Applicant user guide to ERM

Ethical Review Manager (ERM)

Version 1. February 2019

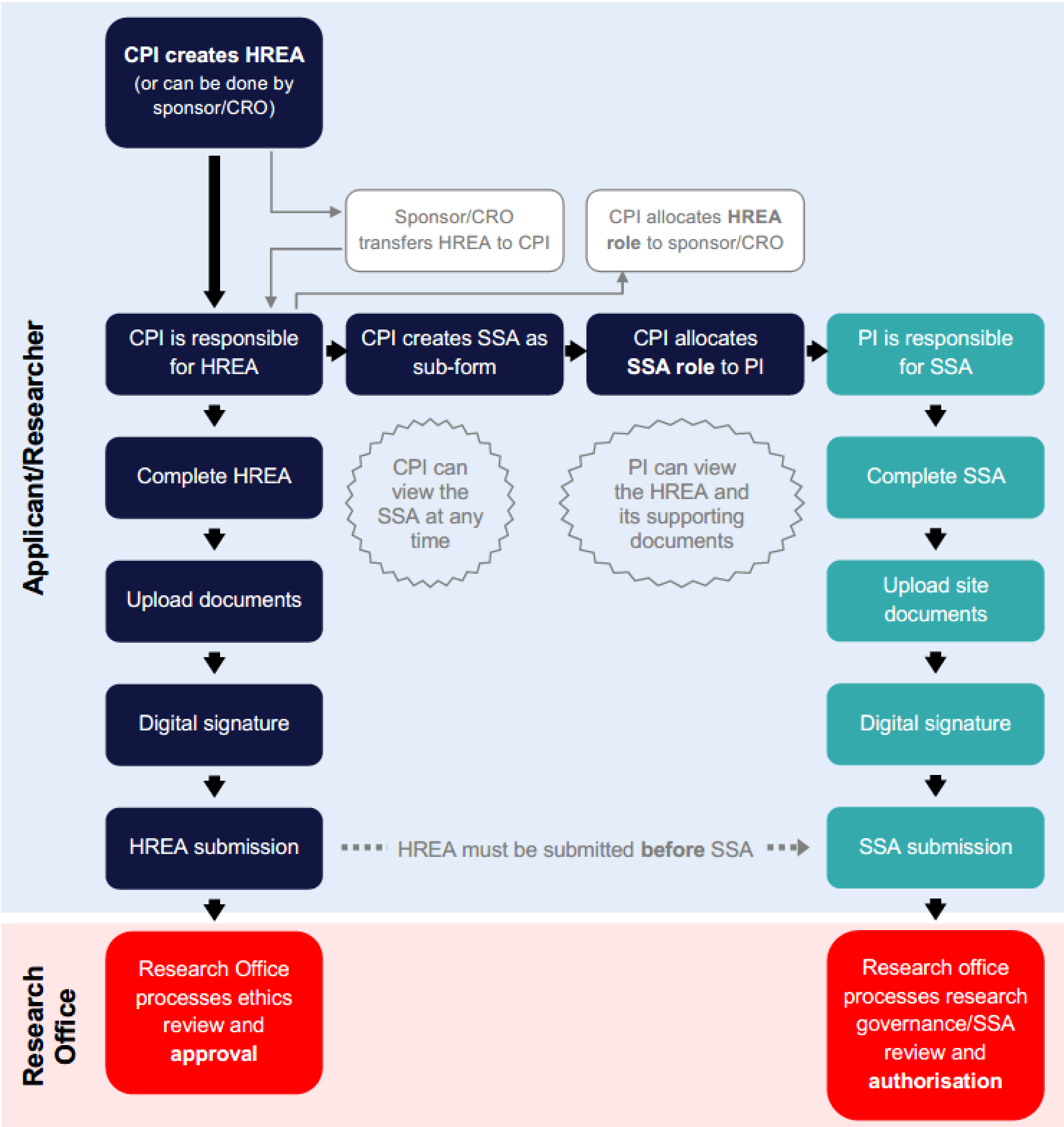
VICTORIA State Government | Health and Human Services

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)
CTN	Clinical Trial Notification
CTRA	Clinical Trial Research Agreement
CTX	Clinical Trial Exemption
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
LNR	Low and Negligible Risk application
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, Queensland, South Australia, 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

Application Process flow



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Section 1: Introduction

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

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.

Create an account

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

To Log in:

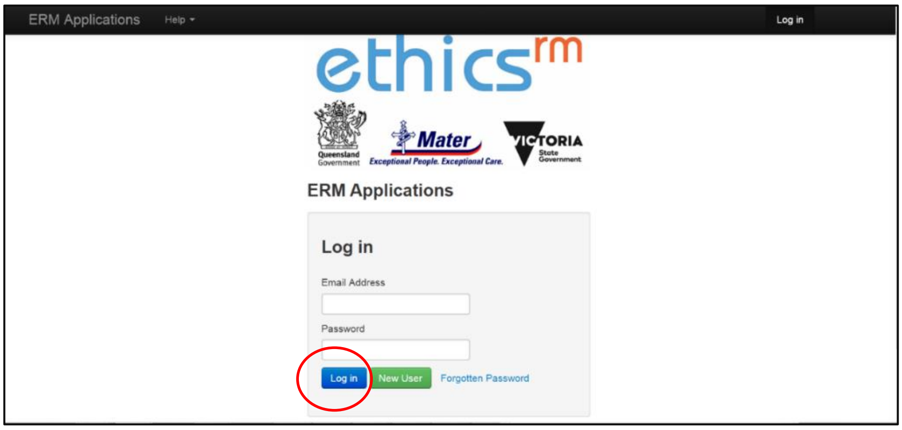
Note: Online Forms was the precursor to ERM. Online Forms account holders may already have an ERM account and can use the same login details.

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 address

4. Select the activation link in the email
5. Click **Log in**
6. Log in with your email address and password

Log in

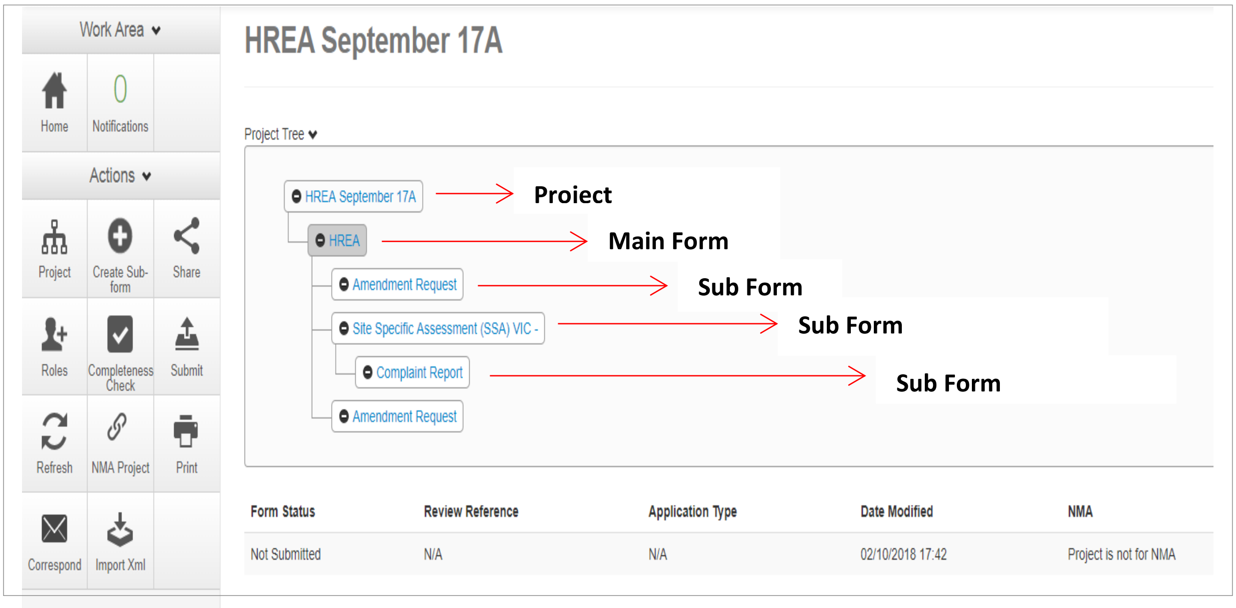


1. Enter your email address and password
2. Select **Log in**

Log out

1. Select arrow at right edge of account name
2. Select **Logout**

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. SSA form, progress report.
- From some sub-forms (SSA and LNR VIC SSA) further sub-forms can be created e.g. site progress report, complaints 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/Negligible Risk Application Form **(LNR VIC)**	Ethics application form for low or negligible 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/Negligible Risk Site Specific Assessment **(LNR VIC SSA)**	Research governance application form; one LNR VIC SSA is required for each site participating in a research project

Sub-forms for post-approval

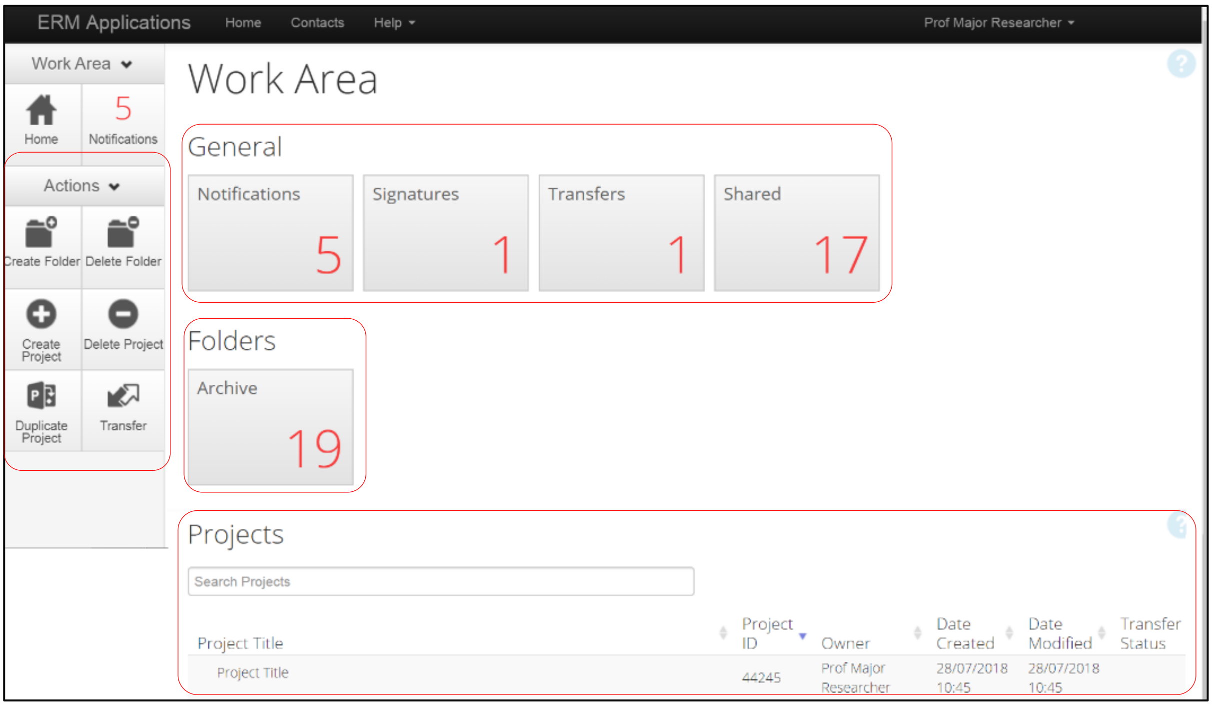
Form	Description
Amendment Request	Request ethical approval for a change to the design or conduct of a research project e.g. the protocol, PICF or change to personnel
Project Notification Form	Report to the reviewing ethics committee on any matters for which there is not a specific post-approval form available
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)
Project Final Report	Report to the reviewing ethics committee on the progress of a research project at the time of its completion
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
Site Closure Report	For a multi-site project, report the closure of one participating site to the reviewing ethics committee

Sub-forms for post-authorisation

Form	Description
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
Complaint Report	Report a research project complaint to the site's research governance officer
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)

Section 2: Work Area

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

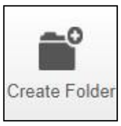


Actions

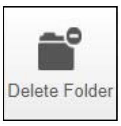
There are six action buttons under the Actions pane

Create a new project

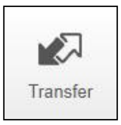
Delete a project (only possible if the main form has **not** been submitted via ERM)



Create a bespoke folder for storage of projects



Delete a folder (only possible if the folder is empty)



Permanently transfer a project to a colleague

Duplicate an existing project

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 and other research team members
- Contain messages automatically generated by ERM e.g. form updates

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

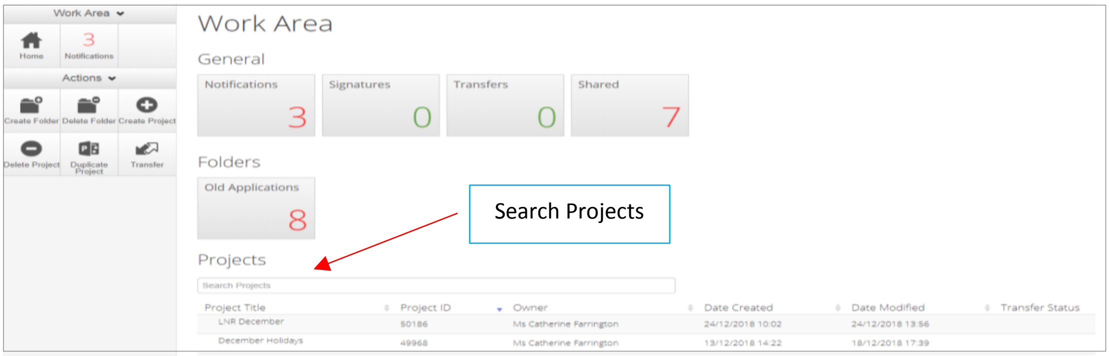
Shared - Contain information about forms and level of access another ERM user has shared with you

Folders

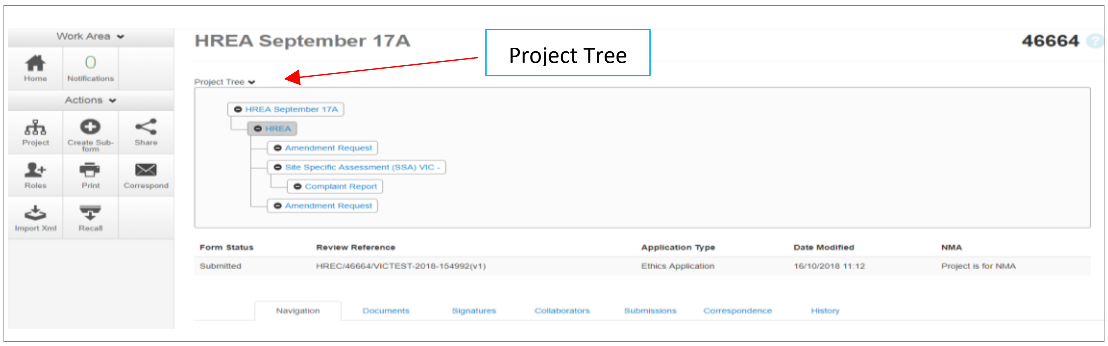
Displays bespoke folders for storage of projects.

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

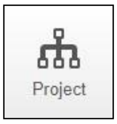


- Select a project from the list displayed
- The project will open under a **Project Tree**



Actions Pane

There are eleven possible action buttons available under the Action pane on the left side of the screen. The actions are listed below:



Go to the Project overview

Create a Sub-form from the main form e.g. SSA

Enable collaborators to view, edit and manage the form

Enable collaborators to view, edit and manage the form

Identify mandatory questions within the form that require information to be entered

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.

Refresh

Record that the project falls within the National Mutual Acceptance (NMA) scheme. Information on NMA is available on the Clinical Trials and Research website.

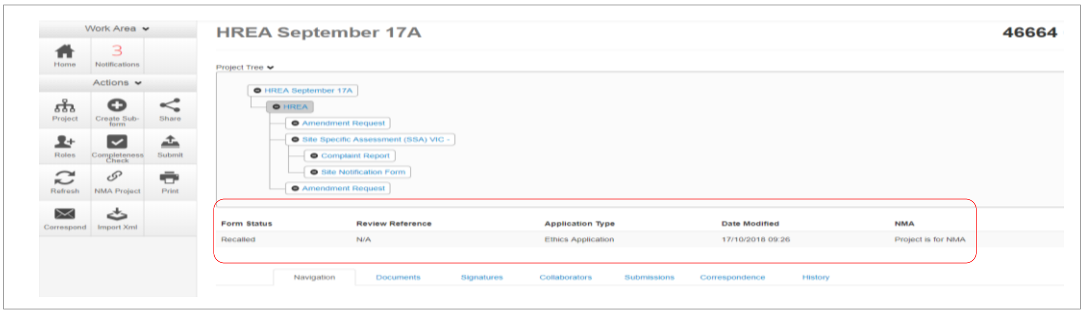
Generate a PDF of the form

Communicate directly with the Research Office selected as the reviewing organisation within the form **only after** the form has been submitted

Import a HREA created on a different website e.g. hrea.gov.au, as an Xml file in to ERM

Form Status Table

The Form Status table displays the current activity of the form



Form Status:

- Not Submitted – the form's completion is still in progress and yet to be submitted
- Submitted – completed form has been submitted to the reviewing organisation in ERM
- Recalled – form has been recalled by the user to make changes. Only possible if the reviewing organisation has **not** started processing the application.

Review Reference:

The unique identification code for a form and is generated when an application is submitted in ERM. It is composed of six parts -

① ② ③ ④ ⑤ ⑥

e.g. HREC/46664/VICTEST-2018-154992(v1)

	Component	Description	Examples
1	Application type	Identifies the type of application form	HREA, LNR VIC, MDF, SSA
2	Project ID	The unique identification number for the research project	46664
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	154992
6	Version number	Version number to track submission history	v1 to v2 to v3

Application Type:

Identifies the type of application/form submitted e.g.

- Ethics Application (the HREA)
- LNR application
- Quality Assurance
- SSA

Date Modified:

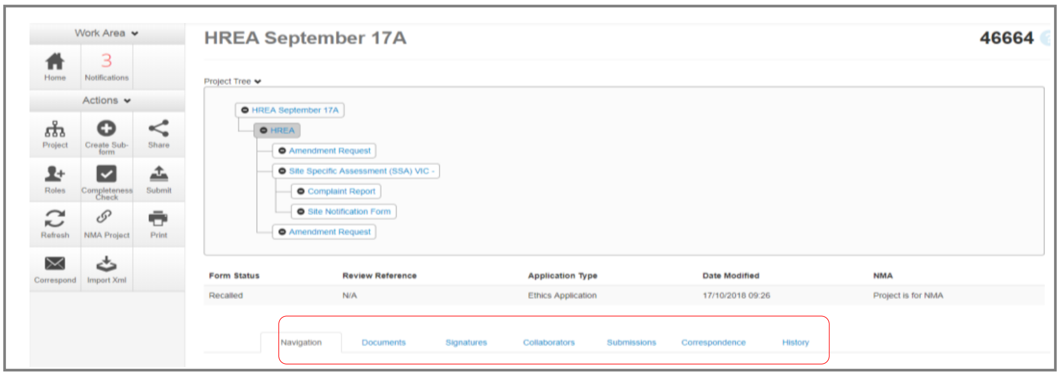
Displays the most recent date a form was updated

NMA:

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

Tab Functions

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

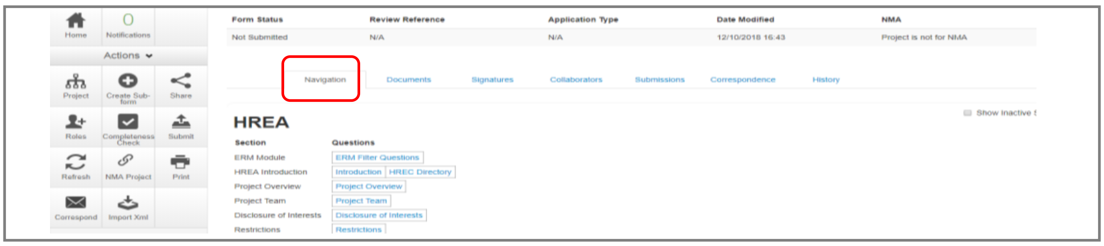


Tab	Explanation
Navigation	Application form is completed under Navigation tab
Documents	Displays all supporting documents that have been uploaded within the form Note: Documents are not uploaded under this tab; documents are uploaded within the relevant section of the form
Signatures	Shows a history of all digital signatures that have been applied to the form, and all signature requests
Collaborators	Displays members of the research team with access to the form; levels of access can be modified
Submissions	Shows a history of all submissions that have been made via ERM
Correspondence	Allows direct communication with the Research Office selected within the form
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:

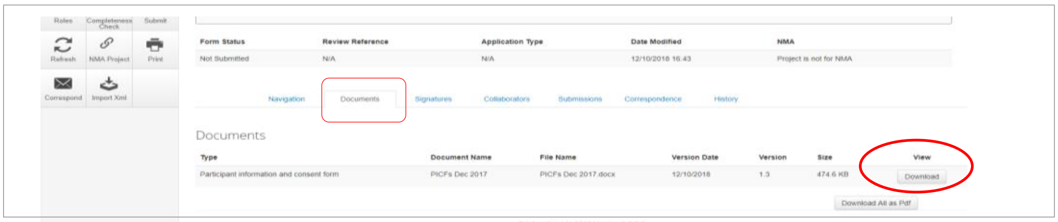
Navigation

- 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



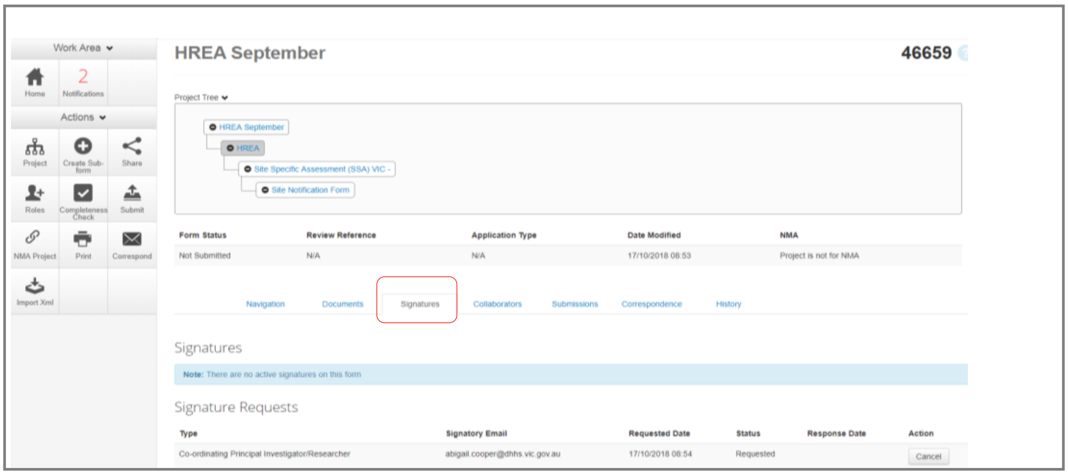
Documents

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



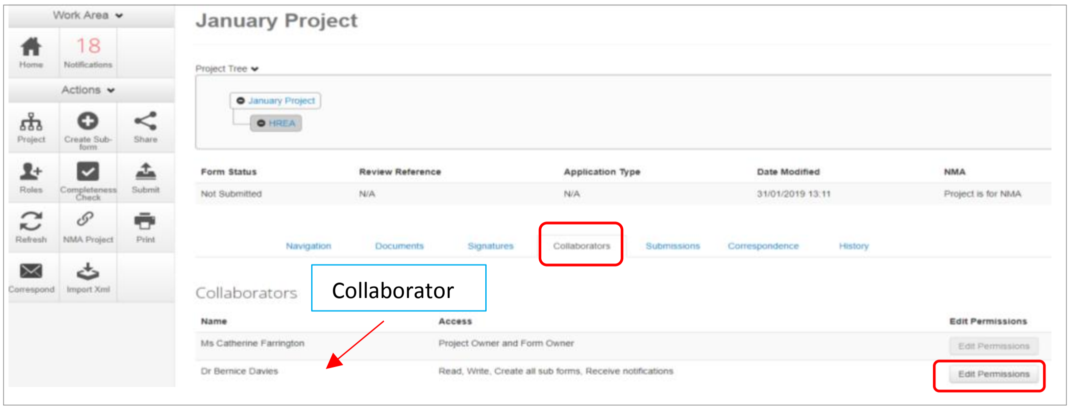
Signatures

- 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



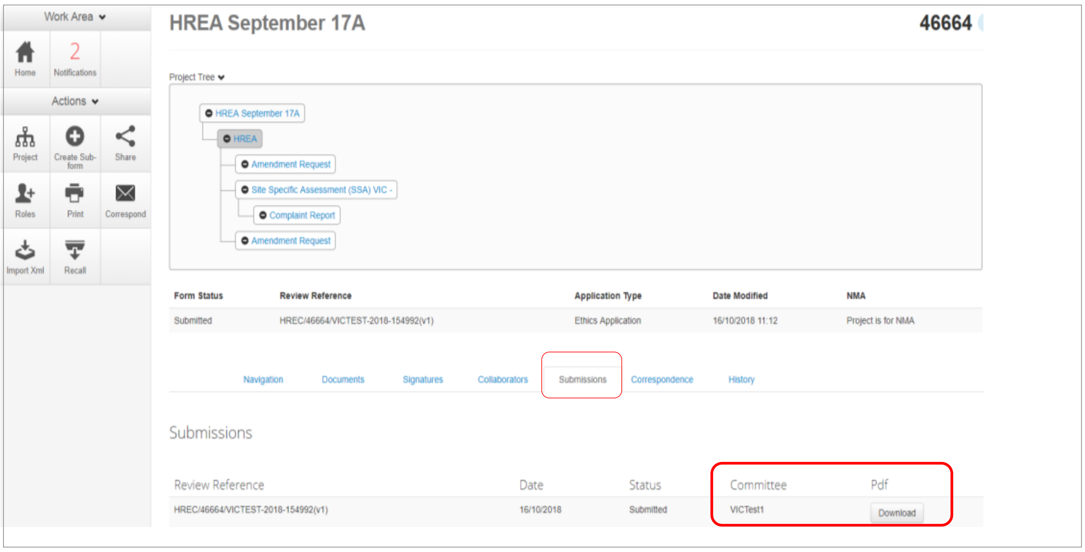
Collaborators

- Displays all members of the research team who have access to the application/form
- The form owner can alter the access level for each collaborator using 'Edit Permissions'



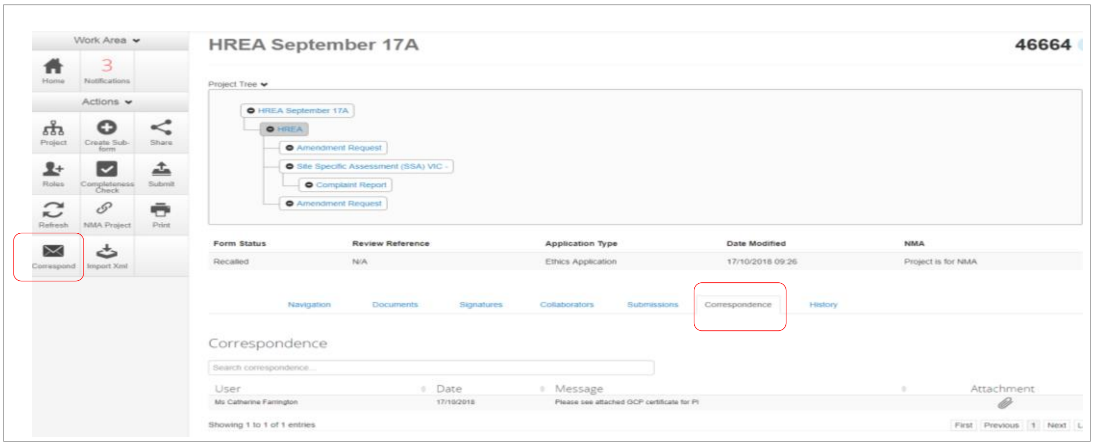
Submissions

- Displays the Review Reference e.g. HREC/46664/VICTEST-2018-154992(v1)
- Displays the current status of the application/form
    - Not Submitted / Submitted / Recalled
- The Committee that will review the application e.g. VICTEST1
- Under **Pdf** select Download to print form if required



Correspondence

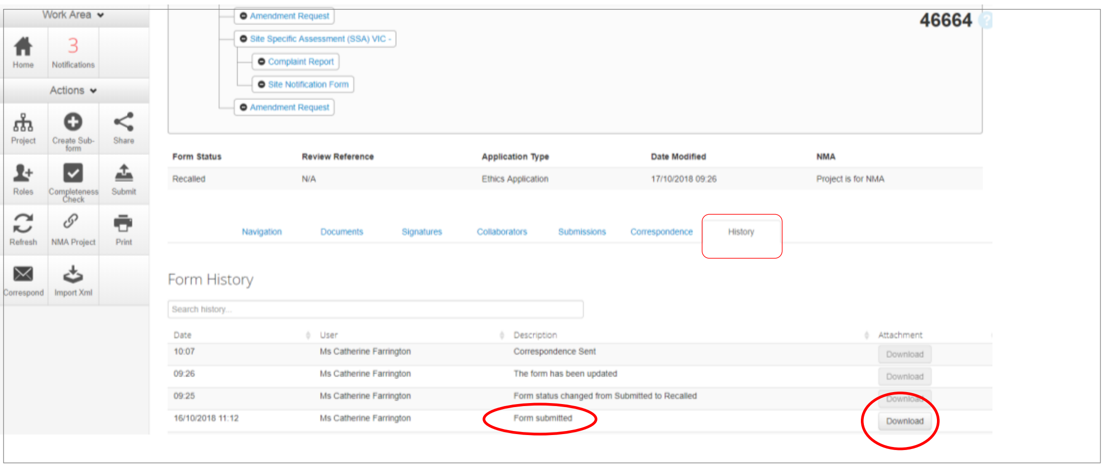
- Displays a record of the communication between the user and the reviewing organisation's research office
- It has no write/send message function



- 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.
- Attachments can be downloaded and viewed if an action includes submitting a form.



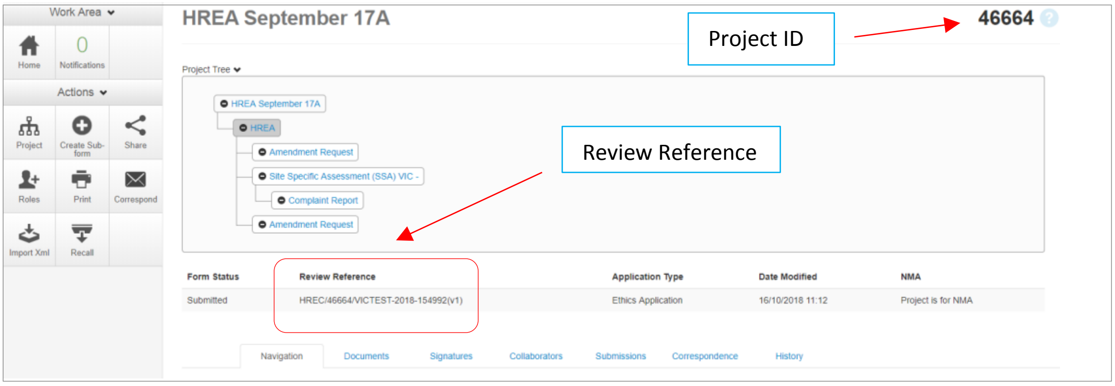
ERM Reference Numbers

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

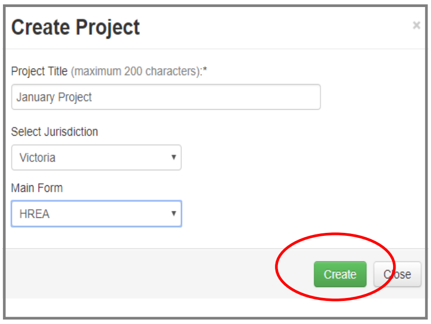
e.g. HREC/46664/VICTEST-2018-154992(v1)

	Component	Description	Example
1	Application type	Identifies the type of application form	HREC – the HREA
2	Project ID	The unique identification number for the research project	46664
3	Organisation/hospital code	The organisation/hospital to which this form was submitted	VICTEST
4	Year	Year of submission	2018
5	Submission number	Identifies the particular submission (version) of this form	154992
6	Version number	Version number	v1

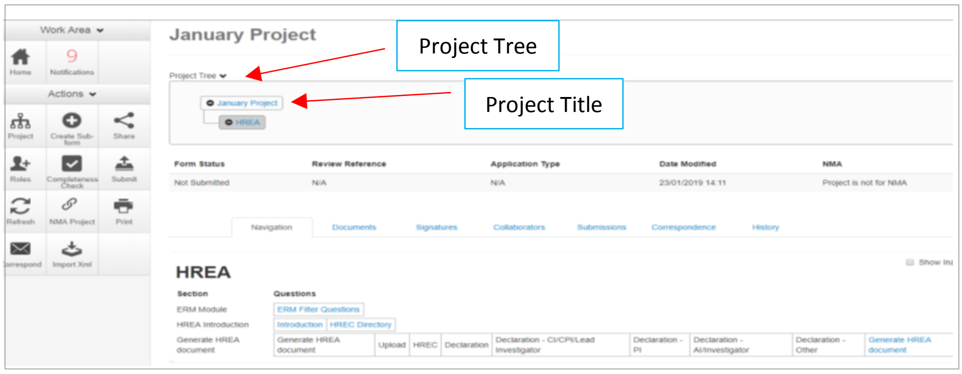
Section 3: The HREA form

Create an HREA

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

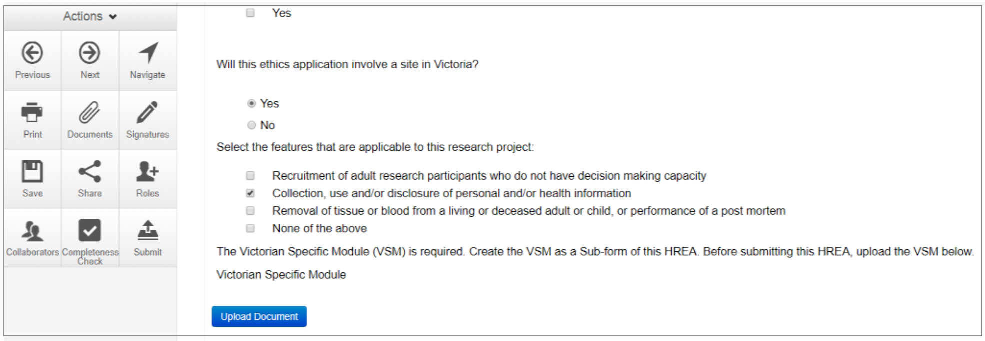


- Enter the Project Title
- Select the jurisdiction where the application will be reviewed
- Select **HREA** from the Main Form options
- Select **Create** button to create the project
- The Project Tree will display the newly created project and HREA



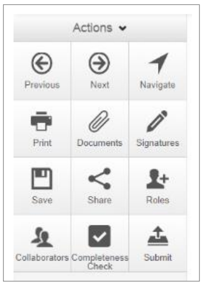
Complete the HREA

- 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

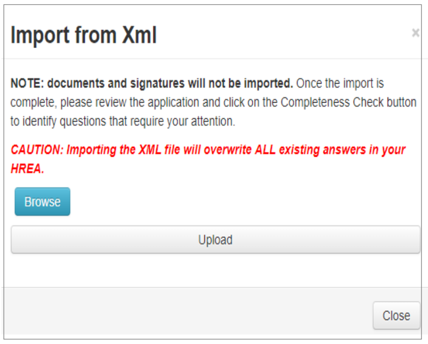


- To save your work select the **Save** button under the **Actions** pane
- Selecting **Previous** and **Next** buttons will also save your work

Import an HREA

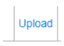
If the HREA has already been completed on another website (NHMRC), the HREA form can be imported into ERM as an xml file.

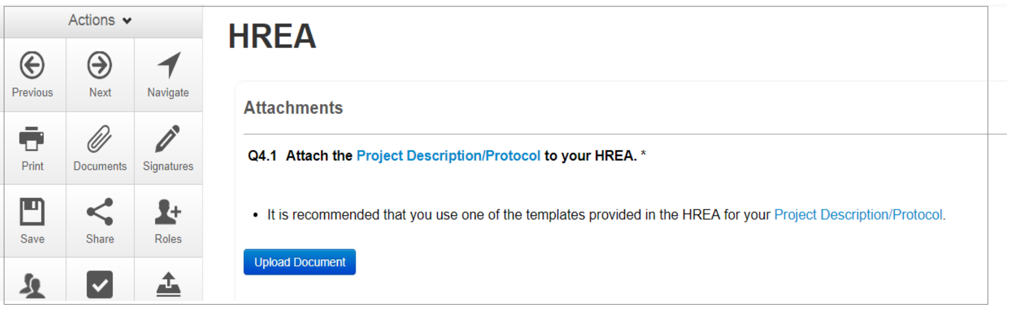
- Details to obtain the xml file are available in [ERM Frequently Asked Questions]() **HREA** section
- Create the project and HREA Main Form in ERM as previously described
- Complete the ERM Filter Questions and continue to 'HREA Introduction'
- Click on the **Navigation**  button under the Actions pane
- Select **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 in to the ERM HREA and signatures will need to be obtained again.

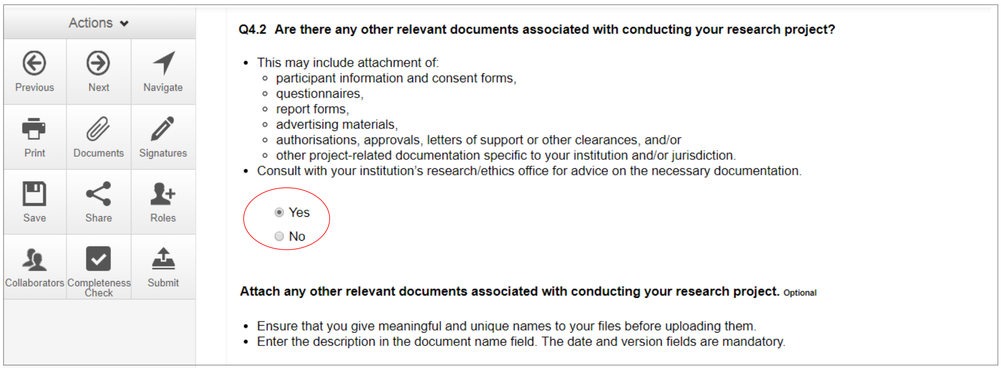
Upload Documents

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

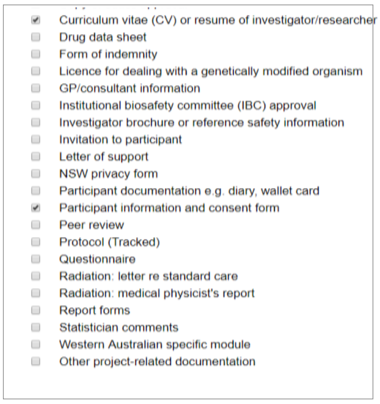


- Press **Upload Document**  to attach the protocol from your local drive

- Other documents e.g. Participant Information Consent Form can be uploaded to the application by responding **Yes** to **Q 4.2**



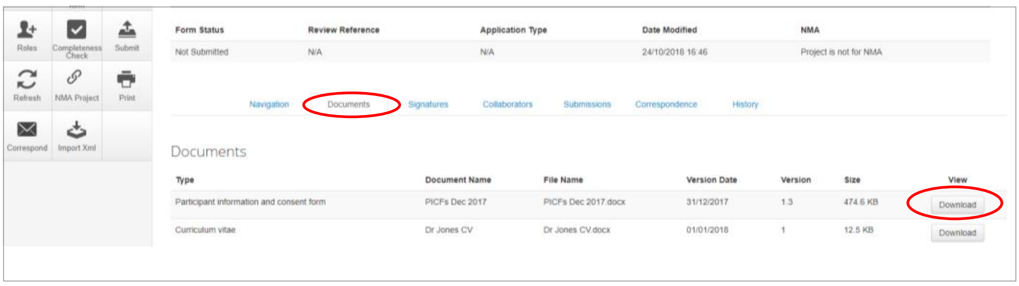
- A drop-down list of Supporting Documents will be displayed



- Press **Upload Document** 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

- Documents will also be displayed under the **Documents** tab and can be downloaded

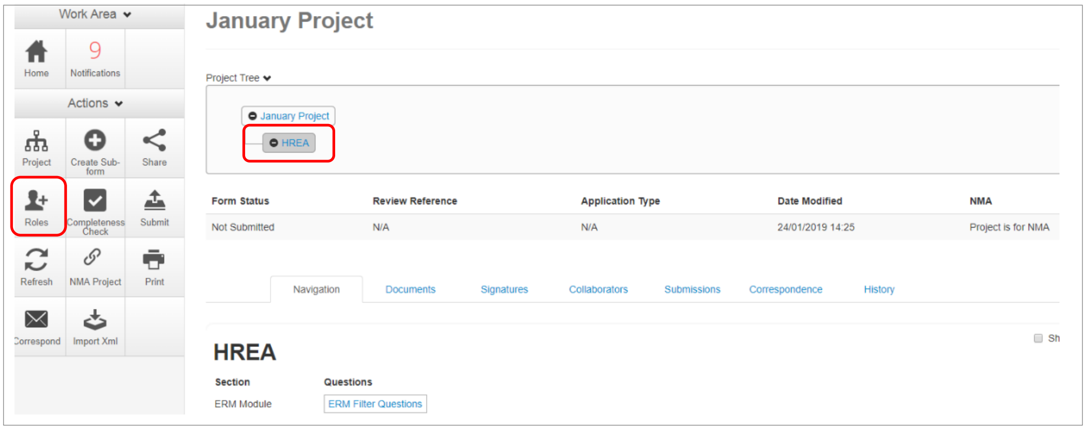


Assign access to the HREA

In ERM, the project owner can make the HREA available to others e.g. sponsors or colleagues. Using the **Roles+** function, the project owner assigns other research team members pre-defined levels of access to the HREA.

Give access

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



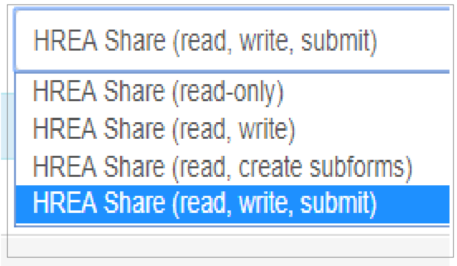
- A dropdown list will display the different levels of access to the HREA

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

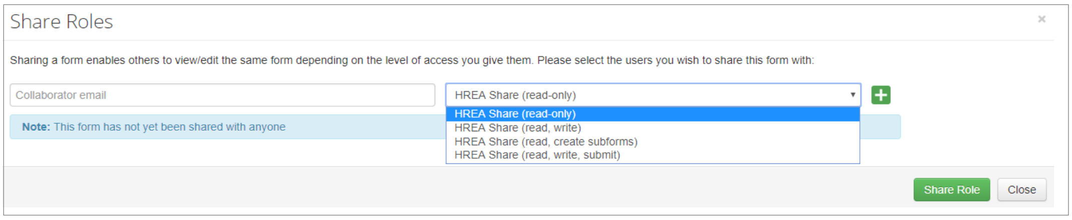
HREA Share (read, write) – to view and edit the form

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

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



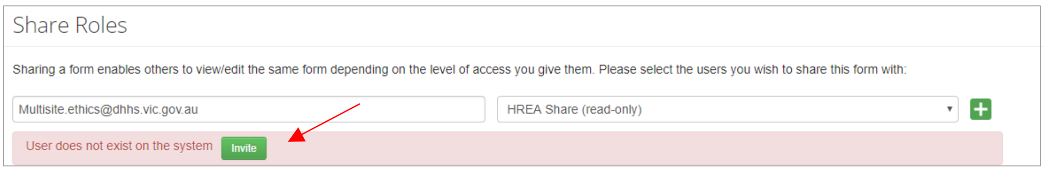
- Enter the collaborator's email address and select the level of access



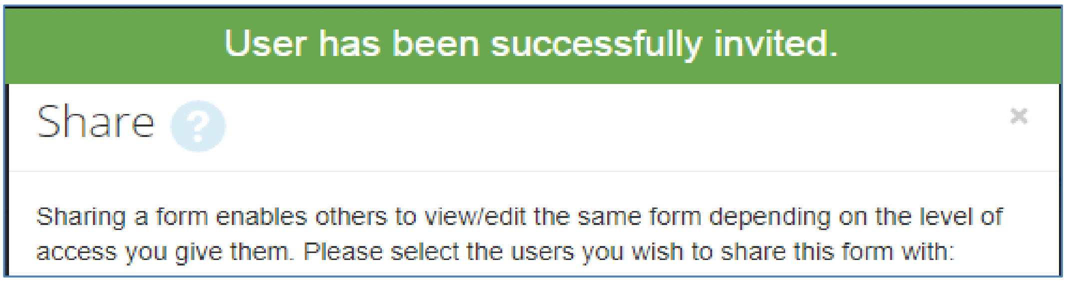
- Select **Share Role** button
- Other research team members can be added using the  button

If the collaborator does not have an ERM account

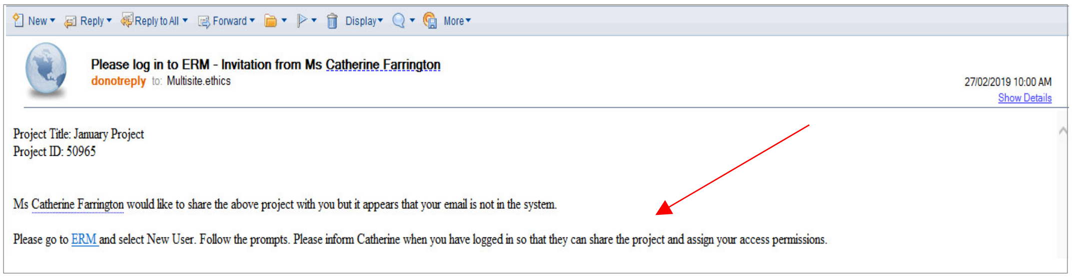
- A message will be displayed if the collaborator's email does not exist in ERM



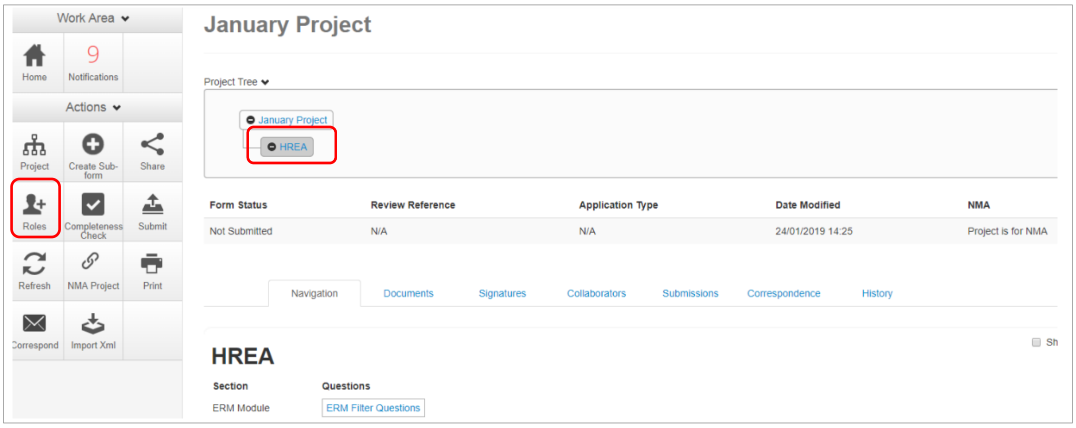
- Select the **Invite** button to invite the collaborator to create an ERM account
- This raises a green bar across the screen advising the collaborator has been successfully invited



- 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



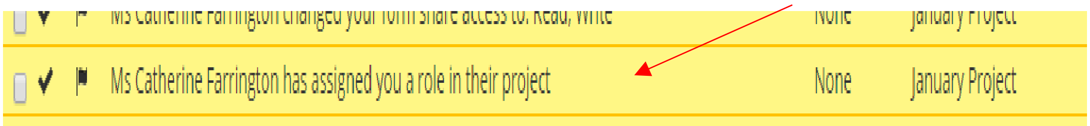
- The project owner will need to repeat the steps to assign the collaborator access to the HREA as described in Give access
- Select **Roles +** button under the Actions pane



Accept access

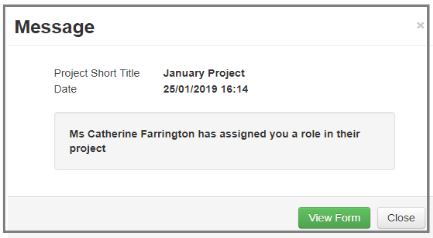
- The collaborator e.g. the PI will receive an email notification on their assigned role for the project
- The collaborator logs into ERM
- From the **Work Area** the collaborator selects **Notifications** tile

- Select the Message title to open the message



- A **Message** text box will be displayed

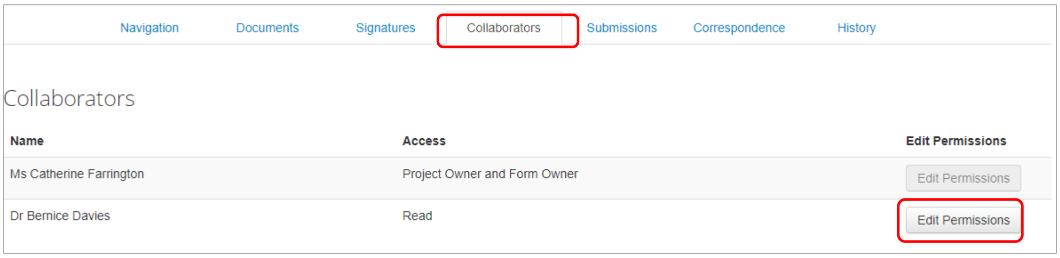
  Select **View Form**



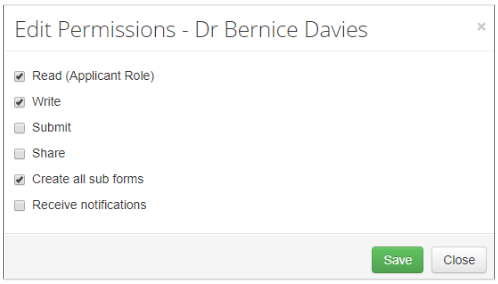
- The project and form will be displayed. Supporting documents attached to the form can also be viewed
- The collaborator can edit and submit sub-forms e.g. the SSA for their site depending on the level of access assigned by the project owner

Manage access

- The level of access previously assigned to a research member can be modified under the **Collaborators** tab and selecting **Edit Permissions**



- Select the revised level of access and select **Save**

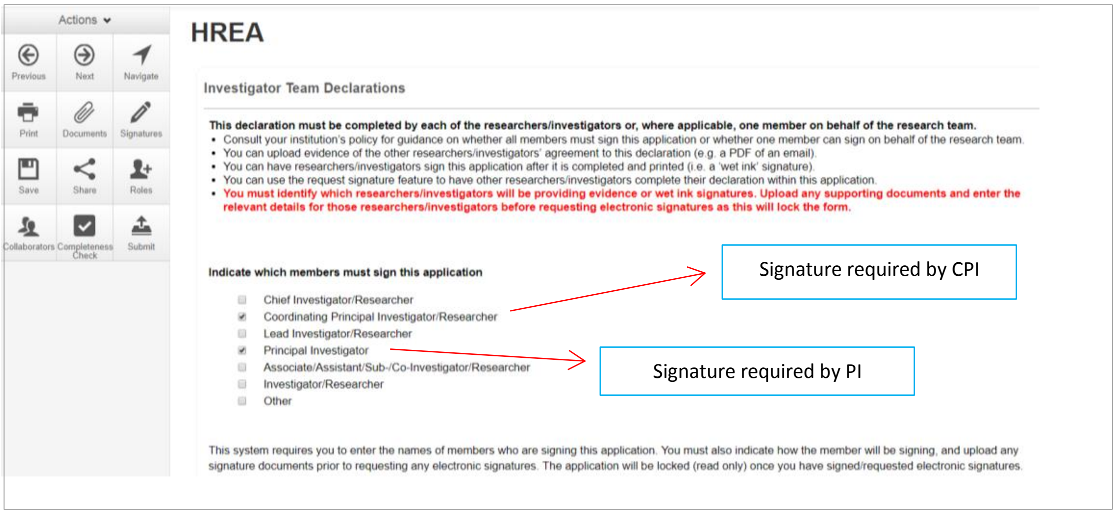


Applying Signatures

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

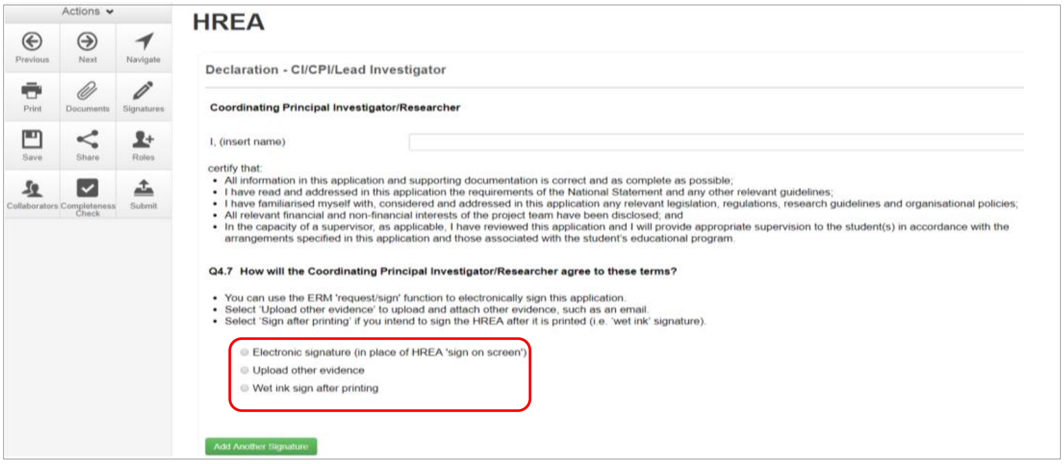
Multiple electronic signatures can occur

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/sign' function to electronically sign the declaration within the application using ERM

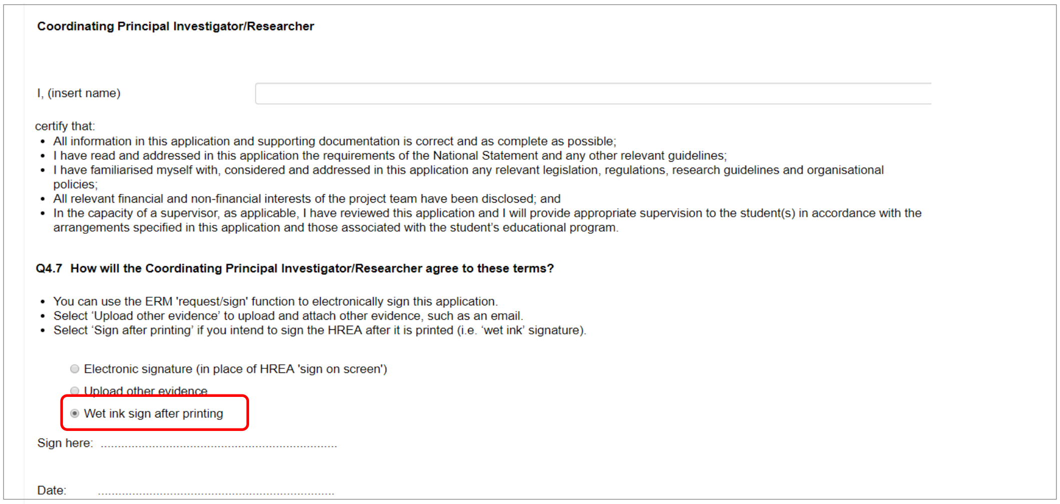
*** Signatories must have an ERM account to provide an electronic signature**



The HREA form owner may request signatures as follows:

1. To use Wet ink signature

- Select Wet ink sign after printing

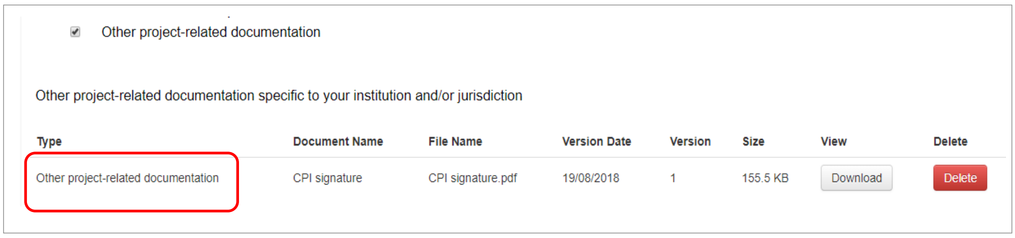


- ‘Wet ink sign after printing’ creates a signature section (at bottom of screen)
- Using the **Print button** 

 from the Actions Pane, print this section 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 

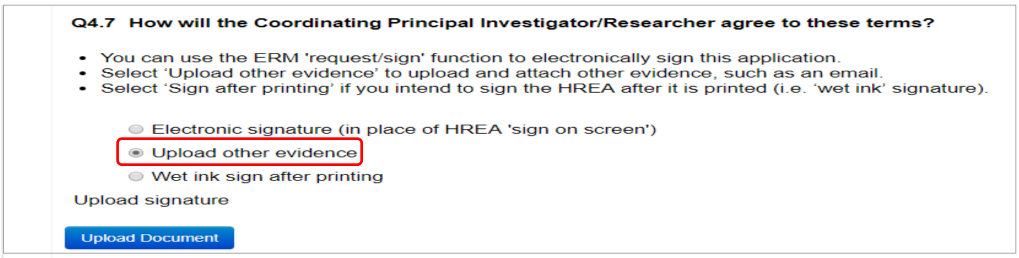
- **Upload** then opens **Q 4.2** to attach the Declaration page
- Select ‘**Yes’** to other relevant documents and select ‘**Other project-related documentation’**
- Select **Upload document** 

 to attach the signature document to the HREA
- The uploaded signature document will be displayed with the document and file name and versions

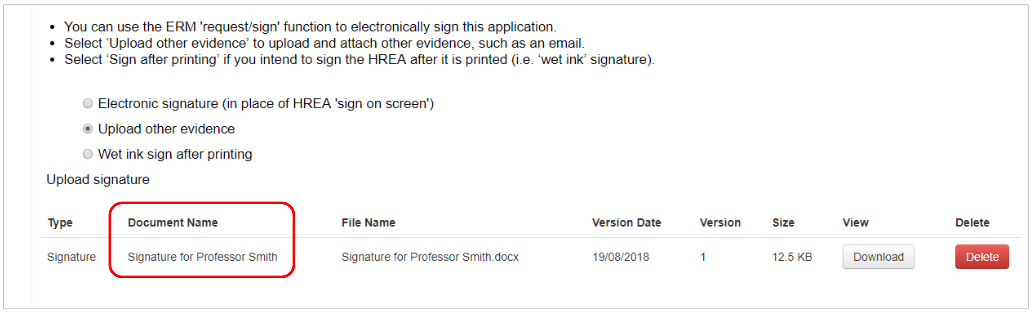


2. To Upload other evidence – to attach an email copy / letter to indicate agreement

- Select 'Upload other evidence'

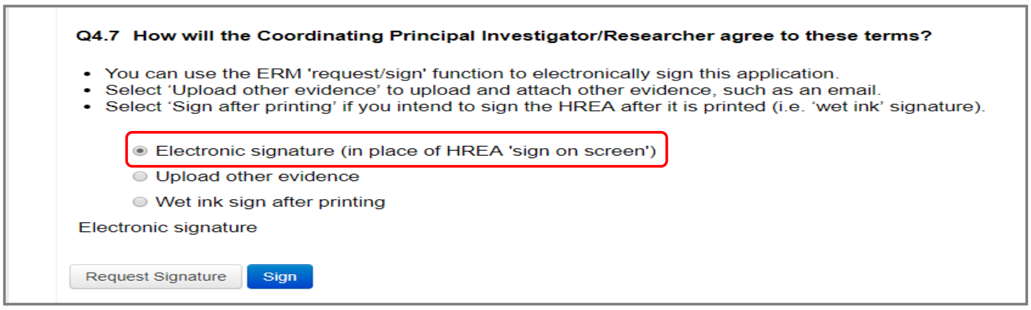


- Select **Upload Document** Upload Document to attach the signature document from your local drive
- The Signature document will be displayed with document and file names and versions



3. To request an Electronic Signature

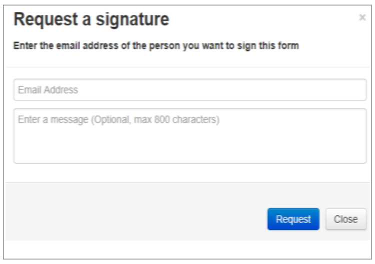
- Select **Electronic signature** and a Request Signature Sign button will appear



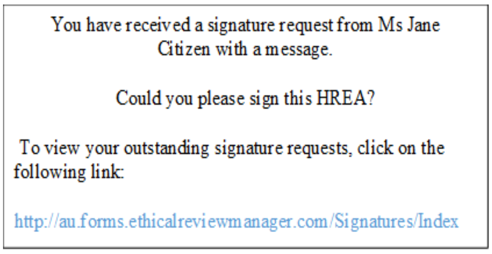
- To request an electronic signature from the Coordinating Principal Investigator / Principal Investigator, select **Request Signature** Request Signature button
- The system performs a completeness check to highlight any incomplete sections that need to be completed. Each incomplete item will be displayed 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 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?

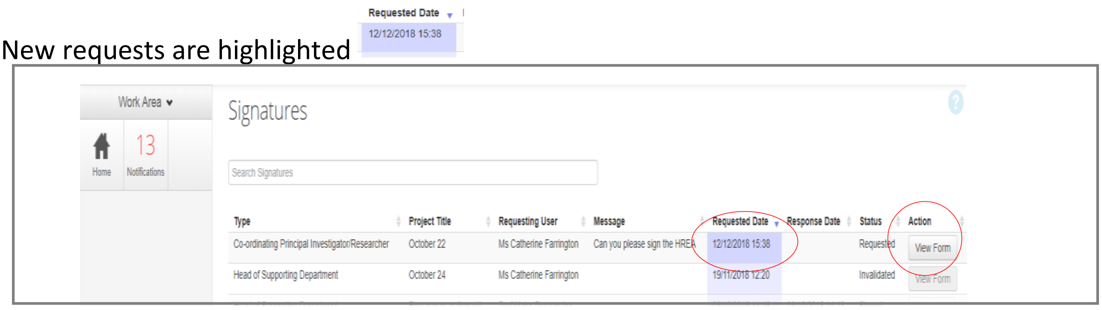
To view your outstanding signature requests, click on the following link:

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 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

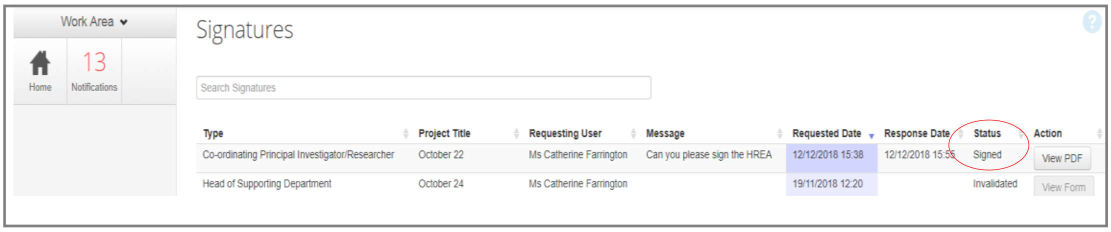
- A **Sign Form** text box is displayed

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

  Select **Sign** 

  button

- The **Status** has changed from Requested to Signed



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

<u>The ERM username and password authentication process for electronic authorisation follows the FDA guidelines on electronic signatures (CFR 21 Part 11).</u>

<u>Consult with the reviewing organisation for their policy on accepting electronic authorisation.</u>

To request additional 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 application is ready for submission

Section 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**

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

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
- This action removes the submitted application from the Research Office's ERM account
- The form can be recalled **until** the submission is actioned by the Research Office
- Select the **Recall** 

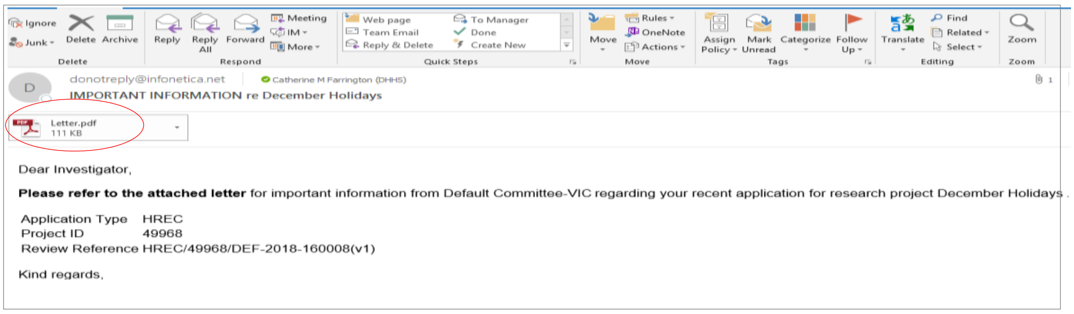
button under the Actions Pane to recall the submission and make any changes / additions
- Select the **Submit** 

button again. The application will be resubmitted

Responding to a Query from the Research Office

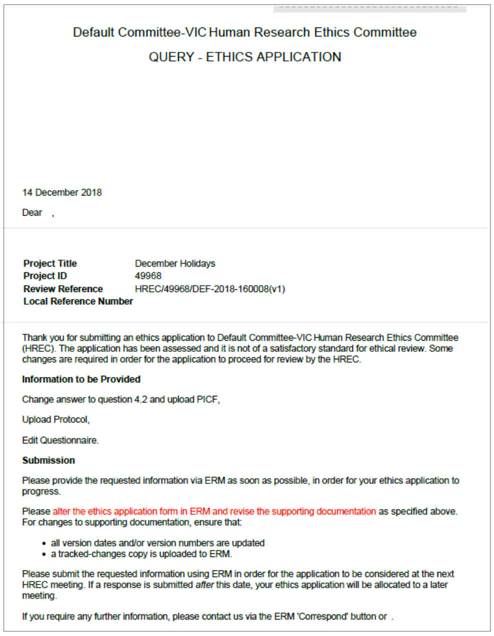
If an application is queried by the Research Office for further clarification or changes, additions (e.g. supporting documents):

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



- An attached 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



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:

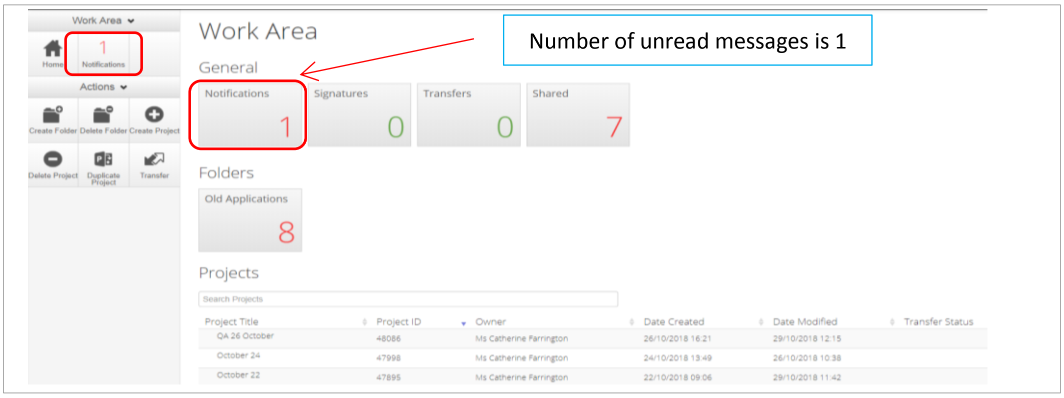
- all version dates and/or version numbers are updated
- a tracked-changes copy is uploaded to ERM.

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.

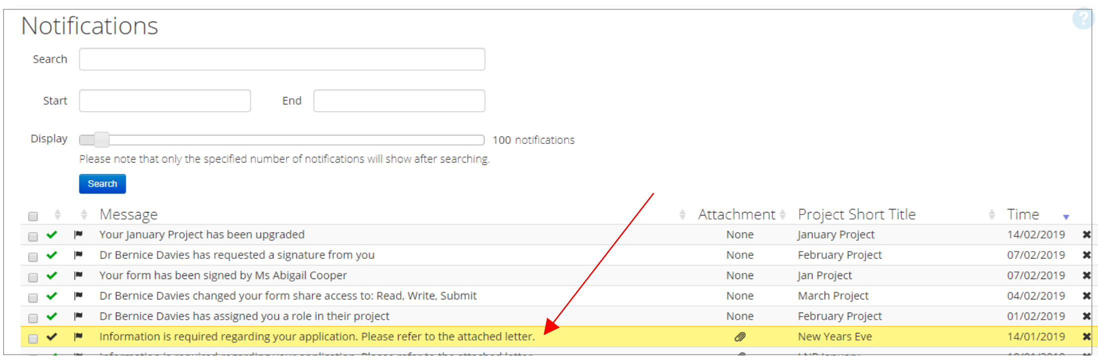
If you require any further information, please contact us via the ERM 'Correspond' button or .

To access the ***Query***

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

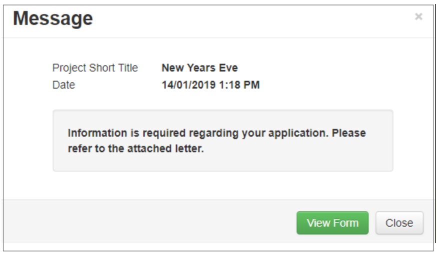


- Select the **Message** title to open and view the message

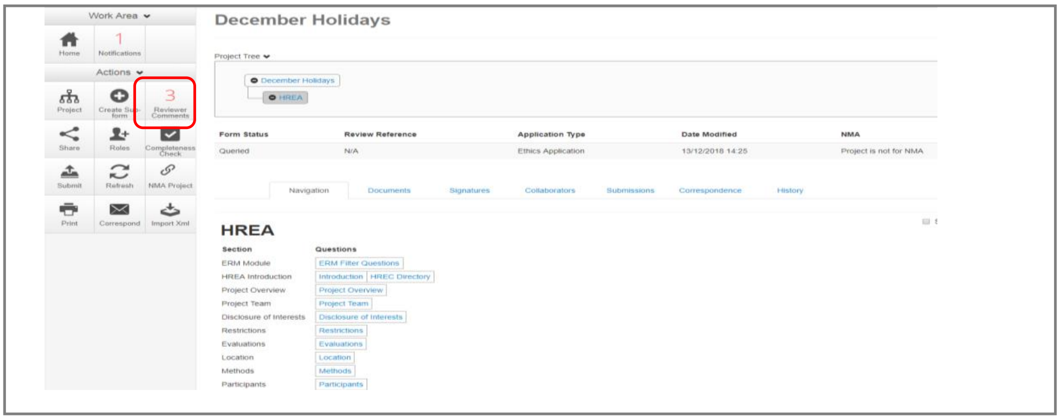


- A Message box will be displayed allowing the user to view the form

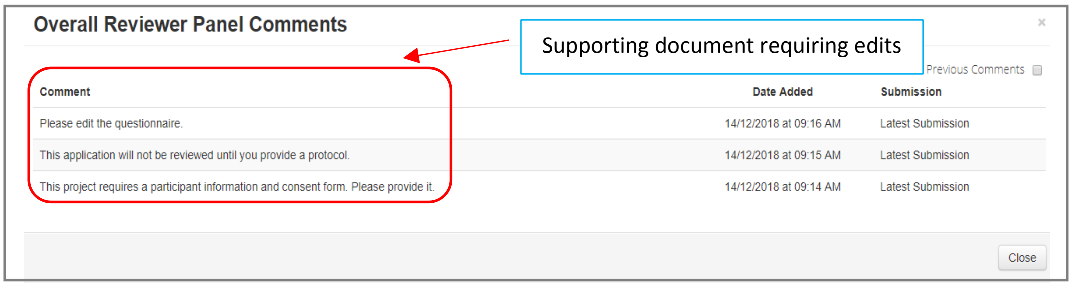
Press **View Form** to be directed to the relevant form



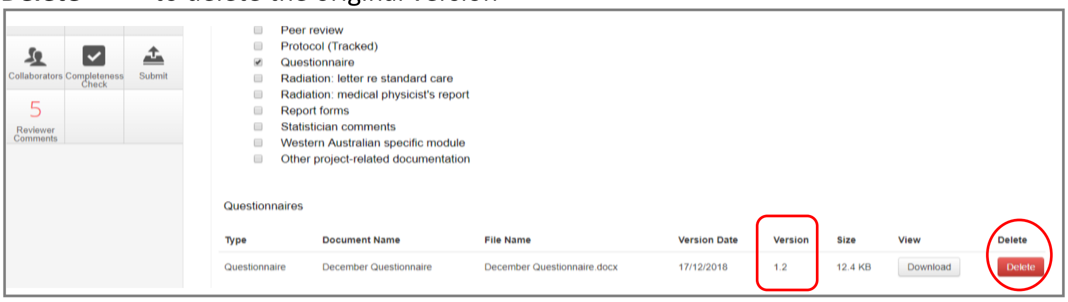
- The form will open under the **Navigation** tab



- Select **Reviewers Comments**  under the Actions pane
- A text box will be displayed of the **Overall Reviewer Panel Comments** (e.g. **3** comments)

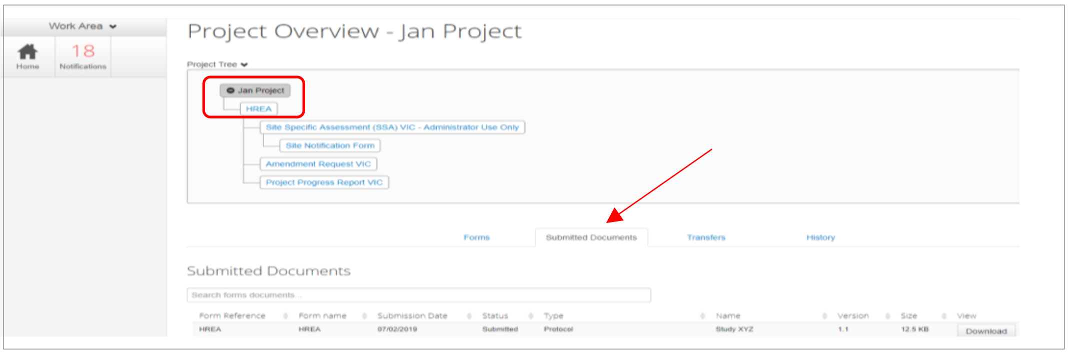


- Select a comment to be directed to the relevant section in the form i.e. to **Q 4.2 Are there any other relevant documents associated with conducting your research project?**
- As the query requires a new version of a document, the original version should be deleted, and the new version uploaded in to the form. Previous document versions are automatically archived
- **Delete** to delete the original version

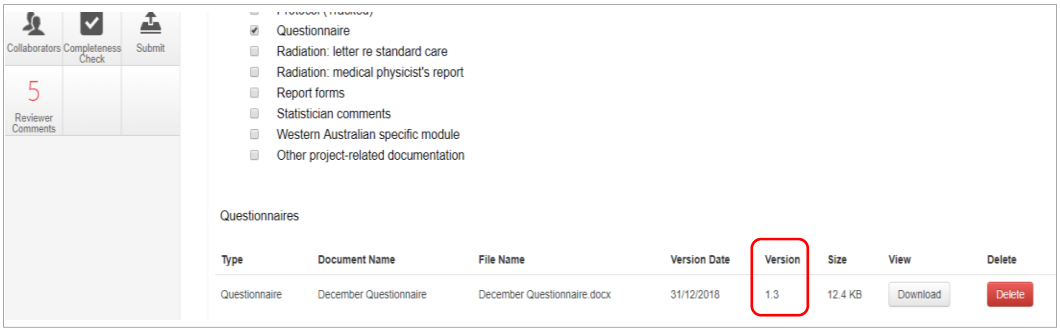


- Select **Upload Document** to upload the revised (new) version of the document with the correct version number and date

- 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



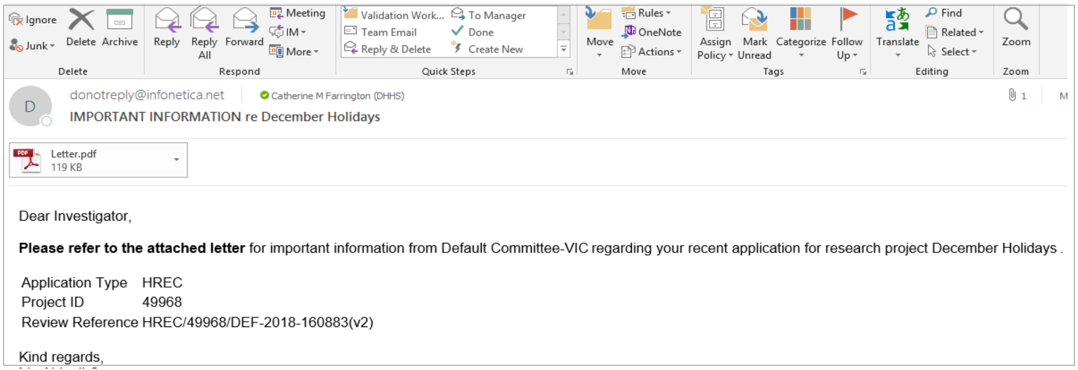
- Continue to complete the other queries as instructed in the **Overall Reviewer Panel Comments** as above
- Once the revisions / additions have been completed, the form and / or supporting documents can be resubmitted
- In the **Actions** pane select the **Submit**  button to resubmit

- 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

Ethics Committee Review Request

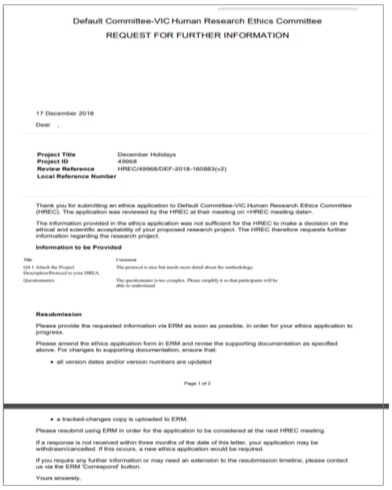
Clarification or requests for further information from the reviewing Ethics Committee to the applicant must be managed through ERM

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



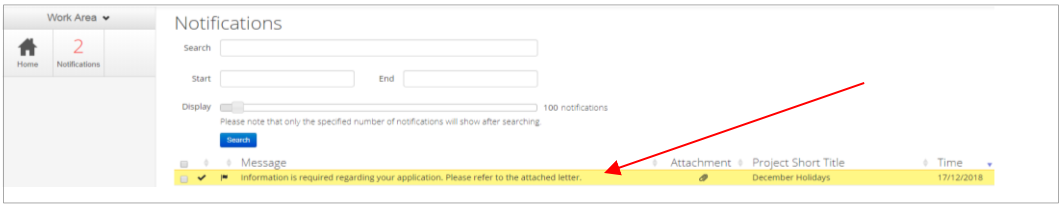
- An attached letter (pdf) from the HREC will include requests for further information to be provided via ERM

- The form is ***unlocked*** to allow the applicant to complete the requests as outlined in the attached letter

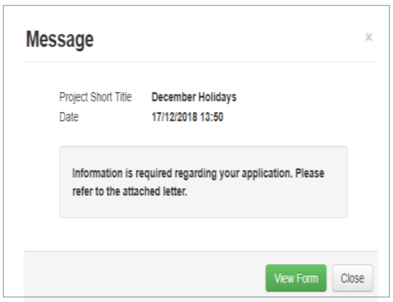


Respond to a request for further information from the Ethics Committee

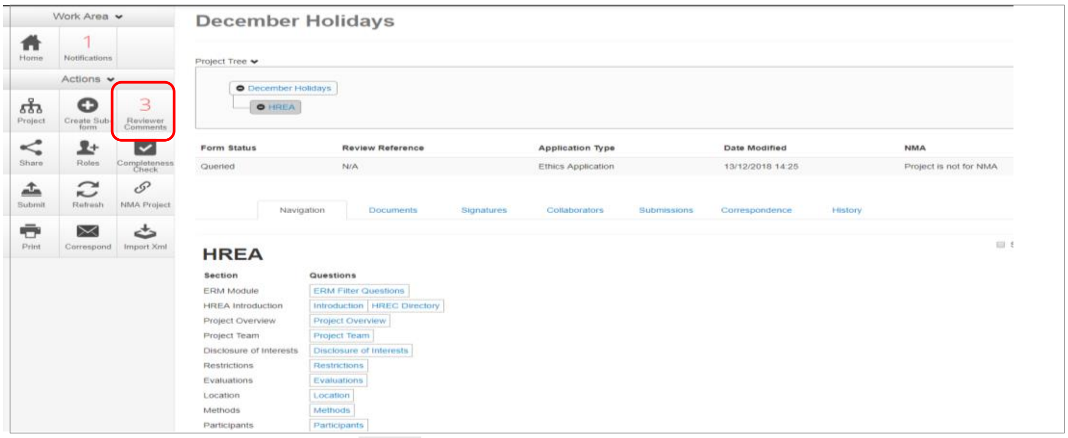
- Depending on the request, the applicant can amend the HREA and add new documents
- Log in to ERM account
- In the Work Area, click on the **Notifications** tile
- Select the Message title to open and view the message



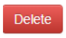
- A **Message** box will be displayed allowing the user to view the form
  Press **View Form** View Form to be directed to the relevant form

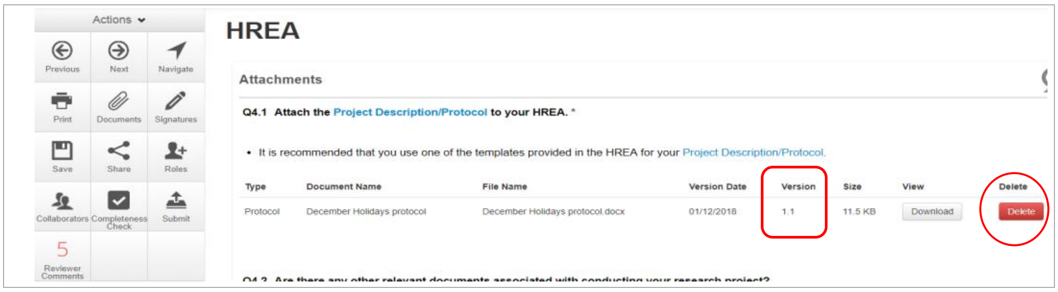


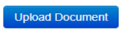
- The HREA, will open under the **Navigation** tab

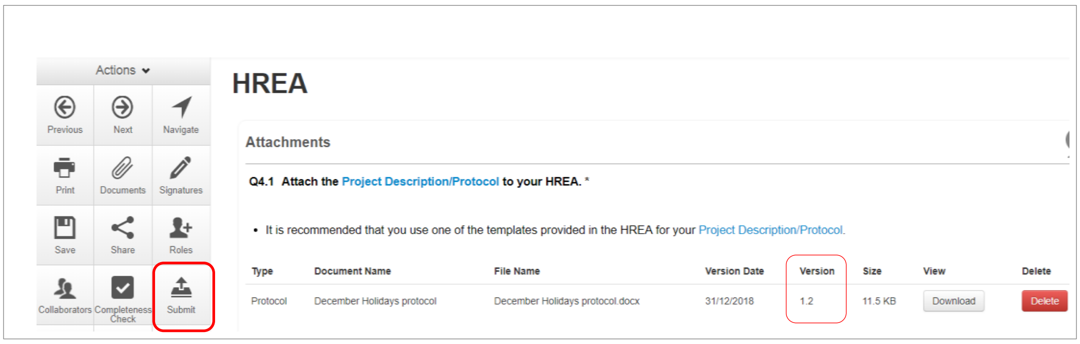


- Select **Reviewers Comments**  under the Actions pane
- A text box will be displayed of the **Overall Reviewer Panel Comments**

- Select a comment e.g. a comment requesting more information in the protocol, to be directed to the relevant section in the form i.e. **Q 4.1 Attach the Project Description/Protocol to your HREA**
- The request requires a new version of a protocol. The original version should be deleted, and the new version uploaded in to the form. Previous document versions are automatically archived.
- Select **Delete**  to delete the original version



- Select **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



- Continue to complete the other requests 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

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

1. The CPI signs - for minor changes the Research Office has all signatures on the initial submission
2. 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

- In the Actions pane select the **Submit** 

button to resubmit

- The reviewing Research Office will receive the resubmission

Approved Applications

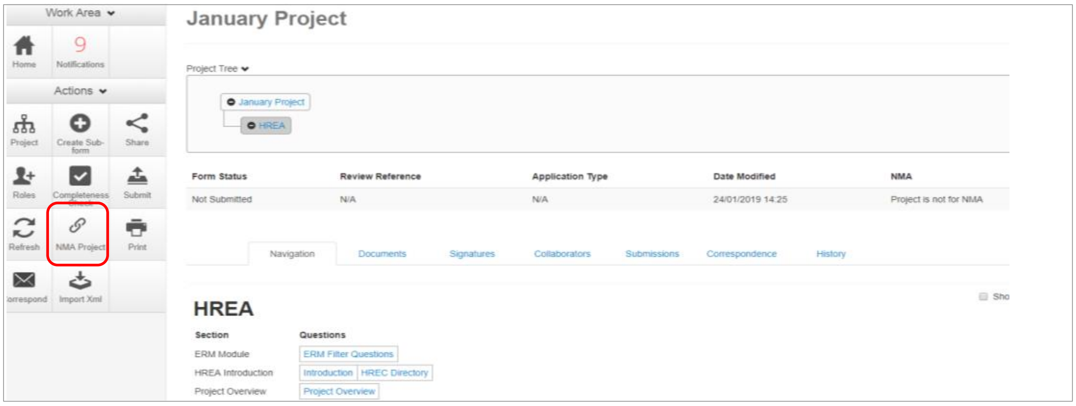
- Applicants are informed of decisions by the HREC via email using ERM. If the application has been approved, the form is locked
- Log on to ERM and click on **Notifications** tile
- A formal approval letter from the HREC can be downloaded by the applicant
- If the application review outcome is **not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

Section 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 six participating states/territories.
If the application is to be reviewed under the NMA scheme, this needs to be recorded in ERM for reporting purposes.

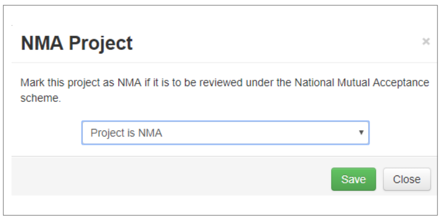
- When completing the HREA, select **Yes** to **Q 4.6 Will this application be reviewed under the National Mutual Acceptance scheme?**
- Navigate 

back to the **Actions** pane and select **NMA Project**



- A NMA Project text box will be displayed
- Select **Project is NMA**

  Select **Save** 

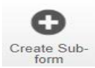


- The **Form Status Table** will be updated to 'Project is for NMA'

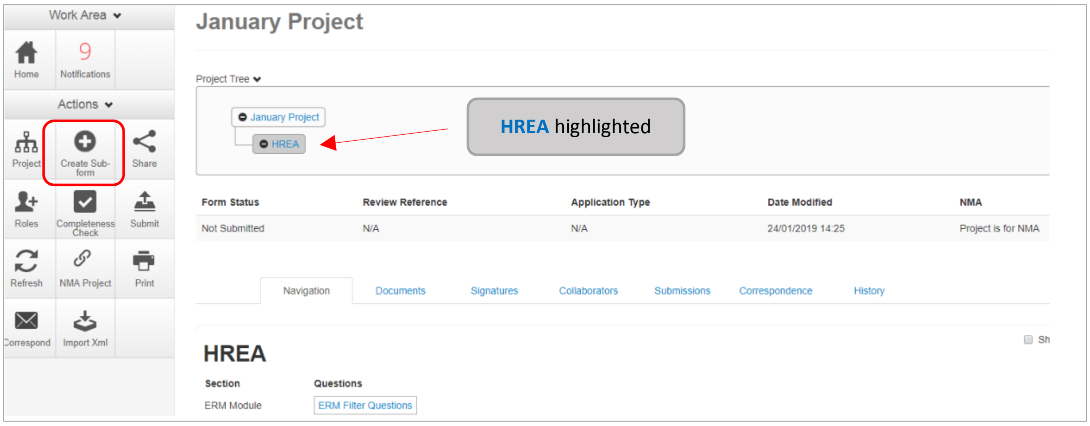
Section 6: Victorian Specific Module (VSM)

For each project that utilises the HREA form and has a site in Victoria, the **Victorian Specific Module (VSM)** must be completed and submitted to the reviewing HREC as part of the ethics application. The VSM is mandatory when the HREA is used. It addresses Victorian legislative requirements.

In ERM:

- The VSM is created as a sub-form of the HREA
- Under the **Actions pane** select **Create Sub-form** 

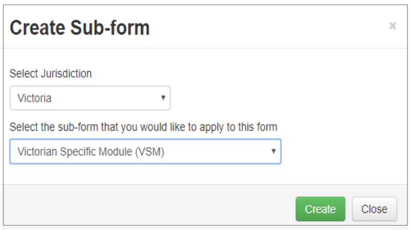
 button

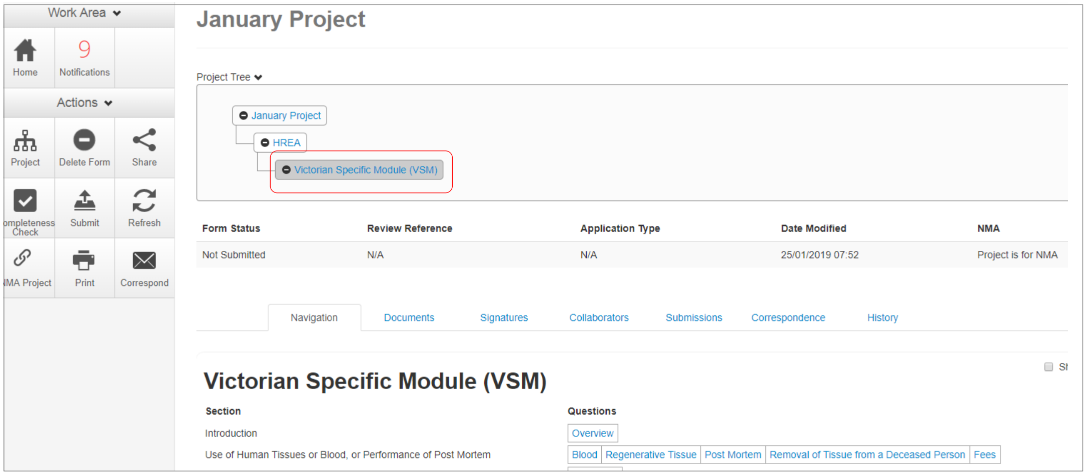


- A text box will be displayed to select the sub-form to be applied to the main form.

  Select the Victorian Specific Module (VSM) from the drop-down list

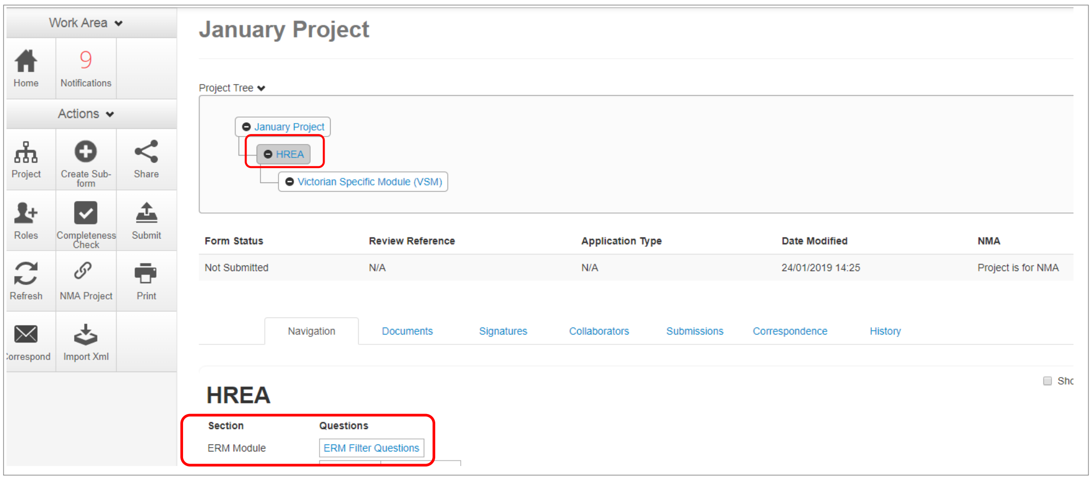
  Select **Create**
- The VSM will appear in the Project Tree as a sub-form of the HREA
- Complete all applicable sections of the VSM form



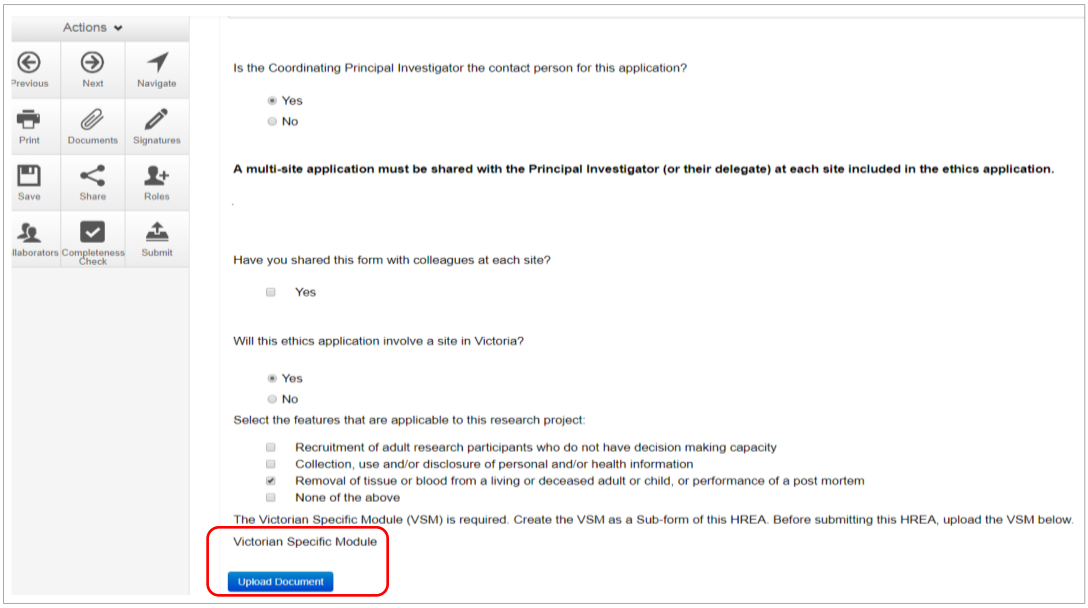


- In the VSM, select **Print** 

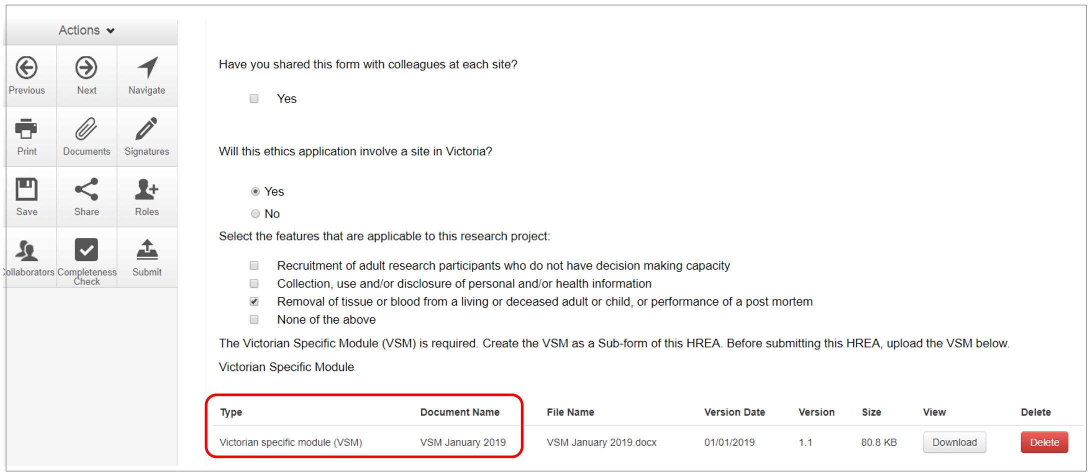
 to generate a pdf and save to your local drive
- Return to the HREA (highlighted in Project Tree) and go to the pre-HREA section **ERM Module**

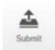


- Select **Upload Document** to upload the pdf of the VSM



- The VSM is attached to the HREA as a supporting document



- When the HREA is complete, all its supporting documents uploaded (including the VSM) and signatures obtained, **Submit**  the HREA
- Return to the VSM in the Project Tree and **Submit**  the VSM

Section 7: Victorian Low and Negligible Risk Application (LNR VIC)

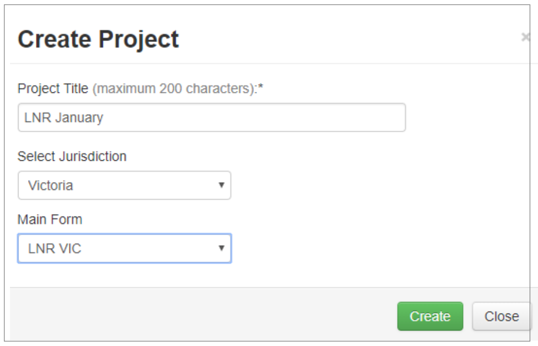
For a single-site low and negligible (LNR) research project, the LNR VIC application form may be utilised instead of the HREA. A Victorian Specific Module is not required for project utilising the LNR VIC application form.

Some reviewing HRECs may not accept the LNR VIC; always discuss the research project with the reviewing organisation's Research Office before creating an ethics application for a low risk research project.

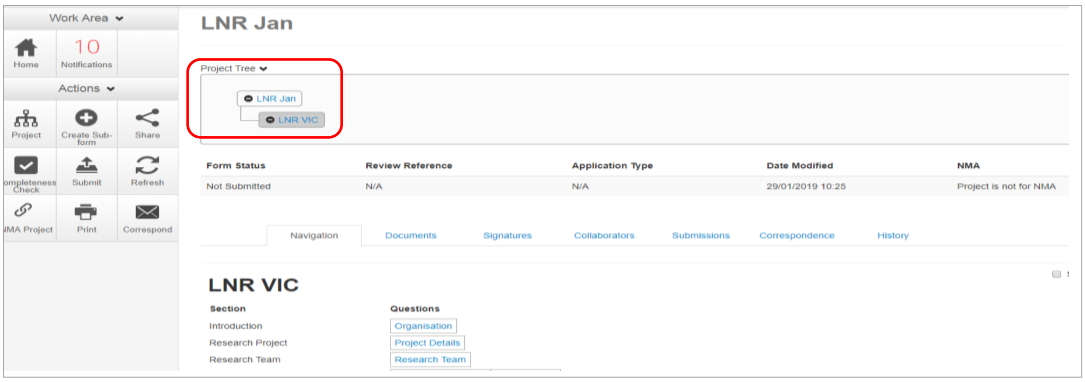
Create a LNR VIC form

- 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 **LNR VIC** from the Main Form options
- Select **Create** button to create the project



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



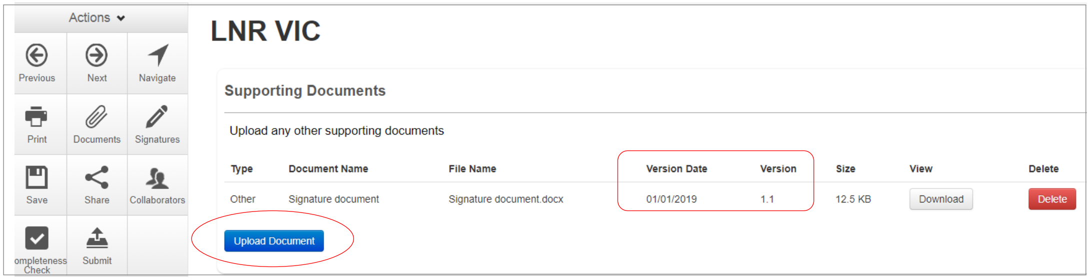
Complete the LNR VIC

- Working under the 'Navigation' tab, the **Introduction** section provides a drop-down list of HRECs that will accept the LNR 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

Upload Documents

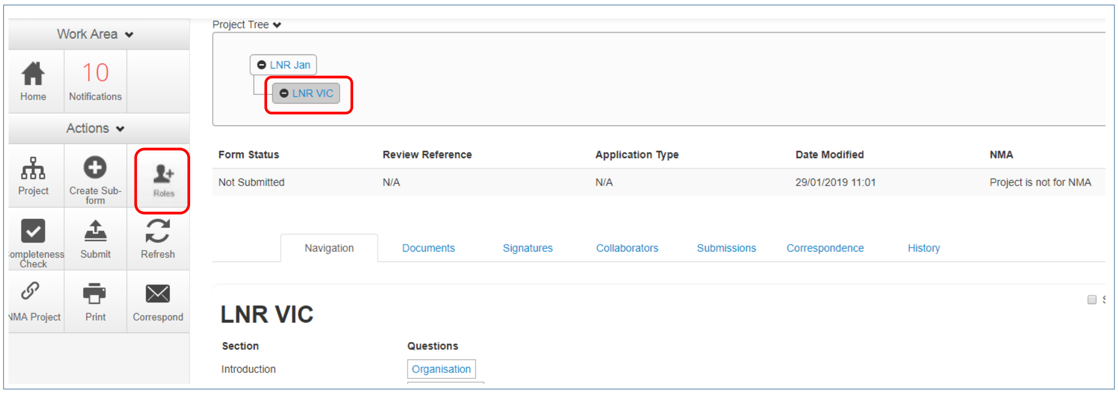
- Sections with the form allow supporting documents e.g. protocol, questionnaire to be uploaded in to the form
- Other supporting documents can be uploaded by selecting **Supporting Documents**  located in the last section of the LNR VIC
- Press **Upload Document**  to attach the selected Supporting 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 to differentiate the documents within the same document type



Assign access to the LNR VIC form

In ERM, the project owner can make the LNR VIC form available to other research team members. Using the **Roles +** function, the project owner assigns other collaborators pre-defined levels of access to the LNR VIC form.

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



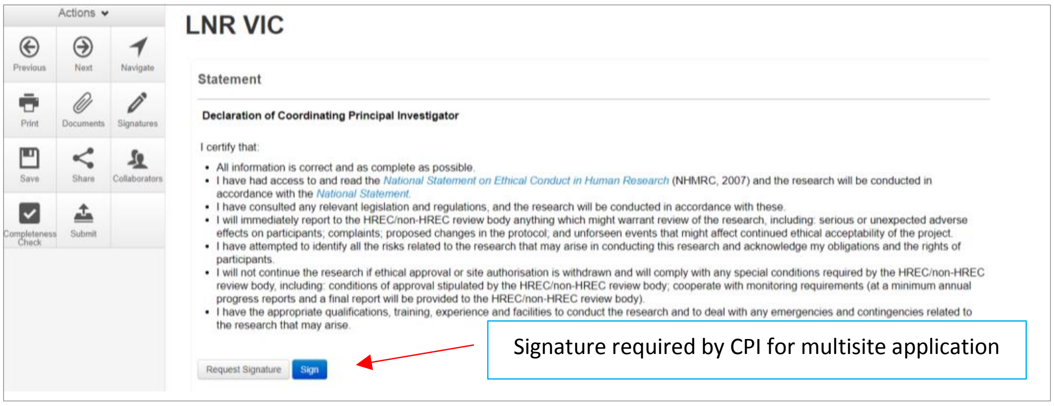
- A dropdown list will display the different levels of access to the LNR VIC form
- Continue to follow the steps as described in **Section 3: The HREA form** Give access

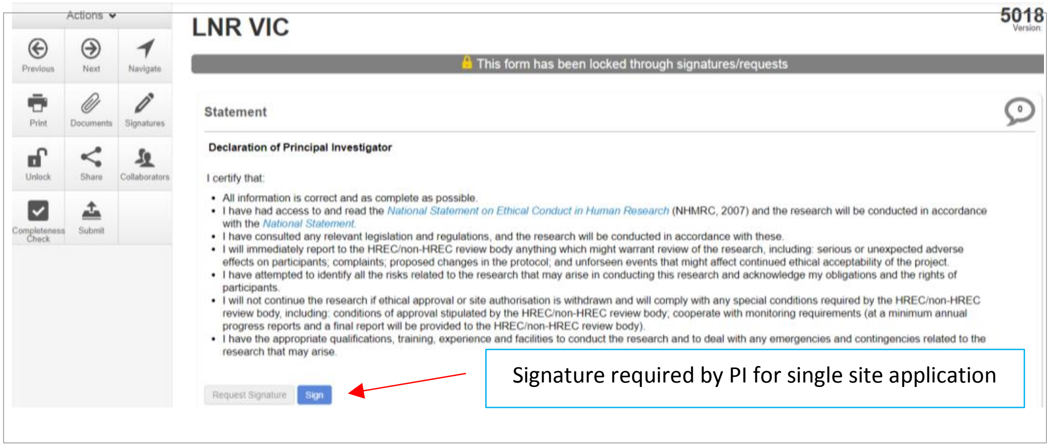
Applying Signatures

Declaration

The Coordinating Principal Investigator is required to sign the Declaration page for the LNR VIC submission if the ethics application is multi-site otherwise the Principal Investigator is required to sign for a single site application.

- 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





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.

The LNR VIC form owner may request signatures as follows:

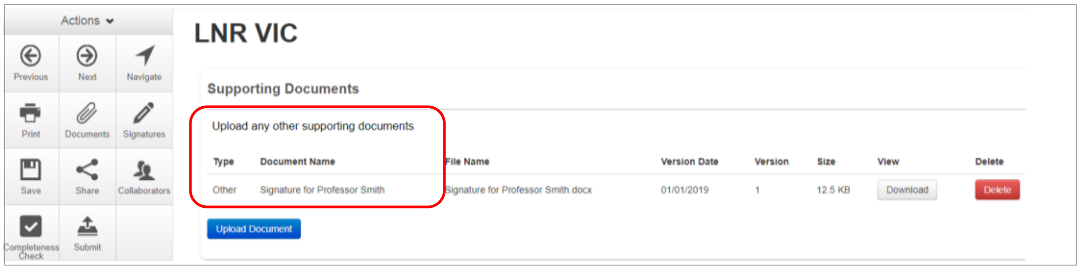
To use Wet ink signature

- Using the **Print** 

 button from the Actions pane, print the Declaration page and obtain the signature from the CPI/PI. Save to your local drive as a pdf
- Navigate to last section of the LNR VIC to find Additional Documents 

- **Supporting Documents** opens to attach the Declaration page
- Select **Upload document** 

 to attach the signed Declaration page to the LNR 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 LNR VIC to find Additional Documents 

- **Supporting Documents** opens to attach the signature document
- Continue as described above to **Upload** the pdf document to the LNR 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** 

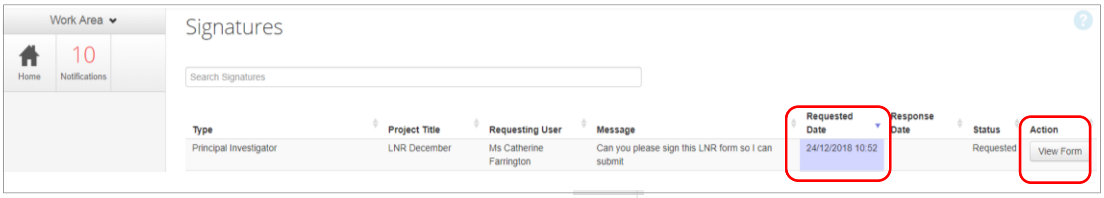
- Enter the signatory's email address and message and select **Request**

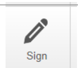
- The signatory will receive an email notification for a signature, a message and a link to ERM Log In page
- The signatory logs in to ERM
- From the **Work Area** the signatory selects **Signatures** tile to open the request

- New requests are highlighted 

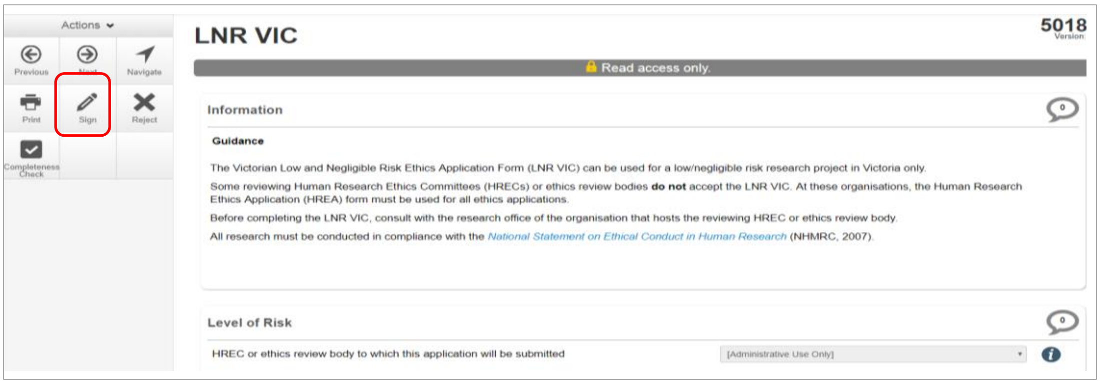
- Under the **Action** tab, select **View Form**

 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 LNR VIC
- Once the signature is complete the application is ready for submission

Section 8: Submission and Review Process – LNR VIC

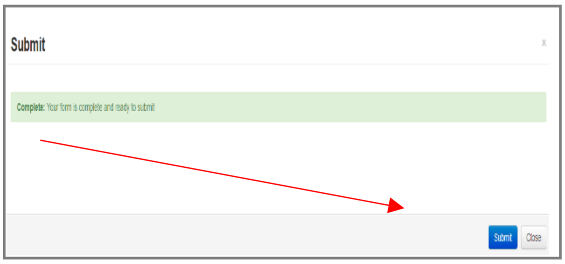
Ethics

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

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 the 'Introduction' section of the LNR VIC form



Recall an application

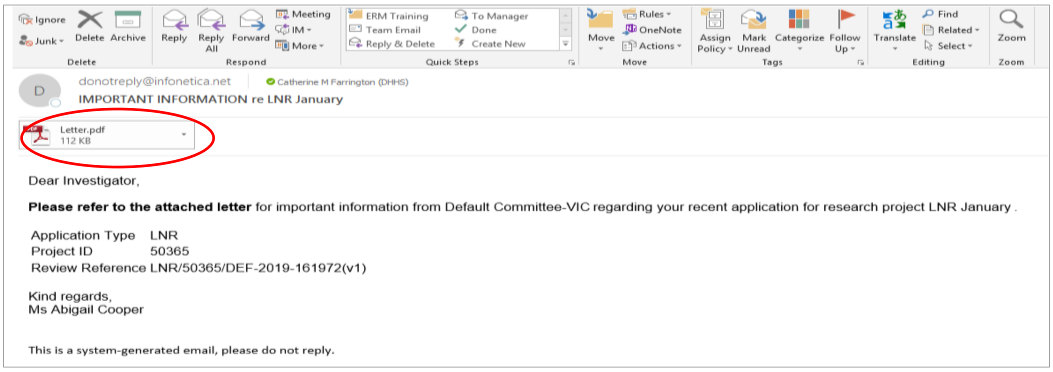
Any changes made to the submission will INVALIDATE all electronic signatures and will require all signature requests again

- Once the application has been submitted, a recall option becomes available
- This action removes the submitted application from the Research Office's ERM account
- The form can be recalled **until** the submission is actioned by the Research Office
- 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

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



- An attached letter (pdf) from the Research Office will include details for further information to be provided via ERM

Your Logo Here

Default Committee-VIC Human Research Ethics Committee

QUERY - ETHICS APPLICATION

9 January 2019

Dear ,

Project Title	LNR January
Project ID	50365
Review Reference	LNR/50365/DEF-2019-161972(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

Please amend the Participant Information and Consent Form to include the duration of the study.

Submission

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

Please 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 by 16 January 2019 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.

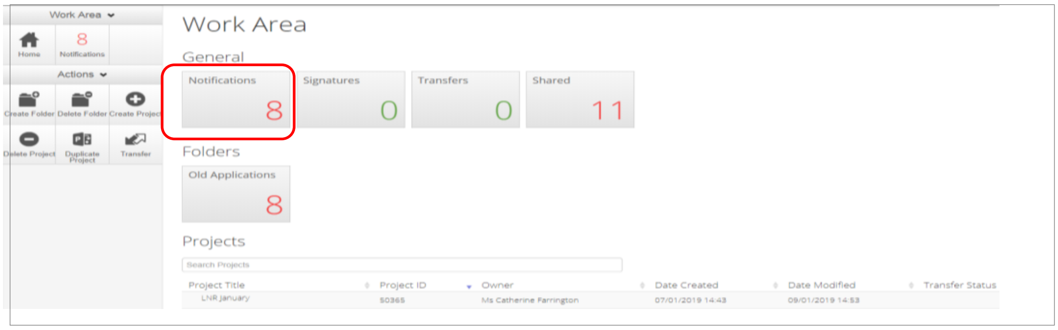
If you require any further information, please contact us via the ERM 'Correspond' button or 1234 5678.

Yours sincerely,

- The form will be ***unlocked*** to allow the applicant to complete the revisions / additions as requested

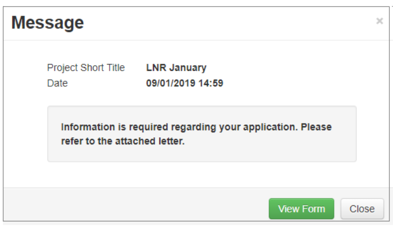
*To access the **Query***

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



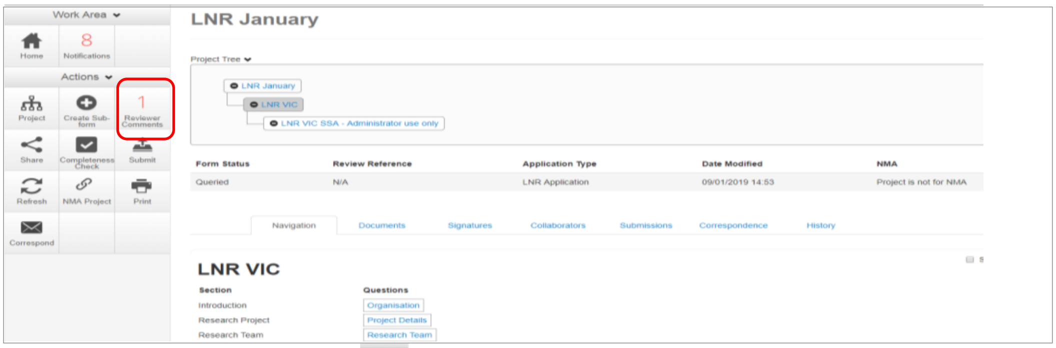
- Select the Message title to open and view the message

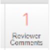
- A **Message** box will be displayed allowing the user to view the form



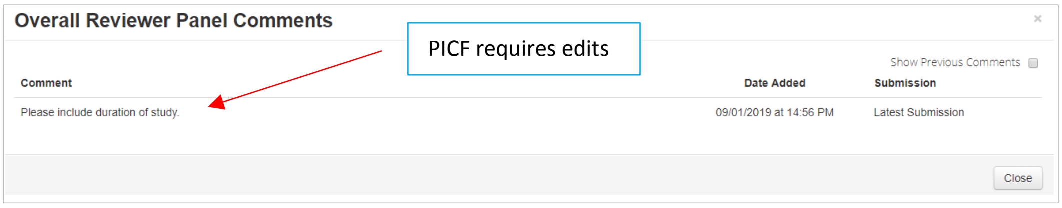
- Press **View Form** View Form to be directed to the relevant form

- The form in this example the LNR VIC, will open under the **Navigation** tab



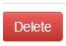
- Select **Reviewers Comments**  under the Actions pane

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

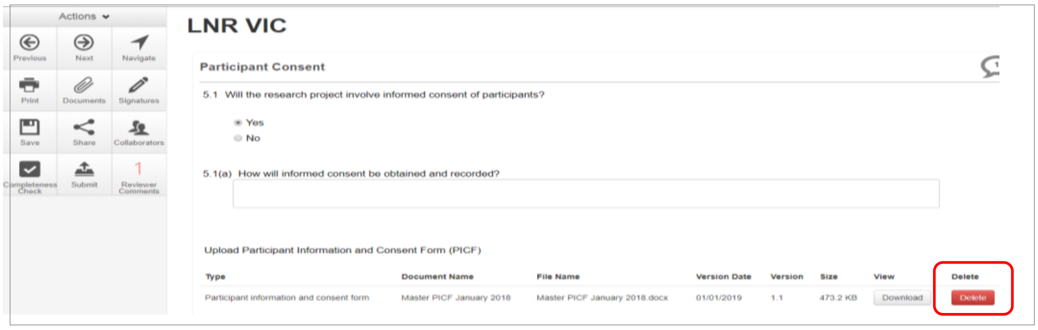


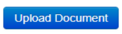
- Select the comment to be directed to the relevant section in the form i.e. to **Participant Consent Q 5.1**

- As the query requires a new version of a **document**, the original version should be deleted, and the new version uploaded in to the form. Previous document versions are automatically archived.

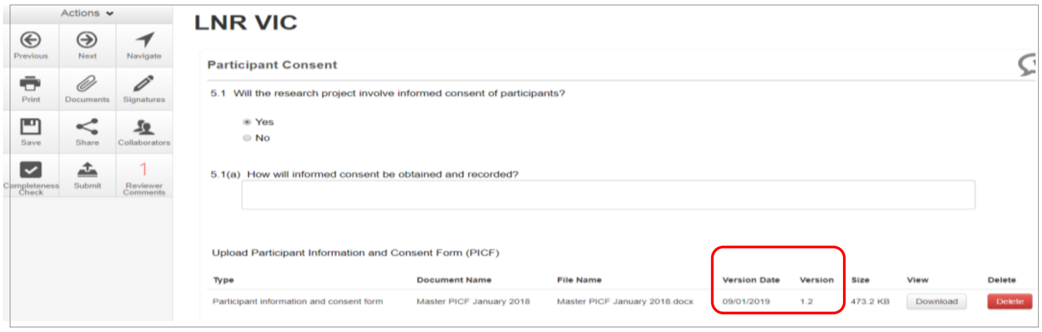
- Select **Delete** 

to delete the original version



- Select **Upload Document** 

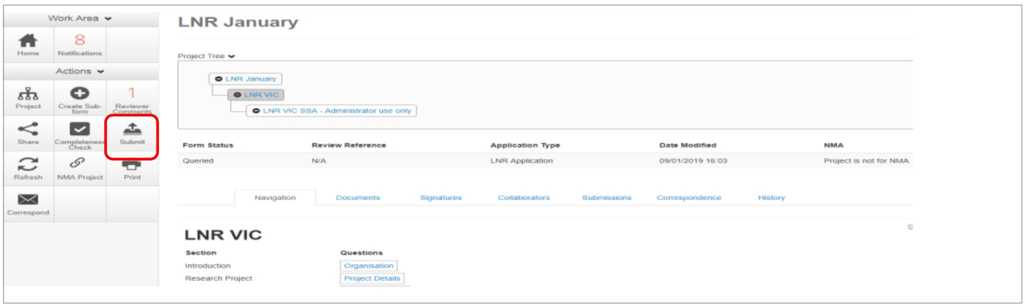
to upload the revised (new) version of the document with the correct version number and date



- 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

- In the **Actions** pane select the **Submit**  button to resubmit

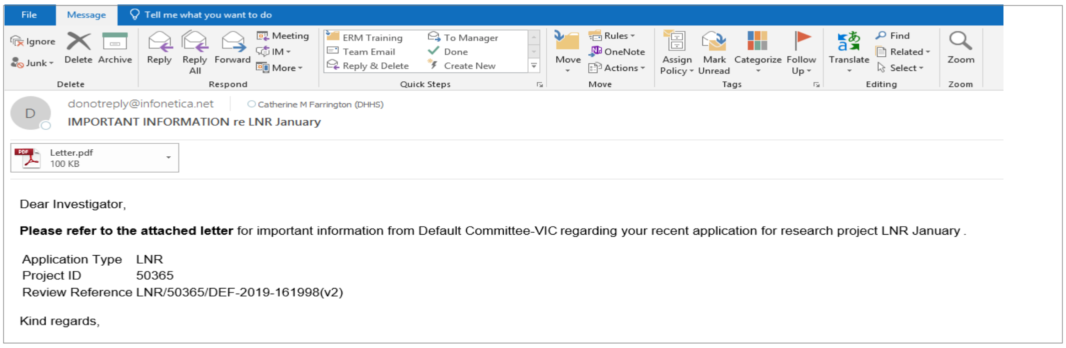


- The Research office will receive the submission
- The application is assigned to a HREC meeting
- Following the HREC review there may be an information request from the Ethics Committee.

Ethics Committee Review Request

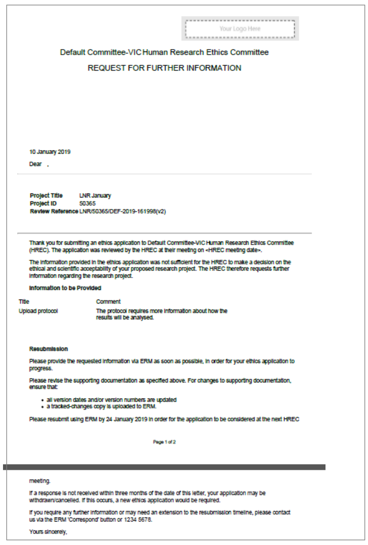
Clarification or requests for further information from the reviewing Ethics Committee to the applicant must be managed through ERM

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



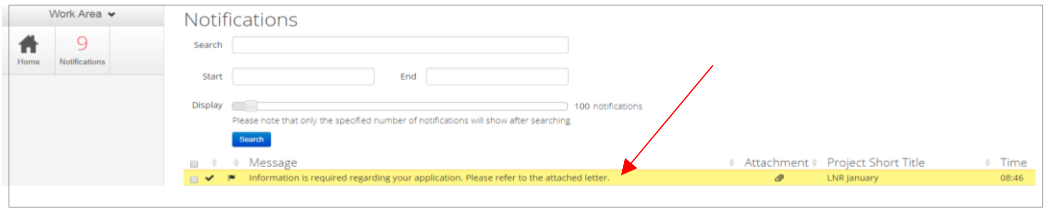
- An attached letter (pdf) from the HREC will include requests for further information to be provided via ERM

- The form is **unlocked** to allow the applicant to complete the requests as outlined in the attached letter



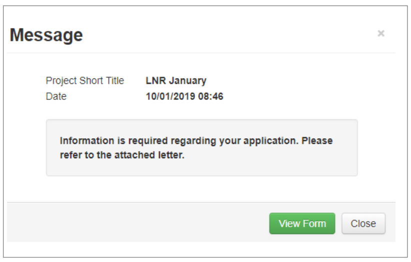
Respond to a request for further information from the Ethics Committee

- Depending on the request, the applicant can amend the LNR 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

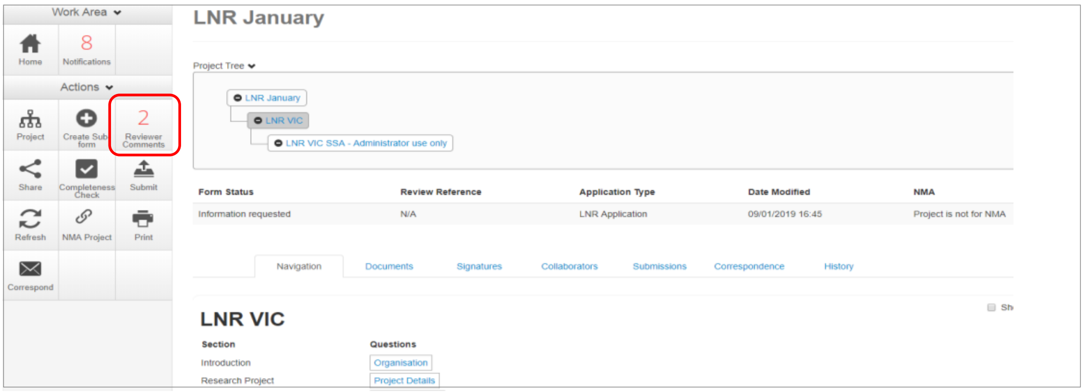


- A message box will be displayed allowing the user to view the form

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



- The LNR VIC, will open under the **Navigation** tab

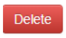


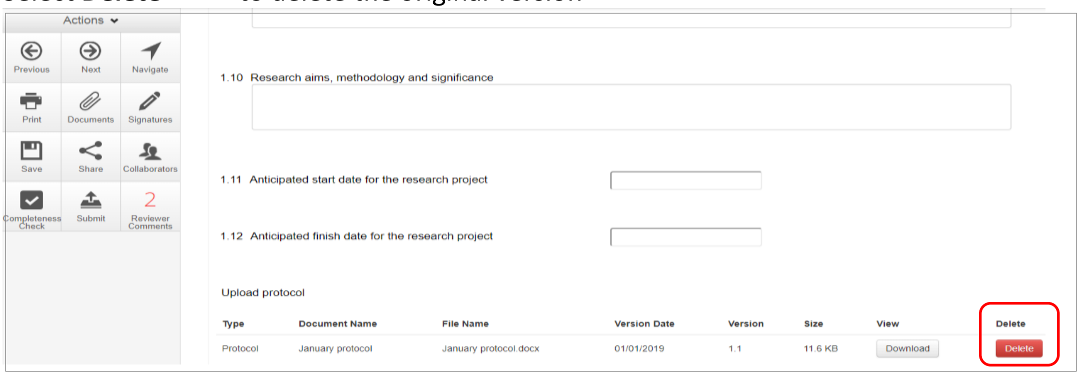
- Select **Reviewers Comments**  under the Action pane
- A text box will be displayed of the **Overall Reviewer Panel Comments**

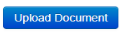
Overall Reviewer Panel Comments

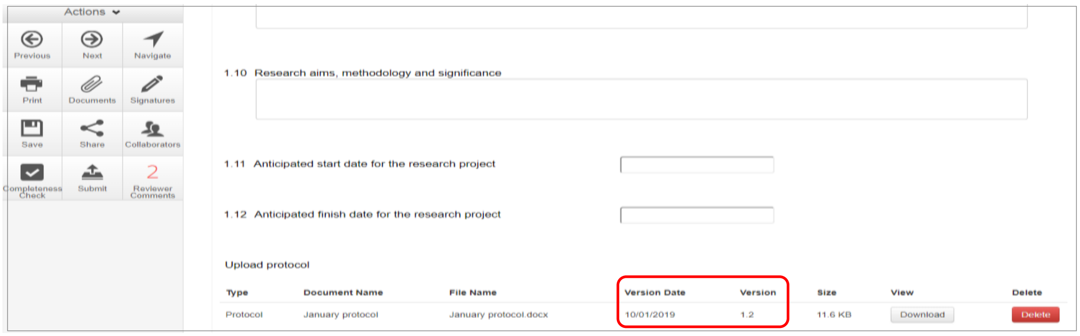
Show Previou

Comment	Date Added	Submission
The protocol requires more information about how the results will be analysed.	10/01/2019 at 08:44 AM	Submission 2
Please include duration of study.	09/01/2019 at 14:56 PM	Submission 1

- Select the comment relating to the Ethics Committee request to be directed to the relevant section in the form i.e. **Project Details Q 1**
- The request requires a new version of a protocol. The original version should be deleted, and the new version uploaded in to the form. Previous document versions are automatically archived.
- Select **Delete**  to delete the original version



- Select **Upload Document**  to upload the revised (new) version of the protocol with the correct version number and date
- The LNR 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 signature/s are required?

1. The CPI/PI signs - for minor changes the Research Office has all signatures on the initial submission
2. Other investigators 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 the **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

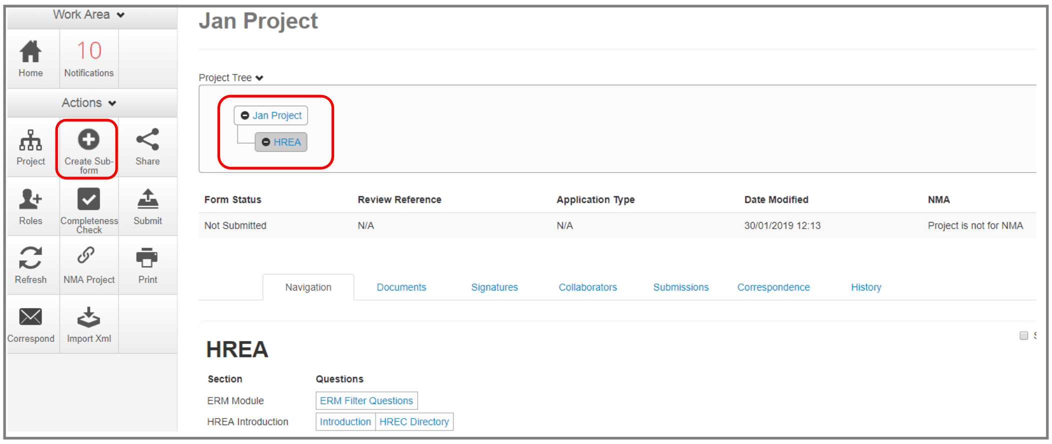
  If the application review outcome is **not approved**, applicants are also informed via email through ERM.

Section 9: Site Specific Assessment (SSA)

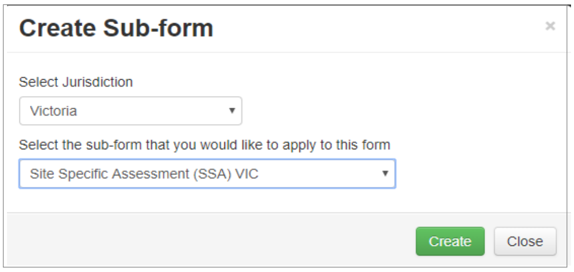
The Victorian SSA form is used to address governance at a public health organisation in Victoria. It is the responsibility of the site Principal Investigator to complete the Victorian SSA form for their site, and to submit the form to the site Research Governance Officer (RGO).

Create a SSA

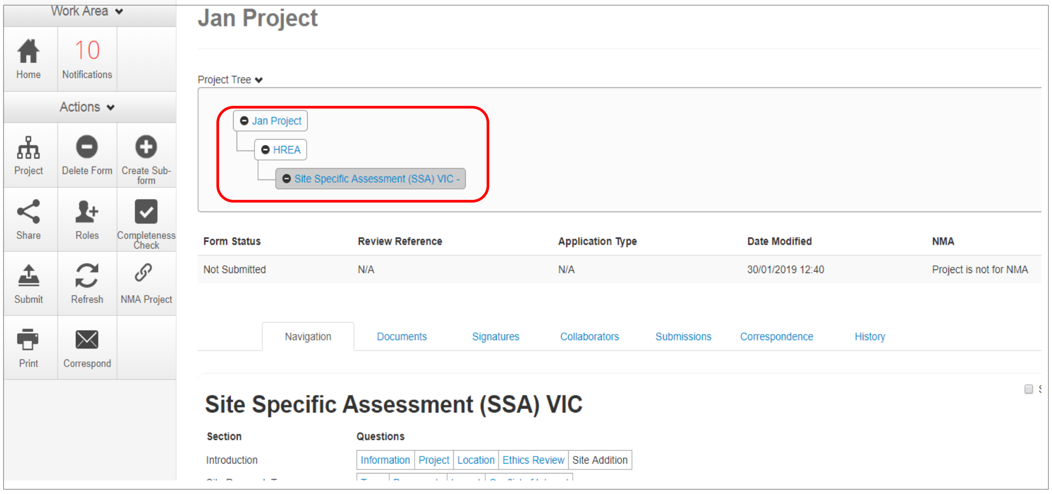
- From the HREA or LNR VIC, select **Create Sub-form** button under the actions pane



- 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

Creating SSAs for Sites

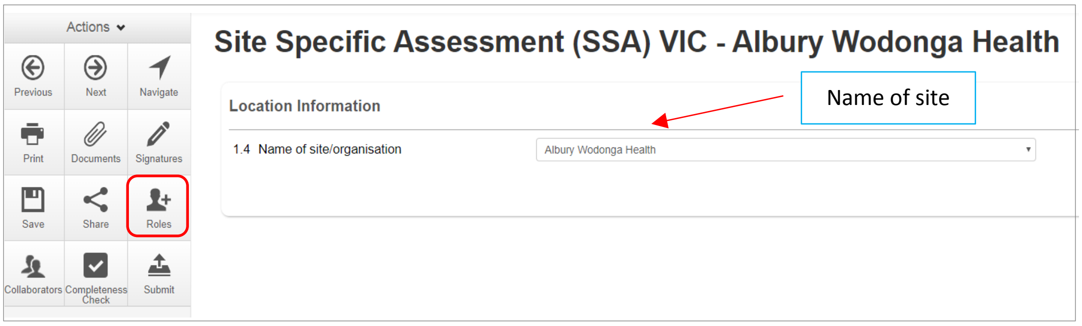
The SSA for a site is created by either the **HREA (or LNR VIC)** project owner **or** by assigning this role to the site PI.

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

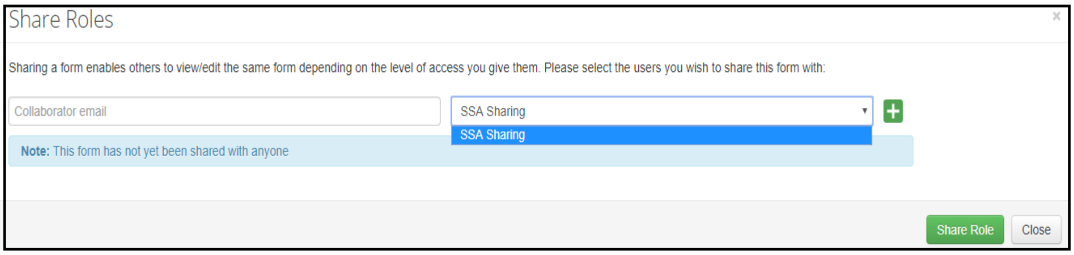
- The HREA project owner creates the SSA as sub-form of the HREA. The creator of the SSA becomes the SSA form owner
- The SSA owner may start to complete the SSA then assign responsibility for its completion and submission to the site PI
- In the **Introduction** section of the SSA form, complete question **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

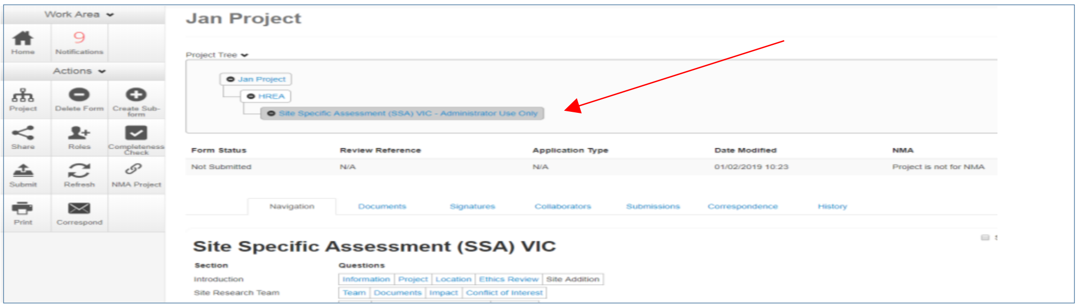
  Enter the collaborator's (site PI) email address and select **SSA Sharing**

  This level of access includes all of the following – read
  write
  create subforms e.g. Site Notification Form
  receive notifications



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

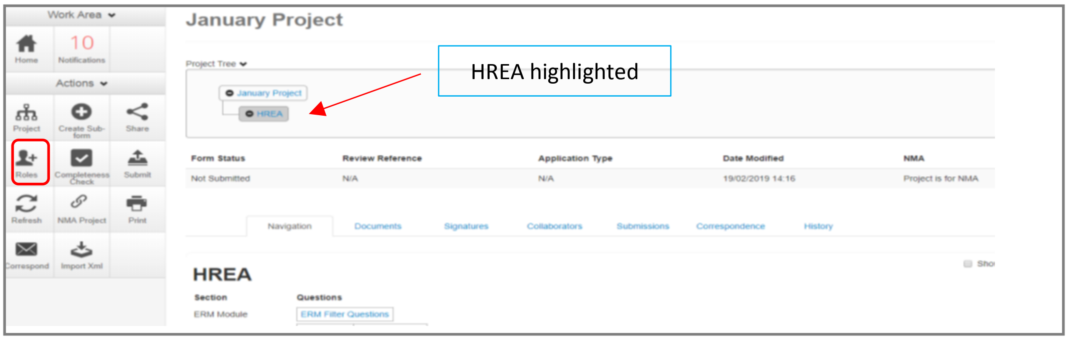
- Using **Roles +** allows the collaborator to also view the HREA form

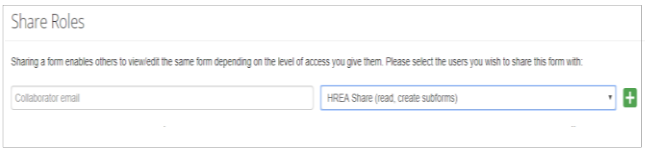


- Complete the SSA form

(ii) Assigning Role to Site PI:

- The HREA project owner selects the **Roles +** button under the Actions

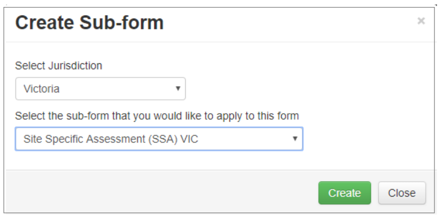


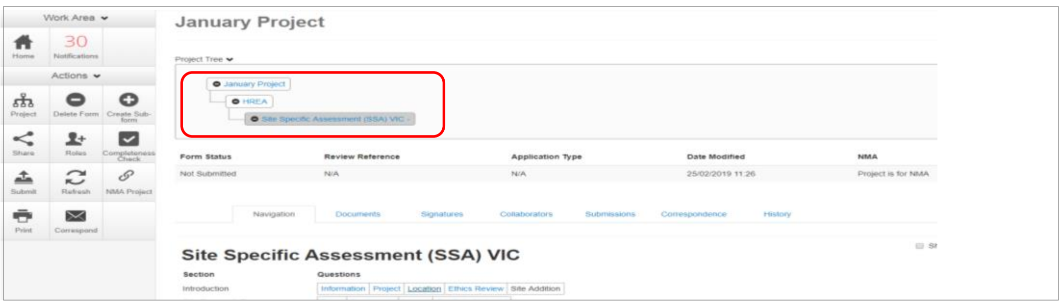


- A **Share Roles** text box will be displayed
- Enter the collaborator's (site PI) email address and select **HREA Share (read, create subforms)**
- Select **Share Role**
- The collaborator will receive an email notification about their assigned role in the project
- The collaborator logs into ERM and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

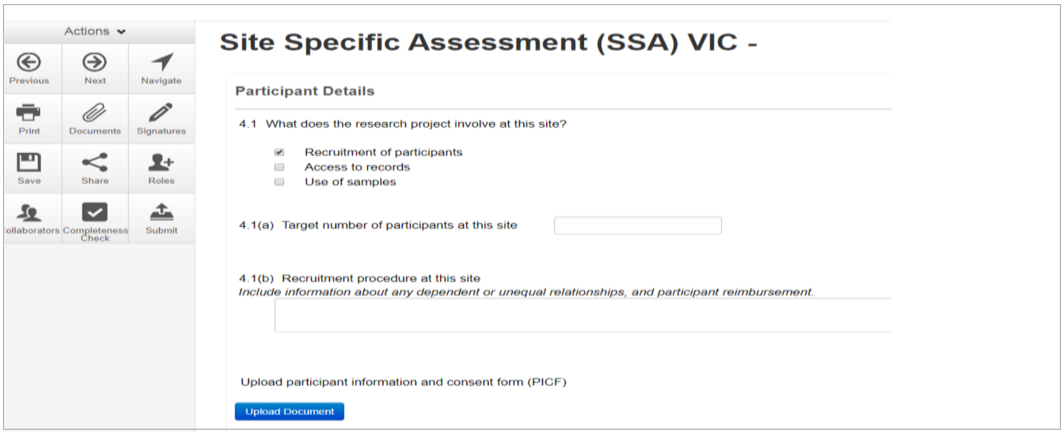
Upload Documents

Supporting documents are uploaded to the SSA when completing the relevant question in the form.

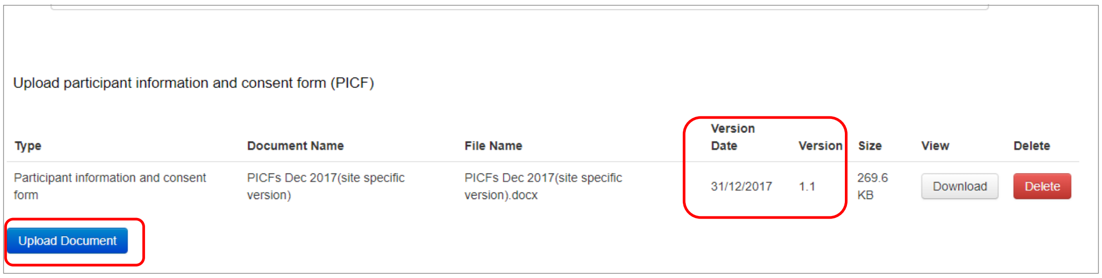
See table below for example of document types.

Section	**Questions** (hyperlink)	**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

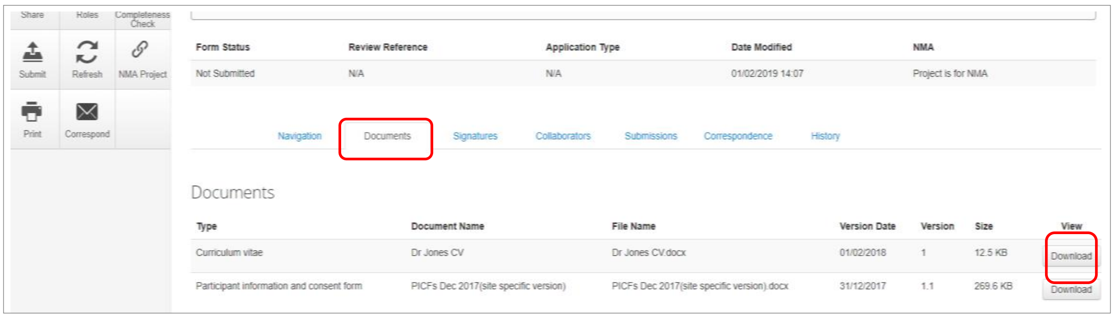
- Example – Site specific PICF



- Press **Upload Document** 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 Upload Document multiple times
- Specify the version and date to differentiate the documents within the same document type



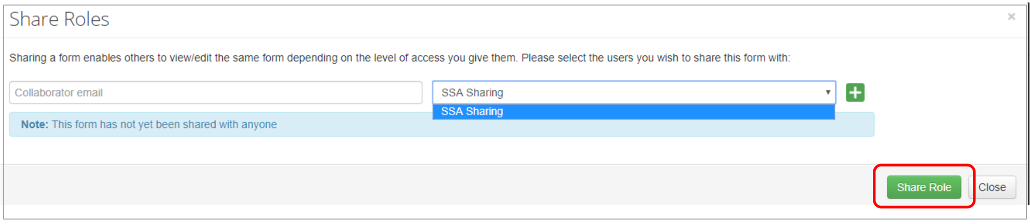
- Documents will also be displayed under **Documents** tab and can be downloaded



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 Sharing.**
  Select **Share Role** button

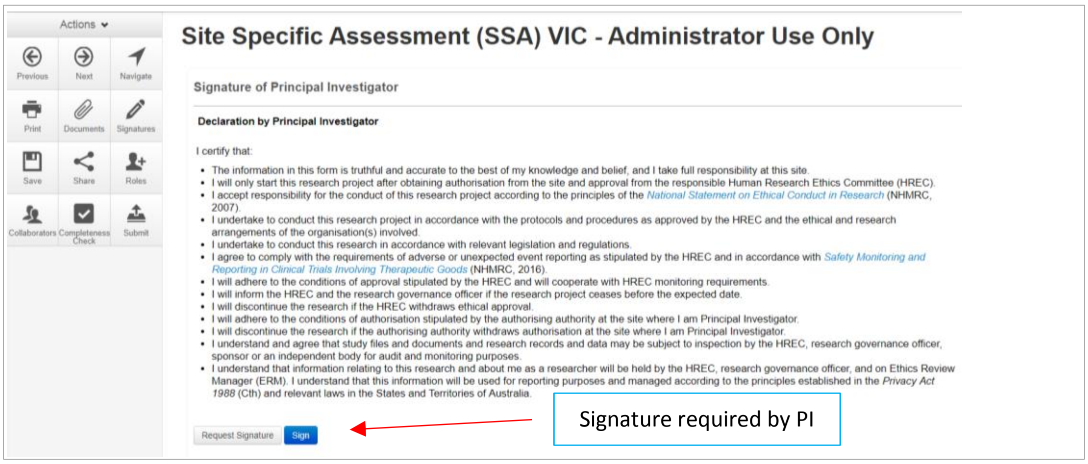


- The collaborator will receive an email notification regarding access to the project
- The collaborator logs in to ERM and follows the steps as described in [Assign access to the HREA]
- The collaborator will be able to view and edit the SSA

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

- 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

Signatures

The SSA form questions / information must be complete, <u>before</u> doing 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

- Using the **Print button** Print from the Actions Pane, print the relevant Declaration page and obtain the signature from the PI /Head of Department /Supporting Head of Department. 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 attach the Declaration page to the SAA form

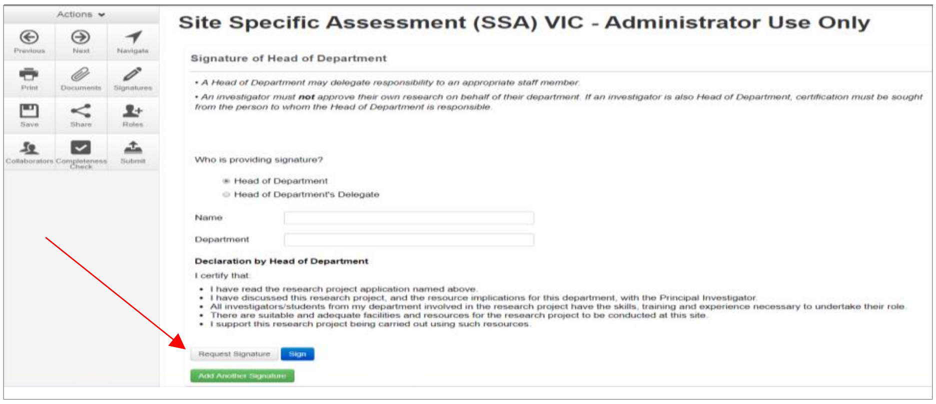
To attach other evidence to indicate agreement

- 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 signature document
- Select **Upload Document** Upload Document to attach the signature document from your local drive to the SSA form

- Other supporting documents can also be uploaded in this section

To request an Electronic Signature

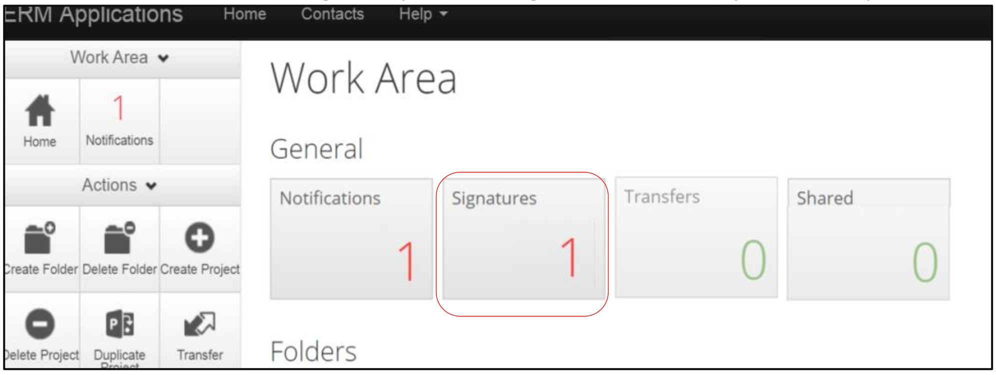
- To request an electronic signature from the Head of Department, Supporting Head of Department or Principal Investigator select **Request Signature** Request Signature button



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

- The requested signatory will receive an email notification for a signature
- The signatory logs into ERM

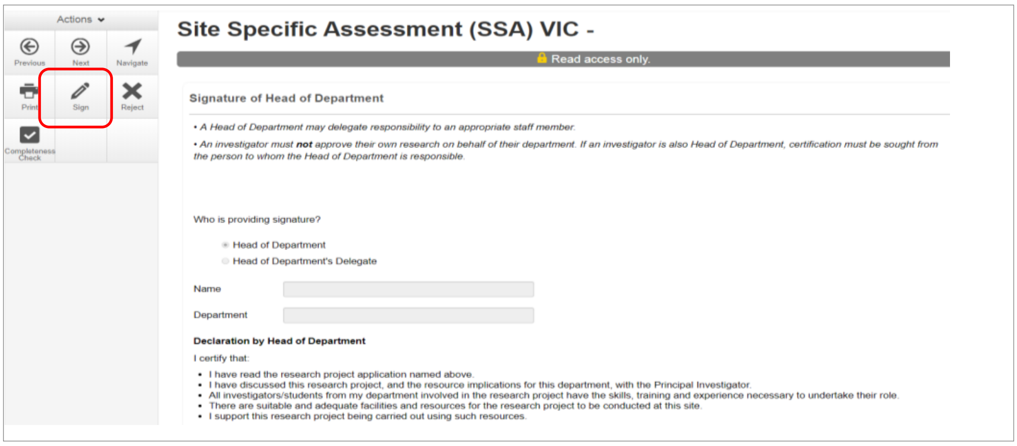
- From the **Work Area** the signatory selects **Signatures** tile to open the request



- New requests are highlighted

- Under the **Action** tab, select **View Form** View Form to review the SSA form
- The ethics application cannot be viewed unless the **HREA** Project/Form Owner has used the **Roles+** function from the **SSA** to share the SSA form with the signatory

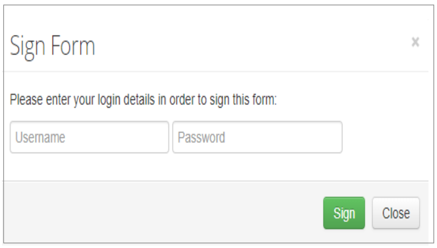
- For endorsement of the SSA application, select **Sign** Sign button under the Actions pane



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

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

  Select **Sign**  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
- Once the signature is complete the application is ready for submission

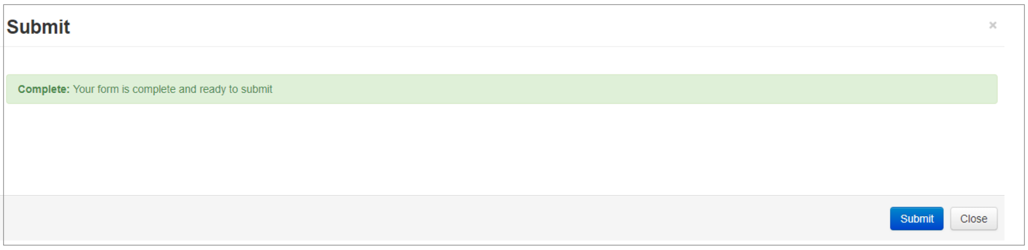
Section 10: Submission and Review Process – SSA

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

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

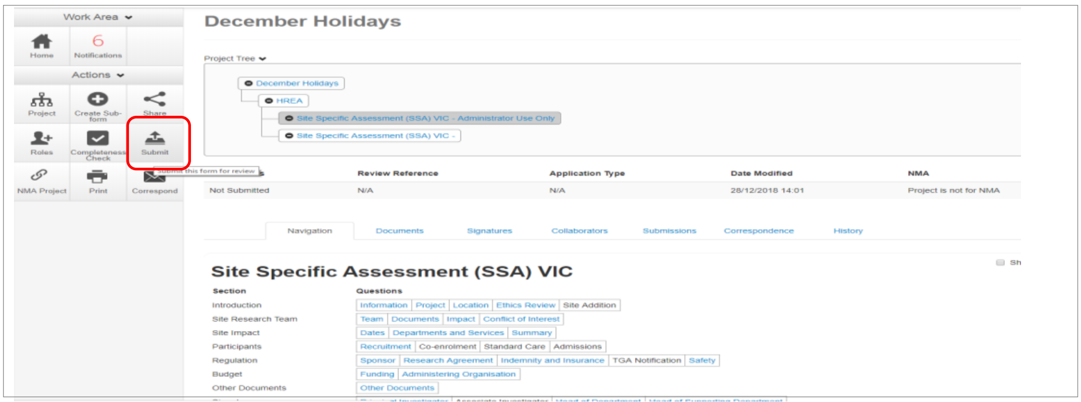


- Select the **Submit**  button

Recall an application

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

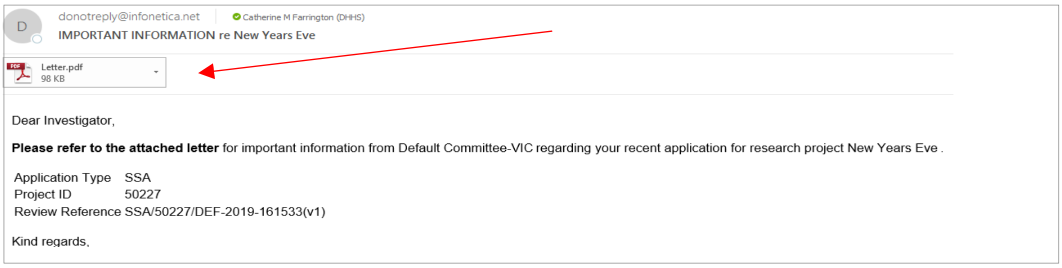
- Once the SSA application has been submitted, a recall option becomes available
- This action removes the submitted application from the Research Office's ERM account
- The form can be recalled **until** the submission is actioned by the Research Office
- Select the **Recall**  button under the Actions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



Responding to a Query from the Research Office

If an SSA 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 SSA application


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

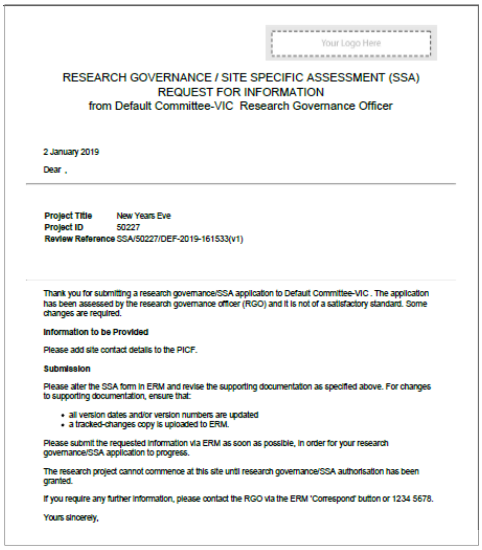
Dear Investigator,

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-2019-161533(v1)

Kind regards,

- An attached letter (pdf) from the Research Office will include details 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-2019-161533(v1)

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 it is not of a satisfactory standard. Some changes are required.

Information to be Provided

Please add site contact details to the PICF.

Submission

Please alter the SSA 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 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.

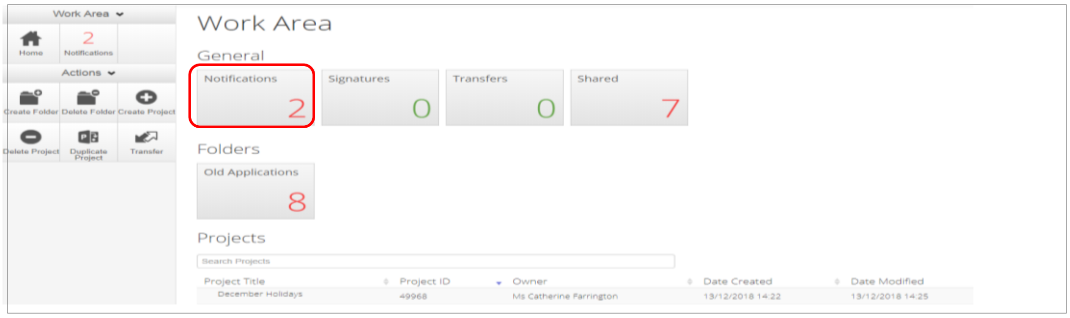
If you require any further information, please contact the RGO via the ERM 'Correspond' button or 1234 5678.

Yours sincerely,

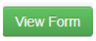
- The form will be ***unlocked*** to allow the applicant to complete the revisions / additions as requested

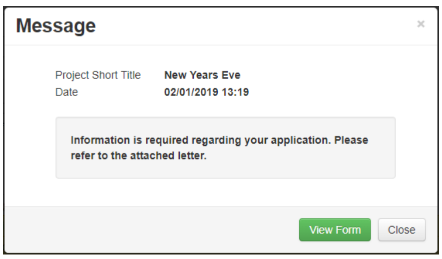
*To access the **Query***

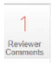
- In the Work Area, click on the **Notifications** tile

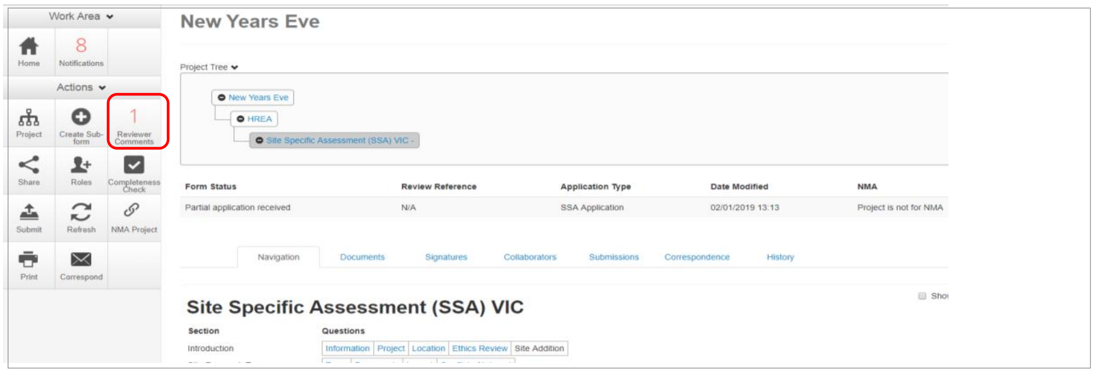


- Select the Message title to open and view the message

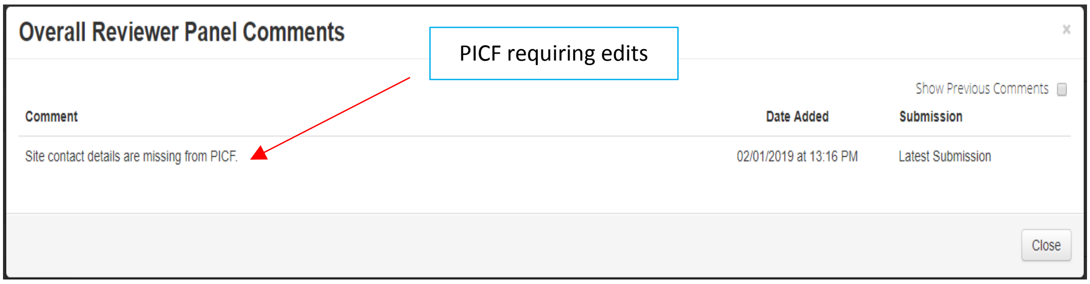
- A **Message** box will be displayed allowing the user to view the form
- Press **View Form**  to be directed to the relevant form

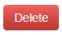


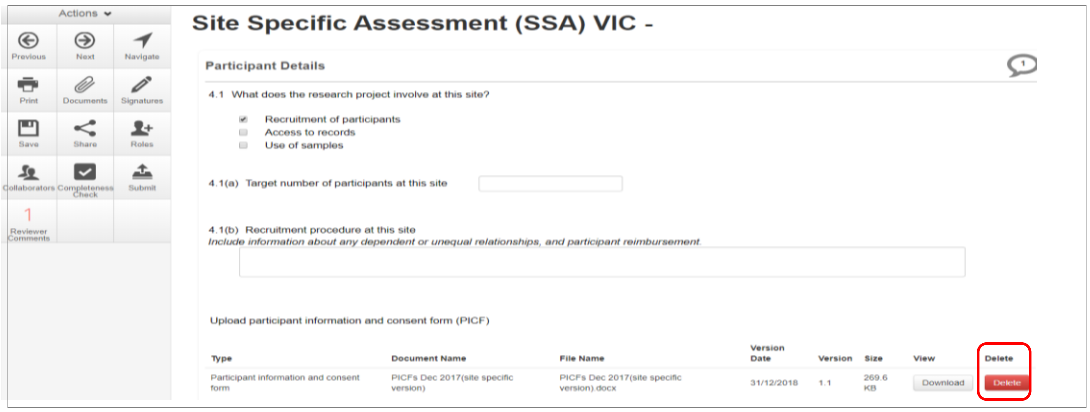
- The SSA form will open under the **Navigation** tab
- Select **Reviewers Comments**  under the Action pane

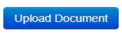


- A text box will be displayed of the **Overall Reviewer Panel Comments**

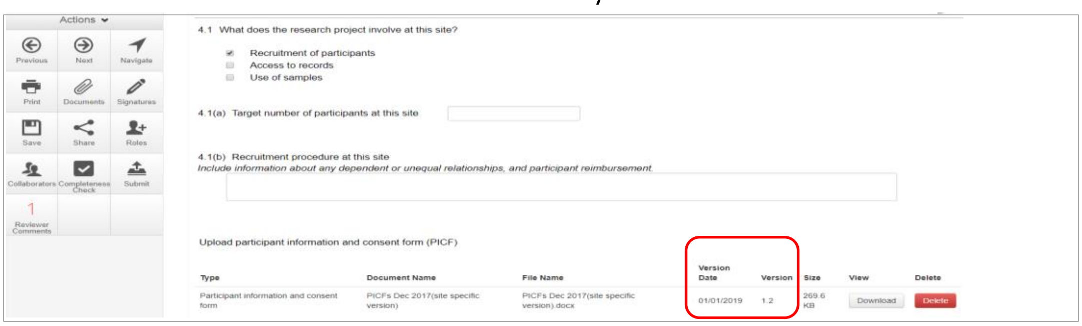


- Select the comment to be directed to the relevant section in the SSA form, i.e. to **Q 4.1 Participant Details**
- As the query requires a new version of a document, the original version should be deleted and the new version uploaded into the form. Previous document versions are automatically archived.
- Select **Delete**  to delete the original version

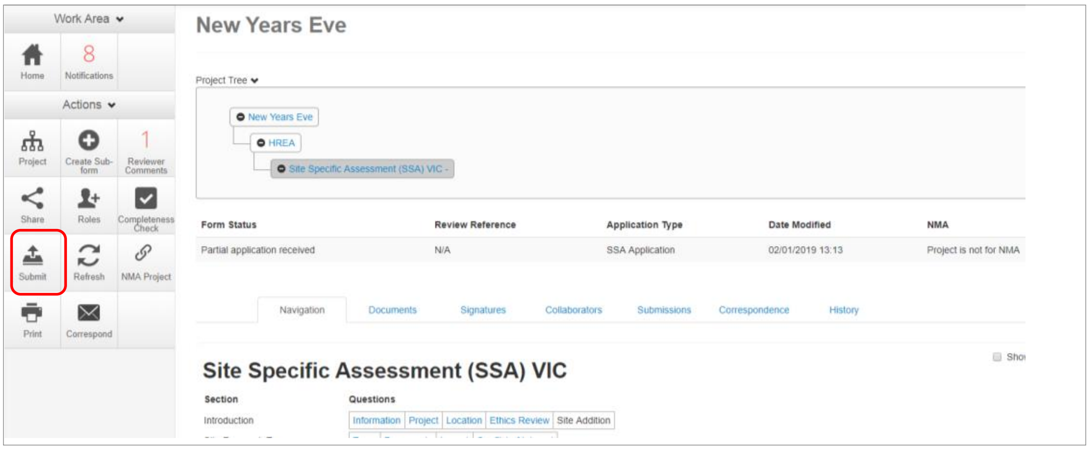


- Select **Upload Document**  to upload the revised (new) version of the document with the correct version number and date

- 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**  button to resubmit

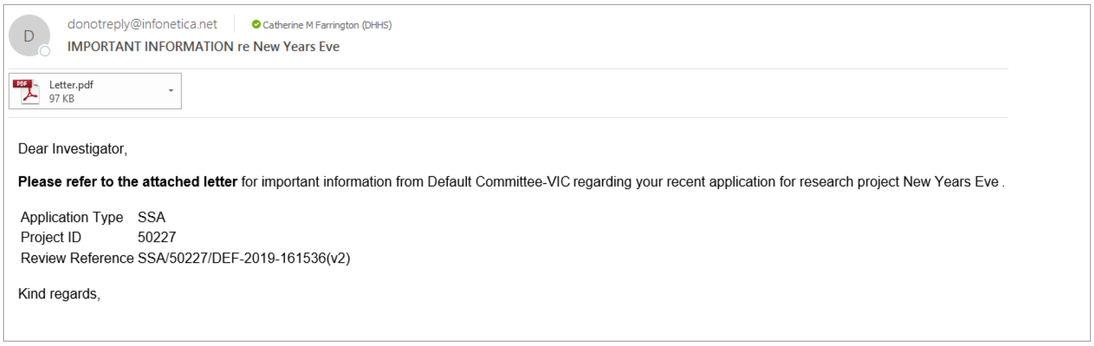


- The Research Office will receive the submission
- The SSA application is assessed by the Research Governance Officer (RGO)
- Following the assessment there may be an information request from the RGO

RGO Review Request

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

- 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,

- An attached letter (pdf) from the RGO will include requests for further information to be provided via ERM
- The SSA form is unlocked to allow the applicant to complete the requests as outlined in the attached letter

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.

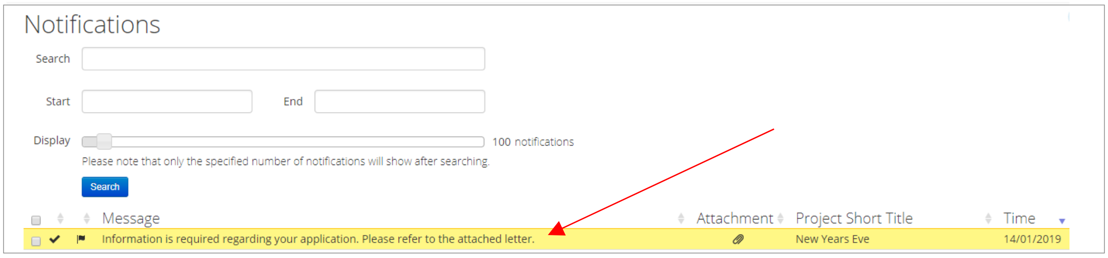
The research project cannot commence at this site until research governance/SSA authorisation has been granted.

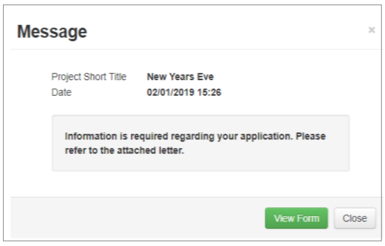
If you require any further information, please contact the RGO via the ERM 'Correspond' button or .

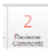
Yours sincerely,

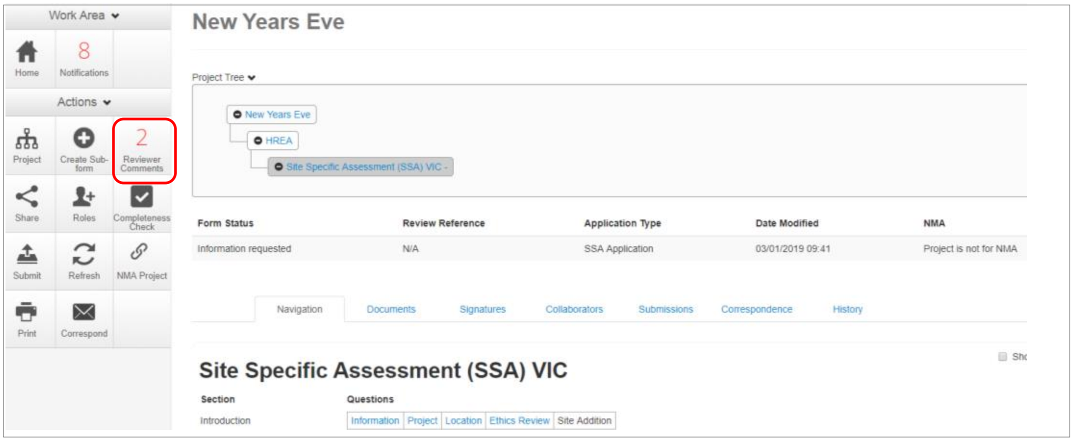
Respond to a request for further information from the RGO

- Depending on the request, the applicant can amend the SSA 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

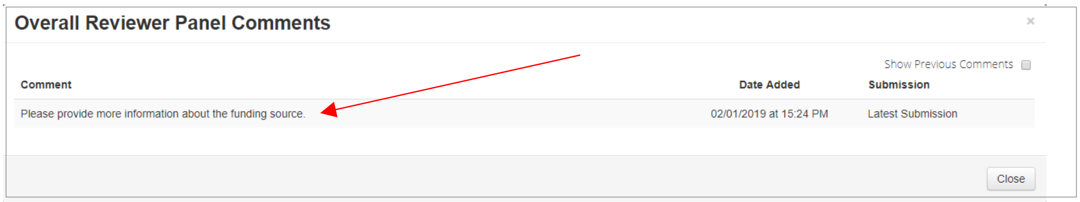




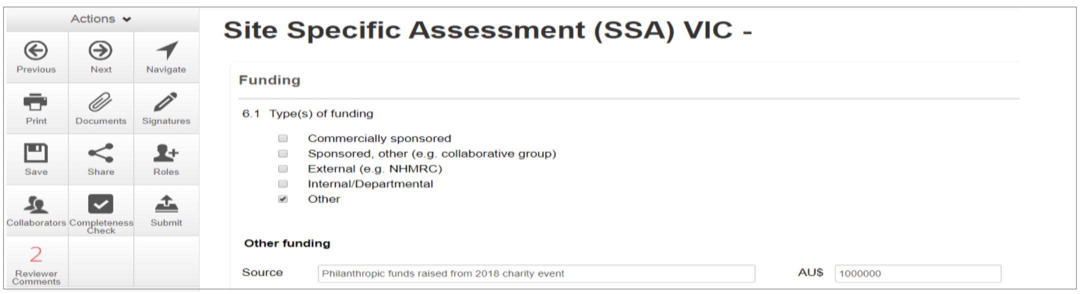
- A message box will be displayed allowing the user to view the SSA form
- Press **View Form**  to be directed to the relevant section in the SSA form
- The SSA will open under the Navigation tab
- Select **Reviewers Comments**  under the Actions pane



- 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** as above
- 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
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 the **Submit** 

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.

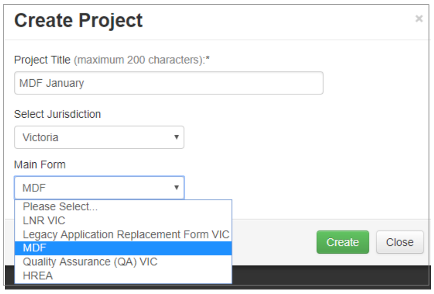
Section 11: Minimal Dataset Form (MDF)

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** 

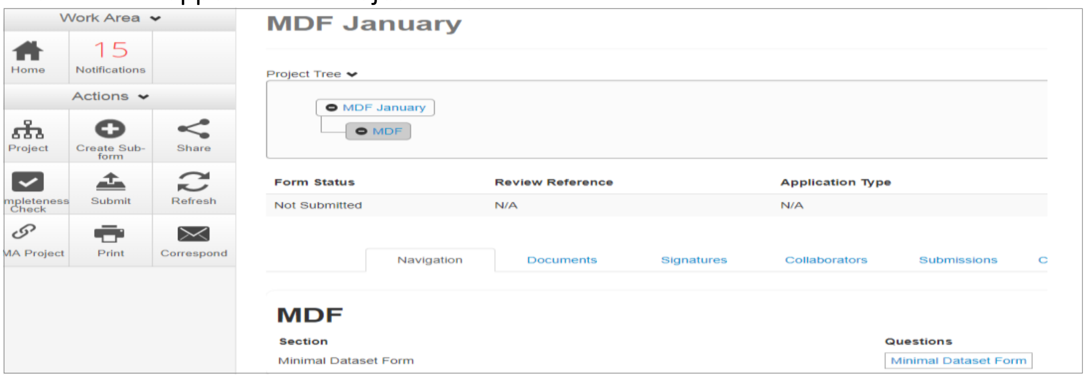
button under the Actions pane to create a new Main Form



- Enter the Project Title, jurisdiction and select **MDF** from the Main Form drop-down list

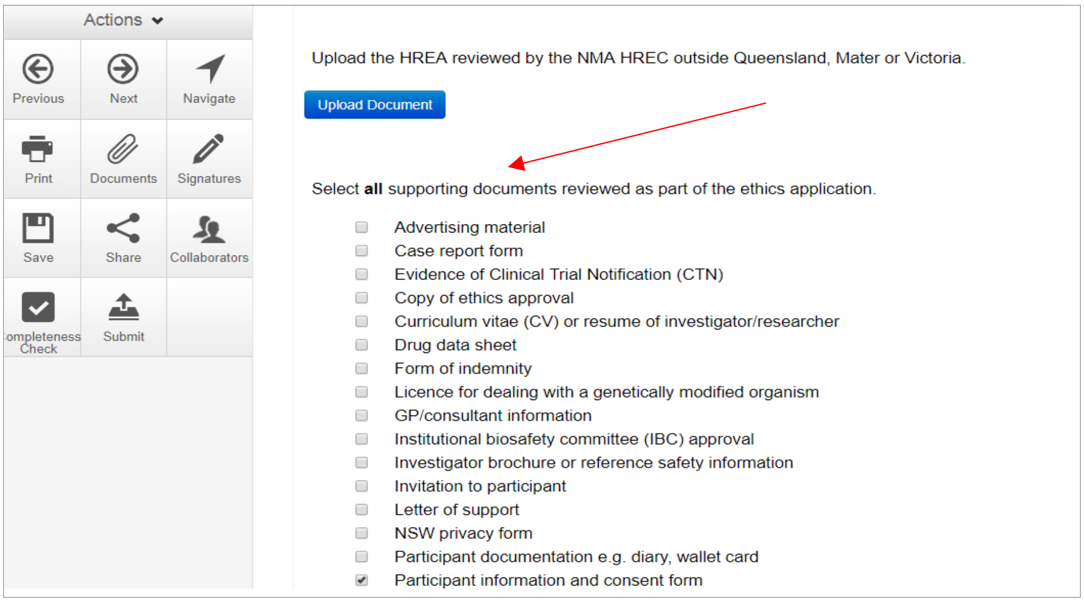
  Select **Create** button

- The MDF will appear in the Project Tree



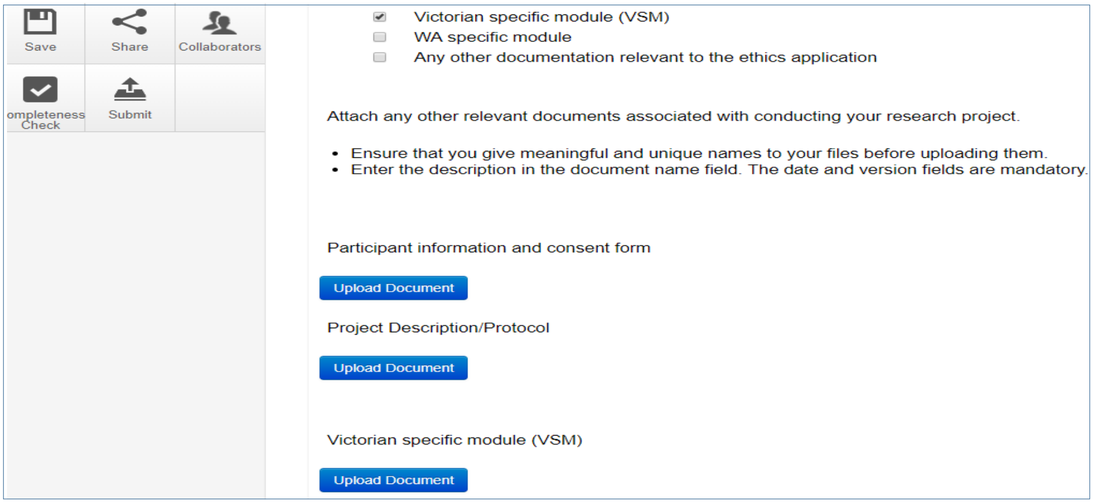
- Complete the questions in the MDF
- In the MDF select **Upload Document** 

to upload a copy of the HREA in to the MDF
- Select the relevant supporting documents e.g. Copy of ethics approval letter, PICF, protocol associated with the research application

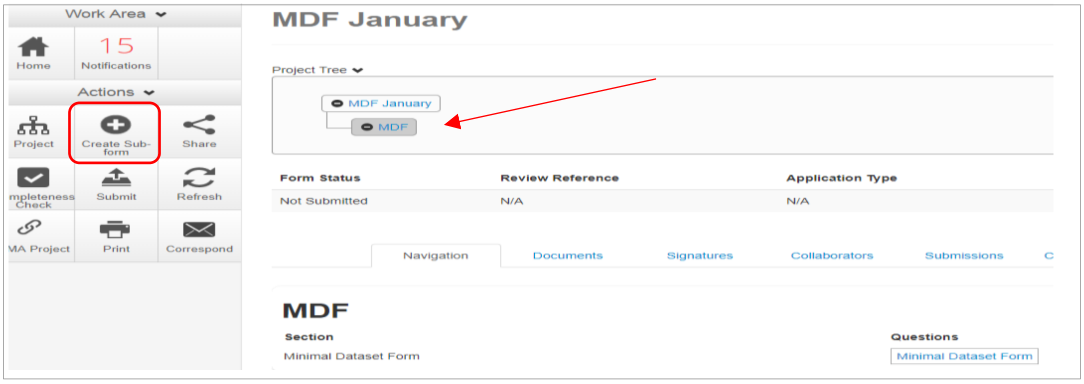


- Select **Upload Document** [Upload Document] to upload the PICF, protocol and other relevant documents from your local drive.

  Ensure the Victorian Specific Module is selected. The CPI should provide a copy of the VSM that was submitted to the reviewing HREC

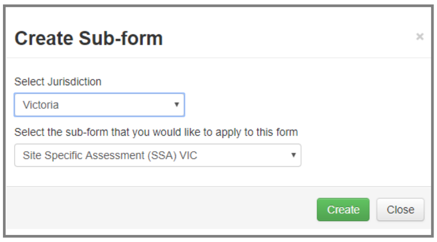


- Select **Submit** button under the Actions pane. The **Submit** action is a systems action and does not submit the form to a HREC
- From the MDF the CPI / delegate creates the SSA as a sub-form



- Select the jurisdiction and Site Specific Assessment (SSA)

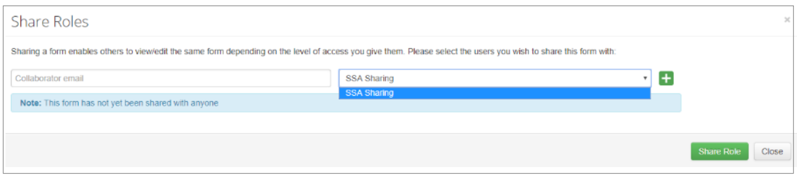
  Select **Create** button



- The CPI / delegate selects the **Roles +** button under the Actions pane to enable the site PI access to the SSA for its completion and submission to the site RGO

- Enter the collaborator's (site PI) email address and select SSA Sharing

  Select **Share Role**



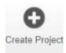
- The site PI will receive an email notification and logs into ERM to complete and submit their SSA.

Section 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.

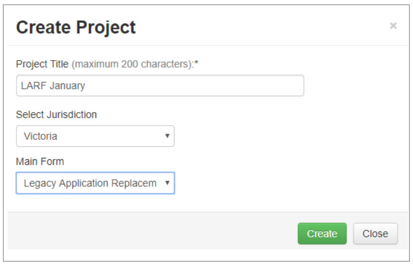
The LARF is not an ethics application form; it is a proxy form that allows sub-forms e.g. post approval forms to be created in ERM. Only **one** LARF is required for the research application.

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

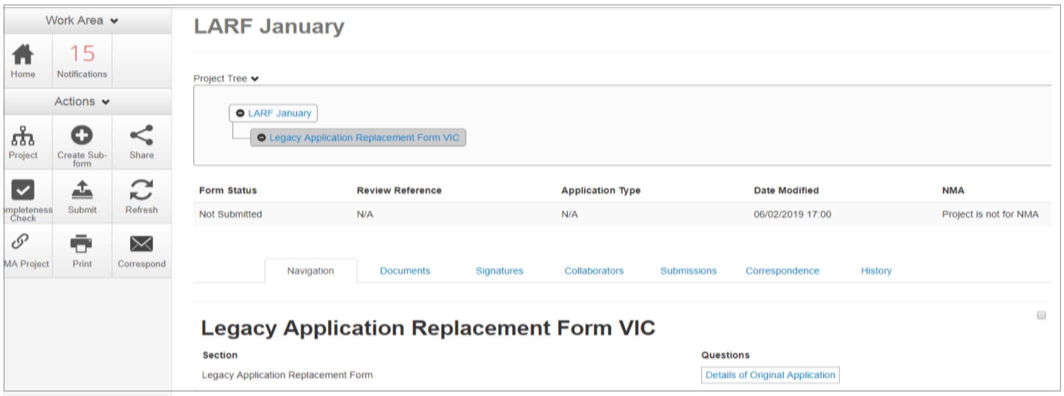
- The CPI / delegate logs onto ERM
- Select **Create Project** 

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

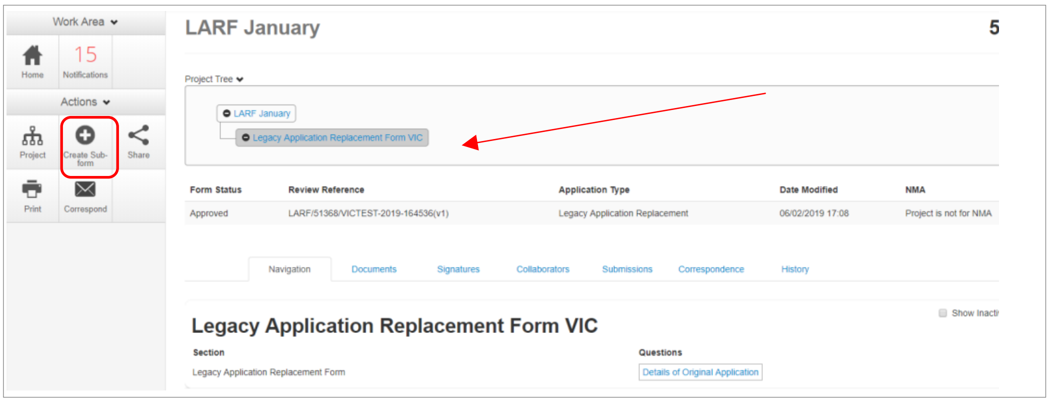


- The LARF will appear under the Project Tree

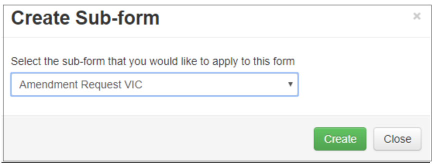


- Complete the questions in the LARF
- Select the **Submit** 

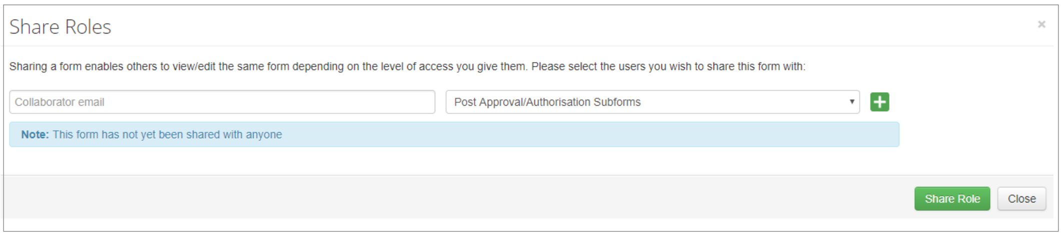
button under the Actions pane
- The form will be submitted to the organisation that reviewed the original application
- From the LARF the CPI / delegate creates a new sub-form



- Select the jurisdiction and appropriate post-approval form e.g. Amendment Request
  Select **Create**



- The CPI / delegate selects the **Roles +** 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**

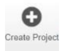


- Complete the questions in the post-approval form
- Sign the post -approval form
- Submit the post-approval form

Section 13: Quality Assurance (QA) Application Form

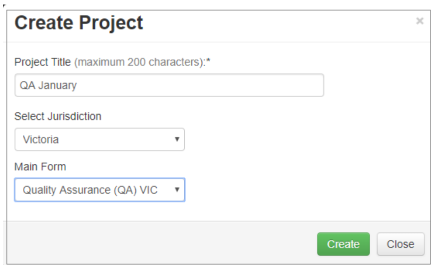
The Quality Assurance (QA) VIC form can be used for the submission of a Quality Assurance or Clinical Audit application.

Consult with the organisation's Research Office before creating the QA application for advice on the criteria for QA.

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

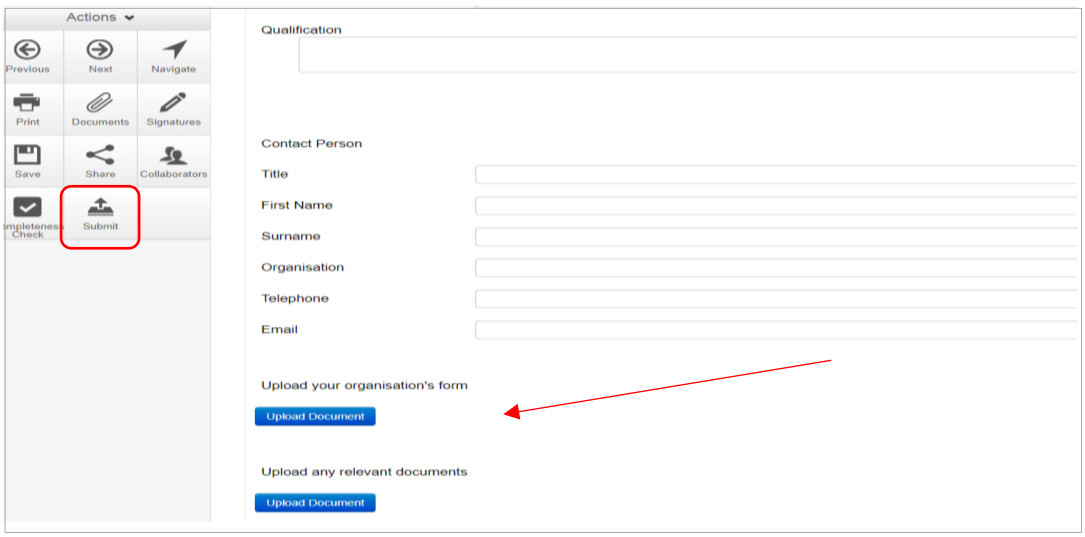
 button under the Actions pane to create a new Main Form
- Enter the Project Title, jurisdiction and select **Quality Assurance (QA) VIC** from the main form drop-down list

  Select **Create**



- The QA form will appear under the Project Tree
- Complete the questions in the QA form
- Select **Upload Document** 

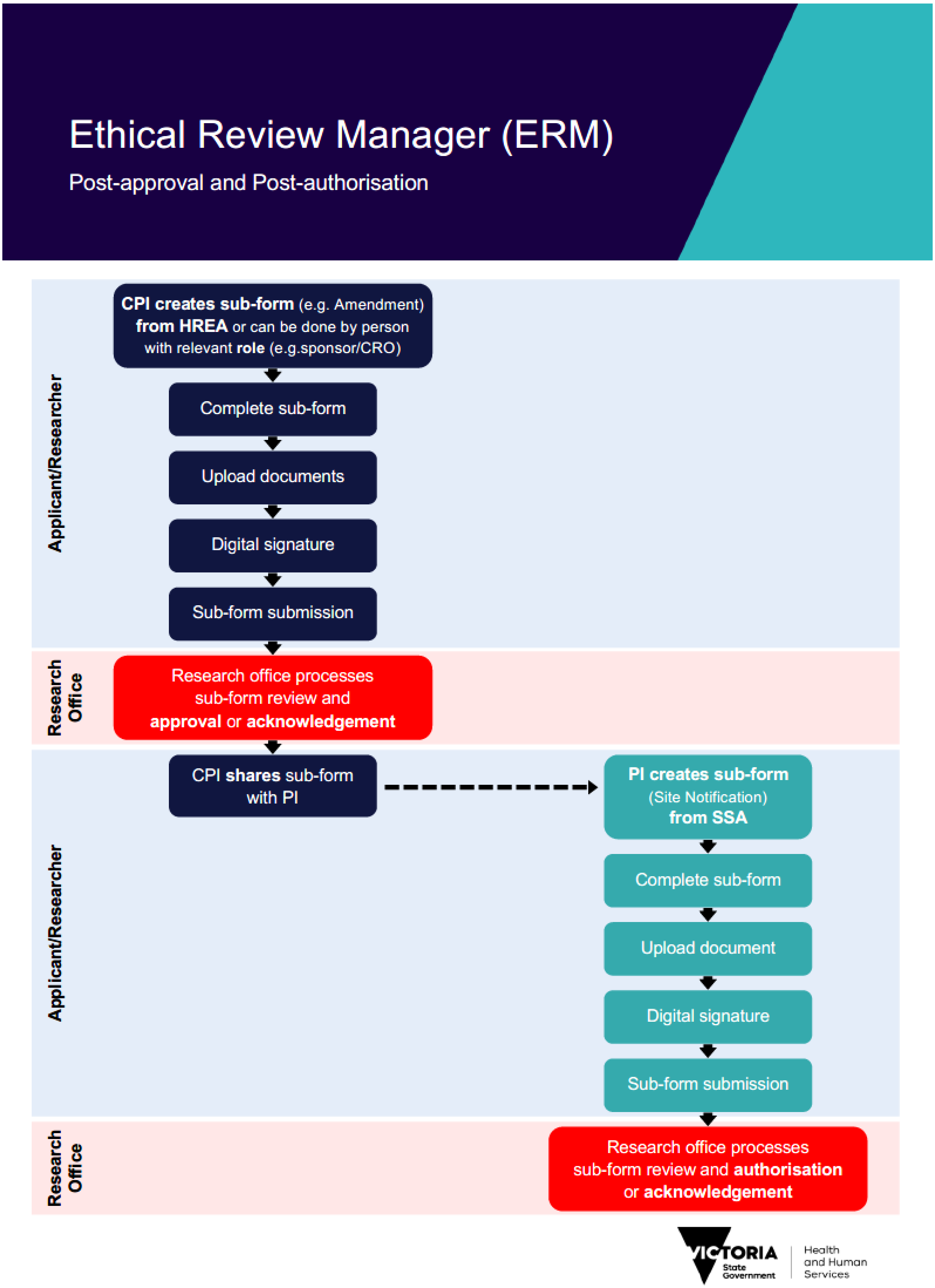
 to attach the organisation's QA Application Form and other relevant documents



- Select **Submit** 

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

Section 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.

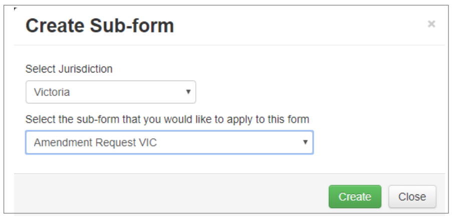
Sub-forms for post approval

- 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

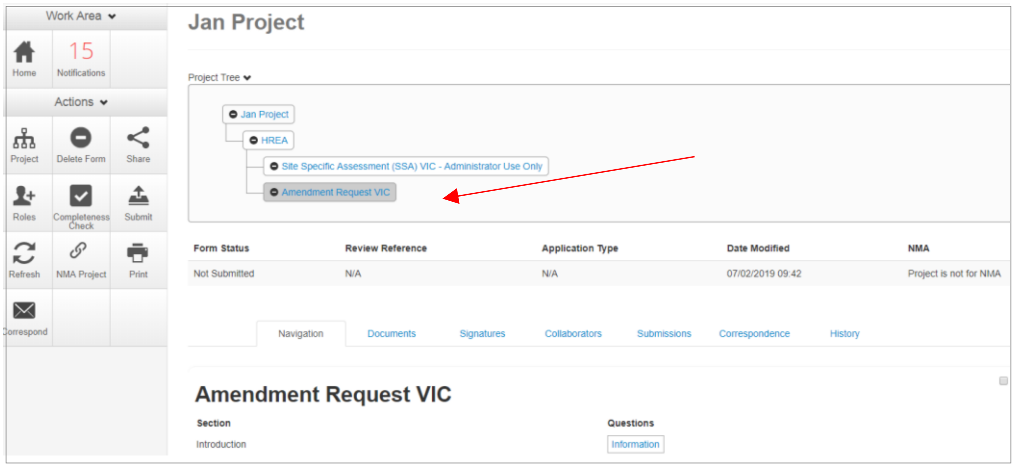
Create a Sub-form

- 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. Amendment Request

  Select **Create**

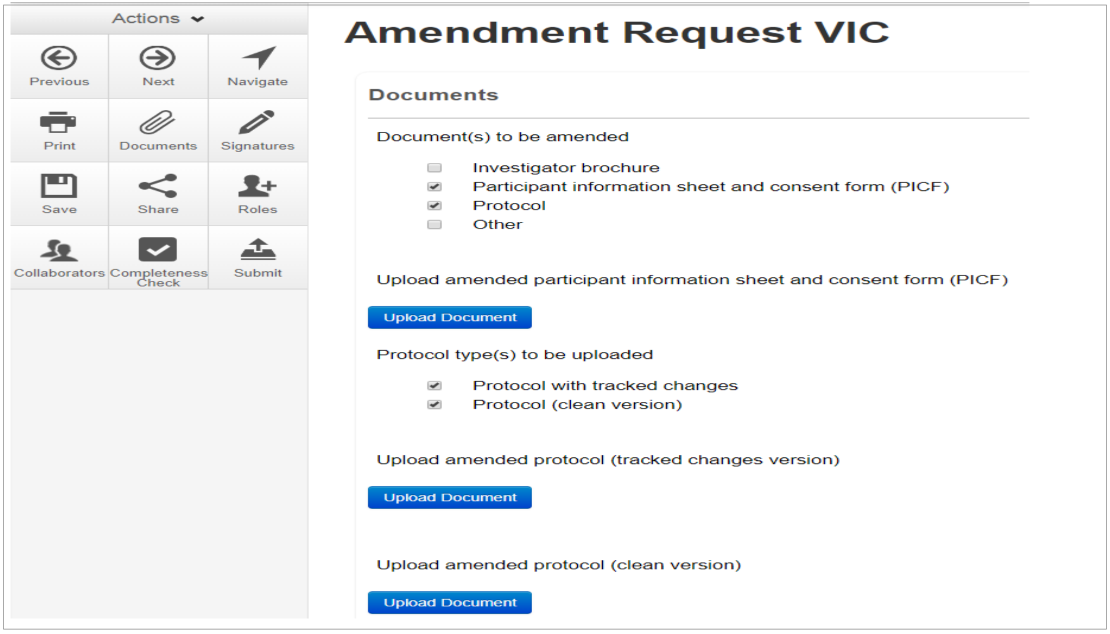


- The Amendment Request form will be displayed under the Project Tree

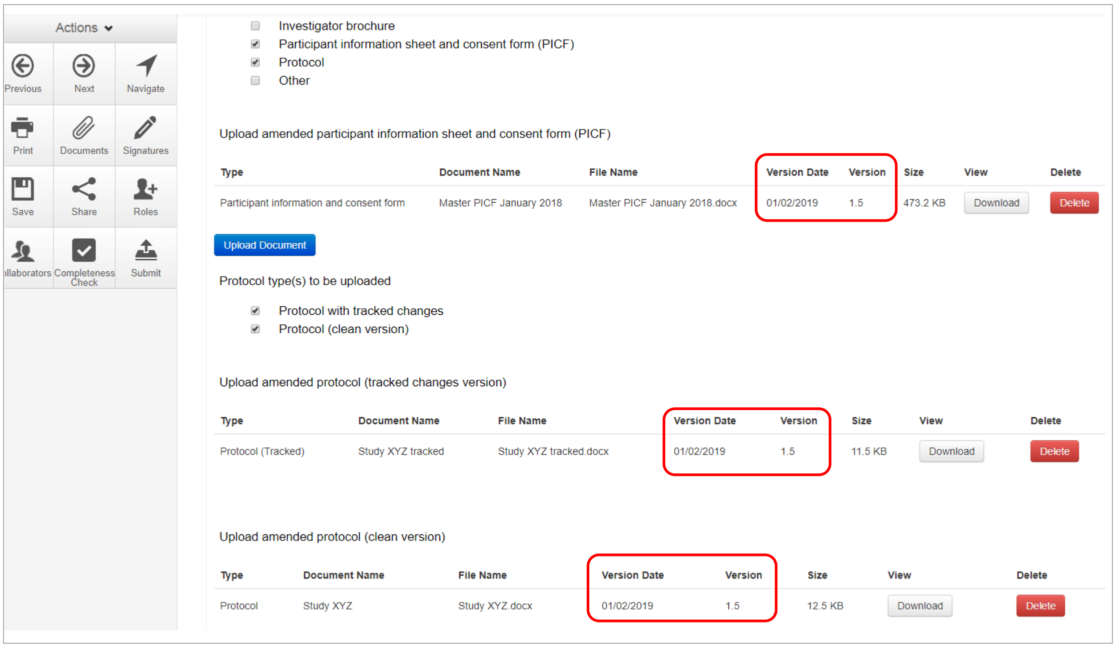


Complete a Sub-form – Amendment Request

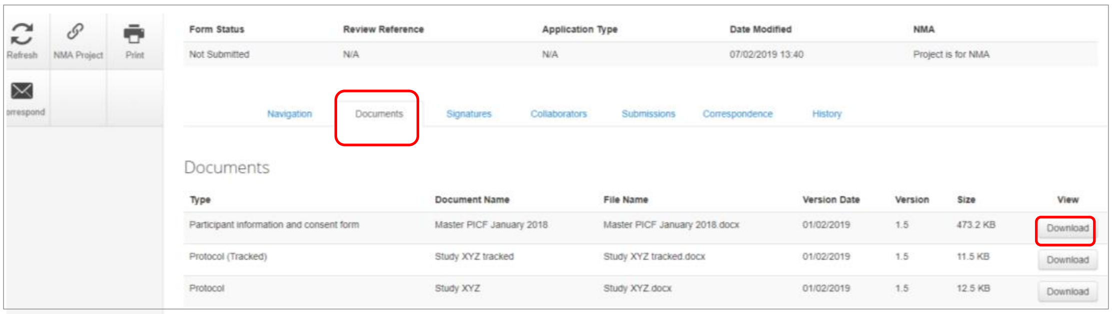
- Complete the questions in the form, in this example the Amendment Request form
- Depending on the amendment category, new versions of documents e.g. PICF, protocol can be attached to the amendment form



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



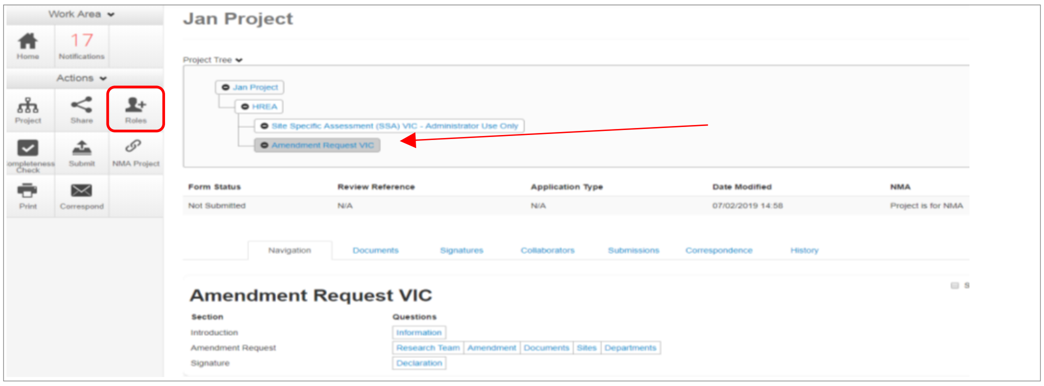
- Documents will also be displayed under the **Documents** tab and can be downloaded

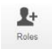


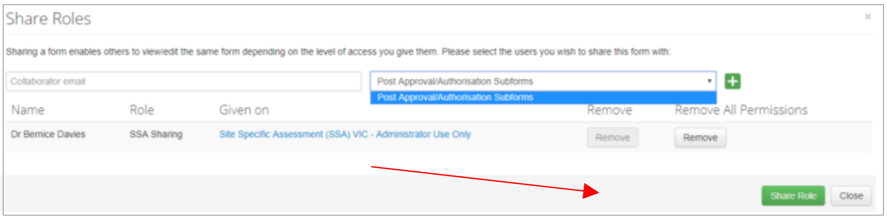
Allowing others to access post approval forms

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

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



- Select **Roles +**  button under the Action pane
- Enter the collaborators 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

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:

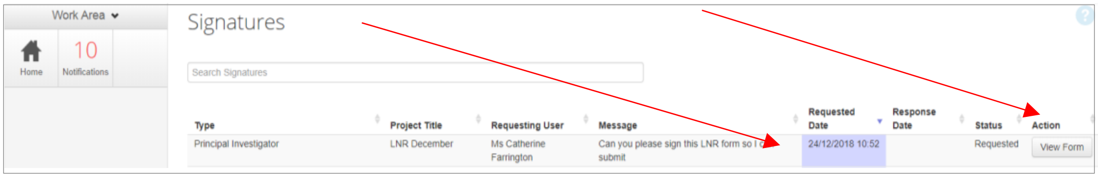
- In the Declaration section, select **Request Signature**  button

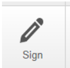
- The system performs a completeness check to highlight any incomplete sections
- Enter the signatory's ERM email address and message

  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**  to review the amendment form



- For endorsement of the amendment, 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, i.e. the form has been signed
- The form is ready for submission

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**  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]

Section 15: Post Authorisation

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).

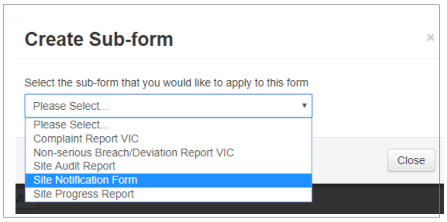
Sub-forms for post authorisation

- Complaint Report
- Non-serious Breach / Deviation Report
- Site Audit Report
- Site Notification Form
- Site Progress Report

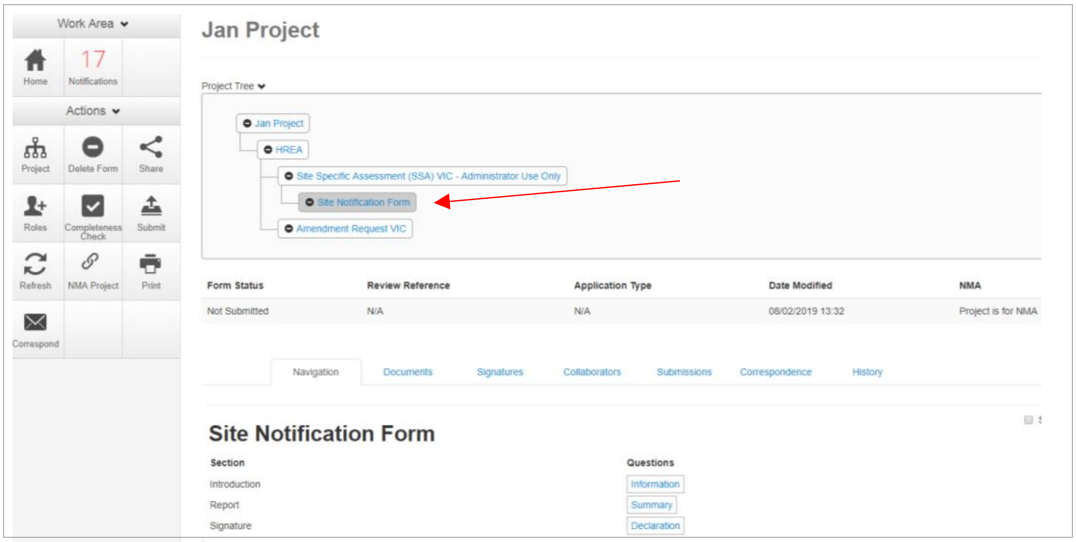
Create a Sub-form

- The PI / delegate logs in to ERM
- Select the project title to display the project under the Project Tree and highlight the SSA
- Select **Create Sub-form**  button under the Actions pane to create a new sub-form e.g. Site Notification Form

  Select **Create**



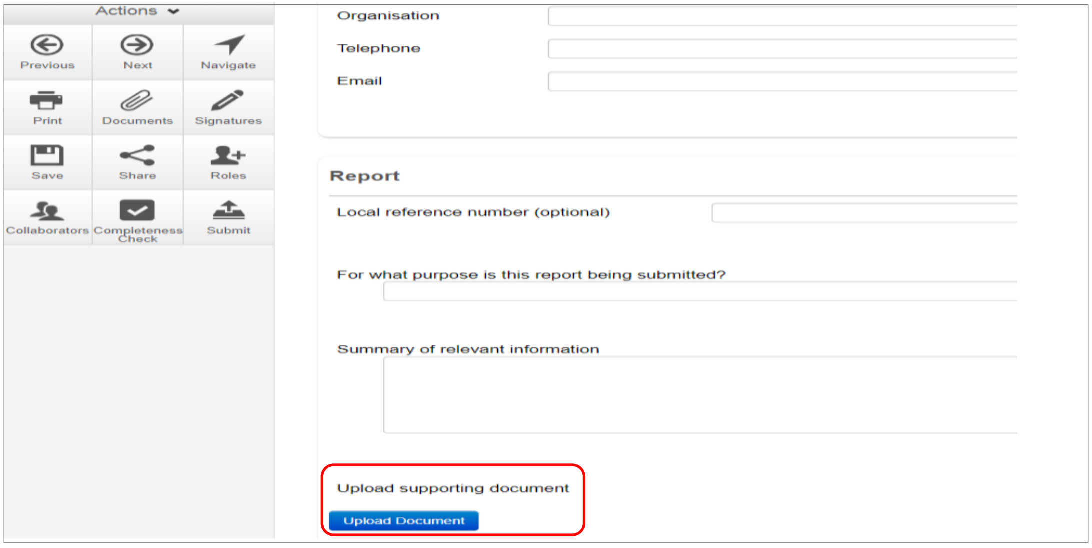
- The Site Notification Form will be displayed under the Project Tree



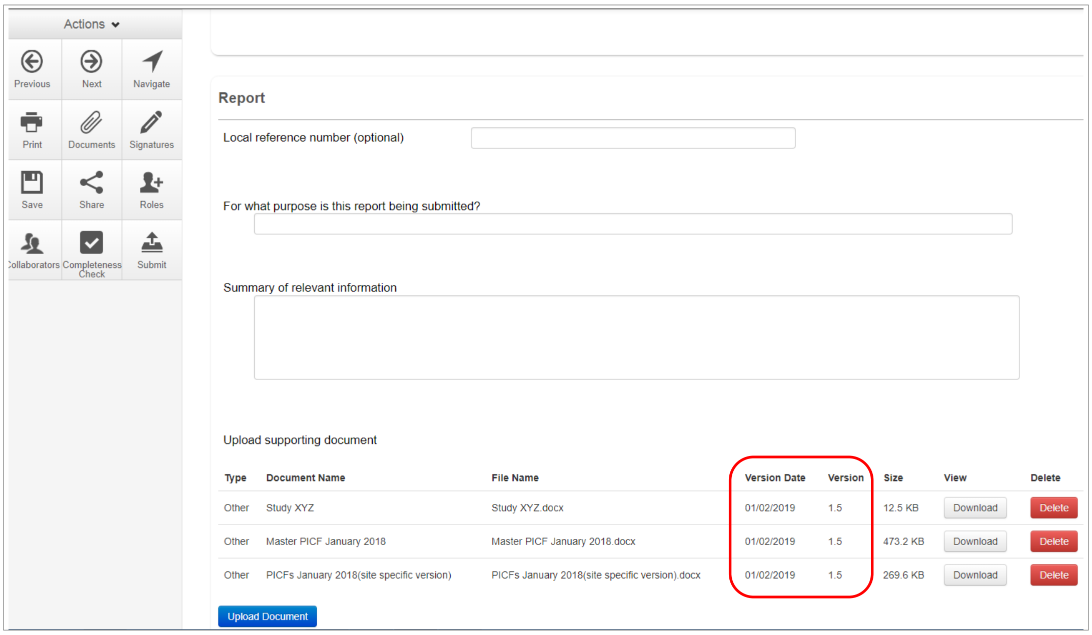
Complete a Sub-form – Site Notification Form

- Complete the questions in the form, in this example the Site Notification Form

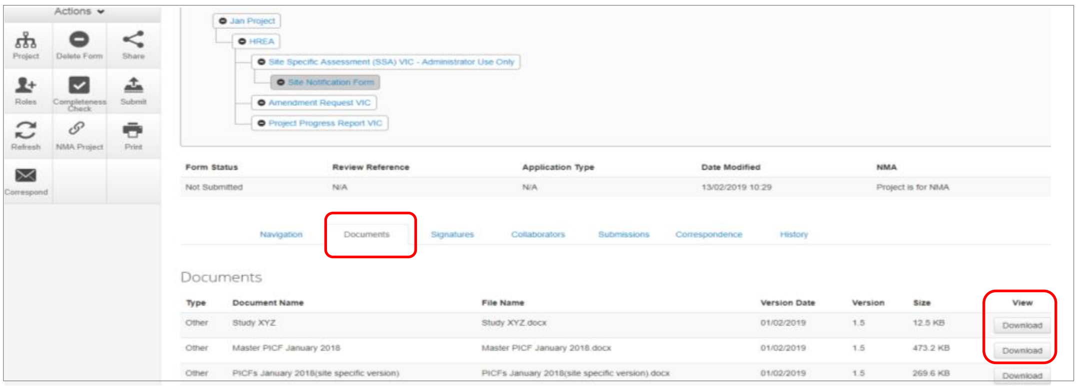
- Ensure the Amendment Request form owner (CPI / delegate) has assigned the site PI access to the amendment documents. See Allowing others to access post approval forms.
- Download the amendment documents e.g. protocol, Master PICF and save to your local drive
- Select **Upload Document** Upload Document to attach amendment documents including site specific documents e.g. site specific PICF from your local drive



- Specify the version and date



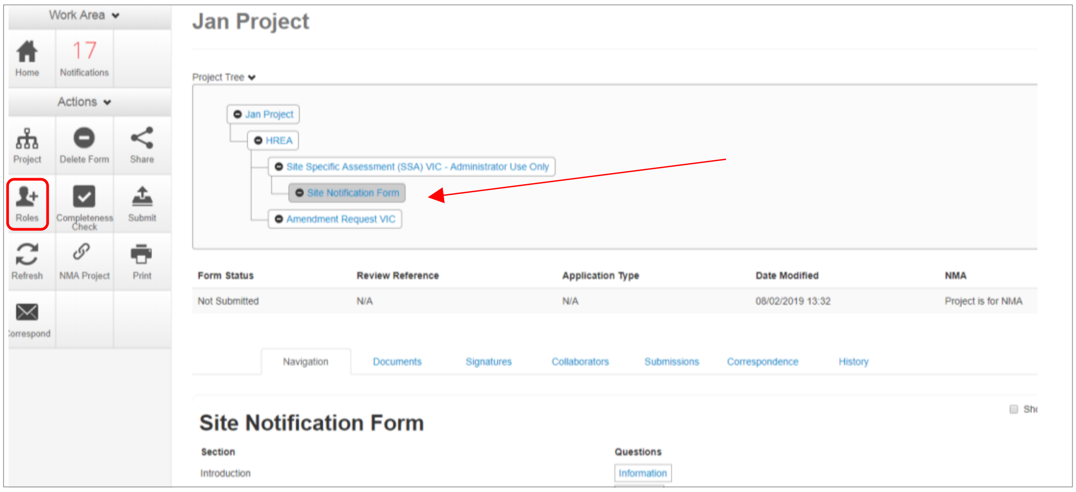
- Documents will also be displayed under the **Documents** tab and can be downloaded



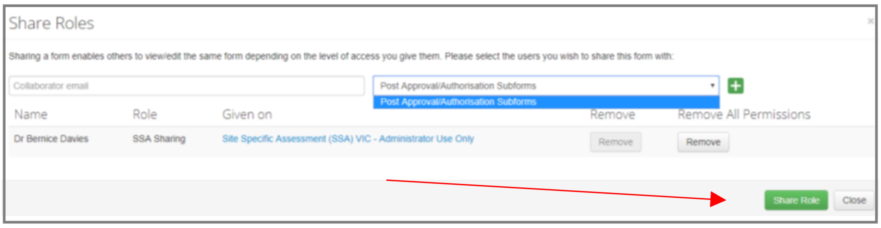
Allowing others to access post authorisation forms

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

- Highlight the post authorisation form e.g. Site Notification Form in the Project Tree



- Select **Roles +**  button under the Action pane
- Enter the collaborators 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 Site Notification Form and associated documents

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 **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** to review the Site Notification Form
- For endorsement of the form, 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, i.e. the form has been signed
- The form is ready for submission

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** 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 - SSA.

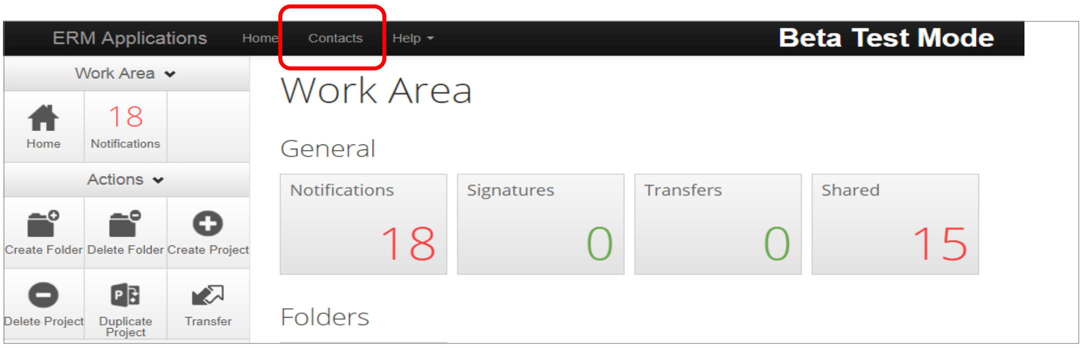
Section 16: Other ERM features

Contacts

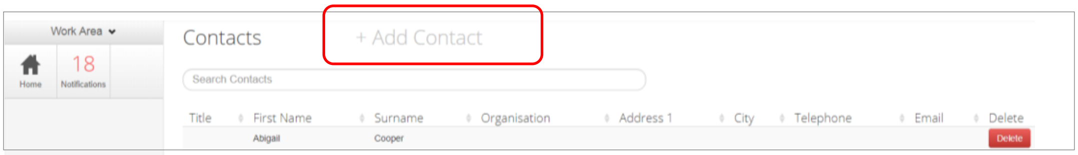
The **Contacts** area can be used to save and edit contact details for project team members. Details saved in **Contacts** can be used to populate all ERM forms avoiding multiple entries.

Add a Contact

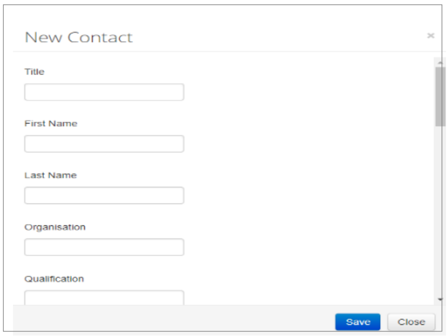
- Select 'Contacts' above Work Area



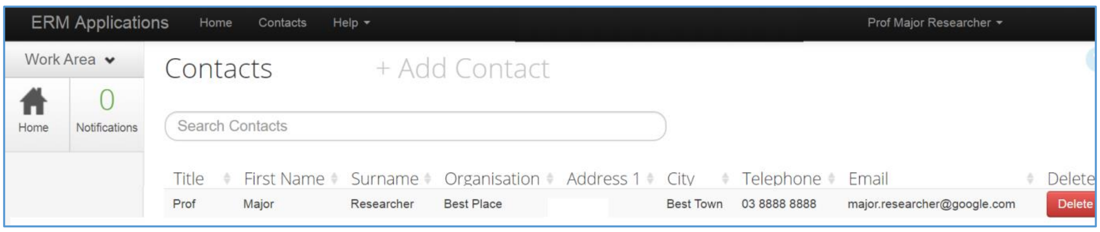
- Select **' + Add Contact'**

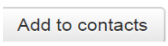


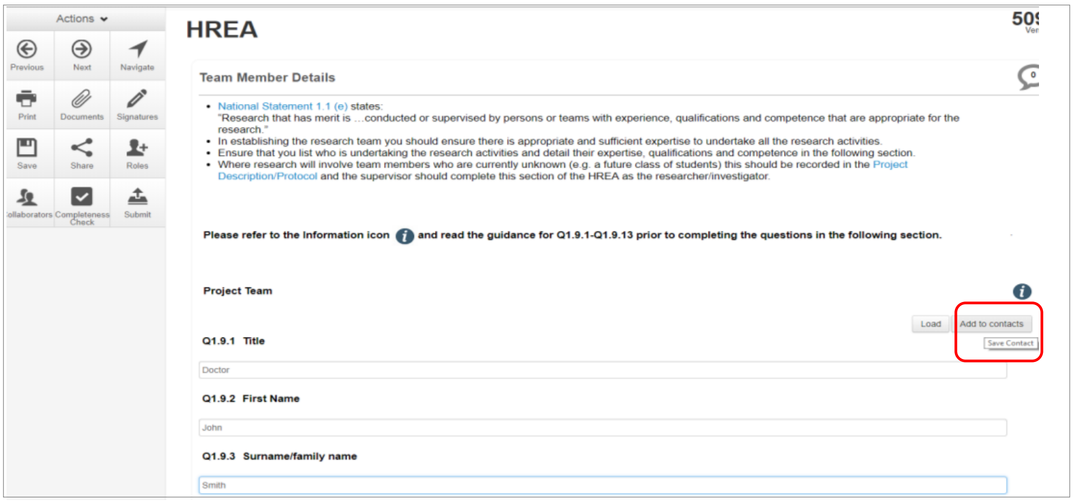
- A **New Contact** textbox will be displayed to enter the new details
- Select **Save** button



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



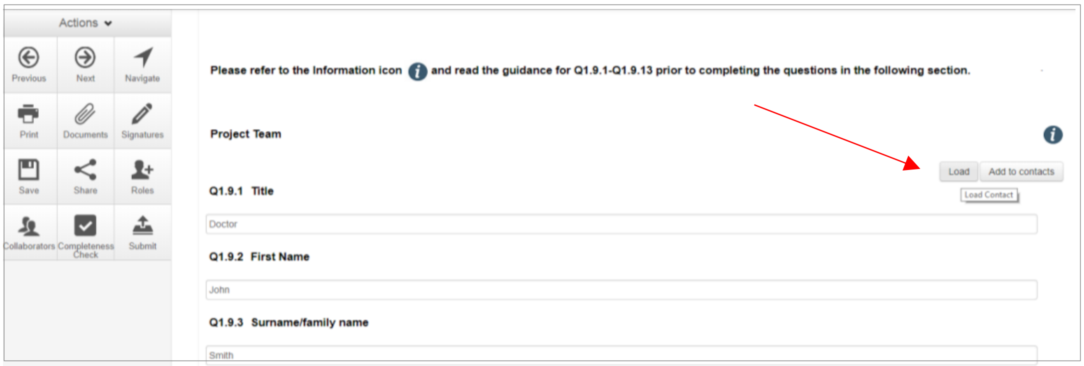
- Contacts can also be added when completing a form
- Select **Add to contacts**  button



- 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** Load button



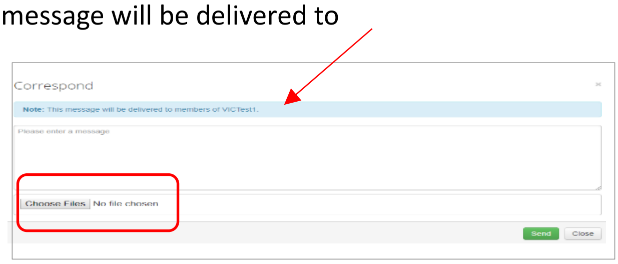
- A **Contacts** text box will be displayed to insert the relevant contact
- Select **insert** button

- Contact details will be successfully loaded into the form

Correspondence

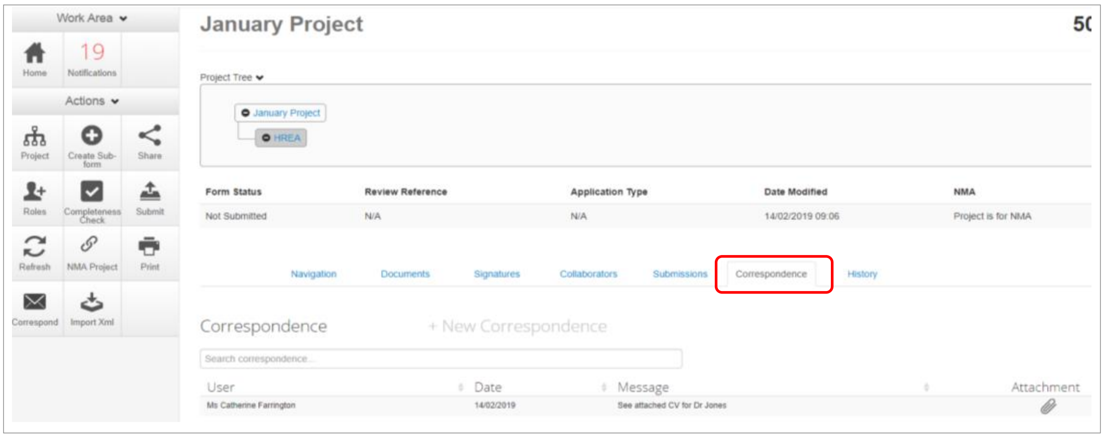
The applicant can use the **Correspond** function to communicate with the reviewing organisation's Research Office and should be used **after** a form has been submitted to the reviewing organisation. Correspondence must **not** be used to respond to a query or information request.

- Select the **Correspond**  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



Folders

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

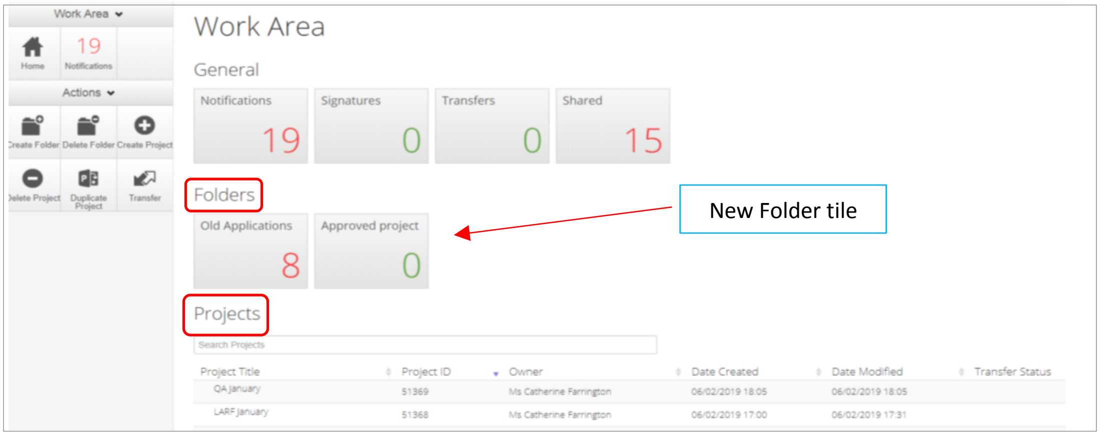
- Select **Create Folder**  button under the Action pane

- A **Create Folder** text box will be displayed

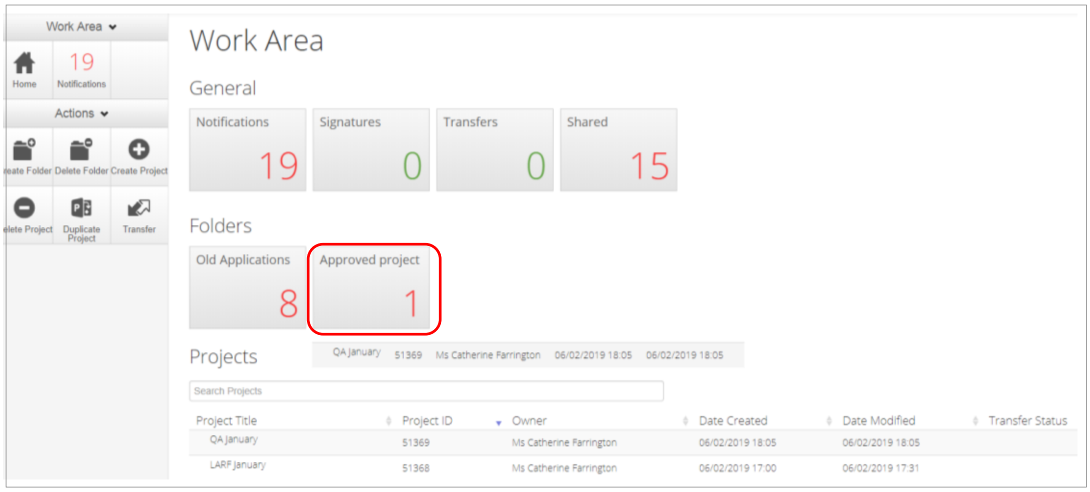
  Enter Folder title e.g. Approved project

  Select **Create**

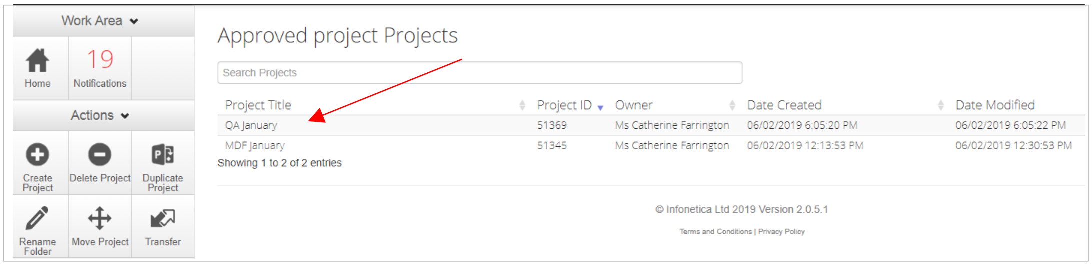
- A new Folder tile (Approved project) is displayed in the Work Area under **Folders**



- 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



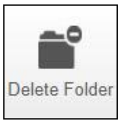
- Select a project to display the application and associated forms



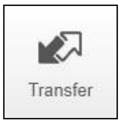
Other Folder Actions

Create a new project

Delete a project (only possible if the main form has **not** been submitted via ERM)



Delete a folder (only empty folders can be deleted)



Permanent transfer of a project to another user e.g. Sponsor creates the HREA and transfers it permanently to the CPI

Duplicate an existing project. Includes all forms in the project but **not** any attached supporting documents

Help

To access ERM

http://au.forms.ethicalreviewmanager.com/Account/Login

For assistance

Infonetica Helpdesk:	02 9037 8404
	helpdesk@infonetica.net
Coordinating Office for Clinical Trial Research:	03 9096 7394
	multisite.ethics@dhhs.vic.gov.au