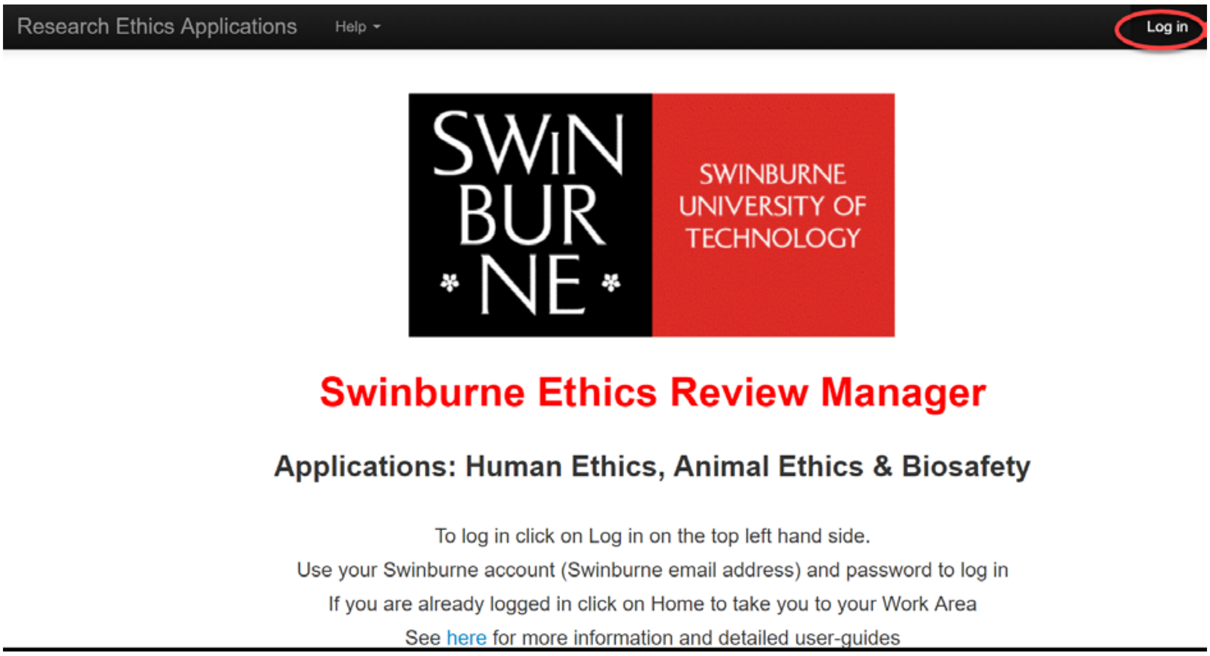
ERM Human Ethics User Guide For Researchers

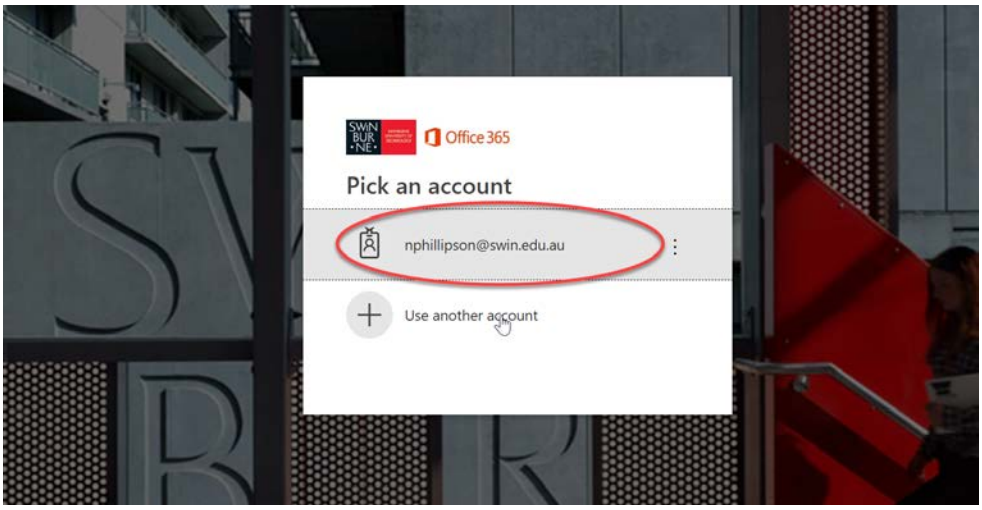
Swinburne Research- Research Ethics, Integrity & Biosafety
Version 17-12-19

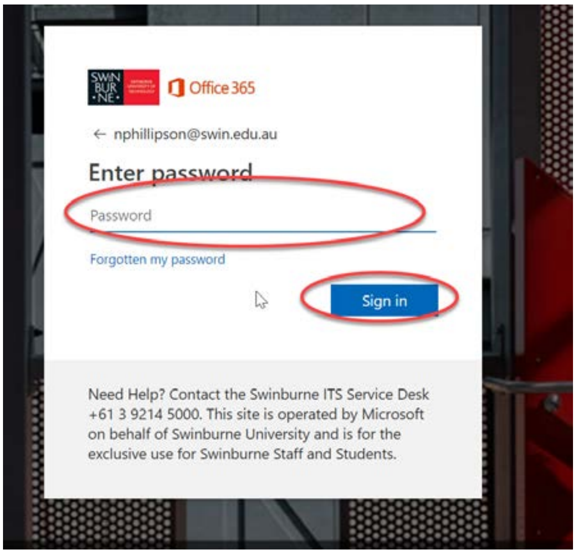
Contents

1 Logging in

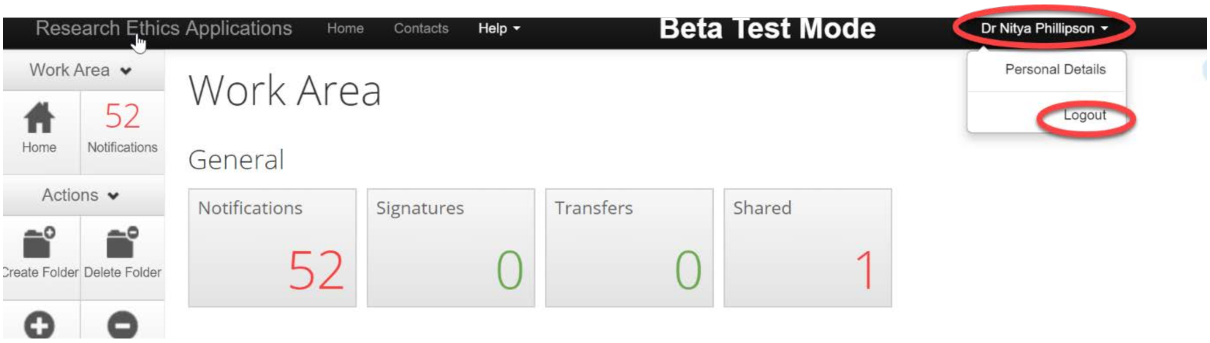
- Go to https://ethicsapps.swin.edu.au/
- Click on Log in on the top right hand corner
- Swinburne (Ethics Review Manager) ERM is fully integrated into the Swinburne Single Sign on. All researchers with an @swin.edu.au or @swin.edu.my will be able to access the application portal
- Use your Swinburne account (Swinburne email address) as the username (or pick your existing account)
- Use your email password for the password- click sign in.
- If you have any issues logging on email resethics@swin.edu.au







- If you have signed in before your name will appear in the top right hand side indicating you are logged in. Click on home to take you to your work area. If you wish to log in as a different user Log out and you can then log back in again using a different username.



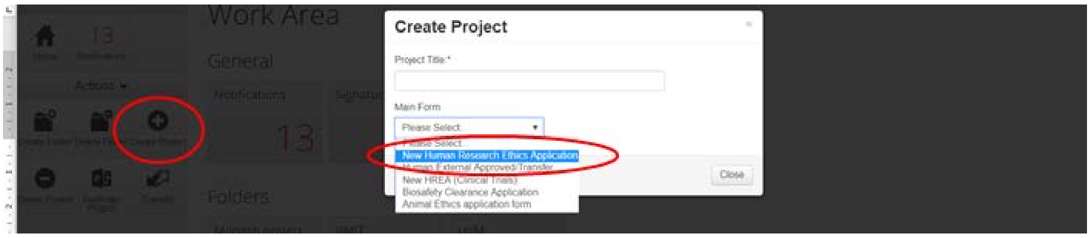
1.1 How to log in as an external applicant (I don't have a Swinburne email address)?

- If you do not have a Swinburne email address contact the Research Ethics team on resethics@swin.edu.au or 03 9214 8145 or 03 9214 3845 and provide the following information
    - The email address you wish to use to access the ERM
    - Information regarding which Swinburne researchers and project you are collaborating with
    - A brief summary about your research and Swinburne's involvement.
- We will then create an account for you and email you a username and password.

2 Selecting the right ethics application for you

2.1 Different applications available

- There are 3 different types of Human Ethics applications available, details of which are listed below.
- These options are found when you select the ‘Create project’ icon in the Actions Panel on the left-hand side of the landing page. The drop-down list for Main Form lists these as options
- For more information about what form to use please email: resethics@swin.edu.au



2.1.1 New Human Research Ethics Application

- 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

2.1.2 Human External Approved/Transferred

- Previously called “Expedited review” applications
- If your project has been reviewed and approved by another Australian Human Research Ethics Committee that is registered with the NHMRC your project can undergo expedited review.
- As your project has already undergone ethical review and approval you can complete the substantially shorter Human Ethics Expedited review form which will be reviewed out of session.

2.1.3 HREA (Clinical Trials)

- The NHMRC’s Human Research Ethics Application (HREA) should be used for all clinical trials of drugs or devices.
- This application form is specifically designed to answer relevant questions about clinical trials and can be used at other sites (including public hospitals) to apply for ethical approval.
- If you have completed a HREA on hrea.gov.au you can upload the completed HREA into this system. For information on how to do this please contact resethics@swin.edu.au.

2.1.4 Other application types

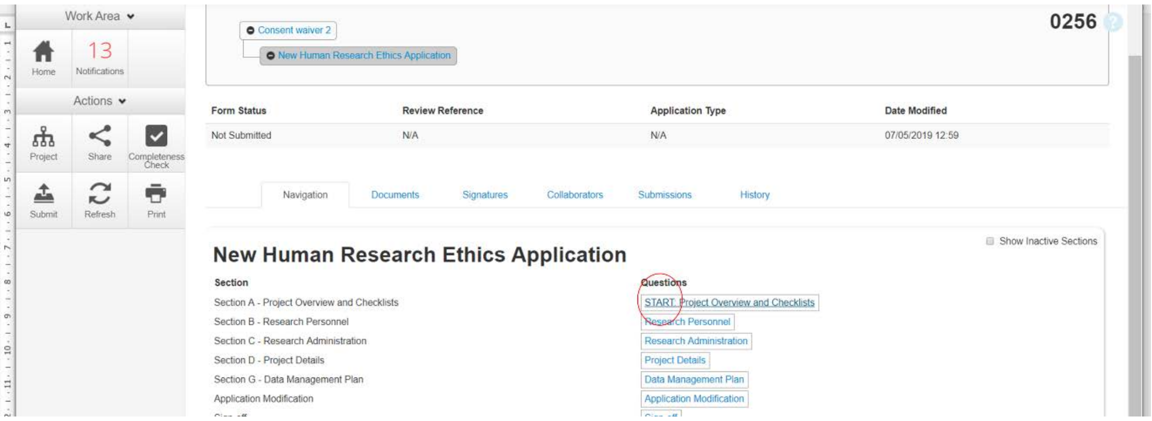
- The drop-down list contains other application types:
  - Biosafety Clearance Application: For research requiring biosafety clearance as you are using biohazardous materials (e.g. venoms or blood products) and/or genetically modified organisms (e.g. genetically modified cell lines, bacteria, plants or other organisms).
  - SAEC 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 How to complete a standard human ethics application

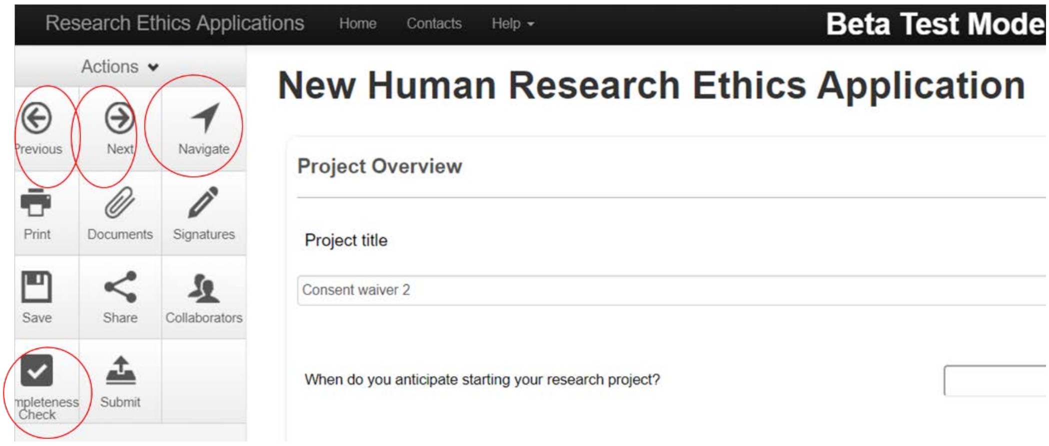
3.1 Drafting your application

Once you have created your application you will be taken to the navigation page displayed below.

We strongly recommend you commence at the START section as this will take you through a series of checklists that will create and remove sections depending on how you answer these

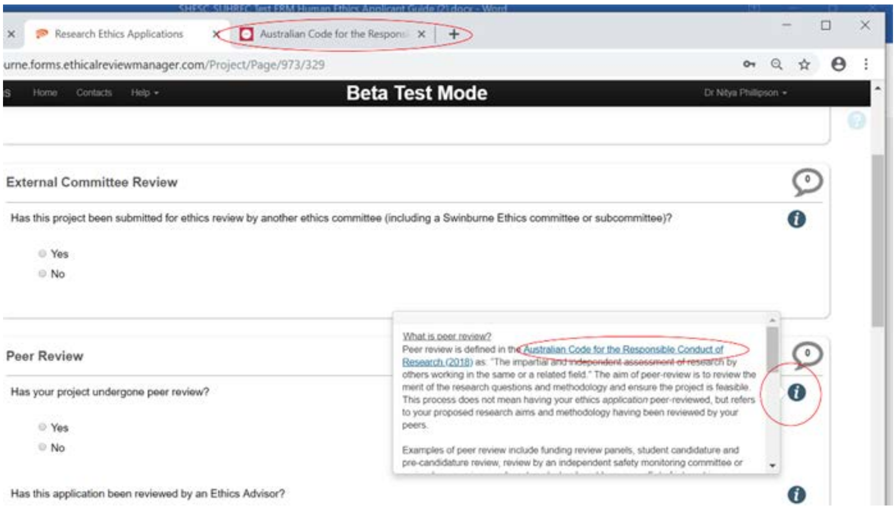


- Navigate through the form by clicking Next or Previous
- You can see the overall structure of the form by clicking on the navigate icon and then click on the relevant sections of the form to take you to that section
- You can conduct a completeness check at any time by selecting the completeness check button in the Actions tab on the LHS and go directly to any incomplete section by clicking on the sections highlighted as incomplete.
- *Please Save your application frequently to avoid losing any work. To do this click on the Save button on the LHS actions tab.*
- Please note that only the Chief Investigator can submit an ethics application. Please see section 6 of this guide for more information



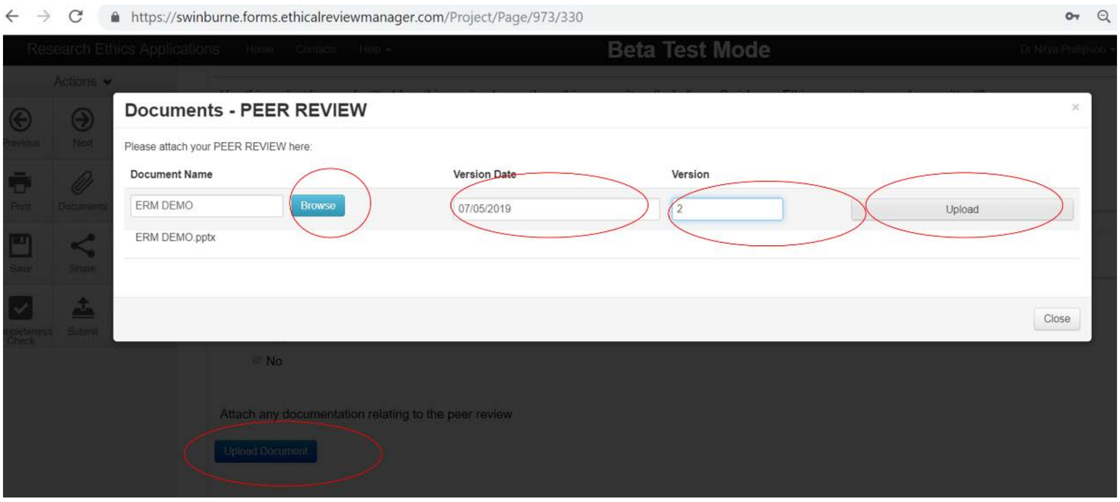
3.2 Need help with a question

- To see help sections click on the *i* icon next to the question
- A help text will pop up in a window. If you click on a hyperlink they will open in a new tab

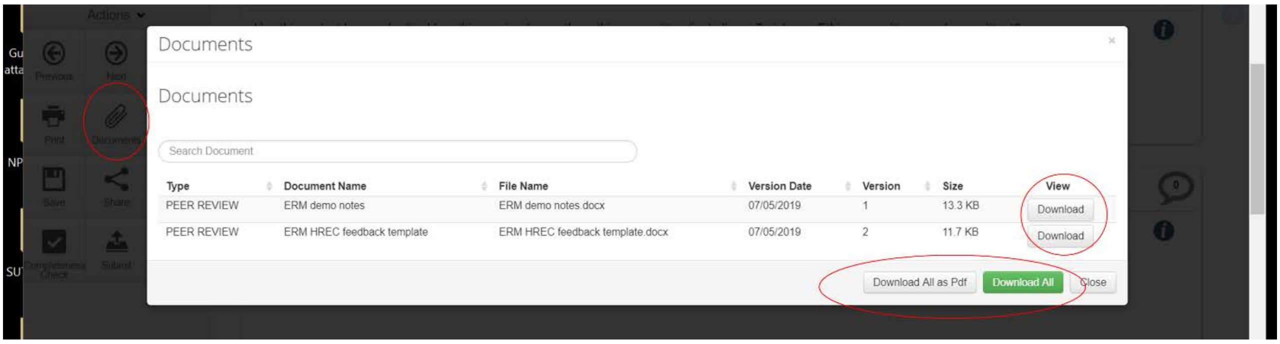


3.3 Attaching relevant documents

- You may be prompted at certain points to upload a document. To do this, click upload documents
- Click Browse to select the file on your computer you wish to upload, enter a version date and number to ensure document control

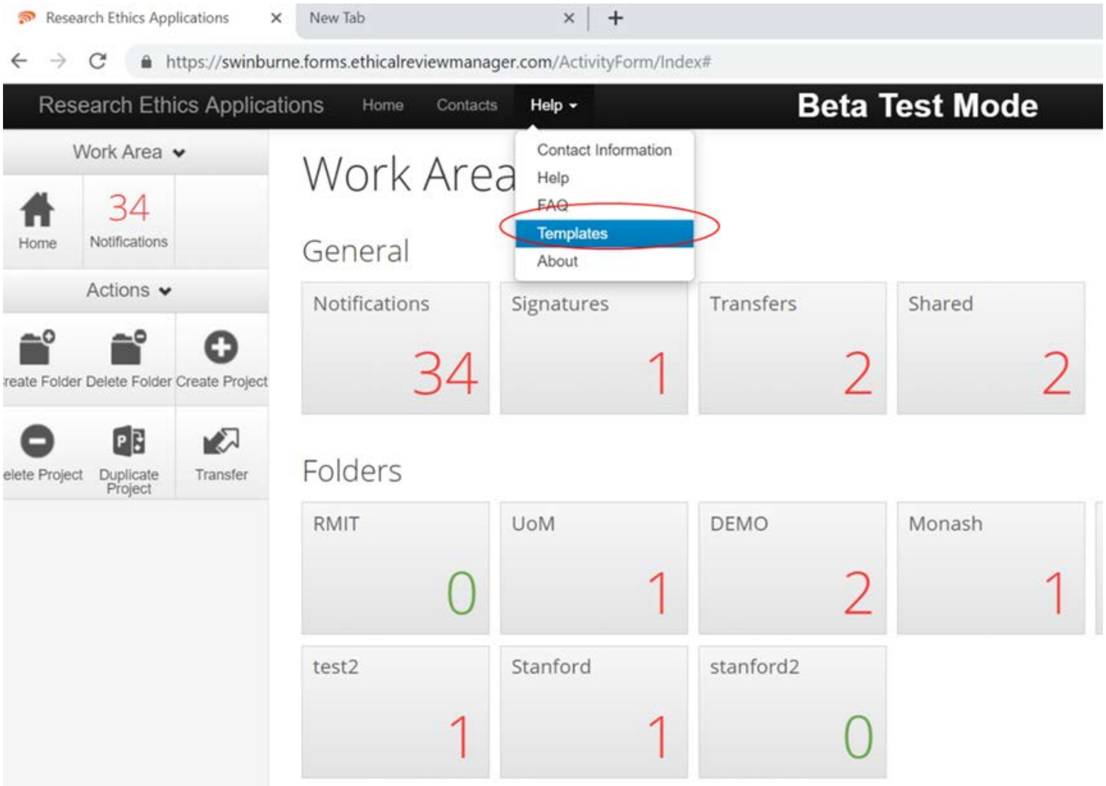


- You can review all documents uploaded to the application using the Document button on the Actions tab that is located on the left hand side (LHS)
- Documents can be downloaded separately or all together



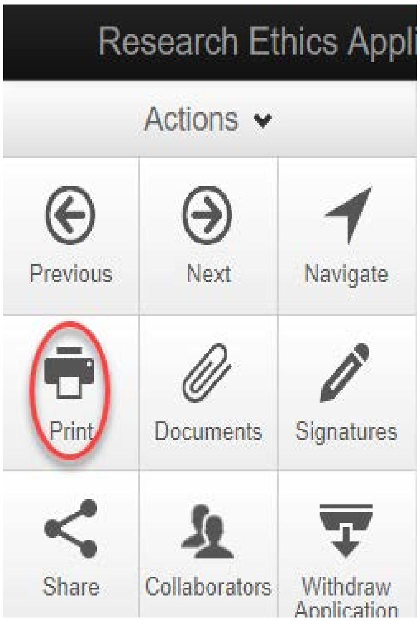
3.4 Using templates for consent information documentation and other associated documents

- We strongly recommend you use the template documents provided to assist you with your applications. These are all stored within the system.
- To access the templates go to the 'Help' tab on the top navigation bar and click on Templates.

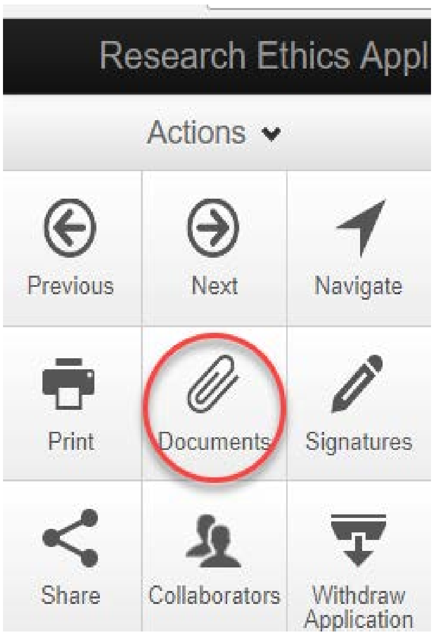


3.5 Downloading the application and application documents

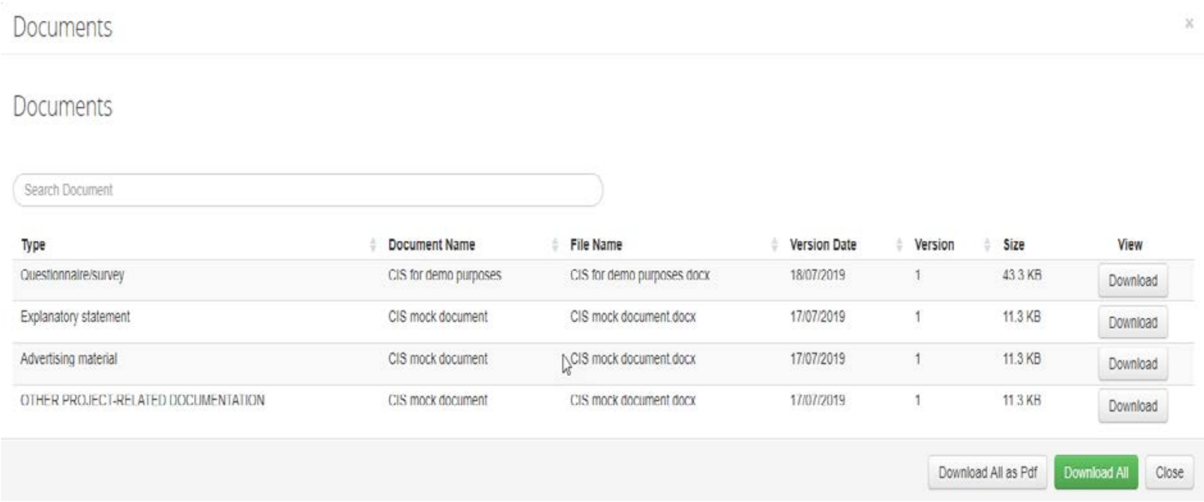
- In order to download a copy of the application in its entirety as a pdf file, select the print button in the Actions tab on the LHS. This will open the application as a pdf file in a separate browser.



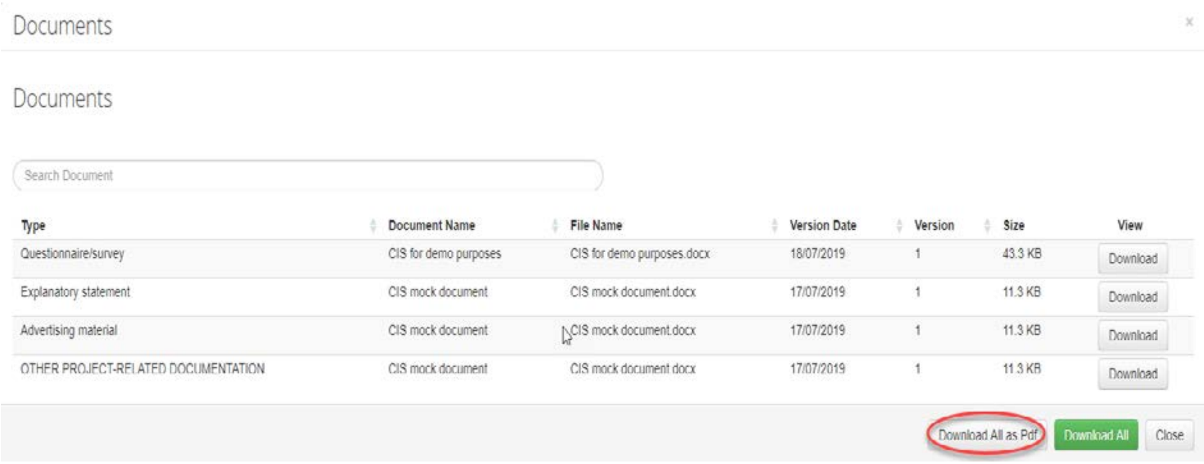
- In order to download individual attachments (e.g. consent instruments), select the documents button in the Actions tab on the LHS.



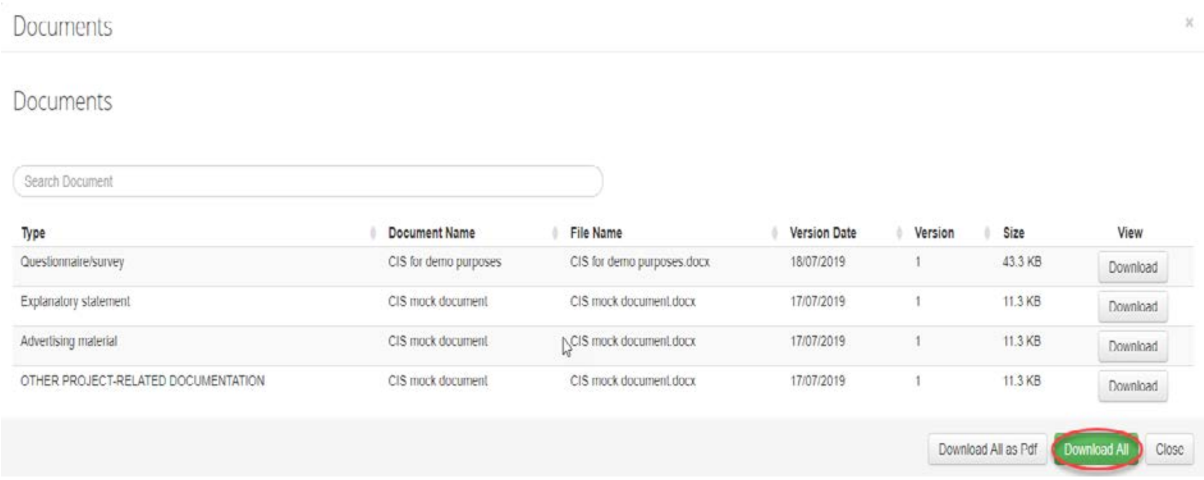
- This will bring up the following:



- In order to download all documents as a pdf file (i.e. application form and all associated documents/attachments), select Download All as Pdf:

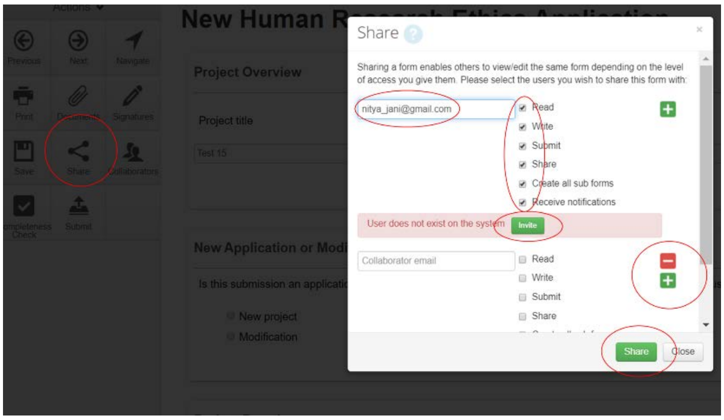


- In order to download all documents in their original format as a .zip file, select Download All:

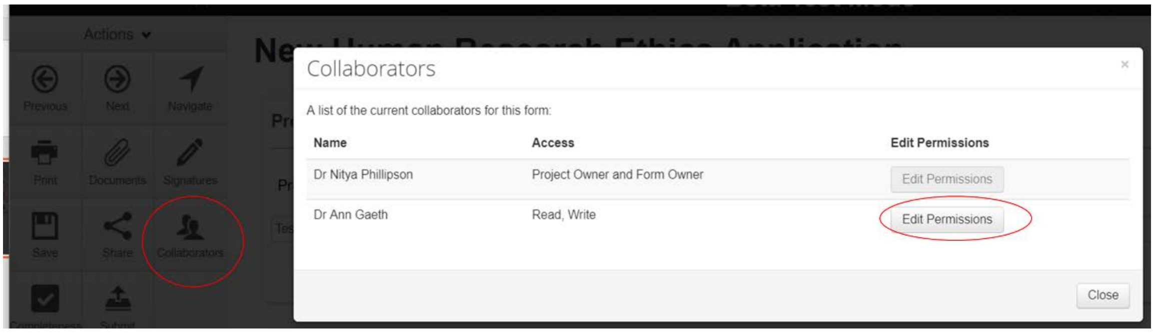


4 How to share and collaborate on a standard human ethics application

- To share your application with other collaborators for their input, click on the Share icon on the LHS action tab
- A pop-up box will appear. Enter the email address of the collaborator.
- Select permission (you can select multiple options)
  - Read - person can read the application
  - Write - person can 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 annual reports and adverse event
  - 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.
- All persons with an @swin.edu.au or @swin.edu.my email address will immediately be set up with access to Swinburne ERM. If named collaborators do not have an '@swin.edu.au' an invite button will appear, the person will receive an email indicating how to obtain access to the system.
- To remove a collaborator, click on the minus button.
- Click Share to finalise. This can be modified at any time. Please note you cannot click share if you have empty collaborator sections present.

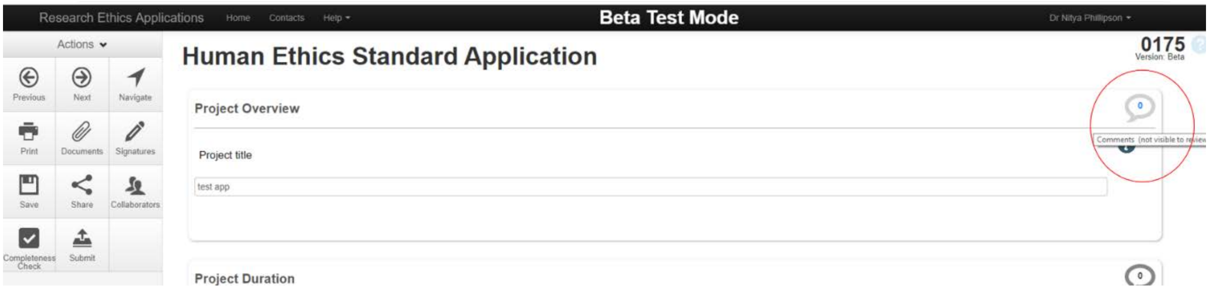


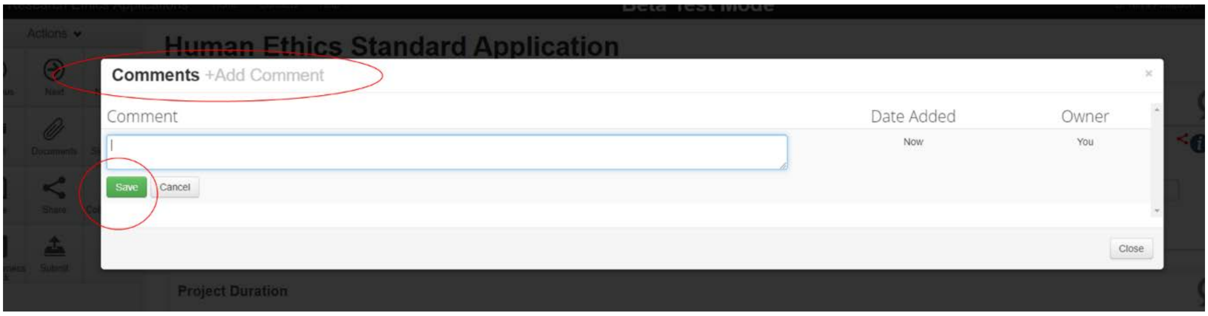
- To review your collaboration or edit permissions click on collaboration icon on LHS Actions tab. You can edit permission by clicking on edit permission button



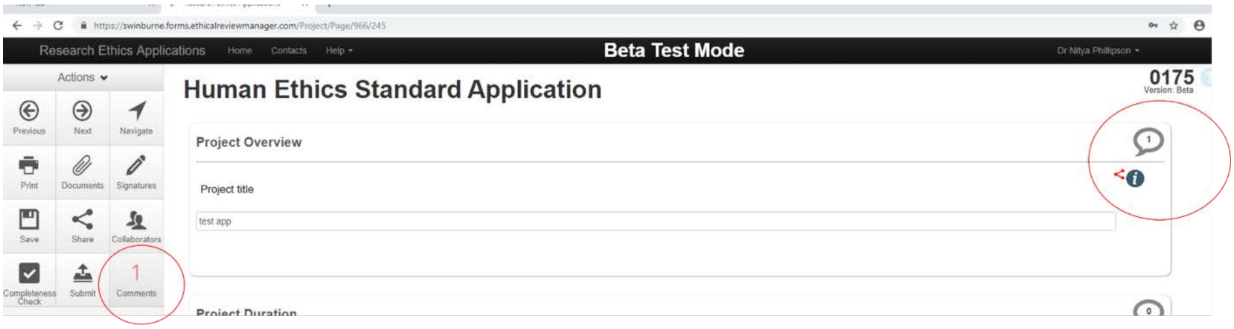
5 How to make comments on yours or a collaborator's ethics application

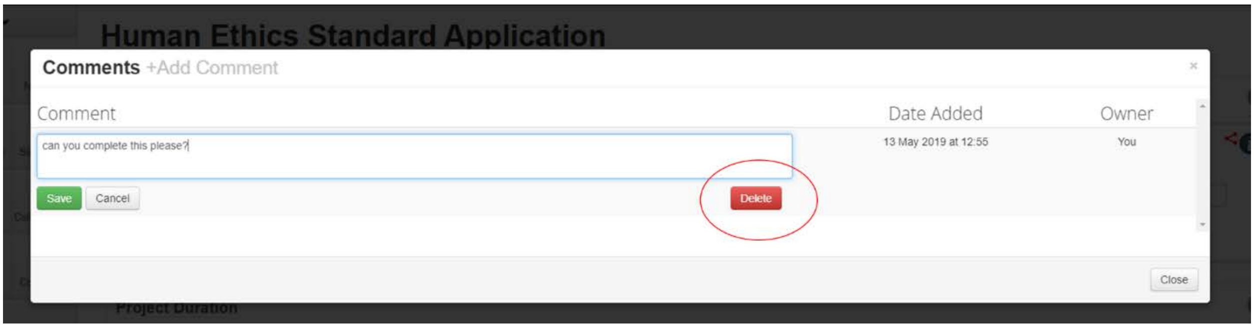
- To make a comment for other researchers or collaborators to see click on the comment bubble on the top right-hand side of a question.
- Enter the comment you wish your collaborators to see. These will only be visible to your collaborators and not the ethics committee reviewer





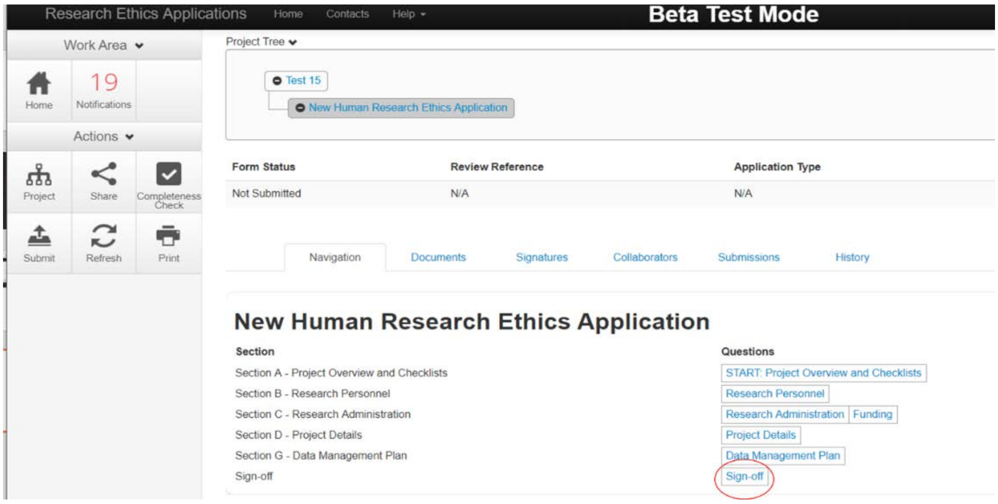
- You and your collaborators can view a summary of comments, click on the Comments button on the LHS action tab
- A list of all comments will appear, you can click on these comments and it will take you directly to the question the comment refers to.
- You can edit or delete a comment by clicking on the comment and the delete button shows up, or you can amend this comment.





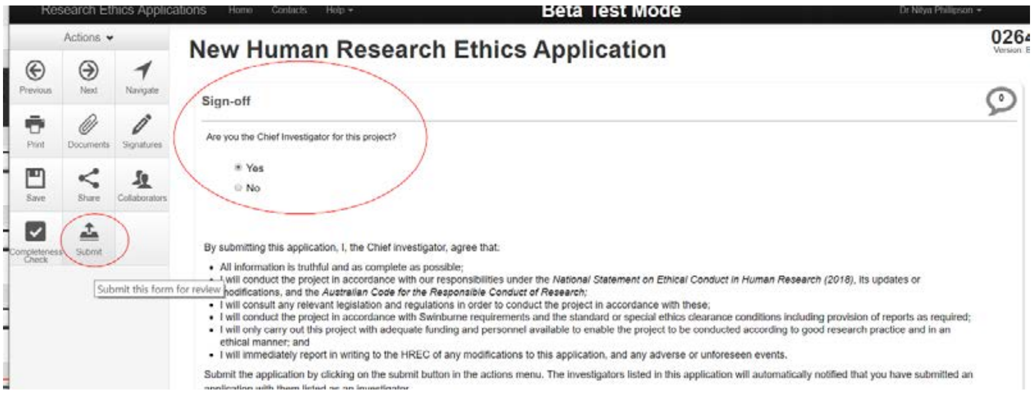
6 How to obtain sign off on a standard human ethics application

- Chief Investigators (CIs) must sign off on ethics applications.
- Students cannot act as CI, the student's primary supervisor should act as CI
- To commence sign off, click on the navigate icon on the LHS actions tab to navigate to the sign off section of the application
- Once an application is submitted, an email will be sent to all ALL investigators and associate investigators listed in the research personnel section of the application notifying them that an application has been submitted with them listed as an investigator. The REO strongly recommends that the application be shared with all listed applicants with at least read permission.



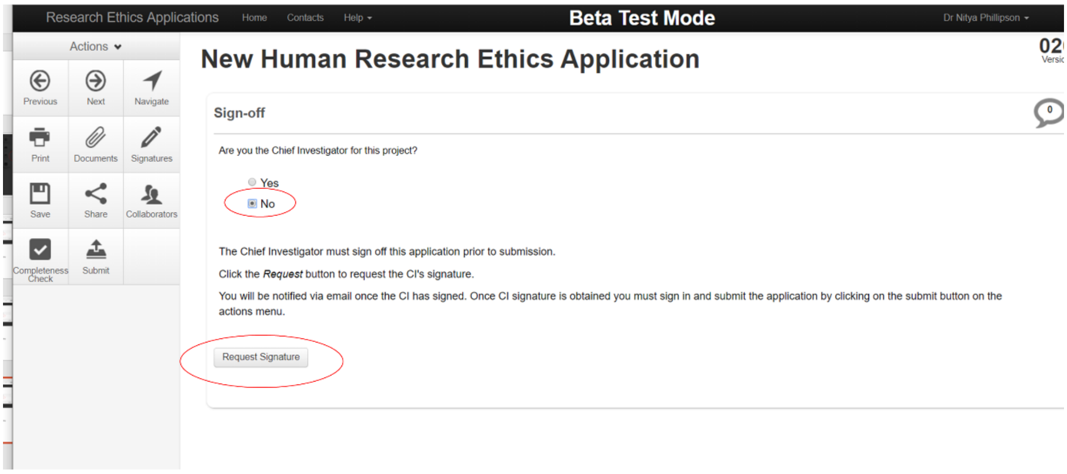
6.1 If the applicant is the CI

- Using the navigate icon on the LHS actions tab to navigate to the sign off section of the application
- The sign off question asks: Are you the chief investigator of this project?
- If the applicant is the CI then then click Yes.
- A completeness check will be undertaken. Sections that are incomplete will be highlighted. Click on the relevant section of the application which will indicate the incomplete section. The application cannot be submitted until all mandatory sections have been completed.
- A CI declaration will appear. This must be carefully read and if agreed to, click on the Submit button.
- Your application has now been submitted and will be locked. The REO will automatically receive this information and an automated email will be sent confirming submission.

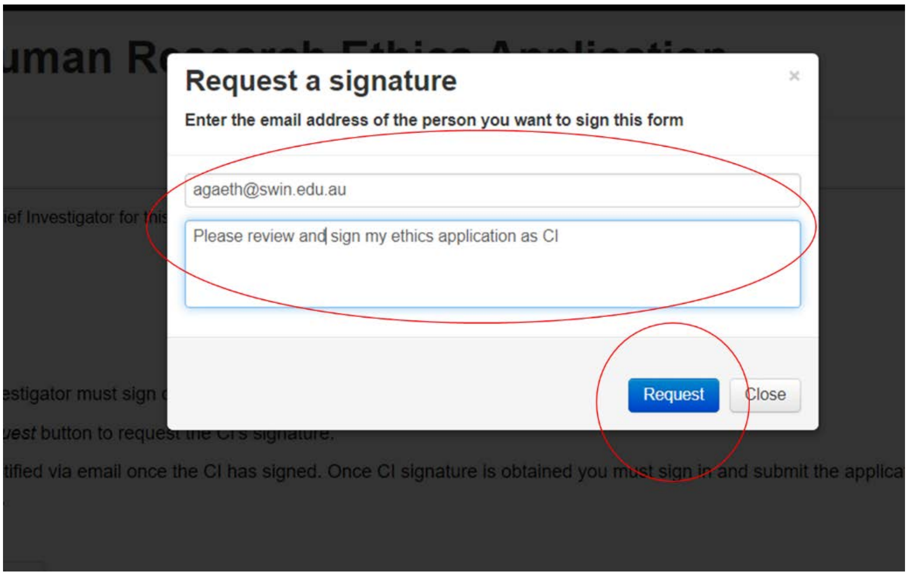


6.2 If the applicant is NOT the CI

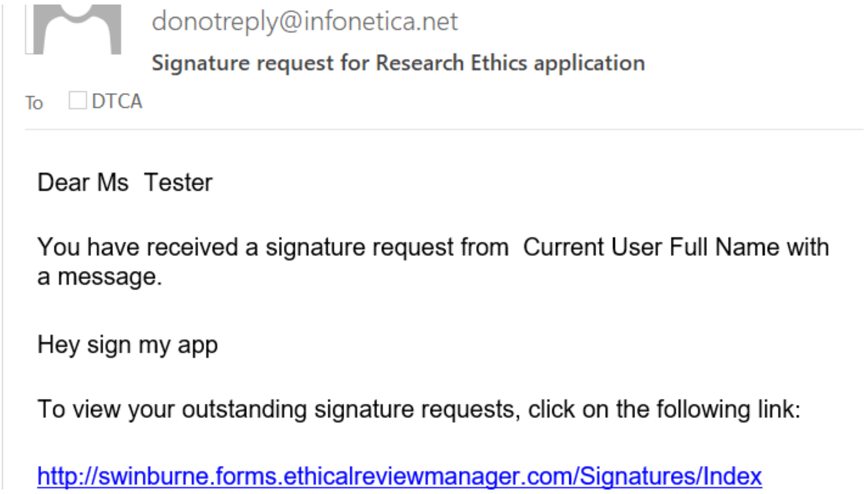
- Use the navigate icon on the LHS actions tab to navigate to the sign off section of the application
- The sign off question asks: Are you the Chief Investigator of this project?
- If the applicant is NOT the CI then then click No. Please note students cannot act as CIs this should be the student's primary supervisor or project lead.
- You will be asked to request a signature of the CI, click on Request Signature



- Enter the CI's email address, a message for the CI (optional) and click on Request
- The CI must also be listed an applicant on the application otherwise an error message will appear.
- When you click on Request, a completeness check will be undertaken. Sections that are incomplete will be highlighted. Click on 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.



- 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 user ID (name@swin.edu.au) and password).


donotreply@infonetica.net
Signature request for Research Ethics application
To DTCA

Dear Ms Tester

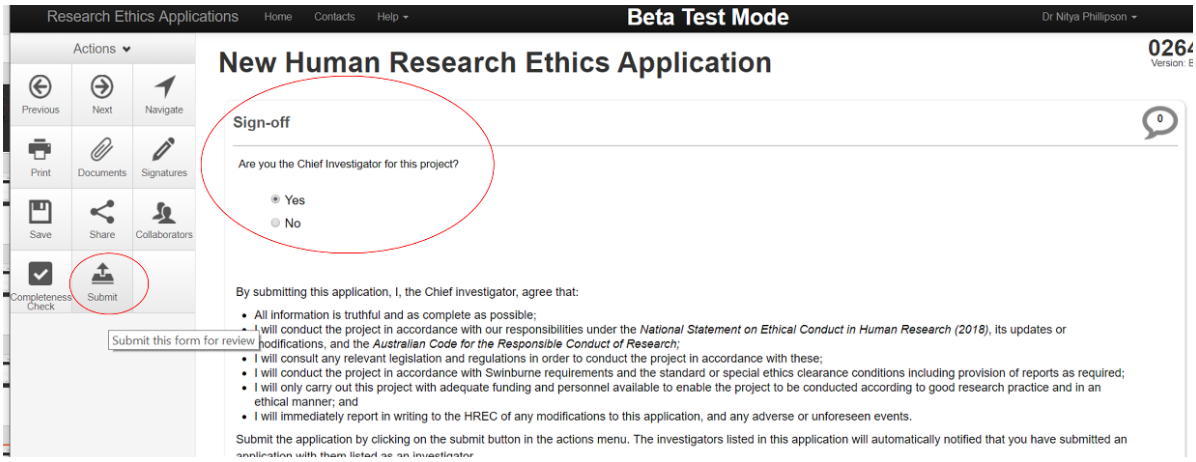
You have received a signature request from Current User Full Name with a message.

Hey sign my app

To view your outstanding signature requests, click on the following link:

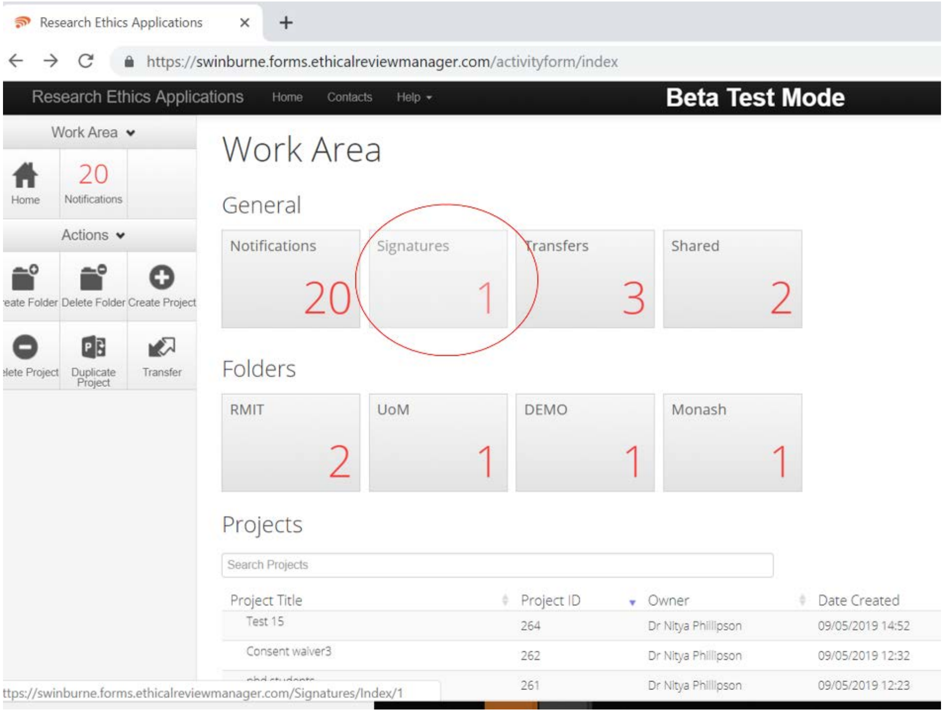
http://swinburne.forms.ethicalreviewmanager.com/Signatures/Index

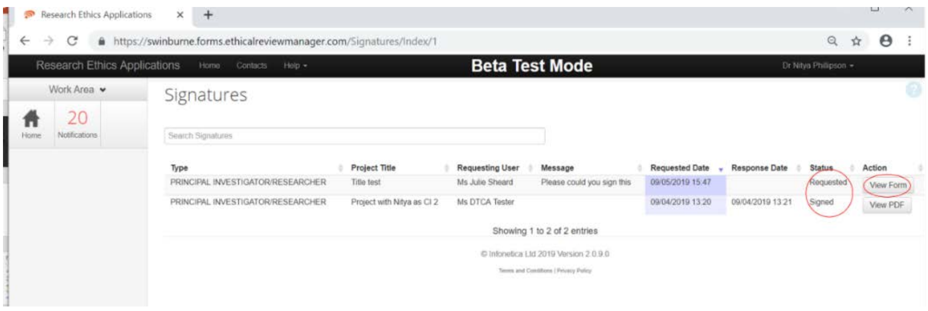
- When the CI signs off on the application you will receive notification via email. You must then go back to the application and select submit in the LHS action tab.

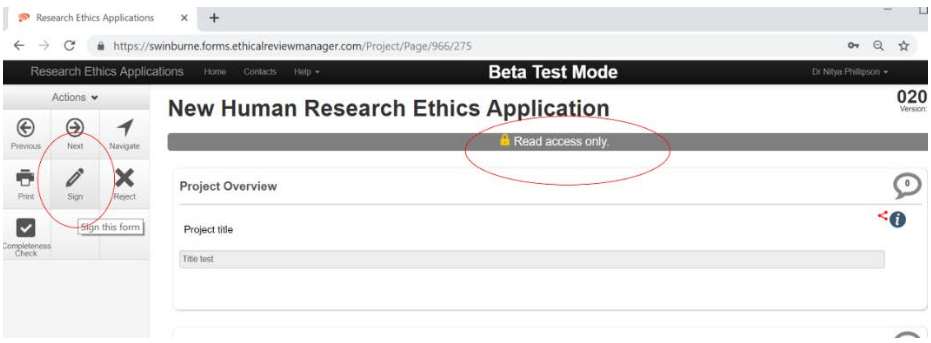


6.3 Signing an ethics application as CI

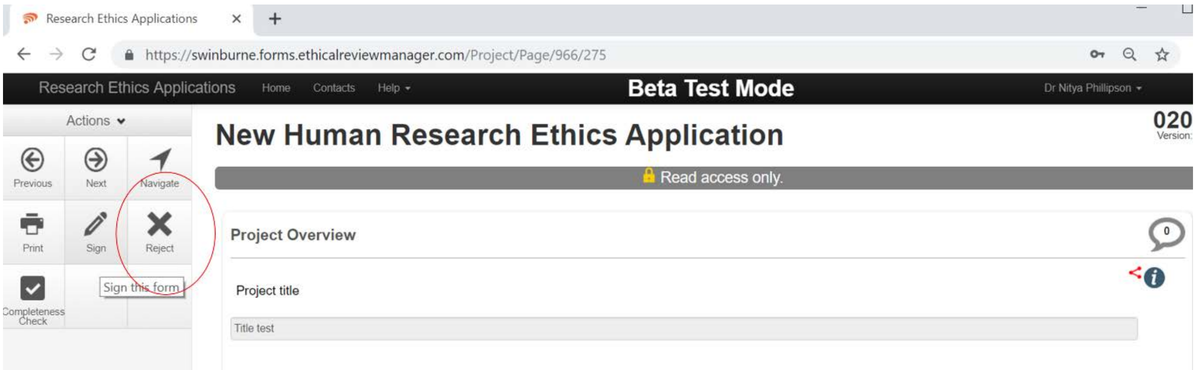
- You will receive an email asking you to sign in to ERM and sign off on an application
- Click on the Signatures tile in the Work Area
- Here you can see all applications waiting on signatures, as well as those previously signed
- Click on view application- you will have read only access to the application.
- If you are happy with the application, click on the Sign icon on the LHS action tab
- You will be prompted to re-enter your email address and password.
- An email will now be sent to the applicant indicating sign off.





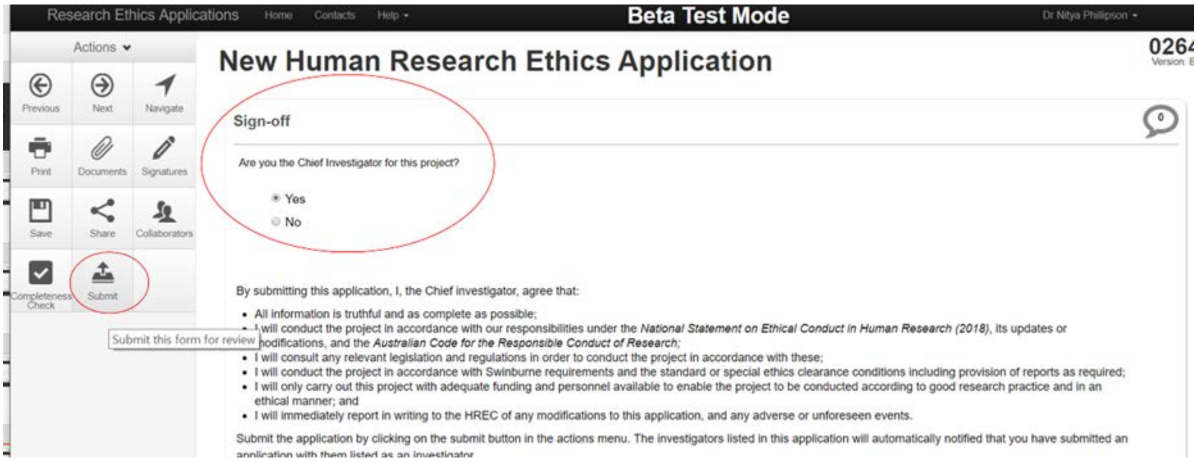


- If you do not wish to sign off on the ethics application, click on the Reject icon on the LHS actions tab.
- You will be prompted to provide feedback to the applicant. This will be sent in an email to the applicant and the form unlocked for changes.



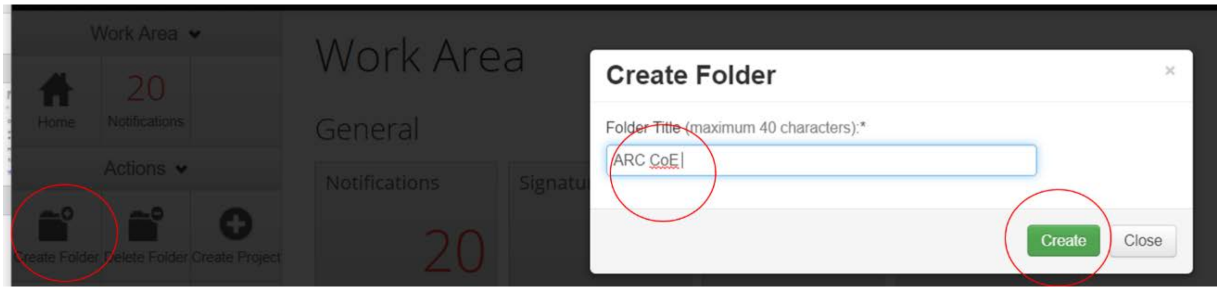
6.4 Submitting an ethics application

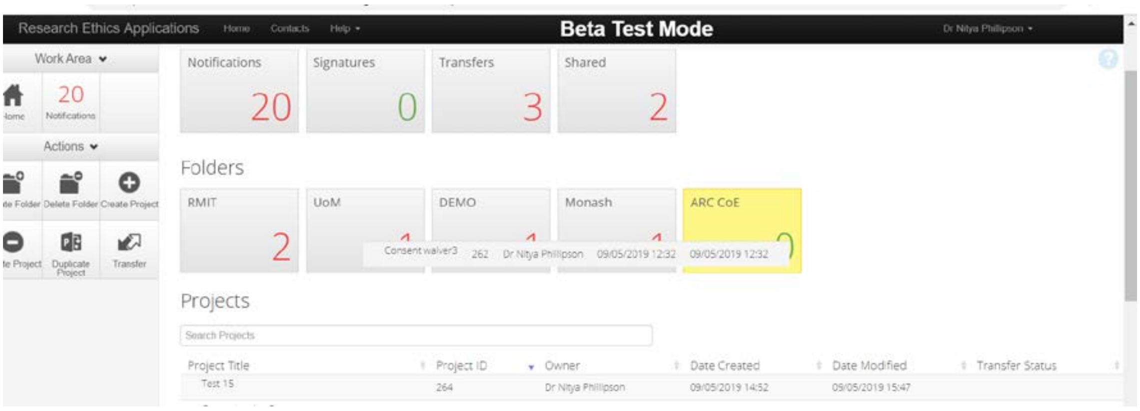
- Once the CI has signed the application (or you are the CI) you may submit the form.
- Click on the Submit button the LHS actions tab

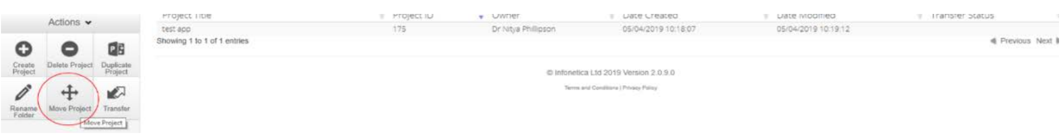


7 How to organise your projects

- You can create custom folders to store your ethics applications
- In the work area click on 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
- Please note that when you search for projects in this list of all applications any projects placed in sub folders will not show up.
- To move a project, click into the folder and select move folder button on LHS action tab. This will then allow you to move the project into other existing folders or the work area.

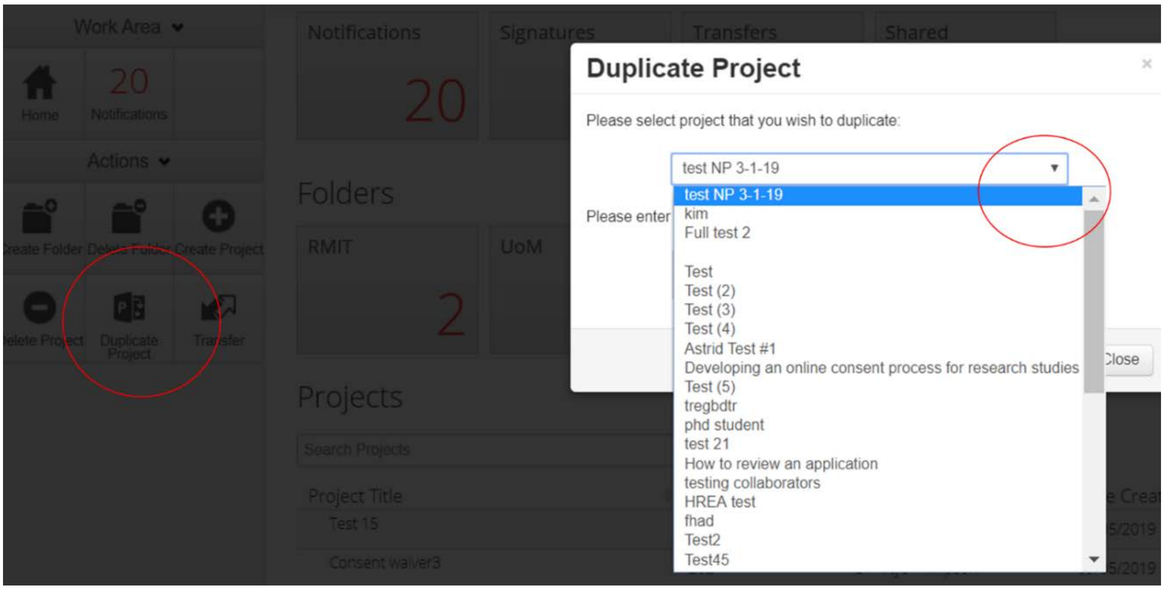






8 How to duplicate an existing application

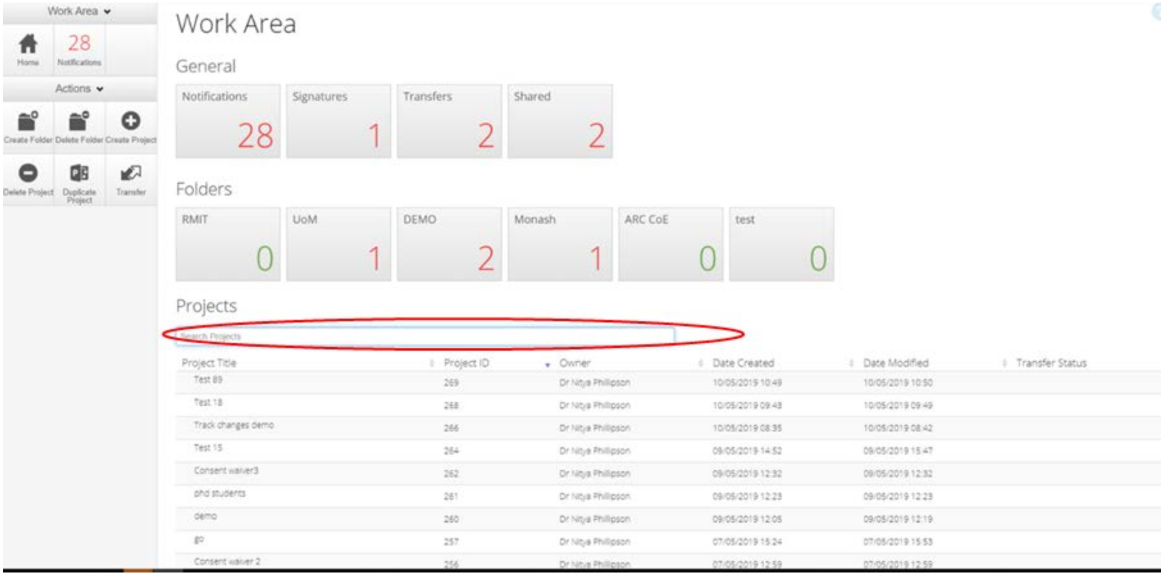
- Click on Duplicate project in the LHS actions tab of the work area
- Select the application you wish to duplicate out of the drop-down list. All applications within the work area will be listed. If the application you wish to duplicate is in a folder, enter that folder and then select duplicate. The applications listed in the drop down available to be duplicated will now only be for those in the folder you are accessing this button from.
- Enter a new title for the duplicate application
- You can now amend the duplicated application as appropriate



9 How to search for a project

To search for projects that you have not allocated to projects follow the steps below:

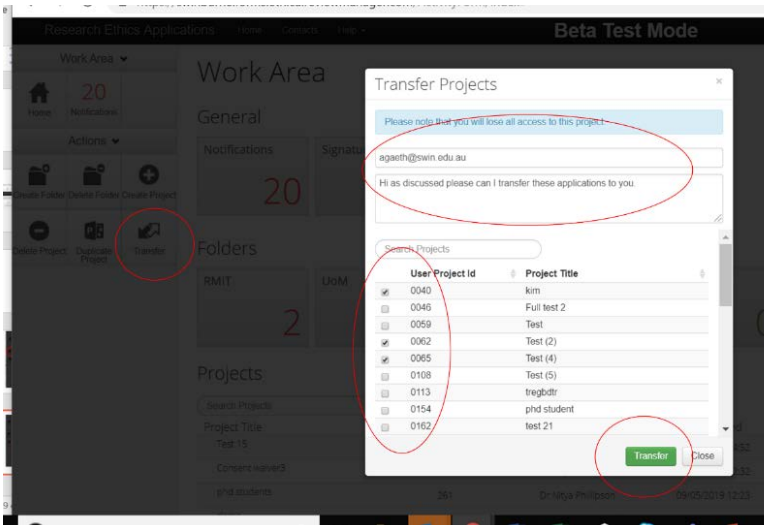
- The work area has all your ethics applications that are not in folders in a searchable list. To search for an ethics application, type in the title or key word. The list of projects will start narrowing down as you type.
- Please note that projects in folders cannot be found using this search bar. For that you must enter the project folder and search within that folder.



10 How to transfer an application

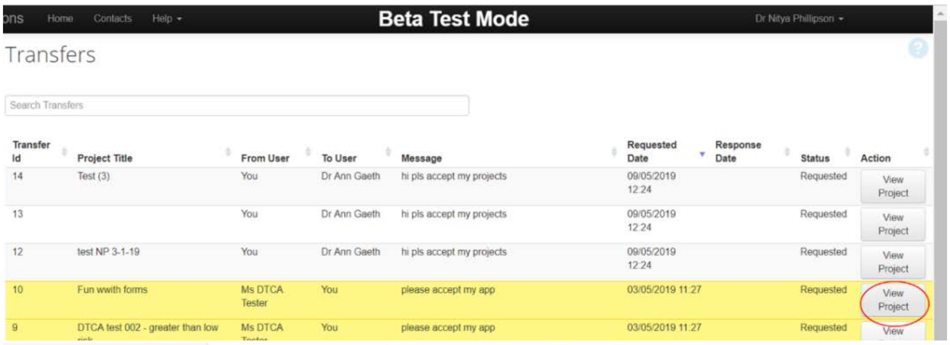
If you are no longer CI on a project or you are leaving Swinburne, you will need to transfer your project to a new CI. To do this:

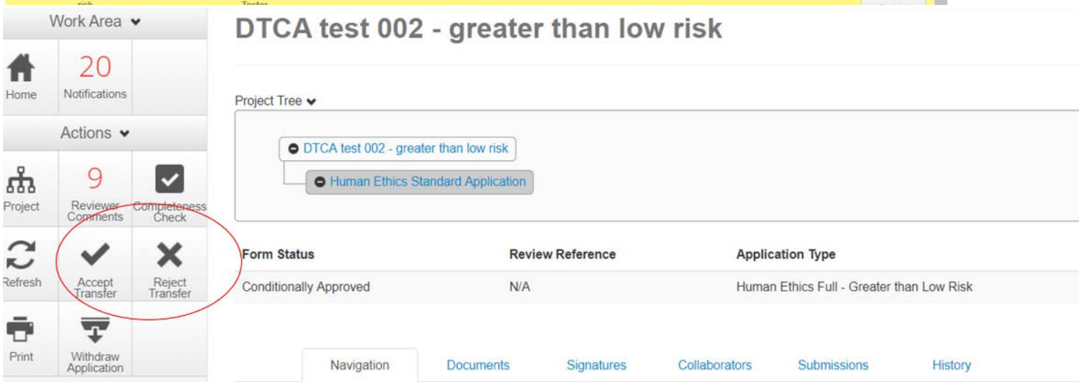
- Click on the Transfer icon on the LHS of the actions tab in the work area
- Enter the email address of the new CI and a message regarding the transfer, then select the applications you wish to transfer.
- The new CI will receive an email indicating the transfer. The Research Ethics Office will also be notified about the transfer so they can support the old and new CI in any changes to documentation required.
- You will no longer have access to a transferred application.



10.1 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 transfer icon on the work area
- This will show you all transfers, transfers requiring your action will be highlighted in yellow. To accept a transfer, click on view project
- You can accept or reject the transfer using accept transfer and reject transfer icon on the LHS actions tab.

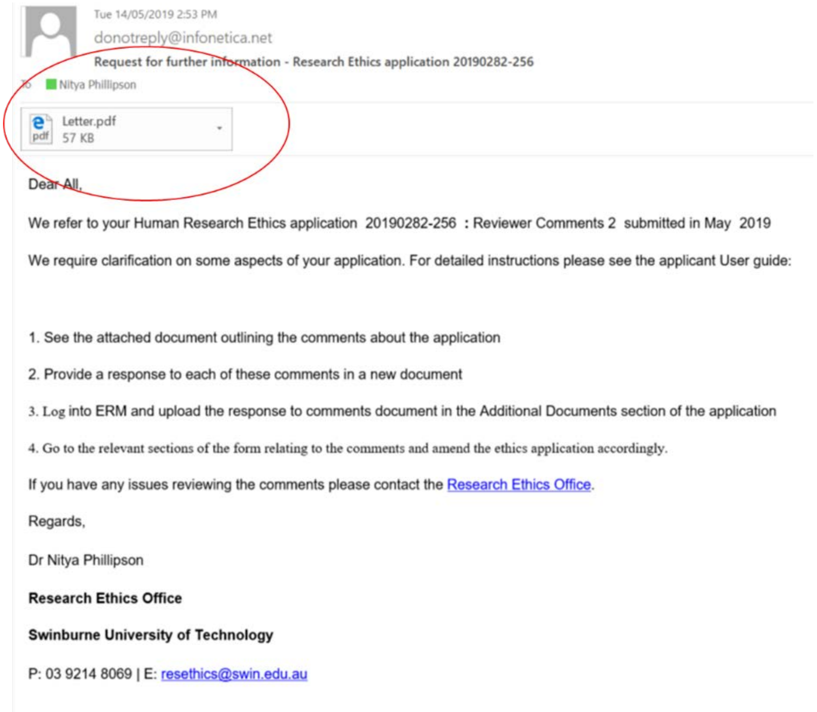

Beta Test Mode
Home
Contacts
Help
Dr Nitya Phillipson
Transfers
Search Transfers
Transfer Id
Project Title
From User
To User
Message
Requested Date
Response Date
Status
Action
14 Test (3) You Dr Ann Gaeth hi pls accept my projects 09/05/2019 12:24 Requested View Project
13 You Dr Ann Gaeth hi pls accept my projects 09/05/2019 12:24 Requested View Project
12 test NP 3-1-19 You Dr Ann Gaeth hi pls accept my projects 09/05/2019 12:24 Requested View Project
10 Fun wwith forms Ms DTCA Tester You please accept my app 03/05/2019 11:27 Requested View Project
9 DTCA test 002 - greater than low Ms DTCA You please accept my app 03/05/2019 11:27 Requested View


Work Area
Home
20
Notifications
Actions
Project
9
Reviewer Comments
Completeness Check
Refresh
Accept Transfer
Reject Transfer
Print
Withdraw Application
DTCA test 002 - greater than low risk
Project Tree
DTCA test 002 - greater than low risk
Human Ethics Standard Application
Form Status
Review Reference
Application Type
Conditionally Approved
N/A
Human Ethics Full - Greater than Low Risk
Navigation
Documents
Signatures
Collaborators
Submissions
History

11 Committee feedback

11.1 Receiving feedback

- You will be notified via email when you have received feedback from the ethics office or ethics committee.
- This email will contain a link to the ethics application in ERM and attachment that includes a list of the comments made in the application



Tue 14/05/2019 2:53 PM
donotreply@infonetica.net
Request for further information - Research Ethics application 20190282-256
Nitya Phillipson
Letter.pdf
57 KB

Dear All,

We refer to your Human Research Ethics application 20190282-256 : Reviewer Comments 2 submitted in May 2019

We require clarification on some aspects of your application. For detailed instructions please see the applicant User guide:

1. See the attached document outlining the comments about the application
2. Provide a response to each of these comments in a new document
3. Log into ERM and upload the response to comments document in the Additional Documents section of the application
4. Go to the relevant sections of the form relating to the comments and amend the ethics application accordingly.

If you have any issues reviewing the comments please contact the Research Ethics Office.

Regards,

Dr Nitya Phillipson

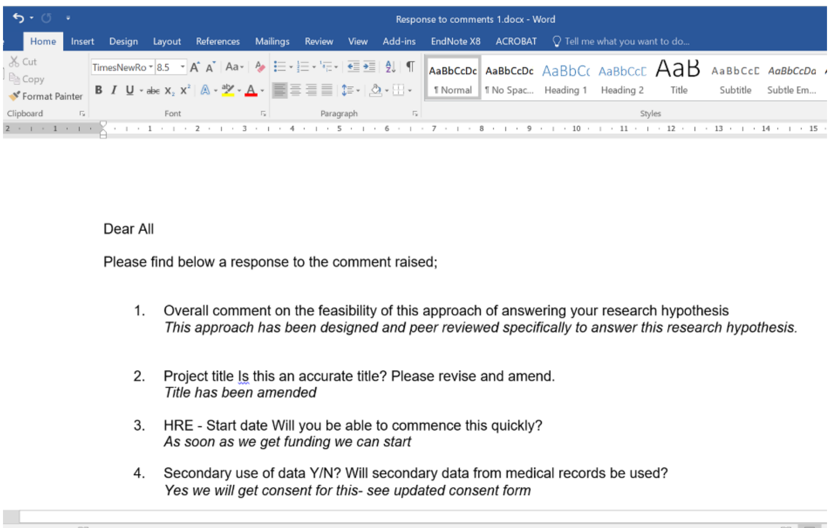
Research Ethics Office

Swinburne University of Technology

P: 03 9214 8069 | E: resethics@swin.edu.au

11.2 How to respond to feedback

- Create a word document and copy and paste all the comments in the attachment into this word document.
- Provide a response to each of the queries in this document

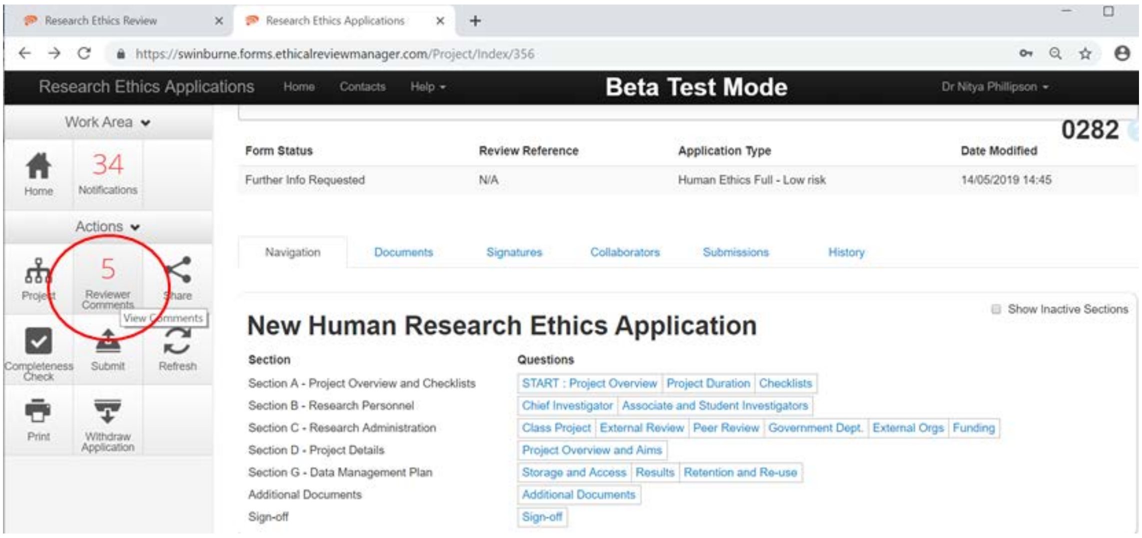


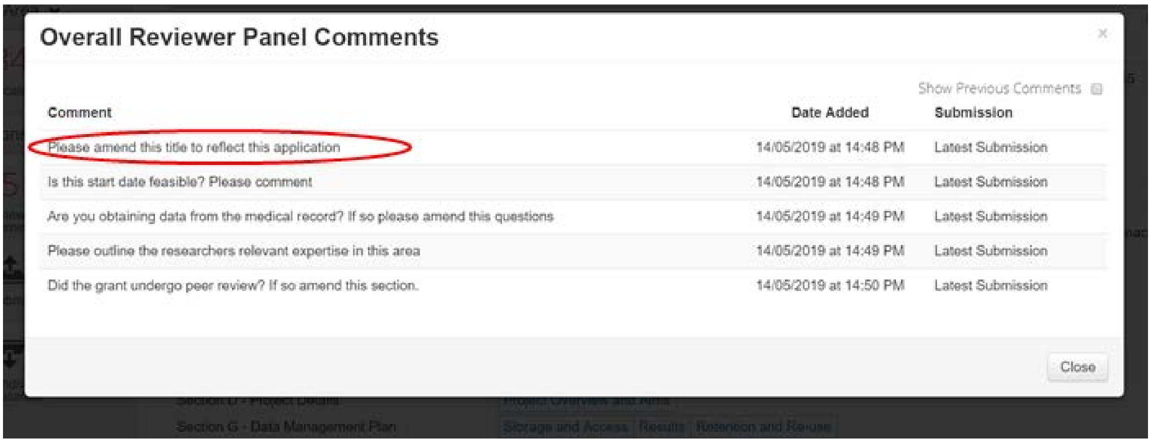
Dear All

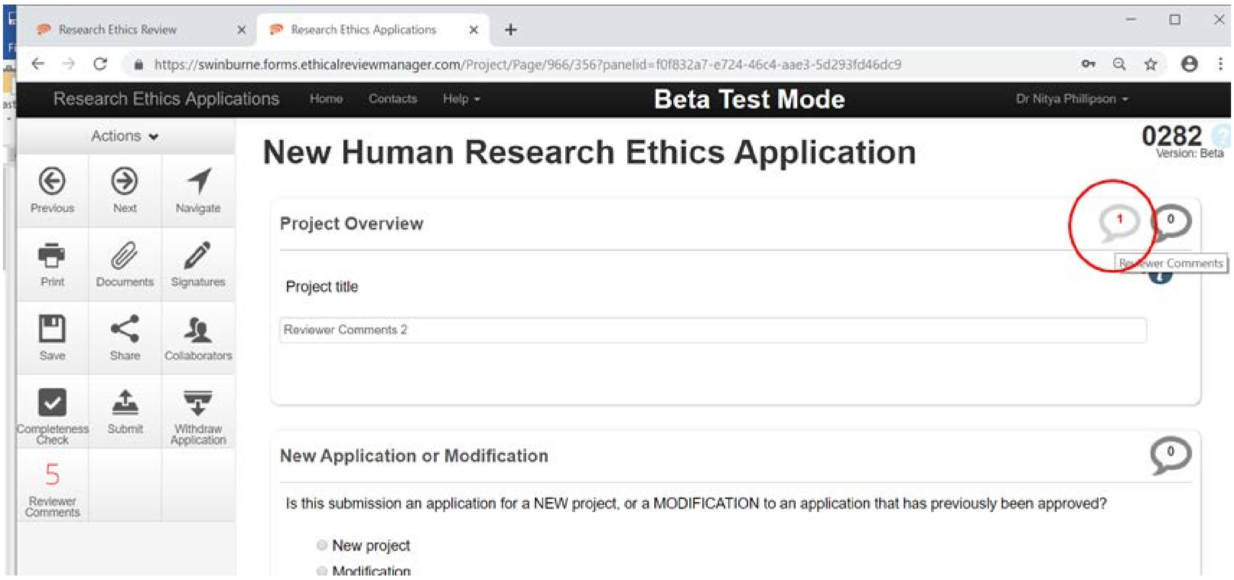
Please find below a response to the comment raised;

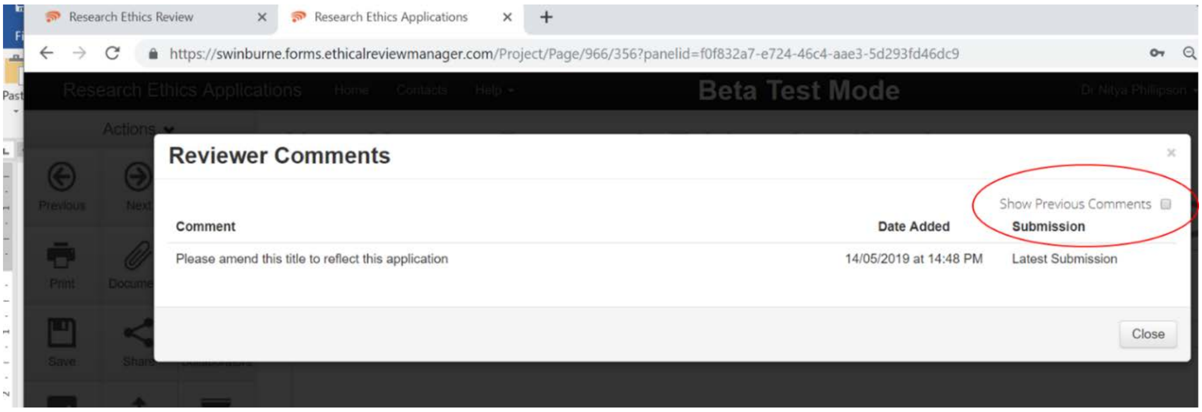
1. Overall comment on the feasibility of this approach of answering your research hypothesis
   This approach has been designed and peer reviewed specifically to answer this research hypothesis.
2. Project title Is this an accurate title? Please revise and amend.
   Title has been amended
3. HRE - Start date Will you be able to commence this quickly?
   As soon as we get funding we can start
4. Secondary use of data Y/N? Will secondary data from medical records be used?
   Yes we will get consent for this- see updated consent form

- Log into ERM and make any relevant changes to the sections required
- To see all the comments made, click on the Reviewer comments button on the LHS actions tab
- 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 on the comment bubble on the top RHS of the question to view the question.
- Amend the response in the application accordingly.
- To see previous comments related to previous submission click on show previous comments.



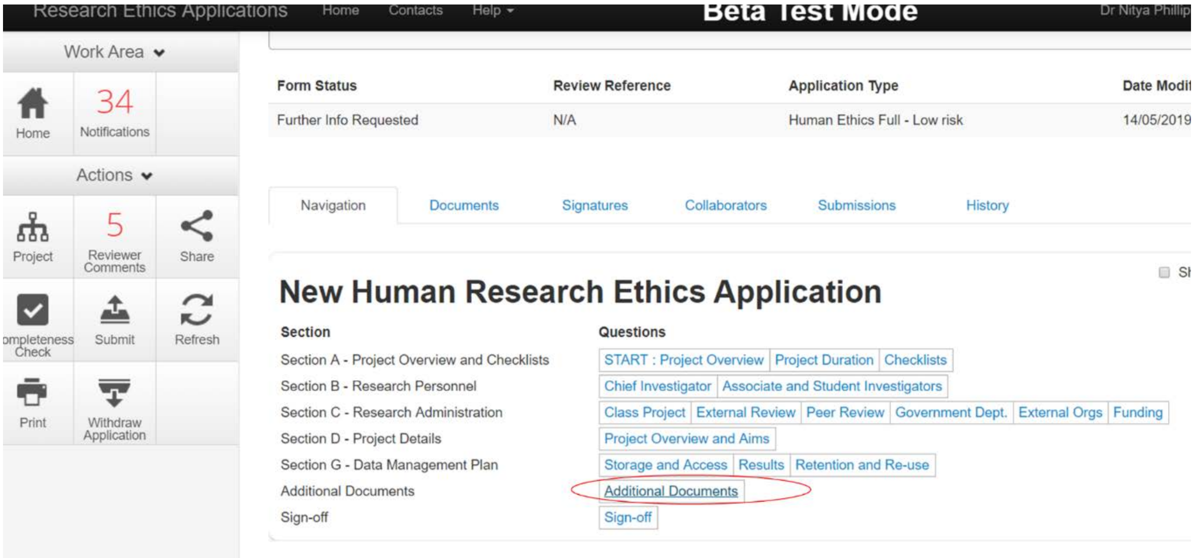


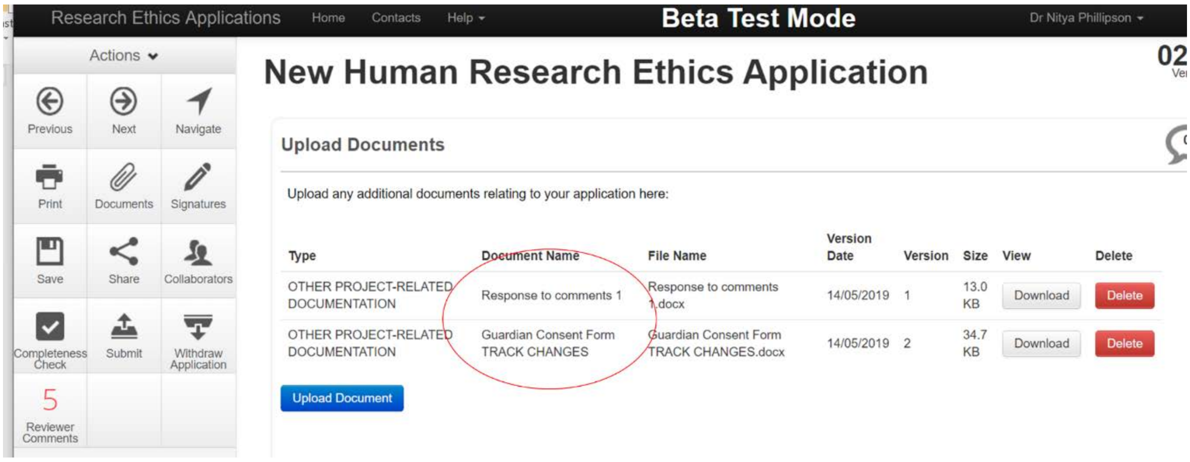


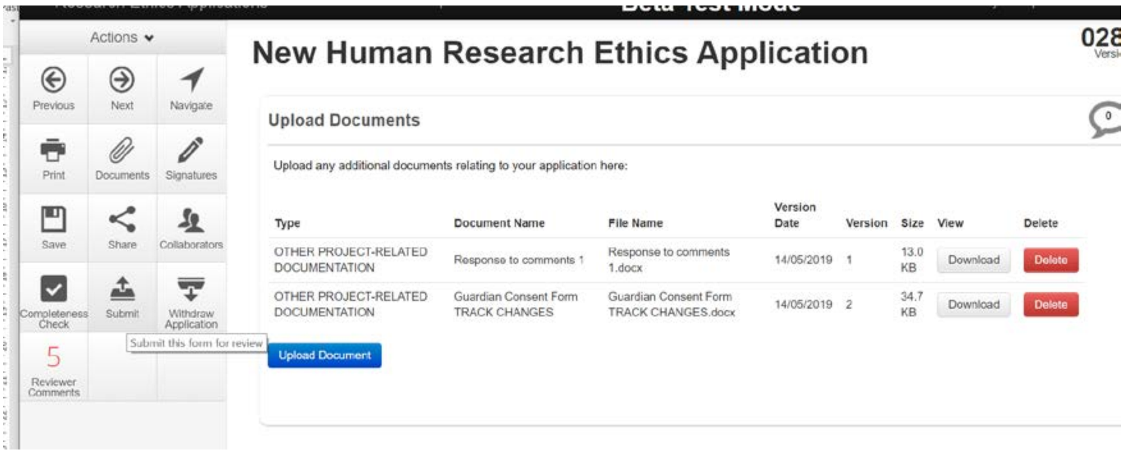


11.3 Upload your responses

- If changes are required to the consent information statement or other documentation use track changes in Word to make any relevant changes to these document
- Upload the “response to queries” document and any amended documents in the upload documents section of the applications
- 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.
- **Resubmit the application**. Note if you are not the CI you will be required to obtain sign off from the CI on this resubmission. To do this see section 6 of this guide.


Research Ethics Applications
Home
Contacts
Help
Beta Test Mode
Work Area
34
Notifications
Home
Actions
Project
5
Reviewer Comments
Share
Completeness Check
Submit
Refresh
Print
Withdraw Application
Form Status
Further Info Requested
Review Reference
N/A
Application Type
Human Ethics Full - Low risk
14/05/2019
Navigation
Documents
Signatures
Collaborators
Submissions
History
New Human Research Ethics Application
Section
Questions
Section A - Project Overview and Checklists
START : Project Overview | Project Duration | Checklists
Section B - Research Personnel
Chief Investigator | Associate and Student Investigators
Section C - Research Administration
Class Project | External Review | Peer Review | Government Dept. | External Orgs | Funding
Section D - Project Details
Project Overview and Aims
Section G - Data Management Plan
Storage and Access | Results | Retention and Re-use
Additional Documents
Additional Documents
Sign-off
Sign-off

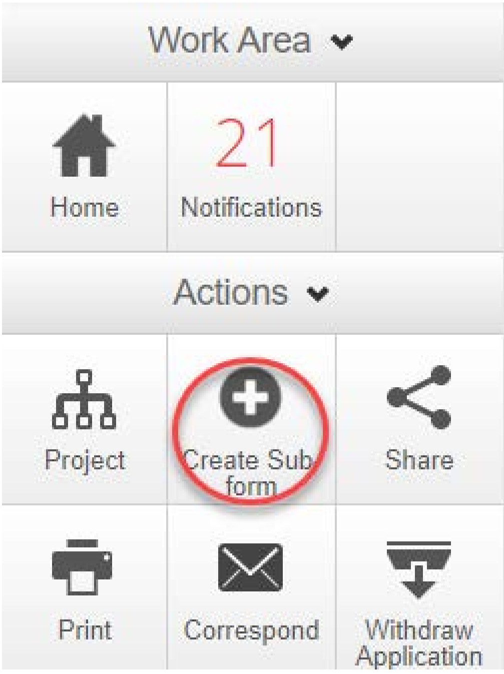

Research Ethics Applications
Home
Contacts
Help
Beta Test Mode
Dr Nitya Phillipson
Actions
Previous
Next
Navigate
Print
Documents
Signatures
Save
Share
Collaborators
Completeness Check
Submit
Withdraw Application
5
Reviewer Comments
New Human Research Ethics Application
Upload Documents
Upload any additional documents relating to your application here:
Type | Document Name | File Name | Version Date | Version | Size | View | Delete
OTHER PROJECT-RELATED DOCUMENTATION | Response to comments 1 | Response to comments 1.docx | 14/05/2019 | 1 | 13.0 KB | Download | Delete
OTHER PROJECT-RELATED DOCUMENTATION | Guardian Consent Form TRACK CHANGES | Guardian Consent Form TRACK CHANGES.docx | 14/05/2019 | 2 | 34.7 KB | Download | Delete
Upload Document


Actions
Previous
Next
Navigate
Print
Documents
Signatures
Save
Share
Collaborators
Completeness Check
Submit
Withdraw Application
Submit this form for review
5
Reviewer Comments
New Human Research Ethics Application
Upload Documents
Upload any additional documents relating to your application here:
Type | Document Name | File Name | Version Date | Version | Size | View | Delete
OTHER PROJECT-RELATED DOCUMENTATION | Response to comments 1 | Response to comments 1.docx | 14/05/2019 | 1 | 13.0 KB | Download | Delete
OTHER PROJECT-RELATED DOCUMENTATION | Guardian Consent Form TRACK CHANGES | Guardian Consent Form TRACK CHANGES.docx | 14/05/2019 | 2 | 34.7 KB | Download | Delete
Upload Document

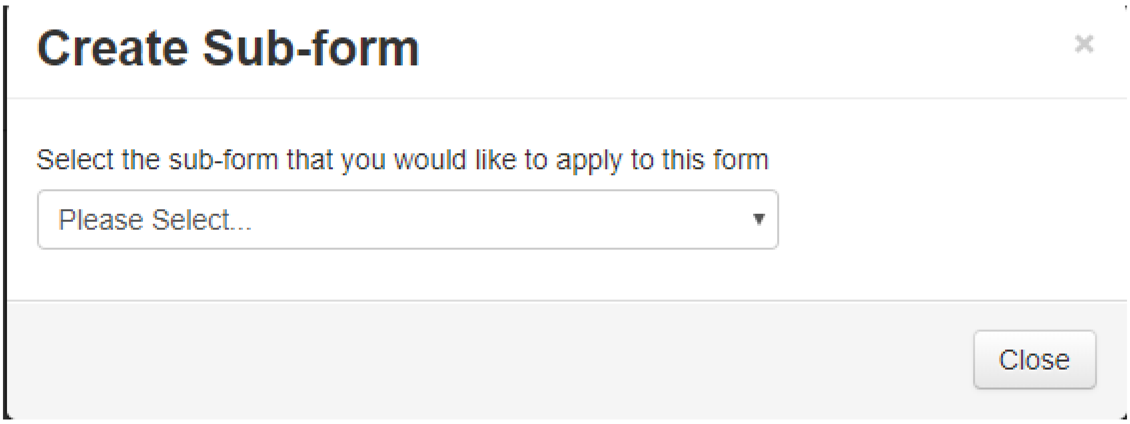
12 Modifications

- **All modifications to approved ethics applications must be submitted and approved prior to implementation**

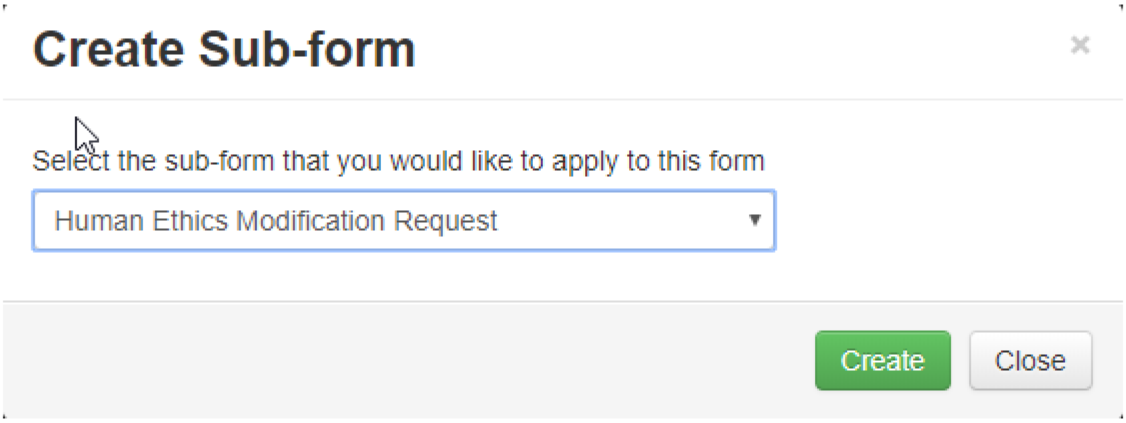
- Select the project you wish to modify
- In the top left-hand corner under ‘Actions’, click on ‘Create Sub-form’



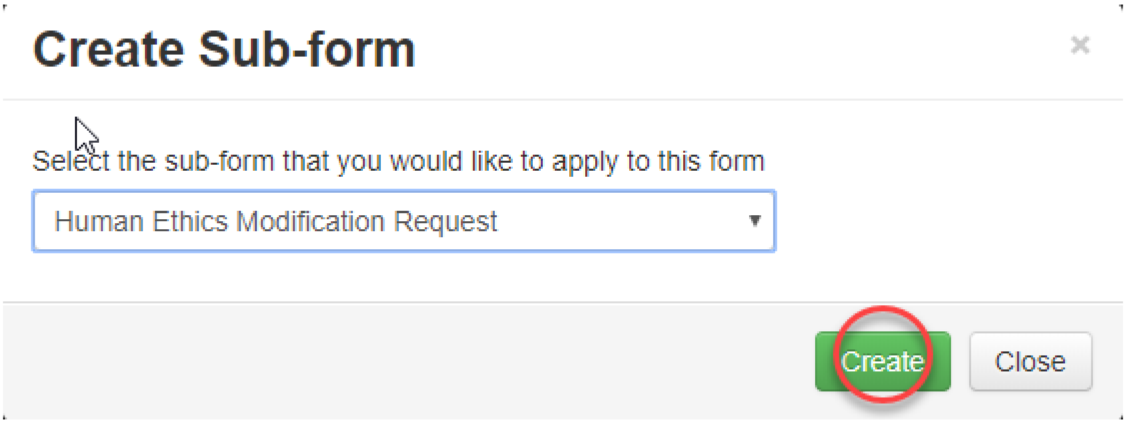
- This will bring up the following



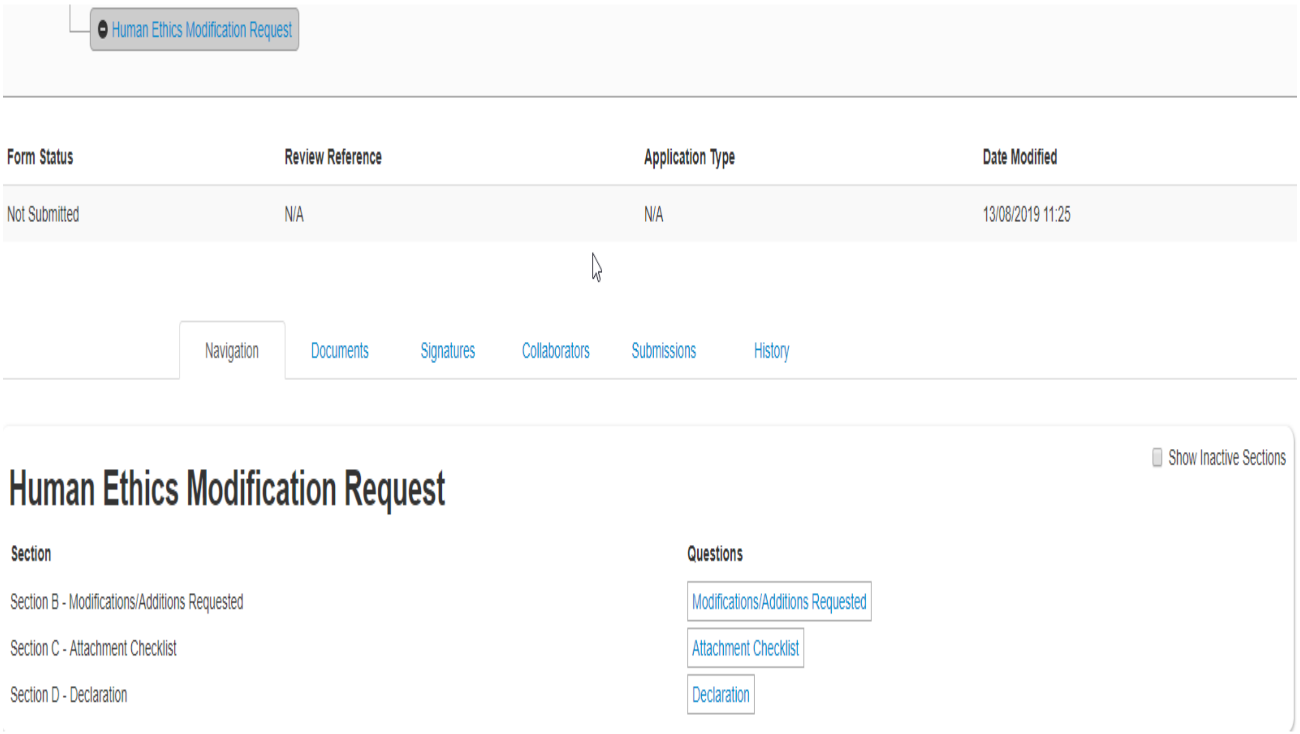
- Select ‘Human Ethics Modification Request’ from the drop-down list



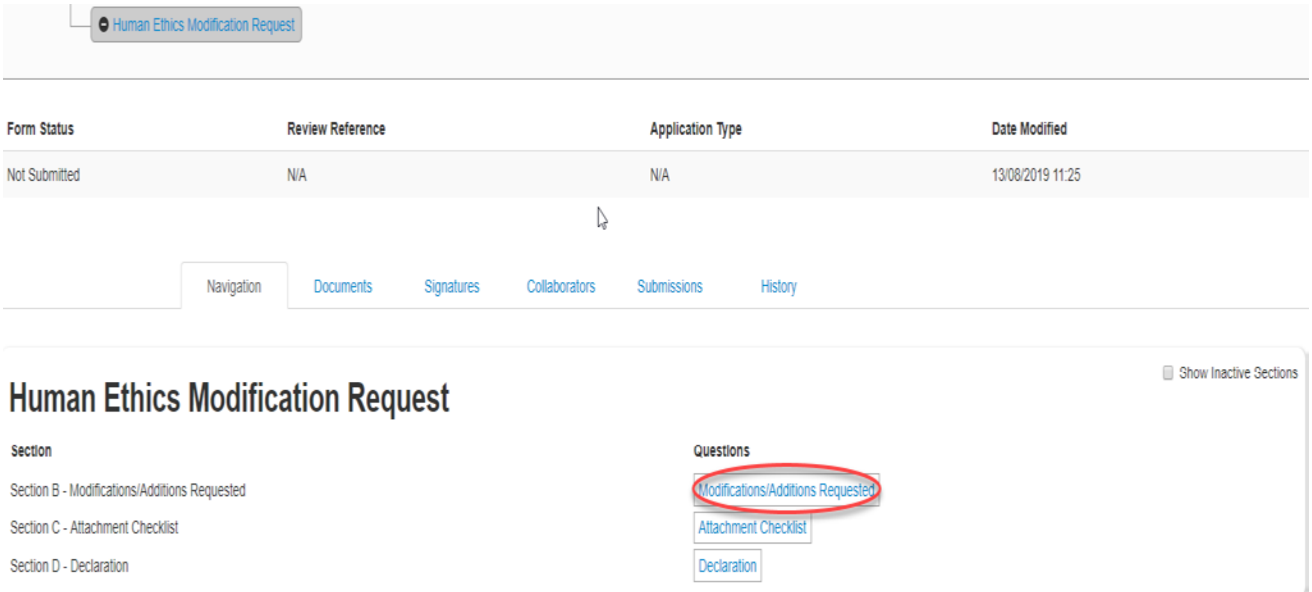
- Then click on ‘Create’



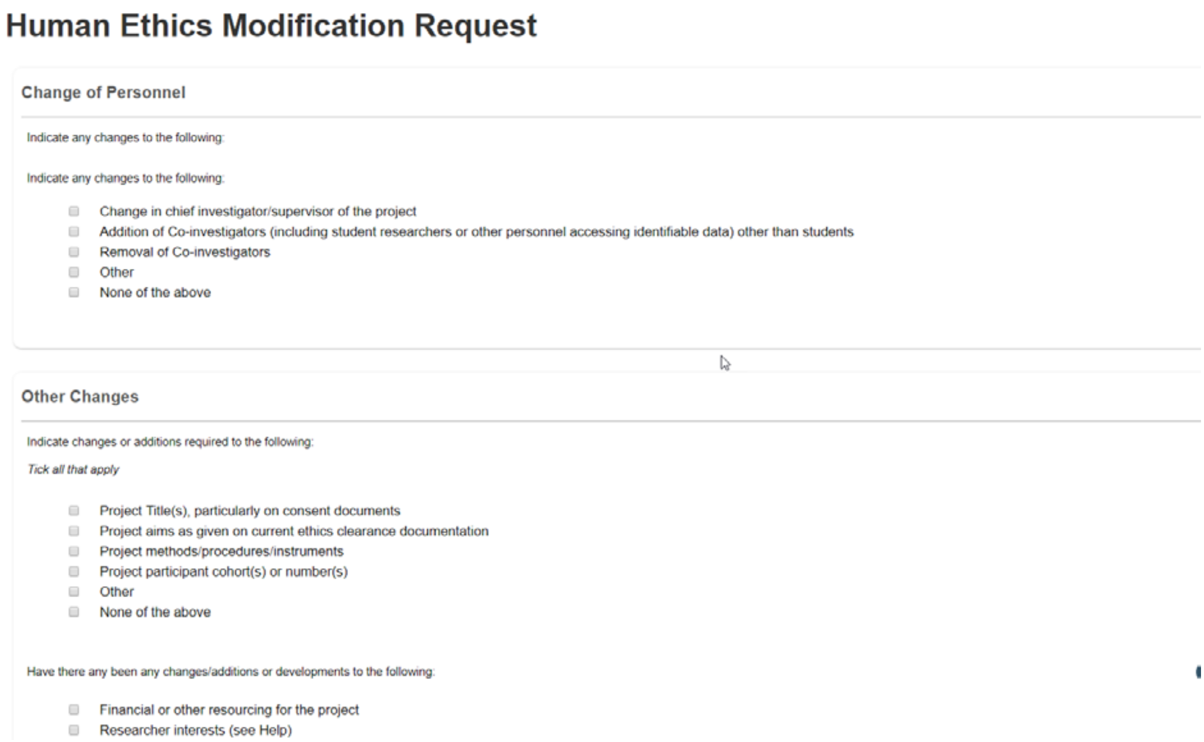
- This will bring up the following



- Click on 'Modifications/Additions Requested'



- This will bring up the following



Human Ethics Modification Request

Change of Personnel

Indicate any changes to the following:

Indicate any changes to the following:

- Change in chief investigator/supervisor of the project
- Addition of Co-investigators (including student researchers or other personnel accessing identifiable data) other than students
- Removal of Co-investigators
- Other
- None of the above

Other Changes

Indicate changes or additions required to the following:

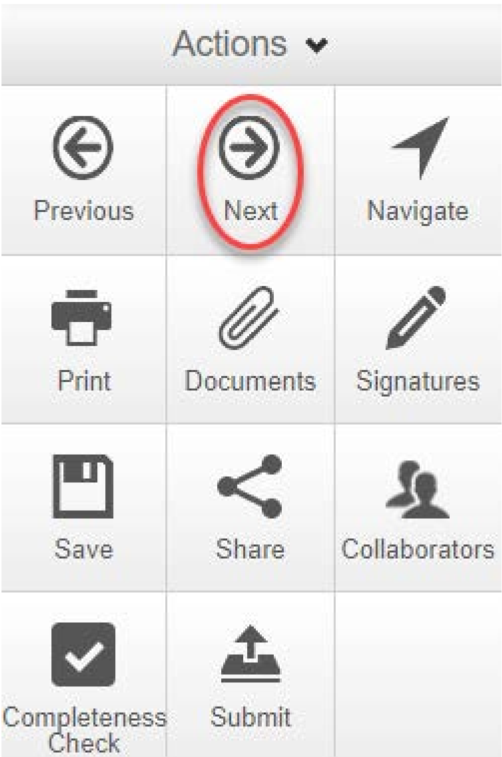
Tick all that apply

- Project Title(s), particularly on consent documents
- Project aims as given on current ethics clearance documentation
- Project methods/procedures/instruments
- Project participant cohort(s) or number(s)
- Other
- None of the above

Have there any been any changes/additions or developments to the following:

- Financial or other resourcing for the project
- Researcher interests (see Help)

- Scroll down and answer the questions and then click on ‘Next’ in the top left-hand corner under ‘Actions’ in order to navigate to the next page



- This will bring up the following

Human Ethics Modification Request

Attachment Checklist

Are any of the following attached?

Tick all that apply

NB. Revised procedures/instruments should preferably be submitted using tracked changes. In addition, a 'clean' version using version control should be submitted. Cross reference attachments to information supplied on this form with clearly delineated/paginated/headed attachments.

- [ ] Additional/revised research instruments (questionnaires, interview schedule, etc.)
- [ ] Additional/revised consent instruments (info statement, consent form, etc.)
- [ ] Additional/revised recruitment or publicity instruments (flyer, advert, etc.)
- [ ] Additional/revised debriefing instrument
- [ ] Additional/revised external permissions/authority
- [ ] Other
- [ ] None of these

- If relevant, click on the relevant documents to be updated and upload them by selecting the 'Upload Document' button

Attachment Checklist

Are any of the following attached?

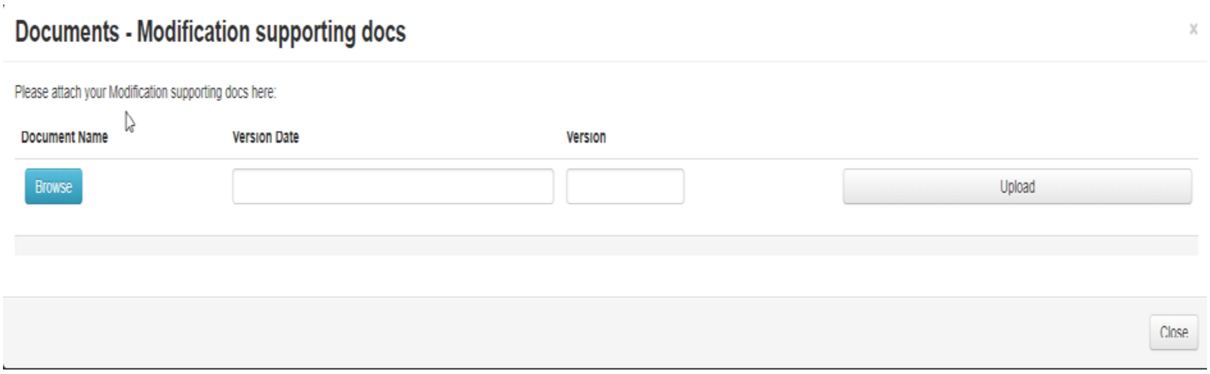
Tick all that apply

NB. Revised procedures/instruments should preferably be submitted using tracked changes. In addition, a 'clean' version using version control should be submitted. Cross reference attachments to information supplied on this form with clearly delineated/paginated/headed attachments.

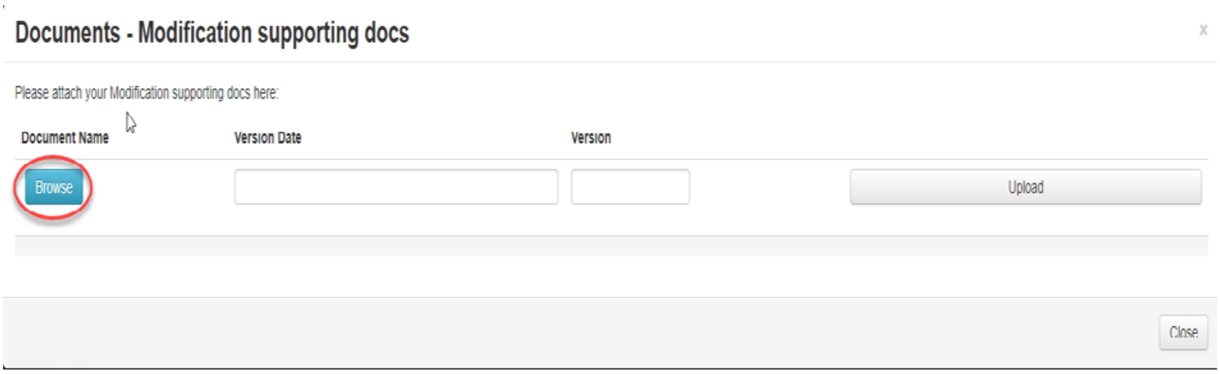
- [ ] Additional/revised research instruments (questionnaires, interview schedule, etc.)
- [x] Additional/revised consent instruments (info statement, consent form, etc.)
- [ ] Additional/revised recruitment or publicity instruments (flyer, advert, etc.)
- [ ] Additional/revised debriefing instrument
- [ ] Additional/revised external permissions/authority
- [ ] Other
- [ ] None of these

Upload Document

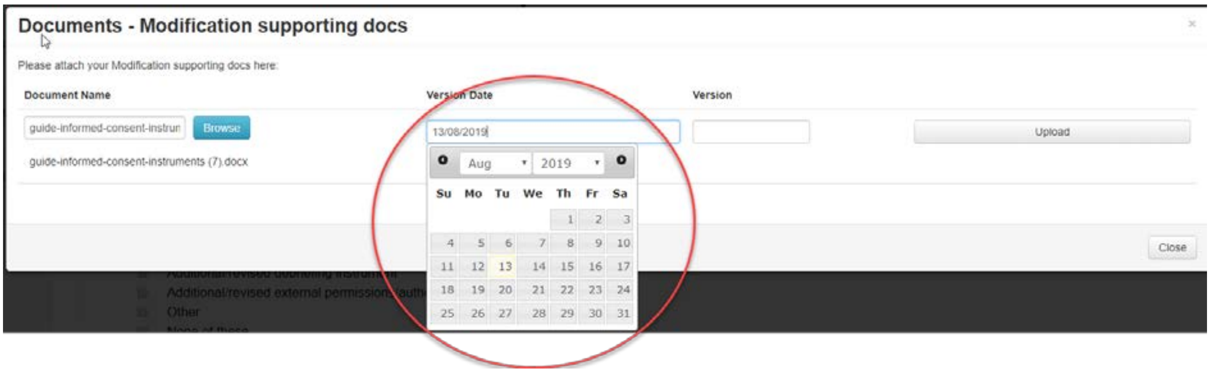
- This will bring up the following



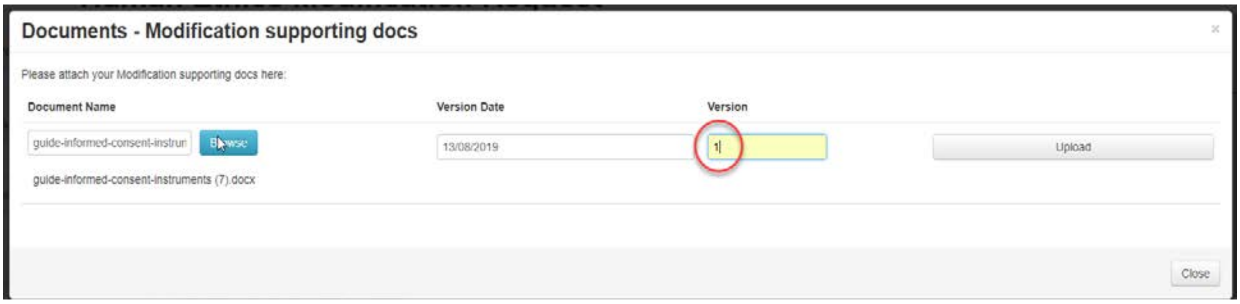
- Click on 'Browse'



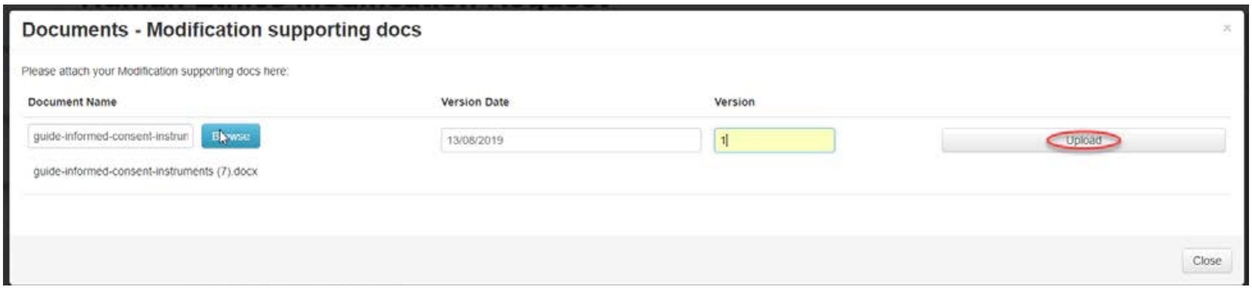
- Select the 'Version Date' from the calendar



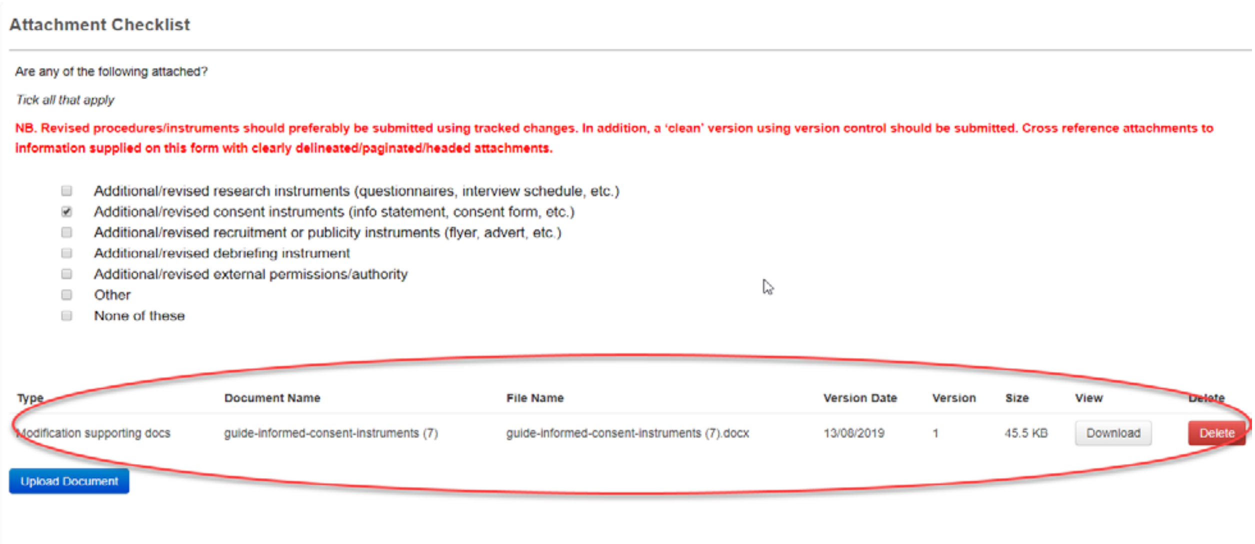
- Enter the ‘Version’ number



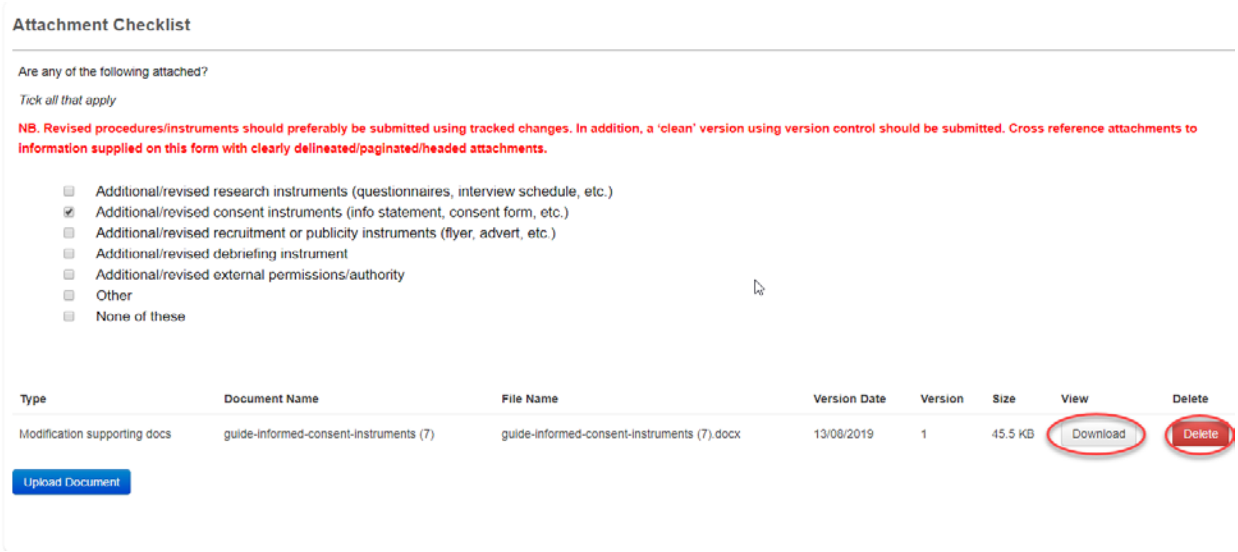
- Click on ‘Upload’



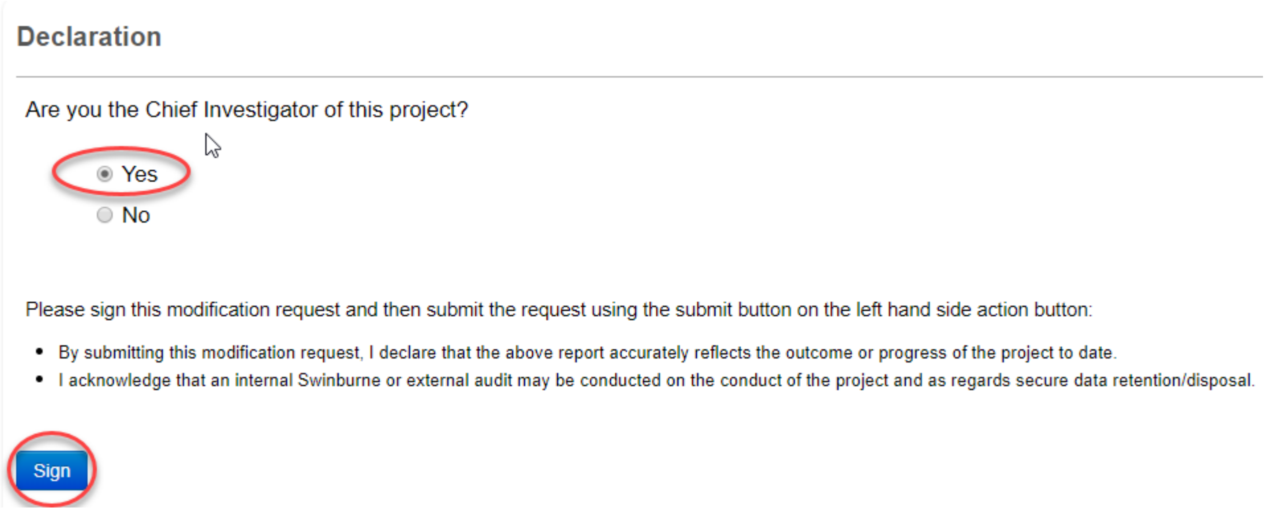
- The uploaded document will then as per the below



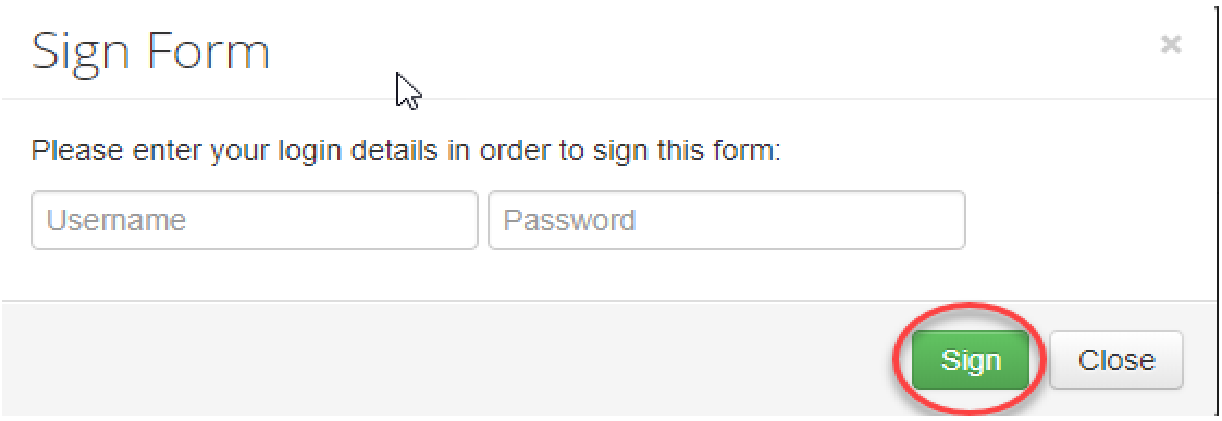
- If you wish to view the document, click on ‘Download.’ If you wish to delete the document, click on ‘Delete’



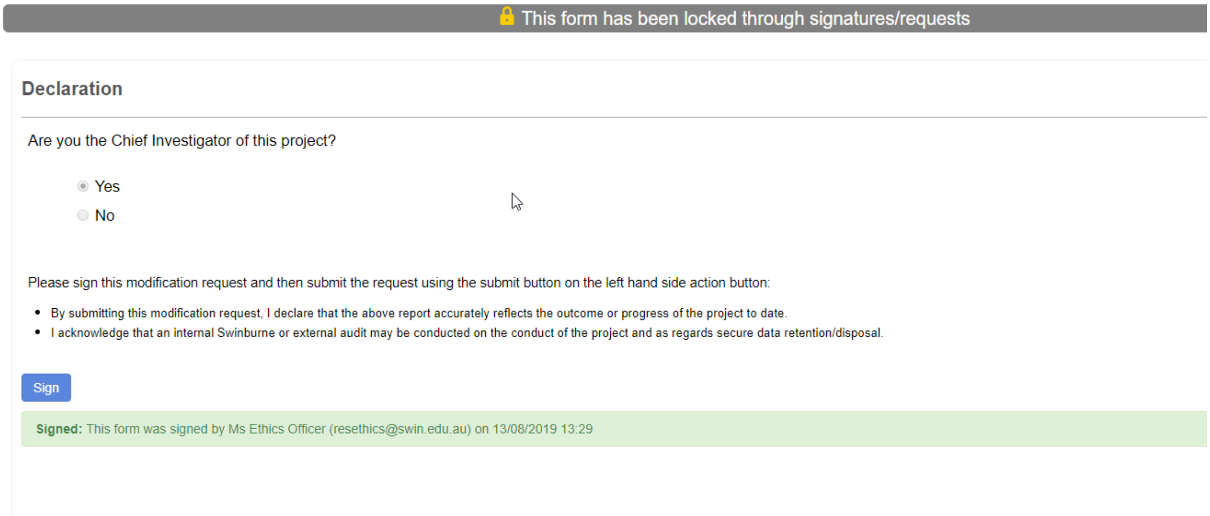
- Click on 'Next' in order to bring up the next page. If you are the Chief Investigator, select 'Yes' and then click on 'Sign'



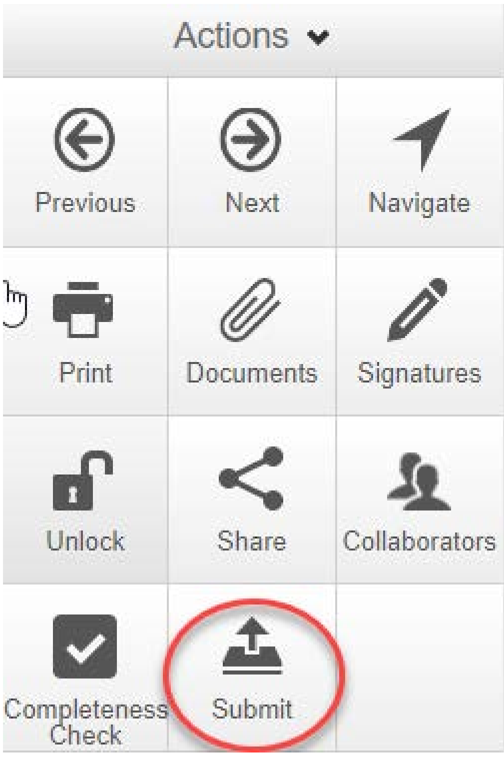
- This will bring up the following. Enter your e-mail address as your Username and enter your password and then click on 'Sign'



- This will bring up the following

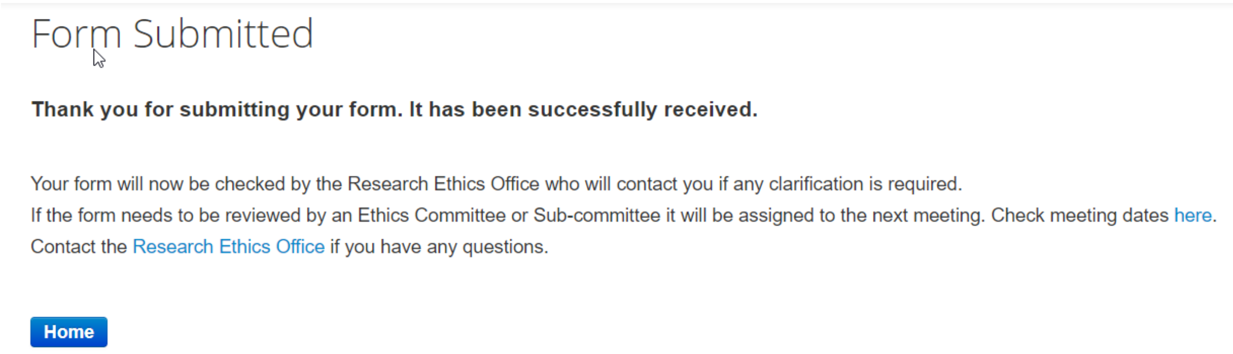


- In order to submit the modification request to the Ethics Office, you then need to click on 'Submit' under 'Actions' in the top left-hand corner

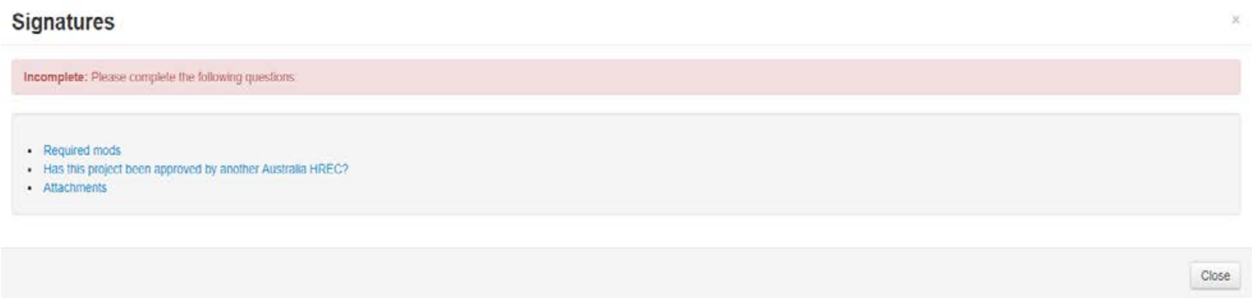


- This will bring up the following. You then need to click on ‘Submit’

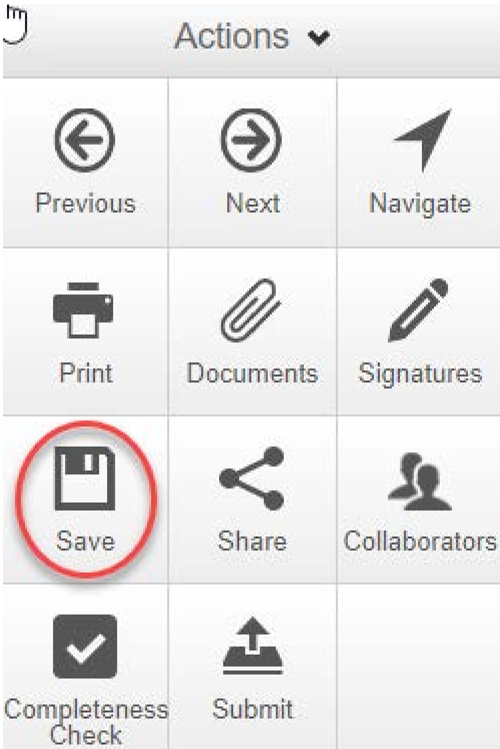
- This will bring up the following



- If some questions haven’t been answered, the following will appear upon sign-off

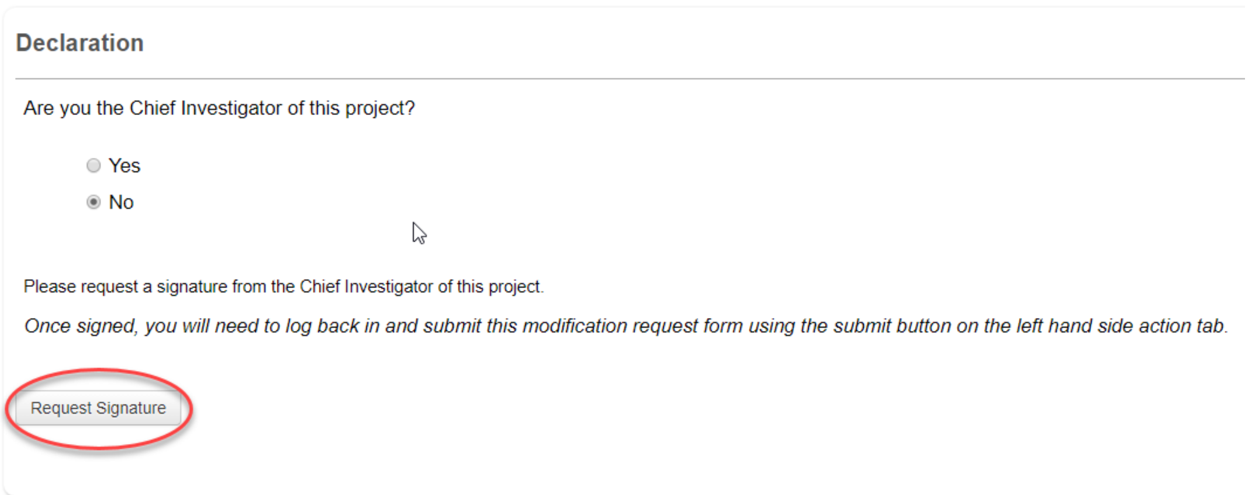


- You will then need to go back and answer these questions, ensuring that you click on ‘Save’ in the top left-hand corner under ‘Actions’ after answering each question



- Once you have answered all of the necessary questions, repeat the sign-off process as per above

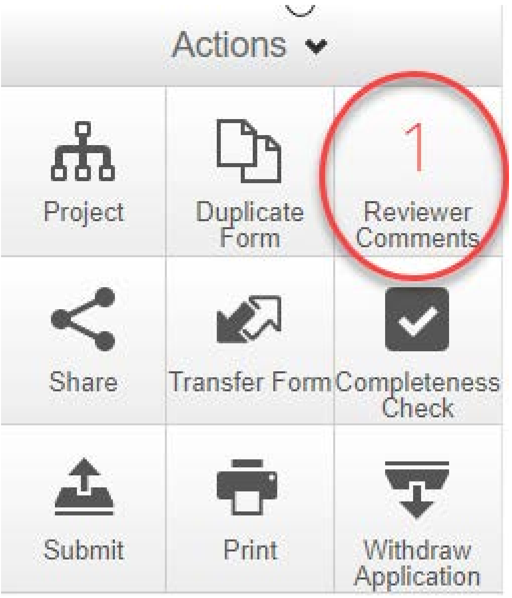
- If you are not the Chief Investigator on the project, you need to indicate this at sign-off and then click on the 'Request Signature' button in order to request the Chief Investigator's sign-off on the request



- This will bring up the following. You then need to enter their e-mail address and, if necessary, a short message. They will then receive a notification from within ERM requesting them to sign off on the request

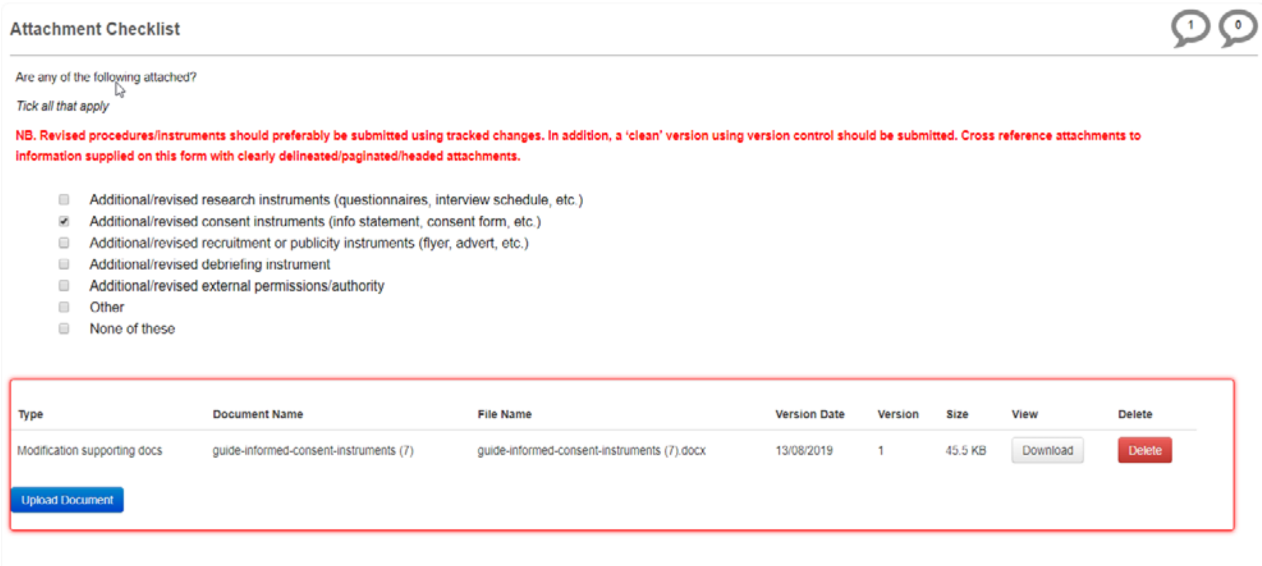
- Once they have signed off on it, you need to log back in and submit the request to the Ethics Office as per the above

- 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 query/ies. You will then need to log into ERM and view the request in question. In order to view the member's query/ies, click on 'Reviewer Comments' under 'Actions' in the top left-hand corner

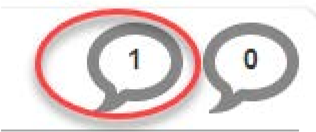


- This will bring up the following

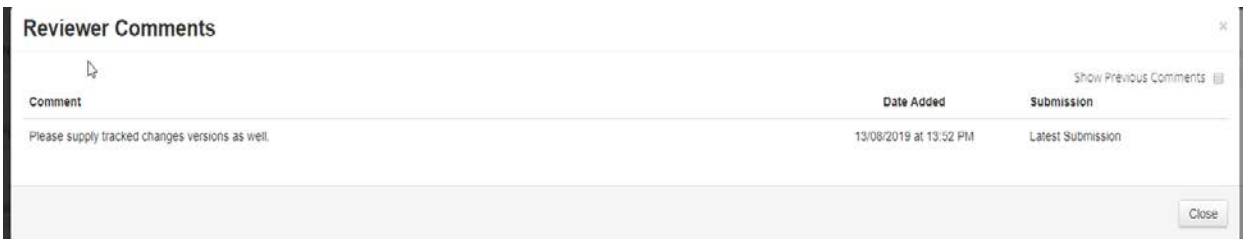
- If you click on the comment/s in question, it will take you to the section being referred to as per the below with the section in question highlighted in red



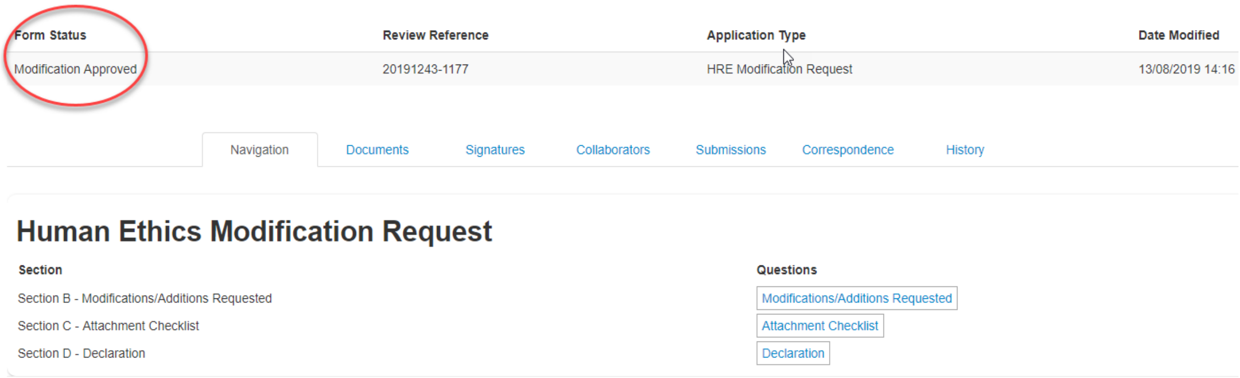
- If you wish to read the comment/s again, click on the speech bubble in the top right-hand corner



- This will bring up the comment

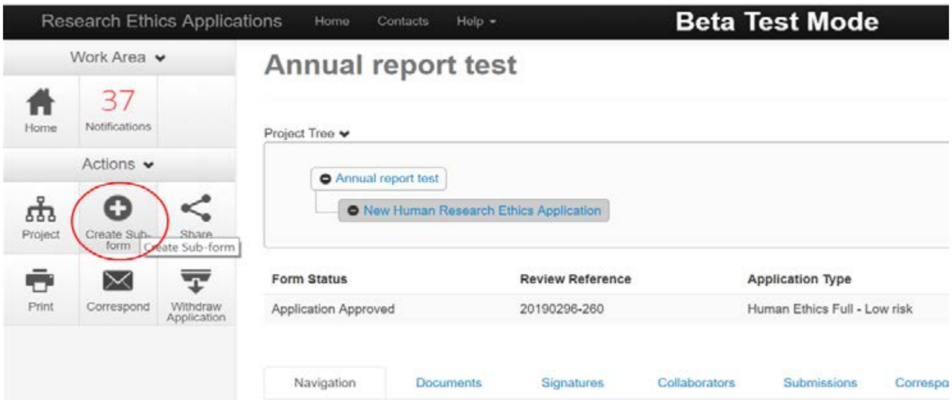


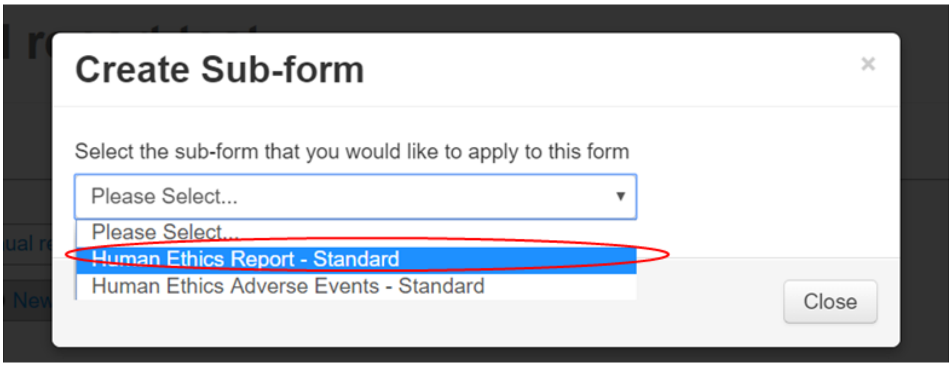
- After you have amended the request as per the member's comment/s, you need to submit the modification request to the Ethics Office as per the process by which it was originally submitted. If the member is satisfied with the revised request, then the request will be approved. If they have further queries, 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



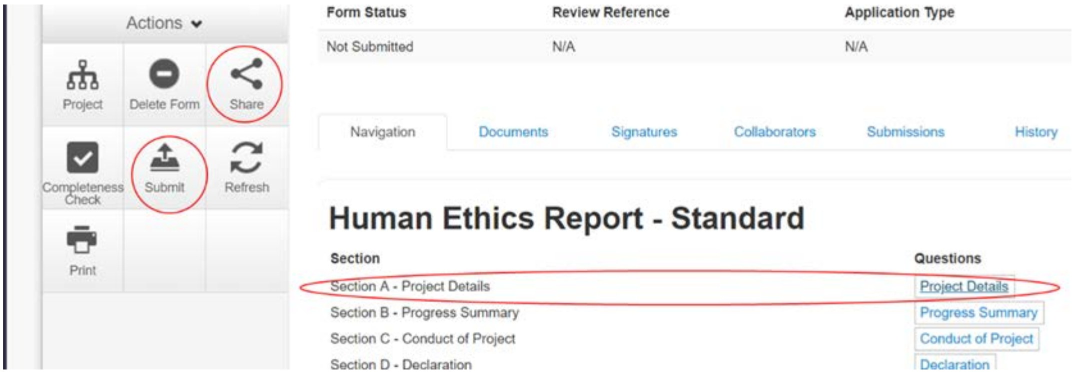
13 Annual/Final Reports

- You will receive an email from the system 30 days before a report is due and the day before a report is due. You will also receive reminder emails after the report is due if you fail to submit one.
- Sign in to ERM and go the project requiring a report (email will indicate project number and title)
- Click on the Create sub form button in the LHS action tab
- Select the Sub form: Human Ethics Report- Standard for projects originally reviewed by Swinburne and Human Ethics Report - Ext. Approved for expedited review projects and click on Create





- For standard expedited review projects, select 'No' under A3 and upload the report that was submitted to the original ethics committee and evidence of this committee's approval of it under A4.
- For expedited review projects that were transferred into Swinburne, select 'Yes' under A3 and work through the rest of the report
- For all other projects, work through the report starting at Section A. Some of this data is auto-generated from the associated ethics application.
- Navigate through the form by clicking the Next or Previous button or Navigate button on the LHS of the Action tab.
- To share the annual report form with investigators click on the Share button on the LHS Action tab. See section 4 on more information on using the Share functionality.
- To submit click on the submit button on the LHS action tab.
- If you have any questions please contact resethics@swin.edu.au



14 Reporting an adverse event

- Sign in to ERM and go to the project requiring an adverse event report
- Click on the Create sub form button in the LHS action tab
- Select the Sub form: Human Ethics- Adverse Events and click on Create
- Work through the report starting at Section A. Some of this data is auto-generated from the associated ethics application
- Navigate through the form by clicking the Next or Previous button or Navigate button on the LHS of the Action tab.
- To share the annual report form with investigators click on the Share button on the LHS Action tab. See section 4 of this user guide for more information on using the Share functionality.
- To submit click on the submit button on the LHS action tab.
- If you have any questions please contact resethics@swin.edu.au