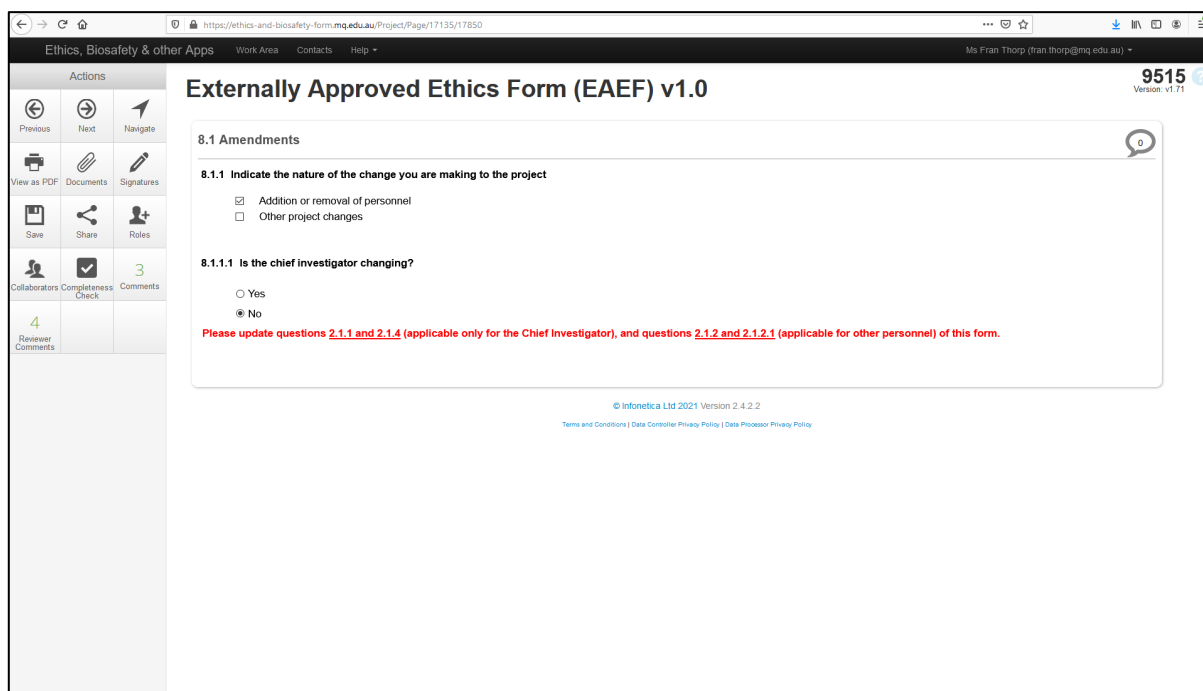
This action will trigger the appearance of **section 8.1 Amendments** where the detail the amendment request can be provided. Use the **Navigation** action icon to access **section 8.1** in the full list of EAEF sections.



Click on section 8.1 and click on the option relevant to your amendment request. Both options can be selected if the amendment is to add or remove personnel and make other project changes.



The following screenshot shows the questions that appear for an addition or removal of personnel only:



The following screenshot shows the questions that appear if the Chief Investigator is changing:

The following screenshot shows the questions that appear if the amendment involves other project changes:

Edit other sections of the EAEF and upload a tracked and clean version of all revised documents to section 9.1 of the form, as needed for the amendment request.

RESPONDING TO REVIEWER COMMENTS ABOUT AN AMENDMENT REQUEST

Your response will need to include:

- A Word or pdf document directly addressing each of the Reviewers' comments, which should be uploaded to section 4.1.4 of the form.
- A tracked and clean copy of all revised documents uploaded to the documents section in the form.
- Amendments to relevant sections of the form in line with the reviewers' comments.

When the response is ready for review, proceed to **section 9.1**.

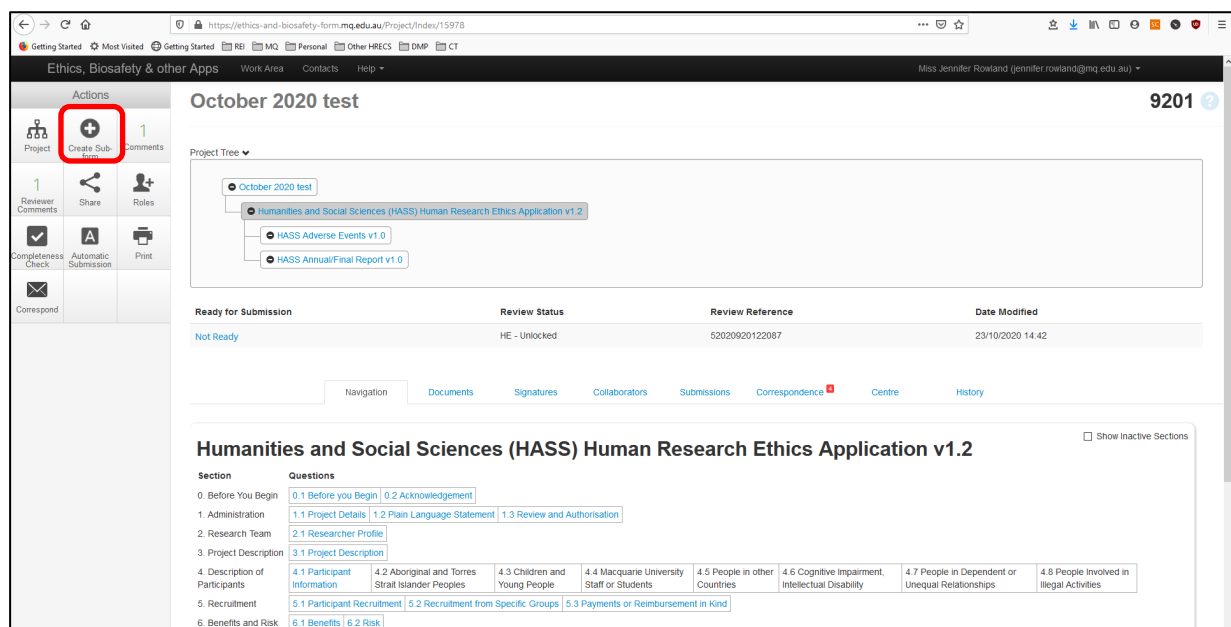
As you have already completed the signature process for the initial submission, you only need to click on the Sign button in **section 9.1.1.1** to move to the Sign Form. Complete the signature process as for your initial submission.

APPROVED AMENDMENTS

When the amendment is approved, the system will send you a notification in the ethics system.

SUBMITTING AN ADVERSE EVENT SUB-FORM

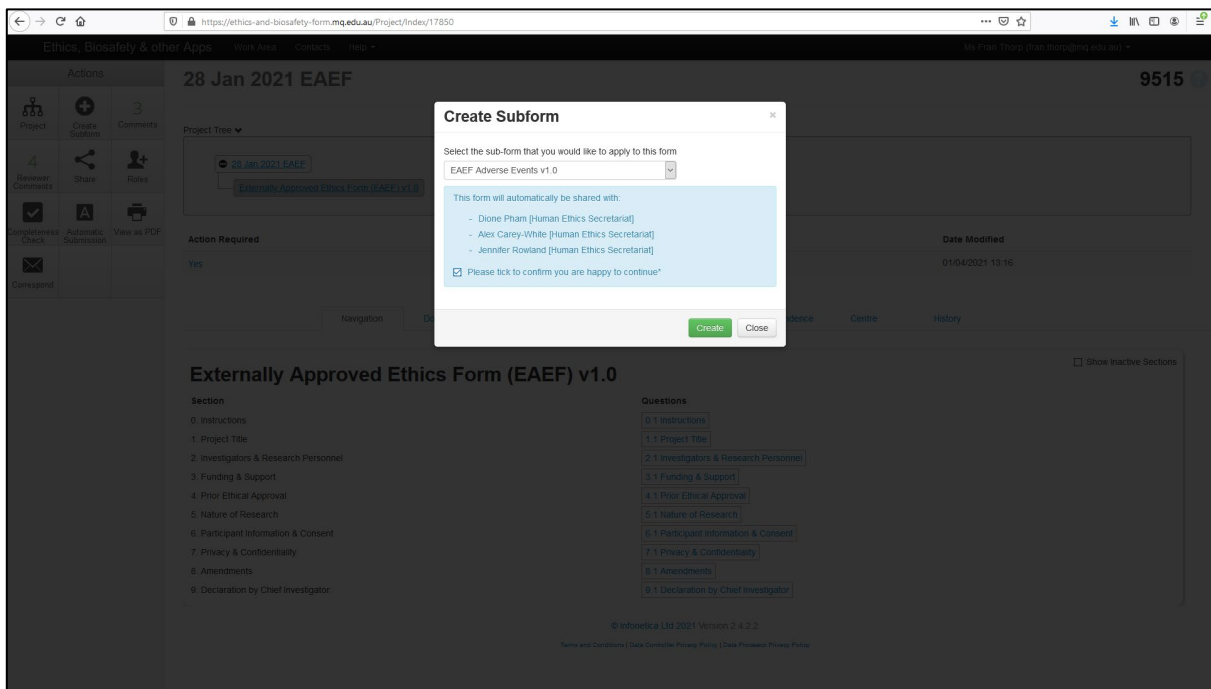
The Adverse Event Form is a sub-form of the main form. Click on the **Create Sub-form** action icon in the project.



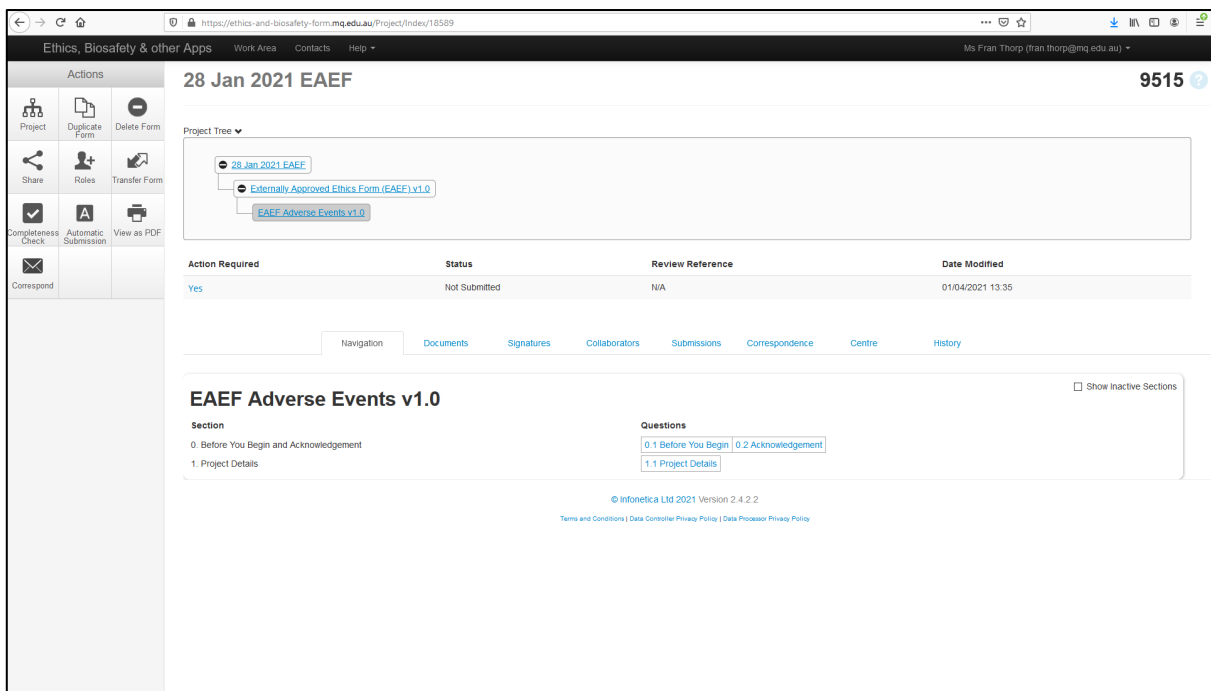
The screenshot displays the 'October 2020 test' project page in the ethics system. The 'Actions' menu on the left is open, and the 'Create Sub-form' icon (a plus sign in a circle) is highlighted with a red box. The main content area shows a project tree with 'Humanities and Social Sciences (HASS) Human Research Ethics Application v1.2' selected. Below the project tree, there is a table with columns for 'Ready for Submission', 'Review Status', 'Review Reference', and 'Date Modified'. The 'Ready for Submission' column shows 'Not Ready'. The 'Review Status' column shows 'HE - Unlocked'. The 'Review Reference' column shows '52020920122087'. The 'Date Modified' column shows '23/10/2020 14:42'. At the bottom, the 'Humanities and Social Sciences (HASS) Human Research Ethics Application v1.2' form is visible, with a 'Show Inactive Sections' checkbox.

Select the **EAEF 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 box to continue then 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 **0.2 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. The upload and sign-off processes are the same as the main form (sections 5.1-5.3).

https://ethics-and-biosafety-form.mq.edu.au/Project/index/18589

Ethics, Biosafety & other Apps Work Area Contacts Help Ms Fran Thorp (fran.thorp@mq.edu.au) 9515

28 Jan 2021 EAEF

Project Tree

- 28 Jan 2021 EAEF
 - Externally Approved Ethics Form (EAEF) v1.0
 - EAEF Adverse Events v1.0

Action Required	Status	Review Reference	Date Modified
Yes	Not Submitted	N/A	01/04/2021 13:36

Navigation Documents Signatures Collaborators Submissions Correspondence Centre History

EAEF Adverse Events v1.0

Section

- Before You Begin and Acknowledgement
- Project Details
- Event Details
- Participant Safety
- Reporting
- Submission and Sign-Off

Questions

- 0.1 Before You Begin 0.2 Acknowledgement
- 1.1 Project Details
- 2.1 Adverse Event Details
- 3.1 Participant Safety
- 4.1 Reporting
- 5.1 Upload 5.2 Declaration 5.3 Submission and Sign-Off

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https://ethics-and-biosafety-form.mq.edu.au/Project/index/18589#navigation-tab

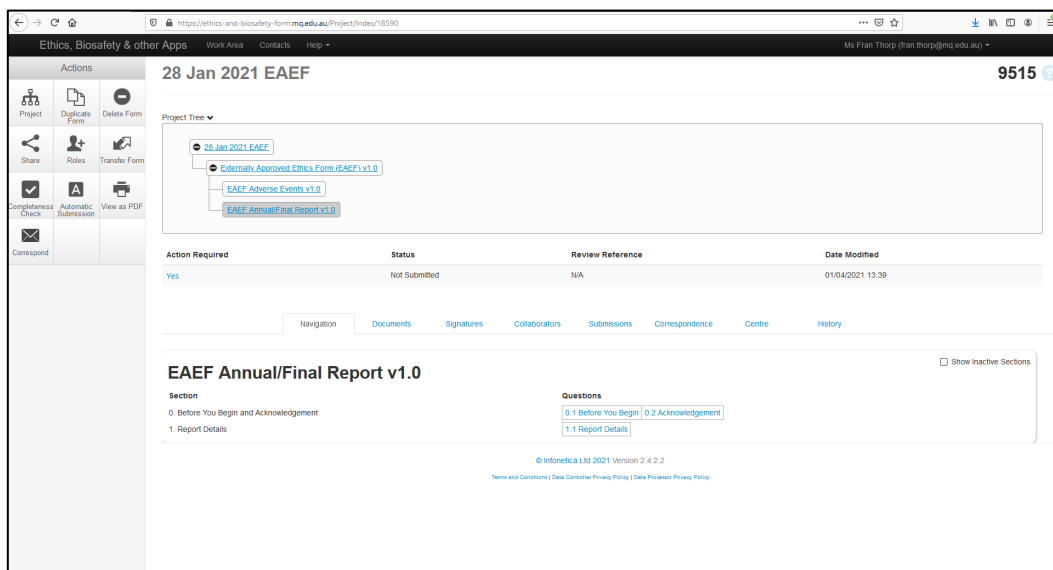
SUBMITTING AN ANNUAL/FINAL REPORT SUB-FORM

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 **EAEF 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 box to continue.

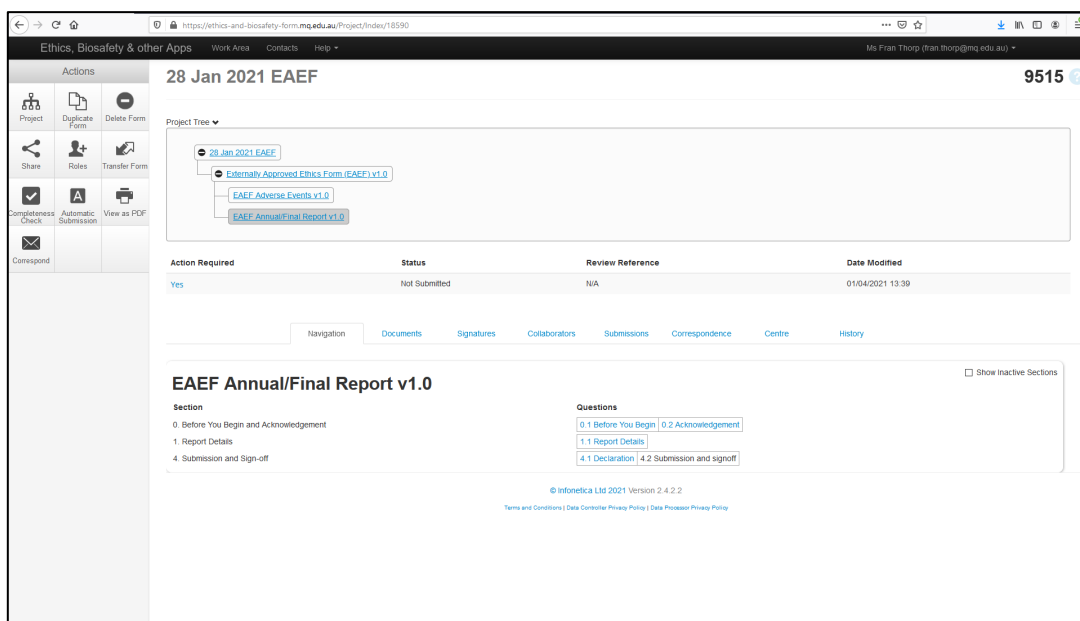
Click on the **Create** button.

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.

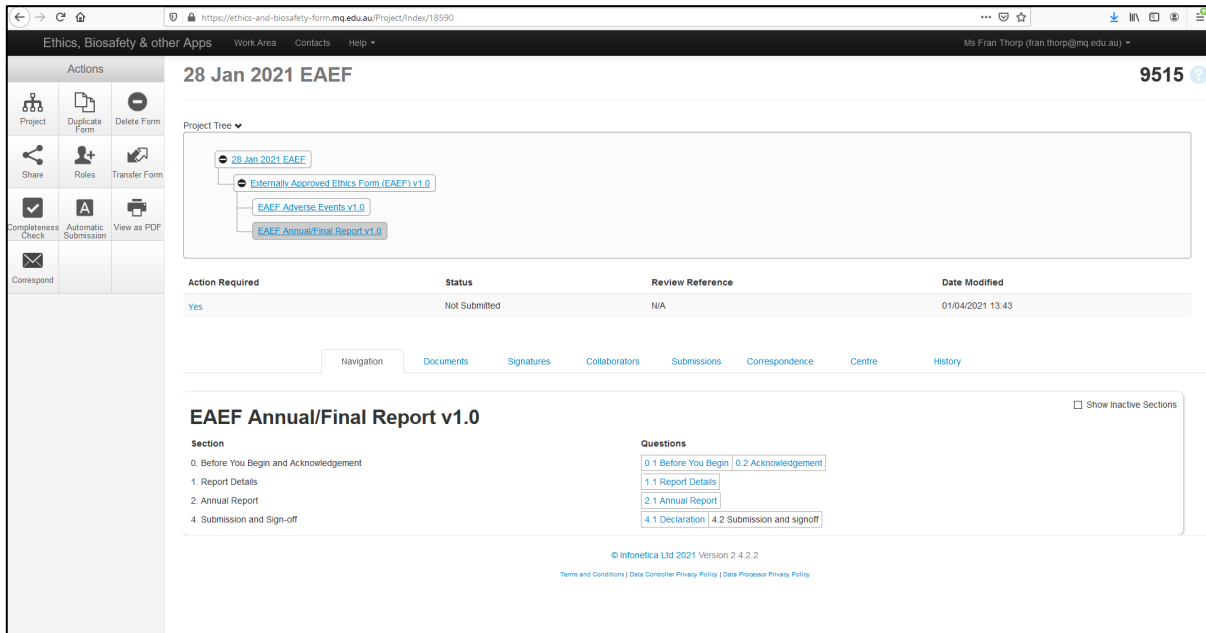
To activate other sections of the form, click into **section 0.2 Acknowledgement** and tick the acknowledgement box. The information will be automatically saved.



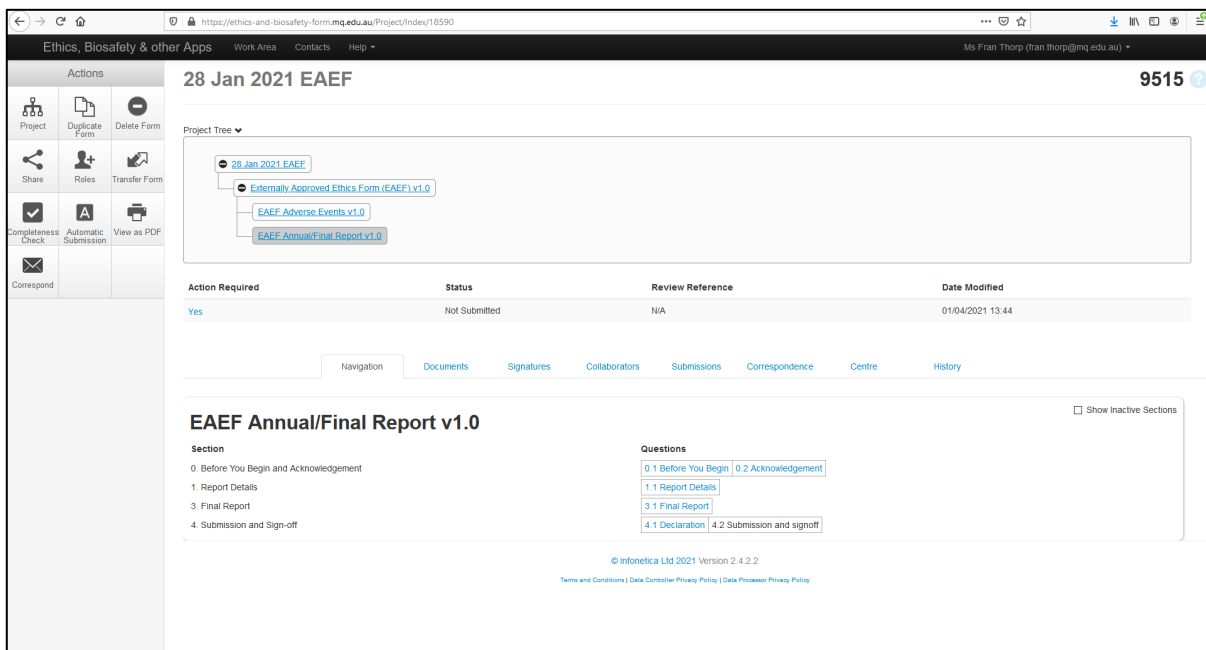
Click on Question 1.1 in Section 1 to select the type of report that you wish to submit, i.e. Annual Report or Final Report. This triggers sections relevant to the type of form chosen, i.e. **section 2.1 for an Annual Report or section 3.1 for a Final report**. Please see the screenshots below.

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.




Annual Report:



Final Report:



HUMAN RESEARCH ETHICS TEAM

		
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RESOURCES AND FURTHER INFORMATION

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

<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>

