August 2026

Applicant user guide to ERM

Ethical Review Manager (ERM)

OFFICIAL

To receive this publication in an accessible format email Research, Strategy and Clinical Trials at Safer Care Victoria <research@safercare.vic.gov.au>

Authorised and published by the Victorian Government, 1 Treasury Place, Melbourne.

ISBN/ISSN

Available at the Safer Care Victoria website <https://www.safercare.vic.gov.au>

Contents

Glossary

CPI	Coordinating Principal Investigator. Overall responsibility for the research project and submits the project for scientific and ethical review
CRO	Contract Research Organisation (may act as local sponsor for non-Australian entities).
CTA	Clinical Trial Approval scheme (scheme's previous name Clinical Trial Exemption (CTX))
CTN	Clinical Trial Notification scheme
CTRA	Clinical Trial Research Agreement
CV	Curriculum Vitae
FDA	Food and Drug Administration (in USA)
GCP	Good Clinical Practice
HREA	Human Research Ethics Application
HREC	Human Research Ethics Committee that has been certified under the NHMRC National Certification Scheme, and be a Certified Reviewing HREC under the NMA scheme
IB	Investigator Brochure
ICH-GCP	International Conference on Harmonisation – Good Clinical Practice
LARF	Legacy Application Replacement Form
MDF	Minimal Dataset Form
NHMRC	National Health Medical Research Council
NMA	National Mutual Acceptance (NMA) is a system for mutual acceptance of scientific and ethical review of multi-centre human research projects conducted in publicly funded health services across jurisdictions. Australian Capital Territory, New South Wales, Northern Territory, Queensland, South Australia, Tasmania, Victoria and Western Australia participate in NMA
PI	Principal Investigator. Responsible for the project at a site
PICF	Participant Information Consent Form
QA	Quality Assurance application
RGO	Research Governance Officer
SSA	Site Specific Assessment
VSM	Victorian Specific Module

1 Introduction

Ethical Review Manager (ERM): https://au.forms.ethicalreviewmanager.com/

1.1 About ERM

ERM is a paperless information management system for completion, submission and storage of:

- ethics applications
- research governance/site specific assessment (SSA) applications
- post-approval (ethics) forms
- post-authorisation (research governance) forms.

ERM is used by research applicants (researchers, trial coordinators, sponsors, contract research organisations etc.). It is also used by Research Office administrators and ethics committee members to manage the review, processing and approval/authorisation of all applications.

The communication features of ERM ensure that the entire life-cycle of a research project can be managed within the ERM system.

ERM is used for all ethics and research governance/SSA applications to public health organisations in Victoria and Queensland. Some private health organisations also use ERM – for details, consult the organisation's Research Office.

Who uses Ethical Review Manager (ERM)

ERM can be used by anyone involved with an ethics or research governance/SSA application, including:

- Coordinating Principal Investigator (or delegate/s)
- Principal Investigators (or delegate/s)
- Sponsors/Contract Research Organisations/Trial Coordinators

ERM is a secure password-protected website. Each user must create their own private account.

1.2 Create an account

Go to the ERM website https://au.forms.ethicalreviewmanager.com/

To Log in: Click 

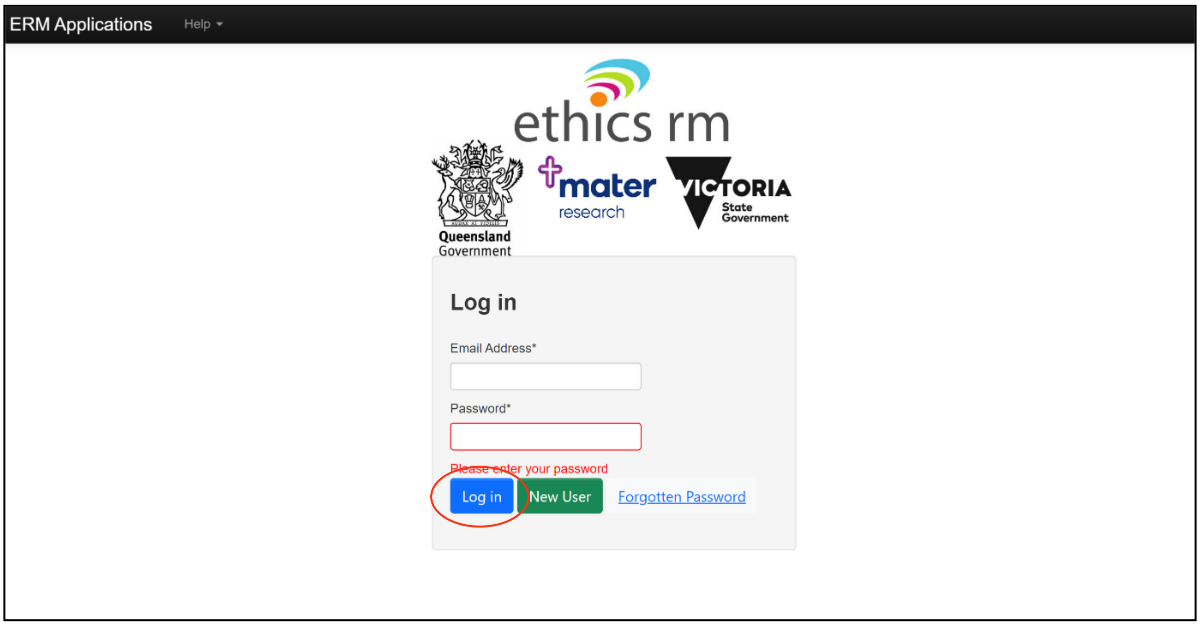
Note: Online Forms was the precursor to ERM. Online Forms account holders may already have an ERM account and can use the same login details.

For users with no previous Online Forms account:

1. Select **New User**
2. Enter the information and agree to the Terms and Conditions.
3. Click **Register** and a verification email is sent to the entered email address
4. Select the activation link in the email
5. Click **Log in**
6. Log in with your email address and password

Log in

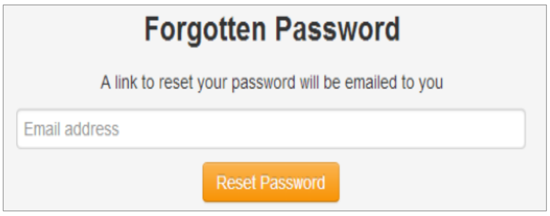
Bookmark the ERM Splash page to keep up to date with recent updates and outages



1. Enter your email address and password
2. Select **Log in**

Forgotten password

When logging in as an applicant, if the password entered is incorrect an error message will appear

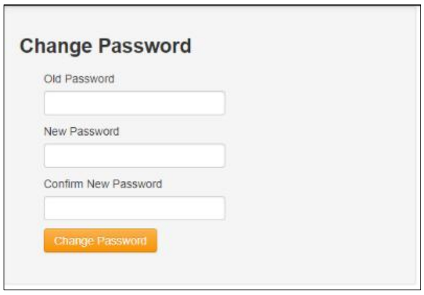


- Select **Forgotten Password**
- Enter the email address of the account to be signed into
- Select **Reset Password**
- An email will be sent with a link to change the password. Enter the new password and select **Reset Password**
- A Message box will be displayed confirming the password change
- Select the link to return to the login page

Changing password

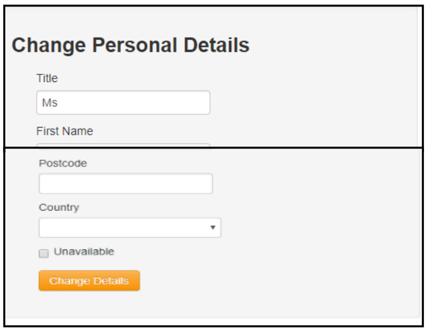
- Log in with usual account details
- Select the account name located on top-right of browser

- Select **Change Password**
- A Change Password message box will be displayed
- Enter old and new password
- Select **Change Password**

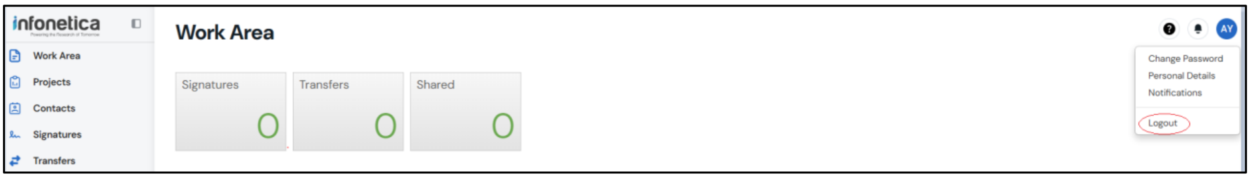


Changing personal details

- Log in with usual account details
- Select the account name located on top-right of browser
- Select **Personal Details**
- A Change Personal Details message box will be displayed
- Enter changes to personal details
- Select **Change Details**

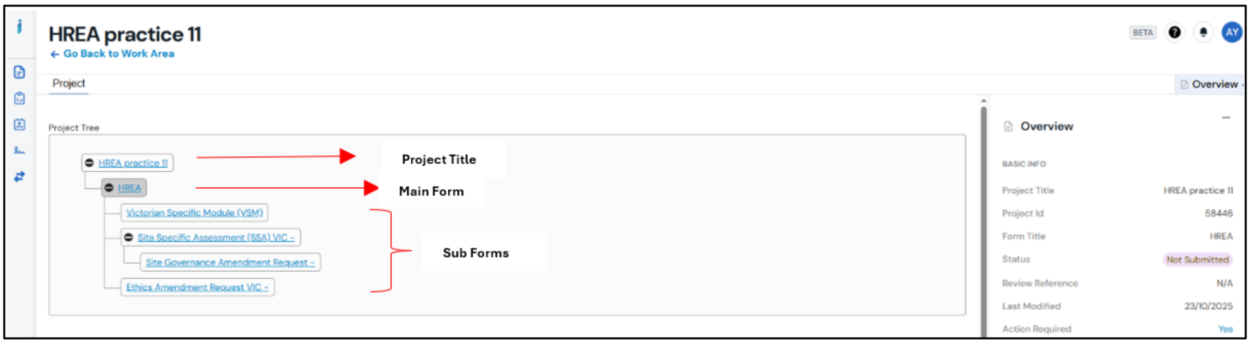


Log out



- Select arrow at right edge of account name
- Select **Logout**

1.3 ERM forms



- ERM is based on **forms**. The applicant creates a **project** and a **main form** simultaneously
- From the **main form**, the applicant can create **sub-forms** e.g. Ethics Amendment Request, SSA form.
- From some sub-forms (SSA and Low Risk VIC SSA) further sub-forms can be created e.g. Site Governance Amendment Request, Site Progress Report and Site Notification Form
- A summary of the forms available in ERM is displayed in the tables below.

Main forms

There is only one main form for each project.

Form	Description
Human Research Ethics Application **(HREA)**	Ethics application form
Victorian Low Risk Form **(Low Risk VIC)**	Ethics application form for low risk research in Victoria; used at selected organisations only
Quality Assurance Application Form **(QA)**	Application form for quality assurance or clinical audit in Victoria; used at selected organisations only
Minimal Dataset Form **(MDF)**	Proxy for an ethics application form; used when the ethics review was performed in a state/territory that does not use ERM; allows creation of SSA form(s) in ERM
Legacy Application Replacement Form **(LARF)**	Proxy for an ethics application form; used when an old project (approved before July 2018) is not in ERM nor reviewed under NMA; allows creation of Sub-form(s) in ERM for Victoria only

Sub-forms for initial application

Form	Description
Victorian Specific Module **(VSM)**	Required as part of the ethics application when the HREA is utilised and the research project involves a site in Victoria; addresses Victorian legislation
Site Specific Assessment **(SSA)**	Research governance application form; one SSA is required for each site participating in a research project
Victorian Low Risk Site Specific Assessment **(Low Risk VIC SSA)**	Research governance application form; one Low Risk VIC SSA is required for each site participating in a research project

Sub-forms for post approval

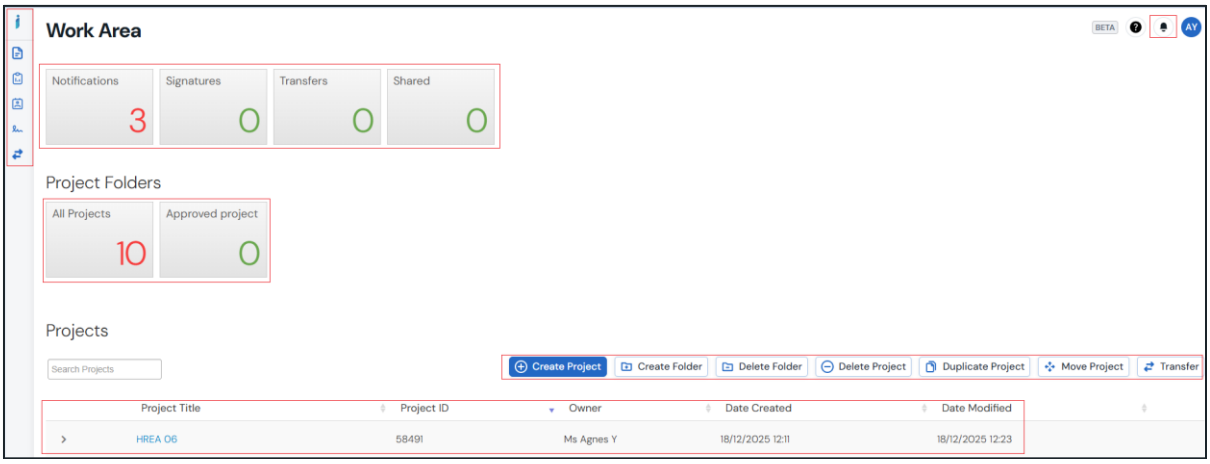
Form	Description
Ethics Amendment Request	Request ethical approval for a change to the design or conduct of a research project e.g. the protocol, PICF or change to personnel
Safety Report	Report a safety event to the reviewing ethics committee
Annual Safety Report	Report to the reviewing ethics committee on the safety profile of an interventional clinical trial
Serious Breach Report	Report a serious breach to the reviewing ethics committee
Suspected Breach Report	Report a suspected breach to the reviewing ethics committee
Project Progress Report	Report to the reviewing ethics committee on the progress of a research project (at least annually, may be more frequent if requested)
Site Closure Report	For a multi-site project, report the closure of one participating site to the reviewing ethics committee
Project Final Report	Report to the reviewing ethics committee on the progress of a research project at the time of its completion
Low Risk Notification	Report to the reviewing ethics committee on post reporting requirements; amendments, progress reports, site audit reports and a final report.
Project Notification Form	Report to the reviewing ethics committee on any matters for which there is not a specific post-approval form available

Sub-forms for post authorisation

Form	Description
Complaint Report	Report a research project complaint to the site's research governance officer
Non-serious Breach/Deviation Report	Report a non-serious breach/deviation to the site's research governance officer
Site Audit Report	If requested by the site's research governance officer, provide a self-audit of the research project
Site Notification Form	Report to the site's research governance officer on any matters for which there is not a specific post-approval form available
Site Progress Report	Report to the site's research governance on the site's progress of a research project (at least annually, may be more frequent if requested) **or** can be adapted and used as a Site Final Report to report to the site's research governance office on the progress of a research project at the time of its completion
Site Governance Amendment Request	Notify the research governance officer of either an amendment that has been approved by the reviewing ethics committee **or** a governance-only amendment that does not require ethical approval

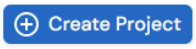
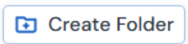
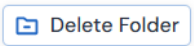
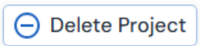
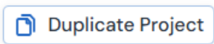
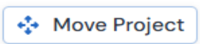
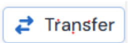
2 Work Area

The Work Area is the ERM home page. The middle part of the screen displays the Actions pane with action buttons below. The right of the screen displays an overview of projects in the user's ERM account.



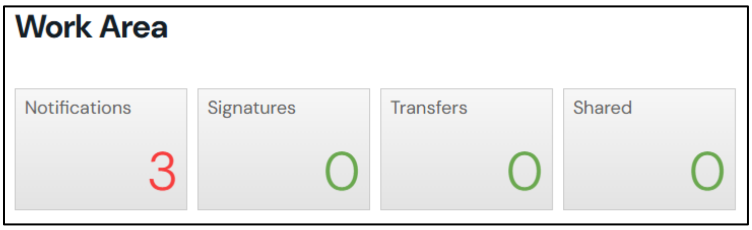
2.1 Actions

There are seven action buttons under the Actions pane

	Create a new project
	Create a bespoke folder for storage of projects
	Delete a folder (only possible if the folder is empty)
	Delete a project (only possible if the main form has **not** been submitted via ERM)
	Duplicate an existing project
	Move a Project filed in Folders to the Work Area. The Project will be listed with other current projects under Project Title
	Permanently transfer a project to a colleague

2.2 General

There are four tiles in the **General** section. If the tile displays a red number, it may contain items that require attention.



Notifications

- Contain messages that are sent to the user from the Research Office:
  - queries or request for information regarding an application
  - approval letters
- Messages automatically generated by ERM e.g. form updates

- Messages from other research team members/collaborators
  - the user has been assigned a level of access to a form
  - a change in the access status of a form
  - an electronic signature has been requested
  - a form has been signed electronically by the signatory

Signature

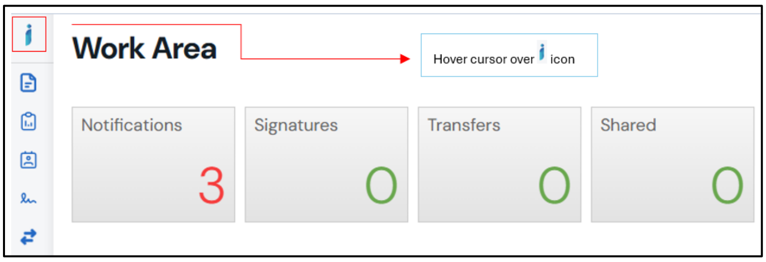
- Contain requests from colleagues to digitally sign an application i.e. a request for an electronic signature

Transfers

- Contain requests to transfer a project to another ERM user

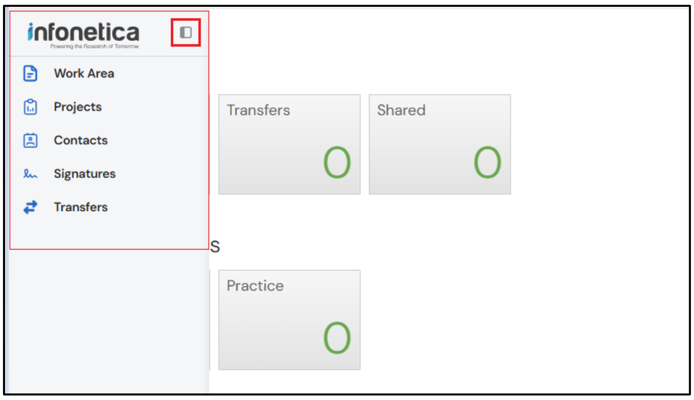
Shared

- Contain information about forms and level of access another ERM user has shared with you



Side Menu

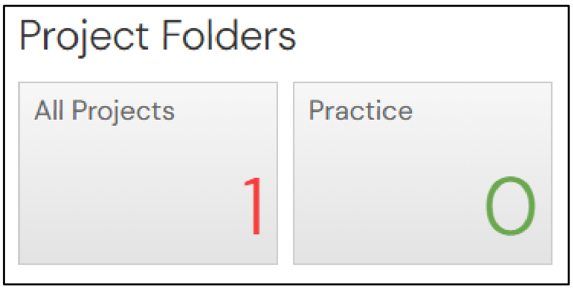
- Hover cursor over to open side navigation bar
- Side navigation bar can be locked in place or unlocked by clicking on



2.3 Folders

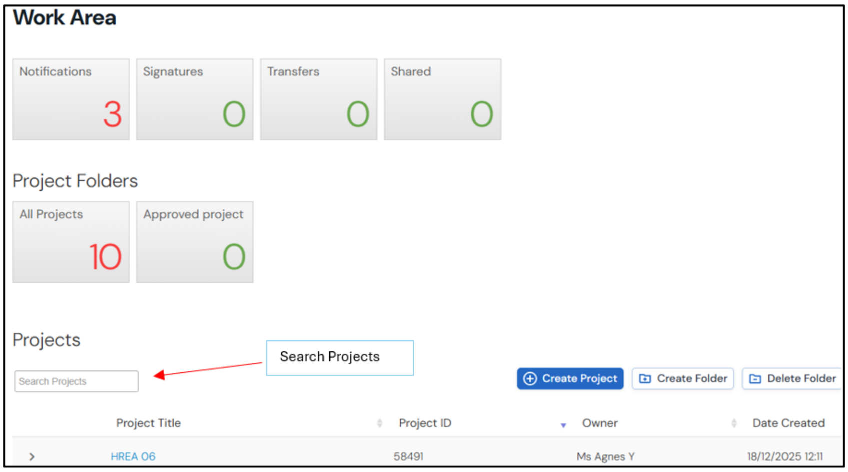
Displays bespoke folders for storage of projects.

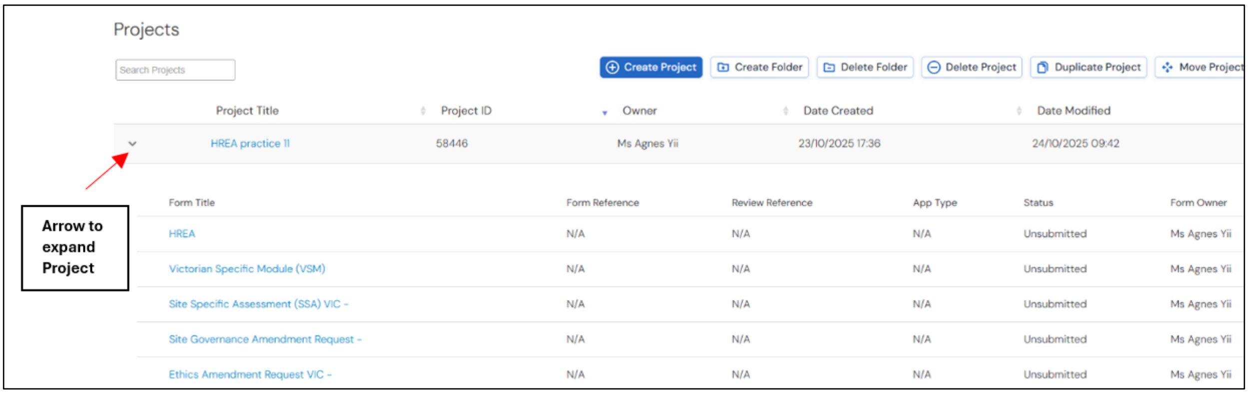
All Projects folder is automatically created when at least one project is stored in a folder.



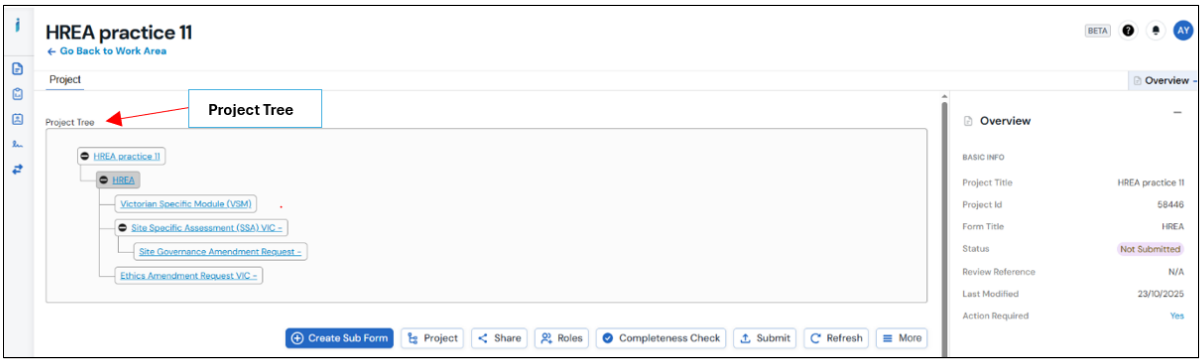
2.4 Projects

- Projects in the user's ERM account are listed under **Projects**
- To access a project begin typing the project's title in the **Search Projects** text box. Select a project from the list displayed. User can also search for projects in search section





- To expand a **Project** from the **Projects** list, select the arrow next to the **Project Title.** Created/associated forms will be displayed with their form reference, review reference, application type, status and name of the form owner
- Each row includes a link directly to that form's index page allowing for quick access into the form
- The project will open under a **Project Tree**



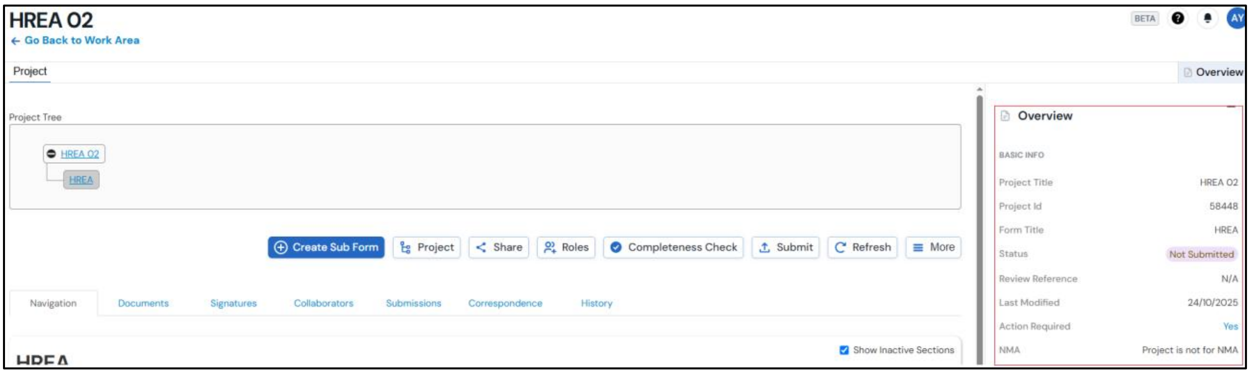
2.5 Actions pane

There are eleven possible action buttons available under the Actions pane, with some available under **More** button. The actions are listed below, in no particular order:

Submit	Submit the application to the reviewing organisation. Note: the reviewing organisation must be selected **within the form**, in order for the submission to be directed to that organisation.
Completeness Check	Identify mandatory questions within the form that require information to be entered
Create Sub Form	Create a Sub-form from the main form e.g. SSA
Project	Go to the Project overview
Share	Enable collaborators to view, edit and manage the form
Roles	Enable collaborators to view, edit and manage the form
Refresh	Refresh
NMA Project	Record that the project falls within the National Mutual Acceptance (NMA) scheme. Information on NMA is available on the Safer Care Victoria Research website.
View as PDF	Generate a PDF of the form for printing or save as soft copy
Correspond	Communicate directly with the Research Office selected as the reviewing organisation within the form **only after** the form has been submitted
Import Xml	Import a HREA created on a different website e.g. hrea.gov.au, as an Xml file into ERM
More	Expand to reveal some of the above action buttons

2.6 Overview panel

The Overview panel has information which displays the current activity of the form.



Overview panel can be hidden or displayed by clicking on Overview – or Overview +

Action Required - if any actions are required by the user

Action Required	Explanation
Yes	To run a ‘Completeness Check’ to identify any incomplete sections To identify whether comments have been added by the reviewing Research Office if returned for resubmission or if there’s any reason preventing the form from being submitted.
No	The form is ready to be submitted or has been submitted.

Status - indicates the status of the form

Status	Explanation
Not Submitted	The application is still in progress
Submitted	The application has been submitted to the reviewing organisation
Recalled	The application has been recalled by the user to make changes and is only possible if the reviewing organisation has not started processing the application
Queried	The application has been queried by the Research Office for further clarification or edits
Archived	If there is a resubmission of an application, the previous submission (v1) becomes ‘archived’ and is no longer the most recent submission. The most recent submission becomes (v2)
Validated	The application is ready for review by the ethics committee
Information Requested	The ethics committee has requested further clarification or information
Approved	The application has been approved by the reviewing ethics committee

Review Reference – unique identification code

This unique identification code for a form is generated when an application is submitted in ERM.

It is composed of six parts -

① ② ③ ④ ⑤ ⑥

e.g. HREC/74950/VICTEST-2021-257683(v1)

	Component	Description	Examples
1	Application type	Identifies the type of application form	HREA, Low Risk VIC, MDF, SSA
2	ERM Project ID	The unique identification number for the research project	74950
3	Organisation/hospital code	The organisation/hospital to which this form was submitted	Austin, RCH, VICTEST
4	Year	Year of submission	Can change when a new form version is submitted in the following year
5	Submission number	System identifier for the particular submission of this form	257683
6	Version number	Version number to track submission history	V1 to v2 to v3

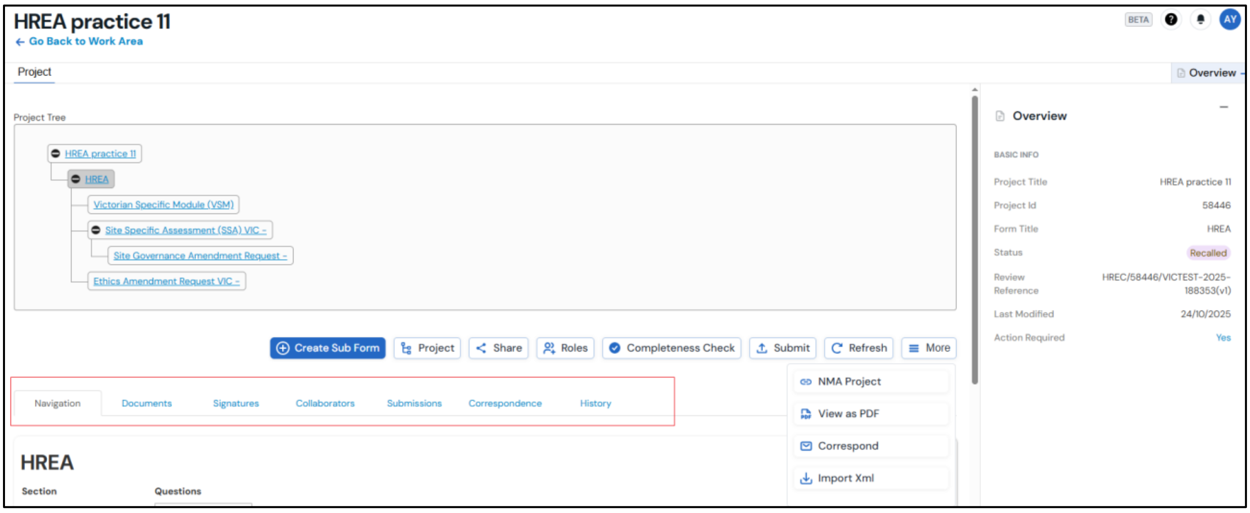
Application Type - Identifies the type of application/form submitted

- Ethics Application (the HREA)
- Low Risk application
- Quality Assurance
- SSA

Date Modified - Displays the most recent date a form was updated

NMA - Whether the research project/application will be reviewed under National Mutual Acceptance (NMA) scheme or not.

2.7 Tab functions



There are seven tabs that cover specific aspects of the application and its submission process

Tab	Explanation
Navigation	Application form is completed under Navigation tab
Documents	Displays all supporting documents that have been uploaded within the form Note: Documents are not uploaded under this tab; documents are uploaded within the relevant section of the form
Signatures	Shows a history of all digital signatures that have been applied to the form, and all signature requests
Collaborators	Displays members of the research team and their level of access to the form
Submissions	Shows a history of all submissions that have been made via ERM
Correspondence	Displays a record of the communication between the user and the reviewing organisation's Research Office
History	An auditable history of actions; if the form has been submitted, an archived version of the submission is available here.

Each tab is described below:

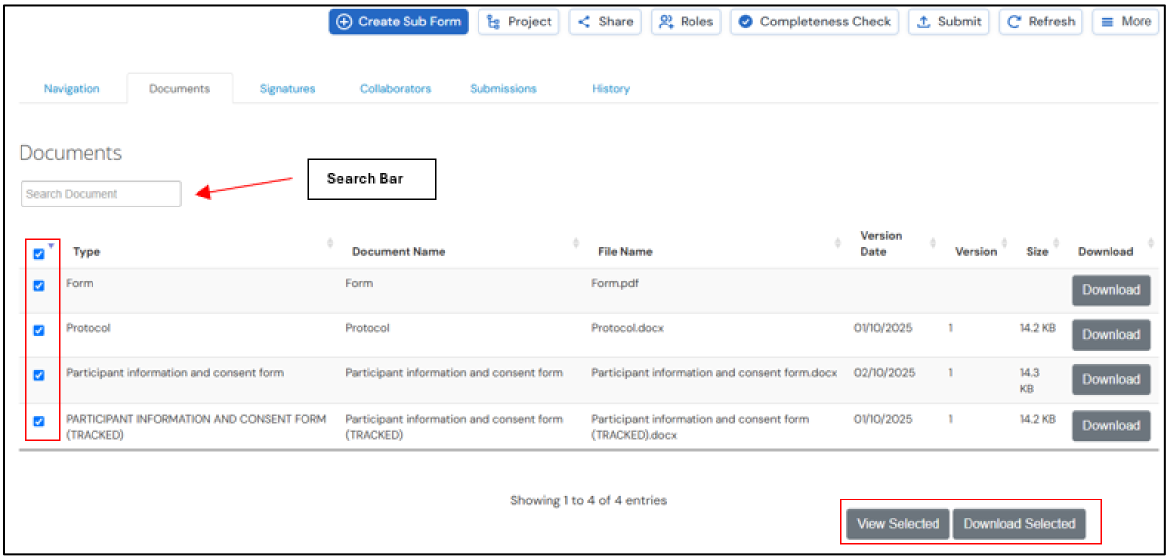
Navigation

- The Navigation tab displays the sections and associated questions within the form. Sections will become accessible or inaccessible depending on the information relative to the application
- Questions are hyperlinked (in blue) for quick navigation to the relevant section within the form

Documents

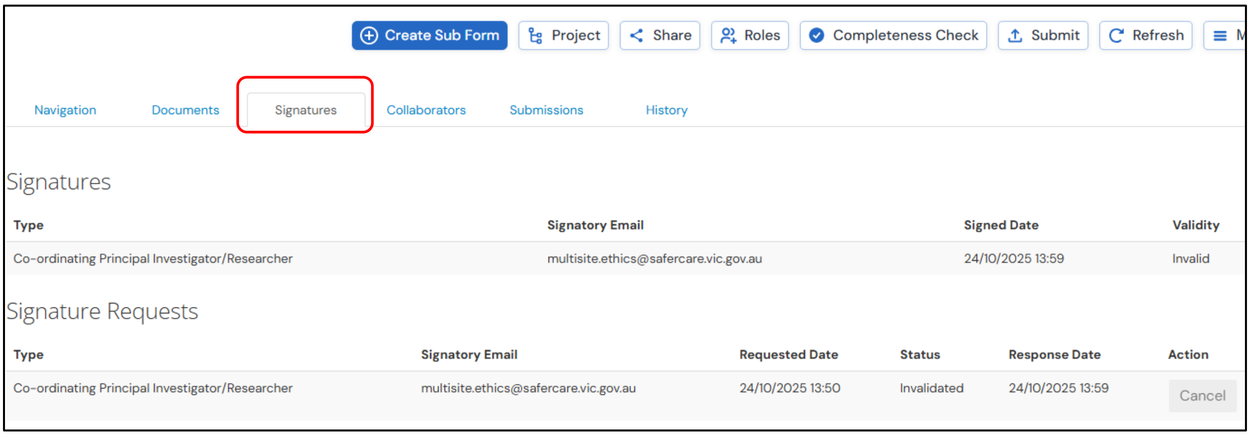
- The Documents tab displays current supporting documents that have been uploaded into a form. The details displayed indicate the document type, name, file name, version date and number

- A column of checkboxes allows documents to be selected or deselected
- Select any combination of documents to either open as a PDF in a new browser using the **View Selected** button or download as a ZIP file using the **Download Selected** button
- A **Search Bar** is available to filter documents and find specific documents types e.g. PICFs



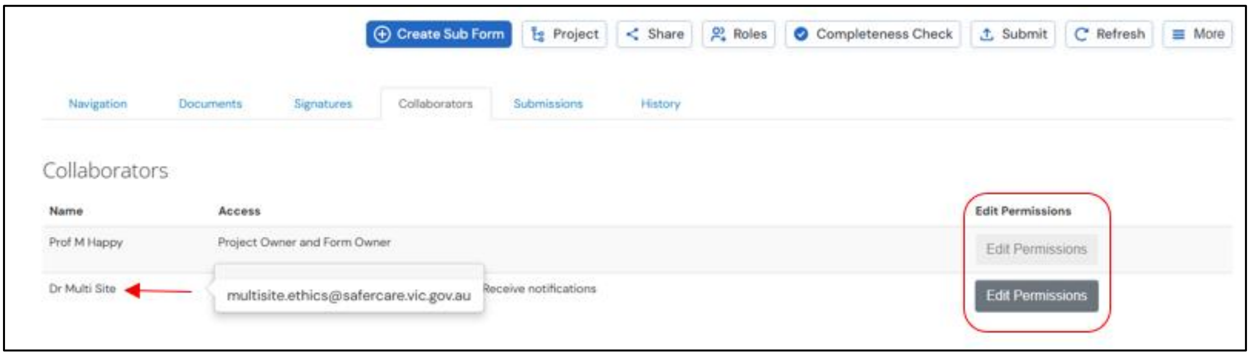
Signature

- Displays a history of all digital signatures that have been applied to the form and shows all signature requests
- Signatures are not applied in this tab. To sign a form, use the Navigation tab to access the relevant section for signature requests



Collaborators

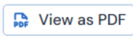
- Displays all members of the research team who have access to the application/form
- To view a collaborator's ERM email account, click on the collaborator's name and their email will be displayed



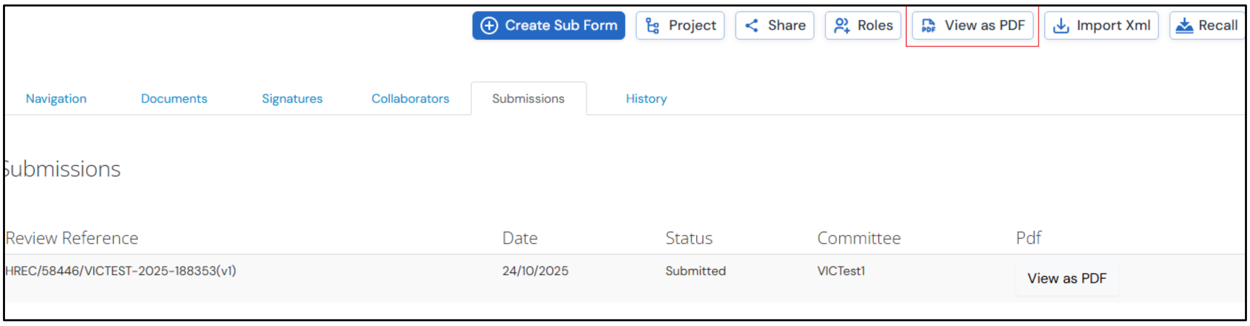
- The **Edit Permissions** button indicate the **Share** 

action was used to assign others access to the form
- The Edit Permissions (greyed out) button indicate the **Roles +** action was used to assign access to the form
- The form owner can only edit the permissions under the collaborators tab for each collaborator if the access was assigned using the **Share** action; otherwise use **Roles +** to edit permissions when **Roles +** is used

Submissions

- Displays the Review Reference e.g. HREC/72733/VICTEST-2021-246469(v3)
- Displays the current status of the application form e.g. Approved
- The Committee that will/has reviewed the application e.g. VICTest1
- Select **View as PDF** 

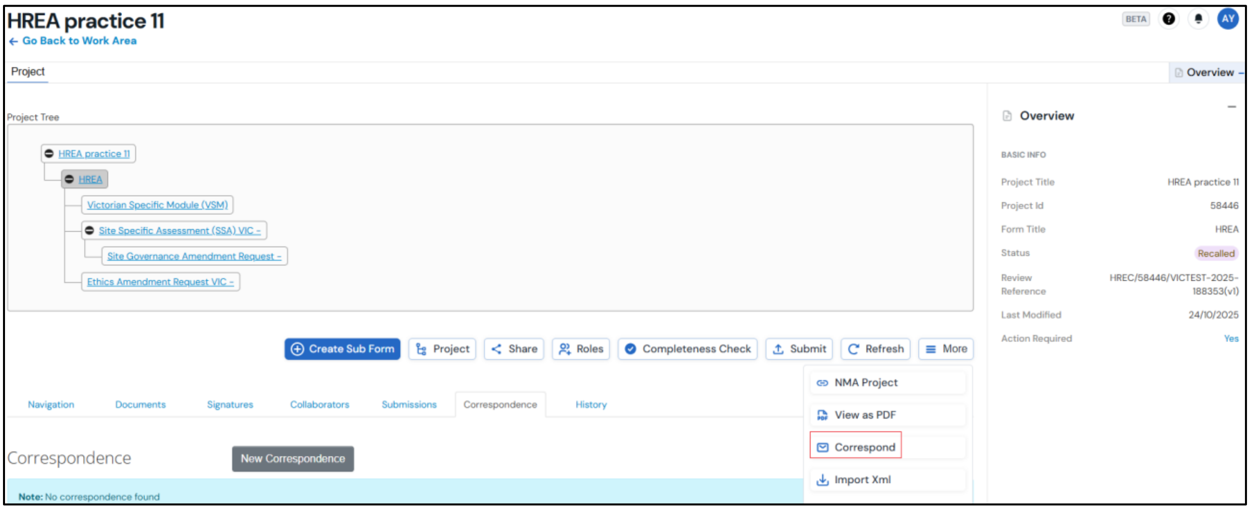
action button to view, download or print the pdf from a new browser tab as required



Correspondence

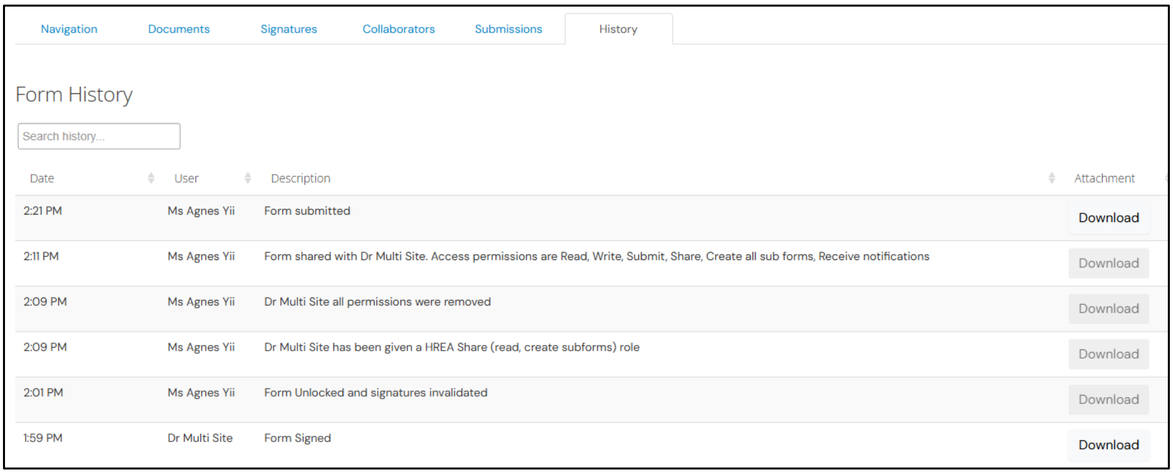
- Displays a record of the communication between the user and the reviewing organisation's Research Office
- It has no write/send message function
- Use the **Correspond** 

button under the Actions pane to write and send a message to the Research Office only after a form has been submitted



History

- Displays an audit trail of the application form. The user actions are recorded including actions from the Research Office once an application/form has been submitted



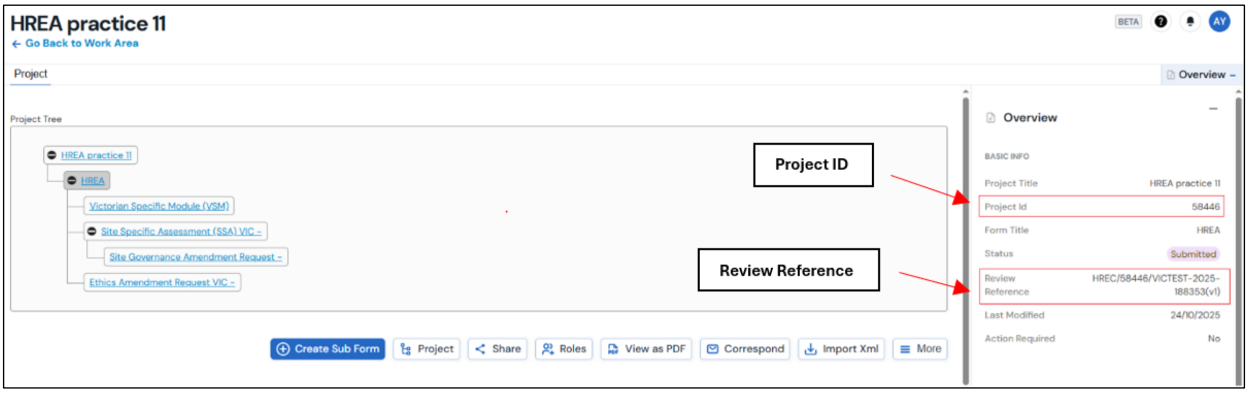
2.8 ERM Reference Numbers

Project ID:

- Is the unique identification number for a research project
- Generated when you **create a project** in ERM
- Used to identify the research project

Review Reference:

- Is the unique identification code for a form submission
- Generated when you **submit the form** in ERM



- Composed of six parts - ① ② ③ ④ ⑤ ⑥

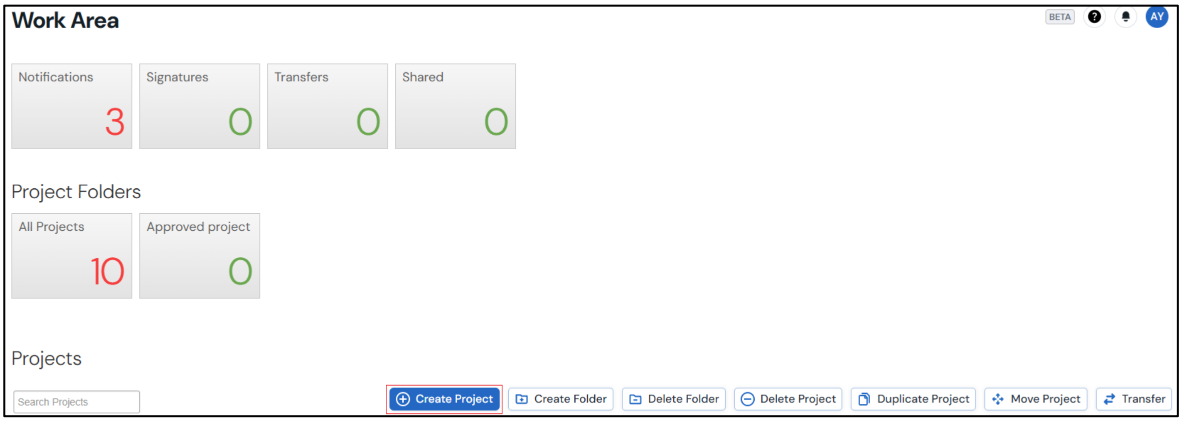
e.g. HREC/74950/VICTEST-2021-257683(v1)

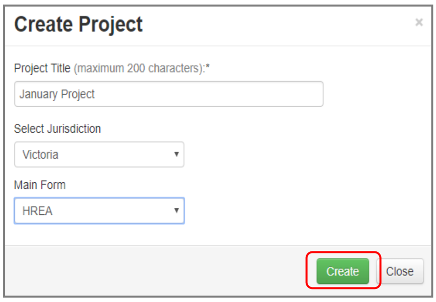
	Component	Description	Examples
1	Application type	Identifies the type of application form	HREC – the HREA
2	Project ID	The unique identification number for the research project	74950
3	Organisation/hospital code	The organisation/hospital to which this form was submitted	VICTEST
4	Year	Year of submission	2021
5	Submission number	Identifies the particular submission (version) of this form	257683
6	Version number	Version number	v1

3 The HREA form

3.1 Create a HREA

- Log into ERM and go to the **Work Area**
- Select the **Create Project** button under the Actions pane

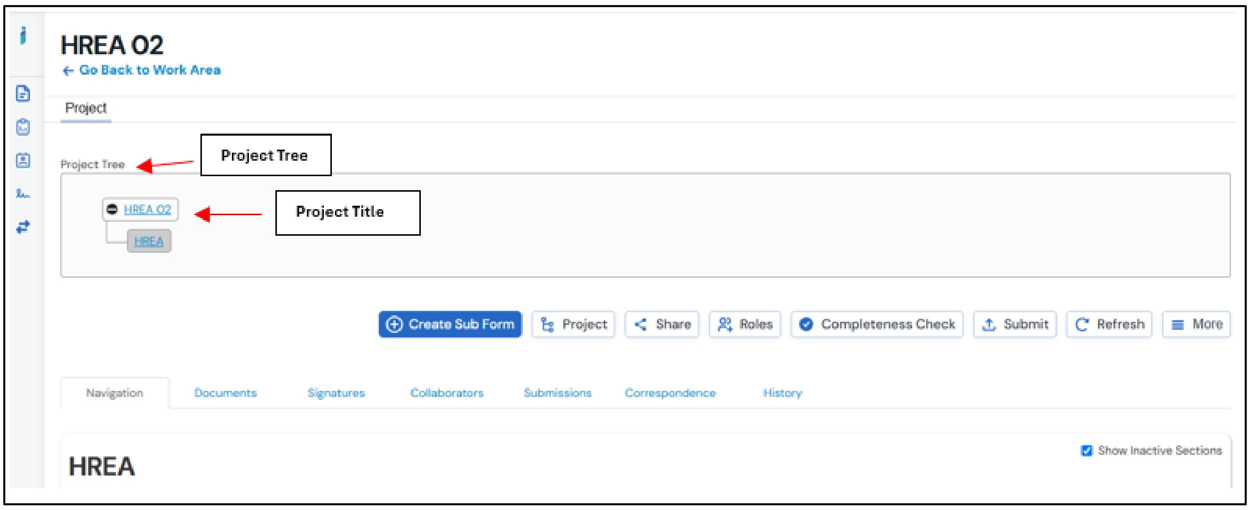




- Enter the Project Title
- Select the jurisdiction where the application will be reviewed
- Select **HREA** from the Main Form options

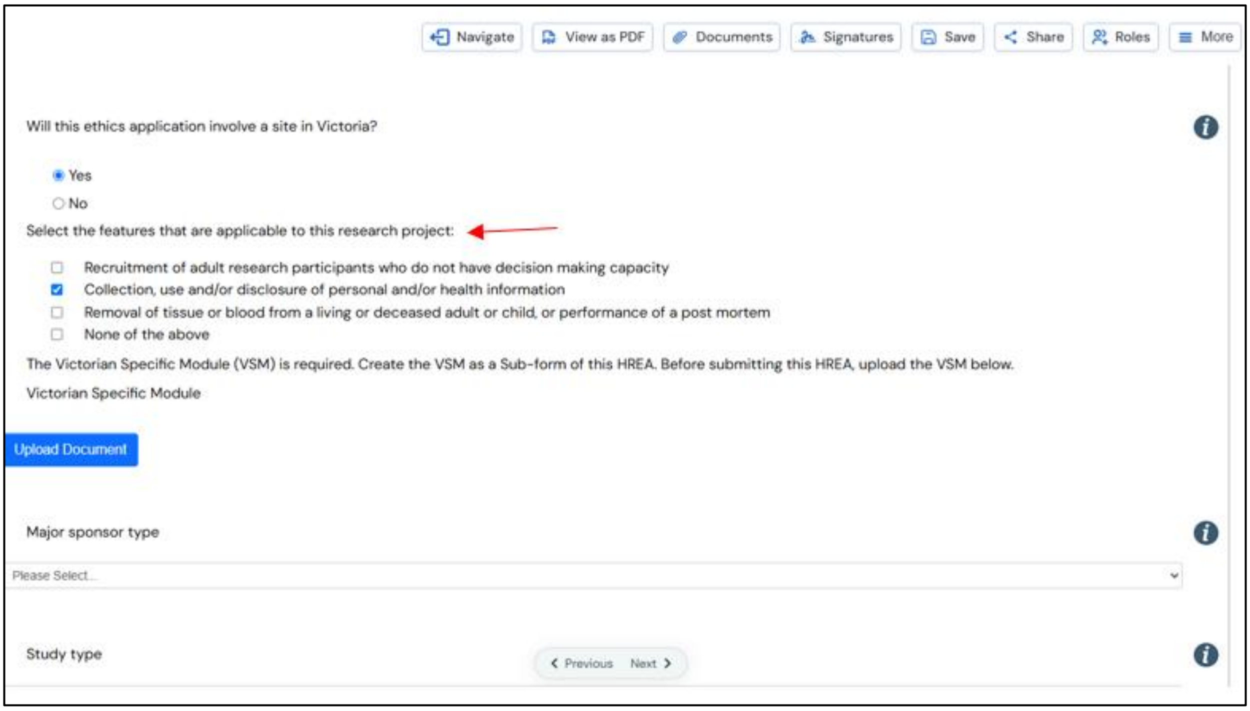
- Select **Create** button to create the project

- The Project Tree will display the newly created project and HREA



3.2 Complete the HREA

- Working under the **Navigation** tab, the ERM Filter Questions and Introduction are mandatory questions to be completed
- If the project involves a site in Victoria, a Victorian Specific Module **(VSM)** must be completed if certain features apply to the research project



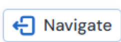
- Refer to the Victorian Specific Module (VSM) section in the manual for detailed instructions on completing the VSM
- In Section 1 of the HREA Introduction, select the **Acknowledge and Continue** button to open the rest of the HREA to complete the application

- To save your work select the **Save** button under the **Actions** pane

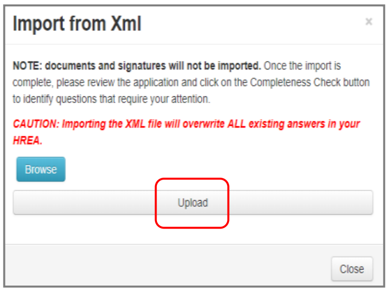
- Selecting **Previous** and **Next** buttons will also save your work

3.3 Import a HREA

If the HREA has already been completed on another website (NHMRC), the HREA form can be imported into ERM as an xml file.

- Details to obtain the xml file are available in ERM Frequently Asked Questions **HREA** section
- Create the project and HREA Main Form in ERM as previously described
- Complete the ERM Filter Questions and continue to 'HREA Introduction'
- Click on the **Navigate**  button under the Actions pane

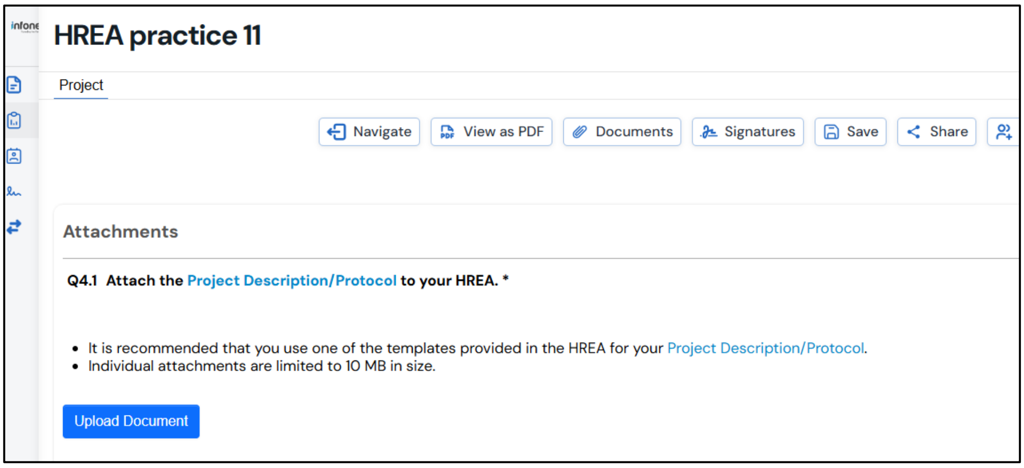
- Select **Import Xml** Import Xml button
- An **Import from Xml** text box will be displayed
- Select **Upload** button



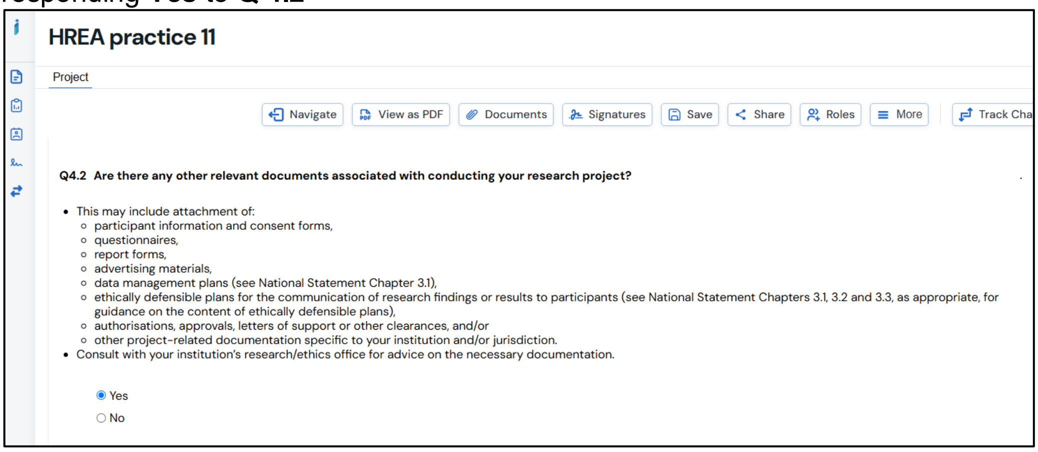
- The xml file will overwrite all existing answers in the HREA in ERM
- Signatures and documents will not be imported in the xml file therefore supporting documents will need to be uploaded into the ERM HREA and signatures will need to be obtained again.

3.4 Upload documents

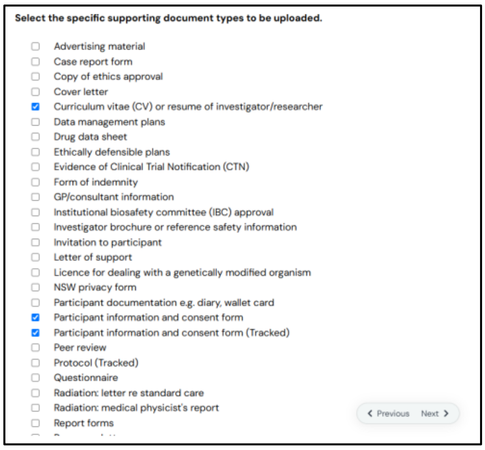
- Supporting documents to be included in the application are uploaded in **Section 4** of the HREA
- Select **Navigate** Navigate button under the Actions pane to go to the **Work Area**
- In the bottom section of the HREA, select **Upload** Upload to be directed to **Attachments Q 4.1** for e.g. the Protocol to be uploaded to the HREA



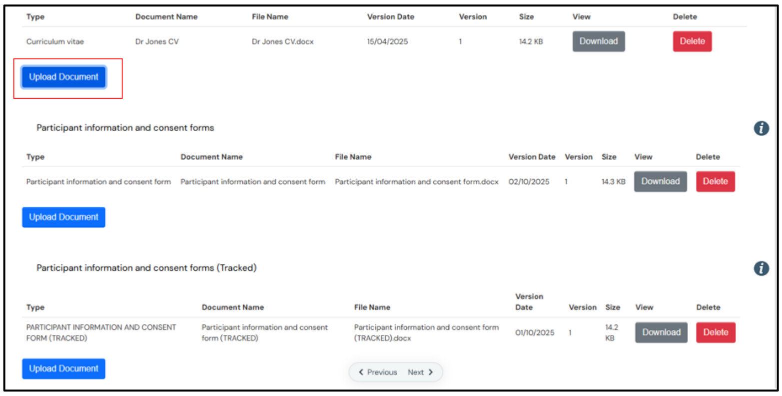
- Press **Upload Document** Upload Document to attach the protocol from your local drive
- Other documents e.g. Participant Information Consent Form can be uploaded to the application by responding **Yes** to **Q 4.2**



- A drop-down list of Supporting Documents will be displayed

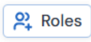


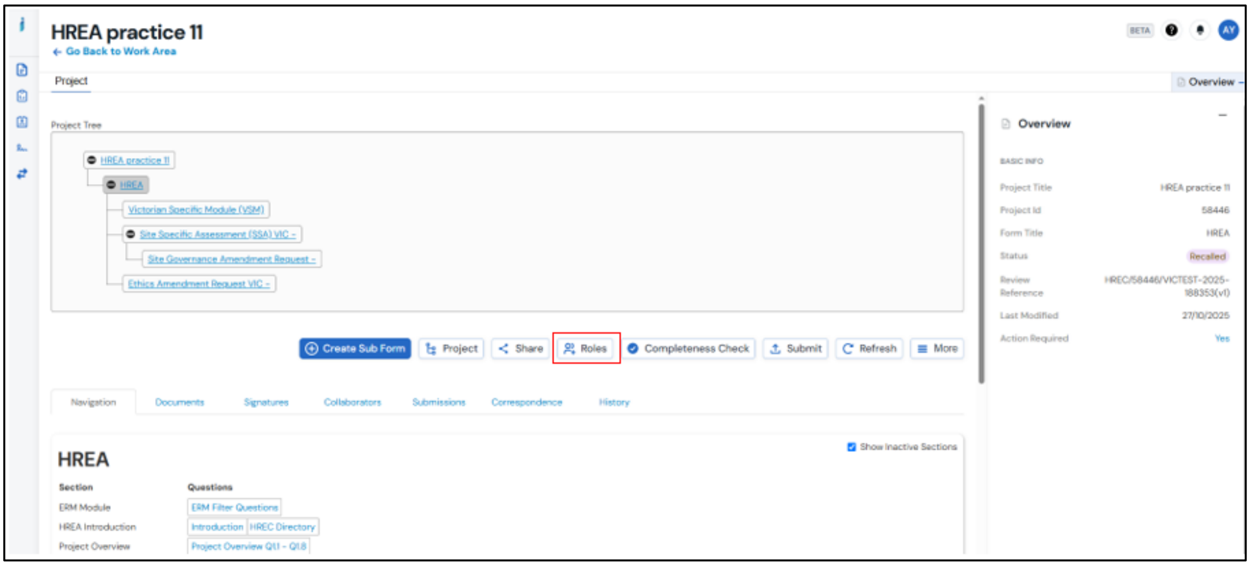
- Press **Upload Document** to attach the selected Supporting Document from your local drive
- Uploaded documents will be displayed under their type, name, file name and version
- Multiple documents of the same document type can be added by selecting multiple times
- Specify the version and date of each document to differentiate the documents within the same document type e.g. Sub-study PICFs



- Documents will also be displayed under the **Documents** tab
- Select the relevant checkbox for document type
- Select the **View Selected** button to open the document as a PDF in a new browser or select the **Download Selected** button to download the document as a ZIP file

3.5 Assign access to the HREA

- Select **Roles+**  button under the Actions pane



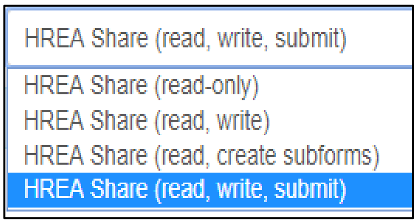
- A dropdown list will display the different levels of access to the HREA

HREA Share (read-only) – to view HREA including uploaded documents

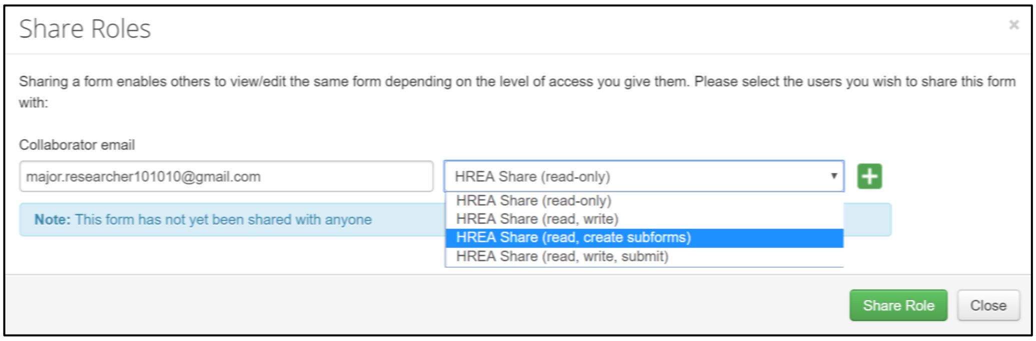
HREA Share (read, write) – to view and edit the form

HREA Share (read, create subforms) – to view, create subforms (SSA)

HREA Share (read, write, submit) – to view, write and submit forms



- Enter the collaborator's email address and select the level of access

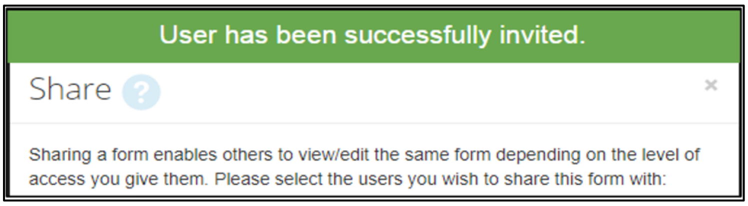


- Select **Share Role** button
- Other research team members can be added using the  button

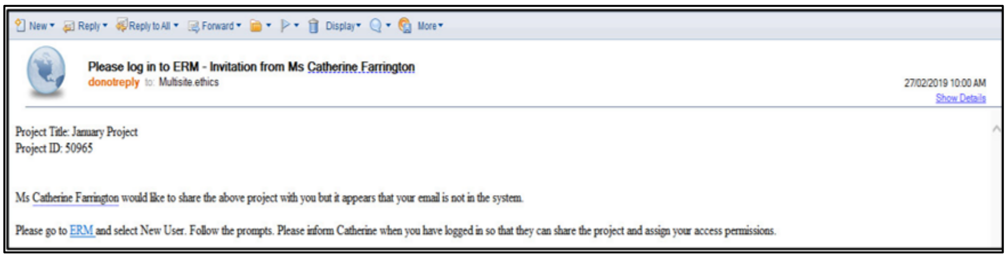
If the collaborator does not have an ERM account

- A message will be displayed if the collaborator's email does not exist in ERM

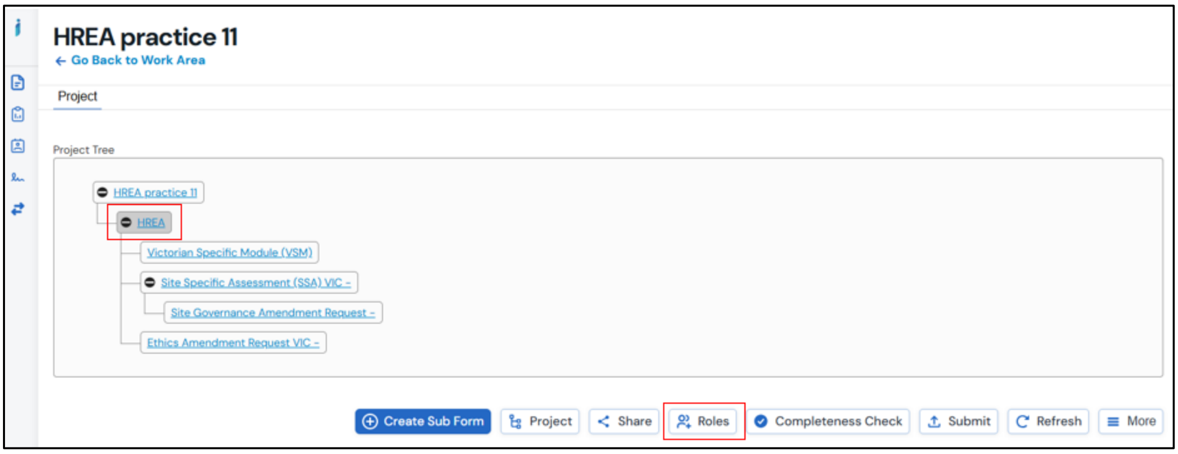
- Select the **Invite** button to invite the collaborator to create an ERM account
- This raises a green bar across the screen advising the collaborator has been successfully invited



- The collaborator will receive an email notification inviting them to share the project and a link to ERM to create an account. The collaborator should also notify the project owner when their ERM account has been activated

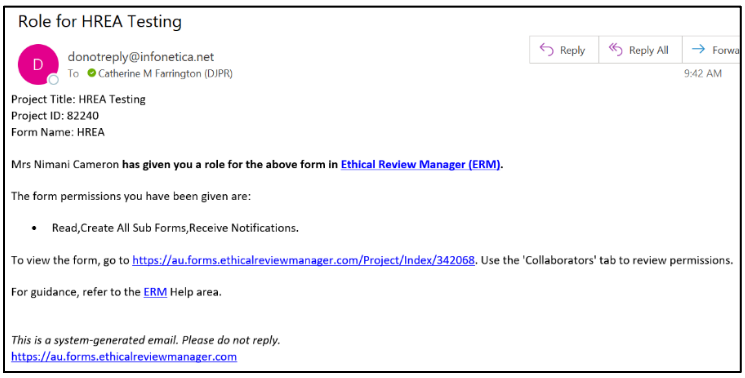


- The project owner will need to repeat the steps to assign the collaborator access to the HREA as described in Give access
- Select **Roles +** button under the Actions pane

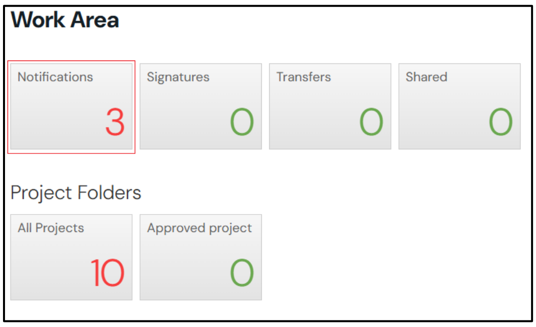


Accept access

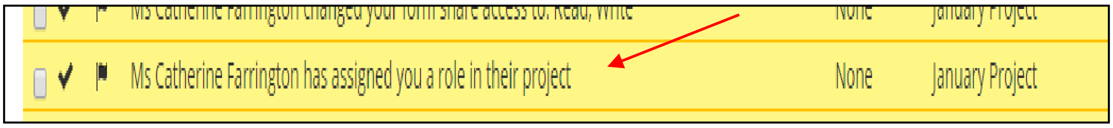
- The collaborator e.g. the PI will receive an email notification on their assigned role for the project



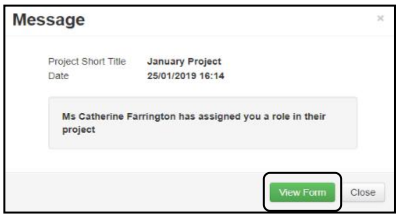
- The collaborator logs into ERM
- From the **Work Area** the collaborator selects **Notifications** tile



- Select the Message title to open the message

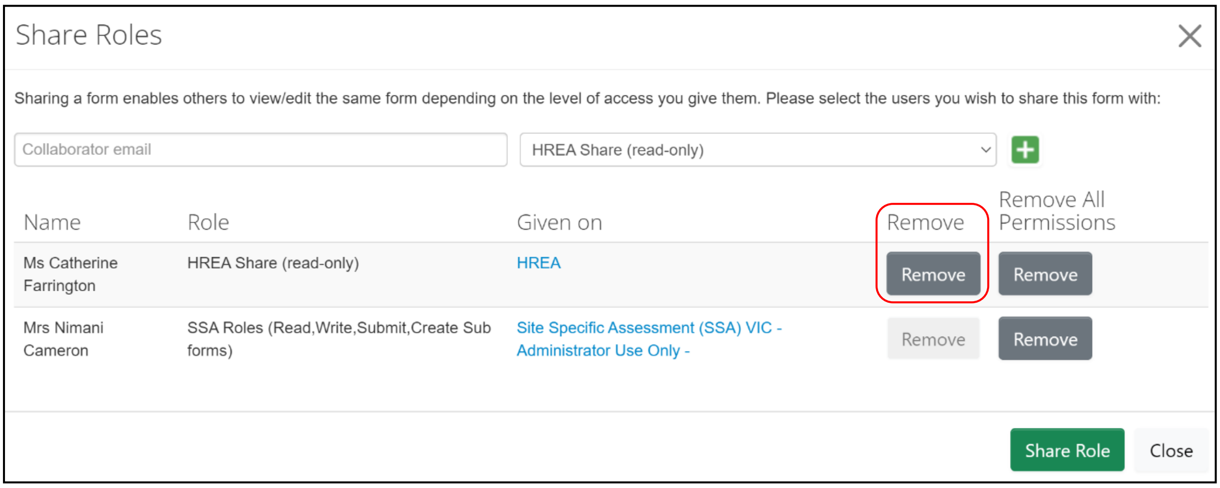


- A **Message** text box will be displayed. Select **View Form**
- The project and form will be displayed. Supporting documents attached to the form can also be viewed
- The collaborator can edit and submit sub-forms e.g. the SSA for their site depending on the level of access assigned by the project owner



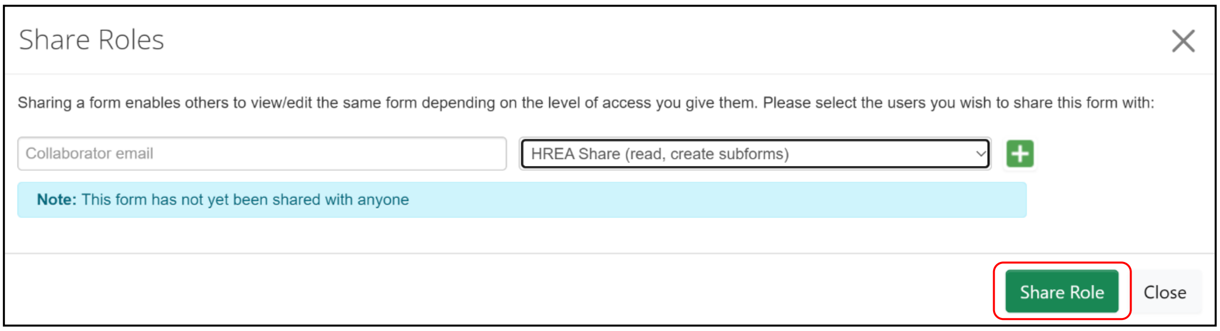
Manage access

- The level of access previously assigned to a research member can be modified in the following way if **Roles +** has been used
- Highlight the relevant form in the Project Tree and select the **Roles +**  button under the Actions pane
- A **Share Roles** textbox will be displayed showing the form's level of access that has been assigned to the collaborator e.g. HREA read only
- Select **Remove**



OFFICIAL

- The **Share Roles** page stays to allow the level of access to be modified
- Enter the collaborator's ERM email address and new level of access e.g. read, create subforms
- Select **Share Role**



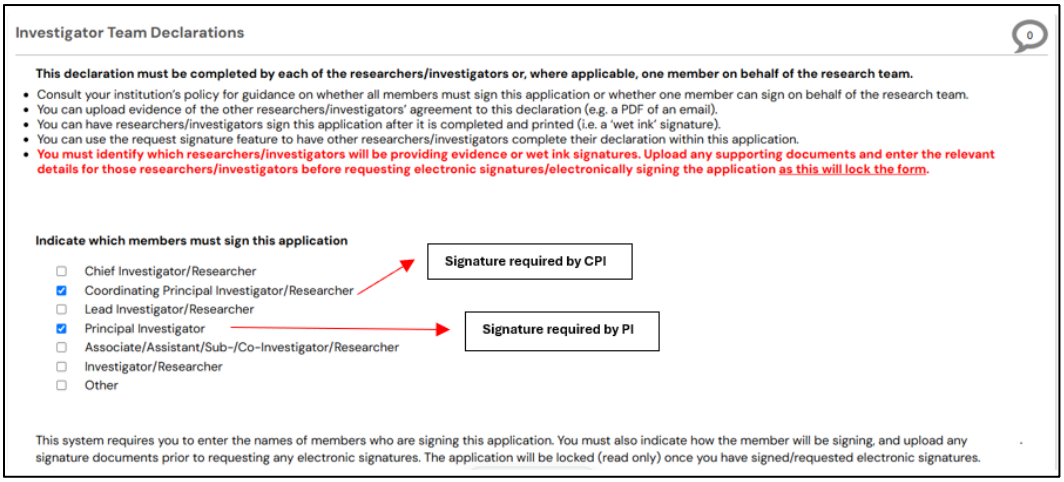
- The collaborator will receive an email notification informing them of the change in their access

3.6 Applying signatures

Declaration

The National Health and Medical Research Council **HREA** requires the applicant to enter the names of members of the research team who are signing the application.

- The Coordinating Principal Investigator is required to sign the Declaration for the HREA submission
- A declaration may be completed by each of the researchers/investigators
- Consult your institution's policy for guidance on whether all members must sign this application or whether the CPI can sign on behalf of the research team



Signatures

The HREA form questions / information must be complete, <u>before</u> doing signatures.
Any change to the HREA form will invalidate signatures.

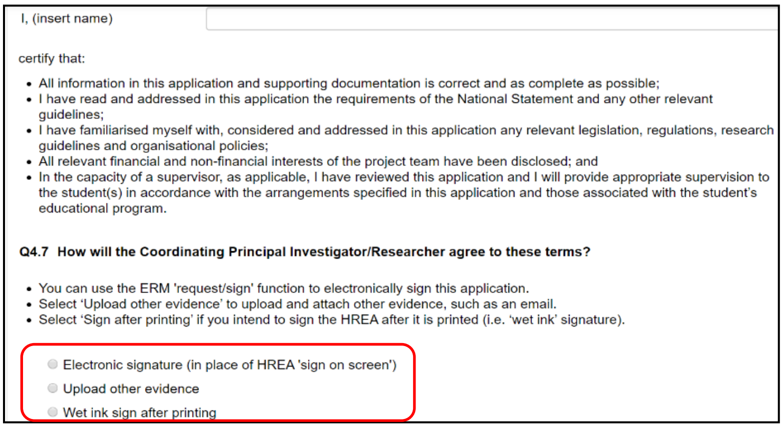
The applicant must indicate how each member will be signing the application **before** requesting any electronic signatures.

Using a combination of signature methods, electronic signatures should be sought LAST as the application/form will be locked once an electronic signature request has been made Multiple electronic signatures can occur

There are three signature methods available:

- If a wet ink signature is preferred, select ‘Wet ink after printing’ to sign after the HREA is completed
- If a document is used to endorse agreement, select ‘Upload other evidence’ to reflect investigator’s agreement then attach the evidence e.g. a PDF of an email
- For electronic signature select ‘Electronic signature’ and use the ERM 'Request Signature / Sign' function to electronically sign the declaration within the application using ERM

*** Signatories must have an ERM account to provide an electronic signature**



I, (insert name)

certify that:

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

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

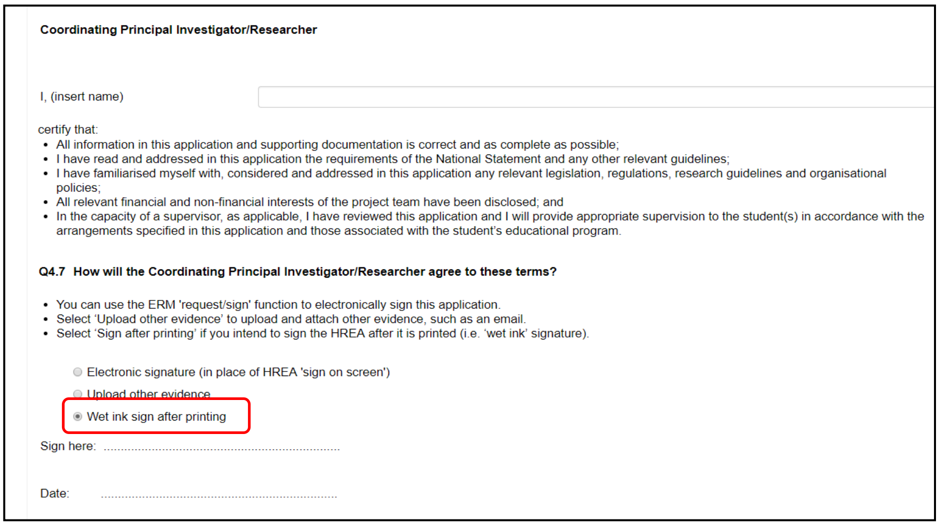
- You can use the ERM 'request/sign' function to electronically sign this application.
- Select ‘Upload other evidence’ to upload and attach other evidence, such as an email.
- Select ‘Sign after printing’ if you intend to sign the HREA after it is printed (i.e. ‘wet ink’ signature).

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

The HREA form owner may request signatures as follows:

1. To use Wet ink signature

- Select ‘Wet ink sign after printing’



Coordinating Principal Investigator/Researcher

I, (insert name)

certify that:

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

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

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

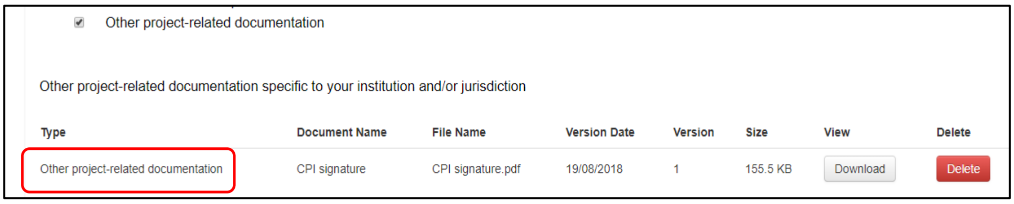
Electronic signature (in place of HREA 'sign on screen')
Upload other evidence
Wet ink sign after printing

Sign here: ....

Date: ....

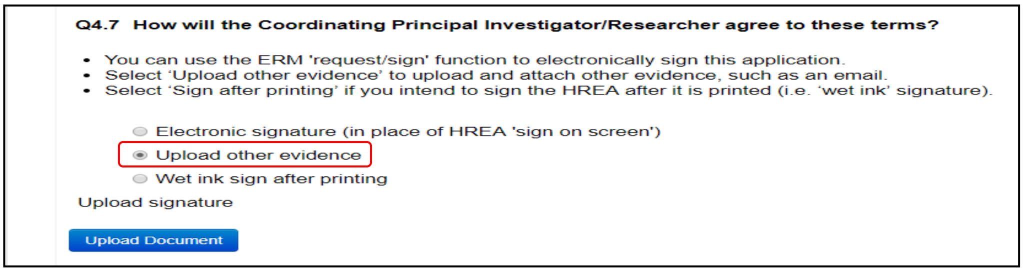
- ‘Wet ink sign after printing’ creates a signature block (at bottom of screen)
- Using the **View as PDF** View as PDF action button, custom print the page and obtain the signature from the CPI/PI. Save to your local drive as a pdf

- Navigate to last section of the HREA to find Upload Q4.1 – Q4.2
- Click then opens **Q 4.2** to attach the Declaration page
- Select '**Yes'** to other relevant documents and select '**Other project-related documentation'**
- Select **Upload document** Upload Document to attach the signature document to the HREA
- The uploaded signature document will be displayed with the document and file name and versions

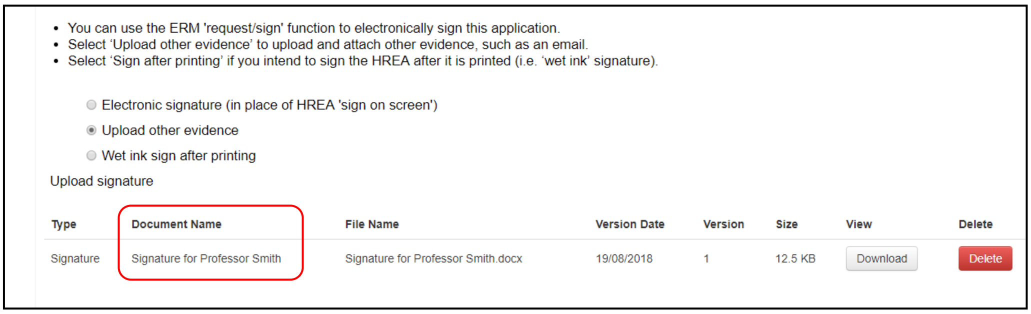


2. To Upload other evidence – to attach an email copy / letter to indicate agreement

- Select 'Upload other evidence'

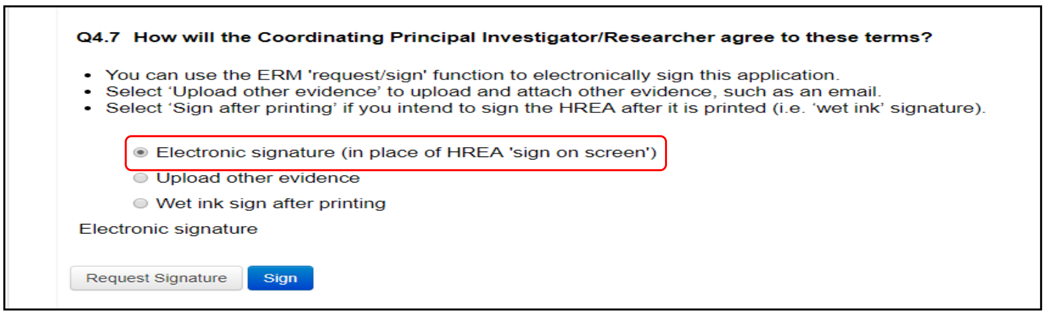


- Select **Upload Document** Upload Document to attach the signature document from your local drive
- The Signature document will be displayed with document and file names and versions



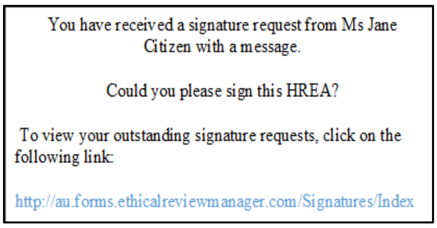
3. To request an Electronic Signature

- Select **Electronic signature** and a Request Signature Sign button will appear



- To request an electronic signature from the Coordinating Principal Investigator / Principal Investigator, select **Request Signature** Request Signature button
- The system performs a completeness check to highlight any incomplete sections that need to be completed. Each incomplete item will be displayed as a link to the relevant section
- When all required sections of the HREA have been completed select **Request Signature** Request Signature
- Enter the signatory's ERM email address and message and select **Request**

- The requested signatory will receive an email notification with the signature request, a message and link to ERM Log in/Signatures page


You have received a signature request from Ms Jane Citizen with a message.

Could you please sign this HREA?

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

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

- The signatory logs into ERM
- From the Work Area the signatory selects **Notifications** or **Signatures** tile to open the signature request

- New requests will be at the top

- Under the **Action** tab, select **View Form** View Form to review the application
- For endorsement of the application, select **Sign** Sign button under the Actions pane

OFFICIAL

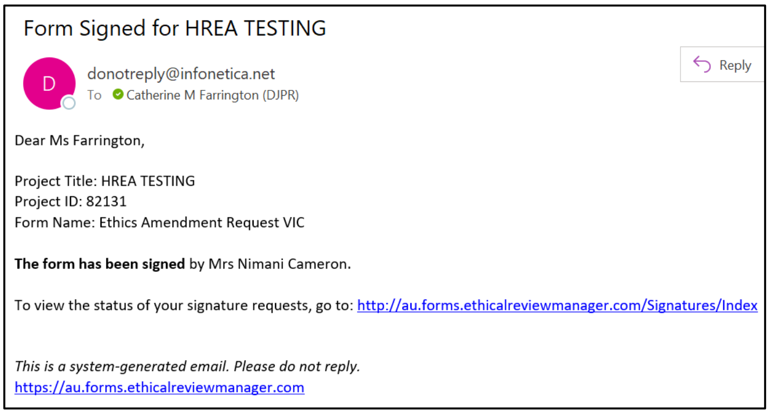
- A **Sign Form** text box is displayed
- The signatory enters their ERM log in details to sign the form
- Select **Sign**  button
- The **Status** has changed from Requested to Signed

Signatures

Search signatures

Type	Project Title	Project ID	Requesting User	Message	Requested Date	Response Date	Status	Action
Co-ordinating Principal Investigator/Researcher	HREA practice 11	58446	Ms Agnes Y		27/10/2025 16:18	28/10/2025 12:47	Signed	PDF being Generated
Co-ordinating Principal Investigator/Researcher	HREA practice 11	58446	Ms Agnes Y		24/10/2025 13:50	24/10/2025 13:59	Invalidated	View Form

- The applicant receives an email notification indicating the signature request has been accepted by the signatory i.e. the form has been signed



Form Signed for HREA TESTING

donotreply@infonetica.net
To Catherine M Farrington (DJPR)

Reply

Dear Ms Farrington,

Project Title: HREA TESTING
Project ID: 82131
Form Name: Ethics Amendment Request VIC

The form has been signed by Mrs Nimani Cameron.

To view the status of your signature requests, go to: http://au.forms.ethicalreviewmanager.com/Signatures/Index

This is a system-generated email. Please do not reply.
https://au.forms.ethicalreviewmanager.com

Consult with the reviewing organisation for their policy on accepting electronic authorisation.

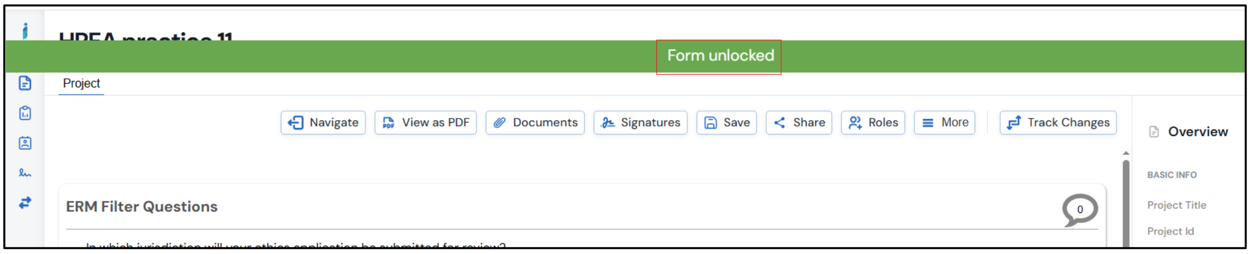
To request multiple signatures - when the applicant / form owner requests authorisation from other investigators

- Repeat the signatory process for electronic signatures from other research members if required e.g. Principal Investigator if indicated on the Investigator Team Declarations in the HREA

- Once the signature process is complete the form is locked

- The form can be unlocked for further editing by selecting the **Unlock** 

button under the Actions pane
- The form must open for the **Unlock** action button to be available
- A **Unlock form** text box is displayed noting this action will <u>invalidate any signatures</u> on the form
- Select **Confirm** to unlock the form
- The form is unlocked for editing



- Complete the edits in the form
- Repeat the signatory process for electronic signatures from research team members
- The application is ready for submission

4 Submission and review process – HREA

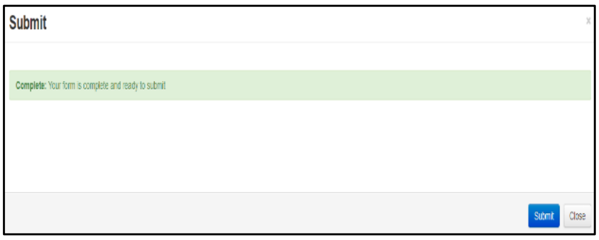
In ERM the submission and review processes are similar for all forms.

For the initial application submission ensure the form is complete and all **documents are uploaded and signatures completed.**

To note, as the project title <u>cannot</u> be changed once approved, ensure the title is correct before submitting or resubmitting the application.

4.1 Submission

- Navigate to the Actions pane and select the **Submit** button
- The system performs a completeness check to highlight any incomplete sections.
- If complete, the form is ready to be submitted
- Select the **Submit** button



- The system will automatically submit the application to the HREC/ethics review body selected in **Q 4.3** of the HREA

Application type	HREC - the HREA
ERM Project ID	74950
Organisation/hospital code	VICTEST
Year	2021- year of submission
Submission number	257683 - submission version number
Version number	v1

- Following the submission, a unique identification code is generated.
  It is composed of six parts - e.g. HREC/74950/VICTEST-2021-257683(v1)
- The **Form Status** of the application under Overview becomes Submitted Status Submitted

Recall an application

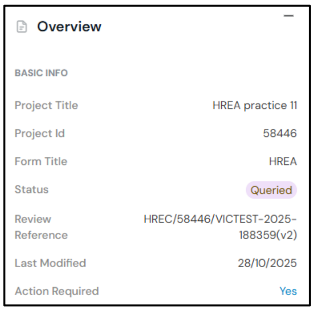
Any changes made to the submission will INVALIDATE all electronic signatures and will require all signature requests again

- Once the application has been submitted, a recall option becomes available
- The form can be recalled **until** the submission is actioned by the Research Office
- The recall removes the submitted application from the Research Office's ERM account
- Select the **Recall** Recall button under More to recall the submission and make any changes / additions
- Select the **Submit** Submit button again. The application will be resubmitted.

4.2 Responding to a query from the Research Office

If an application is queried by the Research Office for further clarification, changes or additions e.g. supporting documents, the form is **unlocked** for the applicant to complete the edits/revisions.

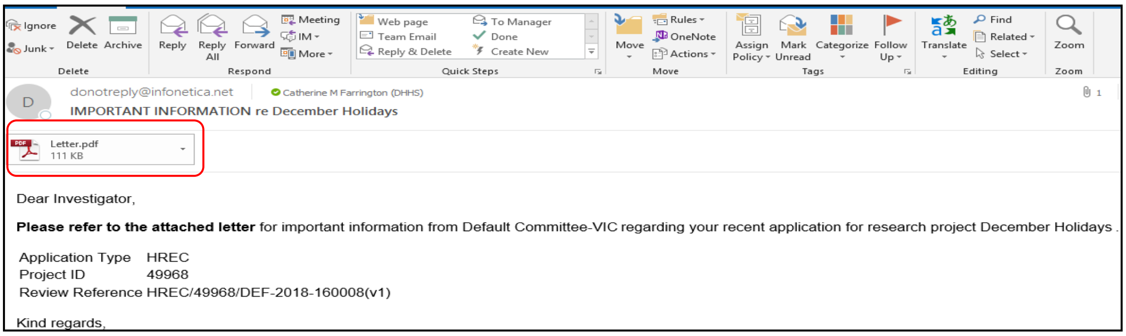
The form Status has changed from 'Submitted' to 'Queried' -


Overview

BASIC INFO

Project Title	HREA practice 11
Project Id	58446
Form Title	HREA
Status	Queried
Review Reference	HREC/58446/VICTEST-2025-188359(v2)
Last Modified	28/10/2025
Action Required	Yes

- The applicant is advised via an ERM email of important information regarding their application


donotreply@infonetica.net

IMPORTANT INFORMATION re December Holidays

Letter.pdf 111 KB

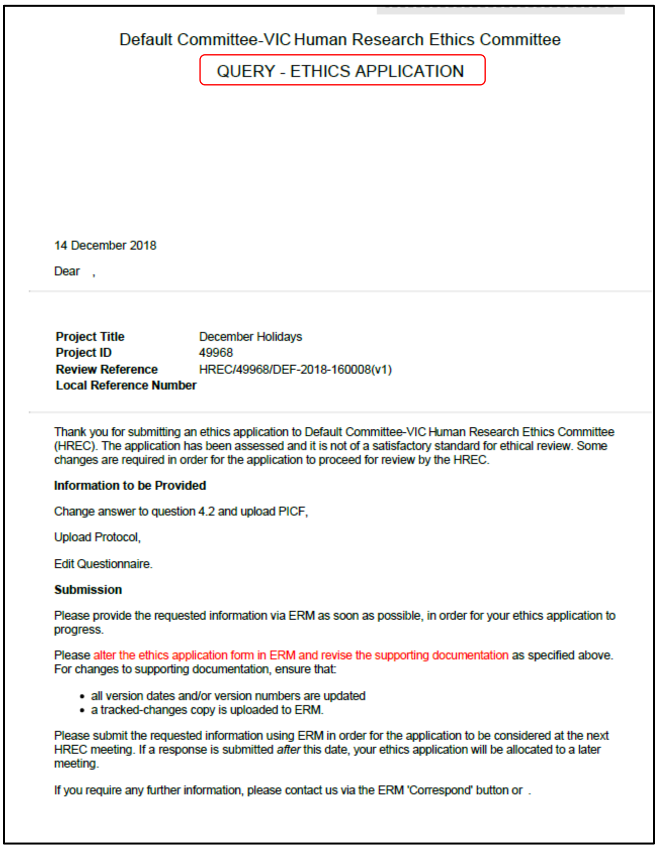
Dear Investigator,

Please refer to the attached letter for important information from Default Committee-VIC regarding your recent application for research project December Holidays .

Application Type HREC
Project ID 49968
Review Reference HREC/49968/DEF-2018-160008(v1)

Kind regards,

- A 'Query – Ethics Application' letter (pdf) from the Research Office will include details for further information to be provided via ERM


Default Committee-VIC Human Research Ethics Committee

QUERY - ETHICS APPLICATION

14 December 2018

Dear ,

Project Title	December Holidays
Project ID	49968
Review Reference	HREC/49968/DEF-2018-160008(v1)
Local Reference Number	

Thank you for submitting an ethics application to Default Committee-VIC Human Research Ethics Committee (HREC). The application has been assessed and it is not of a satisfactory standard for ethical review. Some changes are required in order for the application to proceed for review by the HREC.

Information to be Provided

Change answer to question 4.2 and upload PICF,

Upload Protocol,

Edit Questionnaire.

Submission

Please provide the requested information via ERM as soon as possible, in order for your ethics application to progress.

Please alter the ethics application form in ERM and revise the supporting documentation as specified above. For changes to supporting documentation, ensure that:

- all version dates and/or version numbers are updated
- a tracked-changes copy is uploaded to ERM.

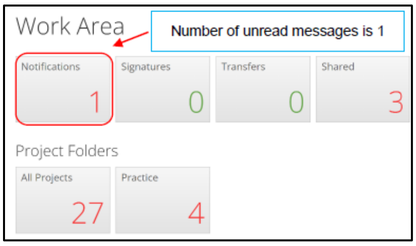
Please submit the requested information using ERM in order for the application to be considered at the next HREC meeting. If a response is submitted *after* this date, your ethics application will be allocated to a later meeting.

If you require any further information, please contact us via the ERM 'Correspond' button or .

To access the Query

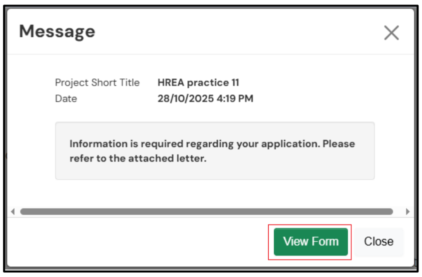
In the Work Area, click on the **Notifications** tile

- Select the **Message** title to open and view the message

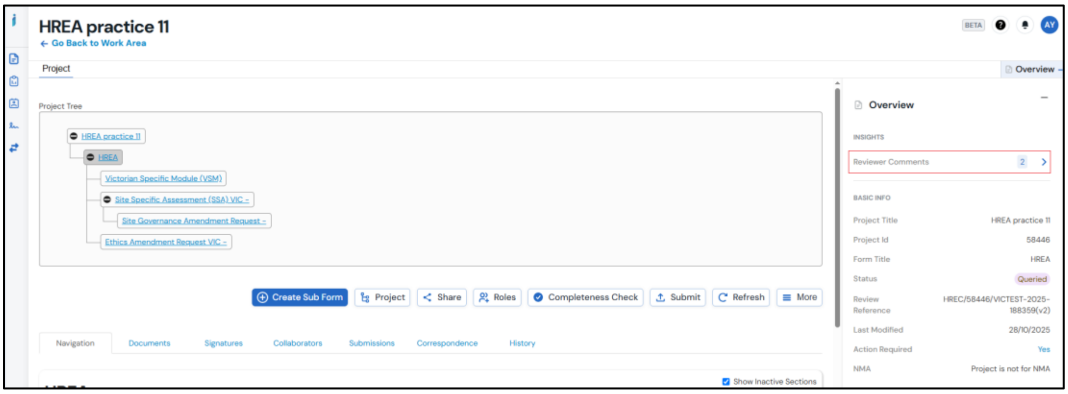


- A Message box will be displayed allowing the user to view the form

Press **View Form**  to be directed to the relevant form



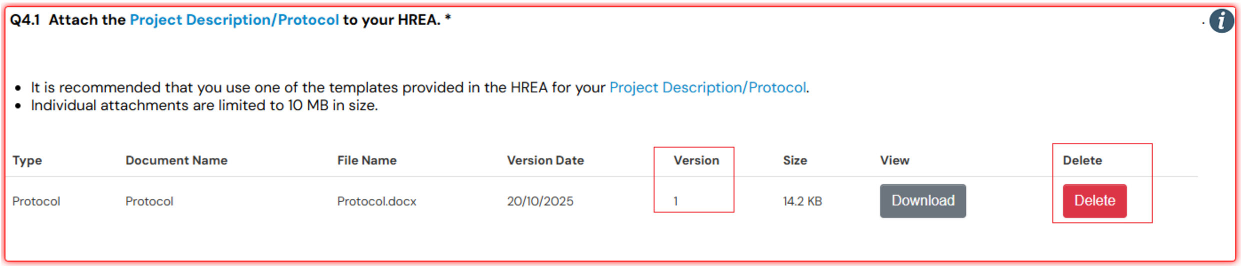
- The form will open under the **Navigation** tab



OFFICIAL

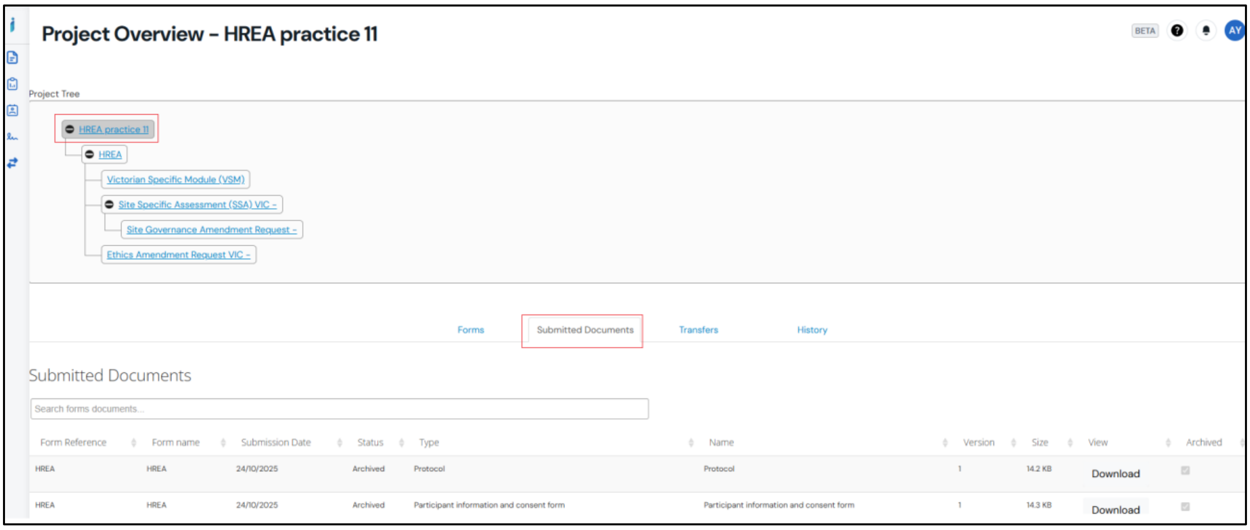
- Select **Reviewers Comments** Reviewer Comments 2 under the Overview pane
- A text box will be displayed of the **Overall Reviewer Panel Comments** (e.g. 2 comments)

- Select a comment to be directed to the relevant section in the form i.e. to **Q 4.1 Attach the Project Description/Protocol to your HREA**
- As the query requires a new version of a document, the original version should be deleted, and the new version uploaded into the form. Deleted/previous document versions are automatically archived. See Archived documents for further information on how to access archived documents.
- **Delete** Delete to delete the original version

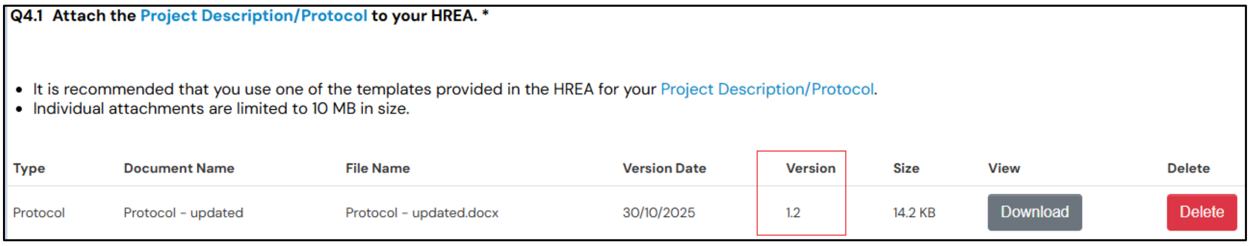


- Select **Upload Document** Upload Document to upload the revised (new) version of the document with the correct version number and date

  Previous document versions are archived in **Submitted Documents** and viewed in the **Project Overview** screen



- The HREA now includes the latest version ready for resubmission



Q4.1 Attach the Project Description/Protocol to your HREA. *

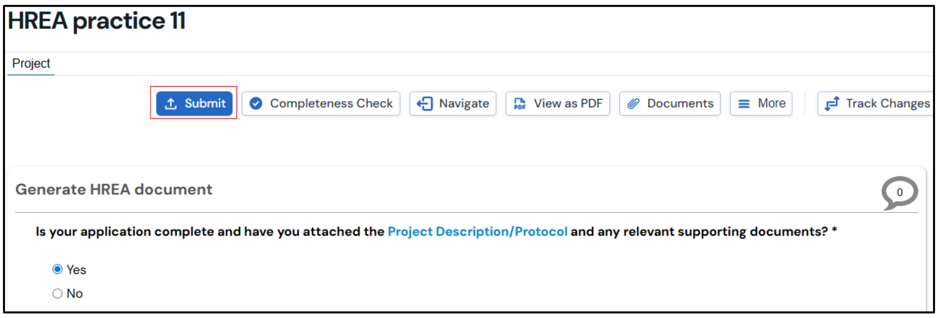
- It is recommended that you use one of the templates provided in the HREA for your Project Description/Protocol.
- Individual attachments are limited to 10 MB in size.

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Protocol	Protocol - updated	Protocol - updated.docx	30/10/2025	1.2	14.2 KB	Download	Delete

- Continue to complete the other queries as instructed in the **Overall Reviewer Panel Comments** as above

Note amending a form and/or adding a new document will invalidate any electronic signatures

- Once the revisions / additions have been completed, the form and / or supporting documents can be resubmitted
- The system will automatically search for a completed electronic signature if ‘Electronic signature’ was selected in **Q 4.7** of the HREA in the previous submission
- If the CPI is not required to complete the Declaration page, proceed to **Q 4.7** of the HREA
- Select **Wet ink sign after printing.** This will reset the signature method to enable the system to resubmit the application
- In the **Actions** pane, select the **Submit** Submit button to resubmit



HREA practice 11

Project

Submit | Completeness Check | Navigate | View as PDF | Documents | More | Track Changes

Generate HREA document

Is your application complete and have you attached the Project Description/Protocol and any relevant supporting documents? *

- (•) Yes
- ( ) No

- The Research Office will receive the submission
- The application is assigned to a HREC meeting
- Following the HREC review there may be an information request from the Ethics Committee

To re-submit the form what signature/s are required?

The CPI signs. For minor changes the Research Office has all signatures on the initial submission

Other Investigators to sign if a substantial change or required by local policy

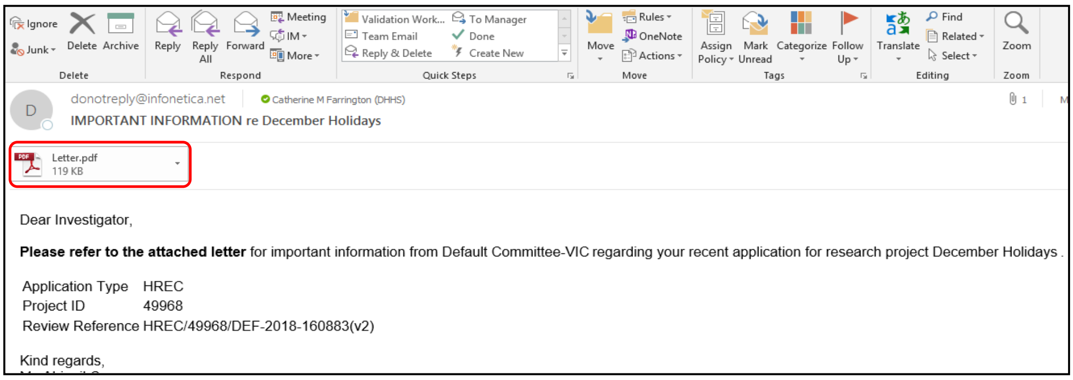
Check with other Investigators and the Research Office policy before requesting signatures and re-submission

4.3 Ethics Committee review request

Clarification or requests for further information from the reviewing Ethics Committee to the applicant must be managed through ERM. The form is unlocked for the applicant to complete the edits/revisions.

The form Status has changed from 'Submitted' to 'Information Requested'.

- The applicant is advised via an ERM email of important information regarding the application



- A 'Request for Further Information' letter (pdf) from the HREC will include details for further information to be provided via ERM

Default Committee-VIC Human Research Ethics Committee

REQUEST FOR FURTHER INFORMATION

17 December 2018

Dear ,

Project Title	December Holidays
Project ID	49968
Review Reference	HREC/49968/DEF-2018-160883(v2)
Local Reference Number	

Thank you for submitting an ethics application to Default Committee-VIC Human Research Ethics Committee (HREC). The application was reviewed by the HREC at their meeting on <HREC meeting date>.

The information provided in the ethics application was not sufficient for the HREC to make a decision on the ethical and scientific acceptability of your proposed research project. The HREC therefore requests further information regarding the research project.

Information to be Provided

Resubmission

Please provide the requested information via ERM as soon as possible, in order for your ethics application to progress.

Please amend the ethics application form in ERM and revise the supporting documentation as specified above. For changes to supporting documentation, ensure that:

- all version dates and/or version numbers are updated

Page 1 of 2

- a tracked-changes copy is uploaded to ERM.

Please resubmit using ERM in order for the application to be considered at the next HREC meeting.

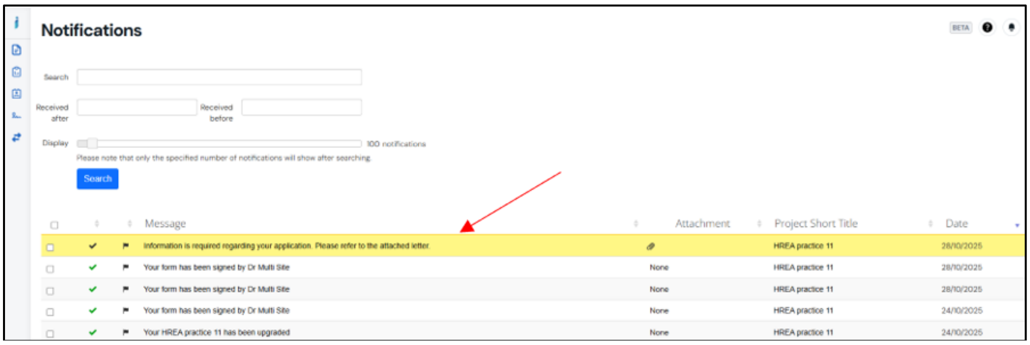
If a response is not received within three months of the date of this letter, your application may be withdrawn/cancelled. If this occurs, a new ethics application would be required.

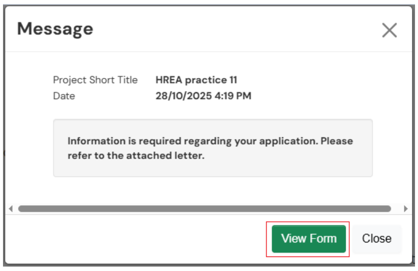
If you require any further information or may need an extension to the resubmission timeline, please contact us via the ERM 'Correspond' button.

Yours sincerely,

Respond to a request for further information from the Ethics Committee

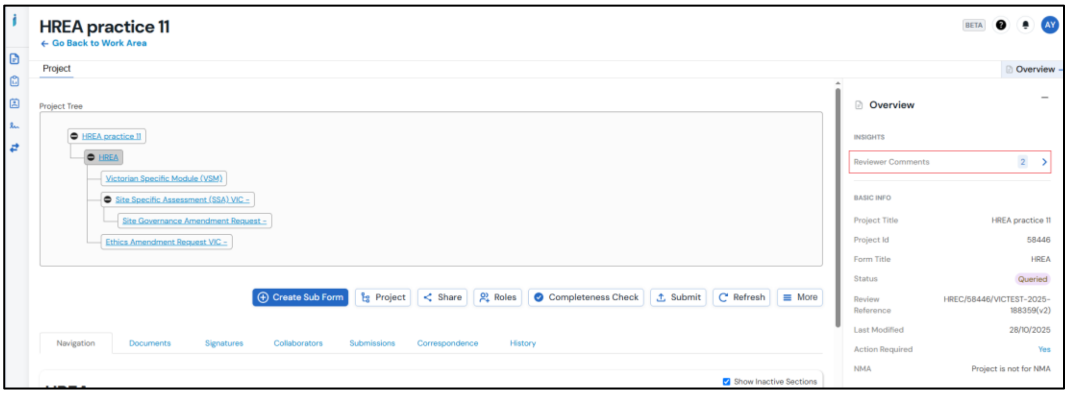
- Depending on the request, the applicant can amend the HREA and add new documents
- Log in to ERM account
- In the Work Area, click on the **Notifications** tile
- Select the Message title to open and view the message

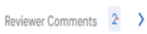




- A **Message** box will be displayed allowing the user to view the form
- Press **View Form**  to be directed to the relevant form

- The HREA, will open under the **Navigation** tab



- Select **Reviewers Comments**  under the Overview pane
- A text box will be displayed of the **Overall Reviewer Panel Comments**

- Select a comment e.g. PICF needs to be updated, to be directed to the relevant section in the form i.e. **Participant information and consent forms**

- The request requires a new version of a PICF. The original version should be deleted, and the new version uploaded into the form. Deleted/previous document versions are automatically archived. See Archived documents for further information on how to access archived documents.

- Select **Delete** Delete to delete the original version

Participant information and consent forms

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Participant information and consent form	Participant information and consent form	Participant information and consent form.docx	01/10/2025	1	14.3 KB	Download	Delete

Upload Document

- Select **Upload Document** Upload Document to upload the revised (new) version of the protocol with the correct version number and date
- The HREA now includes the latest version ready for resubmission

Participant information and consent forms

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Participant information and consent form	Participant information and consent form - updated	Participant information and consent form - updated.docx	30/10/2025	1.2	14.3 KB	Download	Delete

Upload Document

- Continue to complete the other requests as instructed in the **Overall Reviewer Panel Comments** as above
- In the Actions pane, click on **Submit** Submit button to resubmit
- The reviewing Research Office will receive the resubmission

Approved Applications

- Applicants are informed of decisions by the HREC via email using ERM. If the application has been approved, the form is locked
- Log on to ERM and click on **Notifications** tile
- A formal approval letter from the HREC can be downloaded by the applicant
- If the application review outcome is **not approved**, applicants are also informed via email through ERM.

5 National Mutual Acceptance (NMA) applications

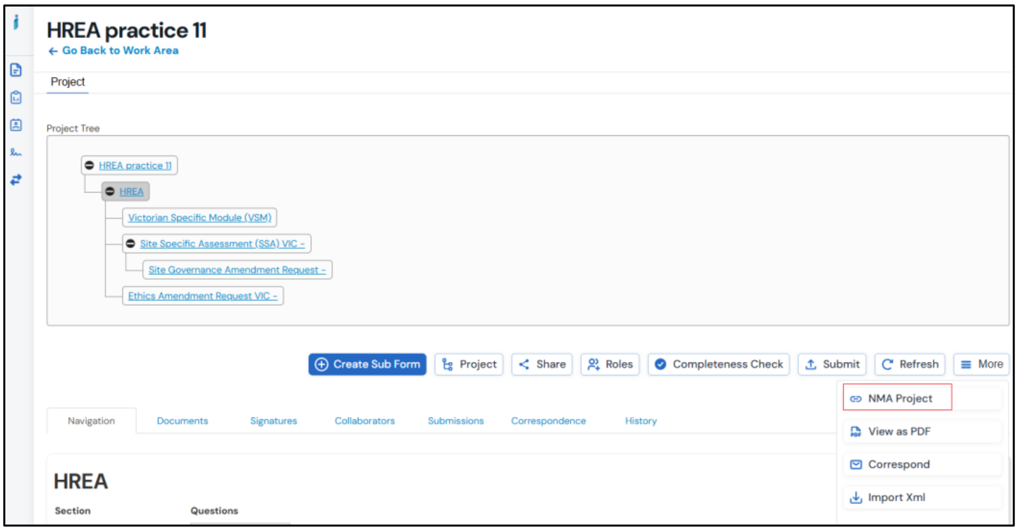
NMA is a national system for mutual acceptance of scientific and ethical review of multi-centre human research projects conducted in publicly funded health services across jurisdictions.

Single ethical and scientific review for a multi-centre human research project can be provided across seven participating states/territories.

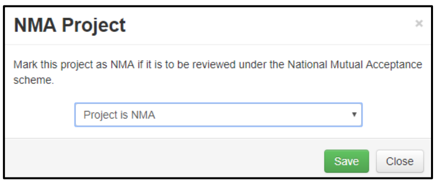
If ethical review is completed in a jurisdiction that does not use ERM (NSW, ACT, SA, WA, NT), a Minimal Dataset Form (MDF) is created. From the ERM MDF, SSAs can be created as sub-forms for sites in VIC and QLD. See page 78 for MDF. Additional information can be found on the Safer Care Victoria Research website under National Mutual Acceptance.

If the application is to be reviewed under the NMA scheme, this needs to be recorded in ERM for reporting purposes.

- When completing the HREA, select **Yes** to **Q 4.6 Will this application be reviewed under the National Mutual Acceptance scheme?**
- Navigate [Navigate] back to the **Actions pane** and select More [More] then select **NMA Project** [NMA Project]



- A NMA Project text box will be displayed
- Select **Project is NMA** from the drop-down list
- Select **Save** [Save]
- The **Overview** pane will be updated to 'Project is for NMA'



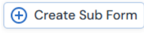
---

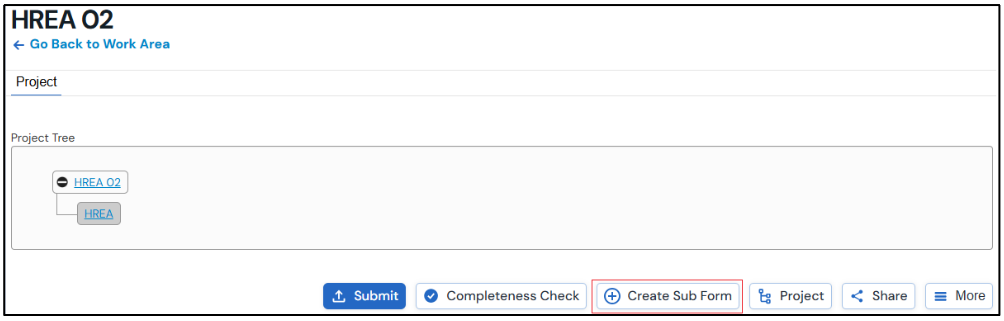
6 Victorian Specific Module

For each project that utilises the HREA form and has a site in Victoria, the **Victorian Specific Module (VSM)** must be completed if certain research features of the project apply as indicated in the HREA – ERM Filter Questions. In these instances, the VSM is mandatory when the HREA is used. It addresses Victorian legislative requirements.

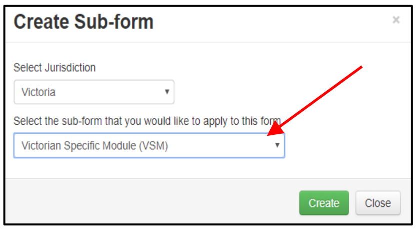
The VSM is submitted to the reviewing HREC as part of the ethics application. The following steps also apply if the ethics review is in QLD but select Victoria when creating the VSM sub-form.

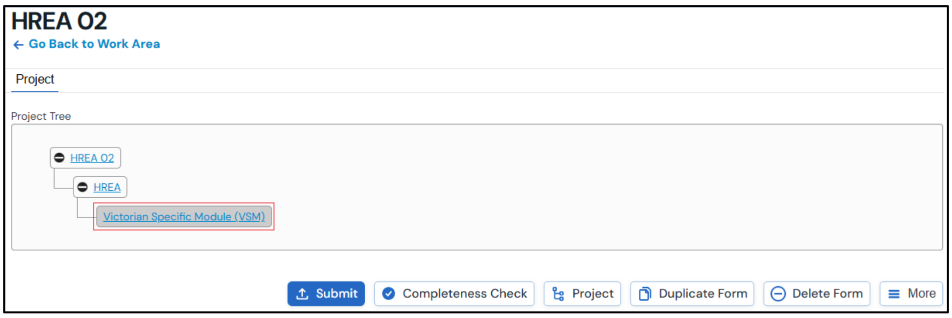
In ERM:

- The VSM is created as a sub-form of the HREA
- Highlight the HREA in the Project Tree and select the **Create Sub-form**  button under the Actions pane

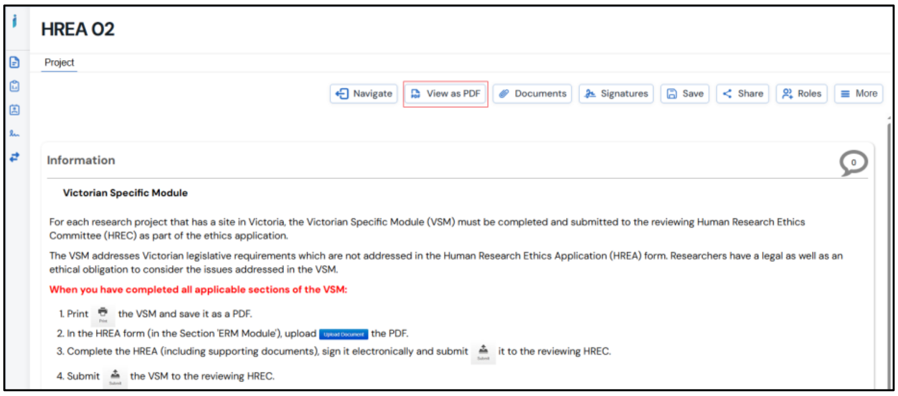


- A **Create Sub-**form text box will be displayed
  Select the Victorian Specific Module (VSM) from the drop-down list
  Select **Create**
- The VSM will appear in the Project Tree as a sub-form of the HREA
- Complete all applicable sections of the VSM form

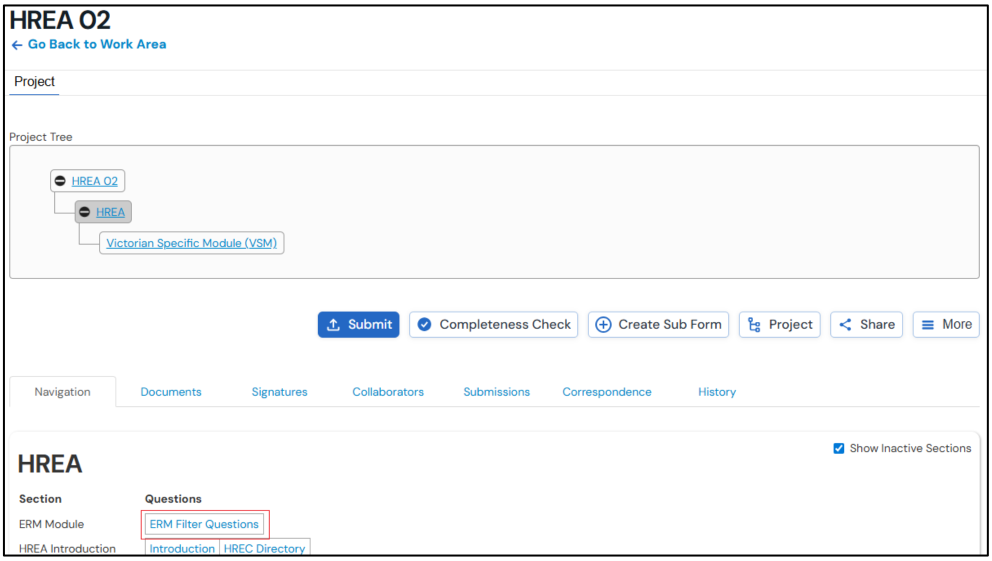




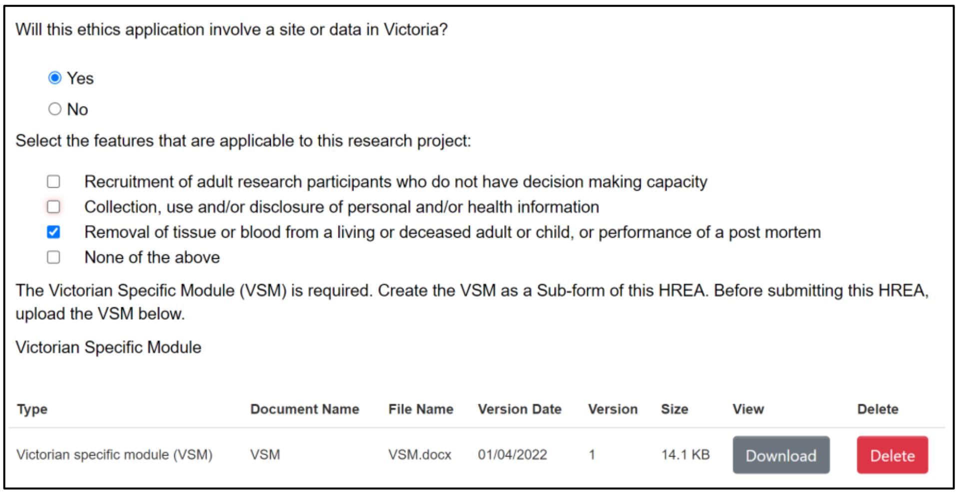
- In the VSM, select **View as PDF** action button to generate a pdf and save to your local drive



- Return to the HREA (highlight in Project Tree) and go to the ERM Filter Questions section



- Select **Upload Document** Upload Document to upload the pdf of the VSM
- The VSM is attached to the HREA as a supporting document


Will this ethics application involve a site or data in Victoria?

- (•) Yes
- ( ) No

Select the features that are applicable to this research project:

- [ ] Recruitment of adult research participants who do not have decision making capacity
- [ ] Collection, use and/or disclosure of personal and/or health information
- [x] Removal of tissue or blood from a living or deceased adult or child, or performance of a post mortem
- [ ] None of the above

The Victorian Specific Module (VSM) is required. Create the VSM as a Sub-form of this HREA. Before submitting this HREA, upload the VSM below.

Victorian Specific Module

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Victorian specific module (VSM)	VSM	VSM.docx	01/04/2022	1	14.1 KB	Download	Delete

- When the HREA is complete and all supporting documents are uploaded (including the VSM) and signatures obtained, select **Submit** Submit the HREA
- Return to the VSM in the Project Tree and **Submit** Submit the VSM
- If edits to the VSM are requested by the reviewing HREC, the Research Office will unlock the form and the form status changes to 'Information Requested'
- Complete the edits within the form
- From the VSM, select **View as PDF** action button to generate a pdf and save to your local drive
- Return to the HREA (highlight in the Project Tree), return to the section where the initial VSM was uploaded (ERM Filter Questions) as a pdf
- **Delete** Delete the previous VSM version and upload the revised version from your local drive to the HREA
- Continue to make revisions to the HREA if requested by the Research Office
- Once the HREA is ready for resubmission, **Submit** the HREA
- Return to the VSM in the Project Tree and **Submit** the VSM.

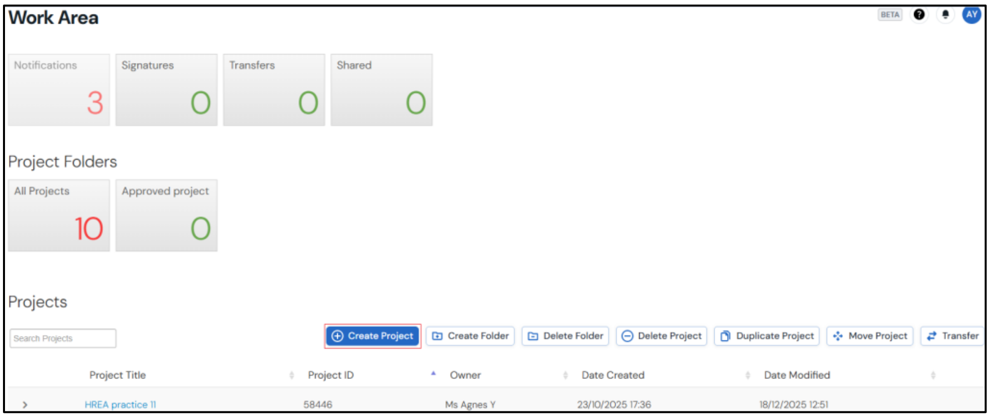
7 Victorian Low Risk Form (Low Risk VIC) application

The Victorian Low Risk Form (Low Risk VIC) can be used for single-site low risk research projects in Victoria only. A Victorian Specific Module is not required for projects utilising the Low Risk VIC application form.

This form is not for ethics review. Before completing the Low Risk VIC Form, consult with the reviewing organisation's Research Office on the non-HREC pathway for your project. Some reviewing organisations may not accept the Low Risk Form.

7.1 Create a Low Risk VIC form

- Log into ERM and go to the **Work Area**
- Select **Create Project** button under the Actions pane



- Enter the Project Title
- Select Victoria as the reviewing jurisdiction
- Select **Low Risk VIC** from the Main Form options
- Select **Create** button to create the project

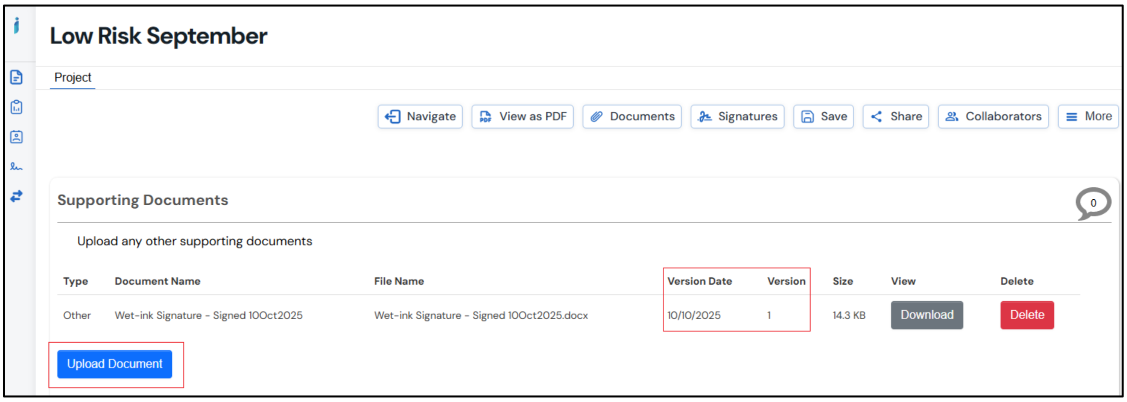
- The Project Tree will display the newly created project and Low Risk VIC

7.2 Complete the Low Risk VIC

- Working under the ‘Navigation’ tab, the **Introduction** section provides a drop-down list of reviewing organisations that will accept the Low Risk VIC form. Review this section before completing the form. If your organisation is not listed, contact your Research Office for guidance.
- Continue to complete each section relevant to your application

7.3 Upload documents

- Sections within the form allow supporting documents e.g. protocol, questionnaire to be uploaded into the form
- Other supporting documents can be uploaded by selecting the Supporting Documents hyperlink Supporting Documents located in the last section of the Low Risk VIC
- Press **Upload Document** Upload Document to attach the selected Supporting Document from your local drive
- Uploaded documents will be displayed under their type, name, file name and version
- Multiple documents of the same document type can be added by selecting Upload Document multiple times
- Specify the version and date to differentiate the documents within the same document type

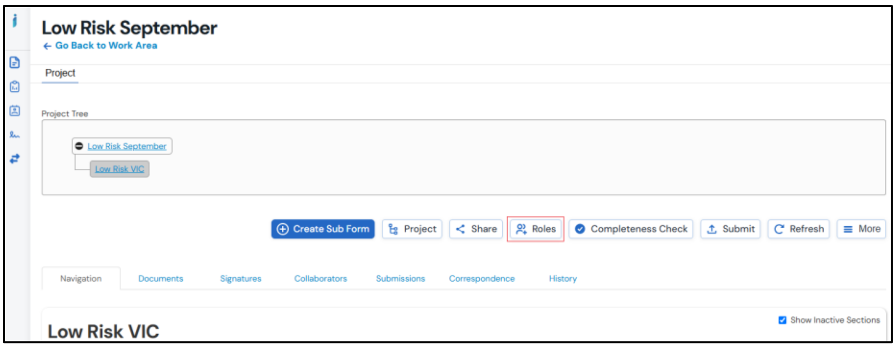


7.4 Assign access to the Low Risk VIC form

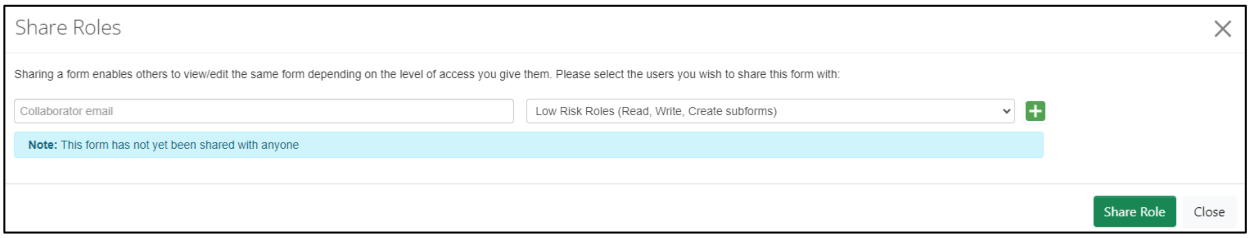
In ERM, the project owner can make the Low Risk VIC form available to other research team members.

Using the **Roles +** function, the project owner assigns other collaborators specific levels of access to the Low Risk VIC form.

- Select the **Roles +** Roles button under the Actions pane



- A **Share Roles** textbox will be displayed. Enter the collaborator’s ERM email address and select **Low Risk Roles**



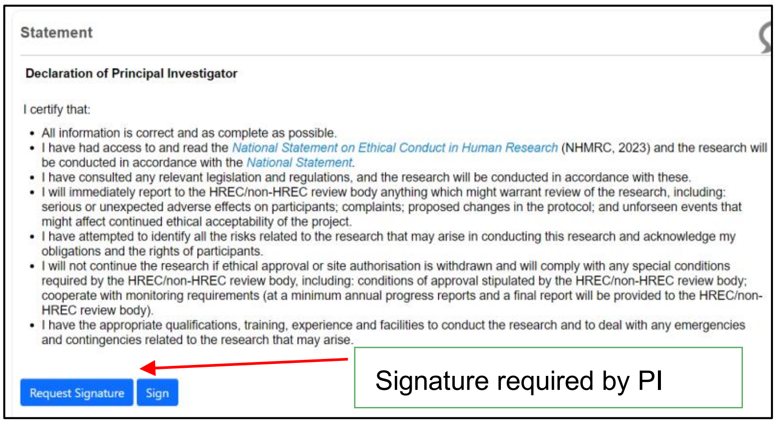
- Select **Share Role**
- The collaborator will receive an email notification of their assigned access to the form

7.5 Applying signatures

Declaration

The Principal Investigator is required to sign the Declaration page for the Low Risk VIC submission.

- A declaration may be completed by other researchers/investigators e.g. Associate Investigators
- Consult your institution’s policy for guidance on whether all members must sign this application or whether the PI can sign on behalf of the research team



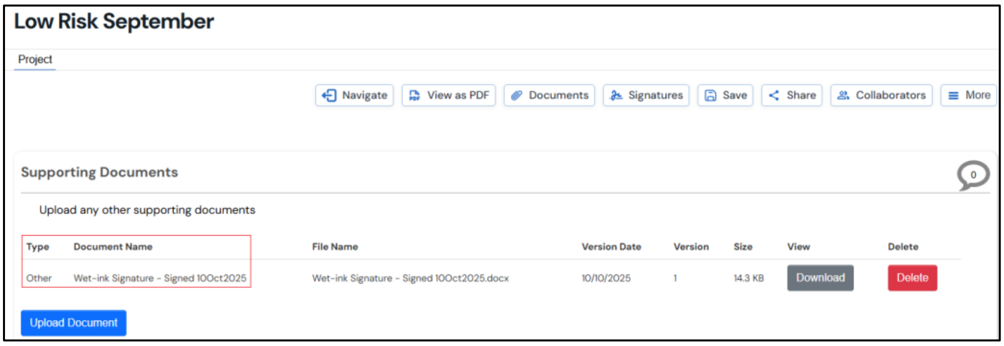
An electronic signature is obtained using **ERM.**

> The signatory must have an **ERM** account to provide an electronic signature
>
> An electronic signature should be sought LAST as the application/form will be locked once the electronic signature request has been made.
>
> If the AI is unable to electronically sign the declaration page, other options are available.

The Low Risk VIC form owner may request signatures as follows:

To use Wet ink signature

- Using the **View as PDF** button from the Actions pane, custom print the Declaration page and obtain the signature from the PI. Scan and save to your local drive as a pdf
- Navigate to last section of the Low Risk VIC to find the Supporting Documents hyperlink
- **Supporting Documents** opens to attach the Declaration page
- Select **Upload document** to upload the signed Declaration page to the Low Risk VIC
- The uploaded signed Declaration page will be displayed with the document, file name and version



To Upload other evidence – to attach an email copy / letter to indicate agreement

- Navigate to last section of the Low Risk VIC to find the Supporting Documents hyperlink
- **Supporting Documents** opens to attach the signature document
- Continue as described above to **Upload** the pdf document to the Low Risk VIC

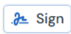
To request an Electronic Signature

- Select **Request Signature** button
- The system performs a completeness check to highlight any incomplete sections that need to be completed
- When all sections have been completed, select **Request Signature**
- Enter the signatory's ERM email address and select **Request**

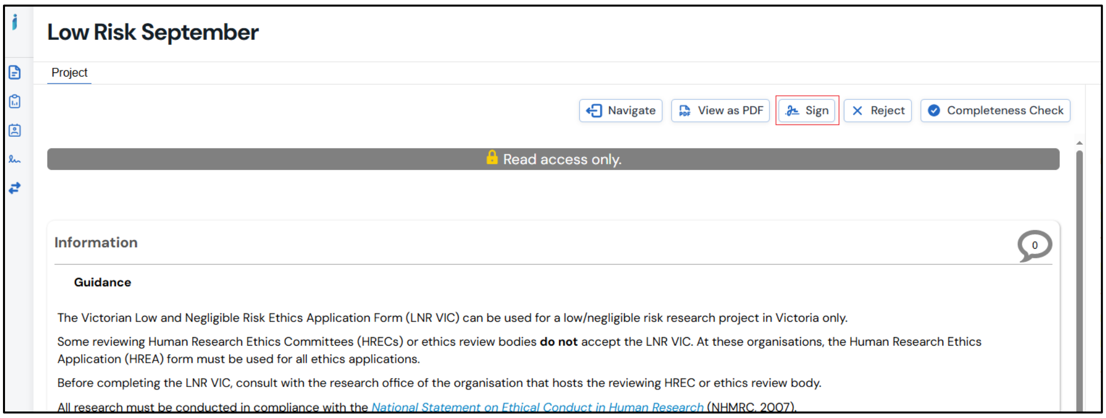
- The signatory will receive an email notification for a signature, a message and a link to ERM Log In page
- The signatory logs in to ERM
- From the **Work Area** the signatory selects **Signatures** tile to open the request

- New requests are highlighted
- Under the **Action** tab, select **View Form** 

to review the application

- For endorsement of the application, select **Sign** 

button under the Actions pane



- A **Sign Form** text box is displayed. The signatory enters their ERM log in details to sign the form
- Select **Sign** 

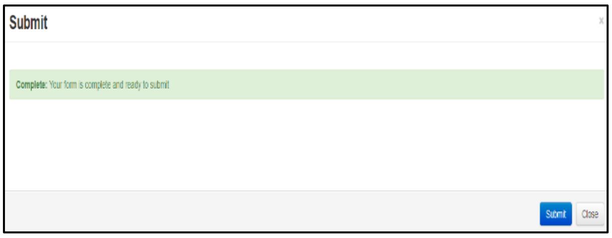
button
- The applicant receives an email notification indicating the signature request has been accepted
- Repeat the signatory process for electronic signatures from other members if required e.g. Associate Investigator if indicated in the Research Team in the Low Risk VIC
- Once the signature is complete the application is ready for submission.

8 Submission and review process – Low Risk VIC

Initial application submission – ensure the Form is complete and all documents are uploaded and signatures completed

8.1 Submission

- Navigate to the Actions pane and select the **Submit** button
- The system performs a completeness check to highlight any incomplete sections
  If complete, the form is ready to be submitted
- Select the **Submit** button



- The system will automatically submit the application to the ethics review body selected in the 'Introduction' section of the Low Risk VIC form

- Following submission, a unique identification code is generated.
  It is composed of six parts – e.g. Low Risk VIC Form/112045/DEF-2024-445600(v1)

Application type	Low Risk
ERM Project ID	112045
Organisation/hospital code	DEF
Year	2024 – year of submission
Submission number	445600 – submission version number
Version number	v1

Recall an application

- Once the application has been submitted, a recall option becomes available

Any changes made to the submission will INVALIDATE all electronic signatures

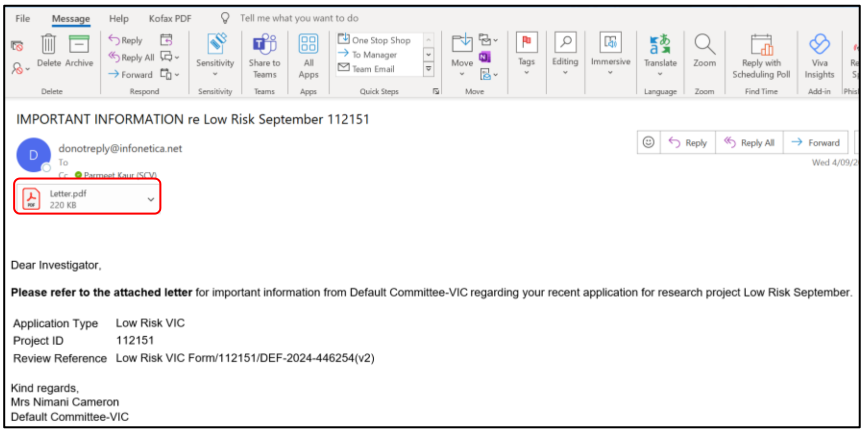
and will require all signature requests again

- The form can be recalled **until** the submission is actioned by the Research Office
- The recall removes the submitted application from the Research Office's ERM account
- Select the **Recall** button under the Actions pane to recall the submission and make any changes / additions
- Select the **Submit** button again. The application will be resubmitted

8.2 Responding to a query from the Research Office

If an application is queried by the Research Office for further clarification or changes, additions (e.g. supporting documents):

- The applicant is advised via an ERM email of important information regarding their application

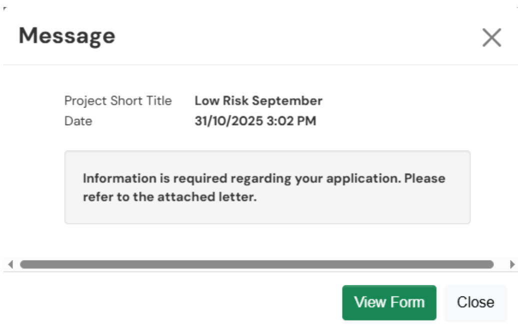


- A 'QUERY-LOW RISK APPLICATION' letter (pdf) from the Research Office will include details for further information to be provided via ERM
- The form will be ***unlocked*** to allow the applicant to complete the revisions / additions as requested

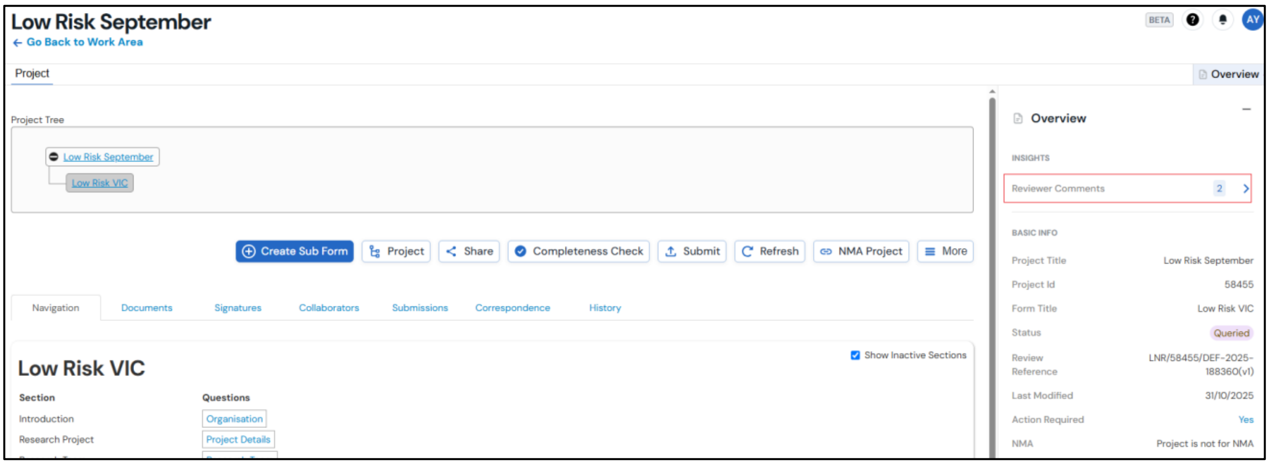
To access the Query

- In the Work Area, click on the **Notification** tile
- Select the Message title to open and view the message

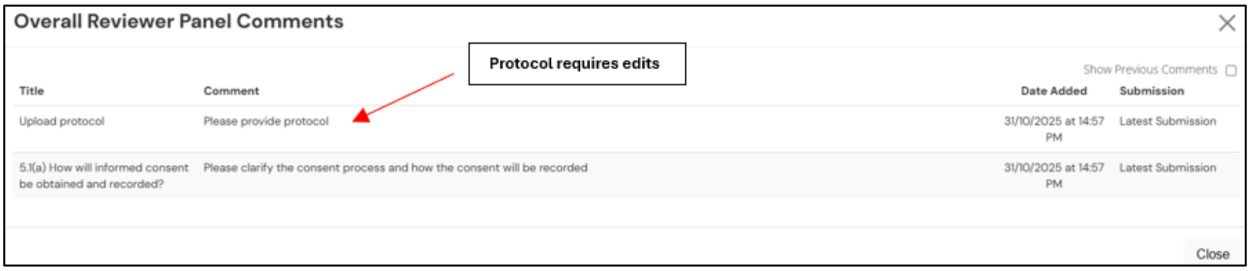
- A **Message** box will be displayed allowing the user to view the form
- Press **View Form** View Form to be directed to the relevant form
- The Low Risk VIC form will open under the **Navigation** tab.
- Select **Reviewers Comments** Reviewer Comments 2 under the Overview pane



OFFICIAL



- A text box will be displayed of the **Overall Reviewer Panel Comments**



- Select the comment to be directed to the relevant section in the form i.e. to **Protocol**
- As the query requires a new version of a **document**, the original version should be deleted, and the new version uploaded into the form. Previous document versions are automatically archived.
- Select **Delete** Delete to delete the original version

Upload protocol

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Protocol	Protocol	Protocol.docx	31/10/2025	1	14.2 KB	Download	Delete

- Select **Upload Document** Upload Document to upload the revised (new) version of the document with the correct version number and date

Upload protocol

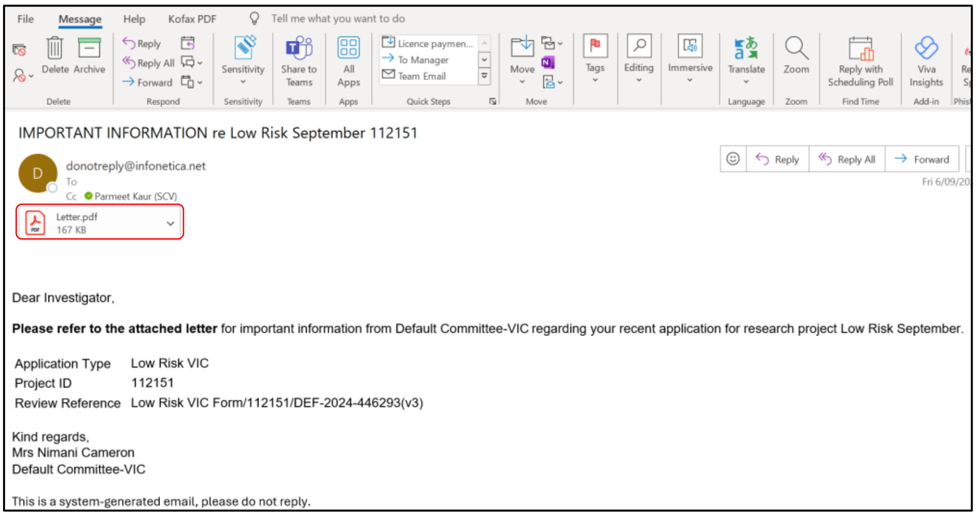
Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Protocol	Protocol - updated	Protocol - updated.docx	31/10/2025	1.2	14.2 KB	Download	Delete

- Continue to complete other queries if instructed in the **Overall Reviewer Panel Comments**
- Once the revisions / additions have been completed, the form and / or supporting documents can be resubmitted
- Select **Submit** Submit button under the **Actions pane** to resubmit the revised application
- The Research Office will receive the submission
- The application is assigned to a Committee meeting
- Following the Committee review there may be an information request from the Committee.

8.3 Committee review request

Clarification or requests for further information from the reviewing Committee to the applicant must be managed through ERM

- The applicant is advised via an ERM email of important information regarding the application



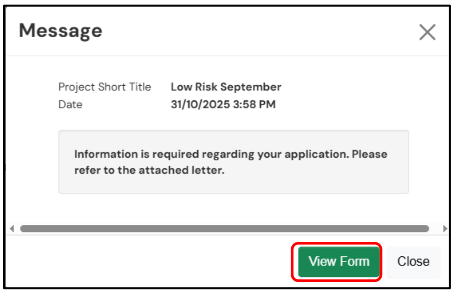
- A 'REQUEST FOR FURTHER INFORMATION' letter (pdf) from the Committee will include requests for further information to be provided via ERM
- The form is **unlocked** to allow the applicant to complete the requests as outlined in the attached letter

Respond to a request for further information from the Committee

- Depending on the request, the applicant can amend the Low Risk VIC form and add new documents
- Log in to ERM account
- In the Work Area, click on the **Notifications** tile
- Select the Message title to open and view the message

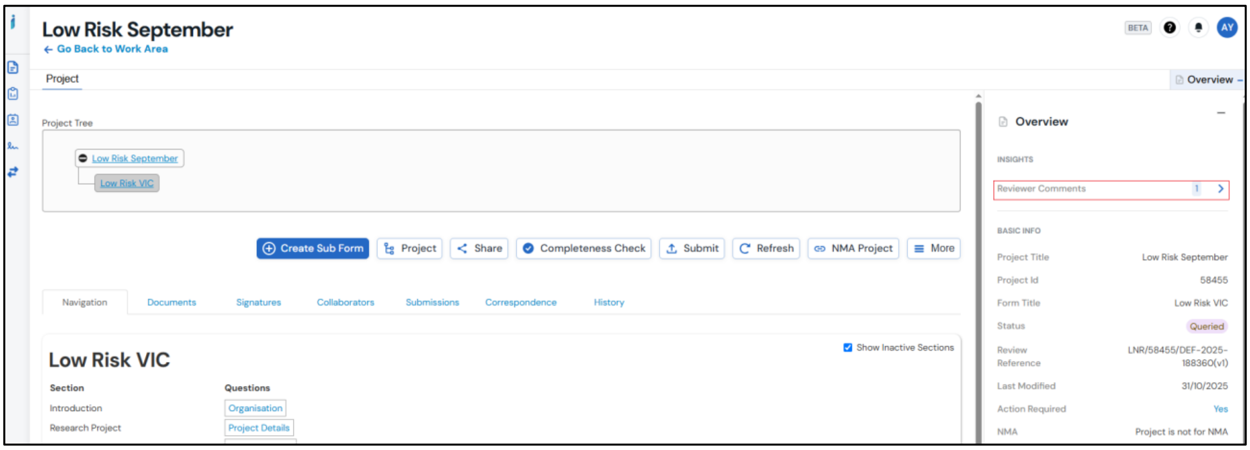
- A message box will be displayed allowing the user to view the form

  Press **View Form** View Form to be directed to the relevant form



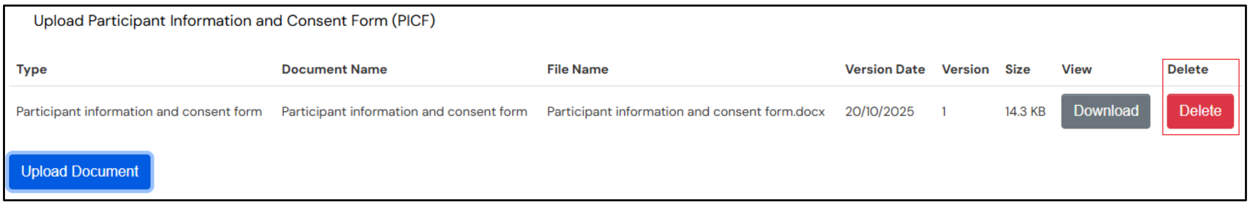
OFFICIAL

- The Low Risk VIC will open under the **Navigation** tab

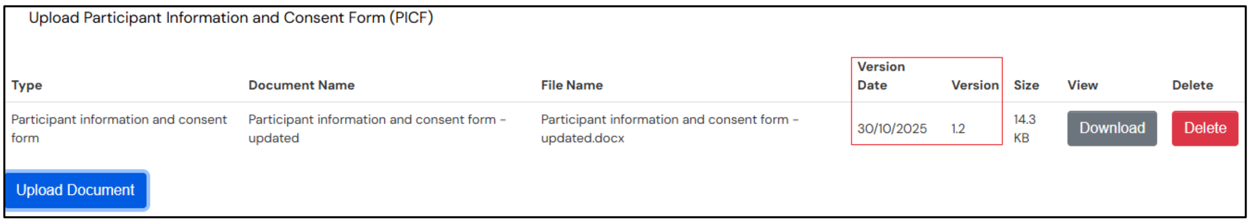


- Select **Reviewers Comments** Reviewer Comments 1 > under the Actions pane
- A text box will be displayed of the **Overall Reviewer Panel Comments**

- Select the comment relating to the Committee request to be directed to the relevant section in the form i.e. **Upload Participant Information and Consent Form (PICF)**
- The request requires a new version of a PICF. The original version should be deleted, and the new version uploaded into the form. Previous document versions are automatically archived.
- Select **Delete** Delete to delete the original version



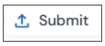
- Select **Upload Document** Upload Document to upload the revised (new) version of the PICF with the correct version number and date
- The Low Risk VIC now includes the latest version ready for resubmission



- Continue to complete other requests if instructed in the **Overall Reviewer Panel Comments**

Note amending a form and/or adding a new document will invalidate any electronic signatures.

To re-submit the form what signatures are required? 1. For minor changes the Research Office has signatures from the initial submission 2. Check with the research office policy before requesting signature(s) for substantial changes and resubmission

- In the Actions pane select **Submit** 

button to resubmit
- The reviewing Research Office will receive the resubmission

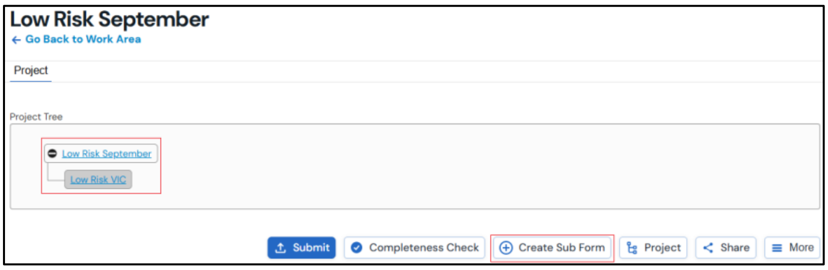
Approved Applications

- Applicants are informed of decisions by the Committee via email using ERM. If the application has been approved, the form is locked
- Log on to ERM and click on **Notifications** tile
- A formal approval letter from the Committee can be downloaded by the applicant
- If the application review outcome is **not approved**, applicants are also informed via email through ERM.

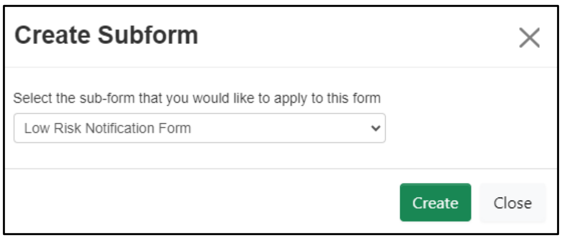
8.4 Low Risk Notification Form

Once a research project has been ethically approved, any changes to its design or conduct must be reviewed by the ethics review body. Post approval information should also be submitted to the reviewing organisation. The Low Risk Notification Form can be adapted for post approval reporting requirements. The Low Risk Notification Form reports to the reviewing committee on post reporting requirements; amendments, progress reports, site audit reports and a final report.

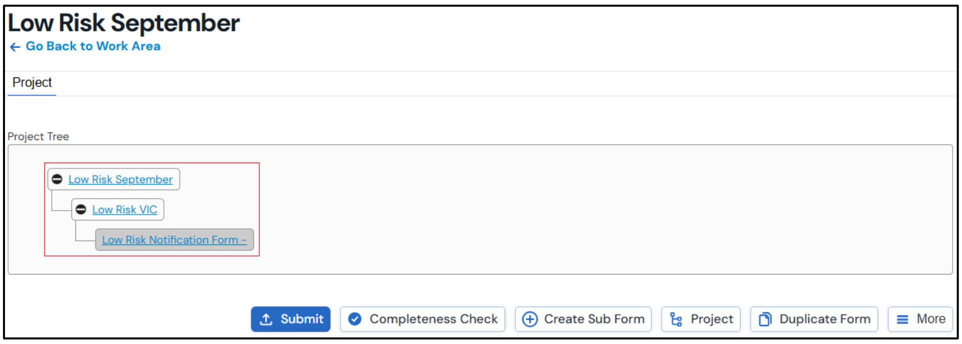
- From the Low Risk VIC, select **Create Sub-form** button under the Actions pane



- A **Create Sub-form** box will be displayed
- Select Low Risk Notification Form from the drop-down list
- Select **Create** button



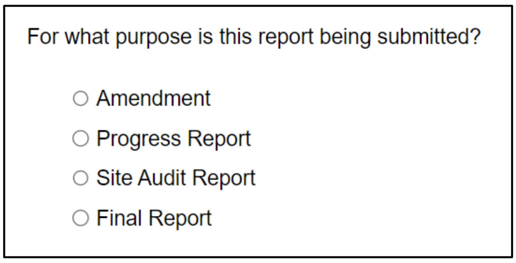
- The Project Tree will display the newly created Low Risk Notification Form



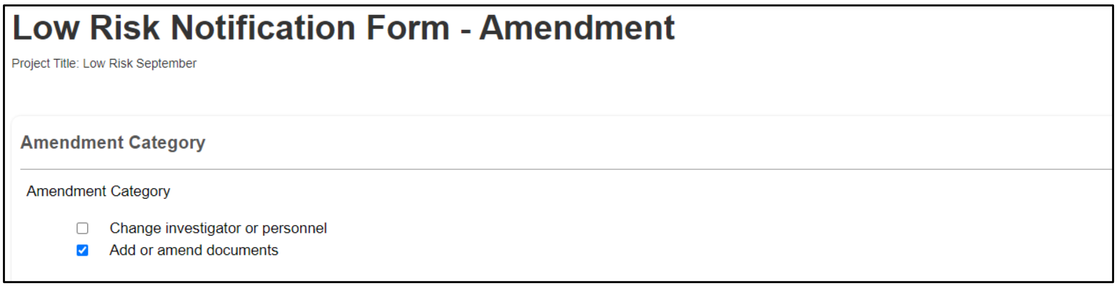
- Information from the Low Risk VIC will not automatically populate the Low Risk Notification Form

8.5 Complete the Low Risk Notification Form

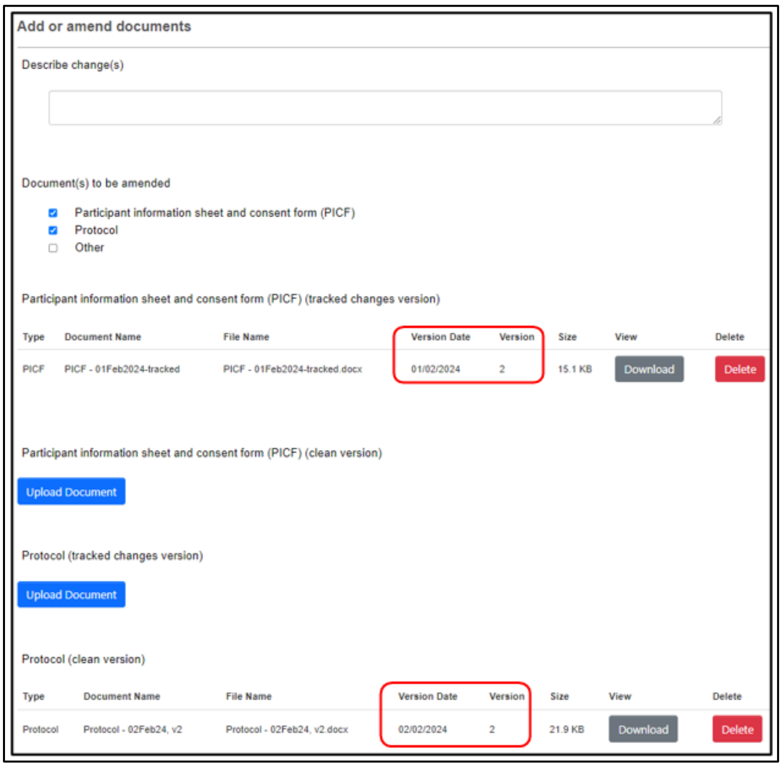
- Complete the questions in the Low Risk Notification Form
- Depending on the purpose of the report, documents can be attached to the form



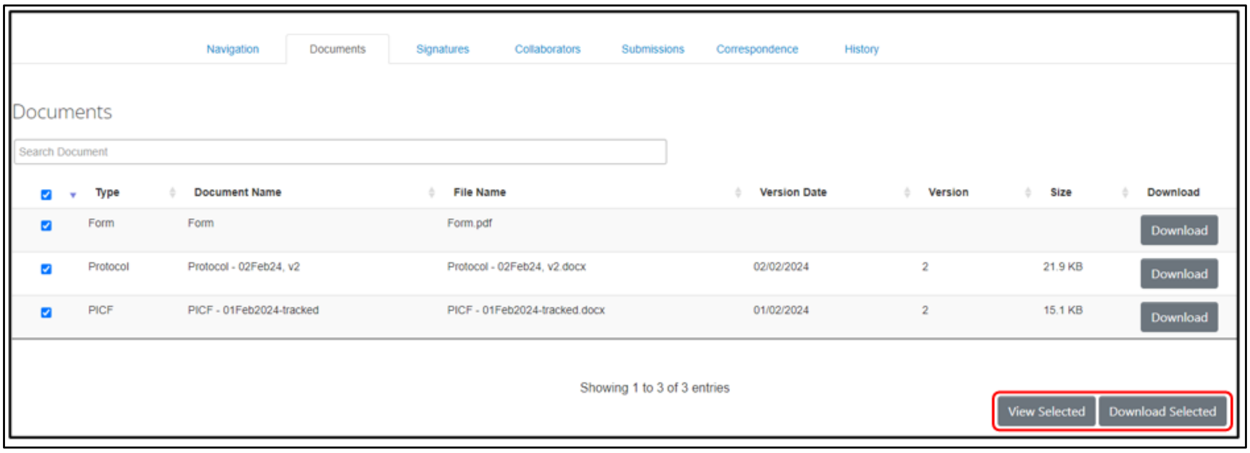
- Add or amend documents will allow for new versions of the documents to be attached e.g. PICF or protocol



- Select **Upload Document** Upload Document to attach the amendment documents form your local drive
- Specific the version and date



- Documents will be displayed under the **Documents** tab and can be viewed or downloaded individually or together
- Select the checkbox for each corresponding document or all documents can be selected at once
- The **View Selected** button to open the document as a PDF in a new browser or select the **Download Selected** button to download as a zip file



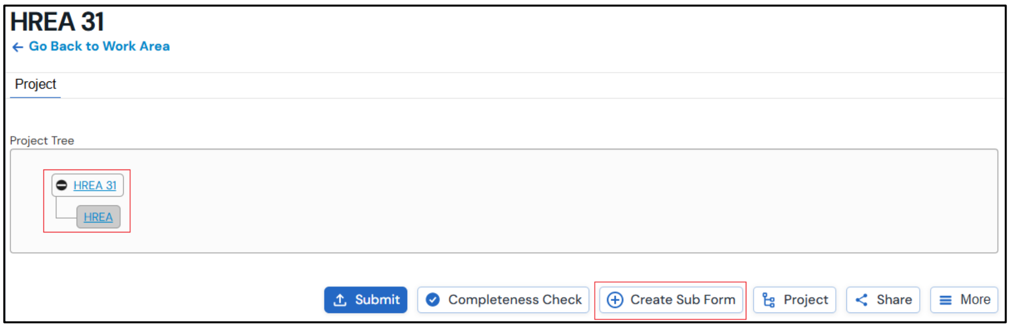
9 Site Specific Assessment (SSA)

The Victorian SSA form is used to address governance at a public health organisation in Victoria.

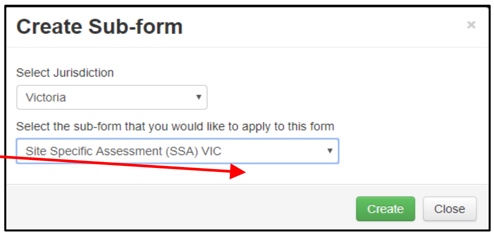
It is the responsibility of the site Principal Investigator to complete the Victorian SSA form for their site, and to submit the form to the site Research Governance Officer (RGO).

9.1 Create an SSA

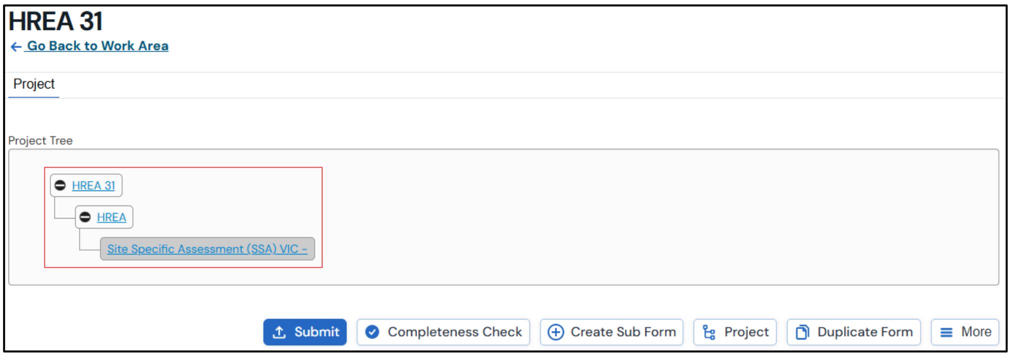
- From the HREA or Low Risk VIC, select **Create Sub-form** button under the Actions pane



- A **Create Sub-form** box will be displayed
- Select the jurisdiction
- Select SSA VIC from the drop-down list
- Select **Create** button



- The Project Tree will display the newly created SSA



- Information from the HREA will not automatically populate the SSA

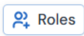
9.2 Creating SSAs for sites

The SSA for a site is created by either the **HREA** (**or Low Risk VIC**) project owner **or** by assigning this role to the site PI.

The creation and management of site SSAs in **ERM** should be determined by the CPI / delegate.

Both options **(i) and (ii)** are described below:

(i) HREA project owner

- The HREA project owner creates the SSA as sub-form of the HREA and becomes the SSA form owner
- The HREA / SSA owner may start the SSA then assign responsibility for its completion and submission to the site PI
- Highlight the SSA in the Project Tree
- In the **Introduction** section of the SSA form, complete question **Q 1.4** to enter the name of the site/organisation
- Select **Roles+** 

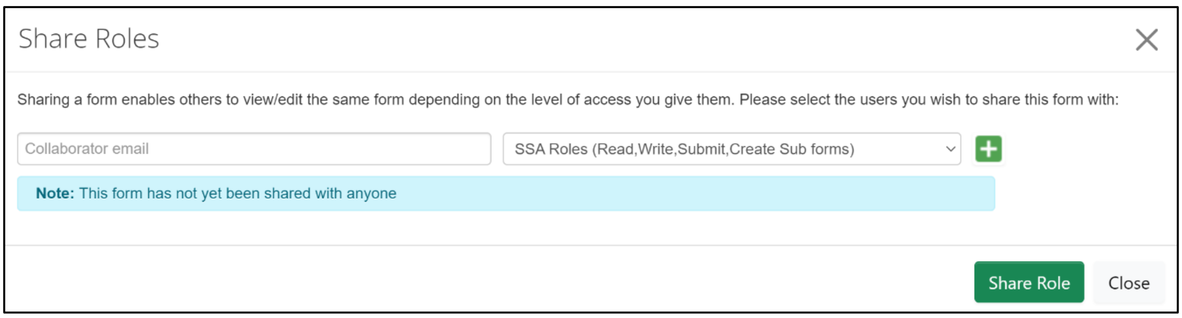
button under the Actions pane

- A **Share Roles** text box will be displayed

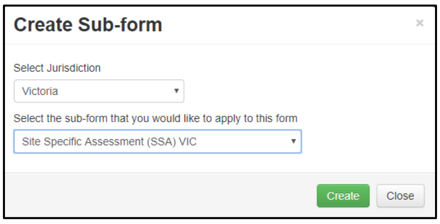
Enter the collaborator’s (site PI) email address and select **SSA Roles**

This level of access includes all of the following:

- read
- write
- submit
- create subforms e.g. Site Notification Form
- receive notifications

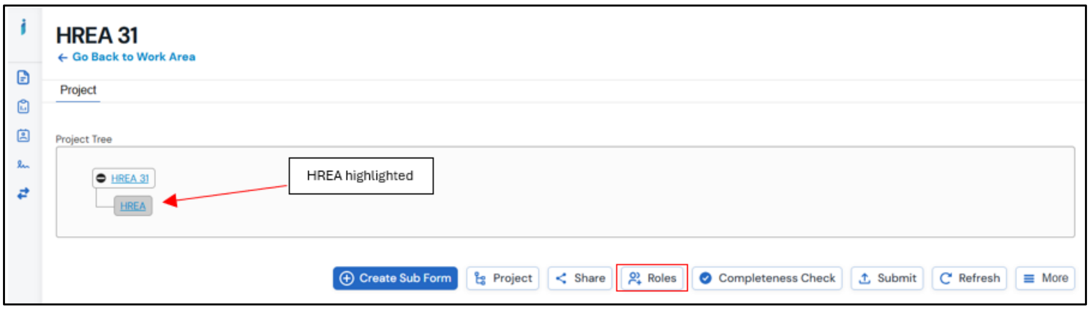


- Other research team members can be added using the button
- Select **Share Role** button
- Access shared using **SSA Roles** will allow the collaborator to view any post authorisation subforms created by other site collaborators after the SSA is authorised
- The collaborator e.g. the site PI will receive an email notification about their assigned role in the project
- The collaborator logs into ERM and follows the steps as described in [Assign access to the HREA]
- The project (HREA) and SSA will be displayed in the Project Tree
- Using **Roles +** allows the collaborator to also view the HREA form and supporting documents. All documents uploaded to the ethics application by the CPI are automatically available when the CPI has shared the SSA (using Roles+) with the site PI
- The collaborator can continue to complete the SSA form

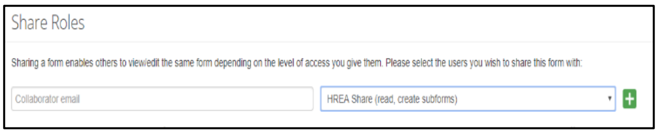


(ii) Assigning Role to Site PI

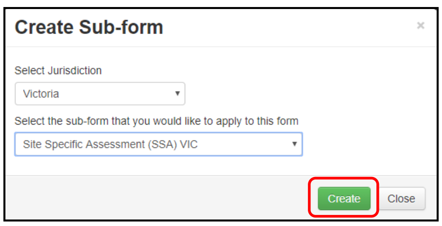
- The HREA is allocated to the PI/delegate using **Roles +** allowing the PI access to the HREA to create their own SSA
- The HREA project owner selects the **Roles +** Roles button under the Actions pane



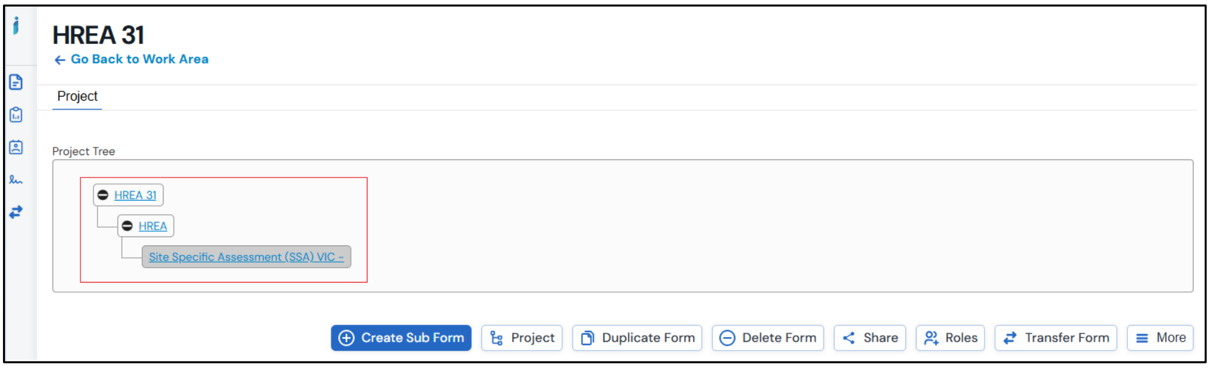
- A **Share Roles** text box will be displayed
- Enter the collaborator's (site PI) email address and select **HREA Share (read, create subforms)**
- Select **Share Role** Share Role
- The collaborator will receive an email notification about their assigned role in the project
- The collaborator logs into ERM and follows the steps as described in [Assign access to the HREA]
- The project (HREA) will be displayed in the Project Tree



- Highlight the HREA in the Project Tree
- Select the **Create Sub-form** Create Sub Form button under the Actions pane
- A **Create Sub-form** text box will be displayed
- Select **Site Specific Assessment (SSA) VIC**
- Select **Create**



- The SSA will be displayed in the Project Tree



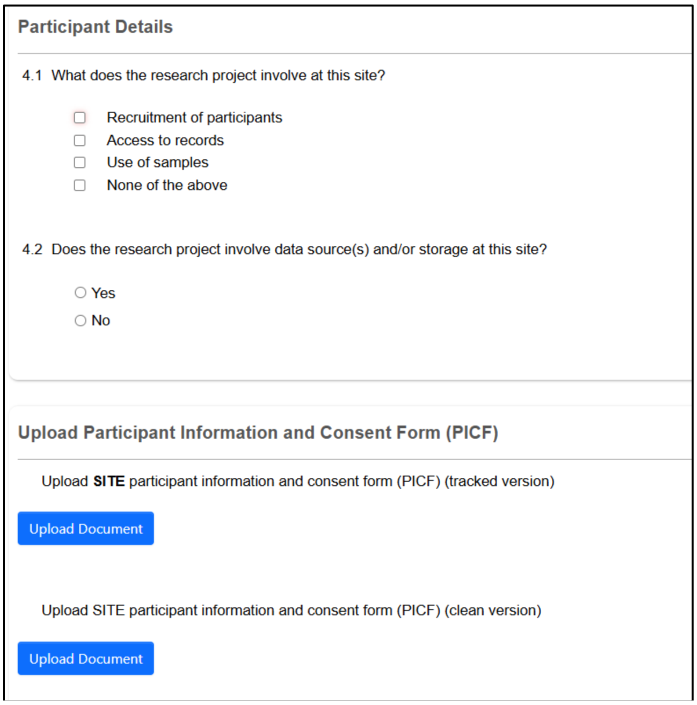
- Complete the SSA form

9.3 Upload documents

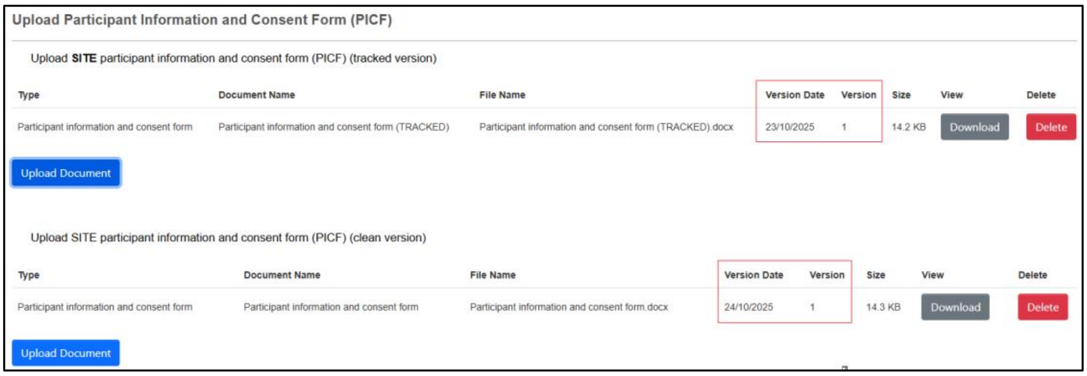
All site specific supporting documents are uploaded to the SSA when completing the relevant question in the form. See table below for examples of document types.

Section	Questions (hyperlinks)		Document Example
Site Research Team	Documents		Curriculum Vitae, GCP training certificates
Recruitment	Participant Details	**Q 4.1**	Site specific PICF
Regulation	Research Agreement	**Q 5.2**	Clinical Trial Research Agreement (CTRA)
Other Documents	Other Documents	**Q 7.1**	Signature document, Departmental forms

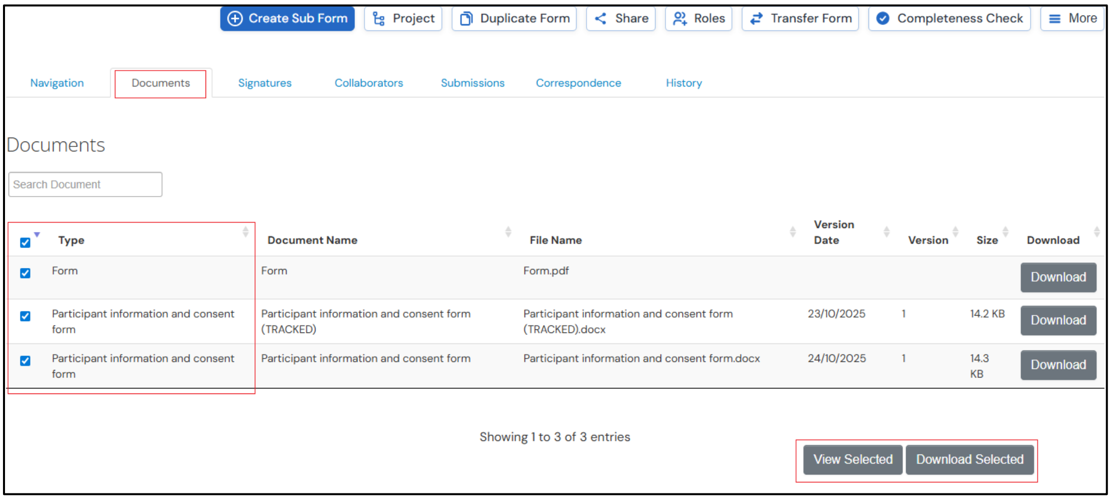
- Example – Site specific PICF



- Press **Upload Document** to attach the site specific PICF from your local drive
- Uploaded documents will be displayed under their type, name, file name and version
- Multiple documents of the same document type can be added by selecting multiple times
- Specify the version and date to differentiate the documents within the same document type



- Documents will be displayed under the **Documents** tab and can be viewed or downloaded individually or together
- Select the checkbox for each corresponding document or all documents can be selected at once

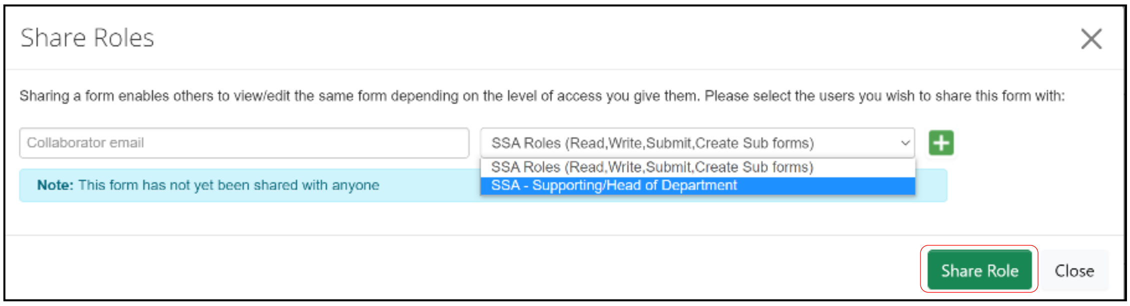


- Select the **View Selected** button to open the document as a PDF in a new browser **or** select the **Download Selected** button to download as ZIP file

9.4 Assign access to the SSA form

In ERM, only the **SSA form owner** can make the SSA available to other research team members using the **Roles+** function.

- Select the **Roles+** button under the Actions pane
- Enter the collaborator's email address and select **SSA Roles.**
  Select **Share Role** button

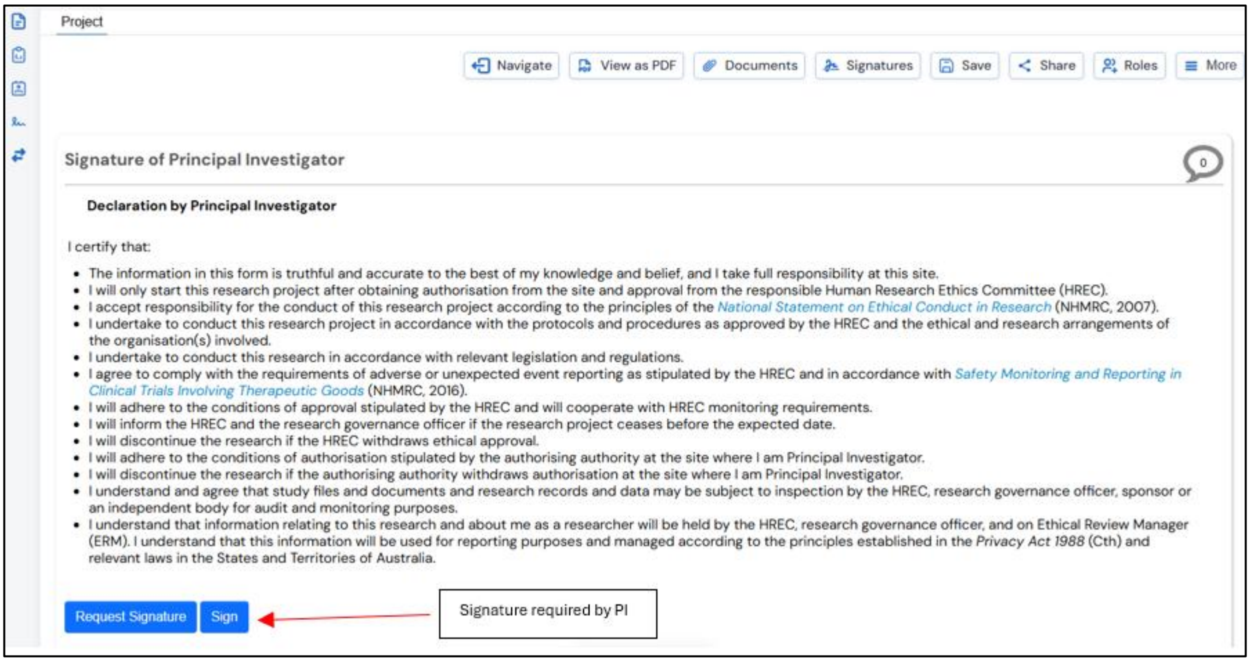


- The collaborator will receive an email notification regarding access to the project
- The collaborator logs in to ERM and follows the steps as described in [Assign access to the HREA]
- The collaborator will be able to view and edit the SSA

9.5 Applying signatures

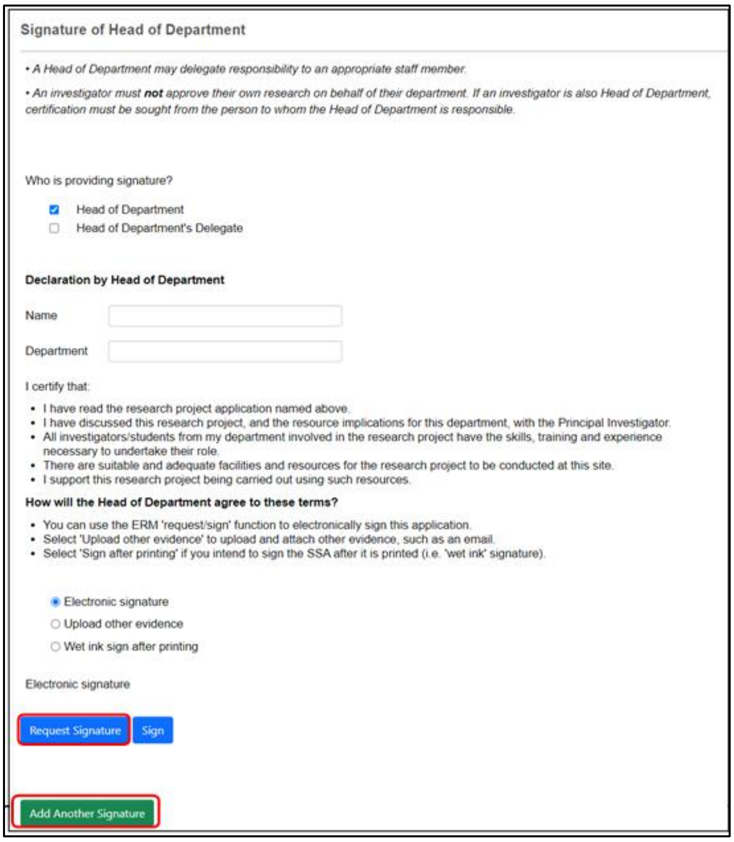
Declaration

The Principal Investigator (PI) is required to sign the Declaration by Principal Investigator page in the SSA form for endorsement of the project at the site.



- For departments directly involved in the research project **(SSA Q 3.3)**, the department head is required to sign the Declaration by Head of Department

- Use the ‘Add Another Signature’ button if multiple departments signatures are required



Signature of Head of Department

• *A Head of Department may delegate responsibility to an appropriate staff member.*

• *An investigator must **not** approve their own research on behalf of their department. If an investigator is also Head of Department, certification must be sought from the person to whom the Head of Department is responsible.*

Who is providing signature?

- [x] Head of Department
- [ ] Head of Department's Delegate

Declaration by Head of Department

Name

Department

I certify that:

- I have read the research project application named above.
- I have discussed this research project, and the resource implications for this department, with the Principal Investigator.
- All investigators/students from my department involved in the research project have the skills, training and experience necessary to undertake their role.
- There are suitable and adequate facilities and resources for the research project to be conducted at this site.
- I support this research project being carried out using such resources.

How will the Head of Department agree to these terms?

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

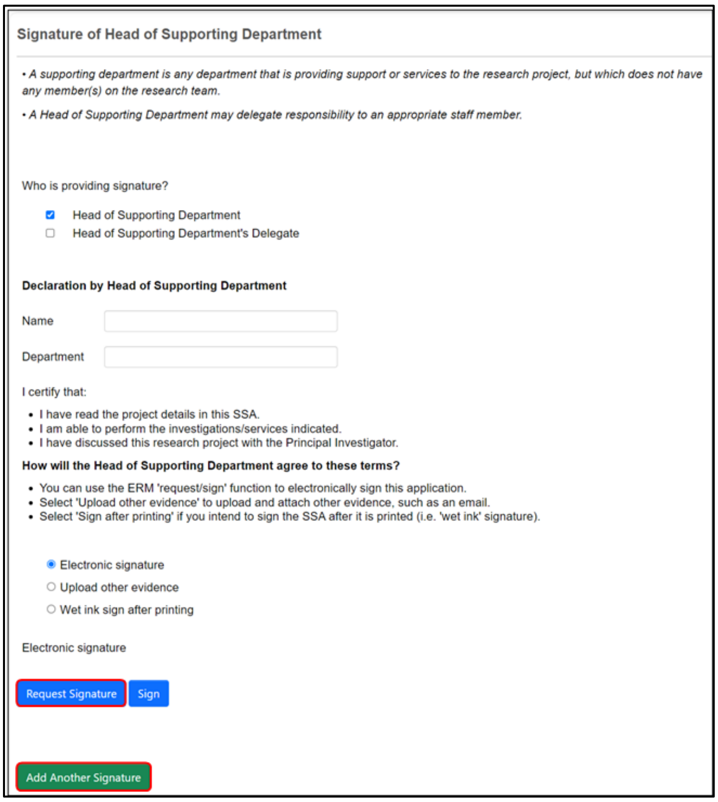
(•) Electronic signature
( ) Upload other evidence
( ) Wet ink sign after printing

Electronic signature

Request Signature Sign

Add Another Signature

- For any department that is providing support or services to the research project, the supporting department head is required to sign the Declaration by Head of Supporting Department



Signature of Head of Supporting Department

• *A supporting department is any department that is providing support or services to the research project, but which does not have any member(s) on the research team.*

• *A Head of Supporting Department may delegate responsibility to an appropriate staff member.*

Who is providing signature?

- [x] Head of Supporting Department
- [ ] Head of Supporting Department's Delegate

Declaration by Head of Supporting Department

Name

Department

I certify that:

- I have read the project details in this SSA.
- I am able to perform the investigations/services indicated.
- I have discussed this research project with the Principal Investigator.

How will the Head of Supporting Department agree to these terms?

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

(•) Electronic signature
( ) Upload other evidence
( ) Wet ink sign after printing

Electronic signature

Request Signature Sign

Add Another Signature

Use the 'Add Another Signature' button if multiple supporting departments signatures are required
Signatures

The SSA form questions / information must be complete, <u>before</u> requesting signatures.

Any change to the SSA form will invalidate signatures.

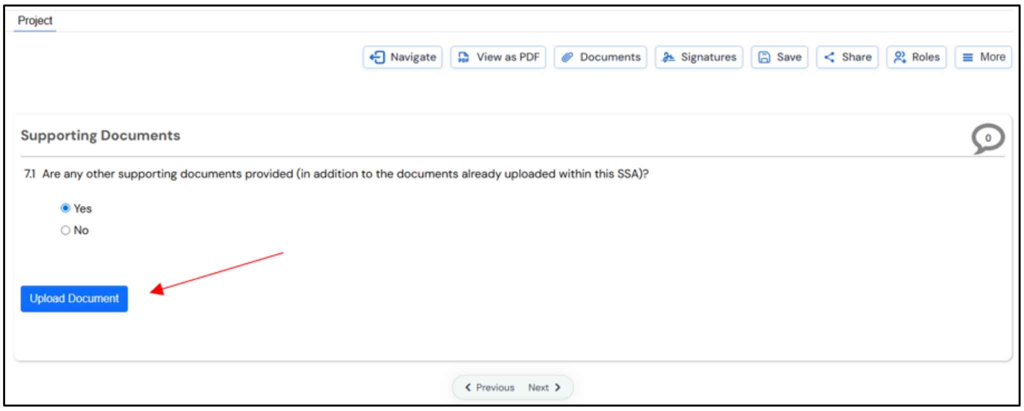
Using a combination of signature methods e.g. wet ink signatures, attaching other evidence, electronic signatures should be sought LAST as the form will be locked once electronic signature requests have been made. Multiple electronic signatures can occur.

*** Signatories must have an ERM account to provide electronic signature**

The SSA form owner / user may obtain signatures as follows:

To use Wet ink signature

- Select the 'Wet ink sign after printing' option
- Using the **View as PDF** View as PDF button from the Actions pane, custom print the relevant Declaration page and obtain the signature and date from the PI /Head of Department /Supporting Head of Department. Scan and save to your local drive as a PDF
- Navigate to Section **Other Documents** of the SSA to find Other Documents
- **Other Documents** opens to **Q 7.1** of the SSA form to attach the Declaration page
- Select **Upload document** Upload Document to upload the Declaration page from your local drive to the SSA form

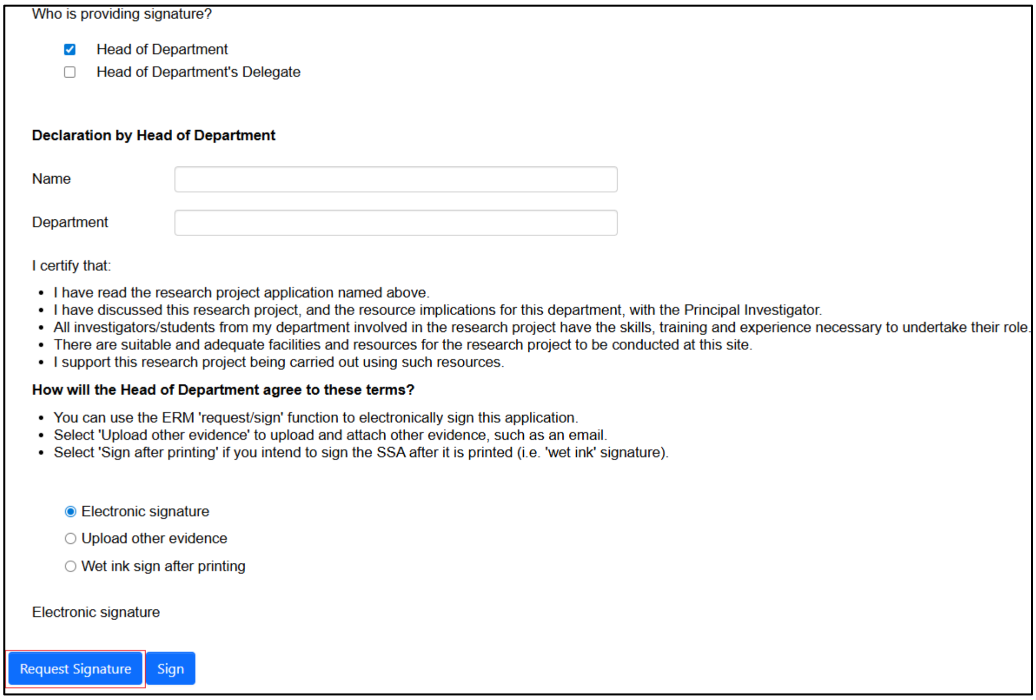


To attach other evidence to indicate agreement

- Select the 'Upload other evidence' option to attach other evidence e.g. an email
- Select **Upload Document** Upload Document to upload the signature document from your local drive to the SSA form

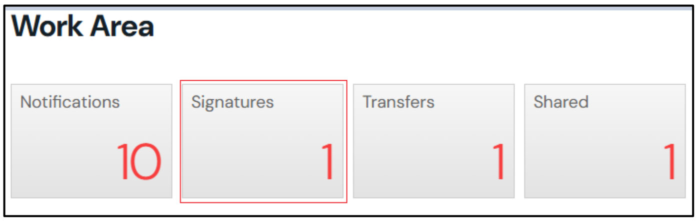
To request an Electronic Signature

- To request an electronic signature from the Head of Department, Supporting Head of Department or Principal Investigator select **Request Signature**  button

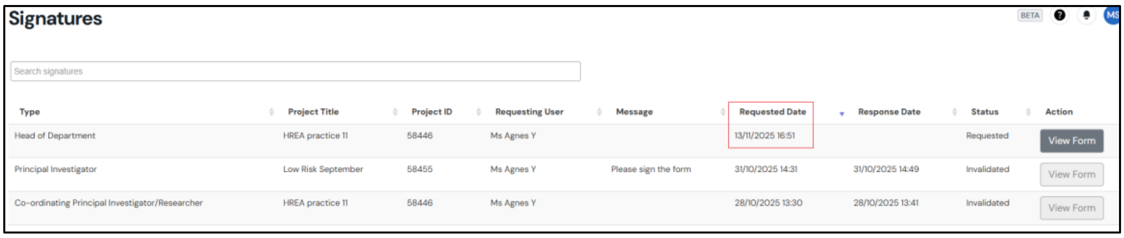


- Enter the signatory's ERM email address and select **Request**

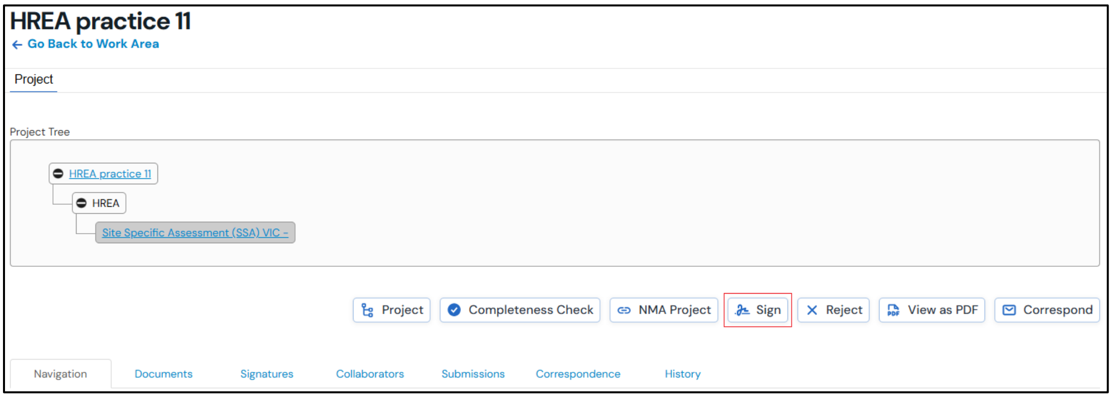
- The requested signatory will receive an email notification for a signature
- The signatory logs into ERM
- From the **Work Area** the signatory selects the **Signatures** tile to open the request



- New requests are highlighted



- Under the **Action** tab, select **View Form** View Form to review the SSA form. The signatory has Read access only
- For endorsement of the SSA application, select **Sign** Sign button under the Actions pane



- The ethics application (**HREA**) can be viewed if the HREA owner has used **Roles +** from the SSA level to share the form with the signatory
- A **Sign Form** text box is displayed

  The signatory enters their ERM log in details to sign the form

  Select **Sign** Sign button

- The applicant receives an email notification indicating the signature request has been accepted by the signatory i.e. the form has been signed
- Repeat the signatory process for electronic signatures for other signatories
- **All signatures must be obtained before the SSA can be submitted to the site Research Governance Officer**
- Once the signature is complete the application is ready for submission

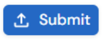
OFFICIAL

10 Submission and review process – SSA form

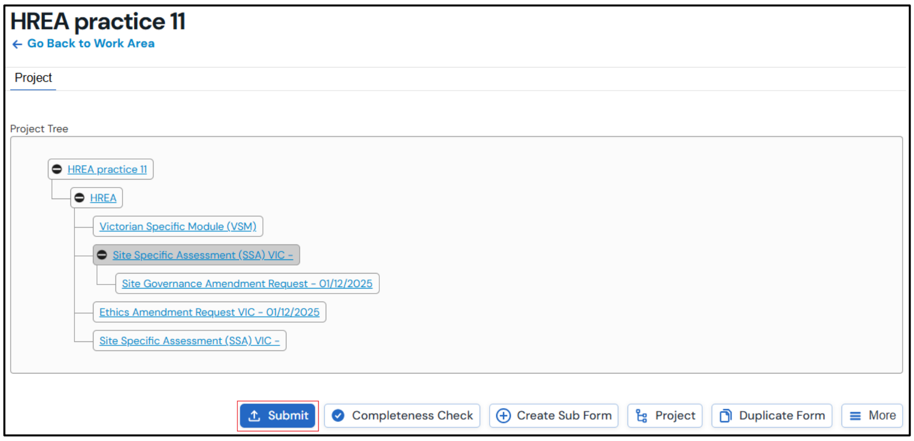
Ensure the SSA form is complete and all site documents are uploaded and **signatures completed**.

When the SSA is submitted, the site Research Governance Officer (RGO) automatically has access to all documents uploaded to the main (ethics) form when the ethics application has been submitted via ERM to a Victorian or Queensland HREC. This means that only site governance documents should be uploaded to the SSA form and submitted for authorisation.

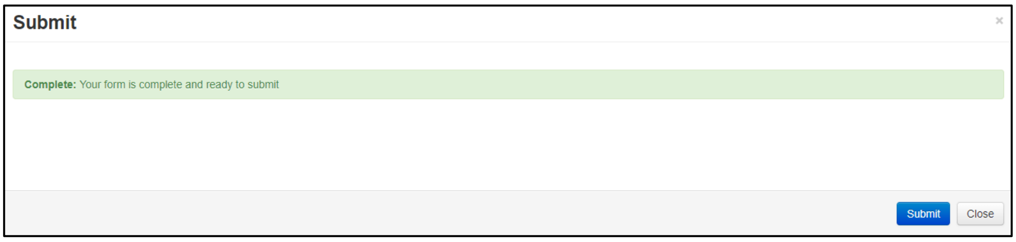
10.1 Submission

- Navigate to the Actions pane and select **Submit** 

button



- The system performs a completeness check to highlight any incomplete sections.
- If complete, the form is ready to be submitted



- Select the **Submit** 

button
- The system will automatically submit the application to the site/organisation selected in **Q 1.4** of the SSA
- Following the submission, a unique identification code is generated.
  It is composed of six parts - e.g. SSA/60889/VICTEST-2020-201446(v1)

Application type	SSA
Project ID	60889 – ERM project number
Organisation/hospital code	VICTEST
Year	2020- year of submission
Submission number	201446 - submission version number
Version number	v1

Recall an application

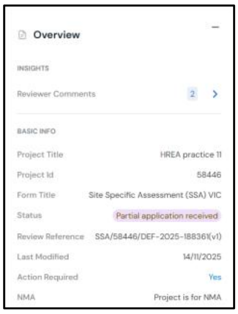
Any changes made to the submission will INVALIDATE all electronic signatures and will require all signature requests again

- Once the SSA application has been submitted, a recall option becomes available
- The form can be recalled **until** the submission is actioned by the Research Office
- This action removes the submitted application from the Research Office's ERM account
- Select the **Recall** Recall button under More to recall the submission and make any changes / additions
- Check that any electronic signatures are completed
- Select the **Submit** Submit button. The application will be resubmitted

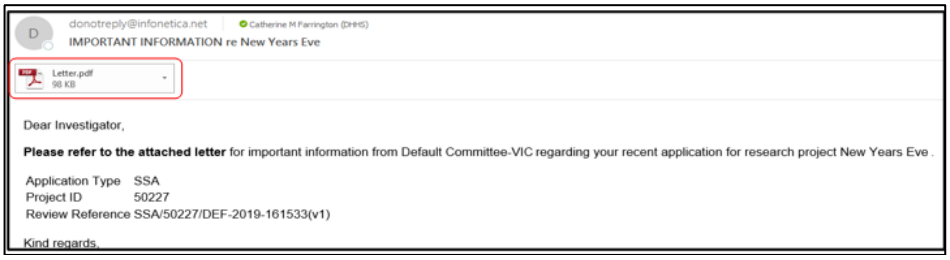
10.2 Responding to a query from the Research Office

The SSA application may be queried by the Research Office for further clarification or changes, additions (e.g. supporting documents). The form is unlocked for the applicant to complete the edits/revisions.

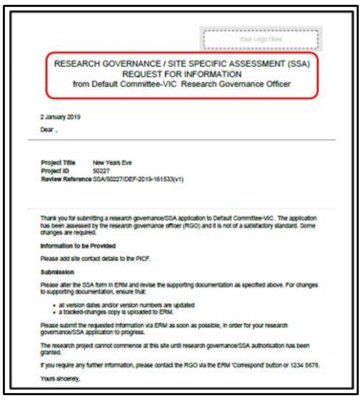
The form Status has changed from 'Submitted' to 'Partial application received' indicating the application is incomplete.



- The applicant is advised via an ERM email of important information regarding their SSA application



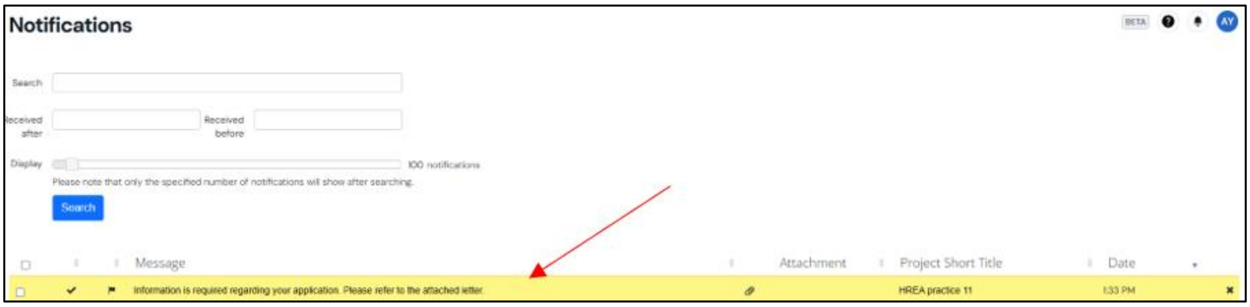
- A 'REQUEST FOR INFORMATION' letter (pdf) from the Research Office will include details for further information to be provided via ERM



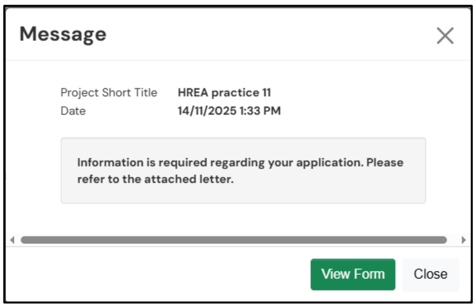
To access the query

- In the Work Area, click on the **Notifications** tile

- Select the Message title to open and view the message

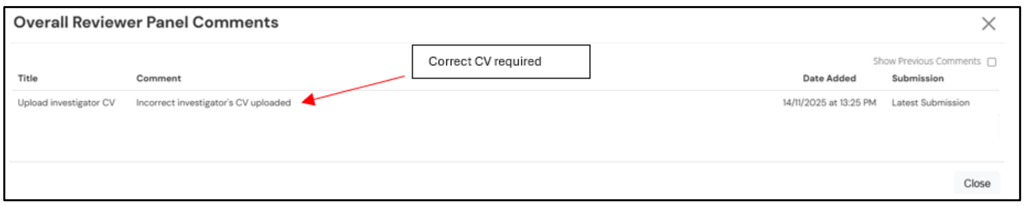


- A **Message** box will be displayed allowing the user to view the form
- Press **View Form** View Form to be directed to the relevant form

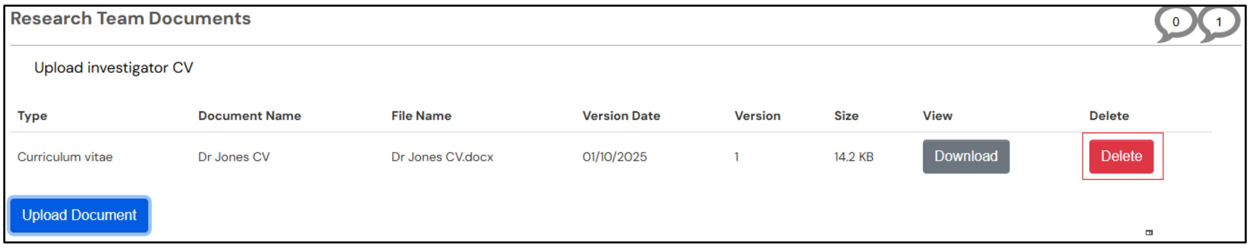


- The SSA form will open under the **Navigation** tab
- Select **Reviewers Comments** Reviewer Comments 2 under the Overview pane

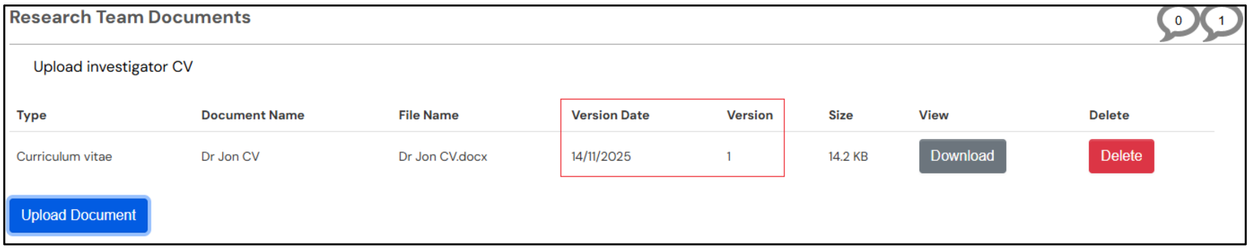
- A text box will be displayed of the **Overall Reviewer Panel Comments**



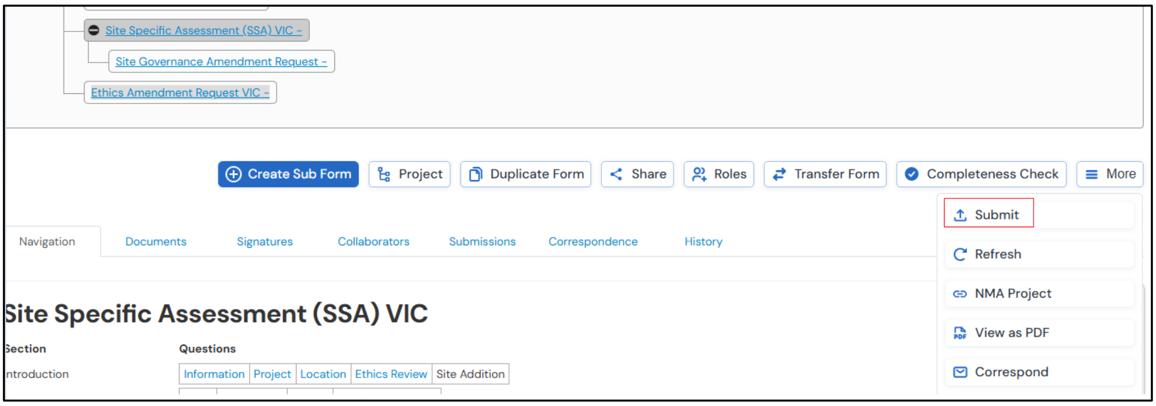
- Select the comment to be directed to the relevant section in the SSA form, e.g. to **Research Team Documents**
- As the query requires a correct version of a document, the original version should be deleted, and the new version uploaded into the form. Previous document versions are automatically archived.
- Select **Delete** Delete to delete the original version



- Select **Upload Document** Upload Document to upload the revised (new) version of the document with the correct version number and date
- The SSA form now includes the latest version ready for resubmission



- Once the revisions / additions have been completed, the form and / or supporting documents can be resubmitted
- In the **Actions pane** select the **Submit** Submit button to resubmit



- The Research Office will receive the submission
- The SSA application is assessed by the Research Governance Officer (RGO)
- Following the assessment there may be an information request from the RGO

10.3 RGO review request

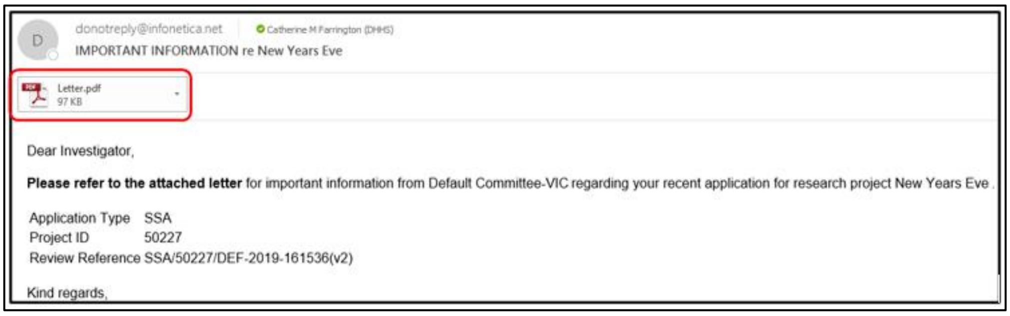
Clarification or requests for further information from the RGO to the applicant must be managed through ERM.

The form is unlocked for the applicant to complete the edits/revisions.

The form Status has changed from 'Submitted' to 'Information requested'-

Action Required	Status	Review Reference	Date Modified	NMA
Yes	Information requested	SSA/74950/VICTEST-2021-257730(v2)	05/04/2021 13:25	Project is for NMA

- The applicant is advised via an ERM email of important information regarding the SSA application


donotreply@infonetica.net
Catherine M Farrington (DHHS)
IMPORTANT INFORMATION re New Years Eve
Letter.pdf
97 KB

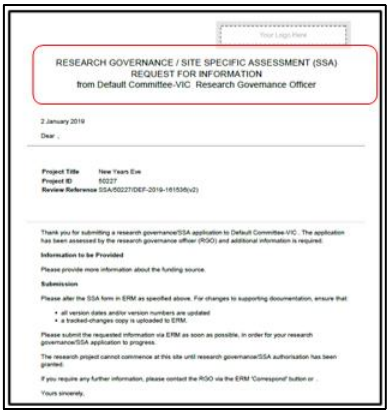
Dear Investigator,

Please refer to the attached letter for important information from Default Committee-VIC regarding your recent application for research project New Years Eve .

Application Type SSA
Project ID 50227
Review Reference SSA/50227/DEF-2019-161536(v2)

Kind regards,

- A 'REQUEST FOR INFORMATION' letter (pdf) from the RGO will include requests for further information to be provided via ERM


Your Logo Here

RESEARCH GOVERNANCE / SITE SPECIFIC ASSESSMENT (SSA)
REQUEST FOR INFORMATION
from Default Committee-VIC Research Governance Officer

2 January 2019

Dear ,

Project Title New Years Eve
Project ID 50227
Review Reference SSA/50227/DEF-2019-161536(v2)

Thank you for submitting a research governance/SSA application to Default Committee-VIC . The application has been assessed by the research governance officer (RGO) and additional information is required.

Information to be Provided

Please provide more information about the funding source.

Submission

Please alter the SSA form in ERM as specified above. For changes to supporting documentation, ensure that:

- all version dates and/or version numbers are updated
- a tracked-changes copy is uploaded to ERM.

Please submit the requested information via ERM as soon as possible, in order for your research governance/SSA application to progress.

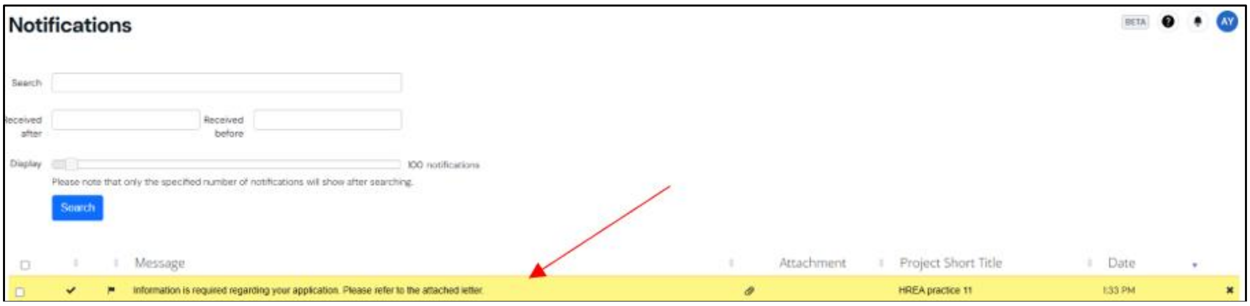
The research project cannot commence at this site until research governance/SSA authorisation has been granted.

If you require any further information, please contact the RGO via the ERM 'Correspond' button or .

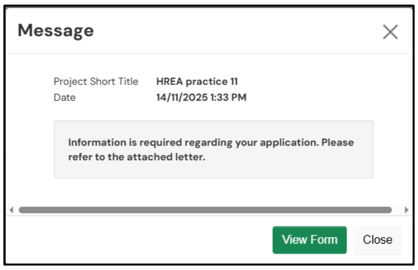
Yours sincerely,

Respond to a request for further information from the RGO

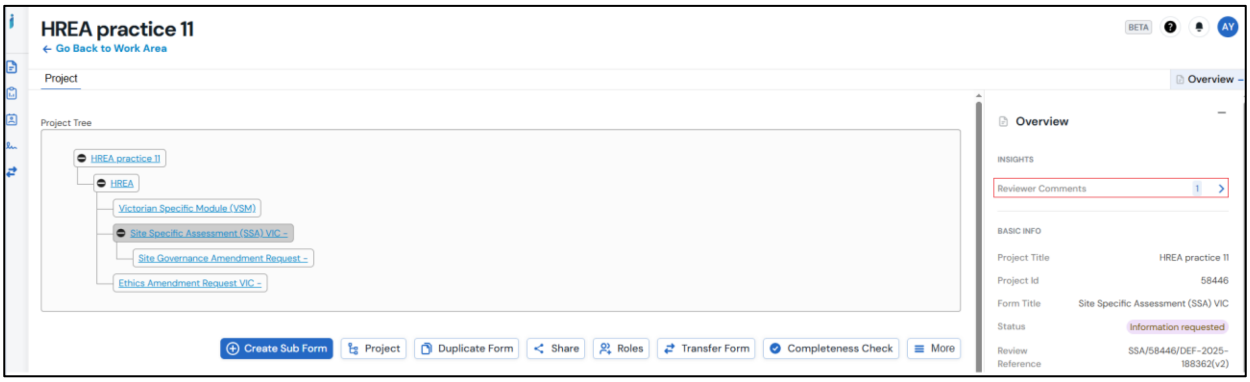
- The applicant can amend the SSA and add new documents if requested by the RGO
- Log into ERM account
- In the Work Area, click on the **Notifications** tile
- Select the Message title to open and view the message



- A message box will be displayed allowing the user to view the SSA form
- Press **View Form** View Form to be directed to the relevant section in the SSA form

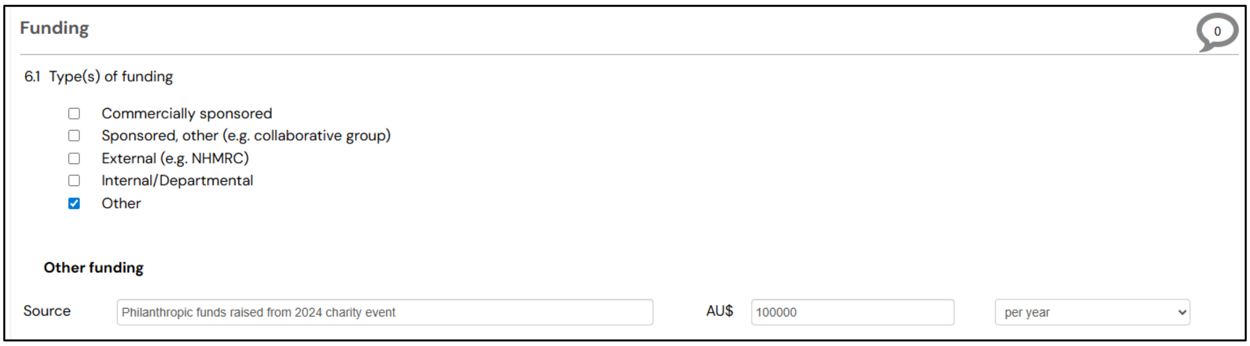


- The SSA will open under the Navigation tab
- Select **Reviewers Comments** Reviewer Comments 1 > under the Actions pane



- A text box will be displayed of the **Overall Reviewer Panel Comments**

- Select a comment e.g. comment requesting more information about the funding source, to be directed to the relevant section in the form i.e. **Q 6.1 Type(s) of funding**



- Enter the requested information as instructed in the **Overall Reviewer Panel Comments**
- Continue to complete other requests if necessary

To re-submit the form what signature/s are required?

1. The PI signs. For minor changes the Research Office has all signatures on the initial submission.
   - If further signatures are not required, change the signature option to either 'wet-ink' or 'upload other evidence' to reset the signature method.
2. Other signatories to sign if a substantial change or required by local policy.

Check with other signatories and the Research Office policy before requesting signatures and re-submission

- In the Actions pane select **Submit** Create Project button to resubmit
- The reviewing RGO will receive the resubmission

Authorised Applications

- Applicants are informed of decisions by the RGO via email using ERM. If the application has been authorised, the form is locked
- Log on to ERM and click on **Notifications** tile
- A formal authorisation letter from the RGO can be downloaded by the applicant
- If the application review outcome is **not authorised**, applicants are also informed via email through ERM.

11 Minimal Dataset Form (MDF)

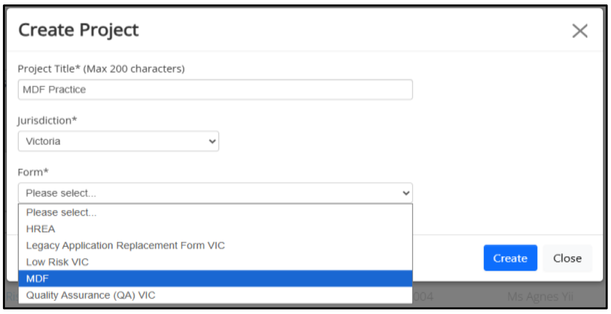
11.1 Creating a MDF and submission

When the ethical review of a research application is in a jurisdiction that does not use ERM, a Minimal Dataset Form (MDF) is used to create the SSA form for sites in Victoria and Queensland.

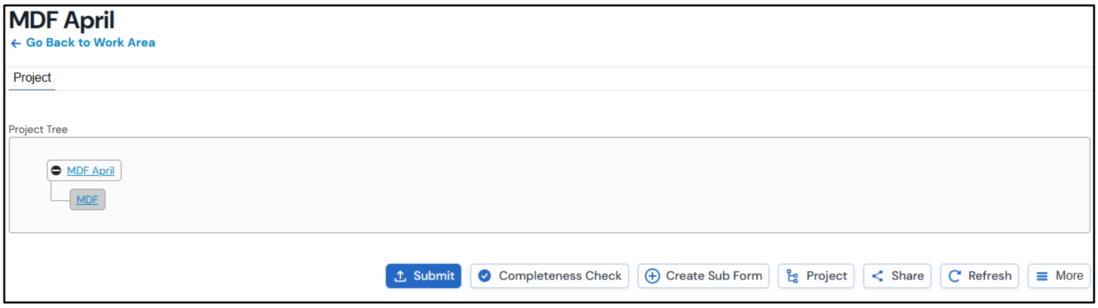
It is a proxy form that is created **once only** for the research application.

The site Principal Investigator uses ERM to complete the SSA and submit to the site Research Governance Officer.

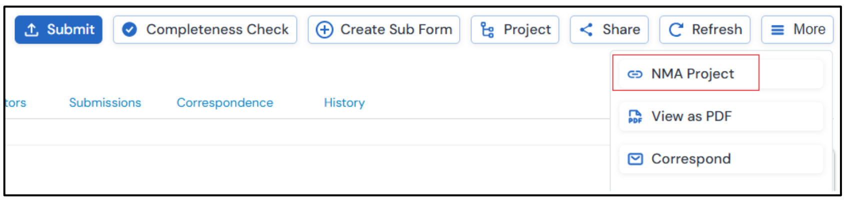
- The CPI / delegate logs onto ERM
- Select **Create Project** button under the Actions pane to create a new Main Form
- Enter the Project Title, jurisdiction and select **MDF** from the Main Form drop-down list
- Select **Create** button



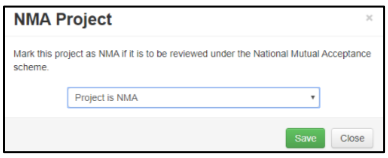
- The MDF will appear in the Project Tree



- Complete the questions in the MDF
- Enter the unique ethics reference number indicating where the ethics application was reviewed and approved e.g. HREC/19/CAL/123
- Select the **Navigate** button to move back to the Project Tree and select the **NMA Project** under the **More** button

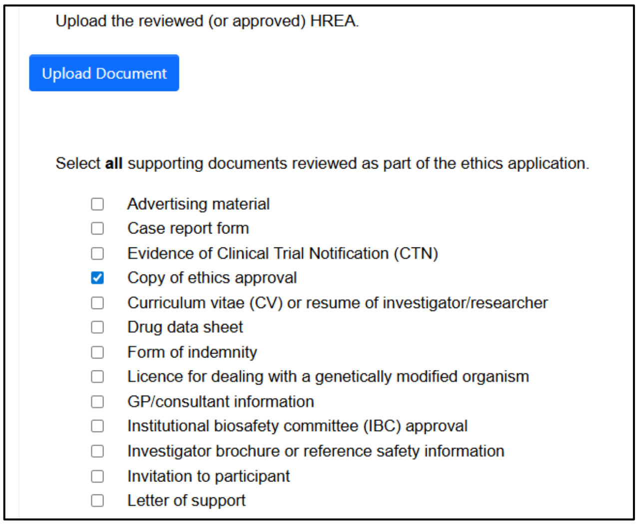


- A **NMA Project** text box is displayed
- Select 'Project is NMA' and **Save**

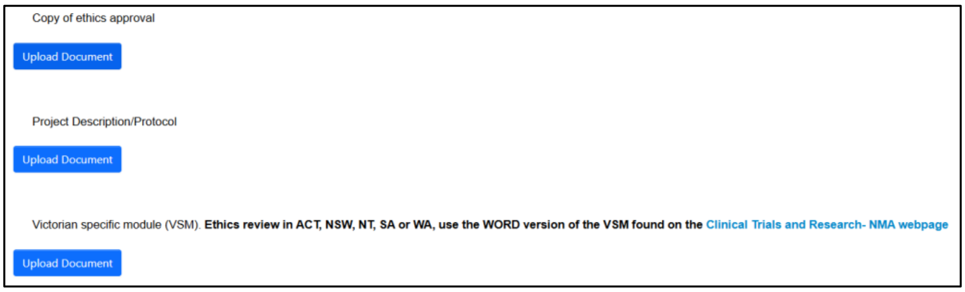


For further information see NMA or research governance applications on the Safer Care Victoria Research website

- Select **Upload Document** to upload a copy of the HREA reviewed by the NMA HREC into the MDF
- Select the relevant supporting documents e.g. Copy of ethics approval letter, Master PICF, protocol associated with the ethics application.



- Select **Upload Document** to upload the PICF, protocol and other relevant documents from your local drive.
  Ensure the Victorian Specific Module (VSM) is selected if a VSM was submitted as part of the ethics application. The CPI should provide a copy of the WORD document of the VSM that was submitted to the reviewing HREC.



- Select **Submit** button under the Actions pane. The **Submit** action is a systems action and does not submit the form to a HREC
- The site RGO will have access to the uploaded ethics documents in the MDF when the site SSA is submitted

11.2 Creating SSAs for sites

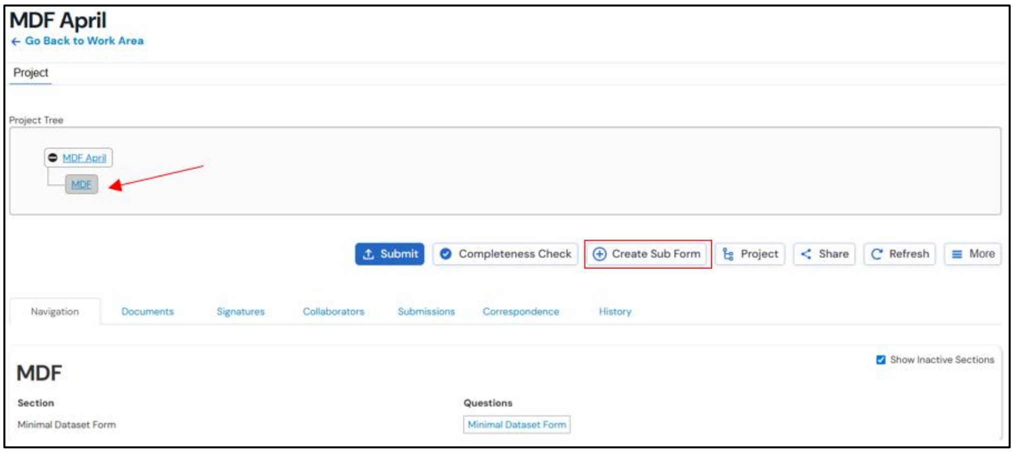
The SSA for a site is created either by the **MDF** project owner e.g. CPI / delegate or by assigning this role to the site PI.

The creation and management of site SSAs in **ERM** should be determined by the CPI / delegate.

Both options are described below:

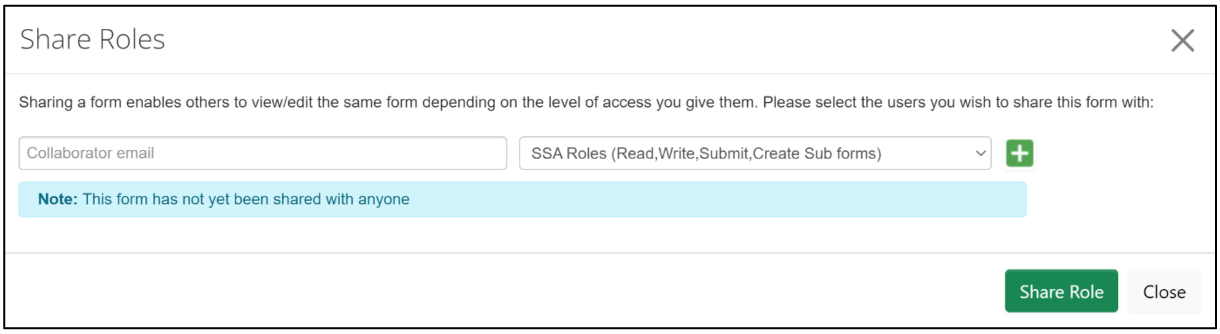
(i) MDF project owner

- The MDF owner creates the SSA as a subform of the MDF and becomes the SSA form owner



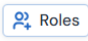
- The MDF / SSA owner may start the SSA then assign responsibility for its completion and submission to the site PI
- Highlight the SSA in the Project Tree
- In the **Introduction** section of the SSA form, complete question **Q 1.4** to enter the name of the site/organisation
- Select the **Roles+** button under the **More** button

- A **Share Role** text box will be displayed
- Enter the collaborator's (site PI) ERM email address and select **SSA Roles**
- This level of access includes Read/Write/Submit/Create subforms



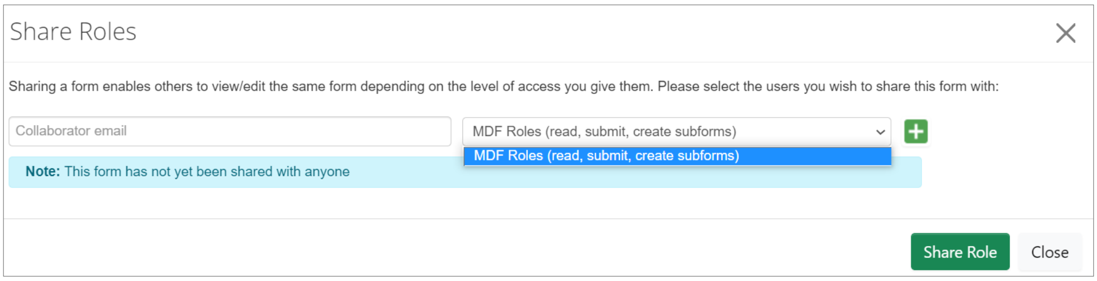
- Select **Share Role**
- The collaborator e.g. the site PI will receive an email notification about their assigned role in the project
- The collaborator logs into ERM and can continue to complete and submit the SSA to the site RGO

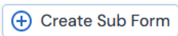
(ii) Assign Role to Site PI

- The MDF owner assigns access to the site PI / delegate to create their own site SSA
- The MDF owner highlights the MDF in the Project Tree and select the **Roles +** 

button under the Actions pane
- A **Share Roles** text box will be displayed
- Enter the collaborator's (site PI/delegate) ERM email address and select **MDF Roles**
- This level of access includes read / submit / create subforms

- Select **Share Role**



- The collaborator e.g. the site PI will receive an email notification about their assigned role in the project
- The collaborator logs into ERM and locates the project
- Highlight the MDF in the Project Tree
- Select the **Create subform** 

action button and select the Site Specific Assessment form from the dropdown list
- Complete the form, upload site specific documents e.g. Site PICF and obtain signature from the PI
- **Submit** to the site RGO for review and authorisation
- The site RGO will be able to view the approved ethics application (HREA, protocol, Master PICF) uploaded in the MDF

12 Legacy Application Replacement Form (LARF)

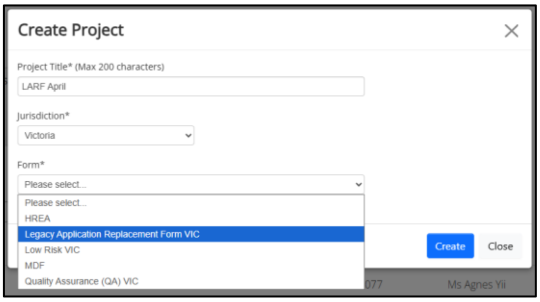
The Legacy Application Replacement Form (LARF) is required for a Victorian-only research project when the original ethics application was not in the previous database system used by Research Offices (AU RED). It cannot be used for NMA research projects.

The LARF is not an ethics application form; it is a proxy form that allows sub-forms e.g. post approval forms to be created in ERM. Only **one** LARF is required for the research application.

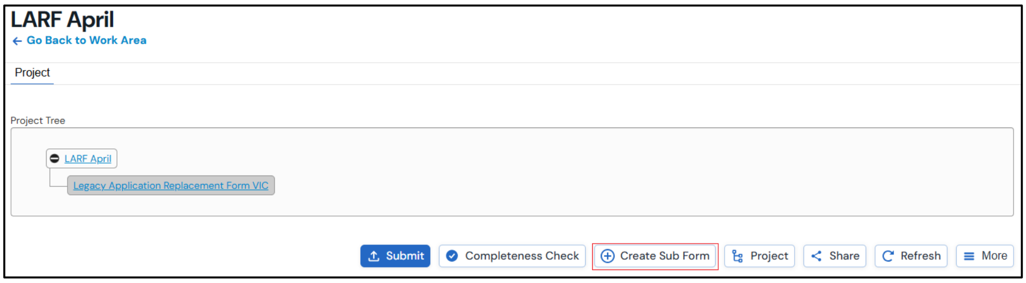
Consult the reviewing organisation's Research Office before creating a LARF to confirm whether the form is required.

- The CPI / delegate logs onto ERM
- Select **Create Project** 

button under the Actions pane to create a new Main Form
- Enter the Project Title, jurisdiction and select **Legacy Application Replacement Form** from the main form drop-down list
- Select **Create** button



- The LARF will appear under the Project Tree

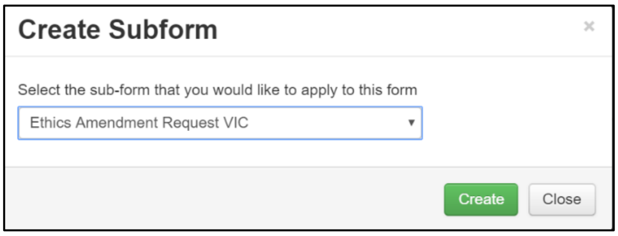


- Complete the questions in the LARF
- Select the **Submit** 

button under the Actions pane
- The form will be submitted to the organisation that reviewed the original application
- From the LARF the CPI/delegate can create post approval sub-forms by selecting the **Create Subform** action button
- Select the jurisdiction and appropriate post-approval form e.g. Ethics Amendment Request

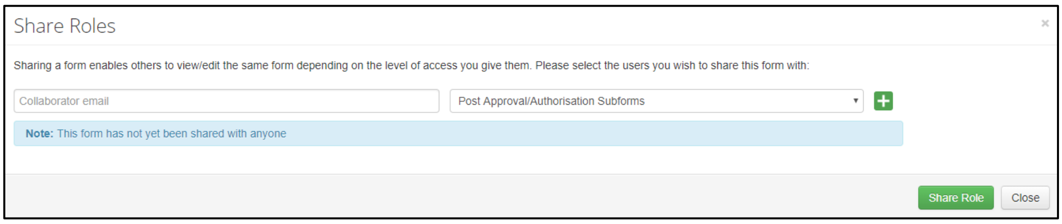
OFFICIAL

- Select **Create**



- The CPI / delegate selects the **Roles +** under **More** button under the Actions pane to share the LARF with other research team members

- Enter the collaborator's email address and select Post Approval/Authorisation Subforms
- Select **Share Role**



- Complete the questions in the post-approval form
- Sign the post -approval form
- Submit the post-approval form

13 Quality Assurance (QA) Application Form

Quality Assurance (QA) is an activity where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation.

The Quality Assurance VIC form can be used for the submission of the following types of projects:

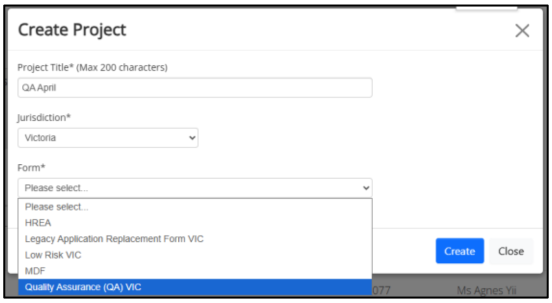
- clinical audit
- quality assurance
- evaluation activities
- a project that involves the potential for no more than negligible risk

Consult with the organisation's Research Office before creating the QA application. The Research Office will advise whether the QA form is the right choice for the project. No subforms are available. Contact the site's Research Office for post approval agreements.

- The applicant logs into ERM
- Select **Create Project** 

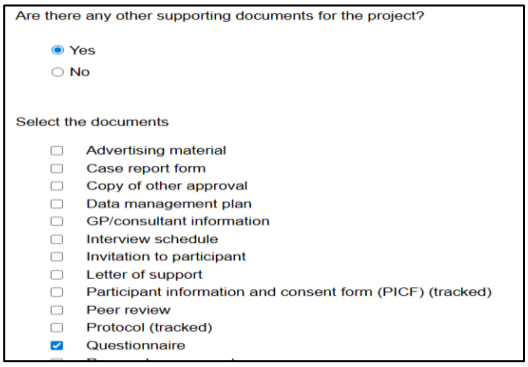
button under the Actions pane to create a new Main Form
- Enter the Project Title, jurisdiction and select **Quality Assurance (QA) VIC** from the main form drop-down list

  Select **Create**

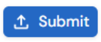


- The QA form will appear under the Project Tree
- Complete the questions in the QA form
- The **Supporting Documents** 

section will enable supporting documents e.g. a Questionnaire to be uploaded into the application

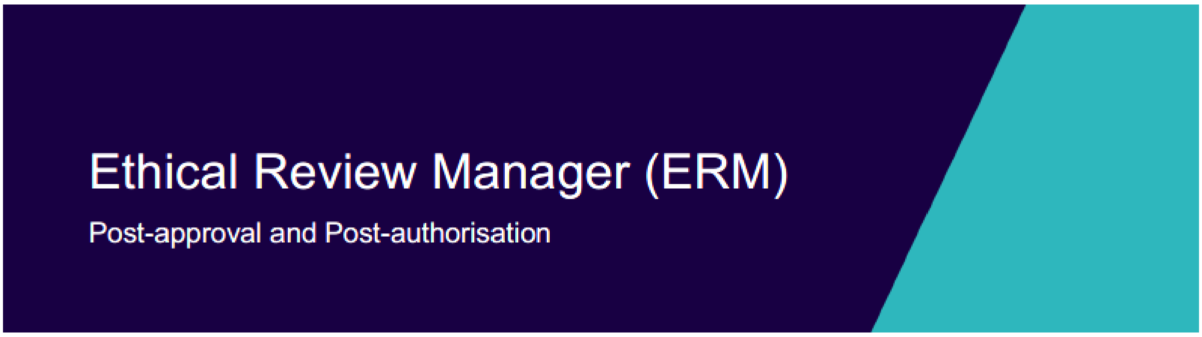


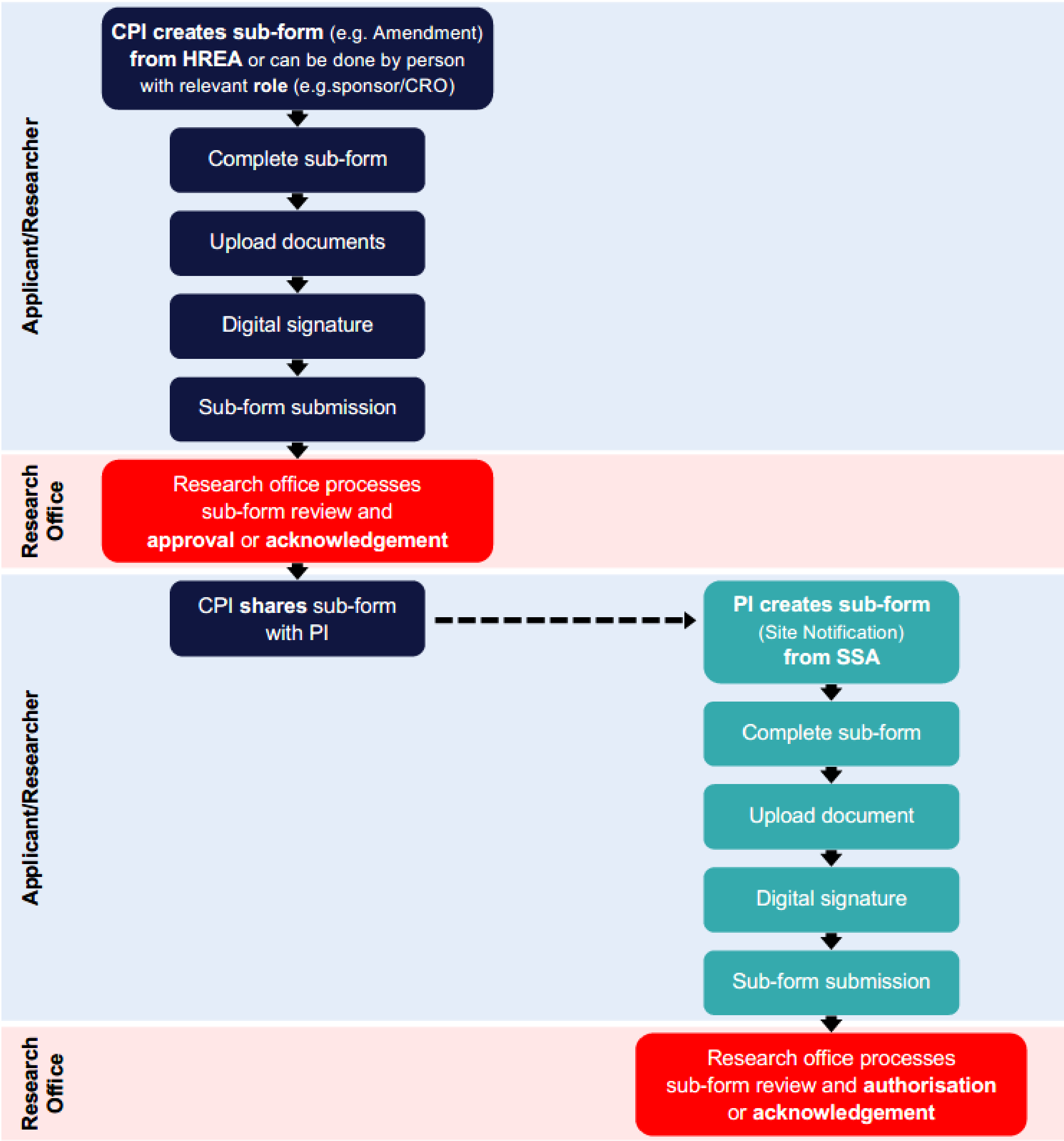
- Select Upload **Document** 

- Select **Submit** 

button under the Actions pane to submit the application to the reviewing organisation.

14 Post Approval





Once a research project has been ethically approved, any change to its design or conduct must be approved by the reviewing HREC or ethics review body.

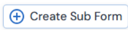
Post approval information should also be submitted to the reviewing organisation.

In ERM, Post Approval forms are created as sub-forms from the original ethics application (HREA) to request amendments and provide information / reports relating to the research project as required by the reviewing HREC.

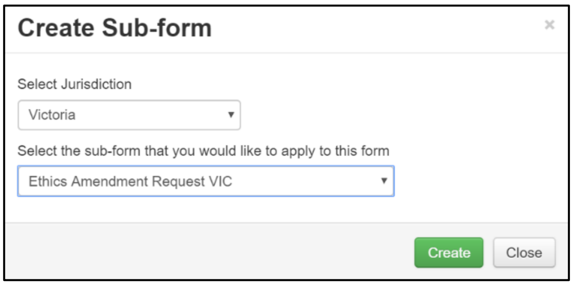
Sub-forms for post approval

- Ethics Amendment Request
- Project Notification Form
- Project Progress Report
- Project Final Report
- Site Closure Report
- Safety Report
- Annual Safety Report
- Serious Breach Report
- Suspected Breach Report

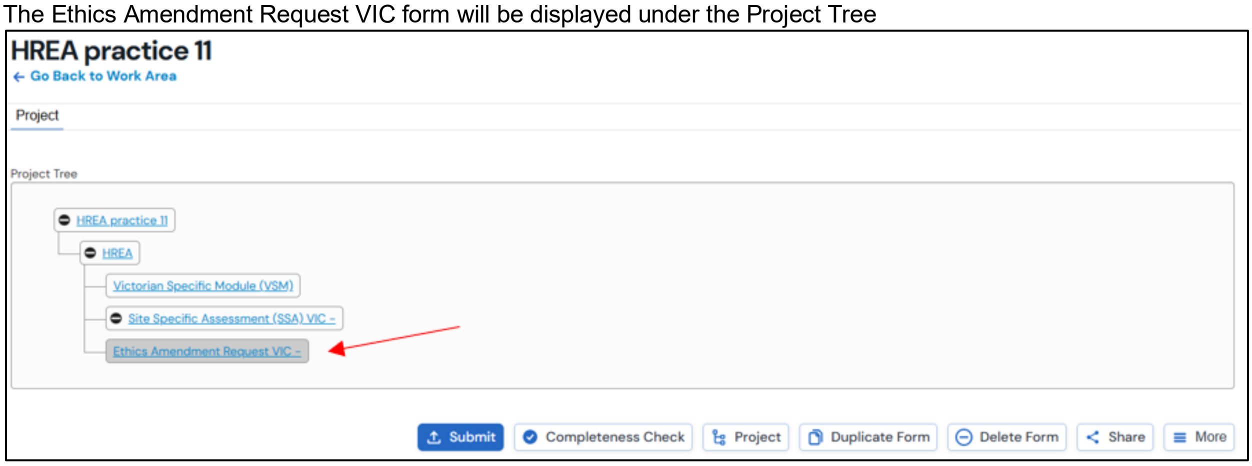
14.1 Create a sub-form

- The CPI / delegate logs in to ERM
- Select the project title to display the project under the Project Tree and highlight the HREA
- Select **Create Sub-form** 

 button under the Actions pane to create a new sub-form
- Select the jurisdiction and the sub-form e.g. Ethics Amendment Request VIC
- Select **Create**

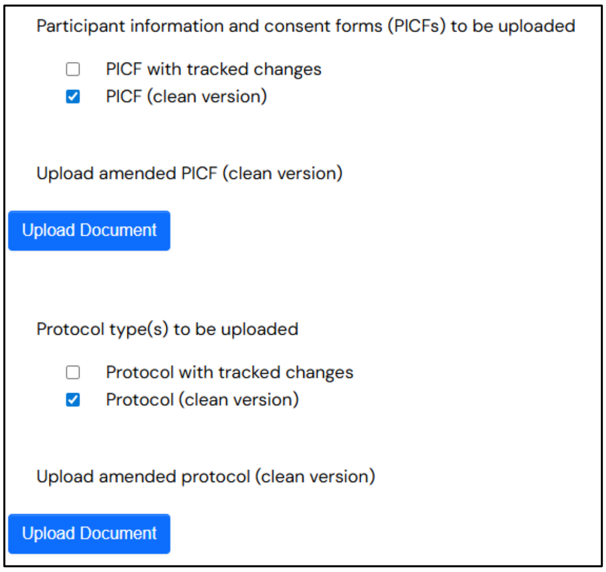


- The Ethics Amendment Request VIC form will be displayed under the Project Tree

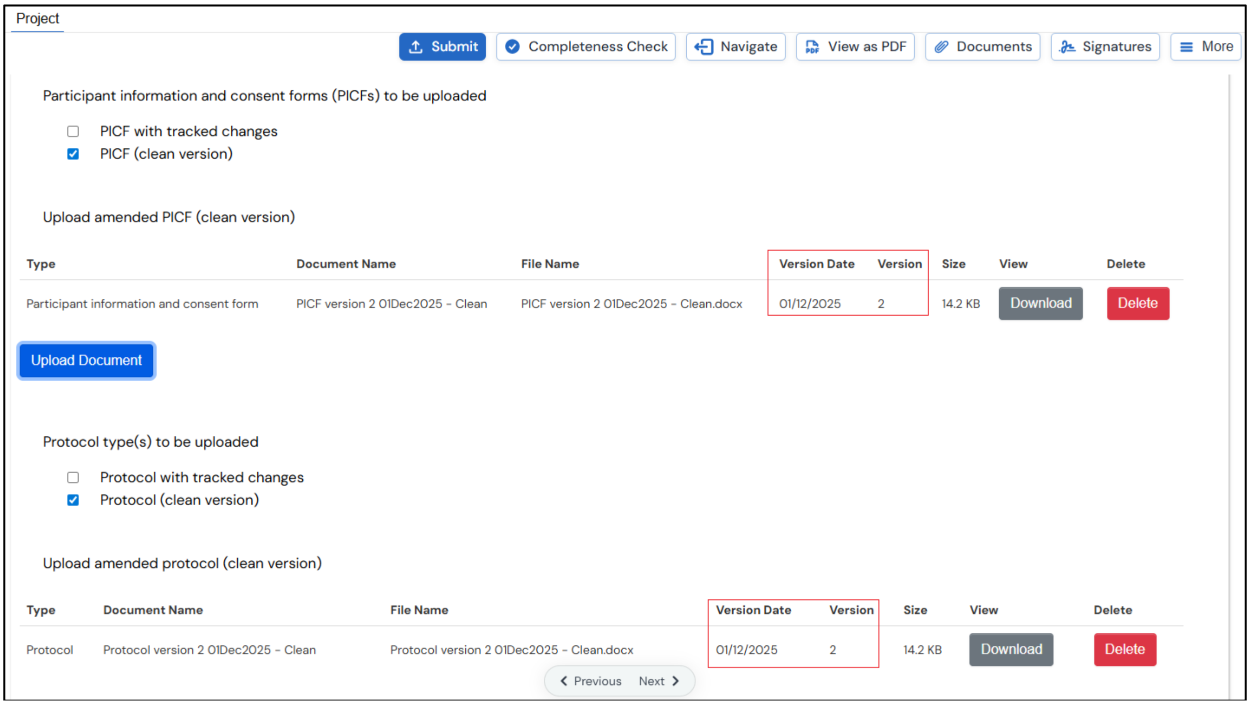


14.2 Complete a sub-form – Ethics Amendment request

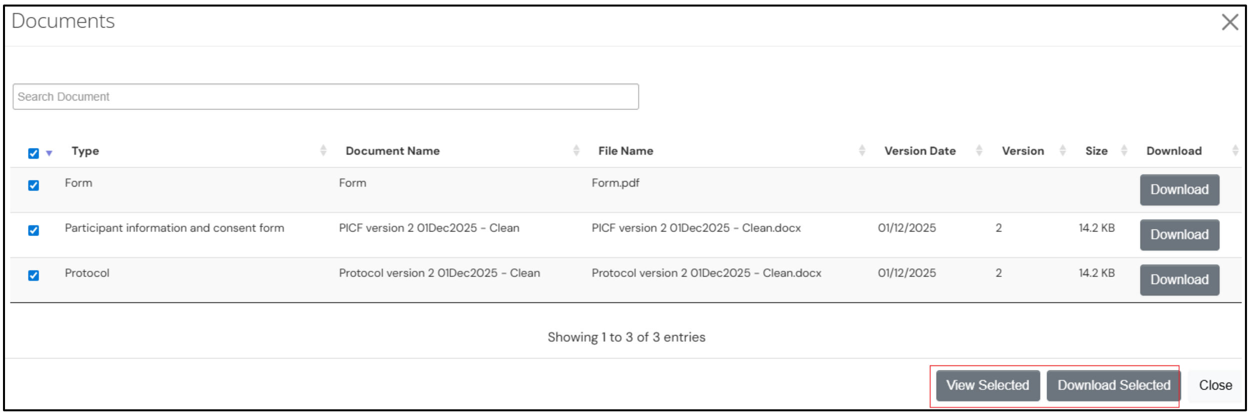
- Complete the questions in the form, in this example the Ethics Amendment Request form
- Depending on the amendment category, new versions of documents e.g. PICF, protocol can be attached to the amendment form



- Select **Upload Document**  to attach the amendment documents from your local drive
- Specify the version and date



- Documents will be displayed under the **Documents** tab and can be viewed or downloaded individually or together
- Select the checkbox for each corresponding document or all documents can be selected at once

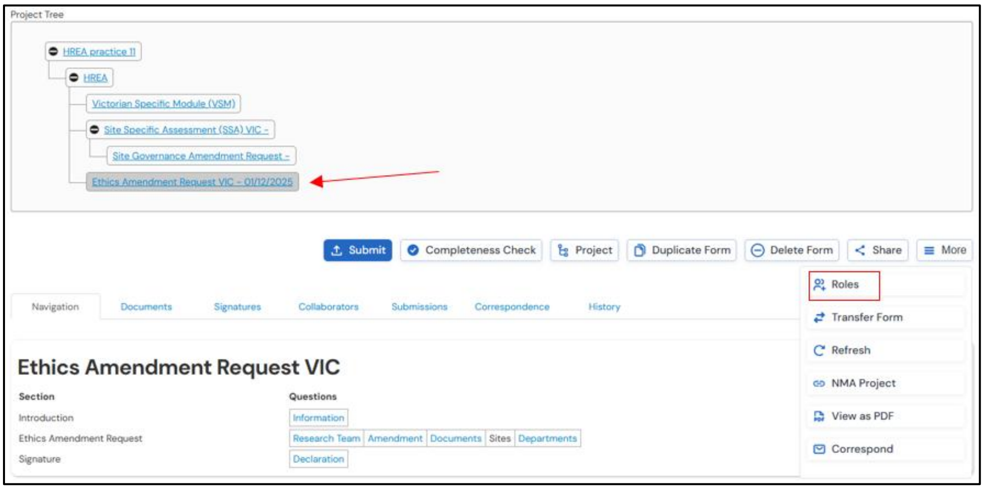


- Select the **View Selected**  button to open the document as a PDF in a new browser **or** select the **Download Selected**  button to download as ZIP file

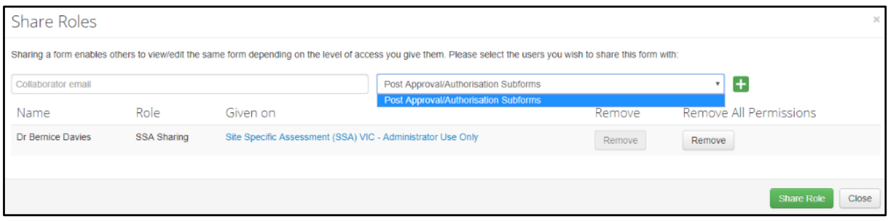
14.3 Allowing others to access post approval forms

Using **Roles +** allows other research team members access to a post approval form.

Highlight the post approval form e.g. Ethics Amendment Request in the Project Tree



- Select **Roles +** under **More** button under the Action pane
- Enter the collaborator's ERM email address and select **Post Approval/Authorisation Subform**
- Other collaborators can be added by selecting  button
- Select Share Role

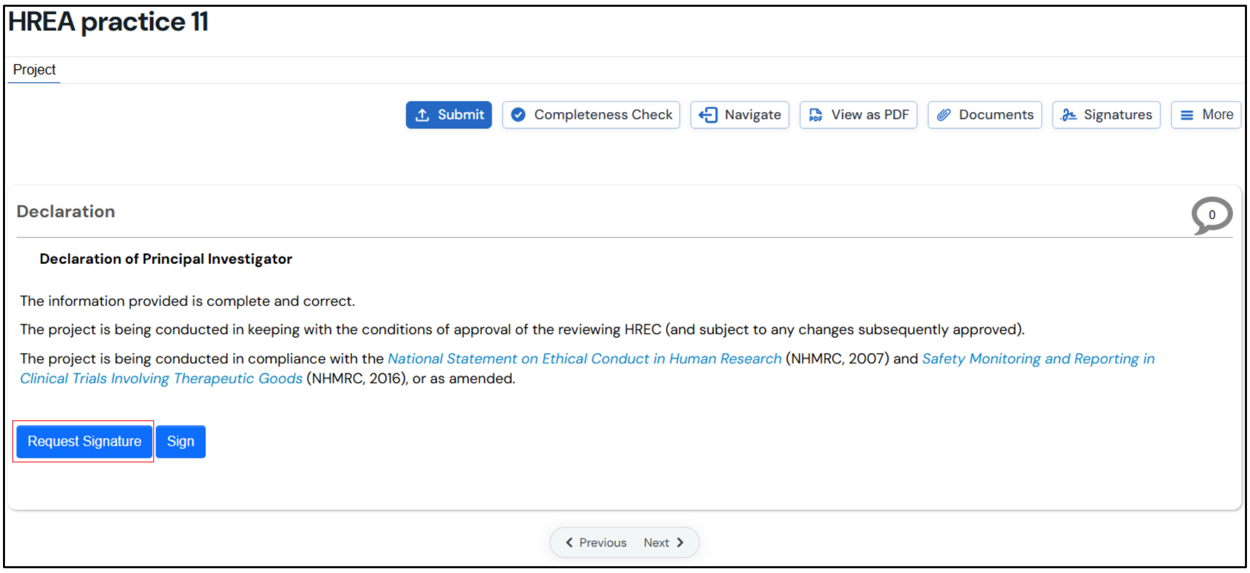


- The collaborator receives an email notification on their assigned role in the project
- The collaborator at the site can view the amendment form and associated documents

14.4 Applying signatures

The Coordinating Principal Investigator is required to sign the Declaration page to indicate the information is complete and correct. To request an electronic signature:

- In the Declaration section, select **Request Signature** Request Signature button



- The system performs a completeness check to highlight any incomplete sections
- Enter the signatory's ERM email address and message
- Select **Request**

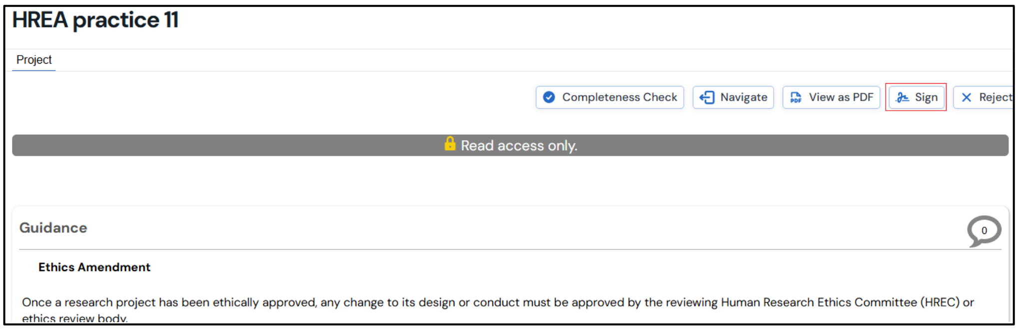
- The requested signatory will receive an email notification for a signature, a message and link to ERM Login/Signatures page
- The signatory logs into ERM
- From the Work Area the signatory selects **Signatures** tile to open the request

- New requests are highlighted. Select **View Form** View Form to review the ethics amendment request form

Signatures

Type	Project Title	Project ID	Requesting User	Message	Requested Date	Response Date	Status	Action
Principal Investigator	HREA practice 11	58446	Ms Agnes Y	Can you please sign the ethics amendment request	15/12/2025 14:34		Requested	View Form
Head of Department	HREA practice 11	58446	Ms Agnes Y		13/11/2025 16:51		Invalidated	View Form

- For endorsement of the amendment, select **Sign** Sign button under the Actions pane



- A **Sign Form** text box is displayed

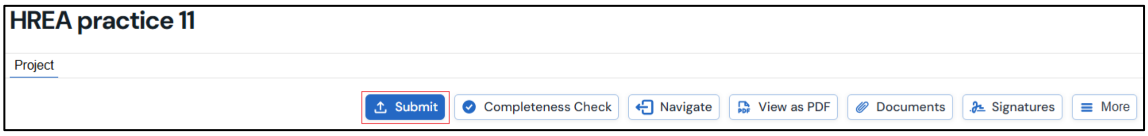
  The signatory enters their ERM log in details to sign the form

  Select **Sign** Sign button

- The applicant receives an email notification indicating the signature request has been accepted, i.e. the form has been signed
- The form is ready for submission

14.5 Submission and review

- Navigate to the Actions pane and select the **Submit** button



- The system performs a completeness check to highlight any incomplete sections. If complete the form is ready to be submitted
- Select **Submit** Submit button
- The post approval form will be received by the reviewing organisation's Research Office.

  How to respond to queries and requests from the Research Office is described in Submission and Review Process

15 Post Authorisation

15.1 Create a sub-form

Post Authorisation forms provide information / reports relating to a research project to the site Research Governance Officer (RGO).

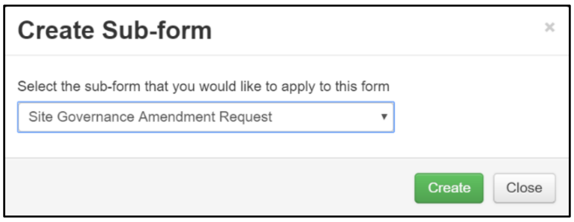
In ERM, Post Authorisation forms are sub-forms created from the Site Specific Assessment (SSA).

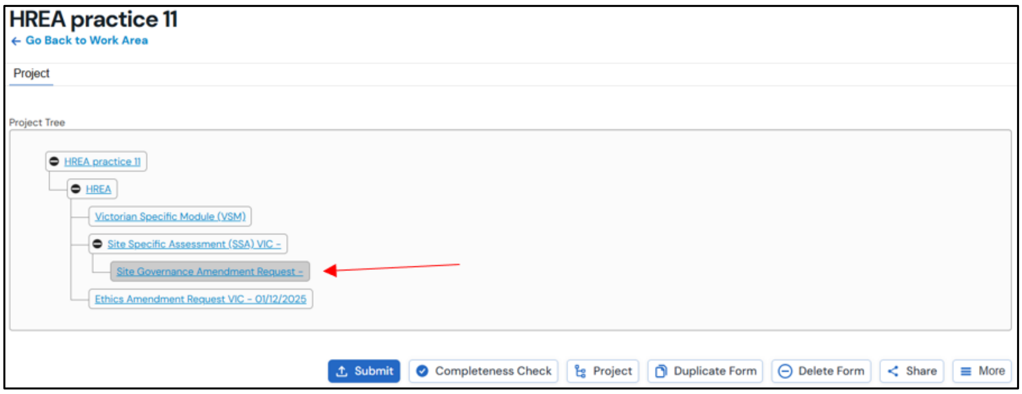
Sub-forms for post authorisation

- Complaint Report
- Non-serious Breach / Deviation Report
- Site Audit Report
- Site Governance Amendment Request
  - To notify the RGO of an amendment that has been approved by the reviewing ethics committee **or**
  - To notify the RGO of a governance-only amendment that does not require ethical approval
- Site Notification Form
- Site Progress Report
  - Report to the site's research governance on the site's progress of a research project **or**
  - Can be adapted and used as a Site Final Report to report to the site's research governance office

Create a Sub-form

- The PI / delegate logs in to ERM
- Select the project title to display the project under the Project Tree and highlight the SSA for your organisation
- Select **Create Sub-form** Create Sub Form button under the Actions pane to create a new sub-form e.g. Site Governance Amendment Request
- Select **Create**
- The Site Governance Amendment Request form will be displayed under the Project Tree





15.2 Complete a sub-form – Site Governance Amendment request

The steps for completing a Site Governance Amendment Request will depend upon which ethics committee reviewed the amendment request. Either **(i)** or **(ii)** apply:

(i) If the amendment request was submitted to an ethics committee in Victoria, ensure the Ethics Amendment Request form owner (CPI / delegate) has assigned the site PI/ delegate access to the ethics amendment submission and documents. See Allowing others to access post approval forms

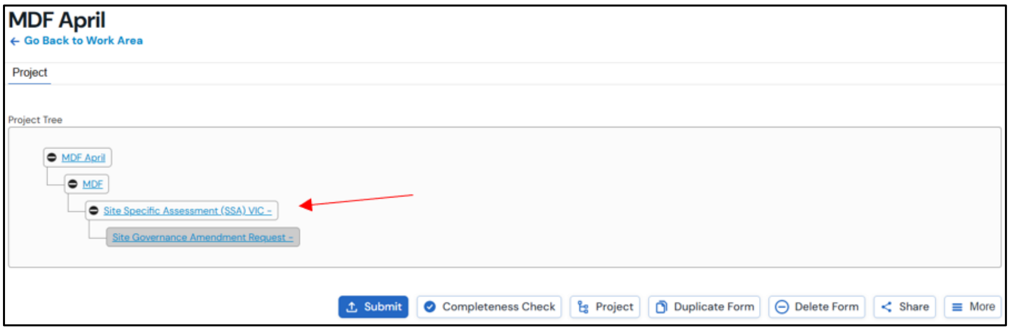
- In the Project Tree, select the Ethics Amendment Request VIC form
- Working under the **Documents** tab select **View Selected** button to open selected documents e.g. Ethics Amendment Request form, Master PICF as a PDF in a new browser or select **Download Selected** to download the Ethics Amendment Request form and selected documents e.g. Master PICF as a zip file, and save to your local drive
- Return to the Site Governance Amendment Request form in the Project Tree
- Upload a copy of the:
  - Ethics Amendment Request to the reviewing ethics committee (PDF copy of the amendment form that was saved from the zip file)
  - Amendment approval from the reviewing ethics committee (PDF copy of amendment approval letter/certificate)
- Other documents if relevant, e.g. the protocol and Site PICF are uploaded in the following documents page or the Amended Documents section

- Select **Upload Document** Upload Document to upload the relevant documents from your local drive
- Specify the version and date
- Continue to complete the form

(ii) If the amendment request was submitted to an ethics committee outside of Victoria, the **Minimal Dataset Form** (MDF) is used to enable the Site Governance Amendment Request form to be completed

- In the Project Tree, select the site SSA for your organisation

- Select the **Create Subform** action to create a Site Governance Amendment Request form



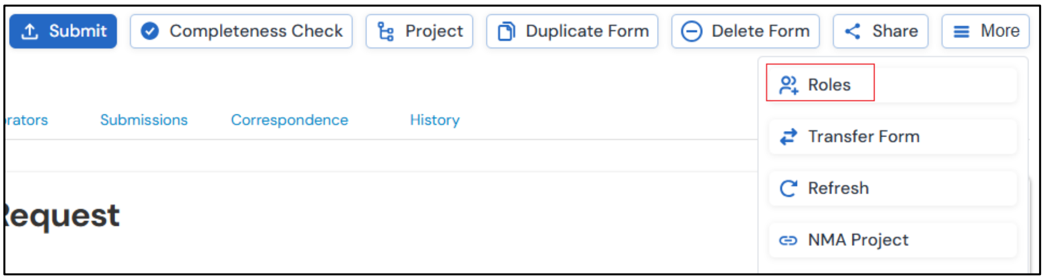
- Upload a copy of the:
  – Amendment submission to the reviewing HREC (PDF copy provided by the CPI/delegate)
  – Amendment approval from the reviewing HREC (PDF copy of approval letter/certificate provided by the CPI/delegate)
- Other documents if relevant, e.g. the protocol are uploaded as described in **(i)**
- Other site specific documents e.g. Site PICF can be uploaded in Amendment Documents section
- Continue to complete the form.

15.3 Allowing others to access post authorisation forms

The **Roles+** function is used to assign access to other research team members.

The SSA form owner assigns access from the site SSA level.

- From the Project Tree, highlight the SSA and select the **Roles +** under **More** button



- A ‘Share Roles’ textbox is displayed
- Enter the collaborator’s ERM email address & select **SSA Roles** from the dropdown list (Other research team members can be added using the option)
- Click **Share Role**
- Predefined levels of access are: Read/Write/Submit/Create post authorisation subforms/Receive notifications
- New collaborators will see any pre-existing post authorisation forms, removing the need to assign access to individual post authorisation forms

OFFICIAL

15.4 Other subforms – Site Notification Form

The Site Notification Form is used to inform the site RGO of either a:

- Serious Breach (e.g. a breach of the protocol that is likely to effect patient safety) reported to the reviewing HREC that has occurred at the site

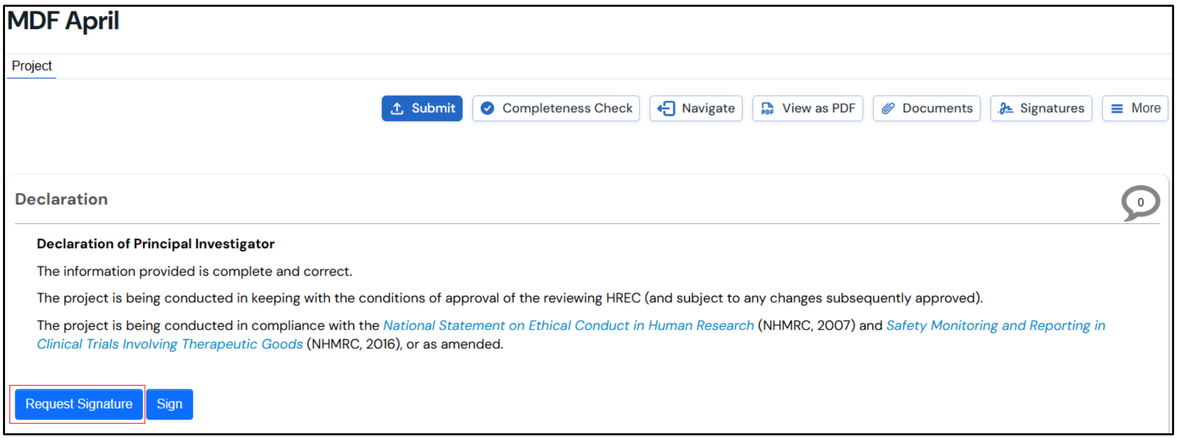
  or
- Site matter for which there is not a dedicated reporting form available

Either purpose is easily identifiable in the Project Tree and for the site RGO once created.

15.5 Applying signatures

The Principal Investigator is required to sign the declaration page to indicate the information is complete and correct. To request an electronic signature:

- In the Declaration section, select the **Request Signature** Request Signature button



- The system performs a completeness check to highlight any incomplete sections

- Enter the signatory's ERM email address and message

  Select **Request**

- The requested signatory will receive an email notification for a signature, a message and link to ERM Login/Signatures page
- The signatory logs into ERM
- From the Work Area the signatory selects the **Signatures** tile to open the request

- New requests are highlighted. Select **View Form** View Form to review the Site Governance Amendment Request form
- For endorsement of the form, select **Sign** Sign button under the Actions pane
- A **Sign Form** text box is displayed

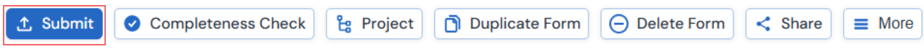
  The signatory enters their ERM log in details to sign the form

  Select **Sign** Sign button

- The applicant receives an email notification indicating the signature request has been accepted, i.e. the form has been signed
- The form is ready for submission

15.6 Submission and review

- Navigate to the Actions pane and select the **Submit** Submit button



- The system performs a completeness check to highlight any incomplete sections. If complete the form is ready to be submitted
- Select **Submit** Submit button
- The post authorisation form will be received by the organisation's RGO.
- How to respond to queries and requests from the RGO is described in Submission and review process – SSA form

16 Other ERM features

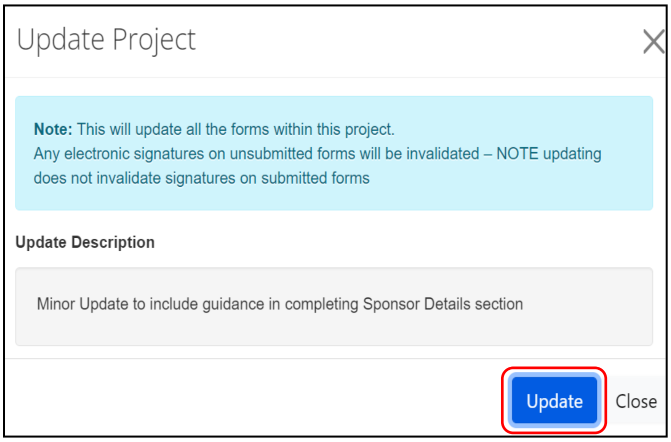
16.1 Project update

- Only the project owner may update a project
- Approved forms retain the version they were approved in
- Forms and sub-forms that have been submitted or under review will also be updated
- Forms with electronic signatures applied but not submitted should be **updated after submission** otherwise updating will invalidate electronic signatures

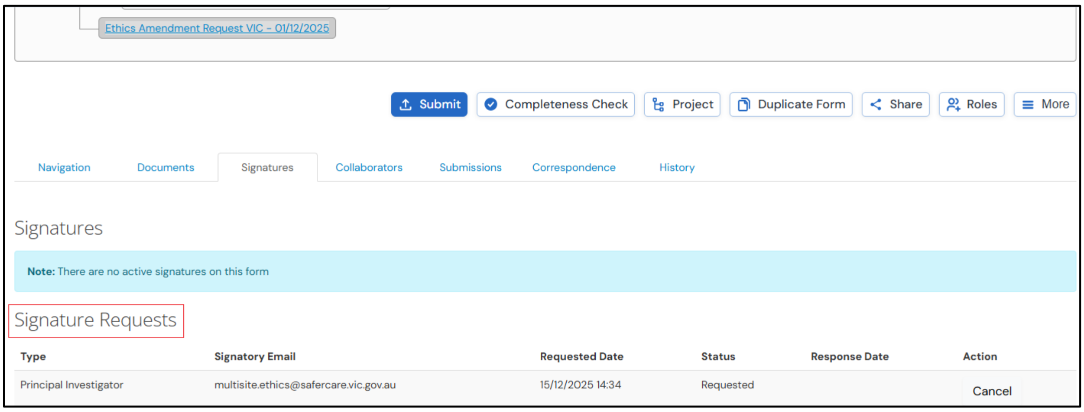
How to update to a newer version

- Print and save a copy of any unsubmitted forms before the project is updated to ensure no data is lost
- The **Update** prompt is viewed by the project owner at the top of the form
- The project owner clicks on the **Update** link

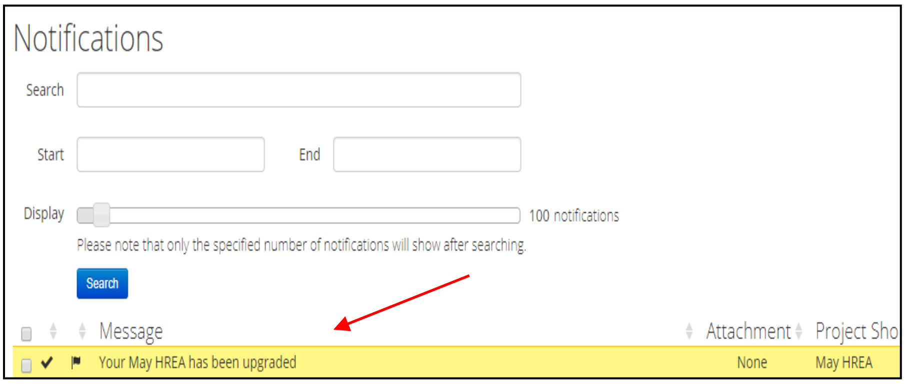
- A pop-up message displays information about electronic signatures on unsubmitted forms which will be invalidated if a project is updated. Description of update reason is also provided.
- Select the **Update** button to update the project



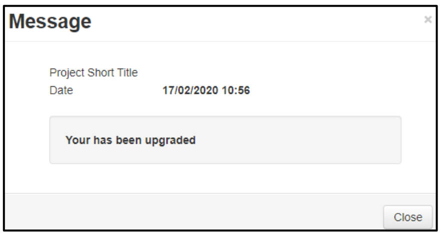
- Project owner can check for pending signatures under the signatures tab to determine the status of pending signatures before updating a project to ensure signatures are not invalidated.



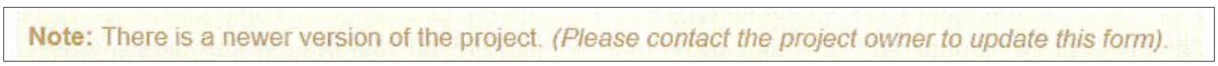
- Notification of the project update will appear in the **Notifications** tile
- From the Work Area select the **Notifications** tile. Select the relevant message



- A **Message** textbox will be displayed informing the project owner of the upgrade



- If the completion of a form is in progress, select the **Completeness Check** button under the Actions pane to check if additional data entry is required as the new version may introduce additional questions into the form
- An Update prompt is also seen by collaborators and form owners should advise the project owner of any need to delay the Update e.g. if the form owner is working on a form with un-submitted electronic signatures



When should the project be updated?

- Before you request electronic signatures
- After a form has been submitted and validated by the Research Office
- When the project has been released back to the applicant for edits after the submission
- After form approval

What are the steps in a multi-site project?

- The project owner should advise all form owners of when the project update will occur
- Form owners should advise the project owner if the Update needs to be delayed
- Print and save a copy of any un-submitted forms before the project is updated
- The project owner updates the project

How to find the form version

- The form version appears at the top right-hand corner of the screen when the form is open
- The most recent date a form has been edited is displayed under **Date Modified** below the Project Tree

16.2 Post approval/authorisation forms in legacy projects

The migration of projects from the legacy IT system occurred in July 2018 and are referred to as Data Migrated (DM) projects.

Applicants that are unable to create the required subform from a DM HREC MDF (ethics application) or a SSA MDF (governance application), will need to have the project updated in ERM by the project owner.

If there is no **Update** project message:

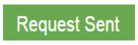
- Create any subform (Create Sub Form) from the existing application. This will be a 'dummy' form and does not need to be completed
- An Update project message will be displayed. Select the **Update** hyperlink
- Once the project is updated, **delete** (Delete Form) the dummy subform. All newly created subforms will now have the correct configuration
- Select the **Create subform** action button to create the relevant post approval/authorisation subform

Allowing others to access post approval/authorisation forms

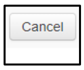
Using Roles +

- DM HREC (original ethics application), select DM HREC Share (read, write, create subforms) from the drop-down list
- SSA MDF (original SSA application), select SSA roles (read, write, create subforms) from the drop-down list

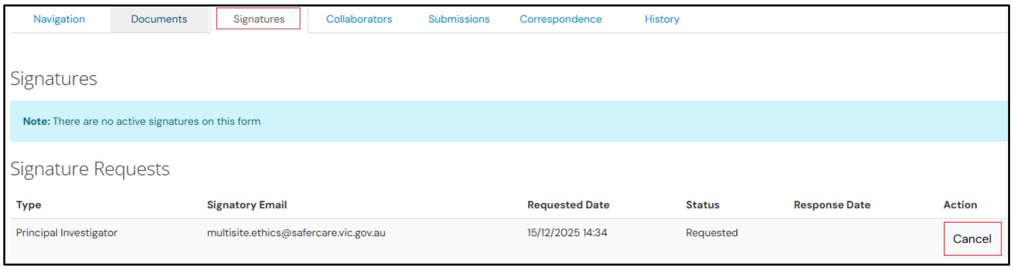
16.3 Cancel a signature

A **Request Sent** 

message is displayed at the top of the screen whenever an electronic signature has been made. The form is locked through signature requests. To cancel a signature:

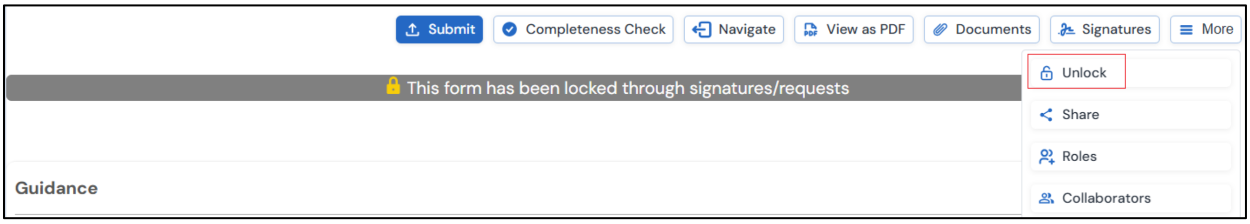
- Move to the Signatures tab and select the **Cancel** 

button under the **Action** heading



- The form is now unlocked and signatures invalidated. The **Status** has changed from Requested to Recalled
- The signatory will also receive a notification email regarding the signature cancellation
- If a Principal Investigator has signed 

their own form directly, their signature can also be cancelled
- To cancel the signature, open the relevant form at any question and select the **Unlock** button under the Actions pane



- An **Unlock Form** text box will be displayed. Select **Confirm**
- The signature has been cancelled (invalidated) and the form is unlocked.

16.4 Changing jobs

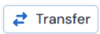
If an applicant changes jobs or moves to another organisation but remains a collaborator on certain projects, the applicant can continue to access their projects in ERM but will need to have their ERM account details updated. Contact Infonetica Helpdesk to update the account details and email.

If a project owner is leaving the project permanently, the project should be transferred to another collaborator in the research team. In addition, Infonetica should be contacted to close the account.

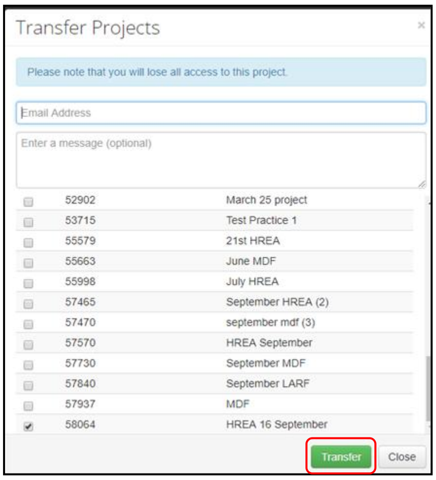
16.5 Transfer a project

The project owner can use the **Transfer** function to permanently transfer a project to another ERM user. This may be when a Sponsor creates an HREA application then transfers it permanently to the CPI or when the project owner intends to leave the project and transfers project responsibilities to another collaborator in the research team.

If the current project owner cannot be contacted, applicants can complete a [Victoria-Project Transfer Form](#) and email it to [Infonetica Helpdesk](#)

From the Work Area, select the **Transfer**  button from the Actions pane

- A **Transfer Projects** text box is displayed noting loss of future access to the project
- The project owner enters the ensuing project owner's ERM email address



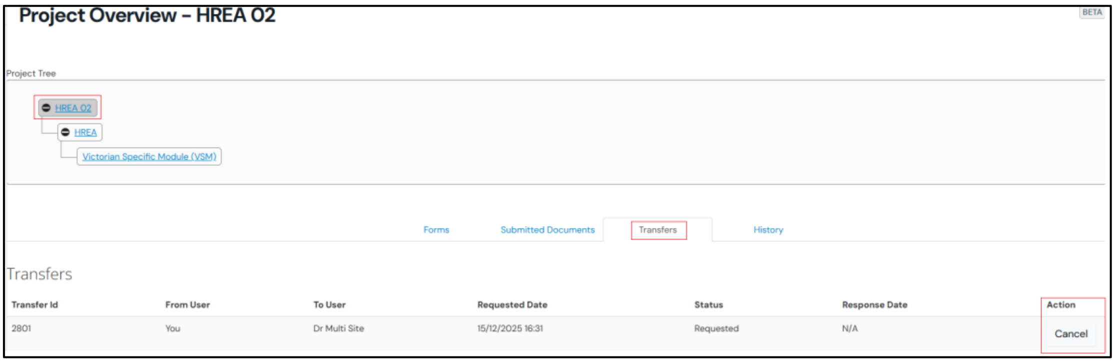
- Enter a message to the new project owner (optional)
- Select the correct project from the list
- Select **Transfer** button
- All forms are locked pending the transfer

- The new project owner will receive an email notification regarding the transfer of the project

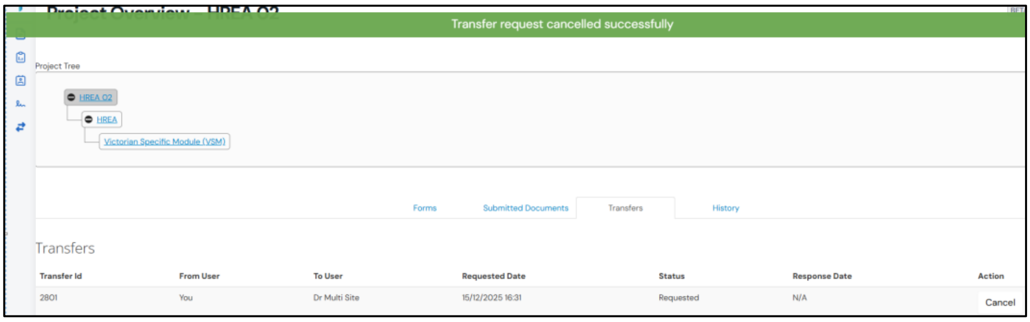
Cancel a transfer request

The project owner can cancel the transfer request if the request has **not** been accepted by the new project owner.

- In the Project Overview screen display under the **Transfers** tab, select the **Cancel** button



- A message indicating the transfer request has been successfully cancelled will be displayed



Accept a transfer

- The new project owner will receive an email notification to log into their ERM account with instructions to accept the transfer

Transfer Request for 85602 HREA 28

donotreply@infonetica.net
To Catherine M Farrington (DJPR)

Dear Ms Farrington,

Project Title: HREA 28
Project ID: 85602

Ms Amanda Walpole **has requested to transfer the above project to you.**

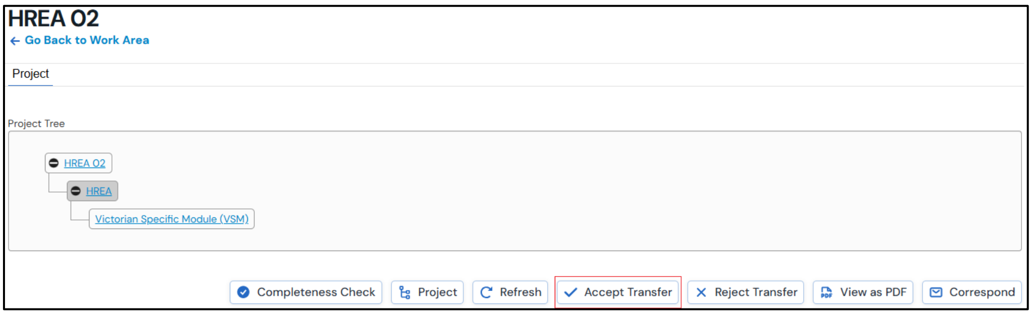
Please take the following action:

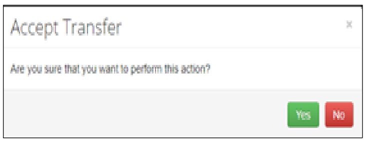
1. Log in to Ethical Review Manager (ERM)
2. Select the 'Transfers' tile
3. Select 'View Project'
4. Accept or reject the transfer

- In the Work Area, select the **Transfers** tile

- A list of all transfers will be displayed. In the relevant message line, select **View Project** [View Project] to open the project as read only

- To accept the transfer, select the **Accept Transfer** [Accept Transfer] button from the Actions pane



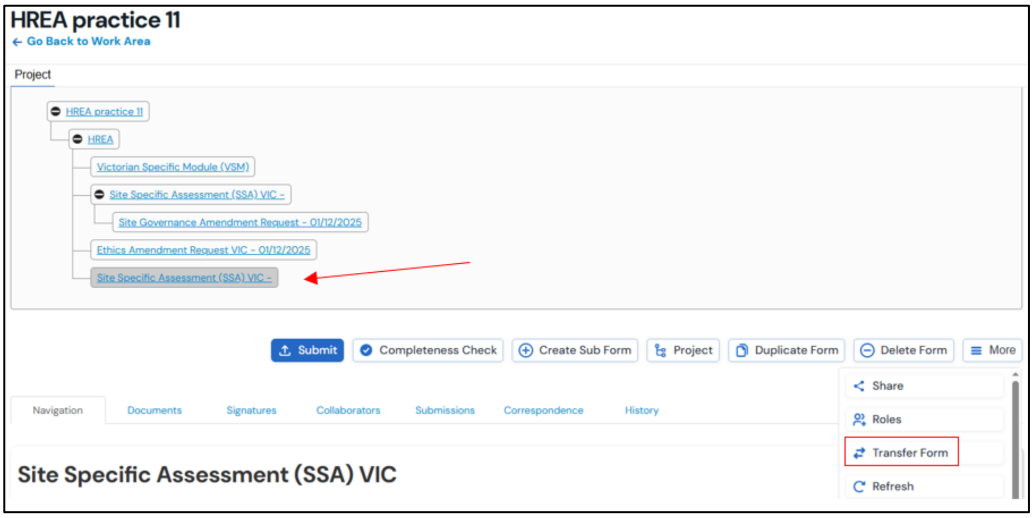


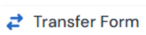
- An **Accept Transfer** text box is displayed
- Select **Yes** to accept the transfer
- Ownership of the project is transferred including all sub-forms e.g. SSAs and associated documents. The new owner can access the project from their Work Area.
- The new owner can assign other research members pre-defined levels of access to the project and forms

16.6 Transfer a sub-form

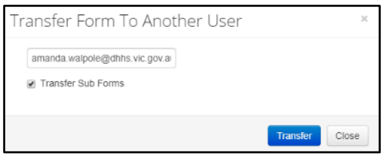
A form owner can transfer sub forms e.g. SSAs to another collaborator independently from the main project.

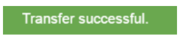
For the form transfer to be successful, the intended owner must first be given access to the form. Use **Roles +** to allow the new form owner to also view the HREA (*look up the project branch*).



- Select **Transfer Form**  under **More** button under the Actions pane

- A **Transfer Form To Another User** text box will be displayed
- Select the **Transfer Sub Forms** checkbox to include other subforms that are associated with the form e.g. a Site Progress Report
- Select **Transfer**



- A **Transfer successful**  message will be displayed at the top of the screen.

- The collaborator will receive an email notification informing them of the transfer with a link to ERM and becomes the new form owner including the owner of any associated subforms

- The new form owner is shown under the **Collaborators** tab
- The new form owner can assign other collaborators access to the form using the **Share** 

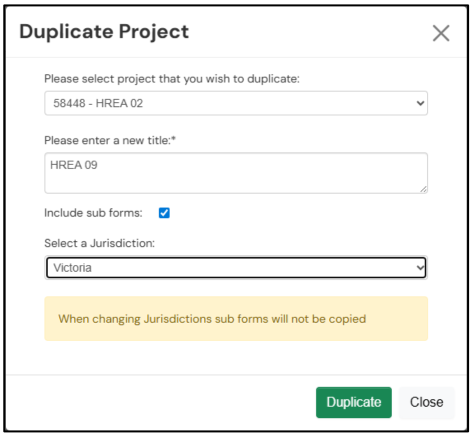
function
- The collaborators can only view the HREA if the Project Owner assigns access from the HREA using the **Roles +** 

function

16.7 Duplicate a project

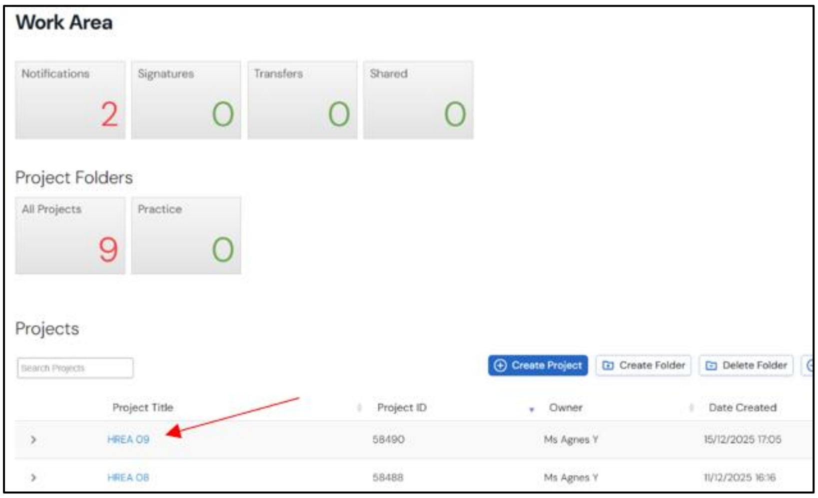
In ERM, an existing project can be duplicated regardless of whether the project has been submitted or not. Subforms can also be duplicated in this process.

- From the Work Area select **Duplicate Project**



- A **Duplicate Project** textbox will be displayed
- Select the project to be duplicated
- Enter a new title for the project and delete the previous project's ID number
- Select **Include sub forms** (SSAs) if subforms are also to be duplicated
- Select **Duplicate**

- The duplicate project with the new title will be displayed under **Project Title**



OFFICIAL

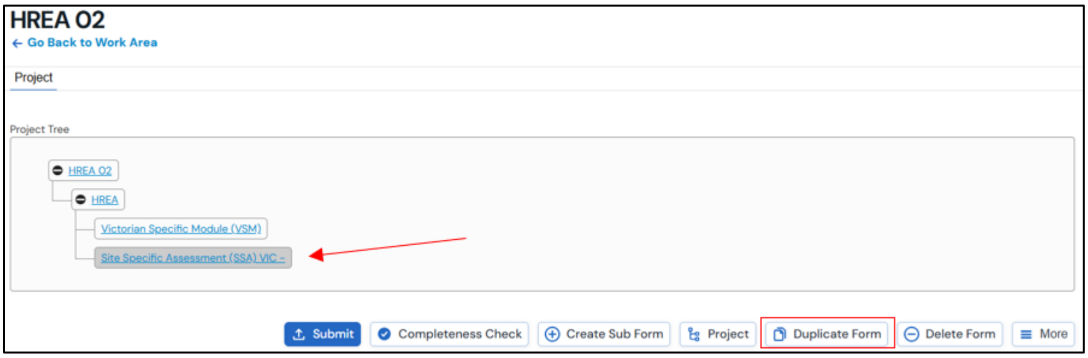
- If subforms have been duplicated, information in the form is also duplicated but will require certain details to be re-entered e.g. Project title and name of site/organisation
- The duplicate function will not copy documents (protocol, PICFs), signatures and permissions (**Roles+**, **Share**) that have been assigned to the original project
- Upload supporting documents and assign other members of the research team pre-defined levels of access to the duplicated project using the **Roles +** or **Share** function.

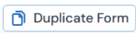
16.8 Duplicate a form

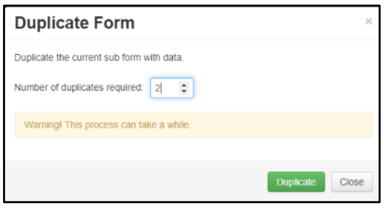
Subforms can be duplicated using a similar duplicate function and can be useful for duplicating SSAs.

The duplicate function will copy all answers in the form but **not** copy documents e.g. site PICFs, signatures and permissions assigned to the original subform. As the SSA site/organisation name will also be duplicated it is important to amend these details for each duplicated SSA.

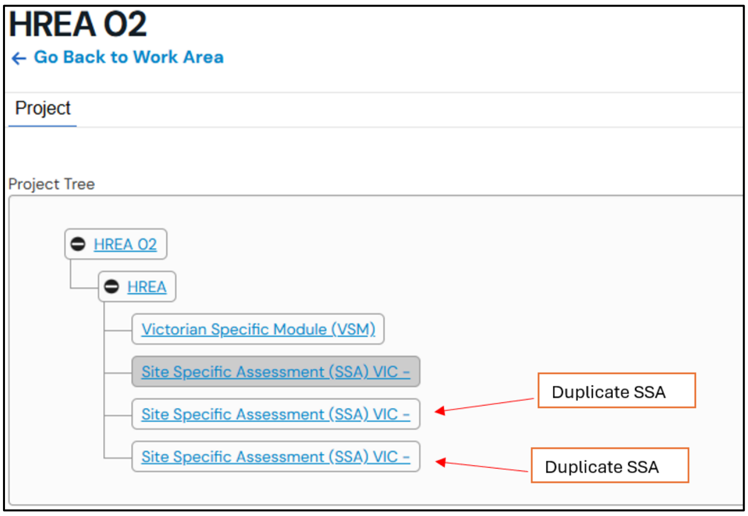
- In the Project Tree highlight the subform to be duplicated



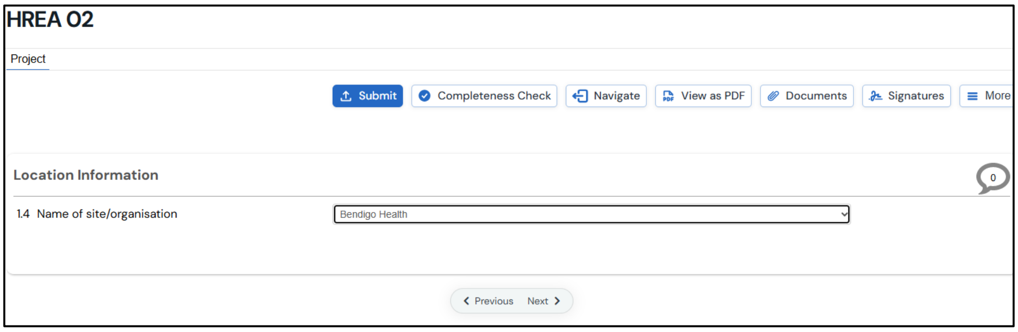
- Select **Duplicate Form**  button under the Actions pane



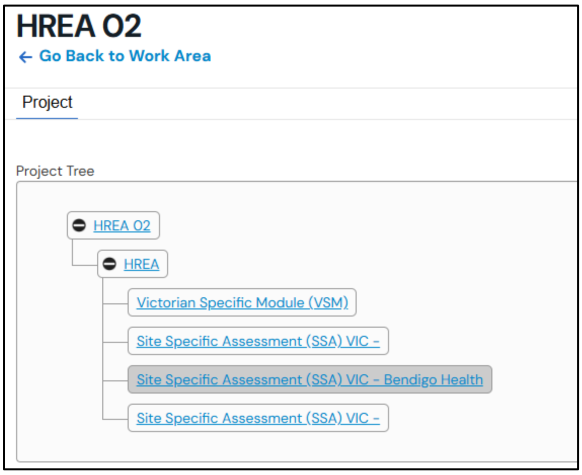
- A **Duplicate Form** textbox will be displayed
- Select number of duplicates required e.g. 2
- Select **Duplicate**
- The duplicated subforms will be displayed in the Project Tree



- Select the duplicate SSA in the Project Tree then select the **Location** hyperlink to be directed to **Q 1.4 Name** of site/organisation
- Select the relevant site/organisation name from the drop-down list



- The correct site/organisation will be displayed with the SSA in the Project Tree

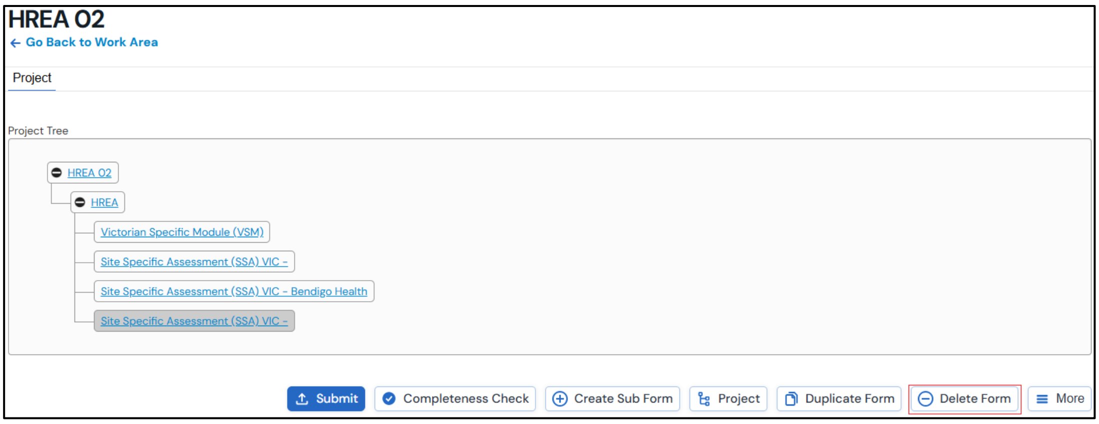


- Upload supporting documents and assign other members of the research team pre-defined levels of access to the duplicated form using the **Roles +** or **Share** function.

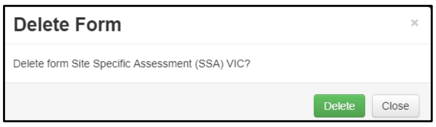
16.9 Delete a form

The applicant can delete a subform if it has been created unnecessarily and can only be performed if the form has **not** been submitted.

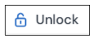
- In the Project Tree highlight the subform which needs to be deleted
- Select the **Delete Form** button under the Actions pane



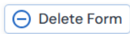
- A **Delete Form** text box is displayed
- Select **Delete** to delete the form



- The subform can still be deleted if an electronic signature request has been made.

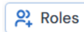
(i) If the form has been signed by the signatory, open the form and select the **Unlock**  under **More** button under the Actions pane.

An **Unlock Form** textbox is displayed. Select **Confirm.**

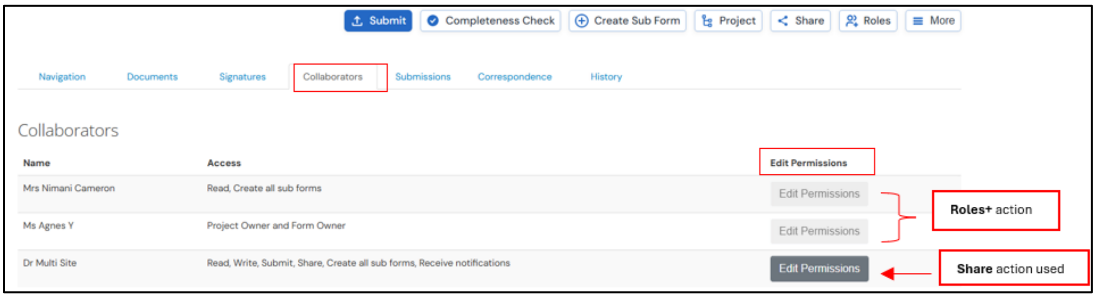
The form becomes unlocked and all signatures are invalidated. The **Delete Form**  button under the Actions pane is now available.

(ii) If the form has not been signed (**Status** is Requested), see Cancel a Signature for further details.

16.10 Edit access permissions using Roles and Share

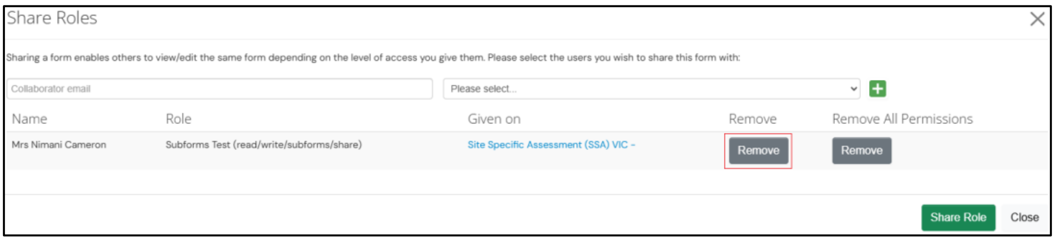
A collaborator's level of access to a form can be changed in two ways depending on whether **Roles+**  or **Share**  has been used to assign access.

- To determine the method used, highlight the relevant form in the Project Tree and move to the **Collaborators** tab
- The collaborators are listed with their assigned level of access
- The **Edit Permissions** in black indicate the **Share** action was used and those greyed out indicate the **Roles+** action was used



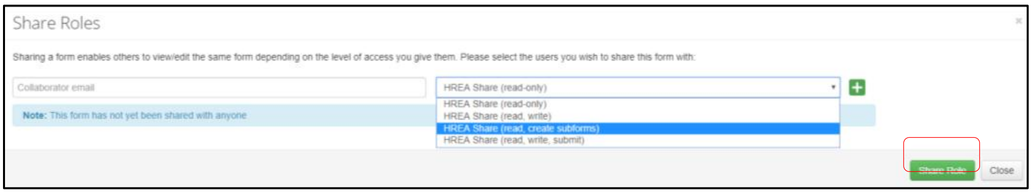
Roles +

- Highlight the relevant form in the Project Tree and select the **Roles +** button under the Actions pane
- A **Share Roles** textbox will be displayed showing the form's level of access that has been assigned to the collaborator e.g. HREA read only
- Select **Remove**



- The **Share Roles** page stays to allow the level of access to be modified

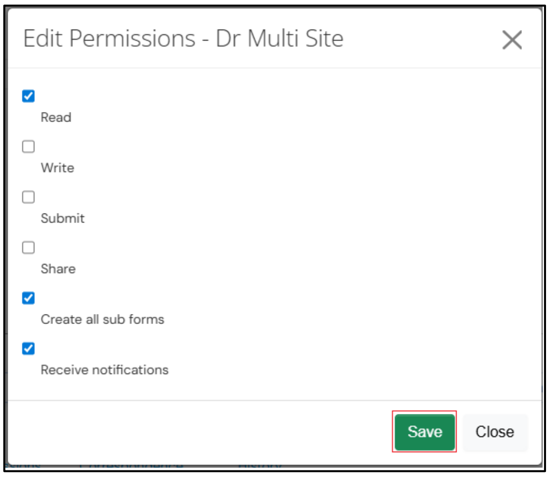
- Enter the collaborator's ERM email address and new level of access e.g. read, create subforms
- Select **Share Role**



- The collaborator will receive an email notification informing them of the change in their access level

Share

- Highlight the relevant form in the Project Tree and move to the **Collaborators** tab
- Select the **Edit Permissions** button and **Edit Permissions** textbox will be displayed
- Select the additional level of permissions e.g. Create all subforms, Receive notifications and select  **Save**
- The collaborator will receive a message in the **Notifications** tile (under the Work Area) informing them of the change in their access level.



16.11 Contacts

The **Contacts** area can be used to save and edit contact details for project team members. Details saved in **Contacts** can be used to populate all ERM forms.

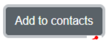
Add a Contact

- Select **Contacts** on the left panel Work Area

- Select **New Contact**

- A **New Contact** textbox will be displayed to enter the new details
- Select **Save** button

- New contact details will be displayed under **Contacts**

- Contacts can also be added when completing a form
- Select **Add to contacts**  button

- The details will be saved in the **Contacts** area for future use in other forms

Insert Contact in a form

- Contact details can be inserted automatically when completing Team Member Details in a form
- Select **Load**  button

- A **Contacts** text box will be displayed to insert the relevant contact
- Select **insert** button

- Contact details will be successfully loaded into the form

16.12 Correspondence

To the Research Office

The applicant can use the **Correspond** function to communicate with the reviewing organisation's Research Office and should be used **after** a form has been submitted to the reviewing organisation.

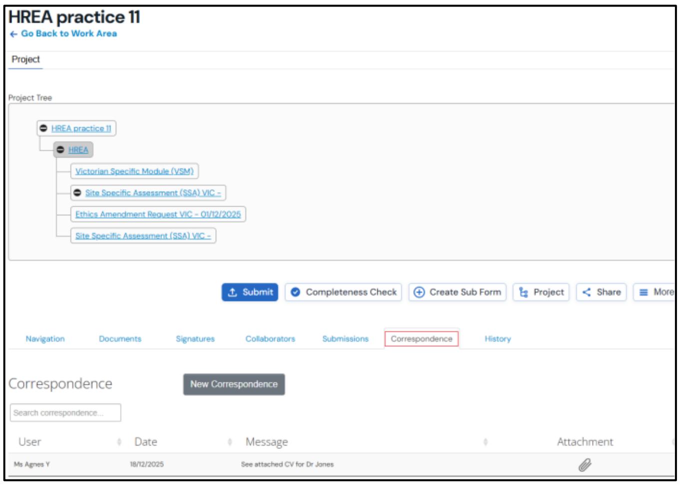
Correspond must **not** be used to respond to a query or information request.

Select the **Correspond** 

under **More** button from the Actions pane to open communication with the designated Research Office.

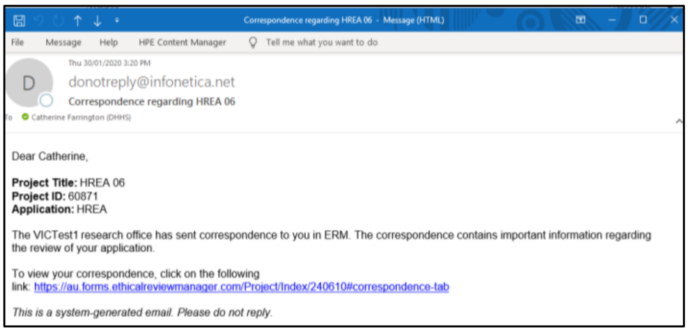
- A **Correspond** text box will display where the message will be delivered to
- Enter message details and attach documents if required
- Select **Send**

- A record of the correspondence can be accessed in the **Correspondence** tab

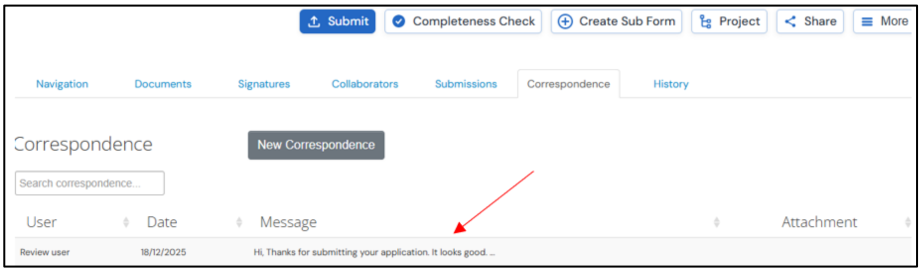


From the Research Office

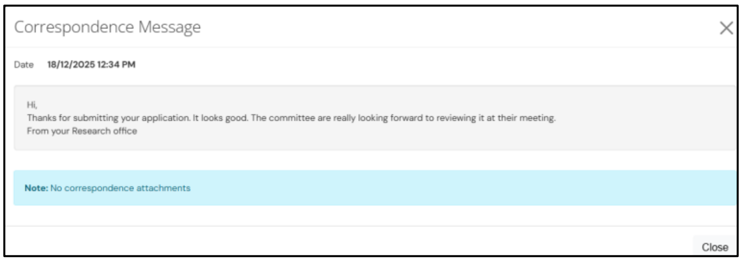
- At times the Research Office may use their Correspondence function to communicate with the applicant. It is **not** used by the Research Office to query or request clarification relating to an application
- The applicant will receive an email notification regarding the new correspondence with a link to the relevant project. Click on the link provided



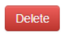
- Select the **Correspondence** tab to display a Correspondence list
- Select the relevant message



- A **Correspondence Message** textbox will display details of the message

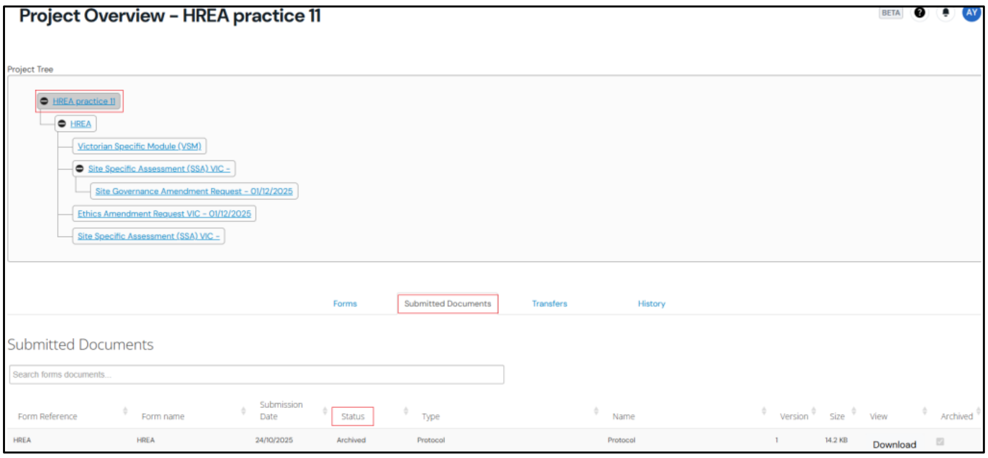


16.13 Archived documents

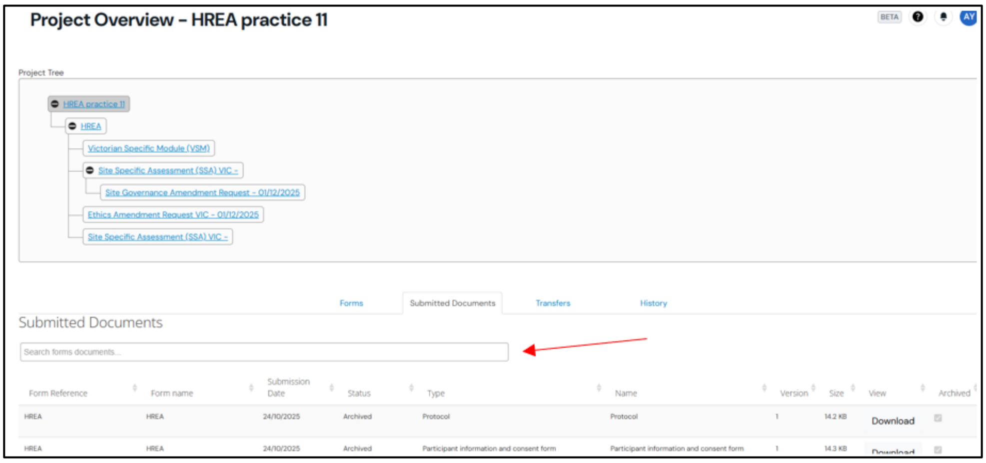
When an application requires resubmission with new document versions, deleted 

documents are automatically archived in ERM. Archived documents can be accessed in the Project Overview screen

- Highlight the project title in the Project Tree and move to the **Submitted Documents** tab



- The **Status** for current document versions is Submitted and previous/deleted versions are now Archived
- When the application has been approved, the **Status** of the submitted documents is Approved
- Select **Download** Download button to view an archived document
- A Search Bar is available to filter documents and find specific document types e.g. PICFs

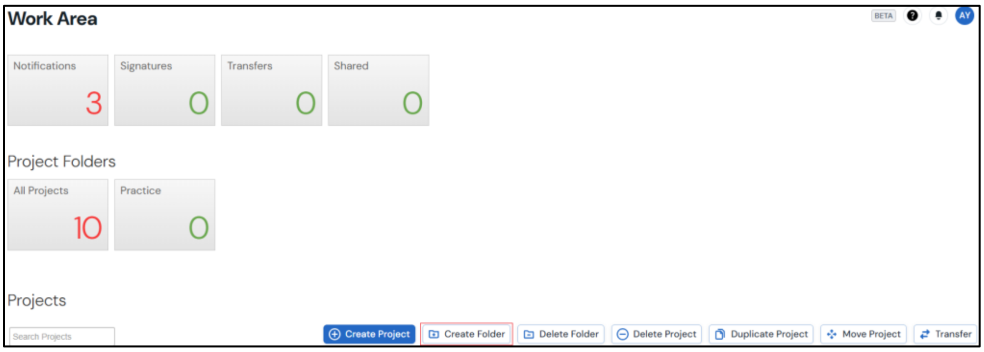


- Other collaborators with assigned access can also view archived documents

16.14 Folders

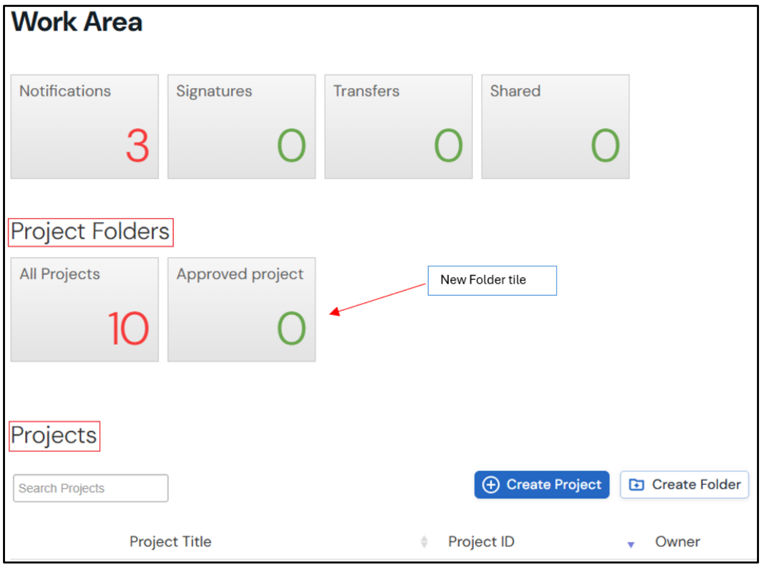
All applications are listed together in the Work Area home page. Folders can be created to organise applications accordingly.

- Select **Create Folder** Create Folder button under the Actions pane

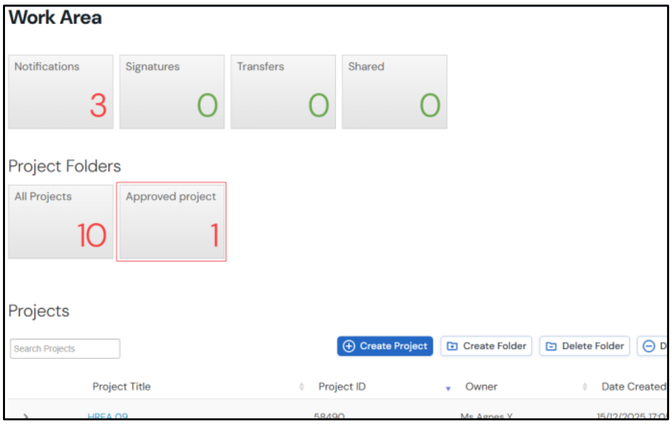


- A **Create Folder** text box will be displayed
  Enter Folder title e.g. Approved project
- Select **Create**

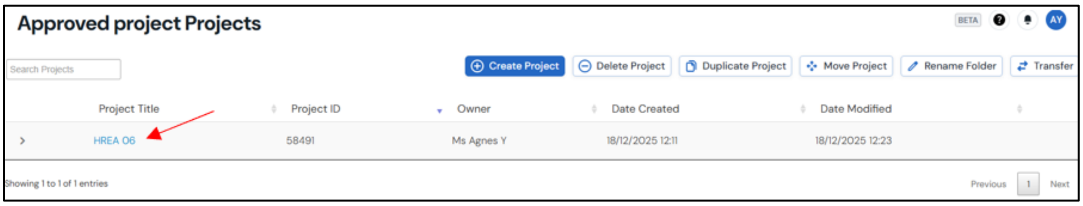
- A new Folder tile (Approved project) is displayed in the Work Area under **Folders**



- Applications listed under **Projects** can be moved to the new folder using ‘drag and drop’
- Select the **Folder** tile to display the list of projects moved to the Folder



- Select a project to display the application and associated forms



Other Folder Actions

Create Project	Create a new project
Delete Project	Delete a project (only possible if the main form has **not** been submitted via ERM)
Delete Folder	Delete a folder (only empty folders can be deleted)
Transfer	**Permanent** transfer of a project to another user e.g. Sponsor creates the HREA and transfers it permanently to the CPI
Duplicate Project	Duplicate an existing project. Includes all forms in the project but **not** any attached supporting documents
Rename Folder	Rename the tiles under **Folders** and enter a new name for the tile
Move Project	Move a Project filed in **Folders** to the **Work Area.** The Project will be listed with other current projects under **Project Title**

16.15 Submission to non ERM Research Offices

For a submission to a HREC that does not use ERM e.g. Private hospital HREC, the HREA can be completed and printed as a pdf.

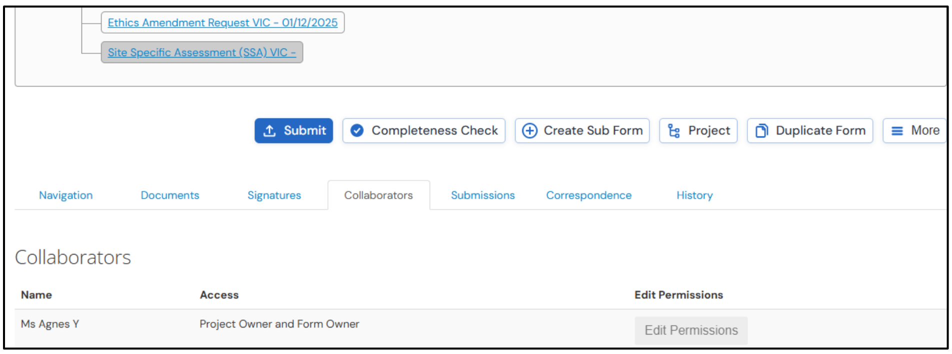
- In the ERM Filter Questions ERM Filter Questions section, select 'Infonetica – Test Committee' from the Committee dropdown list
- In **Q 4.3,** select Infonetica - Test Committee from the Organisation dropdown list
- Select the **View as PDF** View as PDF under **More** button under the Actions pane to generate a pdf of the form. Save the document to your local drive
- Do **not** select Submit

16.16 How to identify the Project Owner

In ERM, each project has an owner who has full access to manage all functions. If any research team member has access to any of the project forms e.g. the HREA or SSA, they will be able to identify the project owner.

The following steps outline how to identify the owner of a project in ERM.

- Log into ERM and select the project
- Select the relevant form in the Project tree e.g. the SSA and move to the Collaborators tab. The Project owner is identified as well as the SSA form owner.



- Click/tap on the project owner's name to display their ERM email address

17 Help

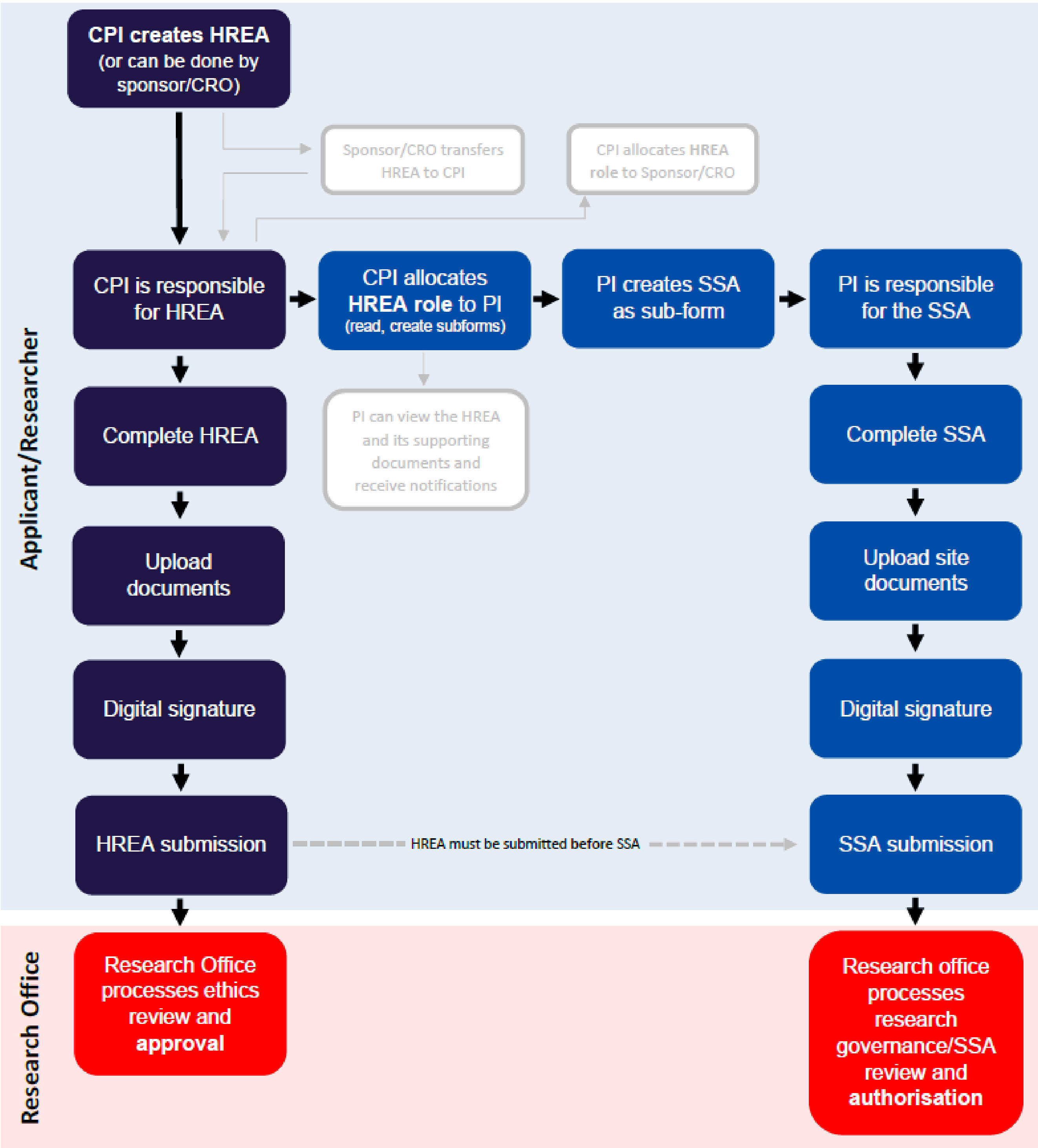
To access ERM

https://au.forms.ethicalreviewmanager.com/

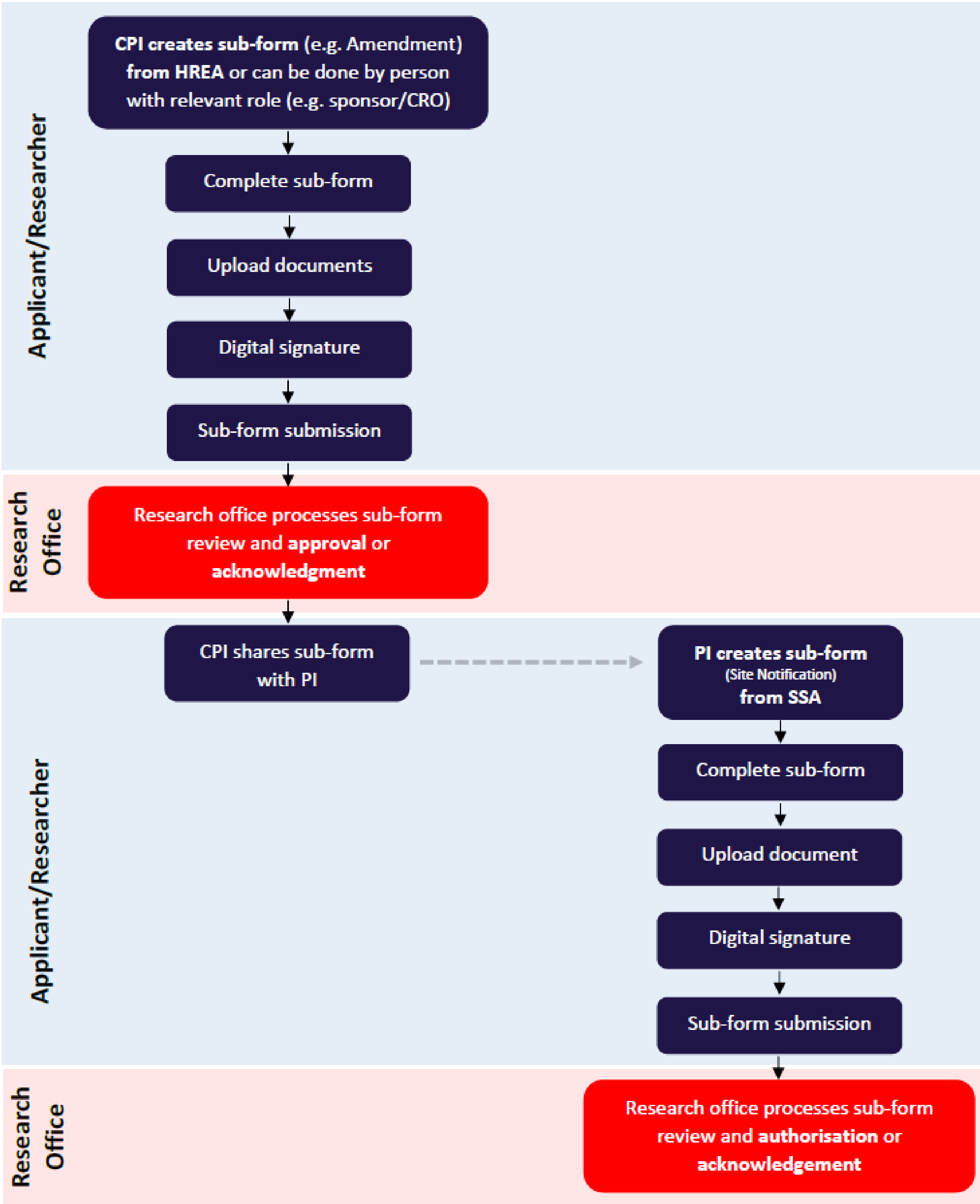
For assistance

Infonetica Helpdesk:	02 9037 8404 helpdesk@infonetica.net
Research, Strategy & Clinical Trials:	0408 274 054 research@safercare.vic.gov.au

Appendix 1: Application process flow



Appendix 2: Post approval & post authorisation chart



Safer Care
Victoria