ERM Human Ethics User Guide for Researchers

Swinburne Research Ethics
Version 31-03-2026

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1 Getting Started

1.1 Logging in

- Go to https://ethicsapps.swin.edu.au/
- Click ‘Log in’ on the top right-hand corner
- Swinburne (Ethics Review Manager) ERM is fully integrated into the Swinburne Single Sign on. All researchers with a @swin.edu.au email will be able to access the application portal.

IMPORTANT: Sarawak-based Swinburne Staff and HDR Students:

If you have an existing @swinburne.edu.my ERM account, please contact resethics@swin.edu.au for assistance in getting access to your existing projects. If you have never logged into ERM before, please use your @swin.edu.au login (two-factor authentication required). If your authenticator app or password needs to be reset, please contact the *Australian Swinburne IT Service Desk* for assistance. See Sarawak Fact Sheet in ERM > Templates.

All Users:

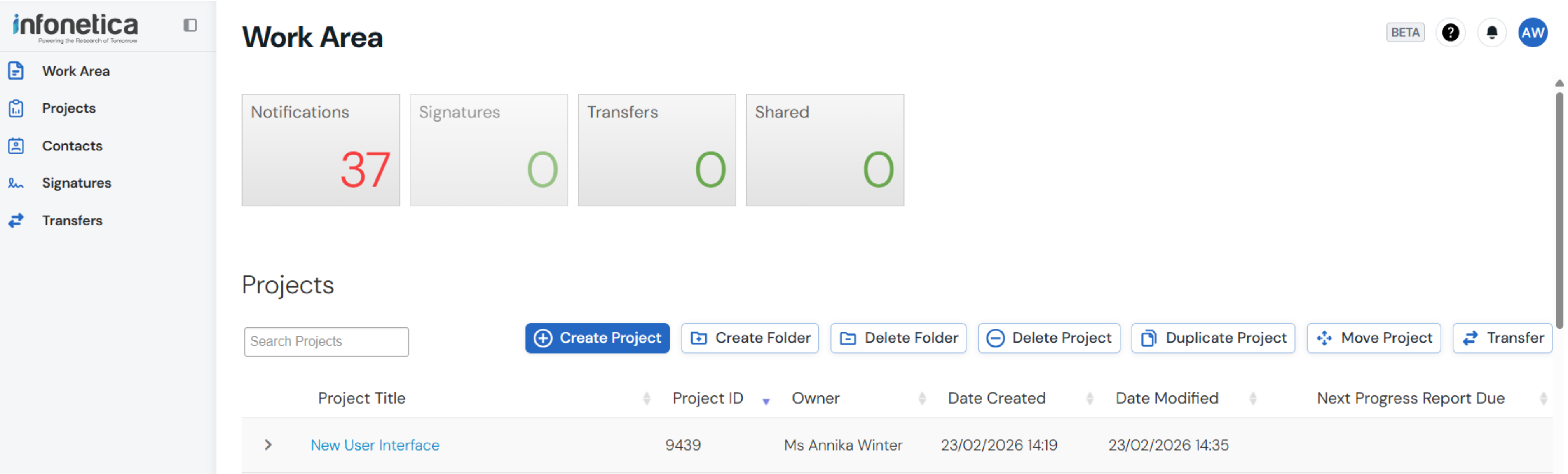
- For first time log in use your Swinburne account email and password.
- If you have any issues logging in, please email resethics@swin.edu.au
- If the log in issue relates to Microsoft authentication/authenticator, please contact the *Australian Swinburne IT Service Desk* as the Ethics Office cannot assist with this.

1.2 Navigation

- Please refer back to the following screenshots for the *Action buttons*. Screenshots have been provided throughout the document only where necessary.
- Please note that screen resolution, zooming in/out, and whether you have the menu or overview panel expanded will impact how many Action buttons appear and in what order. The Ethics Office may also change the order of these buttons once this feature is made available by Infonetica.
- Depending on screen resolution, there may be a ‘More’ menu as the furthest right Action button. Please click this ‘More’ menu to find more Action options.

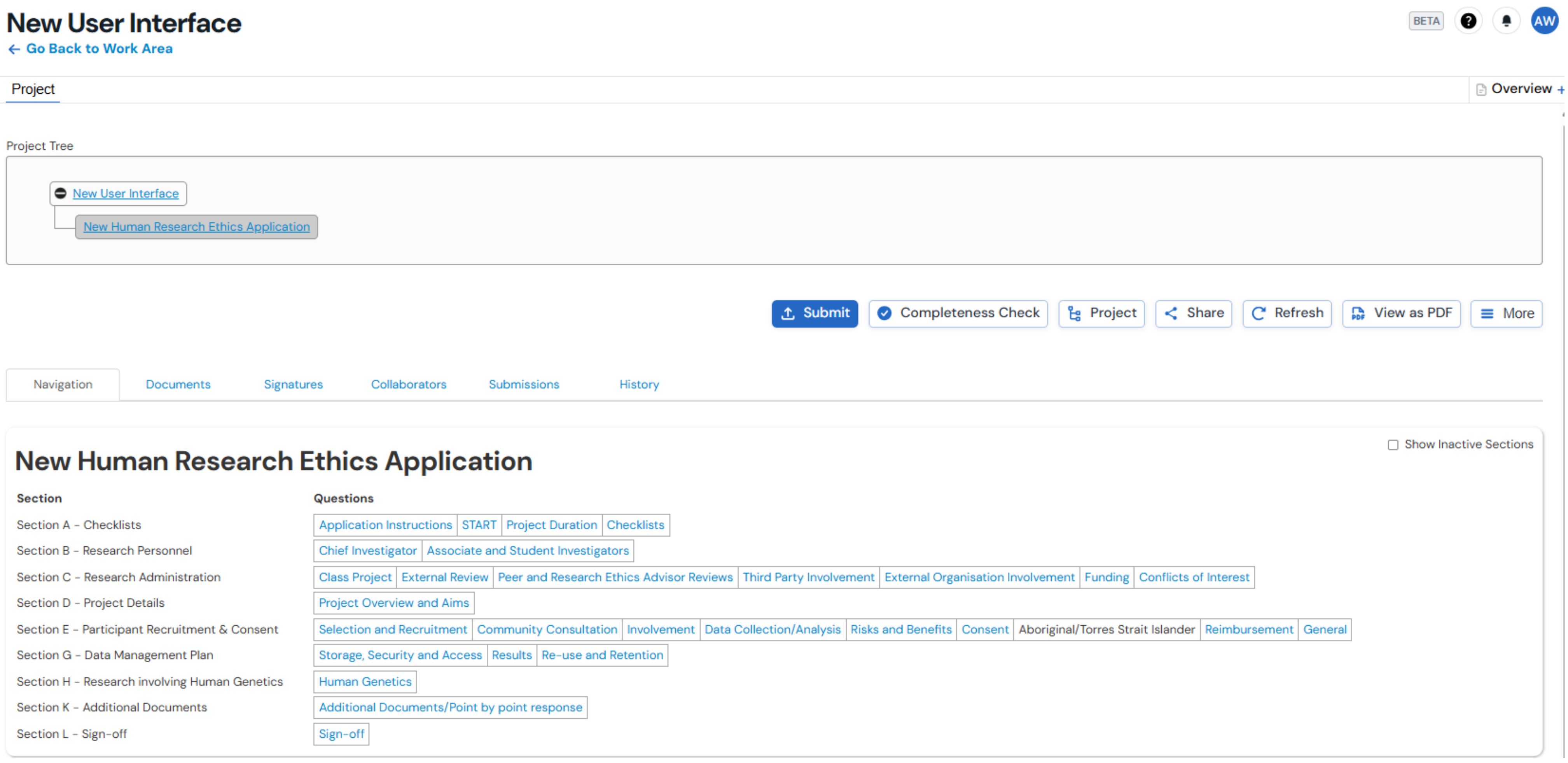
1.3 'Work Area' view

- Your initials will appear on the top right-hand side indicating you are logged in. You are now in the Work Area. Note the menu is on the left (roll-over) and is collapsible/expandable by clicking the square icon next to 'Infonetica'.
- Click '?' in the top right corner to access the help menu including useful templates.
- Click the project title that you wish to access.



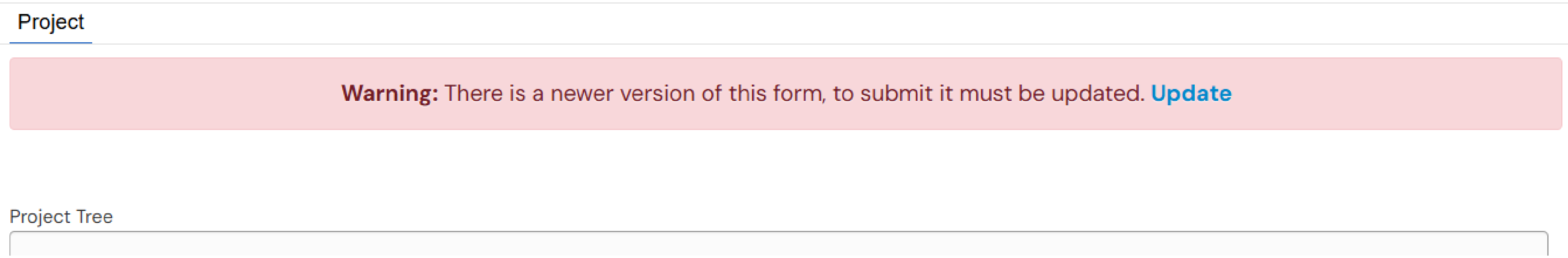
1.4 Project 'Navigate' view

- View when clicked into the navigation menu of the form.



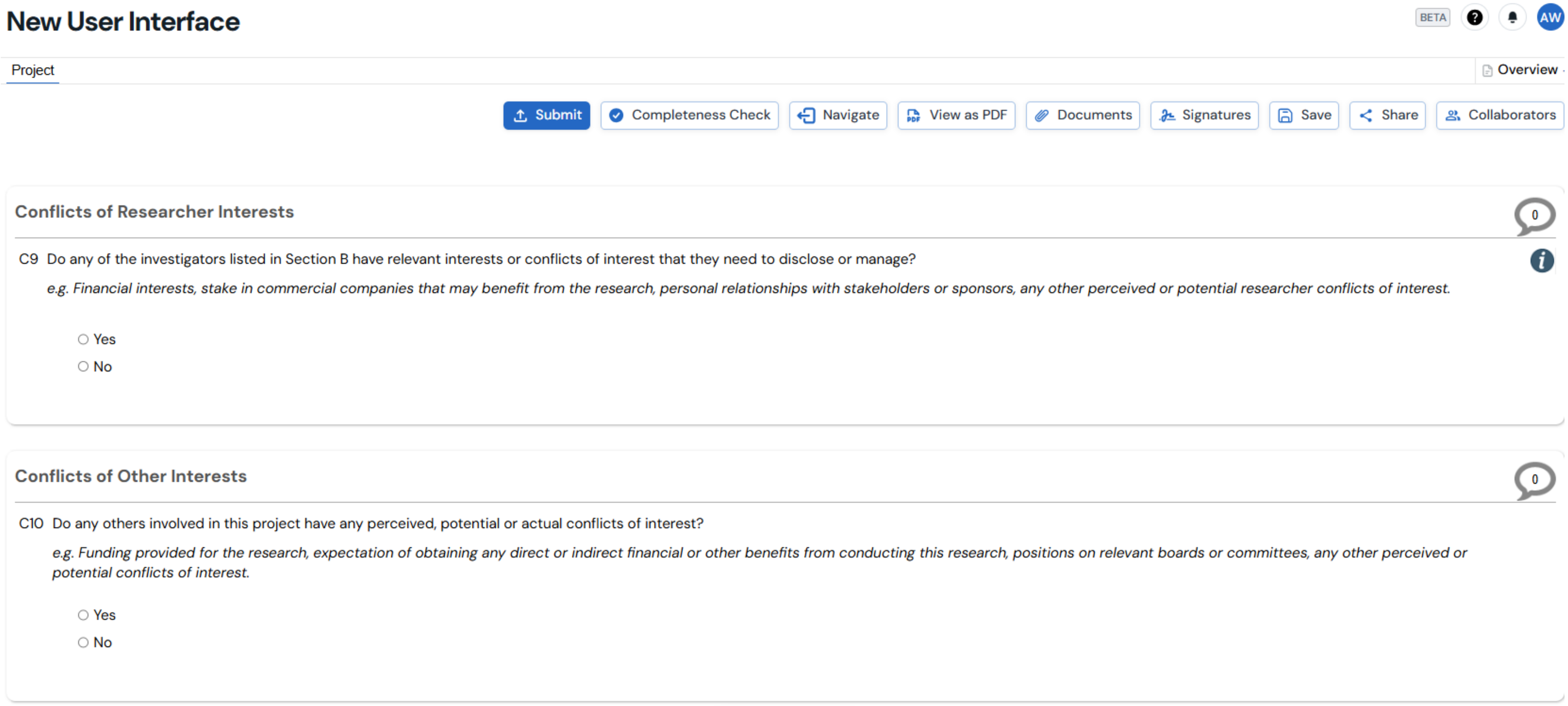
1.5 Update Project

- If there is an 'Update' warning box at top of the page, you must click the blue 'update' button to refresh the form to the latest form version otherwise you will not be able to submit.
- All collaborators that have been granted 'write' access will be able to click the blue 'update' button.
- Save a backup of your application via 'View PDF' as some questions will change and consequently lose their data. Saving a copy will make it easier for you to copy/paste responses into applicable questions that may have moved in the latest form refresh. Only the questions that have changed should lose their data.
- New/changed questions will now need to be answered – a 'completeness' check will indicate what is missing.
- It is highly recommended to click 'update' before creating any new sub-forms or making any edits to the application.
- If the form has already been signed, it will need to be signed again as the 'update' will invalidate signatures.



1.6 Project 'Form' view

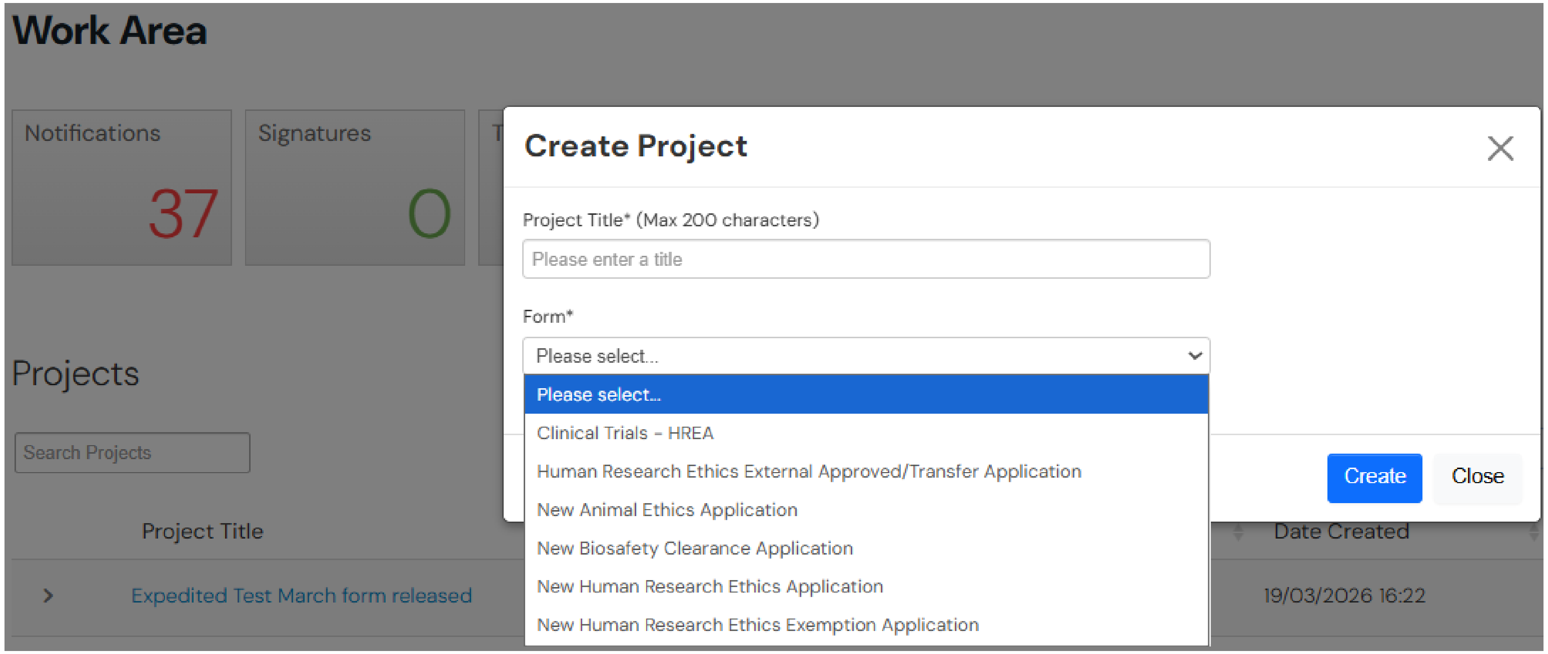
- Example view of when clicked into sections of the form.



2 Creating an application

2.1 Selecting the right application type

- There are 4 different types of Human Ethics applications available, details of which are listed below.
- You only need to apply for ethics approval if you are conducting research with or about humans, or their data or their biospecimens. Research involving animals also requires approval via a separate process.
- In limited cases, more than one application type may need to be completed (e.g. New Human Research Ethics Application AND New Animal Ethics Application for projects involving both human and animal components OR New Animal Ethics Application and New Biosafety Clearance Application).
- For assistance on what form(s) to use please email: resethics@swin.edu.au
- To start a new application, click 'Create Project' and select the appropriate form.
- You will be prompted to enter a Project Title (this can be updated/ amended later up until full approval).



2.1.1 New Human Research Ethics Application

- Most applicants requiring Human Research Ethics will complete this form.
- This is the standard ethics application for all human research ethics that has not been reviewed or approved by any other Human Research Ethics committee and is not a clinical trial.
- Both low risk and greater than low risk applications use the same form but will be reviewed by different ethics committees.
- Please check the Swinburne Research Ethics website for associated review/meeting deadlines before submission.

2.1.2 Human Research Ethics External Approved/Transfer Application

- Also known as 'expedited review' applications.
- This application type should be used if your project has been reviewed and approved by another Australian Human Research Ethics Committee (HREC) that is registered with the National Health and Medical Research Council (NHMRC). By submitting this application type your project can be considered for an expedited ethics review.
- This option cannot be used for projects approved by overseas HRECs or ethics committees that have not been registered with the NHMRC. The registration status of an HREC can be checked here.
- The ethics approval under the primary HREC's remit must be current.
- As your project has already undergone ethical review and approval you can complete this substantially shorter 'expedited' review form which will be reviewed out-of-session (there are no review/meeting deadlines – these applications are processed upon submission, outside of meeting times).

2.1.3 HREA (Clinical Trials)

- The NHMRC's Human Research Ethics Application (HREA – Clinical Trials) should be used for all clinical trial research that fits the following definition.
- The NHMRC accepts the World Health Organisation's definition of a clinical trial as '*Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes'.*
- Clinical trials study a range of interventions including (but not limited to):
- ➢ pharmaceutical interventions: e.g. experimental drugs, nutraceuticals, biological products, vaccines
- ➢ disease detection and treatment methods: new ways to detect and treat disease, diagnostic or screening tests
- ➢ therapeutic strategies: psychotherapeutic and behavioural therapies; medical or surgical procedures and devices
- ➢ health related service changes

- ➢ preventive care and educational interventions
- See also: The clinical trial decision tree is available under ERM > Help menu > Templates: ‘Is my research project a clinical trial’?
- Note: Please contact resgovernance@swin.edu.au before proceeding with the HREA – Clinical Trials form.

2.1.4 New Human Research Ethics Exemption Application

- This form should be used to request that Swinburne University’s Ethics Office assess the specifics of your project involving human participants and/or their data, and to acknowledge it as exempt from ethics review under the National Statement on Ethical Conduct in Human Research (2025) Section 5.1.15-18 and Swinburne University of Technology policy. Honours, Masters by Research and PhD students must submit a full application and not an exemption.
- Note in relation to publication of research results: While some journals will accept evidence of ethics exemption for publication purposes, many require evidence of ethics approval (not exemption). Please therefore consider whether you intend to publish any of the research to which an exemption application pertains and assess whether an application for ethics approval is more appropriate.
- Note that public internet data may be considered private (see NS, p. 37) and therefore will need a consent waiver for use unless seeking individual consent. Consent waivers must be applied for on a full application not exemption (NS 5.1.16).
- If an application for exemption is not approved because the research does not qualify for an exemption, you must submit a new human research ethics application which must be approved before the research can commence.
- These applications will be processed upon submission, outside of meeting times.

2.1.5 Other application types:

- The drop-down list contains other application types:
    - New Biosafety Clearance Application: For research requiring biosafety clearance from the Swinburne Biosafety Committee (SBC) as you are using or generating genetically modified organisms (e.g. genetically modified cell lines, bacteria, plants or other organisms).
    - New Animal Ethics Application Form: For research requiring animal ethics clearance by the Swinburne Animal Ethics Committee (SAEC), as your research is using animals, animal tissue or observing animals.

3 Sharing, collaborating and setting access permissions on an application

3.1 How to share an application

- Once an application has been created, it can be shared with Swinburne staff and students who will require access.

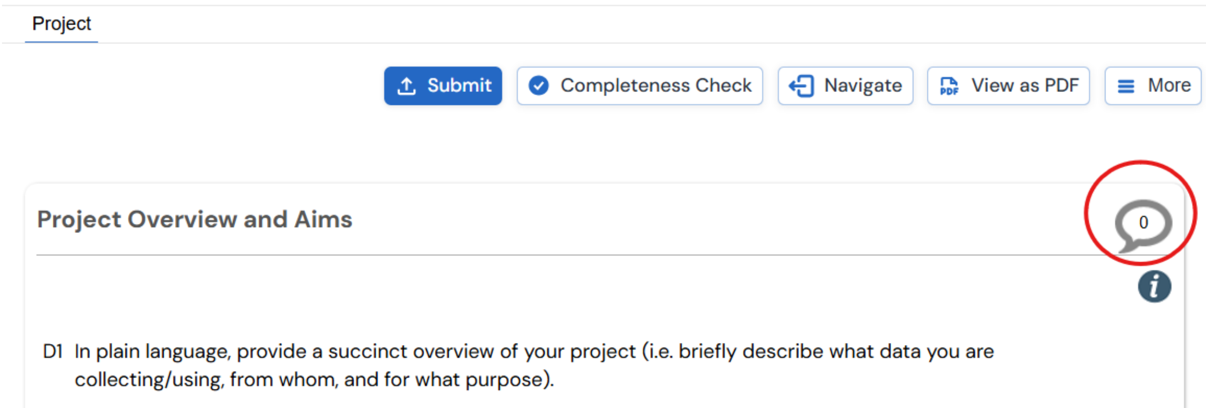
- Applications can only be shared with Swinburne staff and students – External researchers do not have access to ERM at Swinburne.
- To share your application with collaborators for their input, click ‘Share’.
- A pop-up box will appear. Enter the Swinburne email address of the collaborator and select which access to give. Please give the Chief Investigator all access types.
- For external researchers, a pdf of the draft application can be downloaded and sent via email for review (see 4.2.3). It is the responsibility of the Swinburne researchers to make any recommended changes from external researchers in ERM.

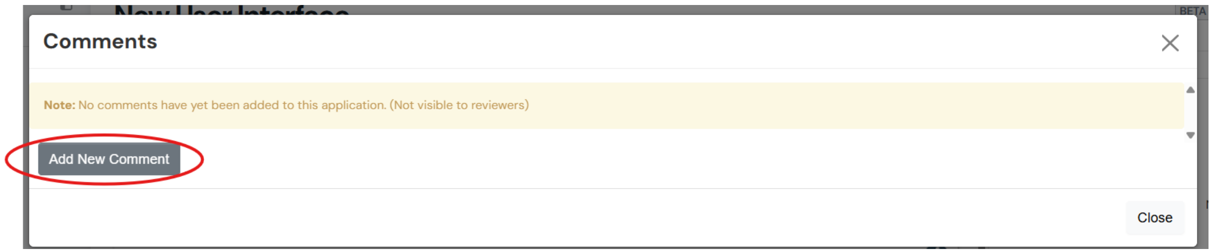
3.1.1 Selecting/setting the type of access and permissions (you can select multiple options)

  - Read - person can read the application only.
  - Write - person can edit/add content to the application.
  - Submit - person can submit the application (see signature section for more information on submission).
  - Share - person can go on to share the application with others and assign these permissions forward.
  - Create all sub-forms - person can create sub-forms like post approval modification requests, annual reports and adverse event forms.
  - Receive notifications - person will receive notifications about the application.
- Do this for multiple collaborators by clicking on the addition (‘+’) button and repeat for additional collaborators.
- If an error message appears stating ‘user does not exist’ check the details are correct, and if so, ask the researcher to login to ERM for the first time. This will automatically create their ERM account.
- To remove a collaborator, click ‘minus’.
- Click ‘Share’ to finalise. This can be modified at any time.
- To review your collaboration or access/edit permissions click the collaborators tab. You can edit permission by clicking ‘edit permissions’.

3.2 How to make comments on ethics applications

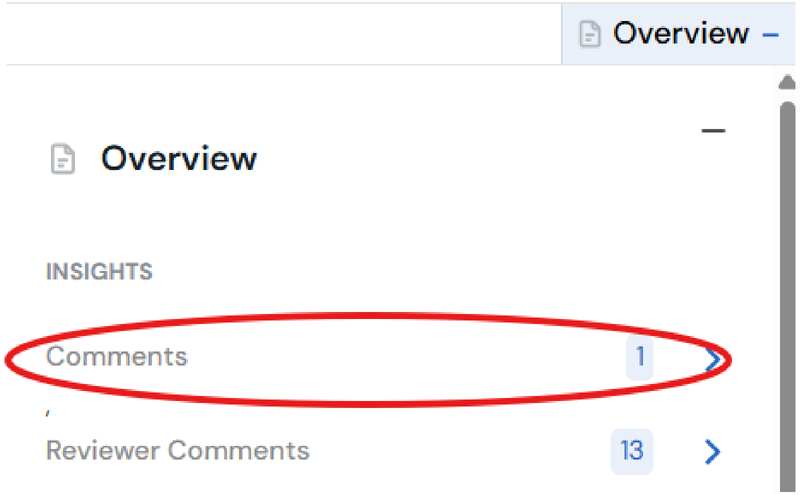
- To make a comment for other researchers or collaborators to see click the comment bubble on the top right-hand side of a question.
- Enter the comment you wish your collaborators to see. These will only be visible to your collaborators and **<u>not</u>** the ethics committee reviewer.



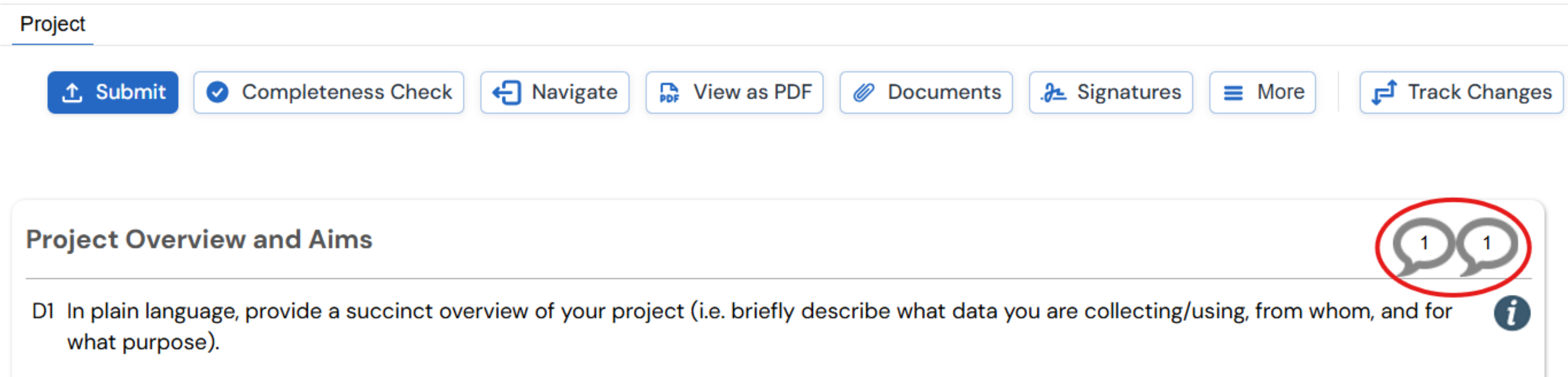


- You and your collaborators can view a summary of comments.
- Click 'Comments' in the right-side 'overview' pane (note this is collapsible, click +/- to collapse or make visible).

- A list of all comments will appear, you can click each of these comments, and it will take you directly to the question the comment refers to.
- You can edit or delete a comment by clicking on the comment and then clicking 'delete', or you can amend this comment and click 'save'.



- You can also access both types of comments in the speech bubble next to the question (indicated by a number greater than 0).
- Two bubbles (pictured) indicate comments from your collaborators and comments from the reviewers or research office if the application has been submitted and returned.



4 How to complete a standard human ethics application

4.1 Access help menu '?'

4.1.1 FAQs

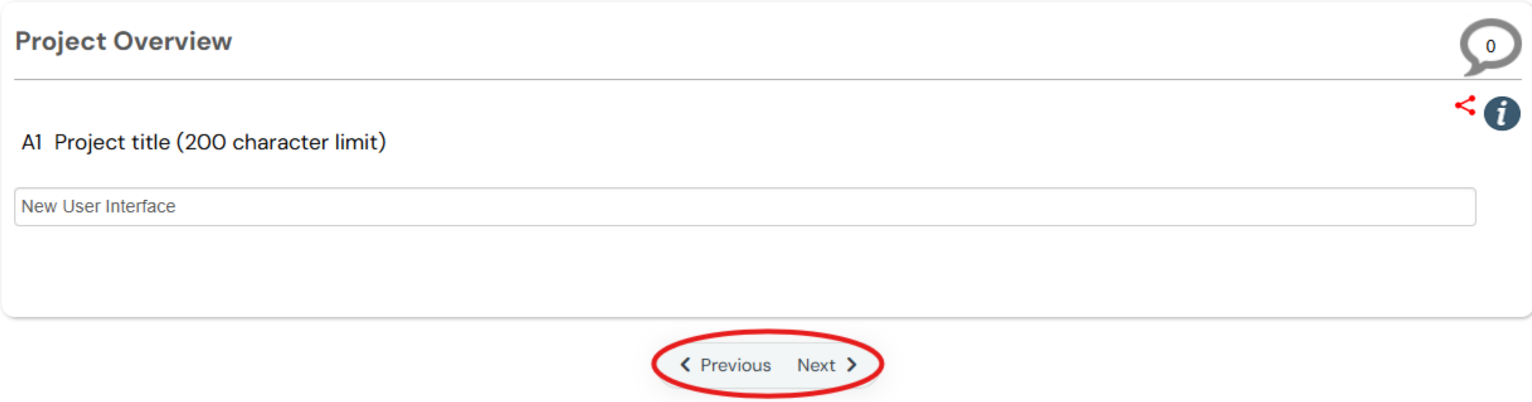
- It is recommended to review the 'Frequently Asked Questions' page before completing an application.

4.1.2 Templates: Using templates for consent information documentation and other associated documents

- It is strongly recommended you use the template documents provided to assist you with your applications. These are all stored within ERM.
- To access the templates, click the help menu '?' at top right of the page then click 'Templates' in the drop-down list.
- Documents available in the Templates section include Consent documents (Explanatory Statement/Consent Information Statement and Consent Form, Peer review template, Exemption Application Explanatory Statement, Parental consent for minors, Report Self Audit Tool, Guide for point-by-point responses etc.)

4.2 Drafting your application

- Once you have created your application you will be taken to the navigation page displayed above (see 1.4).
- You must commence from the beginning section as this will take you through a series of checklists that will create and remove sections (built-in form logic) depending on how you answer the questions.
- Navigate through the form by clicking 'Next' or 'Previous' at the bottom of the page.
- You can see the overall structure of the form by clicking on the 'navigate' icon and then click the relevant sections of the form to take you to that section. Please don't jump around until the form is complete (due to the form logic).
- The application will save the information automatically as you click through the 'next' button. It is still recommended to save your application frequently to avoid losing any work. To do this click 'Save' (Note: this may appear in the 'More' menu).
- By default, only the person who has created an application will have access to edit it. Applications should be shared so multiple collaborators can edit the application information (see 3.1).



4.2.1 Information Bubbles

- Please click the Information Bubbles on the right-hand side of the questions for help responding to the questions. A help pop-up box will appear.
- If you click a hyperlink the page should open in a new tab.

4.2.2 Attaching relevant documents

- Please ensure that all study documents submitted for review are clearly and consistently labelled in the footer with document type, carry version control (i.e. version number, version date) and include pagination (e.g. page 1 of x). If a document has been amended and/or resubmitted, please provide a 'tracked changes' version and note TRACKED or CLEAN in the footer. E.g. Protocol xyz, version 2.0, date 01 Jan 2026 [tracked]. Please use similarly appropriate file names.
- You will be prompted at certain questions throughout the application to upload a document. To do this, click the blue upload documents icon.
- Click 'Browse' to select the file on your computer you wish to upload, enter the version date and number (that matches the document footer) to ensure document control.
- You can review all documents uploaded to the application using the 'Documents' tab on the Project Tree view, or the 'Documents' button when clicked into the application.

4.2.3 Downloading the application and application documents

- All applications and associated documents are submitted and reviewed within ERM. Only Swinburne staff and students have access to log in to ERM. If you would like to share the application with an external collaborator for review or save a copy for your records (applications are always accessible in ERM) a pdf copy can be downloaded.

- Documents can be downloaded separately or all together.
- To download a copy of the application in its entirety as a pdf file, select 'View as PDF' and select the desired options. This will open the application as a pdf file in a separate browser for you to view and save.
- To download individual attachments (e.g. consent instruments), select 'Documents'.

5 Finalising an application

5.1 Completeness Check

- It is recommended to undertake a completeness check before signing off.
- To do this, click 'completeness check'.
- Any sections of the application that are incomplete will be highlighted via a pop-up window. Click the relevant hyperlinked sections of the application. The application cannot be submitted until all mandatory sections have been completed.

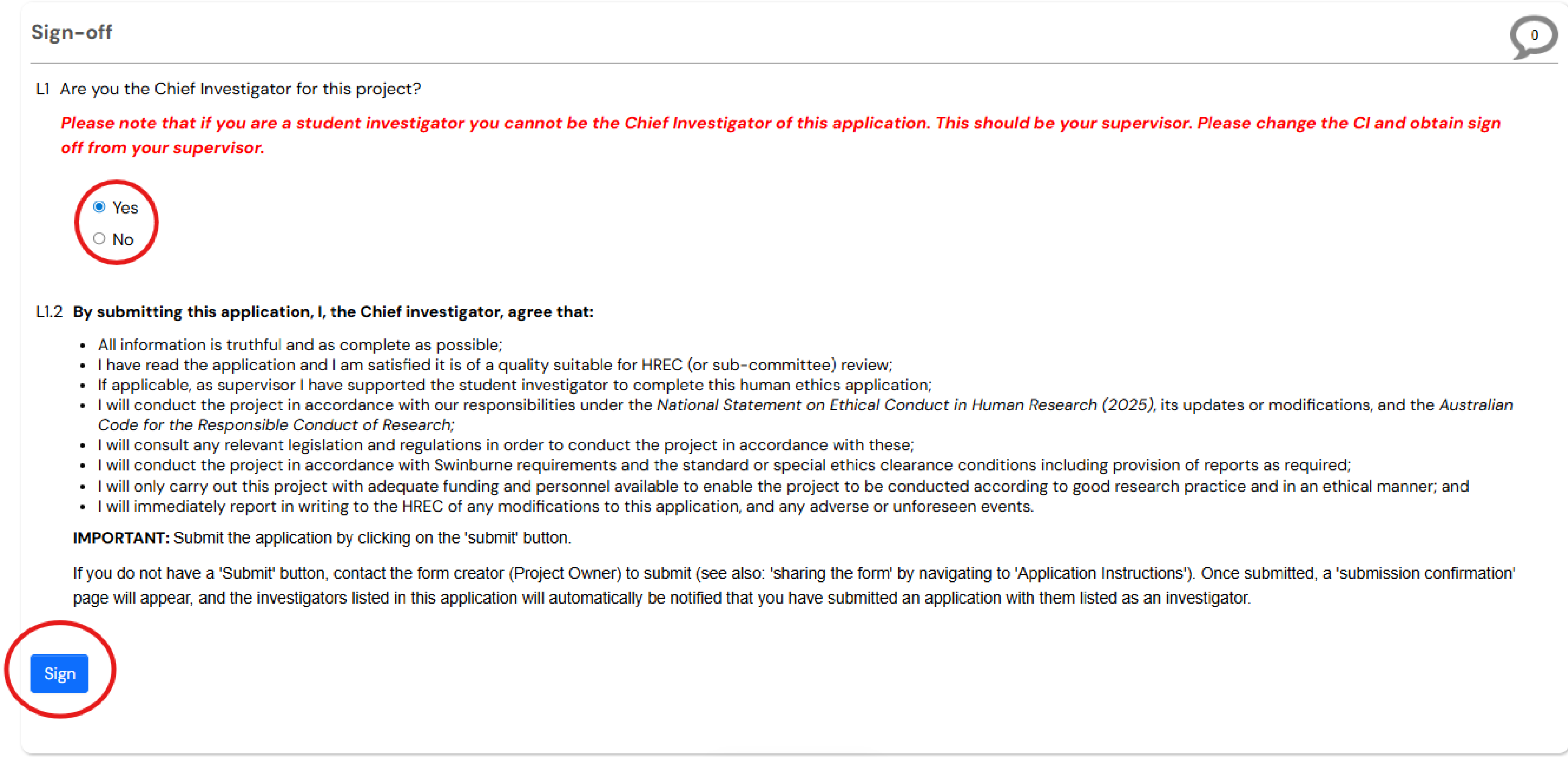
5.2 Sign Off

- Chief Investigators (CIs) must sign off on ethics applications before submission.
- Students cannot act as CI (or be listed as the CI in the ethics application), the student's primary supervisor must act as CI.
- The sign off question asks: 'Are you the Chief Investigator of this project?' and the workflow will depend on the option selected as follows (see 5.2.1-3).

5.2.1 How to sign off and submit an ethics application as the CI

- If the applicant is the CI select 'Yes' at question L1.
- A CI declaration will appear. This must be carefully read and if agreed to, click 'Sign' (this may appear in the 'More' menu). Then click 'Submit'.
- If you sign the application but do not click 'submit' the application will not be visible to the Ethics Office and your application will not be reviewed.

- **You MUST click ‘submit’ to finalise submission.**
- Your application has now been submitted and will be locked. A submission confirmation screen should appear. The Ethics Office will automatically receive this information, and an automated email will be sent confirming submission. If you do not receive an email confirming submission, please check the application has been submitted.



Sign-off

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L1 Are you the Chief Investigator for this project?

Please note that if you are a student investigator you cannot be the Chief Investigator of this application. This should be your supervisor. Please change the CI and obtain sign off from your supervisor.

Yes

No

L1.2 **By submitting this application, I, the Chief investigator, agree that:**

- All information is truthful and as complete as possible;
- I have read the application and I am satisfied it is of a quality suitable for HREC (or sub-committee) review;
- If applicable, as supervisor I have supported the student investigator to complete this human ethics application;
- I will conduct the project in accordance with our responsibilities under the *National Statement on Ethical Conduct in Human Research (2025)*, its updates or modifications, and the *Australian Code for the Responsible Conduct of Research;*
- I will consult any relevant legislation and regulations in order to conduct the project in accordance with these;
- I will conduct the project in accordance with Swinburne requirements and the standard or special ethics clearance conditions including provision of reports as required;
- I will only carry out this project with adequate funding and personnel available to enable the project to be conducted according to good research practice and in an ethical manner; and
- I will immediately report in writing to the HREC of any modifications to this application, and any adverse or unforeseen events.

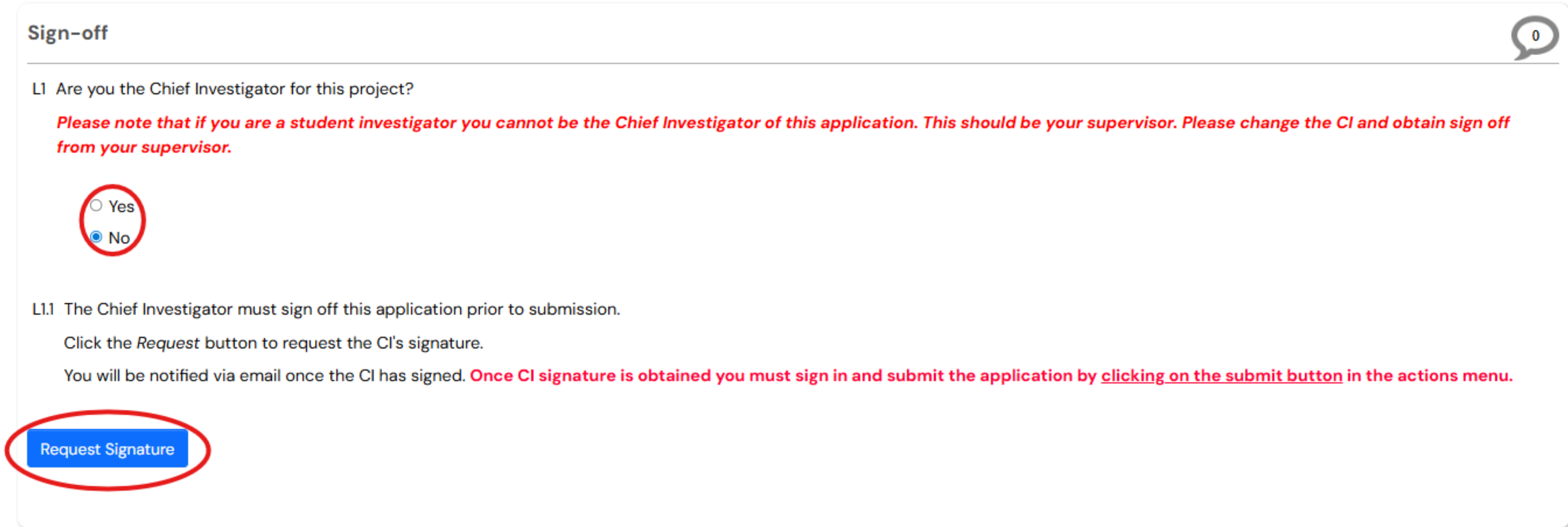
IMPORTANT: Submit the application by clicking on the 'submit' button.

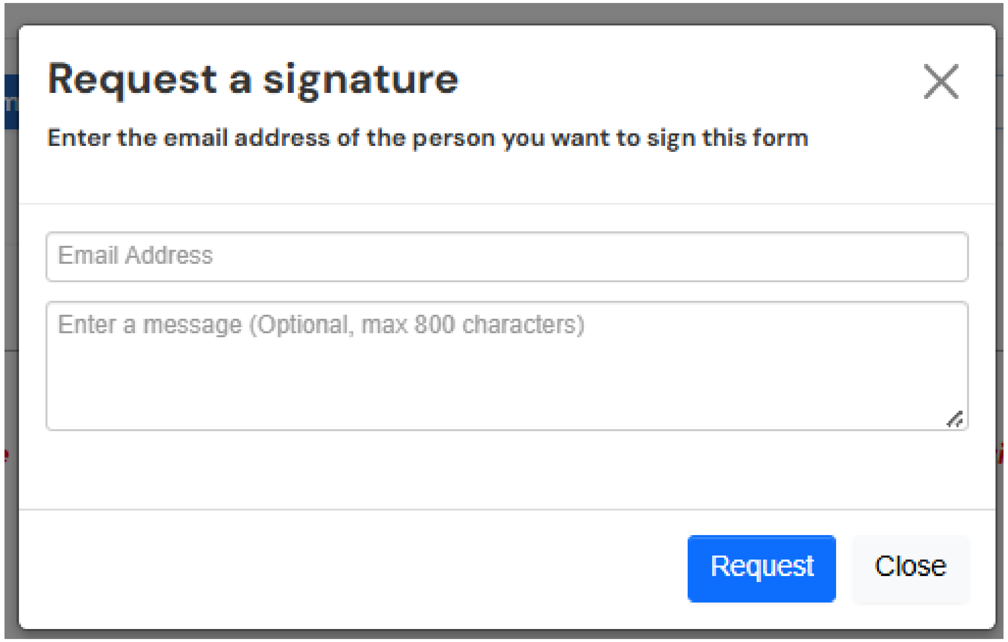
If you do not have a 'Submit' button, contact the form creator (Project Owner) to submit (see also: 'sharing the form' by navigating to 'Application Instructions'). Once submitted, a 'submission confirmation' page will appear, and the investigators listed in this application will automatically be notified that you have submitted an application with them listed as an investigator.

Sign

5.2.2 How to obtain sign off if the applicant is NOT the CI

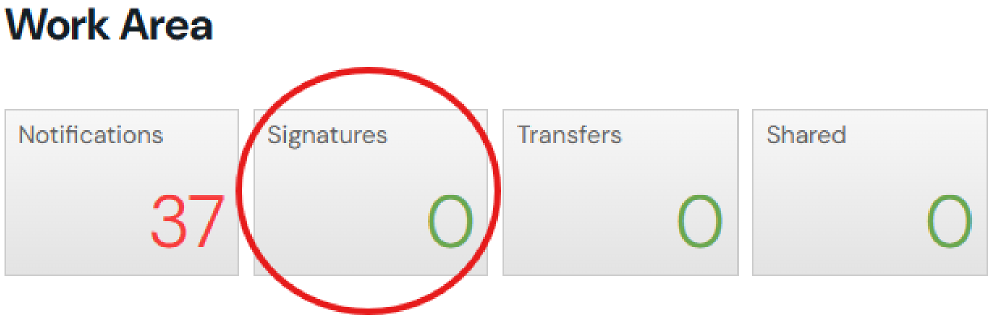
- If the applicant is NOT the CI, click ‘No’. Please note students cannot act as CIs this should be the student's primary supervisor or project lead.
- You will be asked to request a signature of the CI, click ‘Request Signature’.
- Enter the CI’s email address that is associated with their ERM account, a message for the CI (optional), and click ‘Request’.
- The CI must also be listed as an investigator on the application otherwise an error message will appear.
- When you click ‘Request’, an automatic completeness check will be undertaken. Sections that are incomplete will be highlighted in a pop-up window. Click the relevant section of the application which will indicate the incomplete section. The application cannot be submitted until all mandatory sections have been completed. Please note that once the signature has been requested from the CI, the application will be locked, and no further edits can be made by the applicant until the CI actions.
- The CI will receive an email requesting sign off. The link in the email will take the CI to the project (sign in required using Swinburne single sign on (SSO).
- When the CI signs off on the application you will receive notification via email. You must then go back to the application and click ‘Submit’. If you do not click ‘submit’ after the application is signed it will not be received by the Ethics Office and therefore will not be reviewed.
- Only CIs who have been granted ‘submit’ access via the collaborators tab can submit the form after signing. CIs should be granted full access to the ERM application (see Section 3 for instructions on sharing the application).



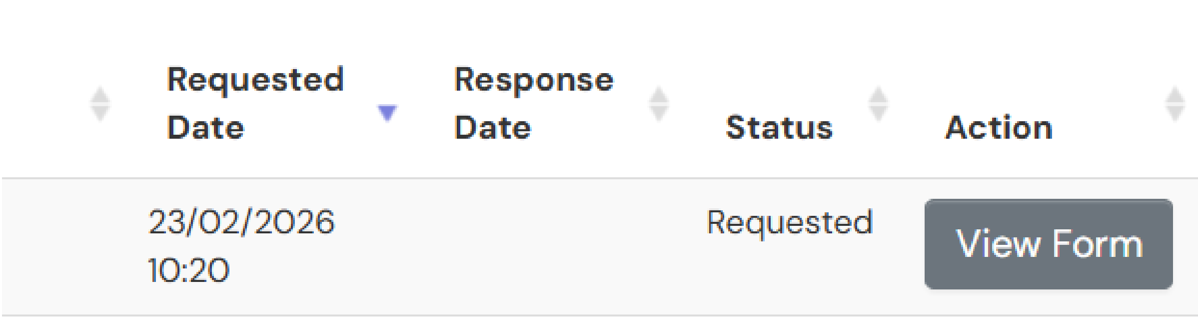


5.2.3 How to respond to a signature request as the CI

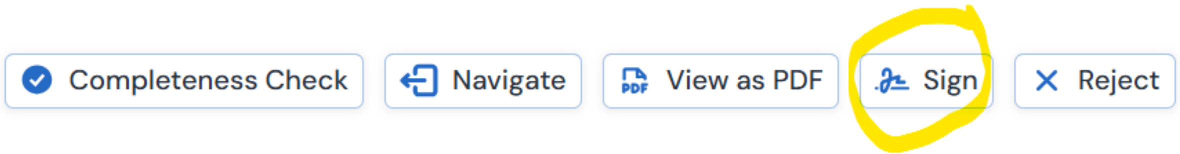
- You will receive an email asking you to sign in to ERM and sign off on an application.
- Click the 'Signatures' tile in the Work Area.



- Here you can see all applications waiting on signatures, as well as those previously signed.
- Click 'view form' - you will have read only access to the application.



- If you are happy with the application, click 'Sign' (may appear in the 'More' menu).
- An email will now be sent to the applicant indicating sign off.
- If you do not wish to sign off on the ethics application, click 'Reject'.
- You will be prompted to provide feedback to the applicant. This will be sent in an email to the applicant, and the form will be unlocked for changes.



6 Navigating the Work Area

6.1 How to organise your projects

- You can create custom folders in the Work Area to store your ethics applications.
- In the work area click 'create folder', and name as you choose.
- You can then drag and drop applications out of the list of all applications into relevant folders, the folder will turn yellow when you are

about to drop something into it.

- To move a project, click into the folder and select ‘move folder’. This will then allow you to move the project into other existing folders or back to the work area.
- Note: the search bar will only search projects in the Work Area, not the ones that have been organised into folders. To search for a project within a folder, you need to know which folder it is in and search within that folder.

6.2 How to duplicate an existing application

- From the Work Area click ‘Duplicate Project’.
- All applications for which you are the *Project Owner* will be listed. Select the application you wish to duplicate out of the drop-down list.
- If the application you wish to duplicate is in a folder, enter that folder and then select ‘duplicate’. The applications listed in the drop down available to be duplicated will now only be for those in this particular folder.
- Enter a new title for the duplicate application.
- The duplicate function makes an exact copy of the application. You can now amend the duplicated application as appropriate.

6.3 How to search for a project

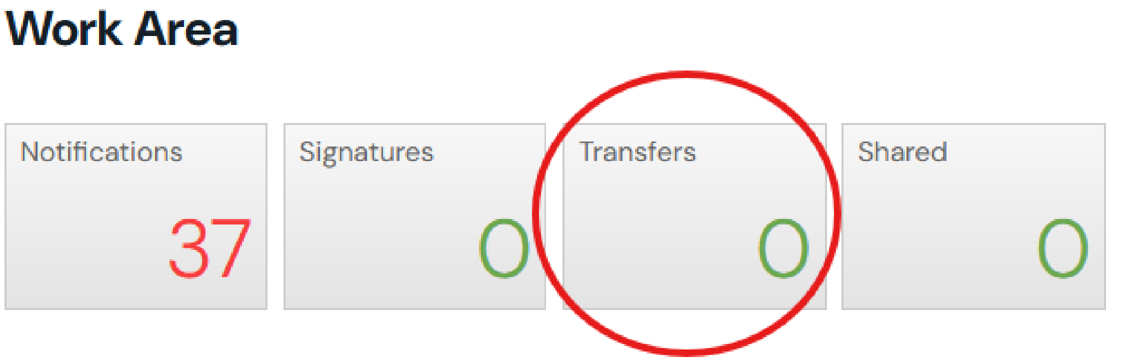
- The work area has all your ethics applications that are **not in folders** in a searchable list. To search for an ethics application, type in the title, four-digit project number or key word.
- Please note that projects in folders cannot be found using this search bar. Enter the applicable project folder and search within that folder.

7 How to transfer ownership of an application

- If you are no longer CI on a project or you are leaving Swinburne, the Project Owner will need to transfer your project to a new CI (a modification request must be submitted to change the CI – see submitting modifications, this should be approved before transferring).
- To transfer ownership of an application, click ‘Transfer’ in the Work Area.
- Enter the email address of the new CI and a message regarding the transfer, then select the applications you wish to transfer from the list.
- The new CI will receive an email indicating the transfer.
- Once the new CI has accepted the transfer request, you will no longer have access to a transferred application. If you continue to need access to the application, the new CI will need to share it with you as a ‘collaborator’ in ERM.

7.1 How to accept or reject a transferred application

- You will receive an email indicating a project has been transferred to you.
- Log into ERM and go to the 'Transfers' tile on the work area.
- This will show you all transfers. Transfers requiring your action will be highlighted in yellow. To accept a transfer, click 'view project'.
- You can accept or reject the transfer by clicking 'accept transfer' or 'reject transfer'.

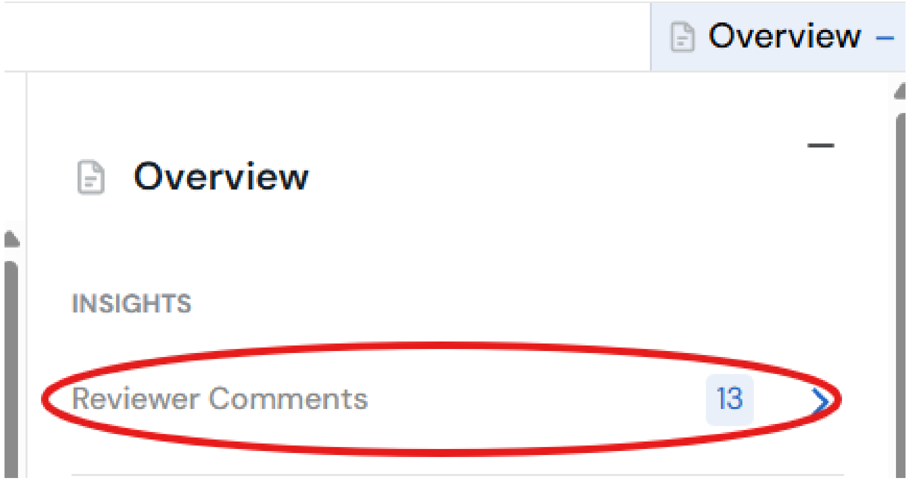


8 Committee feedback

8.1 Receiving and responding to feedback

- You will be notified via email when you have received feedback from the Ethics Office or Ethics Committee.
- This email will contain an attachment that includes a list of the comments made in the application.
- Create a point-by-point response document AND update each relevant section in ERM
- Create a word document and copy and paste all the comments in the attachment into this word document.
- Template available in ERM 'Guide for point-by-point response'.
- Provide a response to each of the queries in this document. Login to ERM and make any relevant changes to the sections required.
- To see all the comments made, click 'Reviewer Comments' in the right-side 'overview' pane (note this is collapsible, click +/- to collapse or make visible).
- A list of all the comments made about specific questions will pop up.
- Clicking on the comment will take you to the page of the application form the comment relates to. You may need to scroll down to find the question that the comment pertains to

- Click the comment bubble on the top right-hand side of the question to view the question. If there is a comment, a number will appear in the bubble (usually '1' or '2')
- Amend the response in the application accordingly.
- To see previous comments related to previous submission click 'show previous comments'.

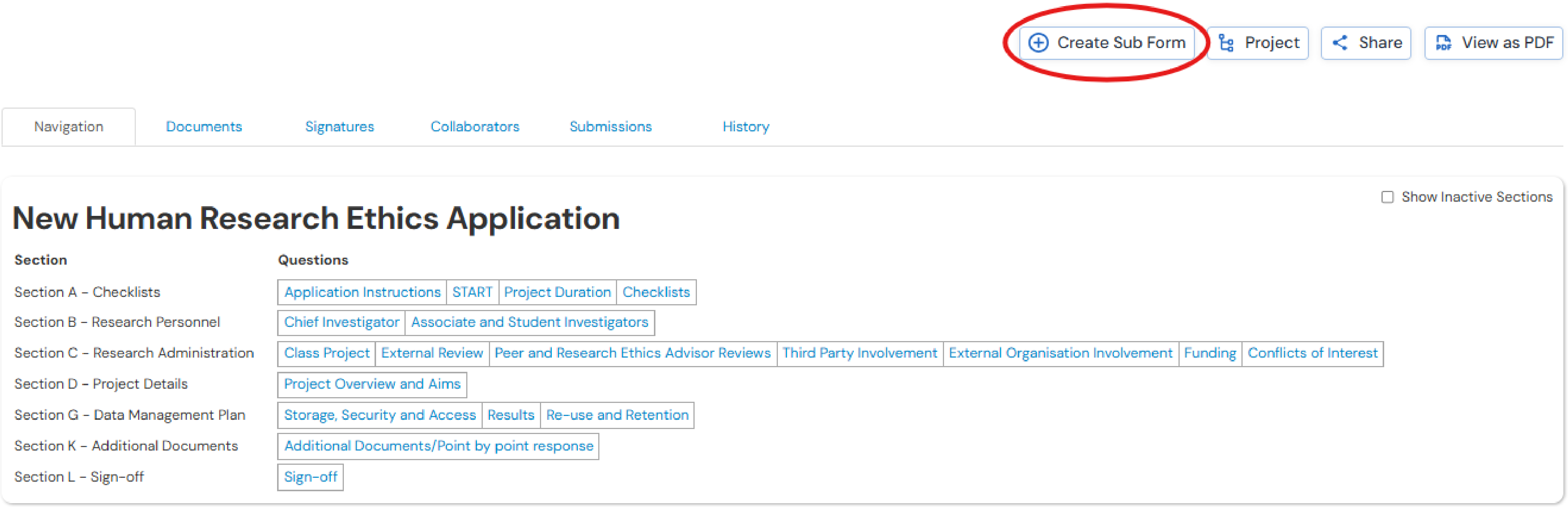


8.2 Upload your responses

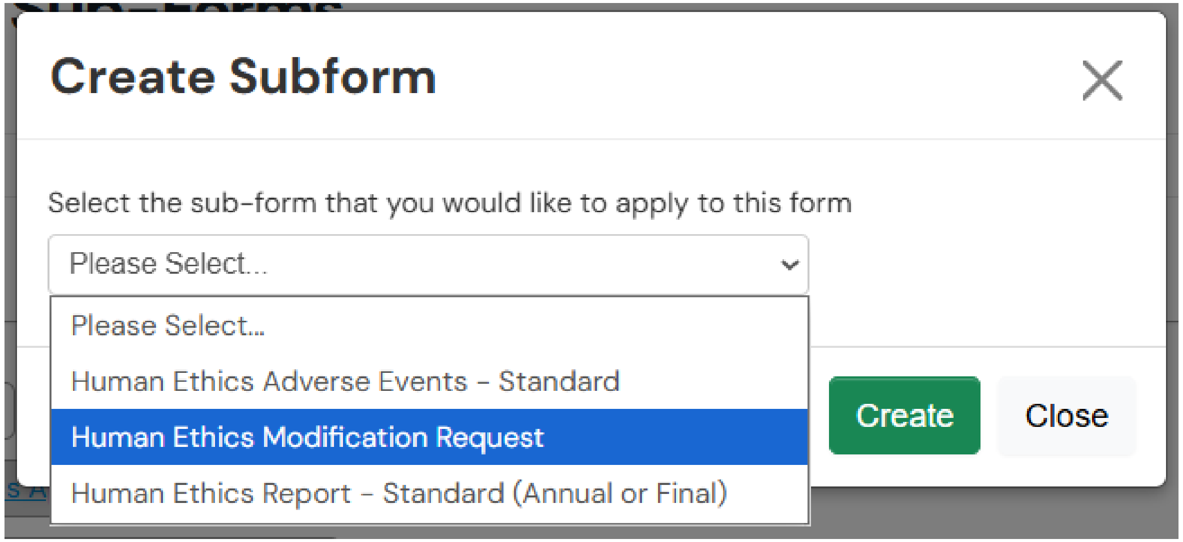
- If changes are required to the consent information statement or other documentation use track changes in Word to make any relevant changes to these documents.
- Please attach track changes and clean versions of all documents in the **relevant sections of the application**. If a tracked version is not attached, a tracked version will be requested.
- Ensure these documents are carefully named and the version date and version number are accurate. This will allow you and the committee to ensure the correct documents are reviewed.
- Upload the 'point-by-point response to Committee queries' document to Section K of the application form.
- **Resubmit the application**. Note: if you are not the CI you will be required to obtain sign off from the CI on this resubmission (see section 5 of this guide).

9 Modifications

- All modifications to approved ethics applications must be submitted and approved in ERM prior to implementation.
- To submit a modification request, click into the approved project you wish to modify from the Work Area.
- Click 'Create Sub form'.



- Select ‘Human Ethics Modification Request’ from the drop-down list.
- Then click ‘Create’.



- Click ‘Modifications/Additions Requested’.
- Scroll down and answer the questions and then click ‘Next’ to navigate to the next page.
- Upload any relevant documents.
- Click ‘Next’ to bring up the next page. If you are the Chief Investigator, select ‘Yes’ and then click ‘Sign’

- To submit the modification request to the Ethics Office, click ‘Submit’.
- Ensure confirmation of the form’s submission is displayed.
- If some questions haven’t been answered, there will be a pop-up warning, you will then need to go back and answer these questions, ensuring that you click ‘Save’ after answering each question.
- Once you have answered all the necessary questions, repeat the sign-off process as per above.
- If you are not the Chief Investigator on the project follow the same process indicated at 5.2.2-3.
- Once they have signed off on it, log back in and submit the request to the Ethics Office. If the CI has been granted ‘submit’ access for this project and modification form, they will be able to ‘submit’ themselves.
- To share the modification form with other investigators, click ‘Share’ (see 3.1).

9.1 Reviewer Feedback on Modifications

- If the committee member reviewing the modification request has queries, the request will be returned to you within ERM, and you will receive a notification from within ERM detailing the queries. You will then need to log into ERM and view the request in question. To view the member’s queries, click ‘Reviewer Comments’ in the right-side ‘overview’ pane (note this is collapsible, click +/- to collapse or make visible).
- Click each comment, and it will take you to the relevant section.
- If you wish to read the comment/s again, click the speech bubble in the top right-hand corner.
- After you have amended the request as per the Committee’s comment/s, you need to submit the modification request to the Ethics Office as per the process by which it was originally submitted. If the member is satisfied with the revised request, then the request will be approved. If they have further queries, the process will be repeated until they are satisfied and able to approve the request
- If the request is approved as submitted, you will receive notification of its approval from within ERM. The status of the request will also indicate this in the ERM record for the modification request, as per the below

10 Annual and Final Reports

- Annual reports are due yearly on the approval anniversary.
- Final Reports are due at the conclusion or abandonment of the project.
- Modifications will not be approved if there are outstanding reports.
- You will receive an email alert from the system 30 days before a report is due and on the day a report is due.
- You will also receive reminder emails after the report is due if you fail to submit one (or until the report is approved by the Ethics Office if submitted).
- Sign in to ERM and go to the project requiring a report (the alert email will indicate project number and title).

10.1 Submitting an Annual or Final Report for a standard project

- For projects approved through Swinburne or transferred to Swinburne from an external HREC click ‘Create sub form’.
- Select the Sub form: Human Ethics Report- Standard (Annual or Final) and click ‘create’.
- Complete the questions in the ‘project details’ section starting with the reporting dates.
- Please report from the date ethics approval was granted. Note, if previous reports have been submitted and approved, please report from the date the previous report was approved per the instructions in the form.
- Annual Reports: Please report to the date the report is submitted.
- Final Reports: Note, if ethics approval has lapsed, please report to the date ethics approval expired. Please also confirm when prompted that no data collection or participant interaction has occurred after this date. If this has occurred, please contact the Ethics Office.
- Please check your most recent ethics clearance letter for dates.
- Some of the data in Section A will be locked as it is auto-generated from the associated ethics application and may no longer be correct (e.g. if the CI has changed). Please disregard this as the Ethics Office can confirm the current CI against any modification forms.
- Navigate through the form by clicking ‘Next’ or ‘Previous’ or ‘Navigate’. It will save upon clicking ‘next’ so, if you are jumping around via ‘navigate’, ensure you click ‘save’.
- To share the Report form with other investigators (to edit) click ‘Share’ (see 3.1).
- If there is a student component that has been (or will soon be) completed, please select the option in Section B that includes a report on completing students.
- Answer the questions and then sign off.

- Follow the same instructions at 5.2.1-3 regarding signing off on the form.
- To submit click ‘submit’.
- Once a Final Report is approved by the Ethics Office, the ethics project will be closed, and no further modifications will be possible.
- If you have any questions, please contact resethics@swin.edu.au

10.2 Submitting an Annual or Final Report for an Externally Approved Application

- For projects that have been approved through an external HREC as the primary HREC please select ‘Human Ethics Report - Ext. Approved Annual OR ‘Human Ethics Report - Ext. Approved Final’. Note: These will only be available in the drop-down menu if your application is on an externally approved form type.
- If your application has been **transferred** to Swinburne, please follow the instructions above to complete a standard report.
- Click ‘create’.
- You will need to attach a full copy of the report that was submitted to the original/primary ethics committee ***and*** evidence of this committee’s approval.
- If the external reports are not available, please contact resethics@swin.edu.au for advice on how to proceed.
- Once a Final Report is approved by the Swinburne Ethics Office, the ethics project will be closed at Swinburne, and no further modifications will be possible.

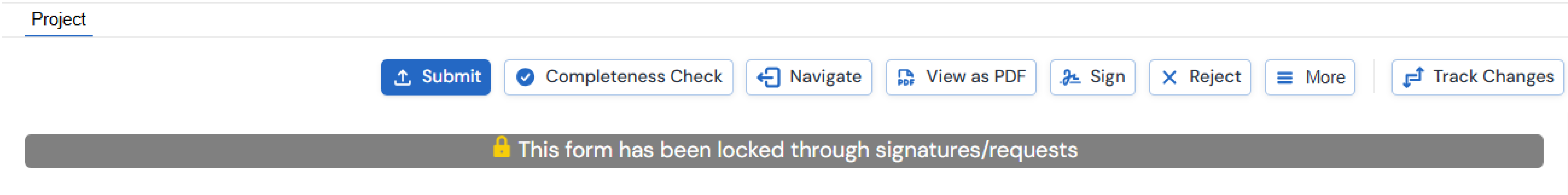
11 Reporting an Adverse Event

- Sign in to ERM and go to the project requiring an Adverse Event report
- Click ‘Create sub form’.
- Select the Sub form: ‘Human Ethics- Adverse Events’ and click ‘Create’
- Some of the data in Section A will be locked as it is auto-generated from the associated ethics application and may no longer be correct (e.g. if the CI has changed). Please disregard this as the Ethics Office can confirm the current CI against any modification forms.
- Navigate through the form by clicking the ‘Next’ or ‘Previous’ or ‘Navigate’.
- Follow the same instructions at 5.2.1-3 regarding signing off on the form.
- To share the Adverse Event report form with investigators, click ‘Share’ (see 3.1).
- To submit click ‘submit’.

12 Unlocking ERM Forms at Swinburne

- Once a form has been submitted, it is 'locked' and is unable to be edited.

- If a form is pending signatures, it cannot be edited until the signature request has been actioned as 'signed' or 'rejected' by the CI (see 5.2.3).



- Under current processes at Swinburne, Human Ethics forms are not unlocked for edits.
- Modifications are requested by completing the Modification Request sub-form (see 9).
- Please note that this differs from the Animal Ethics process.

End of document.

If you have any questions, please contact resethics@swin.edu.au