

Applicant user guide to ERM

Ethical Review Manager (ERM)



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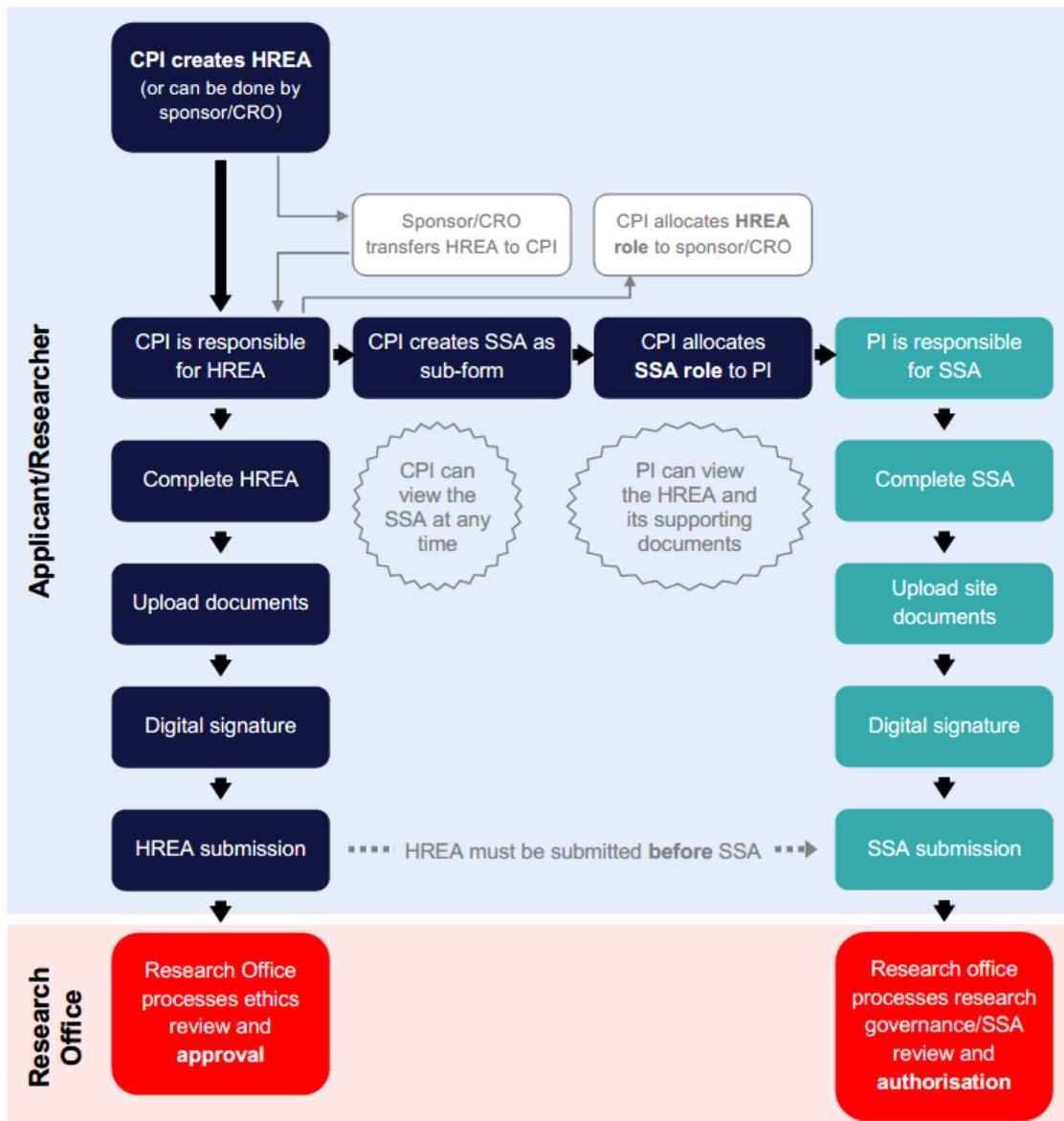
Glossary

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

Ethical Review Manager (ERM)

Ethics and Research Governance/SSA



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:

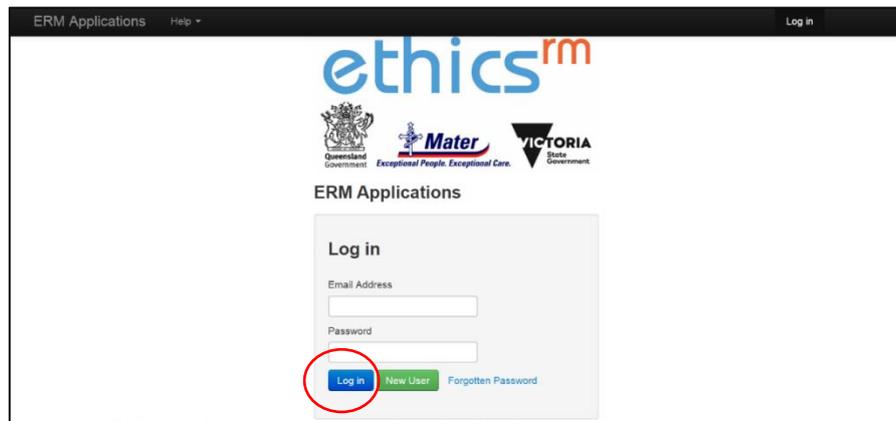
Note: Online Forms was the precursor to ERM. Online Forms account holders may already have an ERM account and can use the same login details.

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

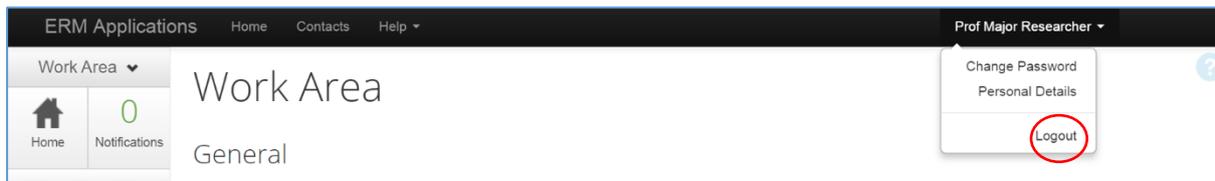
4. Select the activation link in the email
5. Click **Log in**
6. Log in with your email address and password

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

Form Status	Review Reference	Application Type	Date Modified	NMA
Not Submitted	N/A	N/A	02/10/2018 17:42	Project is not for NMA

- 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.

ERM Applications Home Contacts Help Prof Major Researcher

Work Area

Home Notifications 5

Actions

Create Folder Delete Folder

Create Project Delete Project

Duplicate Project Transfer

General

Notifications 5 Signatures 1 Transfers 1 Shared 17

Folders

Archive 19

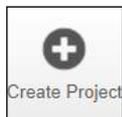
Projects

Search Projects

Project Title	Project ID	Owner	Date Created	Date Modified	Transfer Status
Project Title	44245	Prof Major Researcher	28/07/2018 10:45	28/07/2018 10:45	

Actions

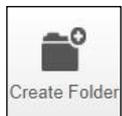
There are six action buttons under the Actions pane



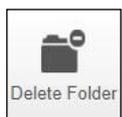
Create a new project



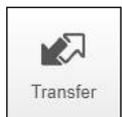
Delete a project (only possible if the main form has **not** been submitted via ERM)



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.



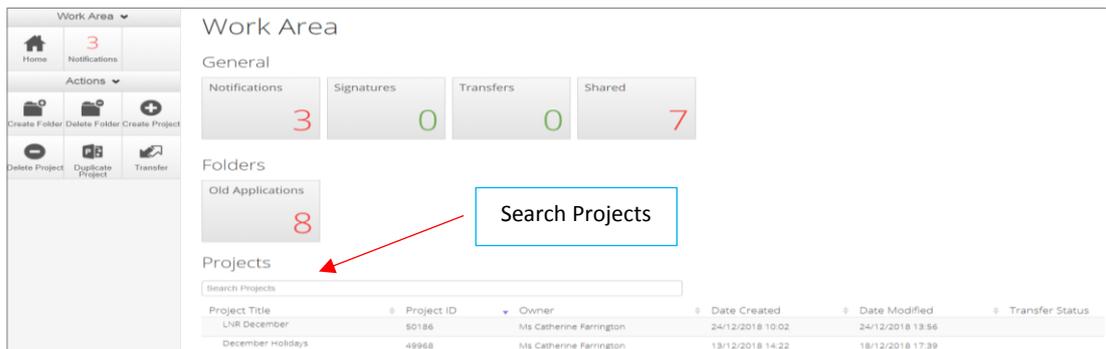
- Notifications** - Contain messages that are sent to the user from the Research Office and other research team members
 - Contain messages automatically generated by ERM e.g. form updates
- Signature** - Contain requests from colleagues to digitally sign an application i.e. a request for an electronic 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

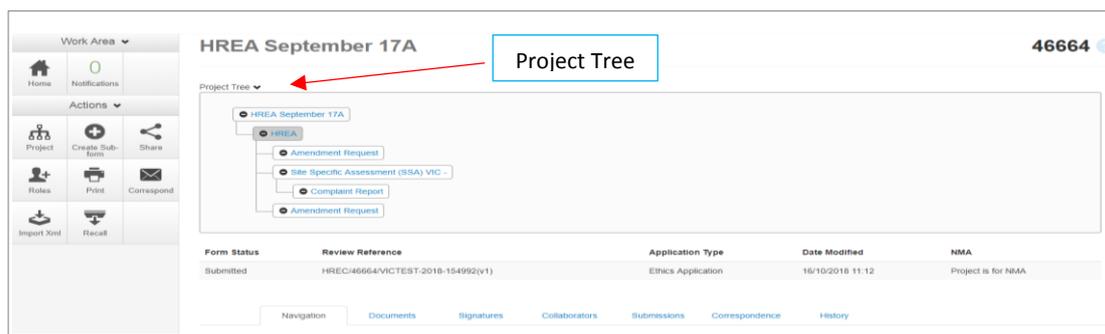
Displays bespoke folders for storage of projects.

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:

- 

Project

Go to the Project overview
- 

Create Sub-form

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

Share

Enable collaborators to view, edit and manage the form
- 

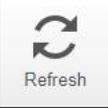
Roles

Enable collaborators to view, edit and manage the form
- 

Completeness Check

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

Submit

Submit the application to the reviewing organisation.
Note: the reviewing organisation must be selected **within the form**, in order for the submission to be directed to that organisation.
- 

Refresh

Refresh
- 

NMA Project

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

Print

Generate a PDF of the form
- 

Correspond

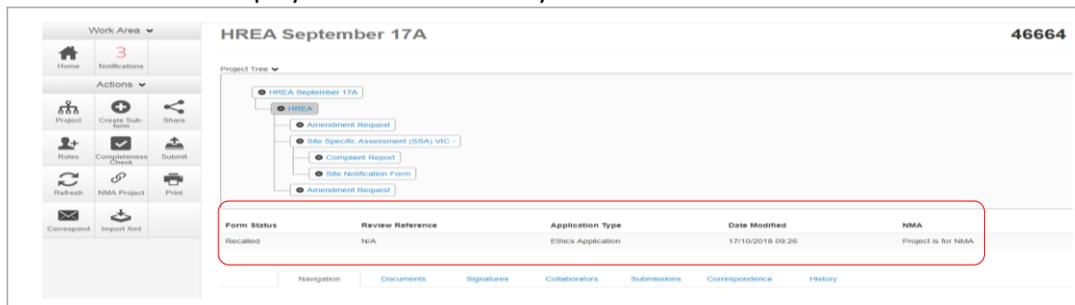
Communicate directly with the Research Office selected as the reviewing organisation within the form **only after** the form has been submitted
- 

Import Xml

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

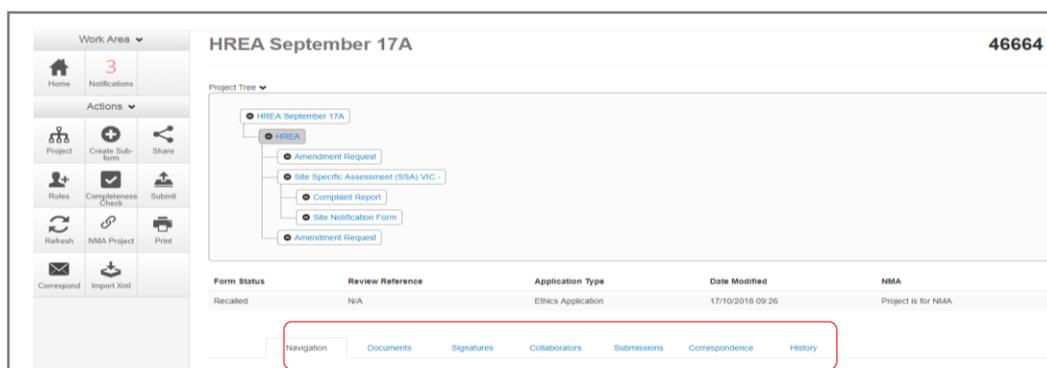
Displays the most recent date a form was updated

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

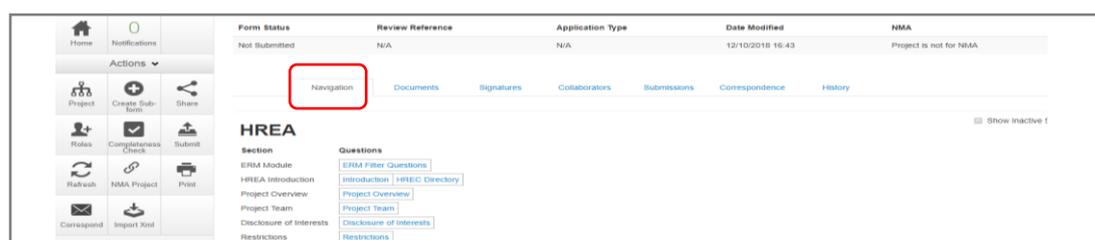


Tab	Explanation
Navigation	Application form is completed under Navigation tab
Documents	Displays all supporting documents that have been uploaded within the form Note: Documents are not uploaded under this tab; documents are uploaded within the relevant section of the form
Signatures	Shows a history 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:

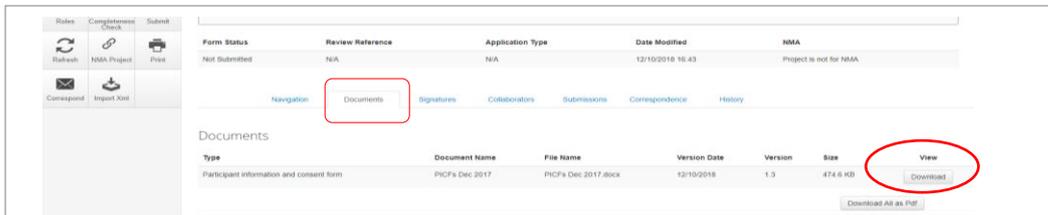
Navigation

- 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



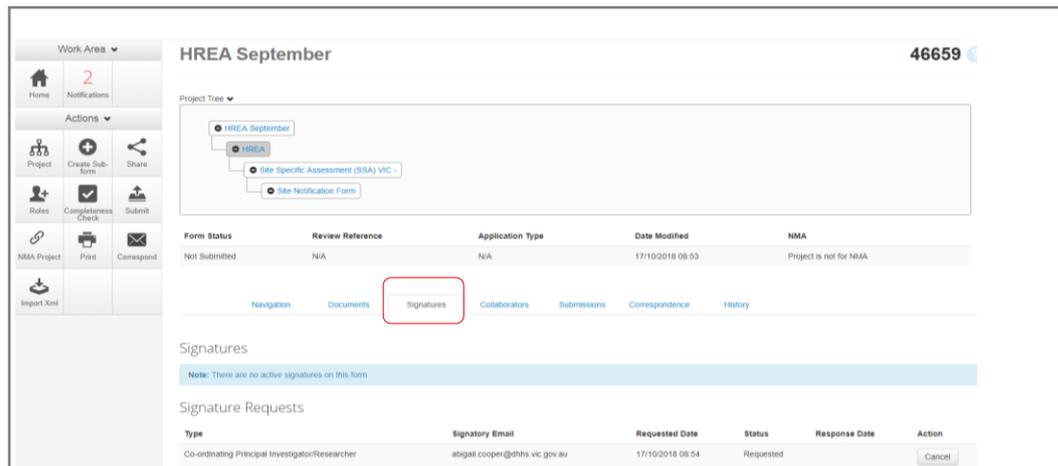
Documents

- 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



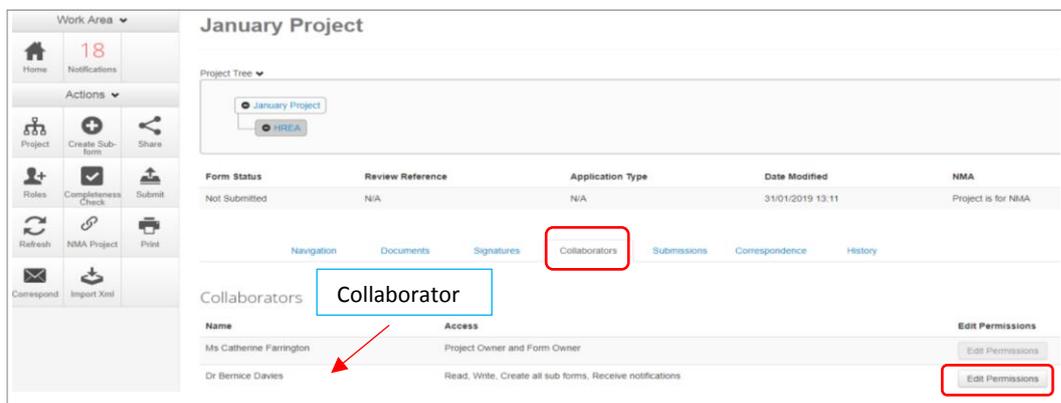
Signatures

- 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 Tree 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

Work Area 2

HREA September 17A 46664

Project Tree

- HREA September 17A
 - HREA
 - Amendment Request
 - Site Specific Assessment (SSA) VIC -
 - Complaint Report
 - Amendment Request

Form Status	Review Reference	Application Type	Date Modified	NMA
Submitted	HREC/46664/VICTEST-2018-154992(v1)	Ethics Application	16/10/2018 11:12	Project is for NMA

Navigation Documents Signatures Collaborators Submissions Correspondence History

Submissions

Review Reference	Date	Status	Committee	Pdf
HREC/46664/VICTEST-2018-154992(v1)	16/10/2018	Submitted	VICTest1	Download

Correspondence

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

Work Area 3

HREA September 17A 46664

Project Tree

- HREA September 17A
 - HREA
 - Amendment Request
 - Site Specific Assessment (SSA) VIC -
 - Complaint Report
 - Amendment Request

Form Status	Review Reference	Application Type	Date Modified	NMA
Recalled	N/A	Ethics Application	17/10/2018 09:26	Project is for NMA

Navigation Documents Signatures Collaborators Submissions Correspondence History

Correspondence

Search correspondence...

User	Date	Message	Attachment
Ms Catherine Farrington	17/10/2018	Please see attached OCP certificate for PI	

Showing 1 to 1 of 1 entries

- 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.

Work Area 3

HREA September 17A 46664

Project Tree

- HREA September 17A
 - HREA
 - Amendment Request
 - Site Specific Assessment (SSA) VIC -
 - Complaint Report
 - Site Notification Form
 - Amendment Request

Form Status	Review Reference	Application Type	Date Modified	NMA
Recalled	N/A	Ethics Application	17/10/2018 09:26	Project is for NMA

Navigation Documents Signatures Collaborators Submissions Correspondence History

Form History

Search history...

Date	User	Description	Attachment
10:07	Ms Catherine Farrington	Correspondence Sent	Download
09:26	Ms Catherine Farrington	The form has been updated	Download
09:25	Ms Catherine Farrington	Form status changed from Submitted to Recalled	Download
16/10/2018 11:12	Ms Catherine Farrington	Form submitted	Download

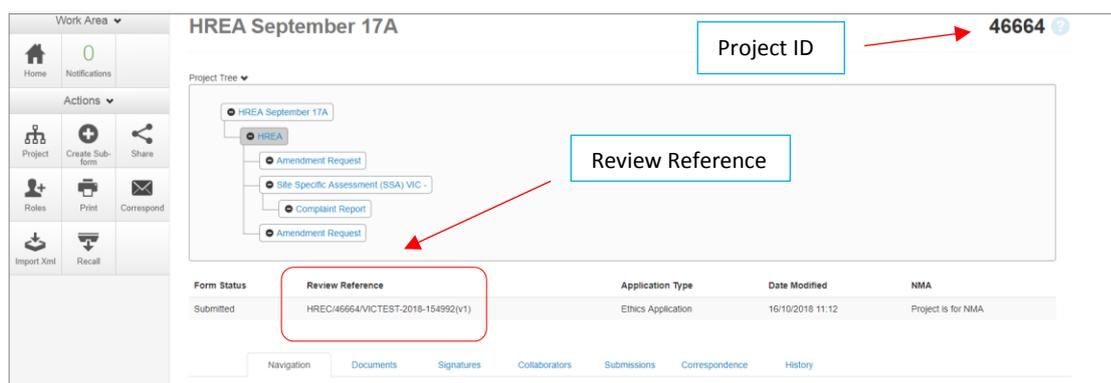
ERM Reference Numbers

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

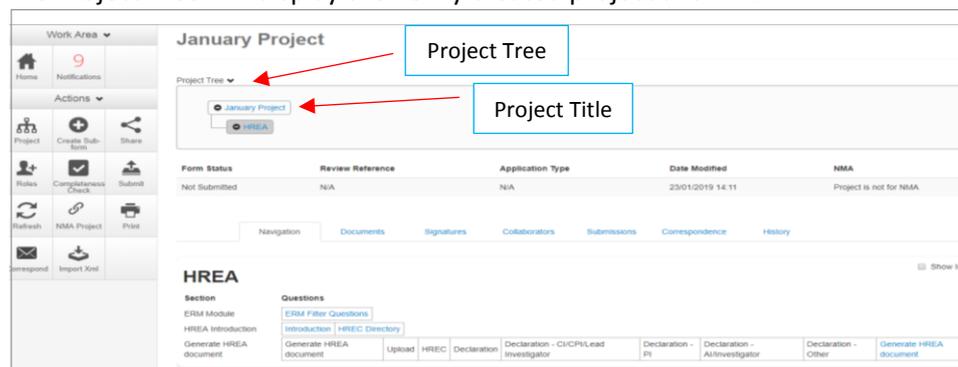
Create an HREA

- 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

The screenshot shows the 'Create Project' form. It has a 'Project Title' field with the text 'January Project'. Below that is a 'Select Jurisdiction' dropdown menu with 'Victoria' selected. Underneath is a 'Main Form' dropdown menu with 'HREA' selected. At the bottom right of the form, there are two buttons: 'Create' (highlighted with a red circle) and 'Close'.



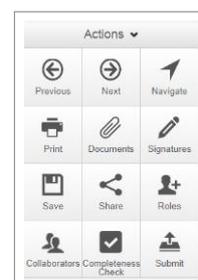
Complete the HREA

- 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

The screenshot shows the HREA form. It has a 'Previous', 'Next', and 'Navigate' section. Below that is a 'Print', 'Documents', and 'Signatures' section. There is a 'Save', 'Share', and 'Roles' section. At the bottom left, there is a 'Collaborators', 'Completeness Check', and 'Submit' section. The main content area has a question: 'Will this ethics application involve a site in Victoria?' with radio buttons for 'Yes' and 'No'. Below that is a section titled 'Select the features that are applicable to this research project:' with checkboxes for 'Recruitment of adult research participants who do not have decision making capacity', 'Collection, use and/or disclosure of personal and/or health information', 'Removal of tissue or blood from a living or deceased adult or child, or performance of a post mortem', and 'None of the above'. At the bottom, there is a note: 'The Victorian Specific Module (VSM) is required. Create the VSM as a Sub-form of this HREA. Before submitting this HREA, upload the VSM below. Victorian Specific Module' and an 'Upload Document' button.

- 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

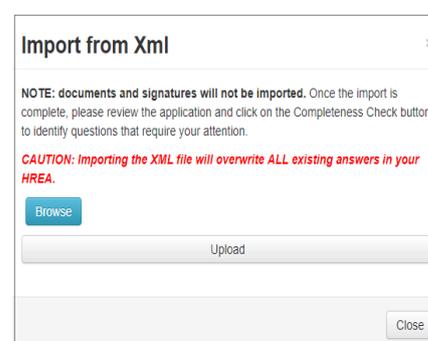


Import an HREA

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'

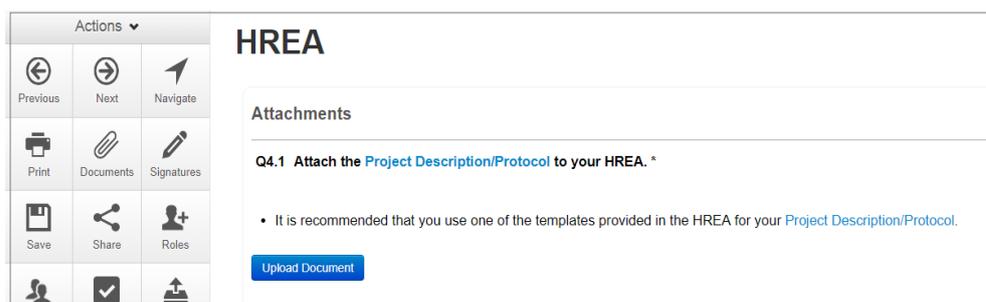
- Click on the **Navigation**  button under the Actions pane
- Select **Import Xml** button
- An **Import from Xml** text box will be displayed
- Select **Upload** button



- 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**

Q4.2 Are there any other relevant documents associated with conducting your research project?

- This may include attachment of:
 - participant information and consent forms,
 - questionnaires,
 - report forms,
 - advertising materials,
 - authorisations, approvals, letters of support or other clearances, and/or
 - other project-related documentation specific to your institution and/or jurisdiction.
- Consult with your institution's research/ethics office for advice on the necessary documentation.

Yes
 No

Attach any other relevant documents associated with conducting your research project. Optional

- Ensure that you give meaningful and unique names to your files before uploading them.
- Enter the description in the document name field. The date and version fields are mandatory.

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

- Curriculum vitae (CV) or resume of investigator/researcher
- Drug data sheet
- Form of indemnity
- Licence for dealing with a genetically modified organism
- GP/consultant information
- Institutional biosafety committee (IBC) approval
- Investigator brochure or reference safety information
- Invitation to participant
- Letter of support
- NSW privacy form
- Participant documentation e.g. diary, wallet card
- Participant information and consent form
- Peer review
- Protocol (Tracked)
- Questionnaire
- Radiation: letter re standard care
- Radiation: medical physicist's report
- Report forms
- Statistician comments
- Western Australian specific module
- Other project-related documentation

- 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

Curriculum vitae							
Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Curriculum vitae	Dr Jones CV	Dr Jones CV.docx	01/01/2018	1	12.5 KB	Download	Delete
Upload Document							
Participant information and consent forms							
Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Participant information and consent form	PICFs Dec 2017	PICFs Dec 2017.docx	31/12/2017	1.3	474.6 KB	Download	Delete
Upload Document							

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

Form Status	Review Reference	Application Type	Date Modified	NMA
Not Submitted	N/A	N/A	24/10/2018 15:46	Project is not for NMA

Navigation: [Documents](#) (circled in red) | [Signatures](#) | [Collaborators](#) | [Submissions](#) | [Correspondence](#) | [History](#)

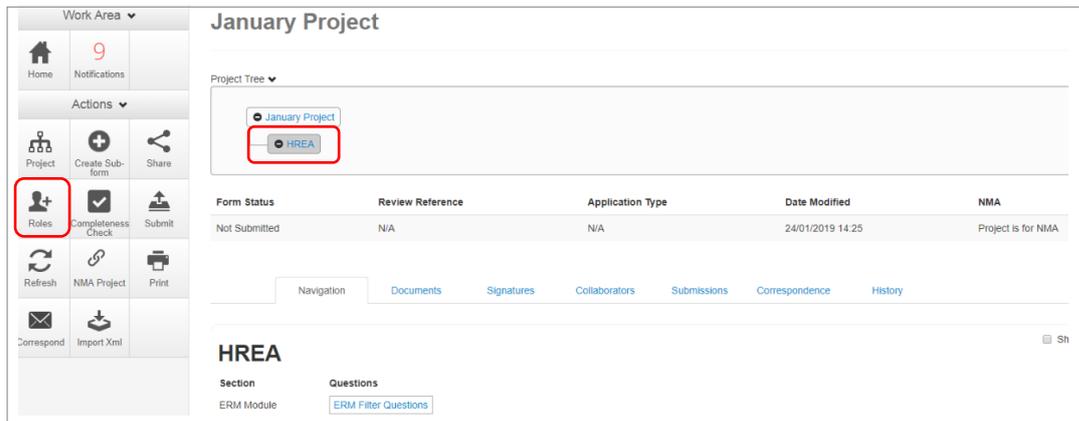
Type	Document Name	File Name	Version Date	Version	Size	View
Participant information and consent form	PICFs Dec 2017	PICFs Dec 2017.docx	31/12/2017	1.3	474.6 KB	Download (circled in red)
Curriculum vitae	Dr Jones CV	Dr Jones CV.docx	01/01/2018	1	12.5 KB	Download

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



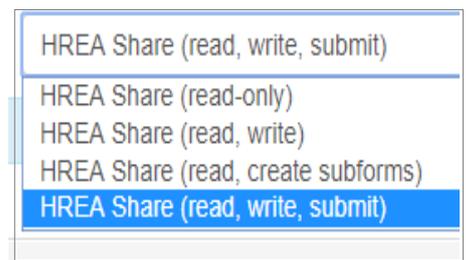
- A dropdown list will display the different levels of access to the HREA

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



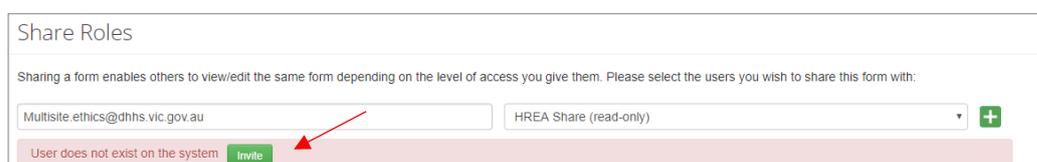
- Enter the collaborator's email address and select the level of access



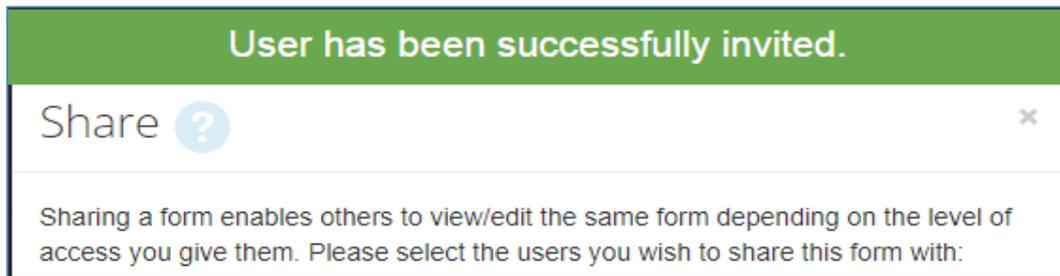
- Select **Share Role** button
- Other research team members can be added using the  button

If the collaborator does not have an ERM account

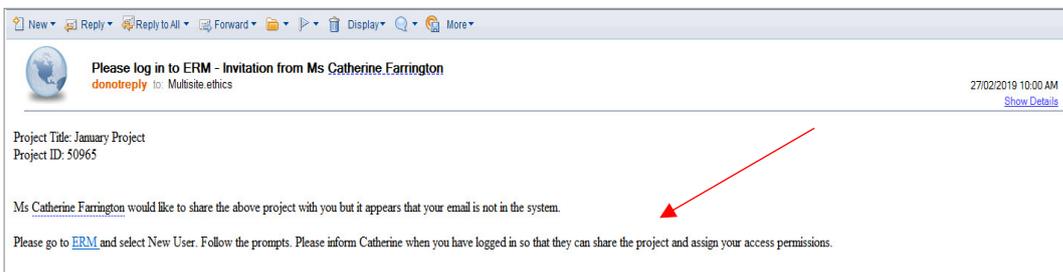
- A message will be displayed if the collaborator's email does not exist in ERM



- 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

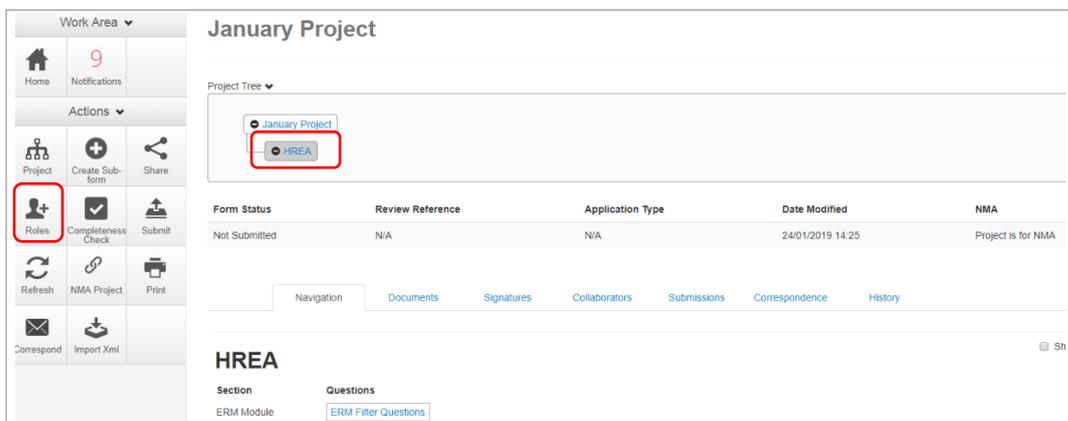


- The collaborator will receive an email notification inviting them to share the project and a link to ERM to create an account. The collaborator should also notify the project owner when their ERM account has been activated



- 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

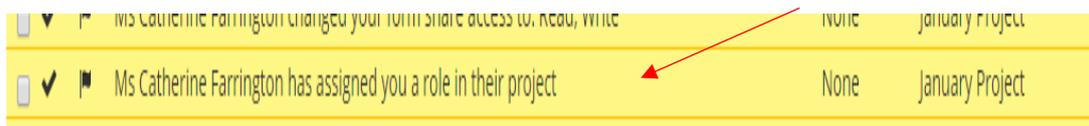


Accept access

- 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

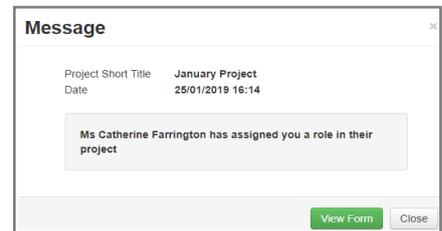


- Select the Message title to open the message



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

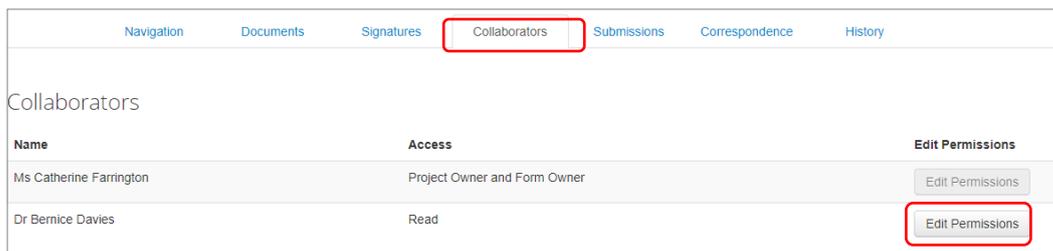
Select **View Form**



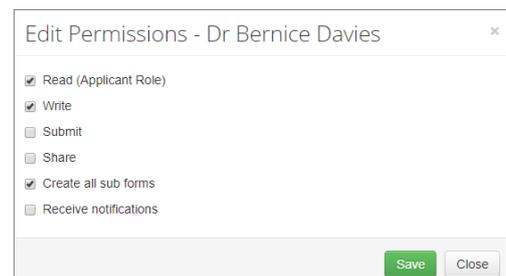
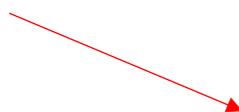
- The project and form will be displayed. Supporting documents attached to the form can also be viewed
- The collaborator can edit and submit sub-forms e.g. the SSA for their site depending on the level of access assigned by the project owner

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

HREA

Investigator Team Declarations

This declaration must be completed by each of the researchers/investigators or, where applicable, one member on behalf of the research team.

- Consult your institution's policy for guidance on whether all members must sign this application or whether one member can sign on behalf of the research team.
- You can upload evidence of the other researchers/investigators' agreement to this declaration (e.g. a PDF of an email).
- You can have researchers/investigators sign this application after it is completed and printed (i.e. a 'wet ink' signature).
- You can use the request signature feature to have other researchers/investigators complete their declaration within this application.
- **You must identify which researchers/investigators will be providing evidence or wet ink signatures. Upload any supporting documents and enter the relevant details for those researchers/investigators before requesting electronic signatures as this will lock the form.**

Indicate which members must sign this application

- Chief Investigator/Researcher
- Coordinating Principal Investigator/Researcher
- Lead Investigator/Researcher
- Principal Investigator
- Associate/Assistant/Sub-/Co-Investigator/Researcher
- Investigator/Researcher
- Other

Signature required by CPI

Signature required by PI

This system requires you to enter the names of members who are signing this application. You must also indicate how the member will be signing, and upload any signature documents prior to requesting any electronic signatures. The application will be locked (read only) once you have signed/requested electronic signatures.

Signatures

The HREA form questions / information must be complete, before 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 screenshot shows the HREA form interface. On the left is an 'Actions' pane with icons for Previous, Next, Navigate, Print, Documents, Signatures, Save, Share, Roles, Collaborators, Completeness Check, and Submit. The main form area is titled 'HREA' and contains a 'Declaration - CI/CPI/Lead Investigator' section. Below this is a field for 'Coordinating Principal Investigator/Researcher' with a text input 'I, (insert name)'. A 'certify that:' section follows with several bullet points. Below that is 'Q4.7 How will the Coordinating Principal Investigator/Researcher agree to these terms?' with three radio button options: 'Electronic signature (in place of HREA 'sign on screen')', 'Upload other evidence', and 'Wet ink sign after printing'. A green 'Add Another Signature' button is at the bottom.

The HREA form owner may request signatures as follows:

1. To use Wet ink signature

- Select Wet ink sign after printing

This screenshot shows the same HREA form section as above, but with the 'Wet ink sign after printing' radio button selected and highlighted by a red box. Below the radio buttons are two text input fields: 'Sign here:' and 'Date:

- '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

Other project-related documentation

Other project-related documentation specific to your institution and/or jurisdiction

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Other project-related documentation	CPI signature	CPI signature.pdf	19/08/2018	1	155.5 KB	Download	Delete

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

- Select 'Upload other evidence'

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

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

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

Upload signature

[Upload Document](#)

- 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

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

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

Upload signature

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Signature	Signature for Professor Smith	Signature for Professor Smith.docx	19/08/2018	1	12.5 KB	Download	Delete

3. To request an Electronic Signature

- Select **Electronic signature** and a [Request Signature](#) [Sign](#) button will appear

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

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

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

Electronic signature

[Request Signature](#) [Sign](#)

- 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

Requested Date: 12/12/2018 15:38

Type	Project Title	Requesting User	Message	Requested Date	Response Date	Status	Action
Co-ordinating Principal Investigator/Researcher	October 22	Ms Catherine Farrington	Can you please sign the HREA	12/12/2018 15:38		Requested	View Form
Head of Supporting Department	October 24	Ms Catherine Farrington		19/11/2018 12:20		Invalidated	View Form

- 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

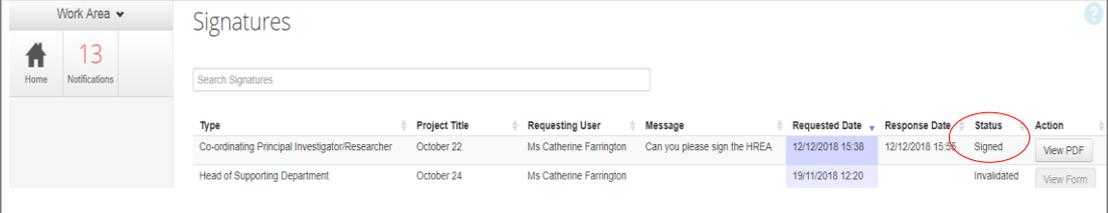


Sign Form

Please enter your login details in order to sign this form:

Username Password

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



Type	Project Title	Requesting User	Message	Requested Date	Response Date	Status	Action
Co-ordinating Principal Investigator/Researcher	October 22	Ms Catherine Farrington	Can you please sign the HREA	12/12/2018 15:38	12/12/2018 15:38	Signed	View PDF
Head of Supporting Department	October 24	Ms Catherine Farrington		19/11/2018 12:20		Invalidated	View Form

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

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

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

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

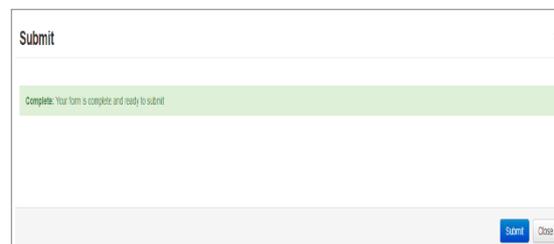
In ERM the submission and review processes are similar for all forms.

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

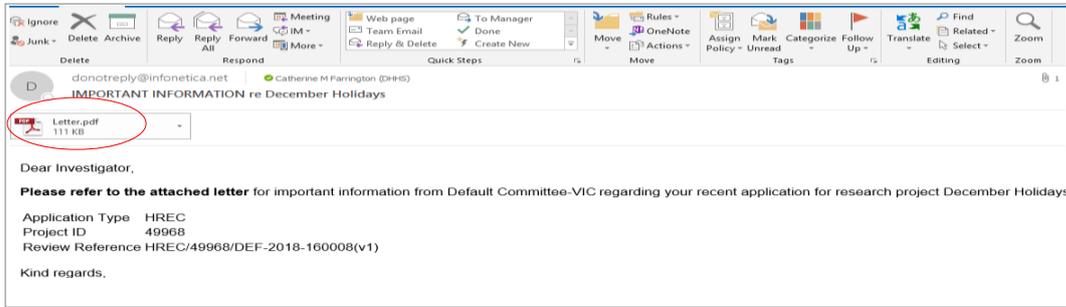
Any changes made to the submission will INVALIDATE all electronic signatures and will require all signature requests again

- 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

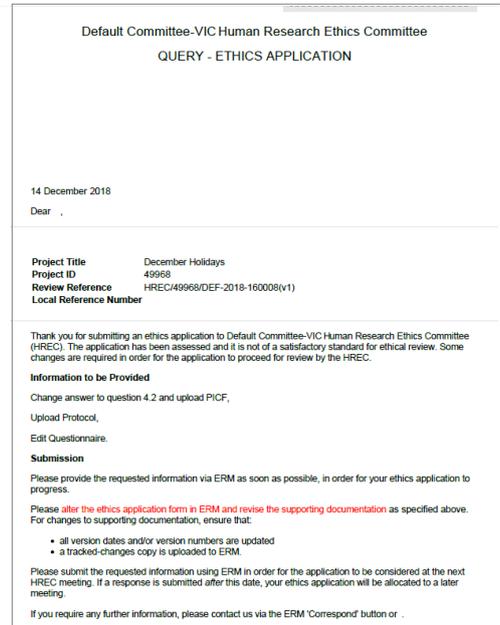
Responding to a Query from the Research Office

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

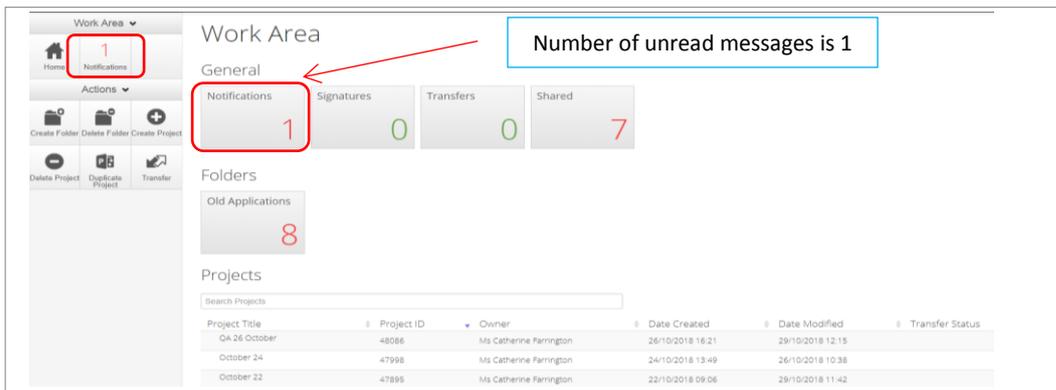


- An attached letter (pdf) from the Research Office will include details for further information to be provided via ERM
- The form will be **unlocked** to allow the applicant to complete the revisions / additions as requested

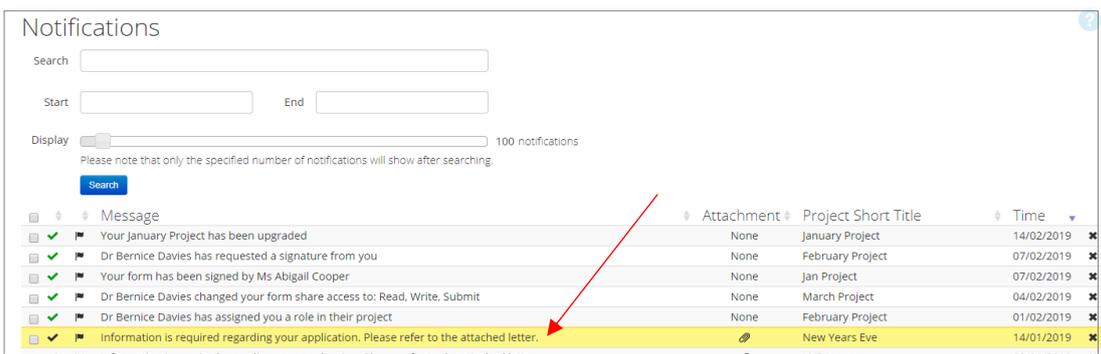


To access the Query

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

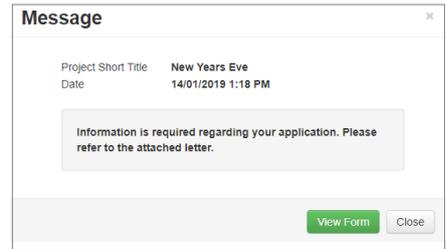


- Select the **Message** title to open and view the message

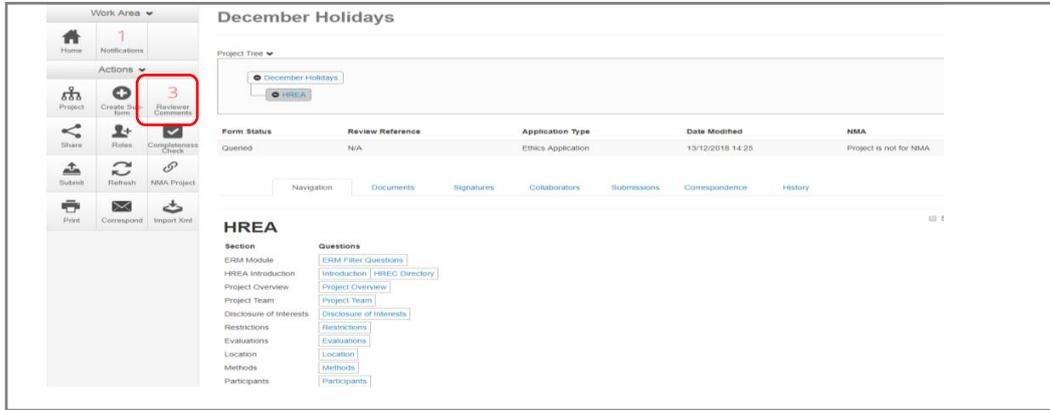


- A Message box will be displayed allowing the user to view the form

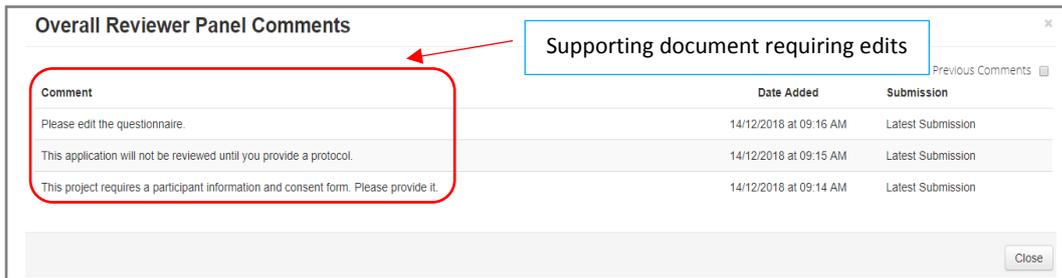
Press **View Form**  to be directed to the relevant form



- 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)



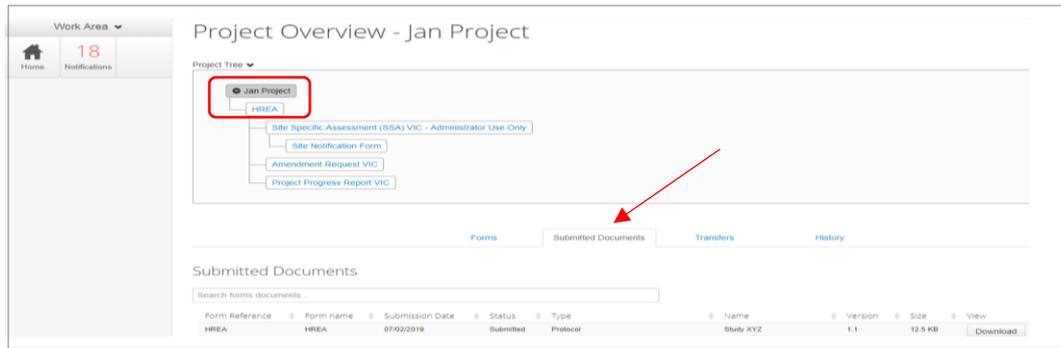
- Select a comment to be directed to the relevant section in the form i.e. to **Q 4.2 Are there any other relevant documents associated with conducting your research project?**
- As the query requires a new version of a document, the original version should be deleted, and the new version uploaded in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

- **Delete**  to delete the original version

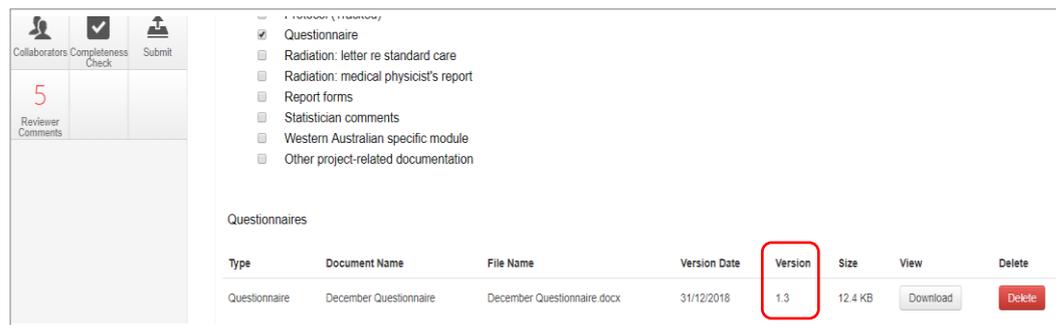


- Select **Upload Document**  to upload the revised (new) version of the document with the correct version number and date

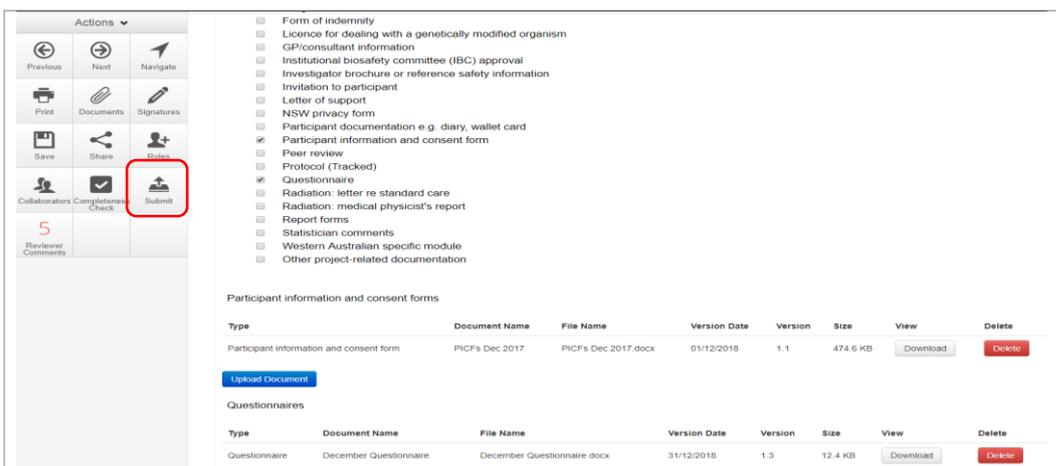
- Previous document versions are archived in **Submitted Documents** and viewed in the **Project Overview** screen



- 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

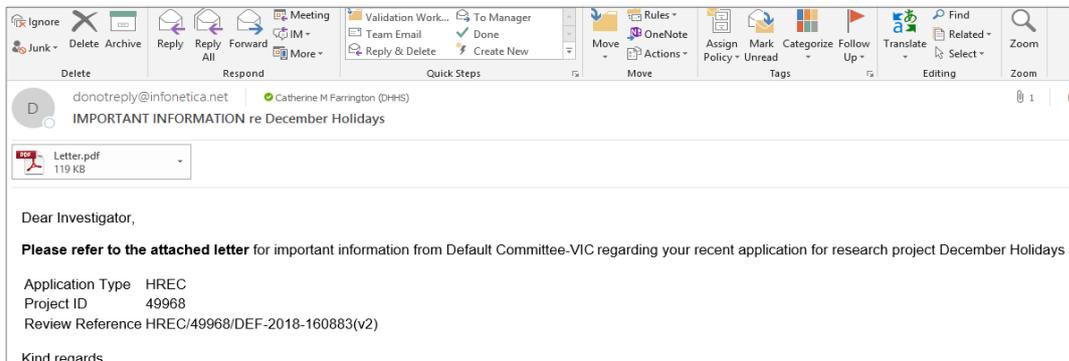


- The Research Office will receive the submission
- The application is assigned to a HREC meeting
- Following the HREC review there may be an information request from the Ethics Committee

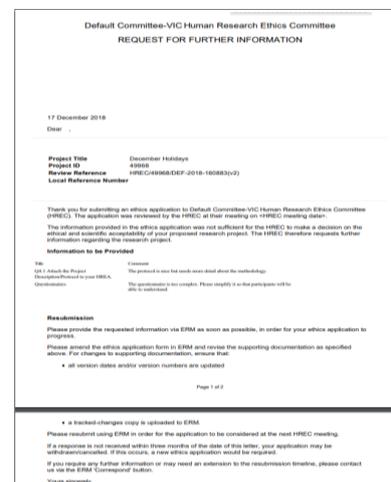
Ethics Committee Review Request

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

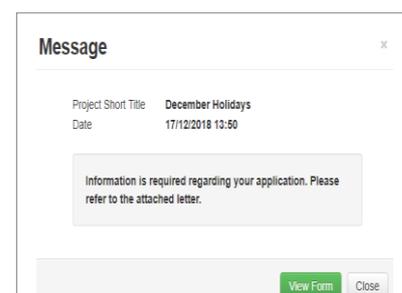


Respond to a request for further information from the Ethics Committee

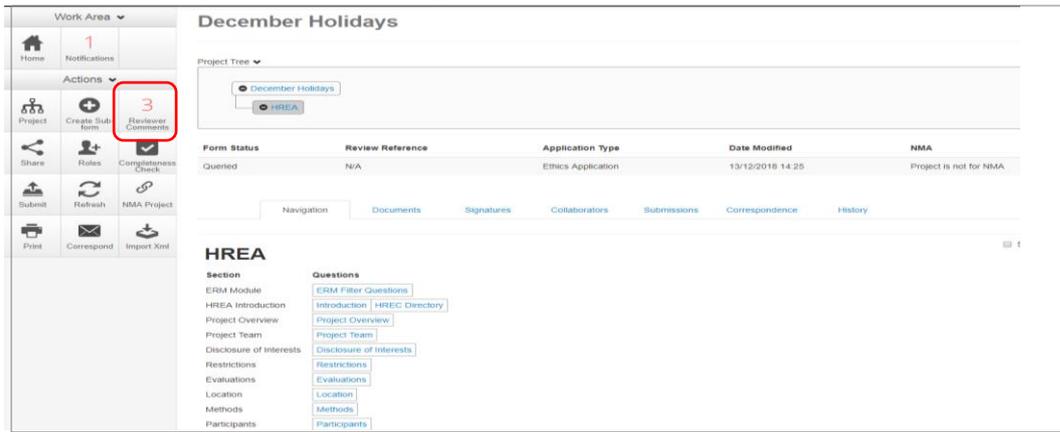
- Depending on the request, the applicant can amend the HREA and add new documents
- Log in to ERM account
- In the Work Area, click on the **Notifications** tile
- Select the Message title to open and view the message



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



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

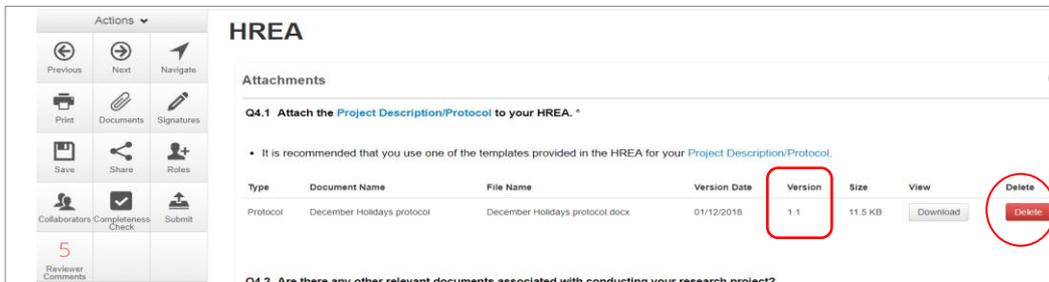


- Select **Reviewers Comments** under the Actions pane
- A text box will be displayed of the **Overall Reviewer Panel Comments**

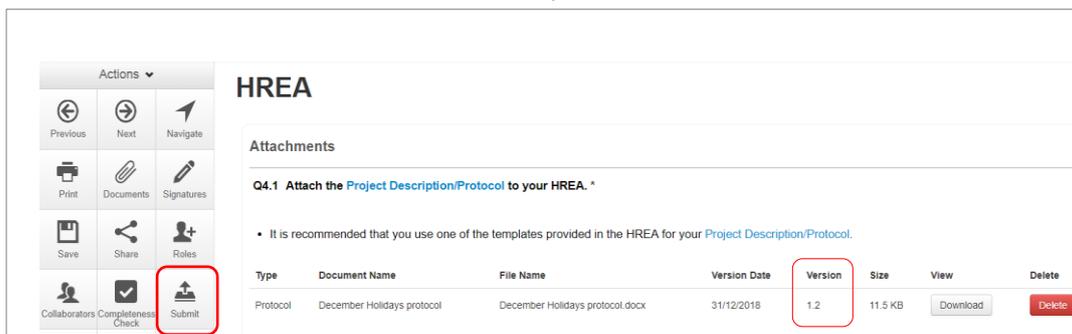


- Select a comment e.g. a comment requesting more information in the protocol, to be directed to the relevant section in the form i.e. **Q 4.1 Attach the Project Description/Protocol to your HREA**
- The request requires a new version of a protocol. The original version should be deleted, and the new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

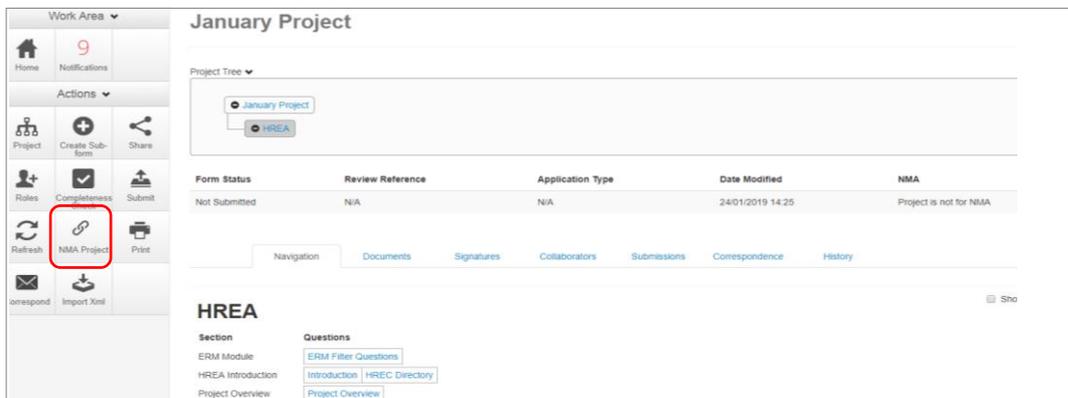
NMA is a national system for mutual acceptance of scientific and ethical review of multi-centre human research projects conducted in publicly funded health services across jurisdictions.

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**

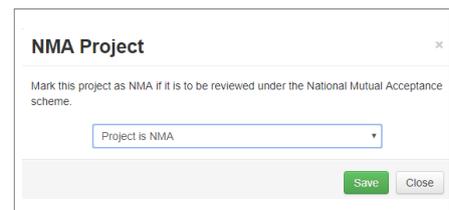


Form Status	Review Reference	Application Type	Date Modified	NMA
Not Submitted	N/A	N/A	24/01/2019 14:25	Project is not for NMA

- A NMA Project text box will be displayed

- Select **Project is NMA**

Select **Save** 



NMA Project

Mark this project as NMA if it is to be reviewed under the National Mutual Acceptance scheme.

Project is NMA

Save **Close**

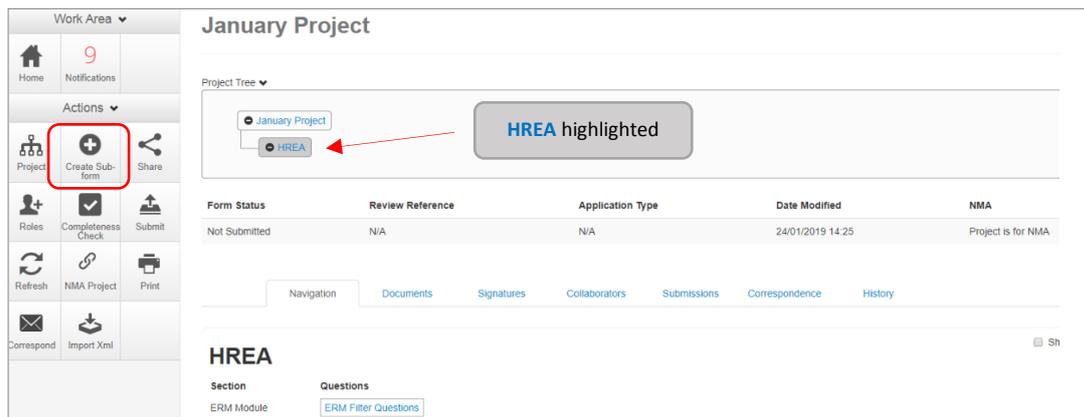
- The **Form Status Table** will be updated to 'Project is for NMA'

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

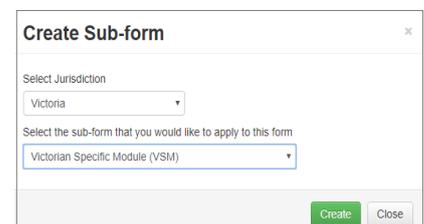


The screenshot shows the 'January Project' page in the ERM system. On the left, the 'Actions' pane contains a 'Create Sub-form' button, which is highlighted with a red box. A red arrow points from this button to the 'HREA' entry in the 'Project Tree' on the right. The 'HREA' entry is highlighted with a grey box and labeled 'HREA highlighted'. Below the Project Tree is a table with columns: Form Status, Review Reference, Application Type, Date Modified, and NMA. The table shows 'Not Submitted', 'N/A', 'N/A', '24/01/2019 14:25', and 'Project is for NMA'. Below the table are tabs for 'Navigation', 'Documents', 'Signatures', 'Collaborators', 'Submissions', 'Correspondence', and 'History'. At the bottom, there is a section for 'HREA' with 'Section' (ERM Module) and 'Questions' (ERM Filter Questions).

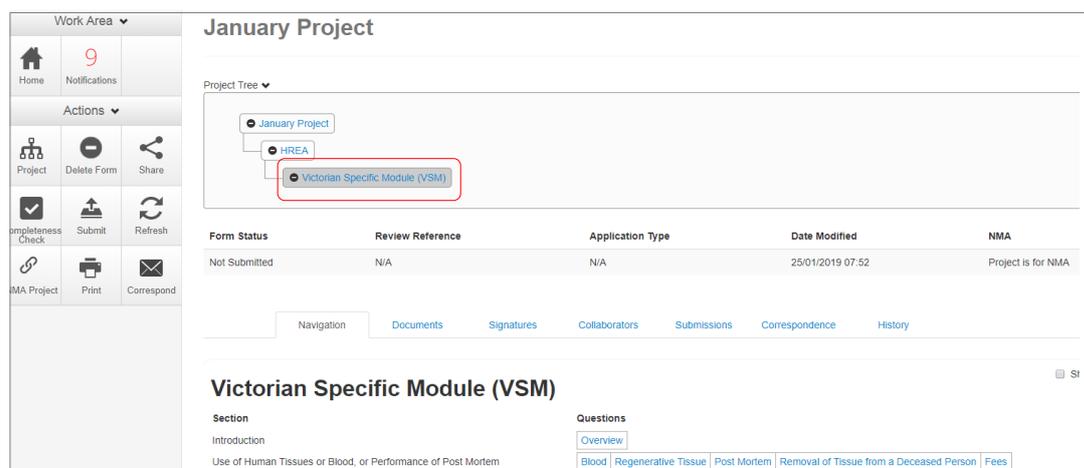
- A text box will be displayed to select the sub-form to be applied to the main form.

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

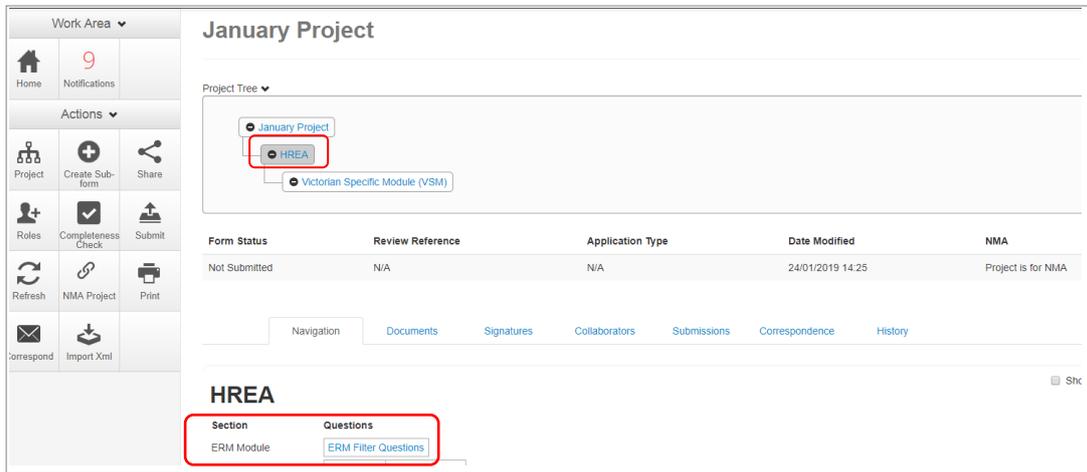


The 'Create Sub-form' dialog box is shown. It has a 'Select Jurisdiction' dropdown menu with 'Victoria' selected. Below it is a text box with the label 'Select the sub-form that you would like to apply to this form' and a dropdown menu with 'Victorian Specific Module (VSM)' selected. At the bottom right, there are 'Create' and 'Close' buttons.

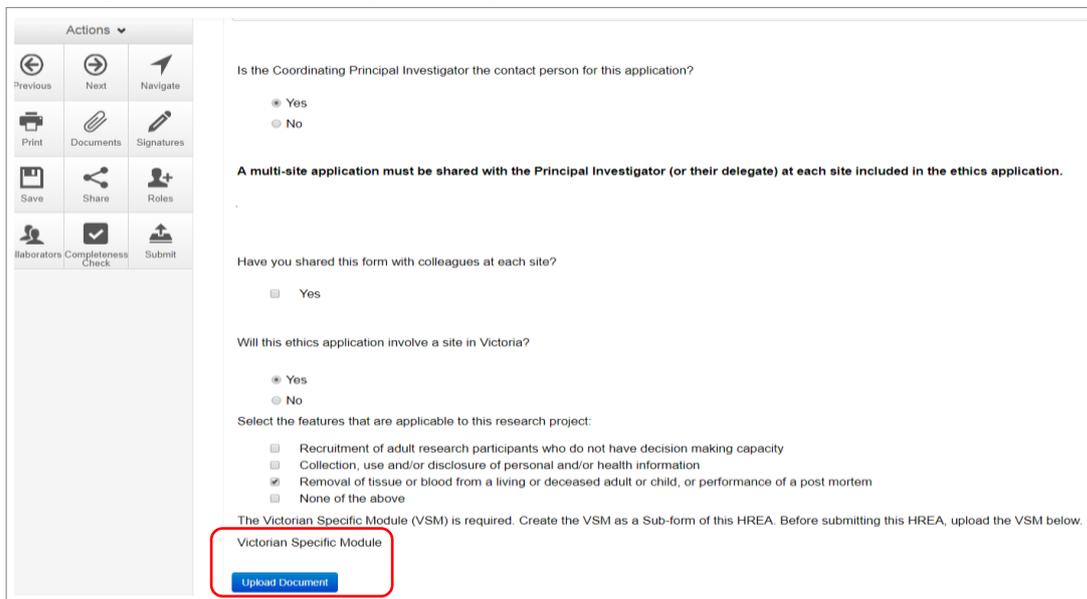


The screenshot shows the 'January Project' page in the ERM system. In the 'Project Tree', the 'Victorian Specific Module (VSM)' entry is highlighted with a red box. A red arrow points from this entry to the 'Create Sub-form' dialog box shown in the previous image. Below the Project Tree is a table with columns: Form Status, Review Reference, Application Type, Date Modified, and NMA. The table shows 'Not Submitted', 'N/A', 'N/A', '25/01/2019 07:52', and 'Project is for NMA'. Below the table are tabs for 'Navigation', 'Documents', 'Signatures', 'Collaborators', 'Submissions', 'Correspondence', and 'History'. At the bottom, there is a section for 'Victorian Specific Module (VSM)' with 'Section' (Introduction, Use of Human Tissues or Blood, or Performance of Post Mortem) and 'Questions' (Overview, Blood, Regenerative Tissue, Post Mortem, Removal of Tissue from a Deceased Person, Fees).

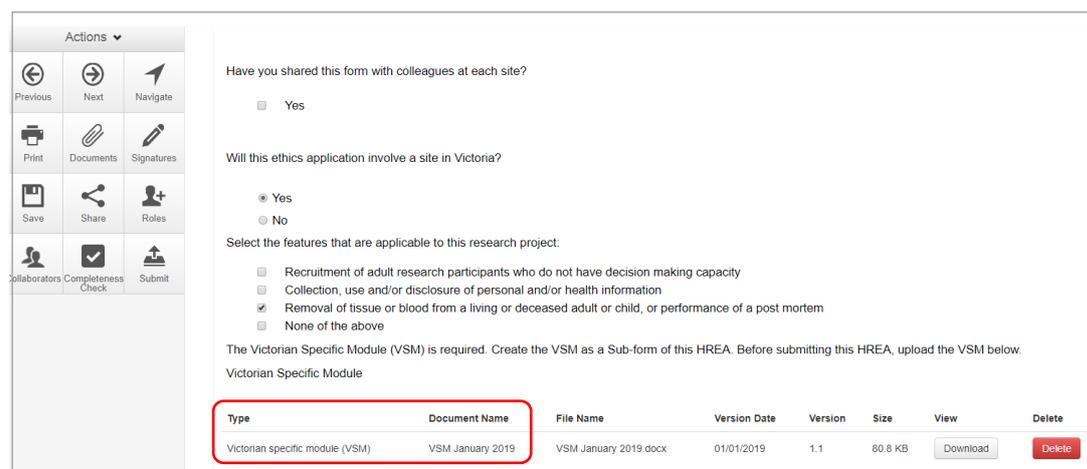
- In the VSM, select **Print**  to generate a pdf and save to your local drive
- Return to the HREA (highlighted in Project Tree) and go to the pre-HREA section **ERM Module**



- 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

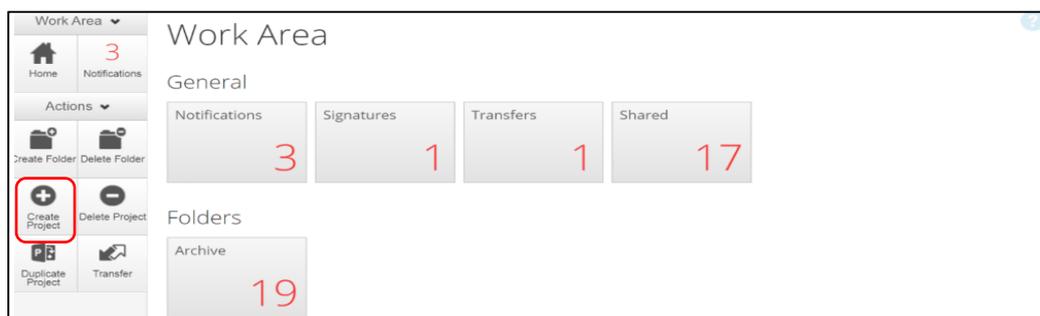
Section 7: Victorian Low and Negligible Risk Application (LNR VIC)

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.

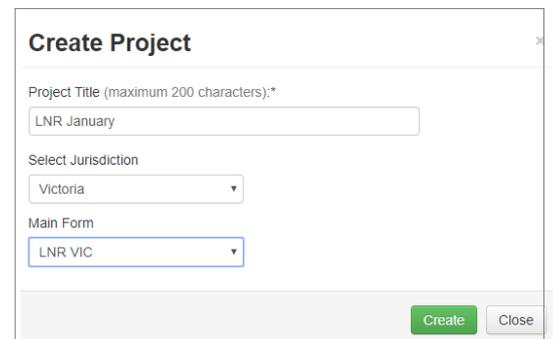
Some reviewing HRECs may not accept the LNR VIC; always discuss the research project with the reviewing organisation's Research Office before creating an ethics application for a low risk research project.

Create a LNR VIC form

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

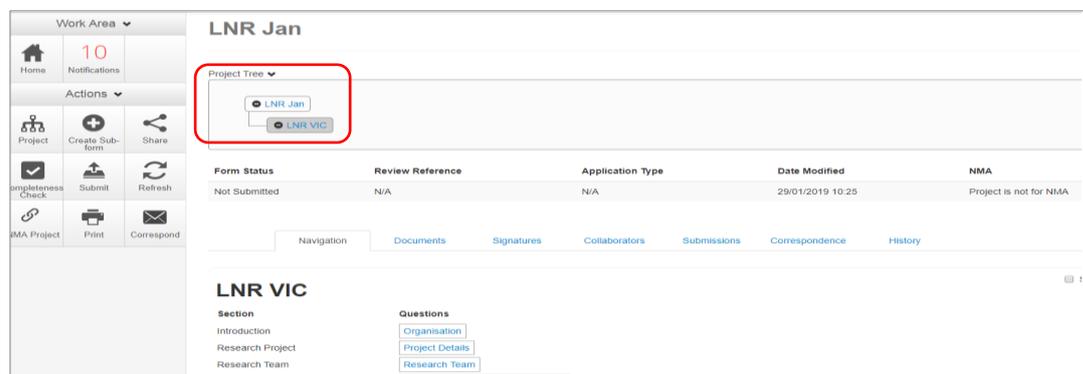


- Enter the Project Title
- Select Victoria as the reviewing jurisdiction
- Select **LNR VIC** from the Main Form options
- Select **Create** button to create the project

A screenshot of the 'Create Project' dialog box. It contains the following fields:

- Project Title (maximum 200 characters):* with the text 'LNR January' entered.
- Select Jurisdiction: A dropdown menu with 'Victoria' selected.
- Main Form: A dropdown menu with 'LNR VIC' selected.
- Buttons: 'Create' (green) and 'Close' (grey).

- 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** [Supporting Documents](#) located in the last section of the LNR VIC
- Press **Upload Document** [Upload Document](#) to attach the selected Supporting Document from your local drive
- Uploaded documents will be displayed under their type, name, file name and version
- Multiple documents of the same document type can be added by selecting [Upload Document](#) multiple times
- Specify the version and date to differentiate the documents within the same document type

LNR VIC

Supporting Documents

Upload any other supporting documents

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Other	Signature document	Signature document.docx	01/01/2019	1.1	12.5 KB	Download	Delete

[Upload Document](#)

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 +** [Roles](#) button under the Actions pane

Work Area

Home 10 Notifications

Actions

Project Create Sub-form **Roles**

Completeness Check Submit Refresh

WMA Project Print Correspond

Project Tree

- LNR Jan
- LNR VIC**

Form Status	Review Reference	Application Type	Date Modified	NMA
Not Submitted	N/A	N/A	29/01/2019 11:01	Project is not for NMA

Navigation Documents Signatures Collaborators Submissions Correspondence History

LNR VIC

Section Introduction Questions [Organisation](#)

- 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

The image displays two screenshots of the LNR VIC Declaration of Coordinating Principal Investigator form. The top screenshot shows the 'Sign' button highlighted with a red arrow and a callout box stating "Signature required by CPI for multisite application". The bottom screenshot shows a lock icon and a message "This form has been locked through signatures/requests" at the top, with the 'Sign' button also highlighted by a red arrow and a callout box stating "Signature required by PI for single site application".

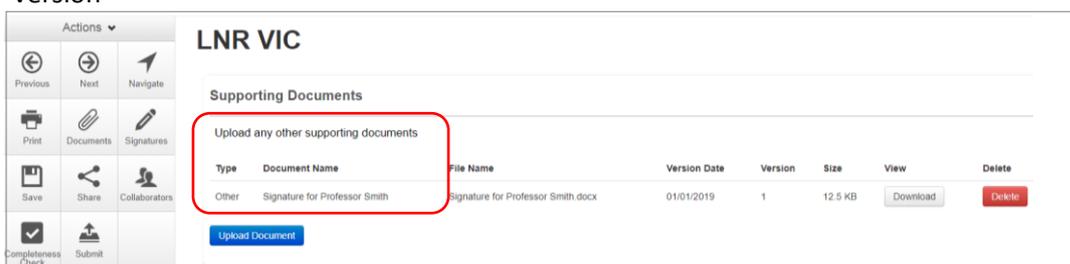
An electronic signature is obtained using **ERM**.

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](#)
- **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](#)
- **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

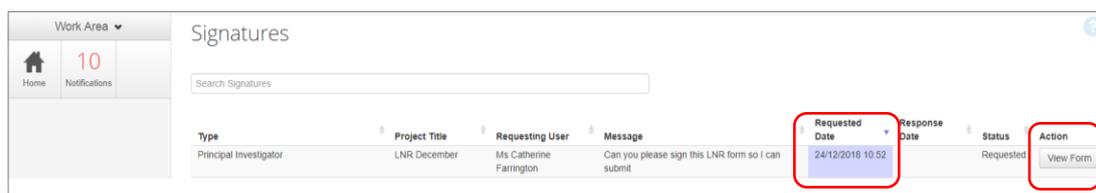
- Select **Request Signature**  button
- The system performs a completeness check to highlight any incomplete sections that need to be completed
- When all sections have been completed, select **Request Signature** 
- Enter the signatory's email address and message and select **Request**



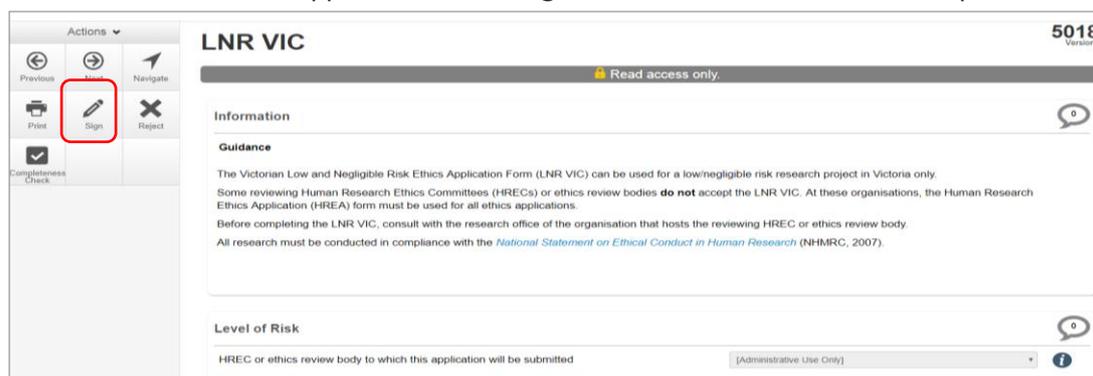
- The signatory will receive an email notification for a signature, a message and a link to ERM Log In page
- The signatory logs in to ERM
- From the **Work Area** the signatory selects **Signatures** tile to open the request



- 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

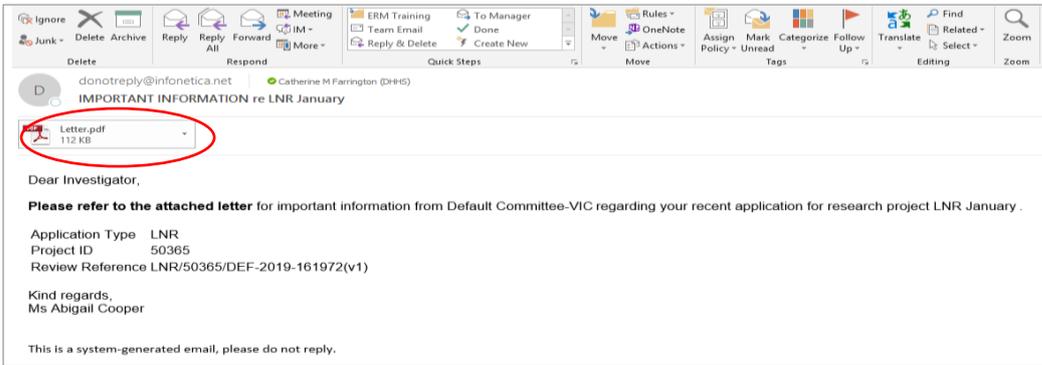
Any changes made to the submission will INVALIDATE all electronic signatures and will require all signature requests again

- 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

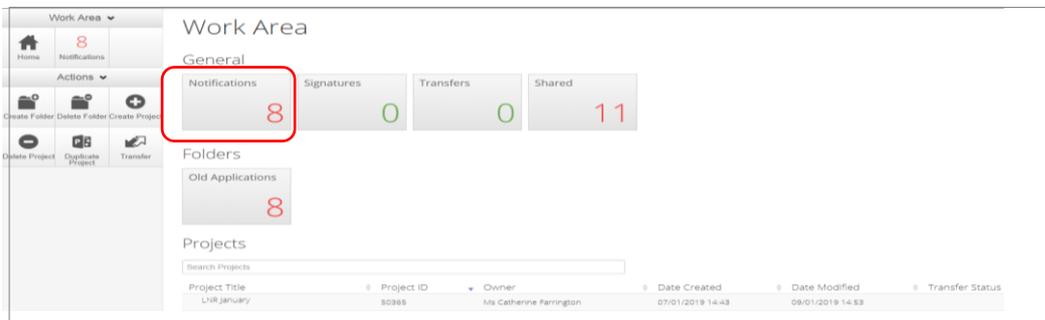


- An attached letter (pdf) from the Research Office will include details for further information to be provided via ERM
- The form will be **unlocked** to allow the applicant to complete the revisions / additions as requested

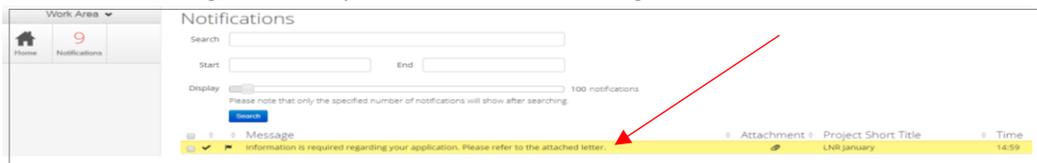


To access the Query

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

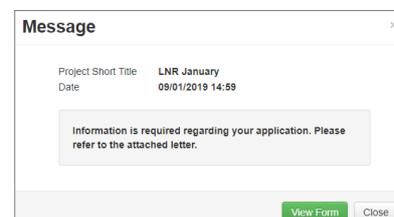


- Select the Message title to open and view the message

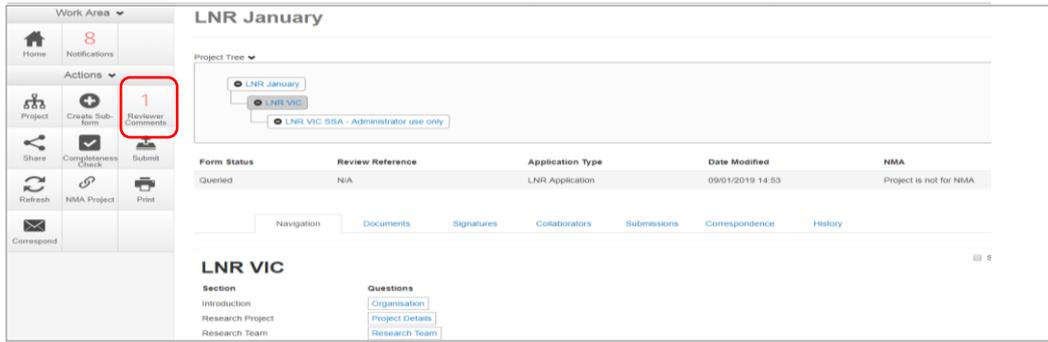


- A **Message** box will be displayed allowing the user to view the form

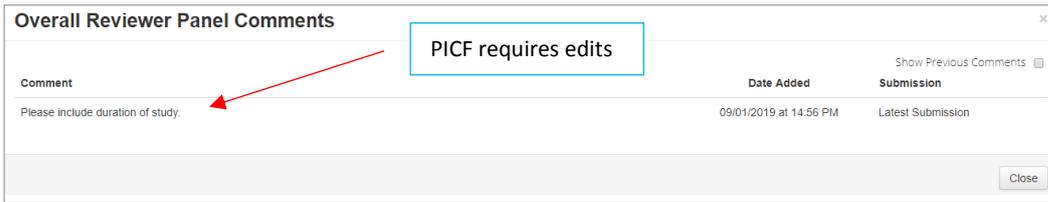
- Press **View Form**  to be directed to the relevant form



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

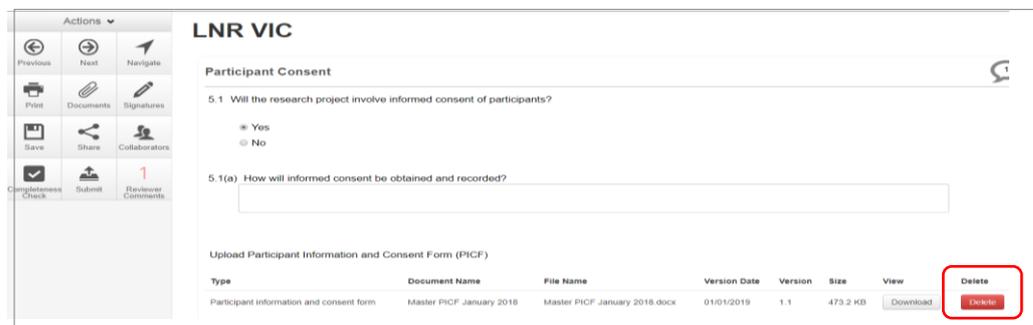


- Select **Reviewers Comments** under the Actions pane
- A text box will be displayed of the **Overall Reviewer Panel Comments**

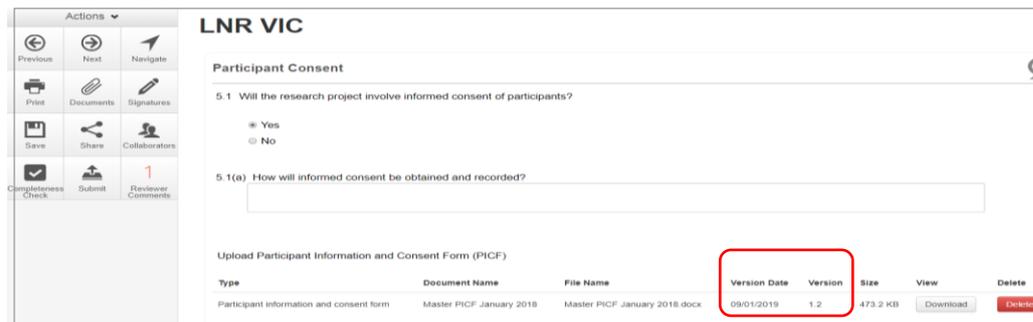


- Select the comment to be directed to the relevant section in the form i.e. to **Participant Consent Q 5.1**
- As the query requires a new version of a **document**, the original version should be deleted, and the new version uploaded in to the form. Previous document versions are automatically archived.

- 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 screenshot shows a web interface for 'LNR January'. On the left is a navigation pane with an 'Actions' section containing a 'Submit' button (highlighted with a red box). The main content area shows a 'Project Tree' with 'LNR January' and 'LNR VIC' nodes. Below this is a table with the following data:

Form Status	Review Reference	Application Type	Date Modified	NMA
Querted	NIA	LNR Application	09/01/2019 16:03	Project is not for NMA

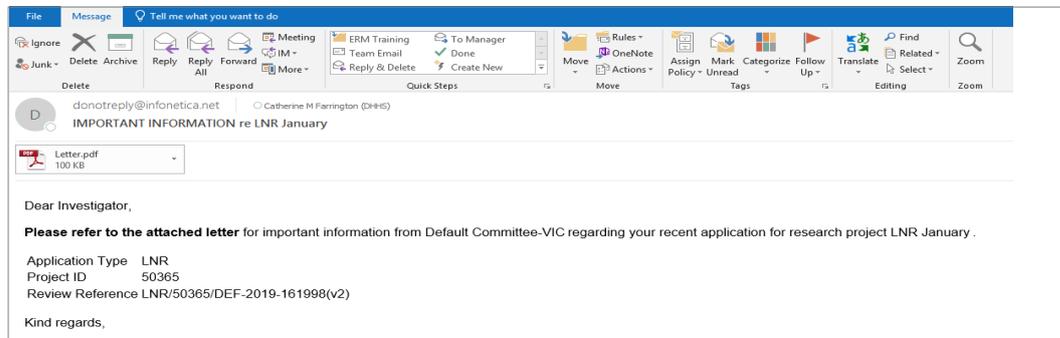
Below the table are navigation tabs: Navigation, Documents, Signatures, Collaborators, Submissions, Correspondence, History. At the bottom, there is a section for 'LNR VIC' with 'Introduction' and 'Research Project' links, and a 'Questions' section with 'Organisation' and 'Project Details' links.

- 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.

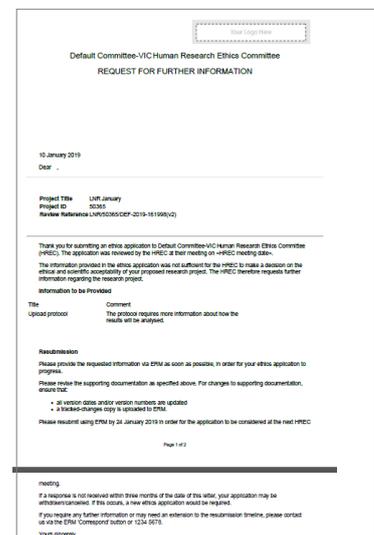
Ethics Committee Review Request

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

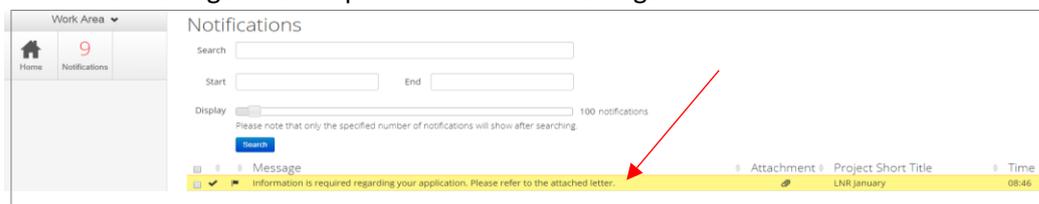


- An attached letter (pdf) from the HREC will include requests for further information to be provided via ERM
- The form is **unlocked** to allow the applicant to complete the requests as outlined in the attached letter

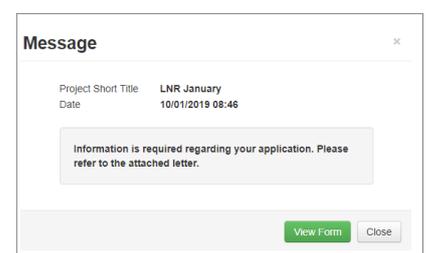


Respond to a request for further information from the Ethics Committee

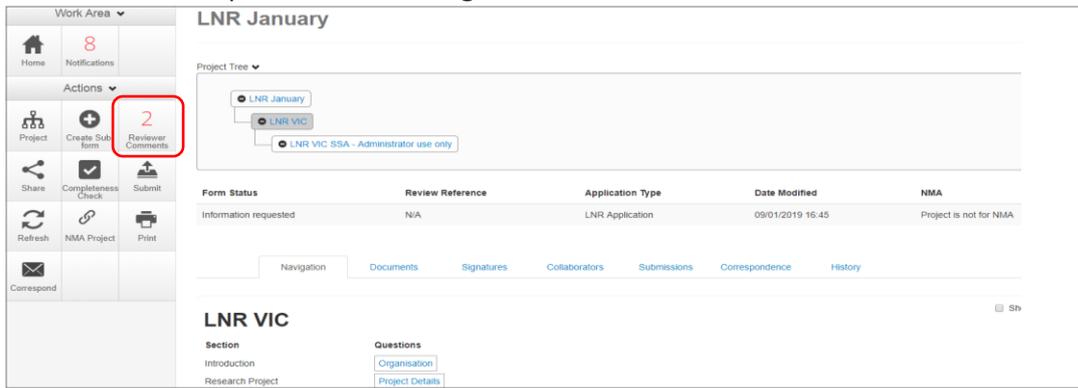
- Depending on the request, the applicant can amend the LNR VIC form and add new documents
- Log in to ERM account
- In the Work Area, click on the **Notifications** tile
- Select the Message title to open and view the message



- 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

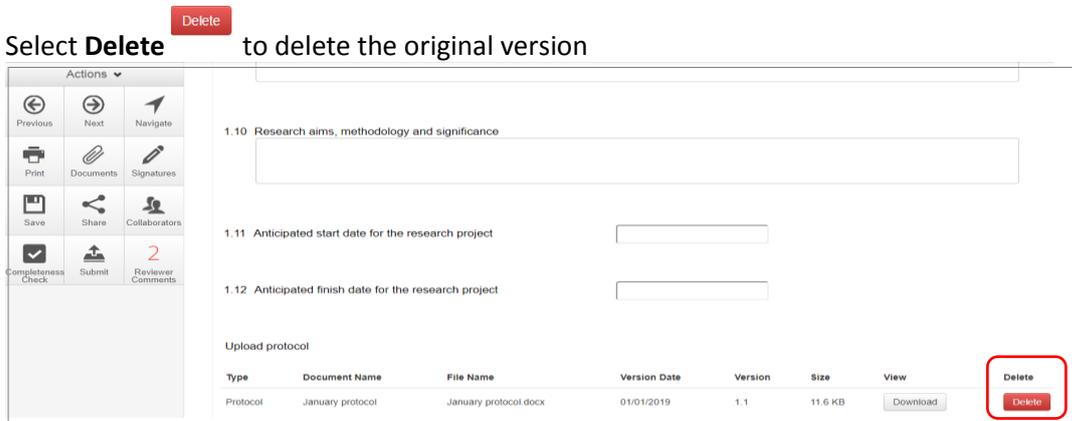


- Select **Reviewers Comments** under the Action pane
- A text box will be displayed of the **Overall Reviewer Panel Comments**

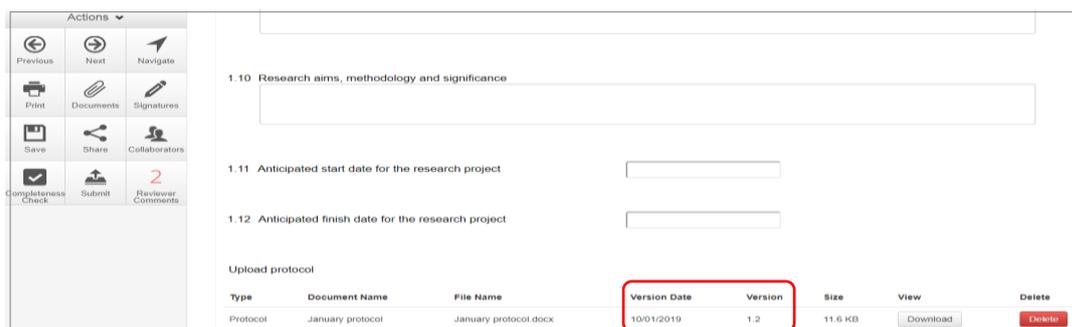
Overall Reviewer Panel Comments

Comment	Date Added	Submission	Show Previous
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

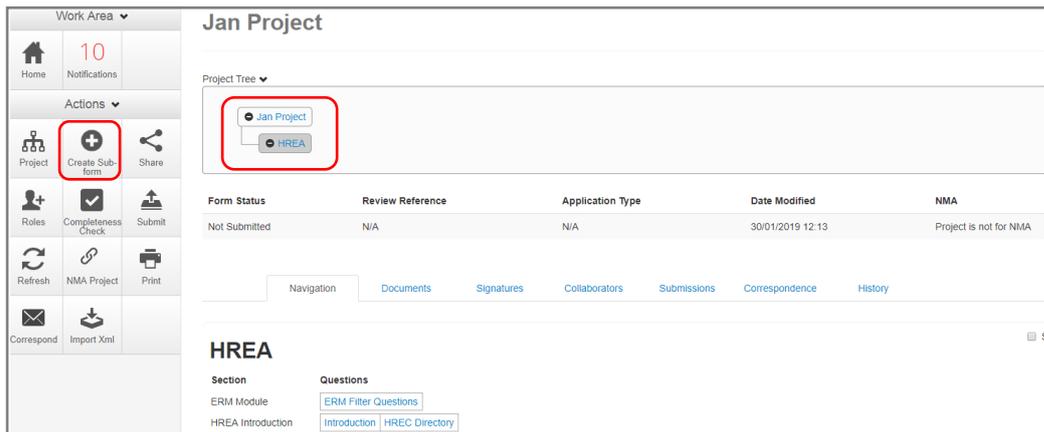
- Applicants are informed of decisions by the HREC via email using ERM. If the application has been approved, the form is locked
 - Log on to ERM and click on **Notifications** tile
 - A formal approval letter from the HREC can be downloaded by the applicant
- If the application review outcome is **not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

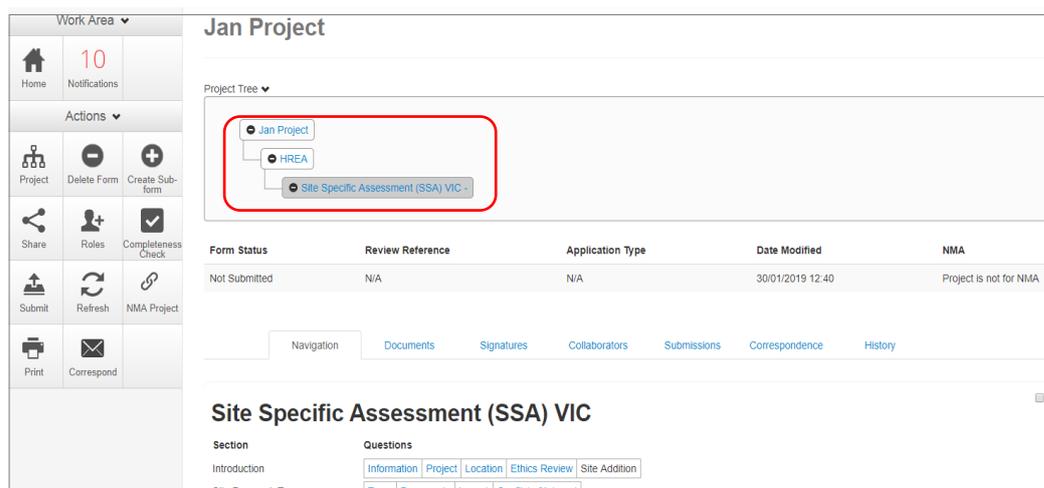
- From the HREA or LNR VIC, select **Create Sub-form** button under the actions pane



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

The 'Create Sub-form' dialog box is shown. It has a title bar with 'Create Sub-form' and a close button. Inside, there is a 'Select Jurisdiction' dropdown menu with 'Victoria' selected. Below it is a text prompt: 'Select the sub-form that you would like to apply to this form'. Underneath is another dropdown menu with 'Site Specific Assessment (SSA) VIC' selected. At the bottom right are two buttons: 'Create' (green) and 'Close' (grey).

- 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.

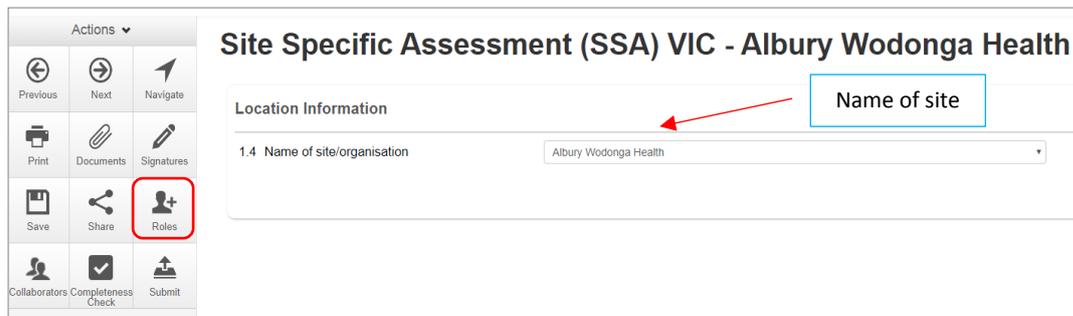
The creation and management of site SSAs in **ERM** should be determined by the CPI / delegate.

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

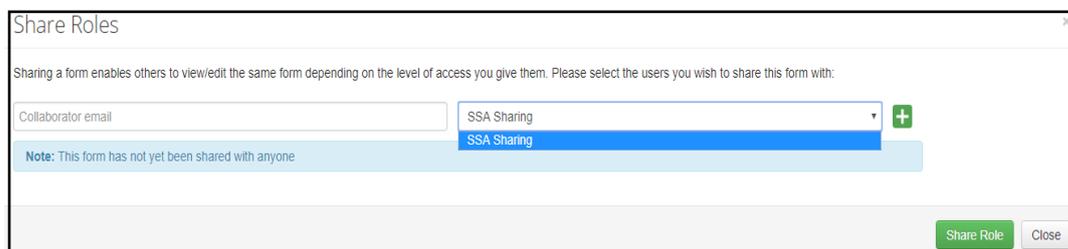
Enter the collaborator's (site PI) email address and select **SSA Sharing**

This level of access includes all of the following – read

write

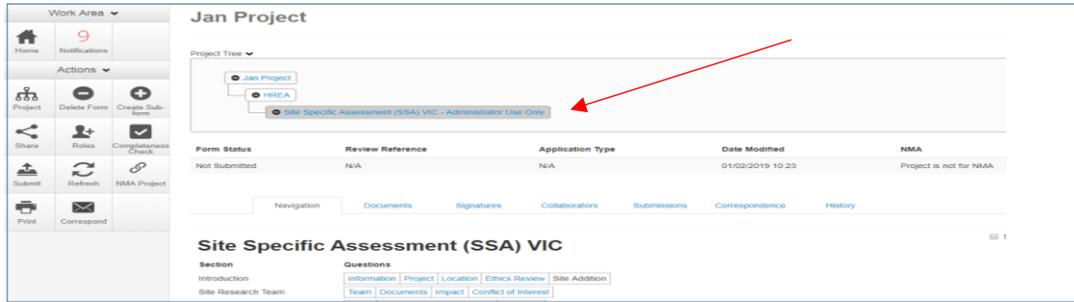
create subforms e.g. Site Notification Form

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

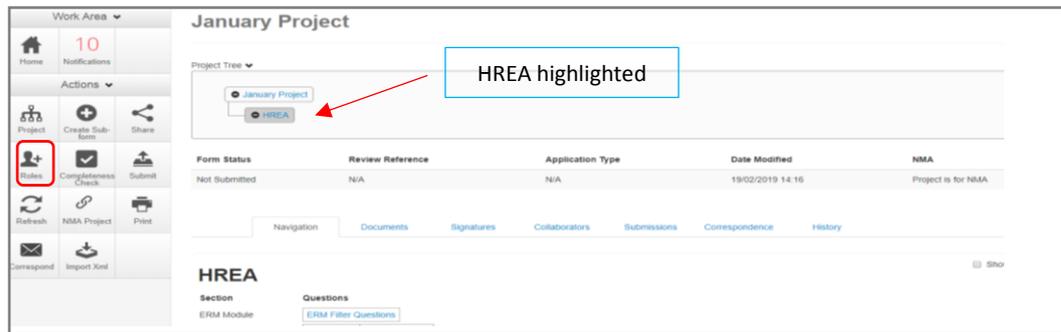
- Using **Roles +** allows the collaborator to also view the HREA form



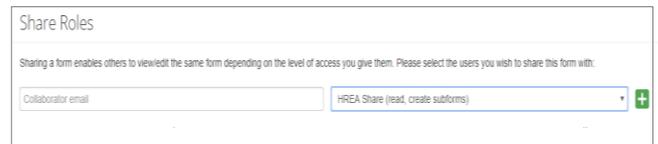
- Complete the SSA form

(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)**



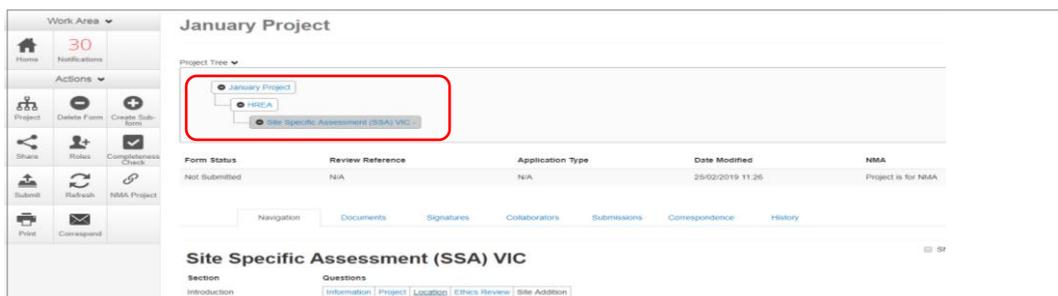
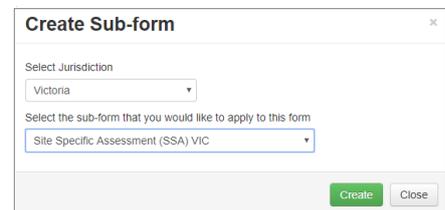
- Select **Share Role** 
- The collaborator will receive an email notification about their assigned role in the project
- The collaborator logs into ERM and follows the steps as described in [Assign access to the HREA](#)
- The project (HREA) will be displayed in the Project Tree

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

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Participant information and consent form	PICFs Dec 2017(site specific version)	PICFs Dec 2017(site specific version).docx	31/12/2017	1.1	269.6 KB	Download	Delete

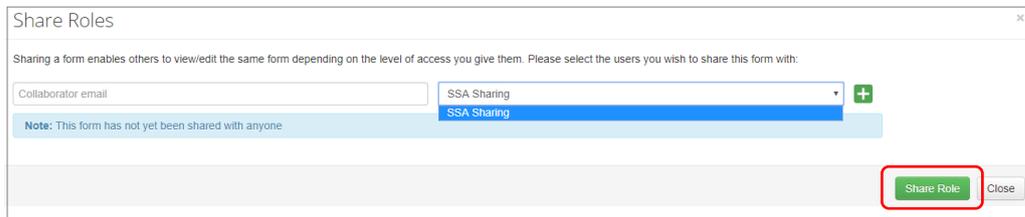
- Documents will also be displayed under **Documents** tab and can be downloaded

Type	Document Name	File Name	Version Date	Version	Size	View
Participant information and consent form	PICFs Dec 2017(site specific version)	PICFs Dec 2017(site specific version).docx	31/12/2017	1.1	269.6 KB	Download

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

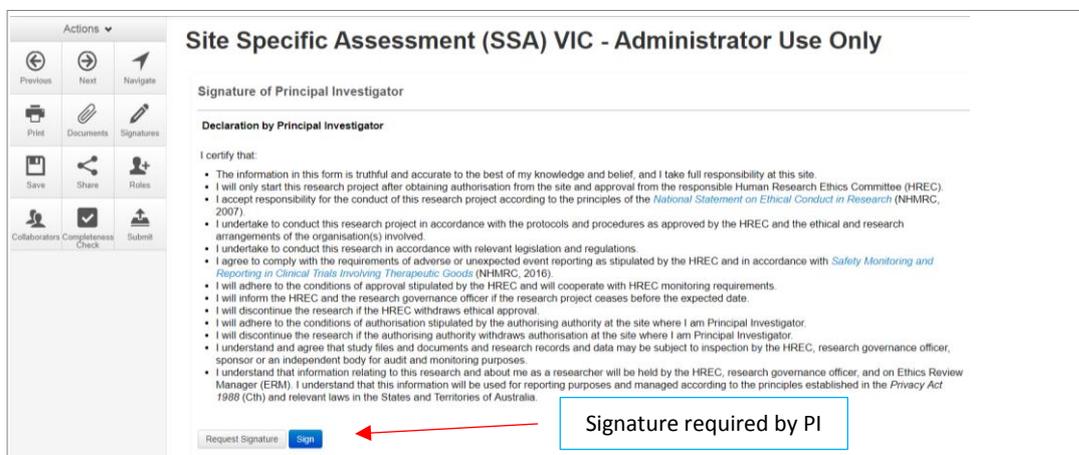


- The collaborator will receive an email notification regarding access to the project
- The collaborator logs in to ERM and follows the steps as described in [Assign access to the HREA](#)
- The collaborator will be able to view and edit the SSA

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, before 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**  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**  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**  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**  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**  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**  button under the Actions pane

Site Specific Assessment (SSA) VIC -

Read access only.

Signature of Head of Department

- A Head of Department may delegate responsibility to an appropriate staff member.
- An investigator must **not** approve their own research on behalf of their department. If an investigator is also Head of Department, certification must be sought from the person to whom the Head of Department is responsible.

Who is providing signature?

Head of Department
 Head of Department's Delegate

Name

Department

Declaration by Head of Department

I certify that:

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

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

Sign Form

Please enter your login details in order to sign this form:

Username Password

Sign Close

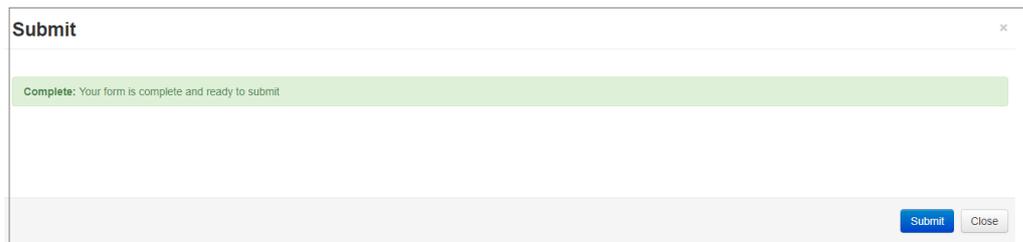
- The applicant receives an email notification indicating the signature request has been accepted by the signatory i.e. the form has been signed
- Repeat the signatory process for electronic signatures for other signatories
- Once the signature is complete the application is ready for submission

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

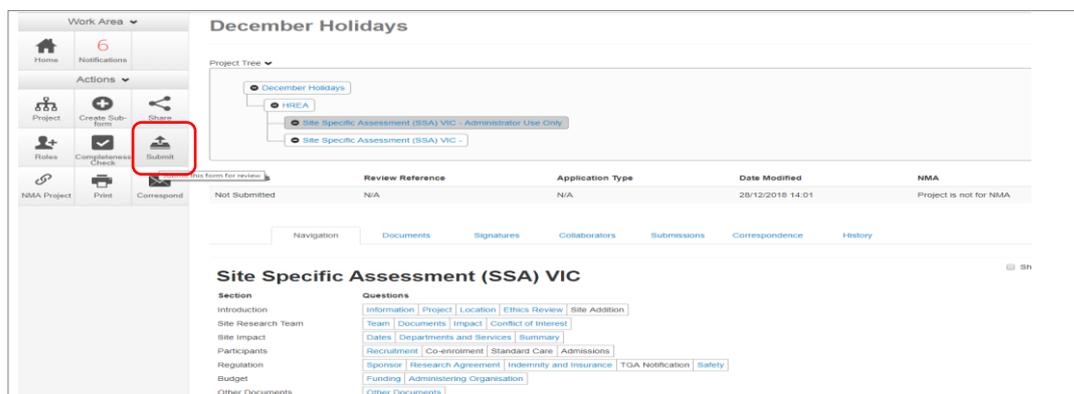


- Select the **Submit**  button

Recall an application

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

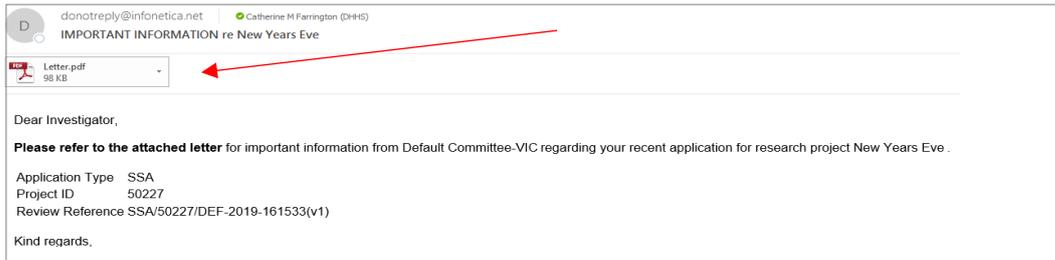
- Once the SSA application has been submitted, a recall option becomes available
- This action removes the submitted application from the Research Office's ERM account
- The form can be recalled **until** the submission is actioned by the Research Office
- Select the **Recall**  button under the Actions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



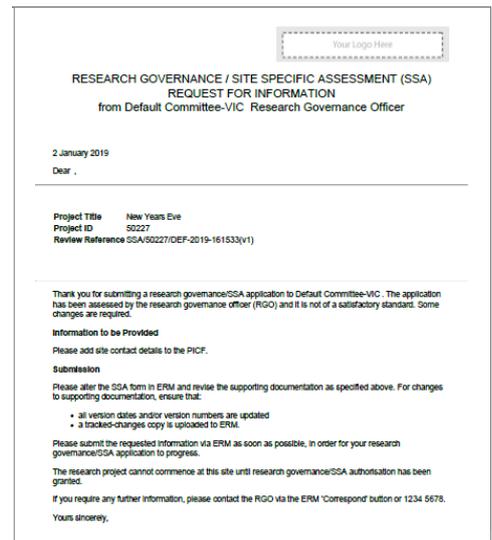
Responding to a Query from the Research Office

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



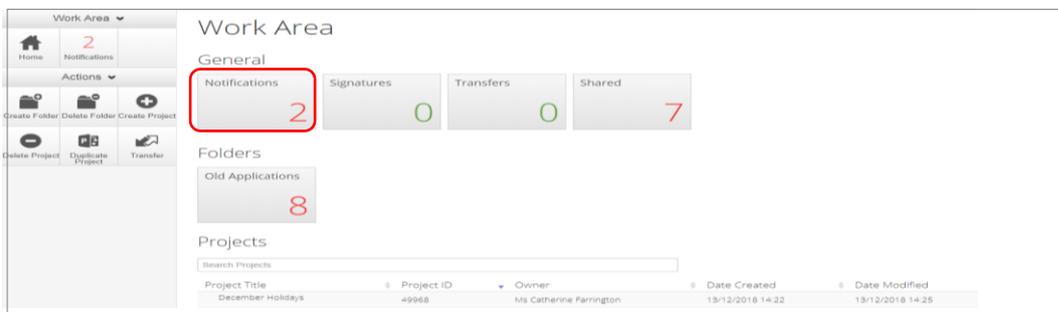
- An attached letter (pdf) from the Research Office will include details for further information to be provided via ERM



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

To access the Query

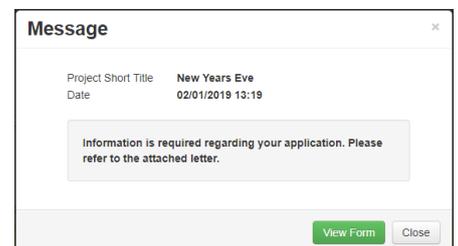
- In the Work Area, click on the **Notifications** tile



- Select the Message title to open and view the message

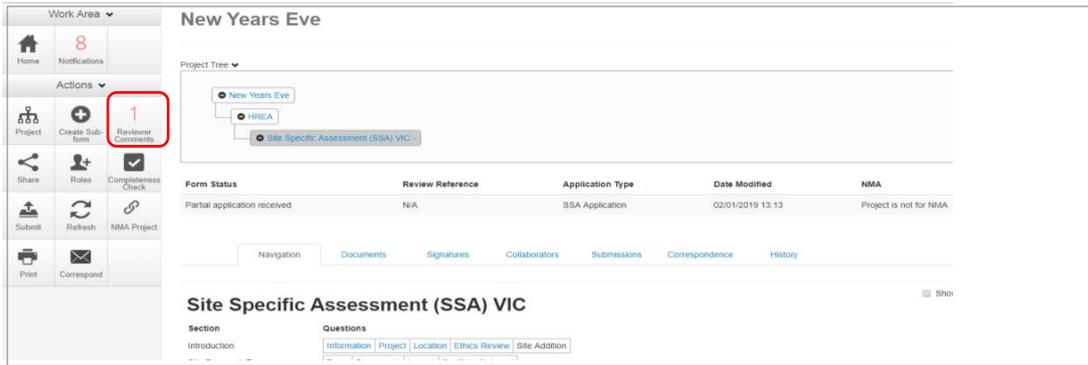


- A **Message** box will be displayed allowing the user to view the form
- Press **View Form**  to be directed to the relevant form

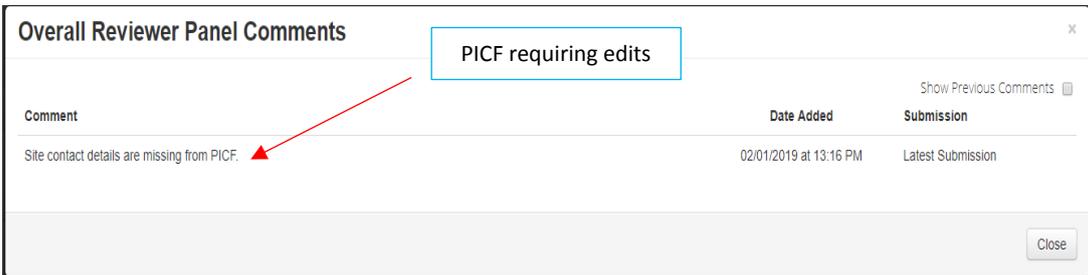


- The SSA form will open under the **Navigation** tab

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



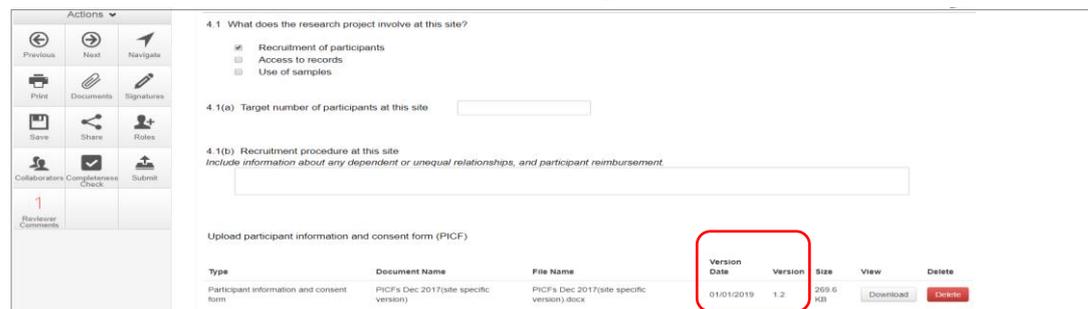
- A text box will be displayed of the **Overall Reviewer Panel Comments**



- 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

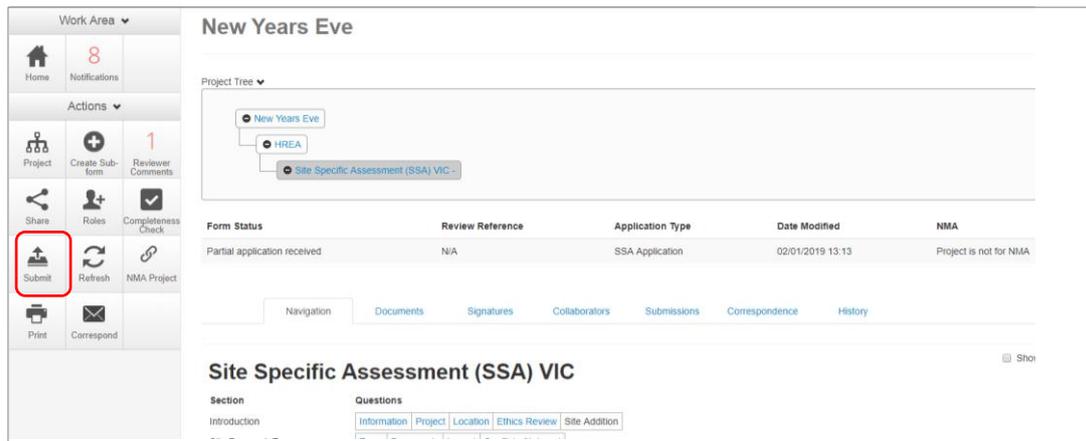


- Select **Upload Document**  to upload the revised (new) version of the document with the correct version number and date
- The SSA form now includes the latest version ready for resubmission



- 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

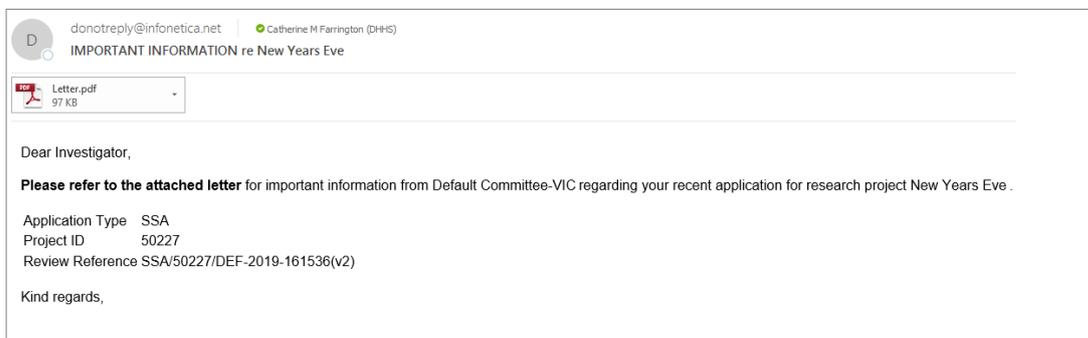


- The Research Office will receive the submission
- The SSA application is assessed by the Research Governance Officer (RGO)
- Following the assessment there may be an information request from the RGO

RG0 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



- 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



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.

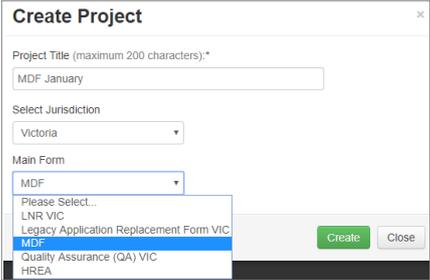
Section 11: Minimal Dataset Form (MDF)

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.

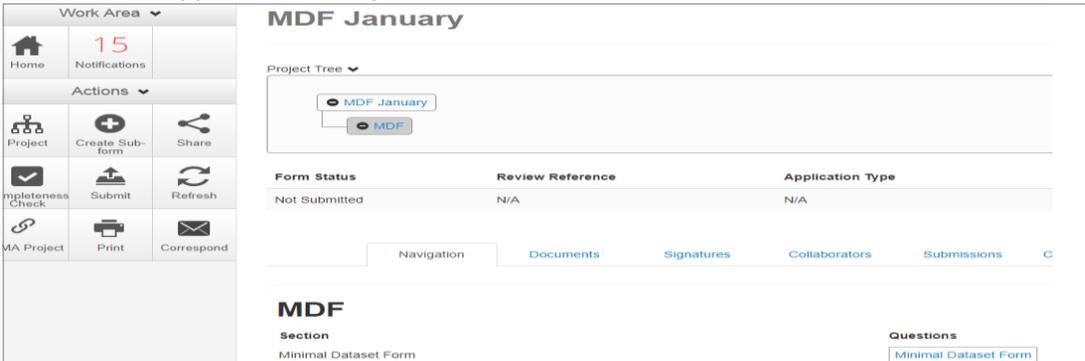
The site Principal Investigator uses ERM to complete the SSA and submit to the site Research Governance Officer.

- The CPI / delegate logs onto ERM
- Select **Create Project**  button under the Actions pane to create a new Main Form

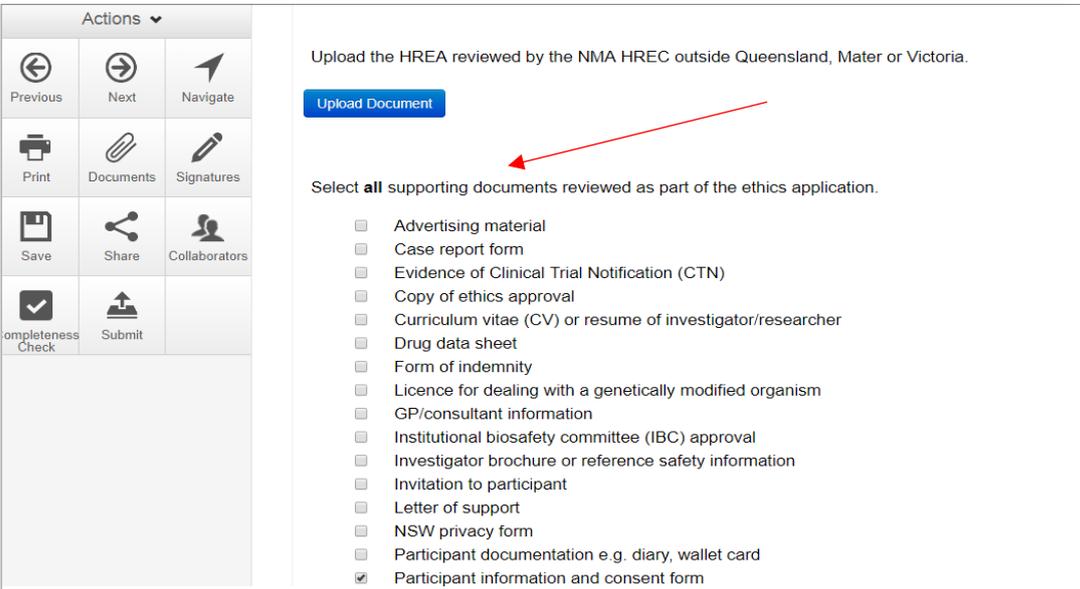
- Enter the Project Title, jurisdiction and select **MDF** from the Main Form drop-down list
- Select **Create** button



- 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

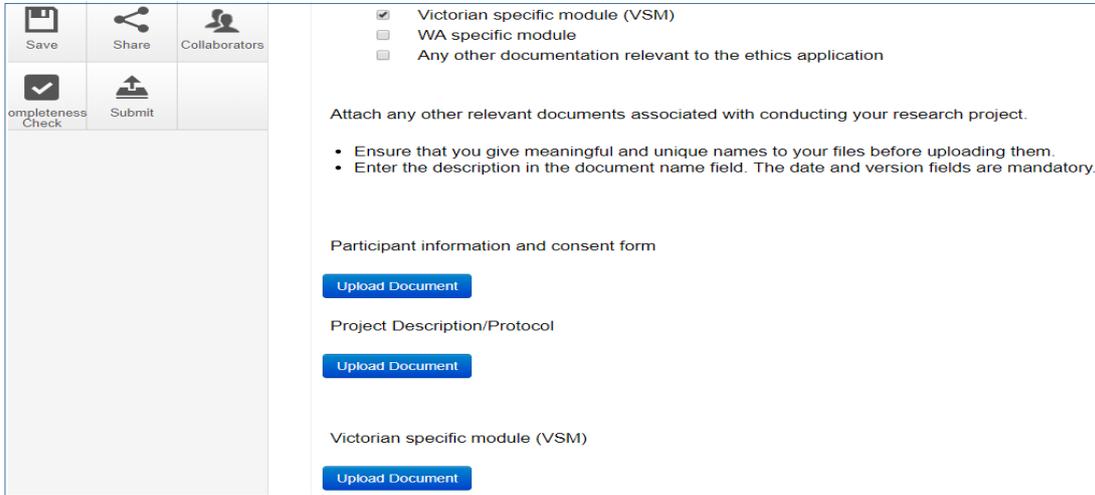


Form Status	Review Reference	Application Type
Not Submitted	N/A	N/A

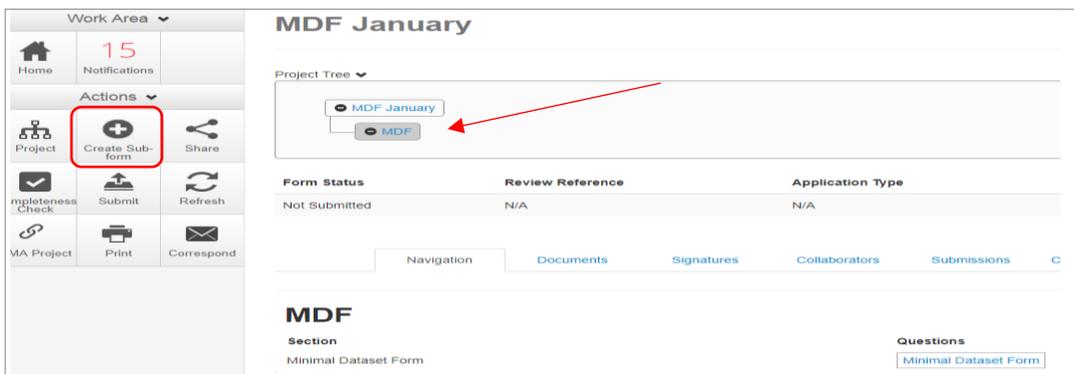
- Advertising material
- Case report form
- Evidence of Clinical Trial Notification (CTN)
- Copy of ethics approval
- Curriculum vitae (CV) or resume of investigator/researcher
- Drug data sheet
- Form of indemnity
- Licence for dealing with a genetically modified organism
- GP/consultant information
- Institutional biosafety committee (IBC) approval
- Investigator brochure or reference safety information
- Invitation to participant
- Letter of support
- NSW privacy form
- Participant documentation e.g. diary, wallet card
- Participant information and consent form

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

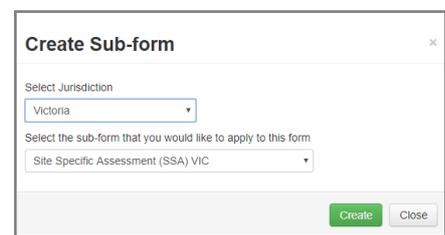
Ensure the Victorian Specific Module is selected. The CPI should provide a copy of the VSM that was submitted to the reviewing HREC



- 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.

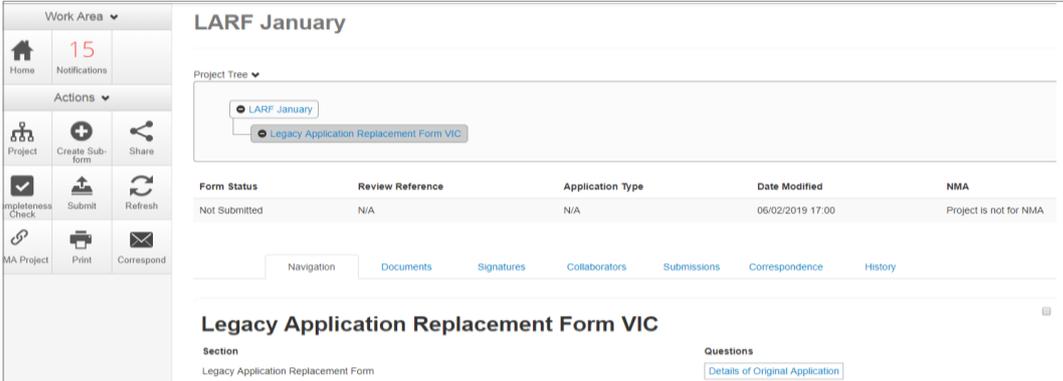
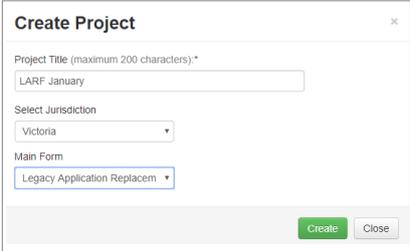
Section 12: Legacy Application Replacement Form (LARF)

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.

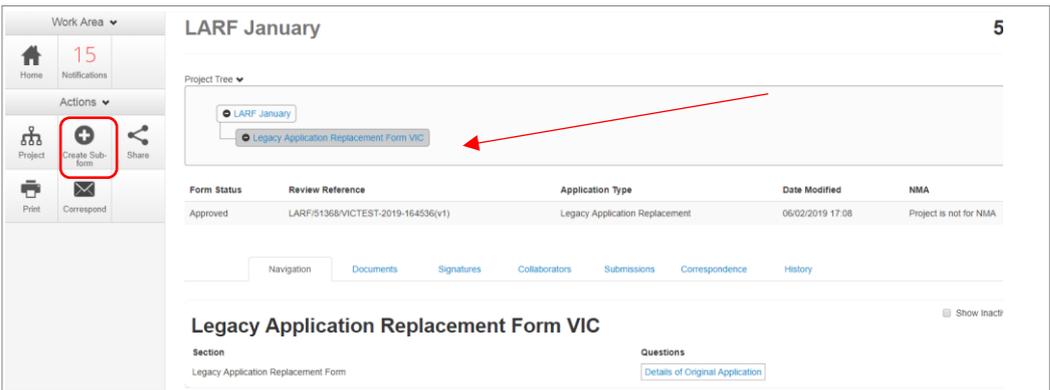
The LARF is not an ethics application form; it is a proxy form that allows sub-forms e.g. post approval forms to be created in ERM. Only **one** LARF is required for the research application.

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

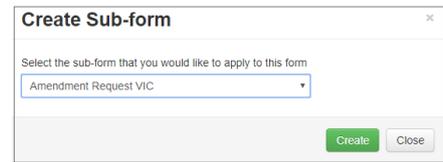
- The CPI / delegate logs onto ERM
- Select **Create Project**  button under the Actions pane to create a new Main Form
- Enter the Project Title, jurisdiction and select **Legacy Application Replacement Form** from the main form drop-down list
- Select **Create** button
- The LARF will appear under the Project Tree



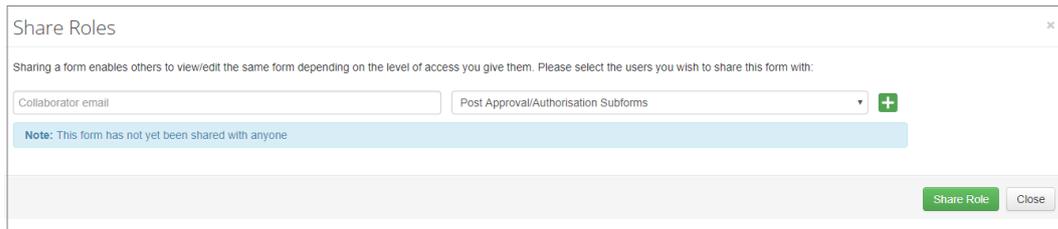
- Complete the questions in the LARF
- Select the **Submit**  button under the Actions pane
- The form will be submitted to the organisation that reviewed the original application
- From the LARF the CPI / delegate creates a new sub-form



- 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.

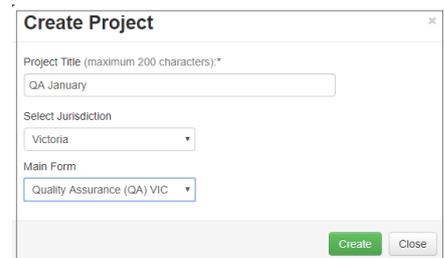
Consult with the organisation's Research Office before creating the QA application for advice on the criteria for QA.

- The applicant logs onto ERM

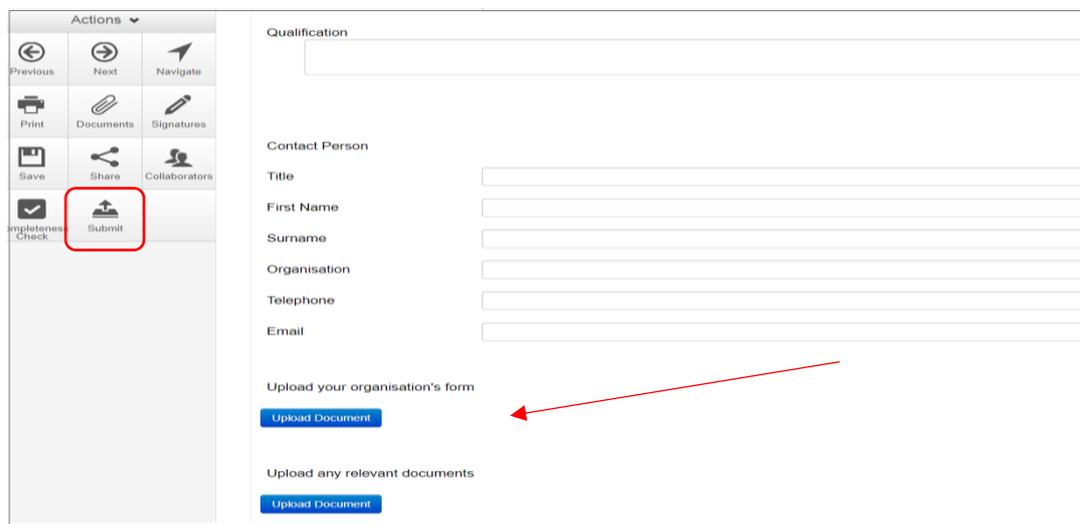
- Select **Create Project**  button under the Actions pane to create a new Main Form

- Enter the Project Title, jurisdiction and select **Quality Assurance (QA) VIC** from the main form drop-down list

Select **Create**



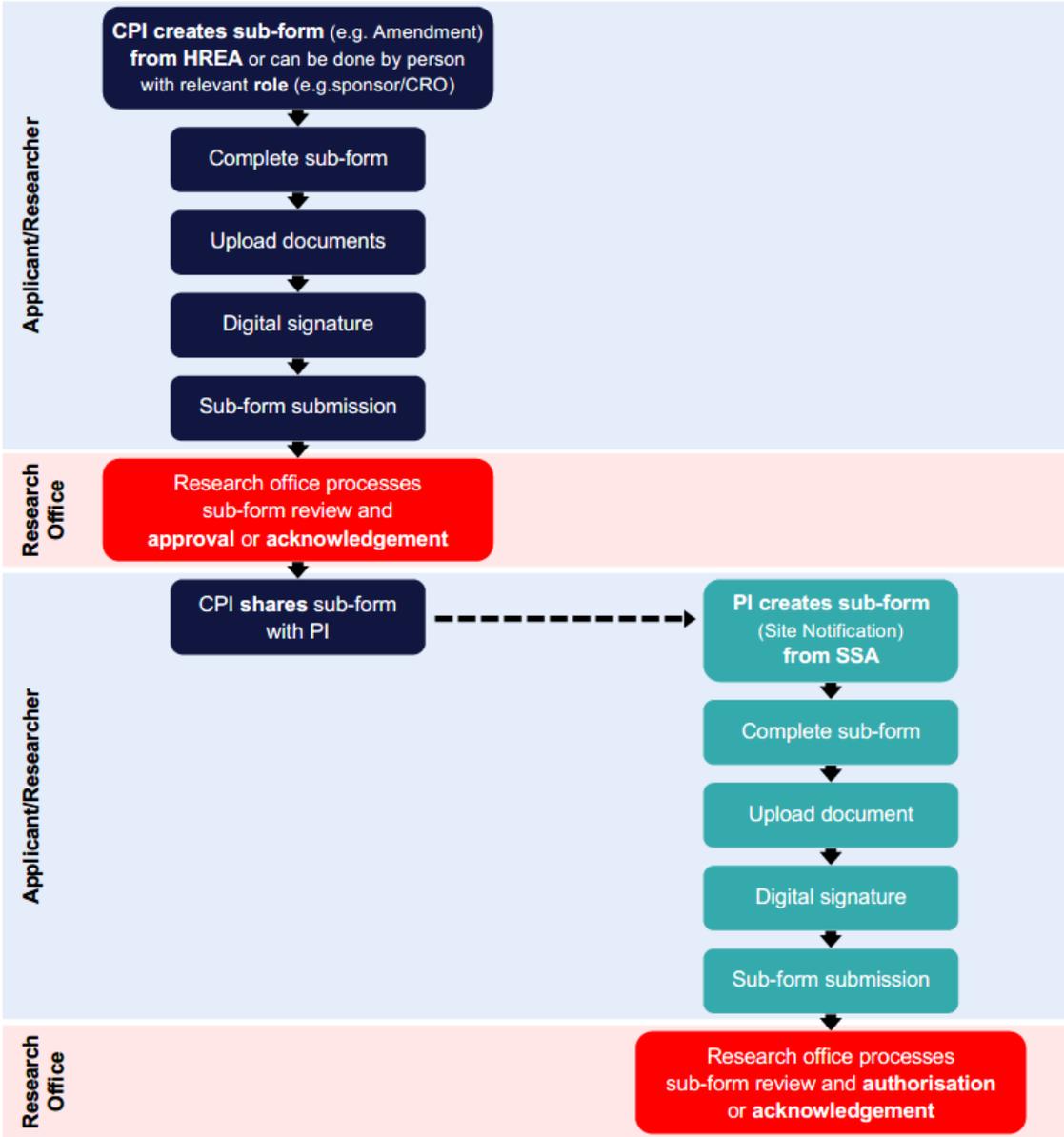
- The QA form will appear under the Project Tree
- Complete the questions in the QA form
- Select **Upload Document**  to attach the organisation's QA Application Form and other relevant documents



- Select **Submit**  button under the Actions pane to submit the application to the reviewing organisation.

Ethical Review Manager (ERM)

Post-approval and Post-authorisation



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

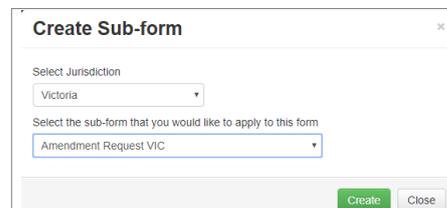
- Amendment Request
- Project Notification Form
- Project Progress Report
- Project Final Report
- Site Closure Report
- Safety Report
- Annual Safety Report
- Serious Breach Report
- Suspected Breach Report

Create a Sub-form

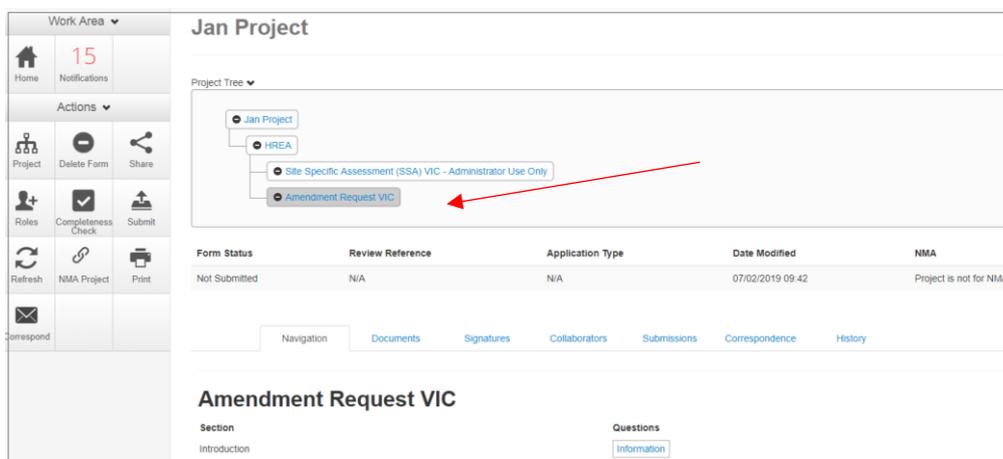
- The CPI / delegate logs in to ERM
- Select the project title to display the project under the Project Tree and highlight the HREA

- 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

Amendment Request VIC

Actions ▾

Previous

Next

Navigate

Print

Documents

Signatures

Save

Share

Roles

Collaborators

Completeness Check

Submit

Documents

Document(s) to be amended

- Investigator brochure
- Participant information sheet and consent form (PICF)
- Protocol
- Other

Upload amended participant information sheet and consent form (PICF)

[Upload Document](#)

Protocol type(s) to be uploaded

- Protocol with tracked changes
- Protocol (clean version)

Upload amended protocol (tracked changes version)

[Upload Document](#)

Upload amended protocol (clean version)

[Upload Document](#)

- Select **Upload Document** [Upload Document](#) to attach the amendment documents from your local drive
- Specify the version and date

Actions ▾

Previous

Next

Navigate

Print

Documents

Signatures

Save

Share

Roles

Collaborators

Completeness Check

Submit

- Investigator brochure
- Participant information sheet and consent form (PICF)
- Protocol
- Other

Upload amended participant information sheet and consent form (PICF)

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Participant information and consent form	Master PICF January 2018	Master PICF January 2018.docx	01/02/2019	1.5	473.2 KB	Download	Delete

[Upload Document](#)

Protocol type(s) to be uploaded

- Protocol with tracked changes
- Protocol (clean version)

Upload amended protocol (tracked changes version)

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Protocol (Tracked)	Study XYZ tracked	Study XYZ tracked.docx	01/02/2019	1.5	11.5 KB	Download	Delete

Upload amended protocol (clean version)

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Protocol	Study XYZ	Study XYZ.docx	01/02/2019	1.5	12.5 KB	Download	Delete

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

Refresh

NMA Project

Print

Respond

Form Status	Review Reference	Application Type	Date Modified	NMA
Not Submitted	N/A	N/A	07/02/2019 13:40	Project is for NMA

[Navigation](#)
[Documents](#)
[Signatures](#)
[Collaborators](#)
[Submissions](#)
[Correspondence](#)
[History](#)

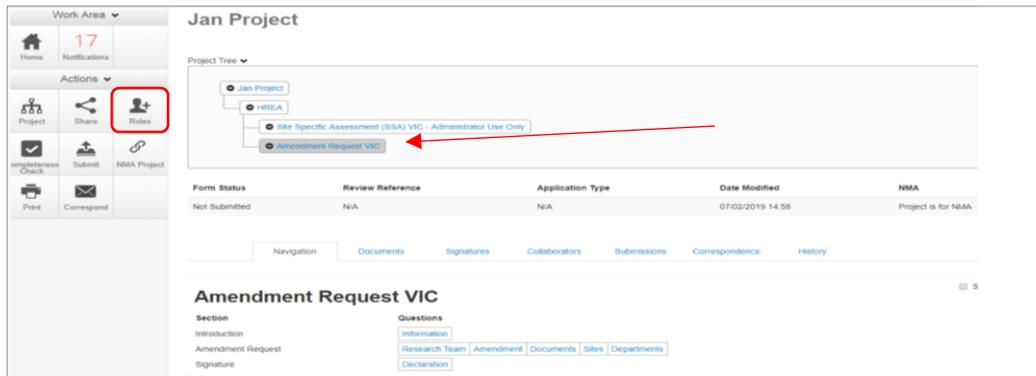
Documents

Type	Document Name	File Name	Version Date	Version	Size	View
Participant information and consent form	Master PICF January 2018	Master PICF January 2018.docx	01/02/2019	1.5	473.2 KB	Download
Protocol (Tracked)	Study XYZ tracked	Study XYZ tracked.docx	01/02/2019	1.5	11.5 KB	Download
Protocol	Study XYZ	Study XYZ.docx	01/02/2019	1.5	12.5 KB	Download

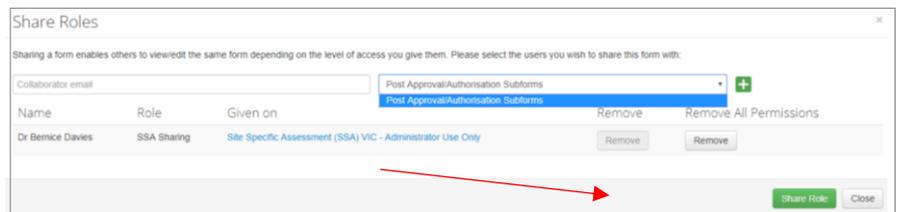
Allowing others to access post approval forms

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

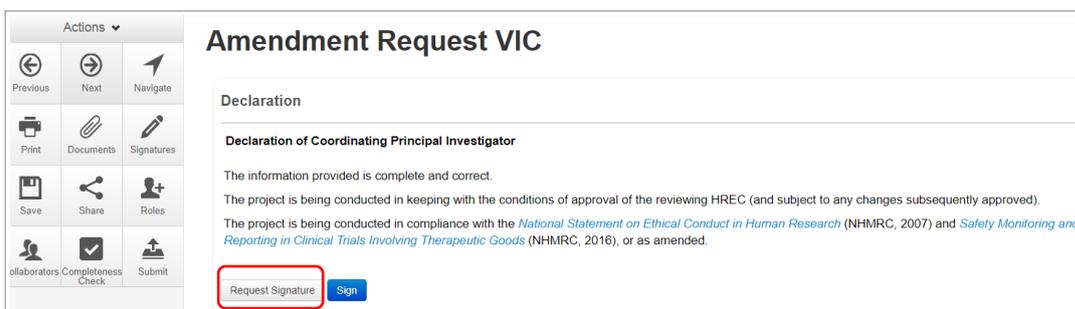


- The collaborator at the site can view the amendment form and associated documents

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

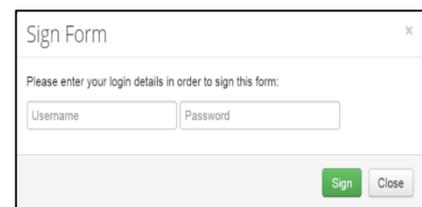


- For endorsement of the amendment, select **Sign**  button under the Actions pane



- 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).

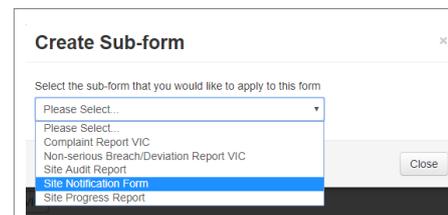
Sub-forms for post authorisation

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

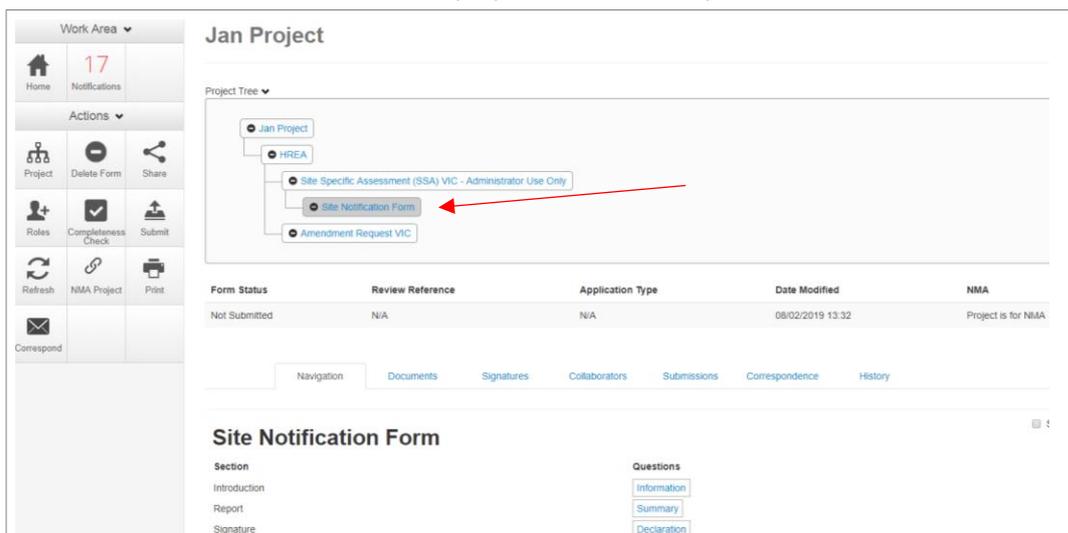
Create a Sub-form

- 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**



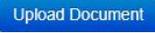
- The Site Notification Form will be displayed under the Project Tree

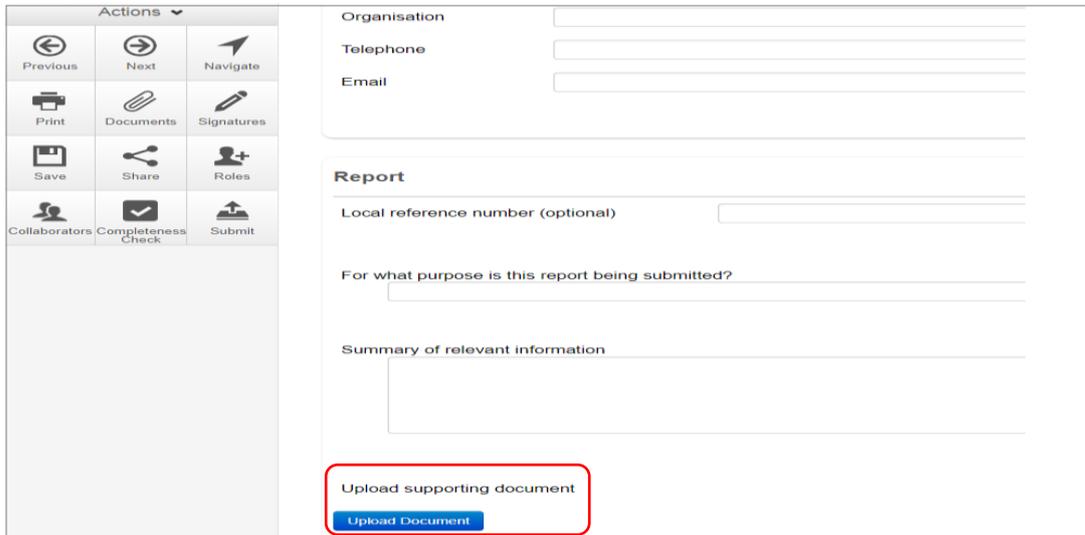


Form Status	Review Reference	Application Type	Date Modified	NMA
Not Submitted	N/A	N/A	08/02/2019 13:32	Project is for NMA

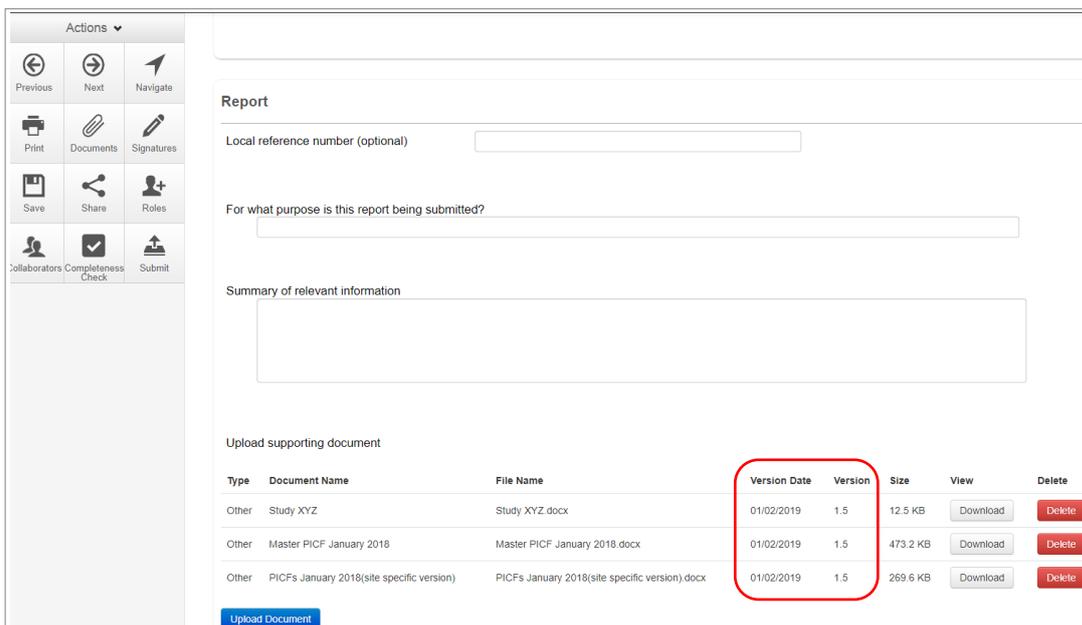
Complete a Sub-form – Site Notification Form

- 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**  to attach amendment documents including site specific documents e.g. site specific PICF from your local drive

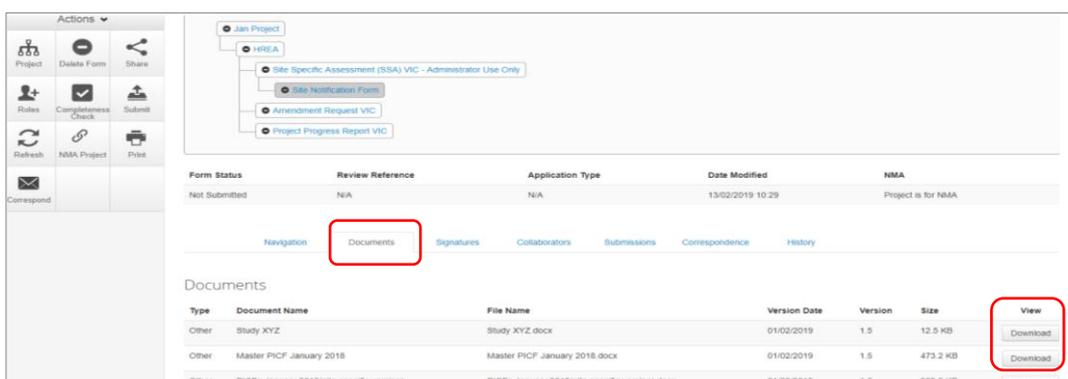


- Specify the version and date



Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Other	Study XYZ	Study XYZ.docx	01/02/2019	1.5	12.5 KB	Download	Delete
Other	Master PICF January 2018	Master PICF January 2018.docx	01/02/2019	1.5	473.2 KB	Download	Delete
Other	PICFs January 2018(site specific version)	PICFs January 2018(site specific version).docx	01/02/2019	1.5	269.6 KB	Download	Delete

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



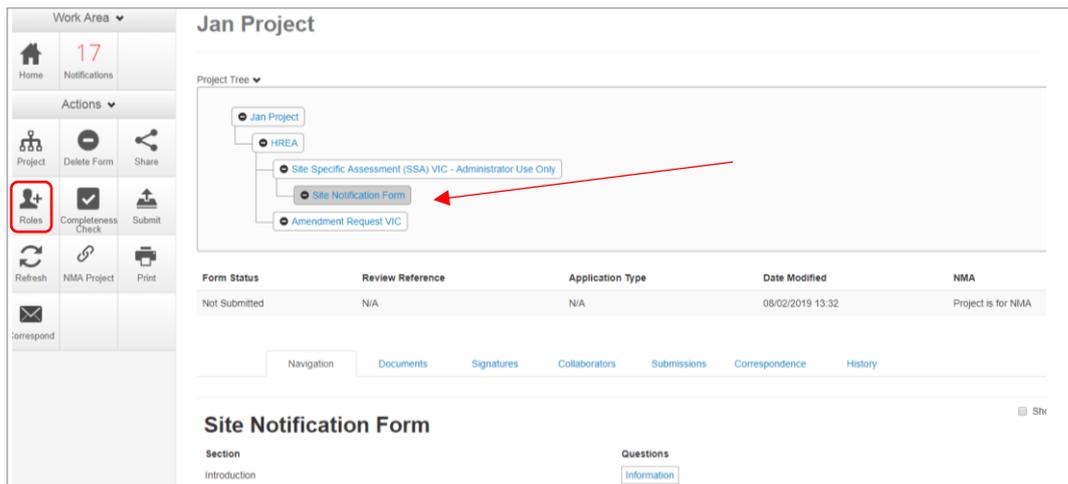
Form Status	Review Reference	Application Type	Date Modified	NMA
Not Submitted	N/A	N/A	13/02/2019 10:29	Project is for NMAA

Type	Document Name	File Name	Version Date	Version	Size	View
Other	Study XYZ	Study XYZ.docx	01/02/2019	1.5	12.5 KB	Download
Other	Master PICF January 2018	Master PICF January 2018.docx	01/02/2019	1.5	473.2 KB	Download
Other	PICFs January 2018(site specific version)	PICFs January 2018(site specific version).docx	01/02/2019	1.5	269.6 KB	Download

Allowing others to access post authorisation forms

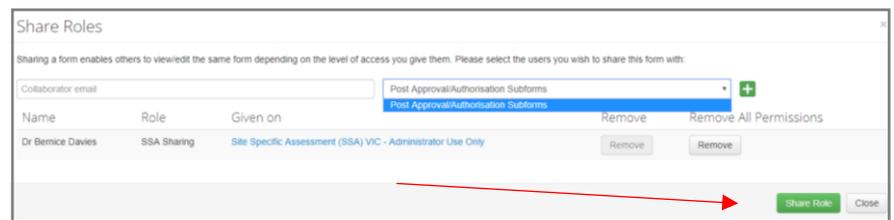
Using **Roles +** allows other research team members access to a post authorisation form

- 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**

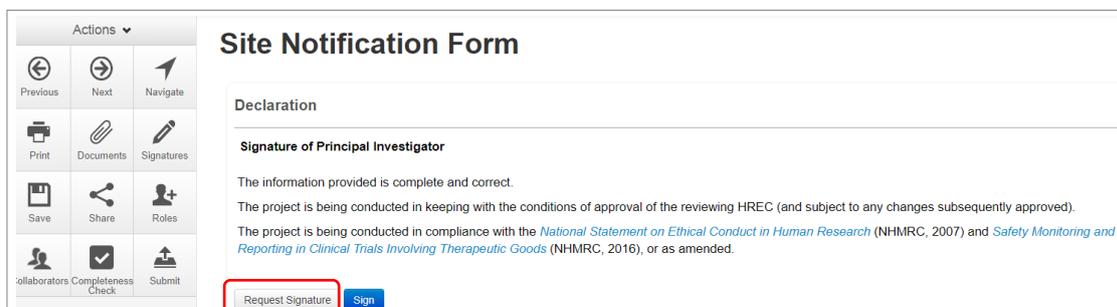


- The collaborator receives an email notification on their assigned role in the project
- The collaborator at the site can view the Site Notification Form and associated documents

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

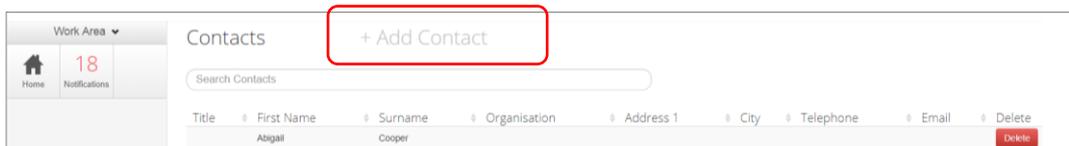
The **Contacts** area can be used to save and edit contact details for project team members. Details saved in **Contacts** can be used to populate all ERM forms avoiding multiple entries.

Add a Contact

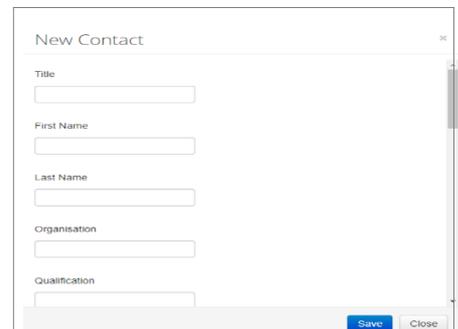
- Select 'Contacts' above Work Area



- Select '+ Add Contact'



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



New Contact

Title

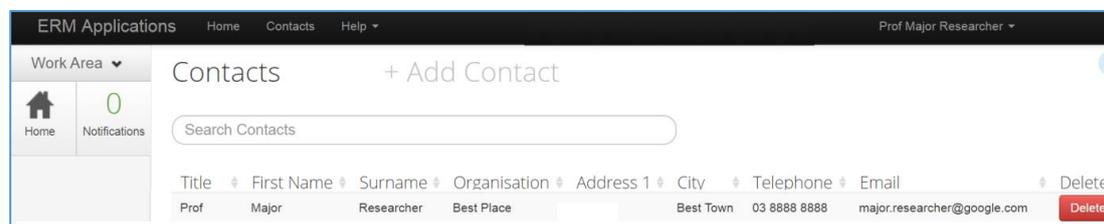
First Name

Last Name

Organisation

Qualification

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



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

HREA 501 Ver

Team Member Details

- National Statement 1.1 (e) states: "Research that has merit is ...conducted or supervised by persons or teams with experience, qualifications and competence that are appropriate for the research."
- In establishing the research team you should ensure there is appropriate and sufficient expertise to undertake all the research activities.
- Ensure that you list who is undertaking the research activities and detail their expertise, qualifications and competence in the following section.
- Where research will involve team members who are currently unknown (e.g. a future class of students) this should be recorded in the [Project Description/Protocol](#) and the supervisor should complete this section of the HREA as the researcher/investigator.

Please refer to the information icon **i** and read the guidance for Q1.9.1-Q1.9.13 prior to completing the questions in the following section.

Project Team

Q1.9.1 Title Load Add to contacts Save Contact

Doctor

Q1.9.2 First Name

John

Q1.9.3 Surname/family name

Smith

- 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

Please refer to the information icon **i** and read the guidance for Q1.9.1-Q1.9.13 prior to completing the questions in the following section.

Project Team

Q1.9.1 Title Load Add to contacts Load Contact

Doctor

Q1.9.2 First Name

John

Q1.9.3 Surname/family name

Smith

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

- Select **insert** button

Contacts

Search Contacts

Title	First Name	Surname	Organisation	Address 1	City	Telephone	Email
Doctor	John	Smith					
Professor	David	Jones					

Close

- Contact details will be successfully loaded into the form

Project Team Load Add to contacts

Q1.9.1 Title

Professor

Q1.9.2 First Name

David

Q1.9.3 Surname/family name

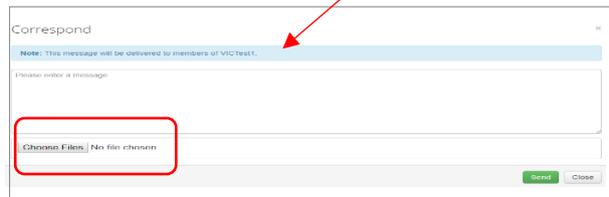
Jones

Q1.9.4 Email Address

Correspondence

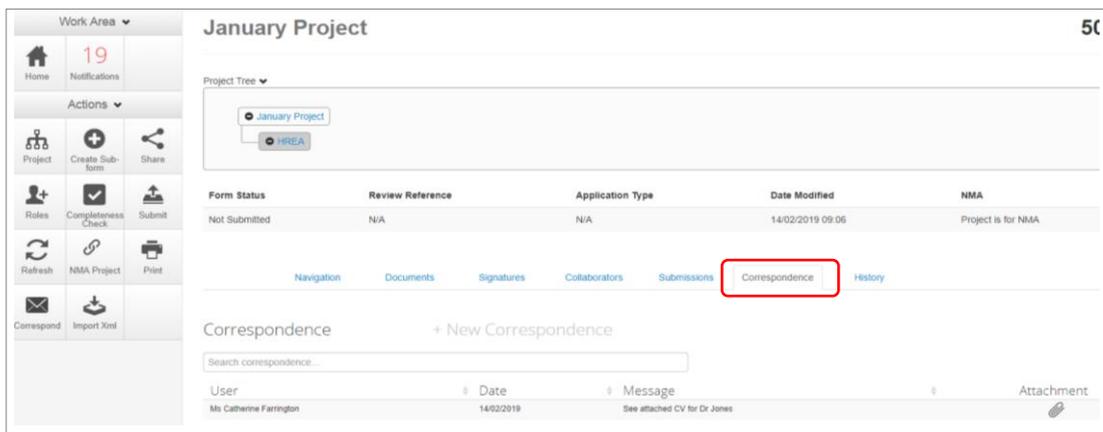
The applicant can use the **Correspond** function to communicate with the reviewing organisation's Research Office and should be used **after** a form has been submitted to the reviewing organisation. Correspondence must **not** be used to respond to a query or information request.

- 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

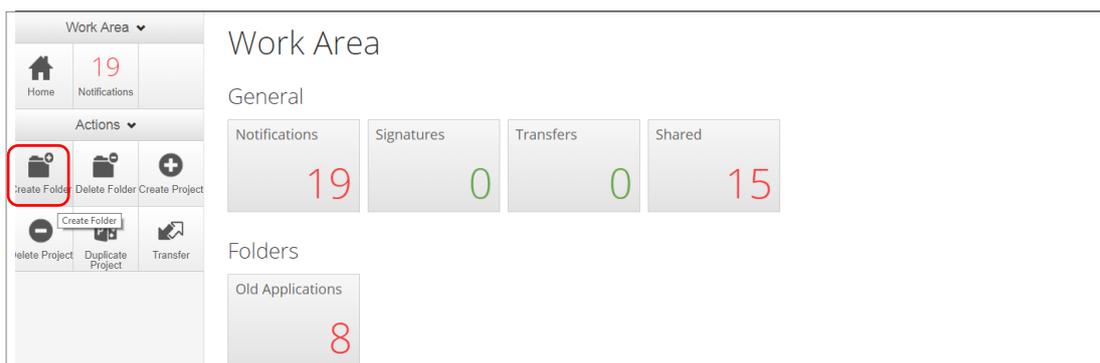


User	Date	Message	Attachment
Ms Catherine Farrington	14/02/2019	See attached CV for Dr Jones	

Folders

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

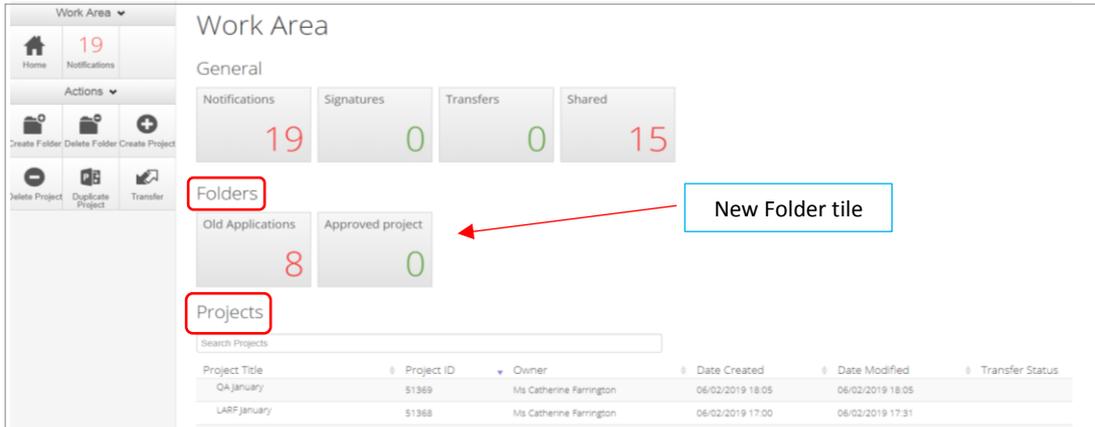
- Select **Create Folder**  button under the Action pane



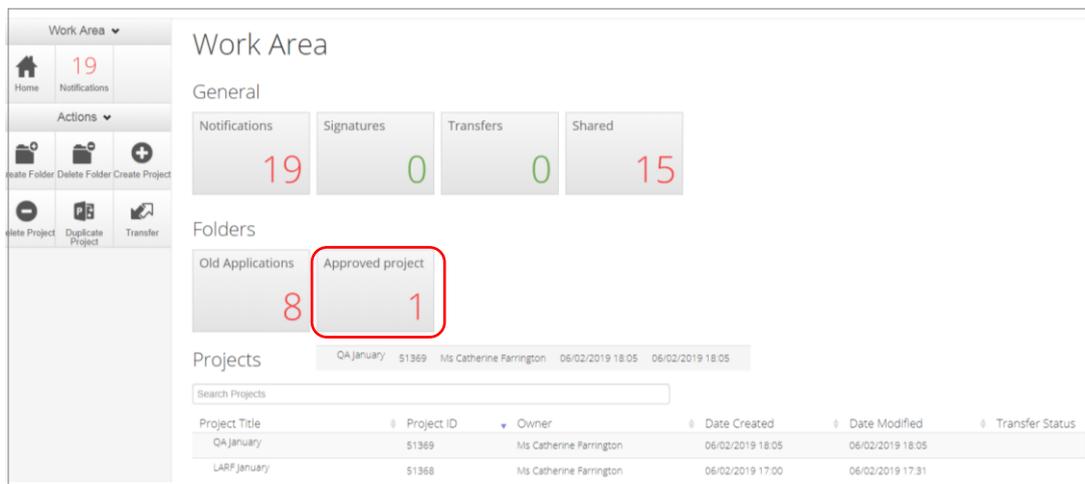
- A **Create Folder** text box will be displayed
Enter Folder title e.g. Approved project
Select **Create**



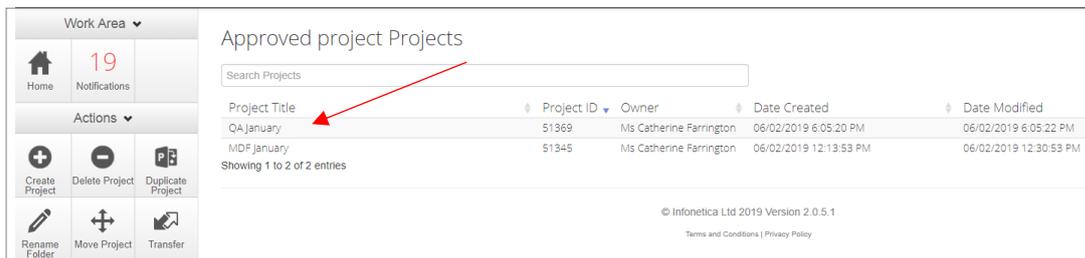
- A new Folder tile (Approved project) is displayed in the Work Area under **Folders**



- 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



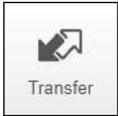
Create a new project



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