

Applicant user guide to ERM

Ethical Review Manager (ERM)

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Available on [Clinical trial research](#) webpage.

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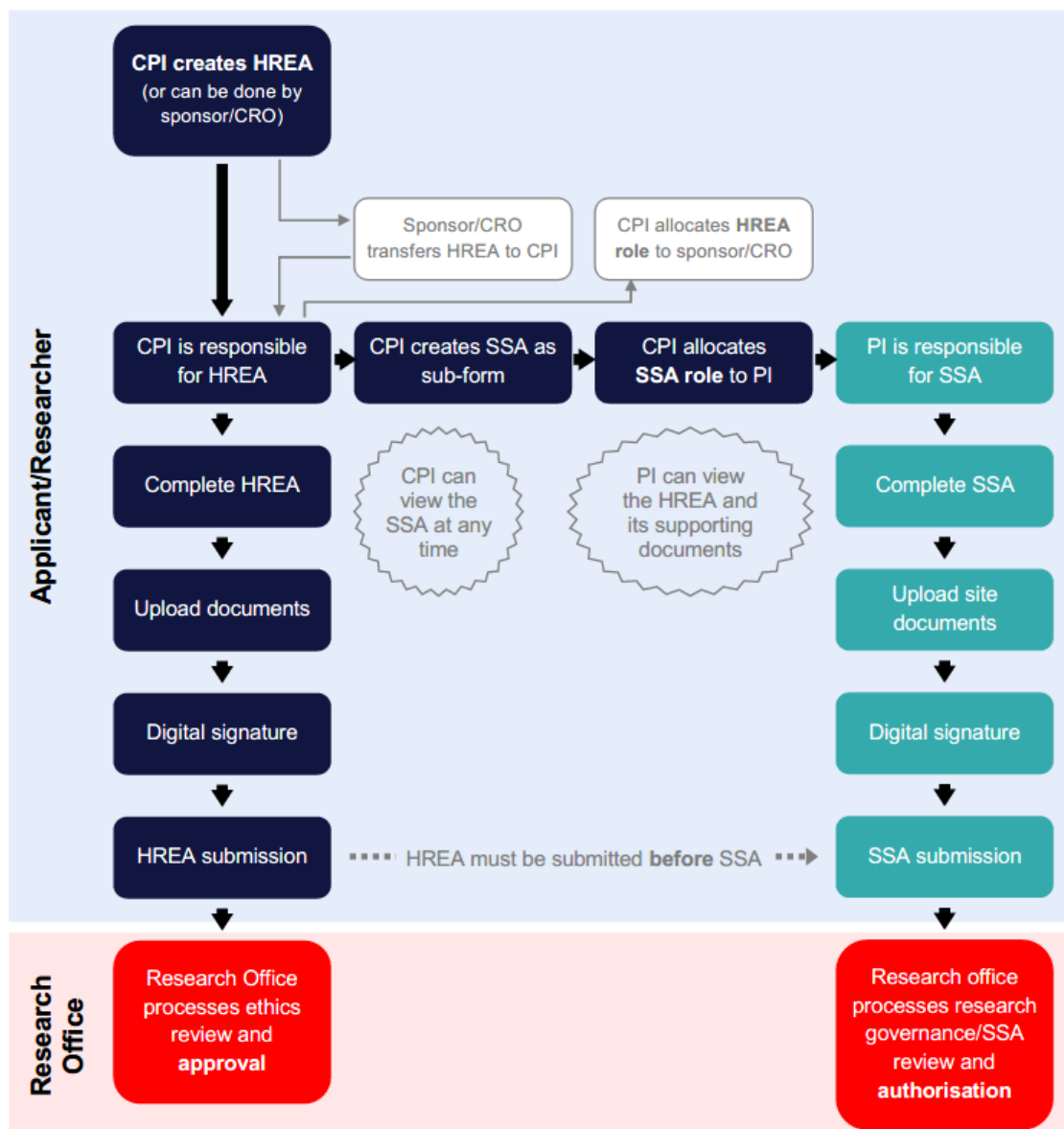
Glossary

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**

Forgotten password

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

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


Your password has successfully been reset, please click [here](#) to return to login page.

Changing password

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

- Select **Change Password**

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



Change Password

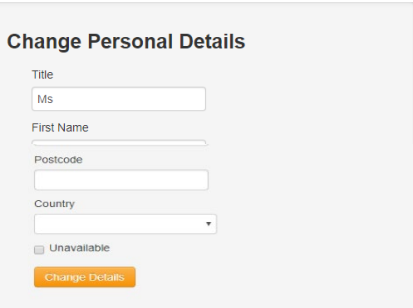
Old Password

New Password

Confirm New Password

Changing personal details

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



Change Personal Details

Title

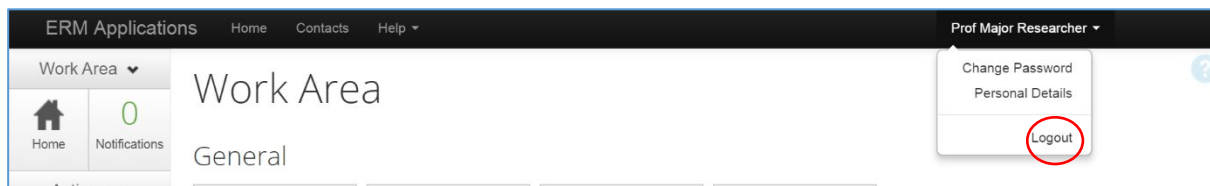
First Name

Postcode

Country

☐ Unavailable

Log out



- Select arrow at right edge of account name
- 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, Project Progress Report.
- From some sub-forms (SSA and LNR VIC SSA) further sub-forms can be created e.g. Site Progress Report, Complaint 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

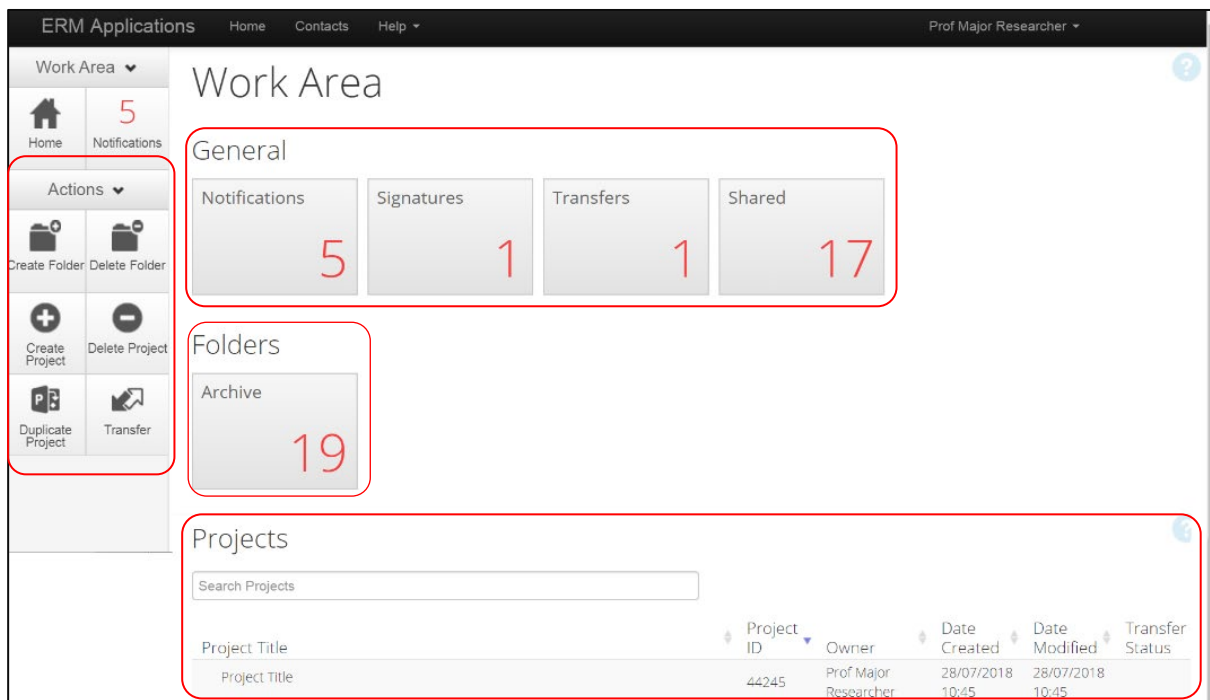
Form	Description
Ethics Amendment Request	Request ethical approval for a change to the design or conduct of a research project e.g. the protocol, PICF or change to personnel
Safety Report	Report a safety event to the reviewing ethics committee
Annual Safety Report	Report to the reviewing ethics committee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

Sub-forms for post-authorisation

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

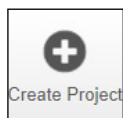
Section 2: Work Area

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

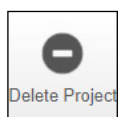


Actions

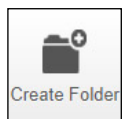
There are six action buttons under the Actions pane



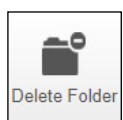
Create a new project



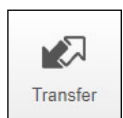
Delete a project (only possible if the main form has **not** been submitted via ERM)



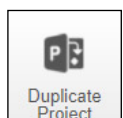
Create a bespoke folder for storage of projects



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



Permanently transfer a project to a colleague



Duplicate an existing project

General

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



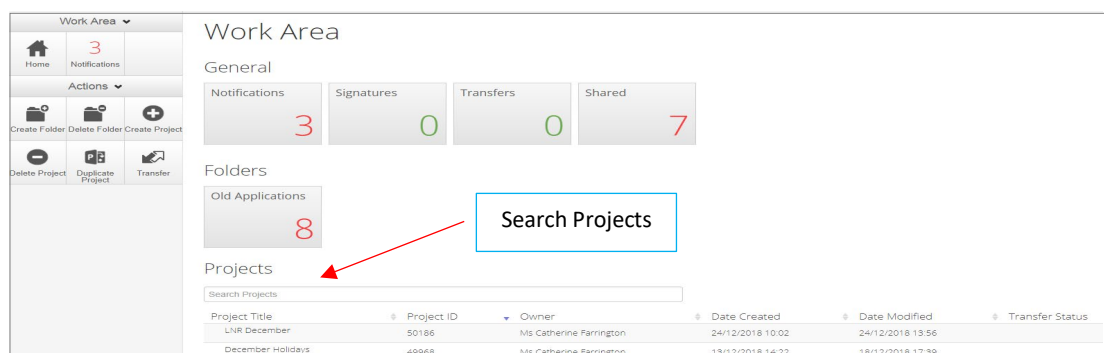
- Notifications**
- Contain messages that are sent to the user from the Research Office:
 - o queries or request for information regarding an application
 - o Approval letters
 - Messages automatically generated by ERM e.g. form updates
 - Messages from other research team members/collaborators
 - o the user has been assigned a level of access to a form
 - o a change in the access status of a form
 - o an electronic signature has been requested
 - o a form has been signed electronically by the signatory
- Signature**
- Contain requests from colleagues to digitally sign an application i.e. a request for an electronic signature
- Transfers**
- Contain requests to transfer a project to another ERM user
- Shared**
- Contain information about forms and level of access another ERM user has shared with you

Folders

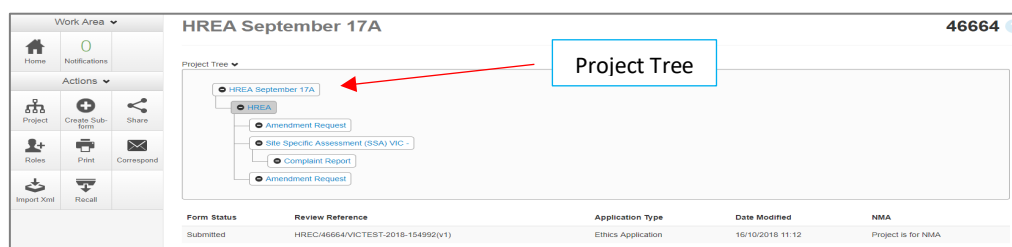
Displays bespoke folders for storage of projects.

Projects

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

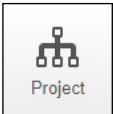
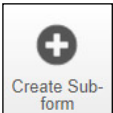
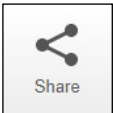
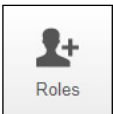
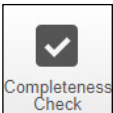
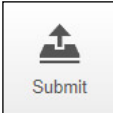
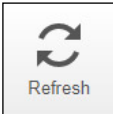
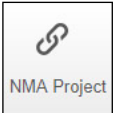

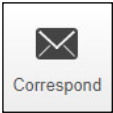



- The project will open under a **Project Tree**



Actions Pane

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

- | | |
|---|--|
|  | Go to the Project overview |
|  | Create a Sub-form from the main form e.g. SSA |
|  | Enable collaborators to view, edit and manage the form |
|  | Enable collaborators to view, edit and manage the form |
|  | Identify mandatory questions within the form that require information to be entered |
|  | Submit the application to the reviewing organisation.
Note: the reviewing organisation must be selected within the form , in order for the submission to be directed to that organisation. |
|  | Refresh |
|  | Record that the project falls within the National Mutual Acceptance (NMA) scheme.
Information on NMA is available on the Clinical Trials and Research website. |
|  | Generate a PDF of the form |
|  | Communicate directly with the Research Office selected as the reviewing organisation within the form only after the form has been submitted |
|  | Import a HREA created on a different website e.g. hrea.gov.au, as an Xml file in to ERM |

Form Status Table

The Form Status table displays the current activity of the form

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

Form Status:	Description
Not Submitted	the application is still in progress and yet to be submitted
Submitted	the application has been submitted to the reviewing organisation
Recalled	the application has been recalled by the user to make changes. Only possible if the reviewing organisation has not started processing the application
Queried	the application has been queried by the Research Office for further clarification or edits
Validated	the application is ready for review by the ethics committee
Information Requested	the ethics committee has requested further clarification or information
Approved	the application has been approved by the reviewing ethics committee

Review Reference:

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	ERM 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	Displays a record of the communication between the user and the reviewing organisation's research office
History	An auditable history of actions; if the form has been submitted, an archived version of the submission is available here.

Each tab is described below:

Navigation

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

The screenshot shows the HREA form interface. On the left is a sidebar with icons for Home, Notifications, Actions, Project, Create Sub-form, Share, Roles, Completeness Check, Submit, Refresh, NMA Project, Print, Correspond, and Import Xml. The main area has a top bar with 'Form Status' (Not Submitted), 'Review Reference' (N/A), 'Application Type' (N/A), 'Date Modified' (12/10/2018 16:43), and 'NMA' (Project is not for NMA). Below this is a tabbed interface with 'Navigation' selected and highlighted by a red box. Other tabs include Documents, Signatures, Collaborators, Submissions, Correspondence, and History. The 'Navigation' tab shows a 'Section' list (ERMA Module, HREA Introduction, Project Overview, Project Team, Disclosure of Interests, Restrictions) and a 'Questions' list (ERMA Filter Questions, Introduction, HREC Directory, Project Overview, Project Team, Disclosure of Interests, Restrictions).

Documents

- The Documents 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

The screenshot shows the HREA form interface with the 'Documents' tab selected and highlighted by a red box. The sidebar is the same as in the previous screenshot. The main area shows a table of documents. The table has columns: Type, Document Name, File Name, Version Date, Version, Size, and View. A 'Download All as Pdf' button is at the bottom right. The 'View' button in the first row is highlighted by a red box.

Type	Document Name	File Name	Version Date	Version	Size	View
Participant information and consent form	PICF's Dec 2017	PICF's Dec 2017.docx	12/10/2018	1.3	474.6 KB	Download

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

The screenshot shows the HREA form interface with the 'Signatures' tab selected and highlighted by a red box. The sidebar is the same as in the previous screenshots. The main area shows a 'Project Tree' on the left with 'HREA September' selected. Below the tree is a table with columns: Form Status, Review Reference, Application Type, Date Modified, and NMA. The 'Signatures' tab shows a 'Signatures' section with a note: 'Note: There are no active signatures on this form'. Below this is a 'Signature Requests' section with a table. The table has columns: Type, Signatory Email, Requested Date, Status, Response Date, and Action. The first row shows a request from 'Co-ordinating Principal Investigator/Researcher' with email 'atigall.cooper@oiths.vic.gov.au'.

Type	Signatory Email	Requested Date	Status	Response Date	Action
Co-ordinating Principal Investigator/Researcher	atigall.cooper@oiths.vic.gov.au	17/10/2018 08:54	Requested		Cancel

Collaborators

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

Project Tree


- HREA 09
 - HREA
 - Site Specific Assessment (SSA) VIC -

Form Status	Review Reference	Date Modified	NMA
Not Submitted	N/A	24/01/2020 14:44	Project is not for NMA

Navigation Documents Signatures **Collaborators** Submissions Correspondence History

Collaborators

Name	Access	Edit Permissions
Ms Abigail Cooper	abigail.cooper@dhhs.vic.gov.au forms, Receive notifications	Edit Permissions
Ms Catherine Farrington	Project Owner and Form Owner	Edit Permissions

- The form owner can edit the permissions for each collaborator only if the access level is assigned through the **Share**  **Share** action

Submissions

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

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

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 09:28	Project is for NMA

Navigation Documents Signatures Collaborators Submissions **Correspondence** History

Correspondence

User	Date	Message	Attachment
Ms Catherine Farrington	17/10/2018	Please see attached DCP certificate for R...	

Showing 1 to 1 of 1 entries

- Use the **Correspond**  **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

The screenshot shows the ERM interface with the 'Form History' tab selected. The table below is a representation of the data shown in the screenshot:

Date	User	Description	Attachment
10/07	Ms Catherine Farrington	Correspondence Sent	Download
09/25	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

The screenshot shows the ERM interface with the 'Review Reference' tab selected. The table below is a representation of the data shown in the screenshot:

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

- Composed of six parts - ① ② ③ ④ ⑤ ⑥

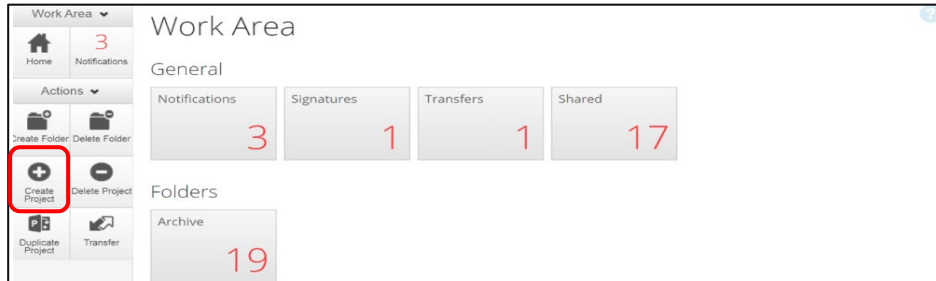
e.g. HREC/46664/VICTEST-2018-154992(v1)

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

Section 3: The HREA form

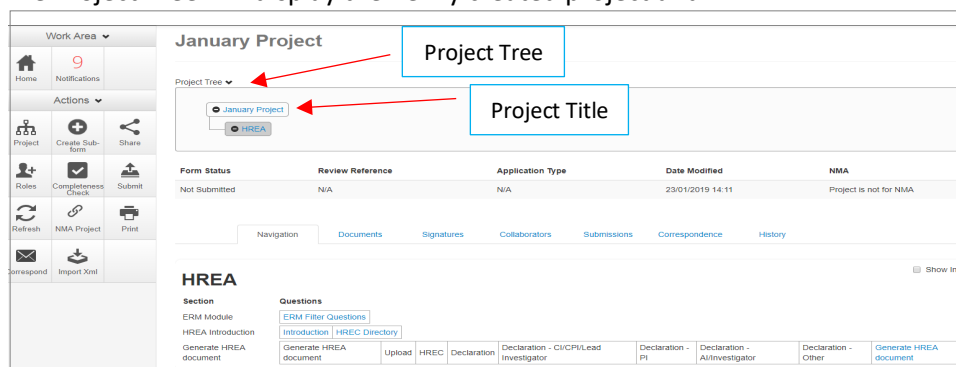
Create an HREA

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



- Enter the Project Title
- Select the jurisdiction where the application will be reviewed
- Select **HREA** from the Main Form options
- Select **Create** button to create the project

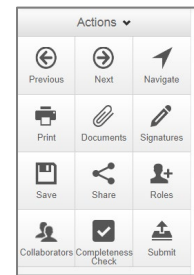
- The Project Tree will display the newly created project and HREA



Complete the HREA

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


- Refer to the [Victorian Specific Module \(VSM\)](#) section in the manual for detailed instructions on completing the VSM
- In Section 1 of the HREA Introduction, select the **Acknowledge and Continue** button to open the rest of the HREA to complete the application
- To save your work select the **Save** button under the **Actions** pane
- Selecting **Previous** and **Next** buttons will also save your work

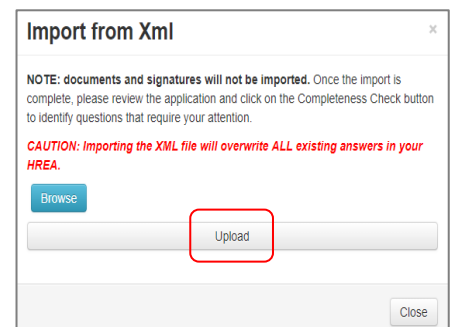


Import an HREA

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



- Details to obtain the xml file are available in [ERM Frequently Asked Questions](#) HREA section
- Create the project and HREA Main Form in ERM as previously described
- Complete the ERM Filter Questions and continue to 'HREA Introduction'

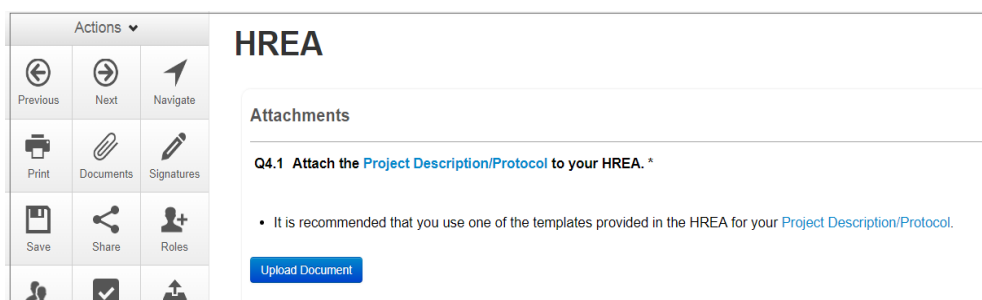
- Click on the **Navigation**  button under the Actions pane
- Select **Import Xml** button
- An **Import from Xml** text box will be displayed
- Select **Upload** button




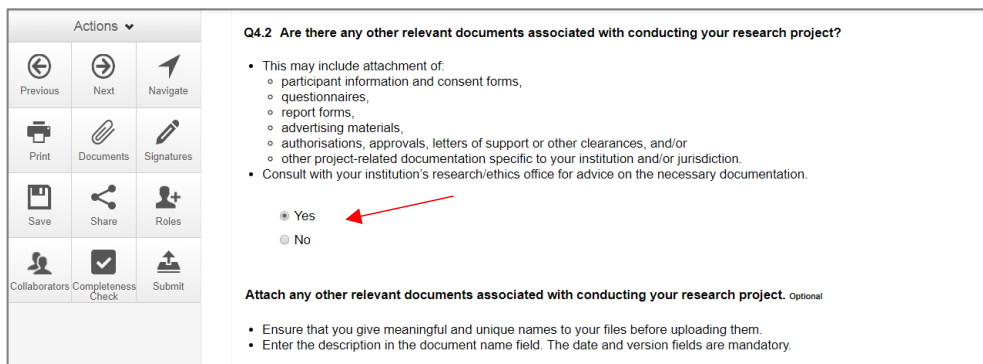
- The xml file will overwrite all existing answers in the HREA in ERM
- Signatures and documents will not be imported in the xml file therefore supporting documents will need to be uploaded in to the ERM HREA and signatures will need to be obtained again.

Upload Documents

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




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



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 **Upload Document**  multiple times
- Specify the version and date of each document to differentiate the documents within the same document type e.g. Sub-study PICFs

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	<button>Download</button>	<button>Delete</button>
<button>Upload Document</button>							

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	<button>Download</button>	<button>Delete</button>
<button>Upload Document</button>							

- 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 16:46	Project is not for NMA

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
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

Work Area: January Project

Project Tree: January Project, HREA (highlighted)

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

Navigation: Documents, Signatures, Collaborators, Submissions, Correspondence, History

HREA Section: ERM Module

Questions: ERM Filter Questions

Share button: Sh

- 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

HREA Share (read, write, submit)
HREA Share (read-only)
HREA Share (read, write)
HREA Share (read, create subforms)
HREA Share (read, write, submit)

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

Share Roles

Sharing a form enables others to view/edit the same form depending on the level of access you give them. Please select the users you wish to share this form with:

Collaborator email: [input field]

Note: This form has not yet been shared with anyone

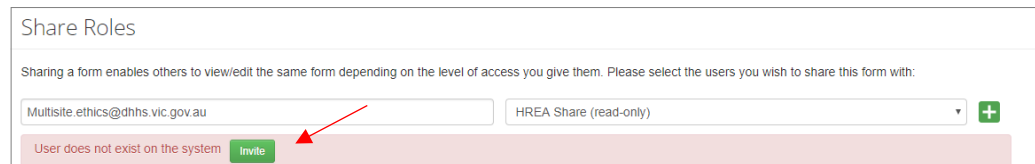
Level of access: HREA Share (read-only), HREA Share (read, write), HREA Share (read, create subforms), HREA Share (read, write, submit)

Share Role Close

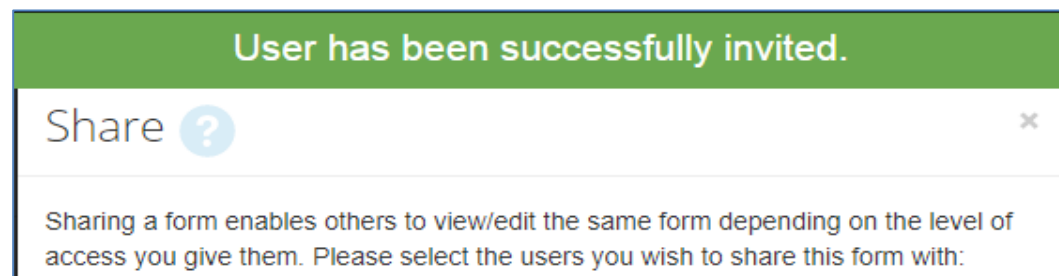
- Select **Share Role** button
- Other research team members can be added using the button

If the collaborator does not have an ERM account

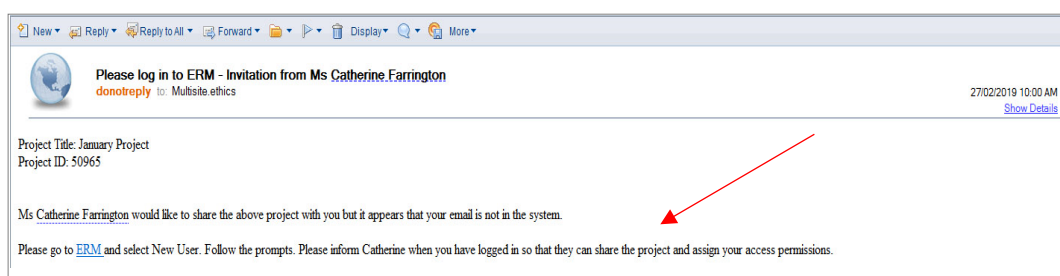
- A message will be displayed if the collaborator's email does not exist in ERM



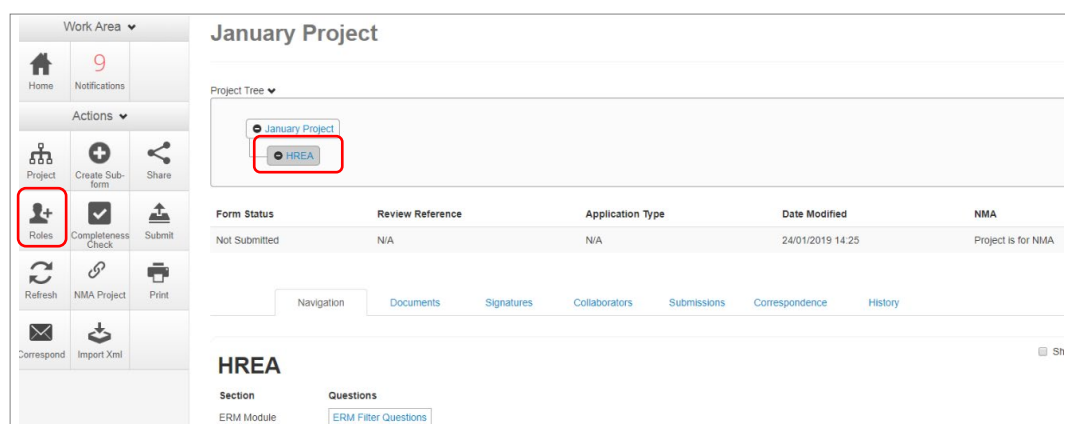
- Select the **Invite** button to invite the collaborator to create an ERM account
- This raises a green bar across the screen advising the collaborator has been successfully invited



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



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



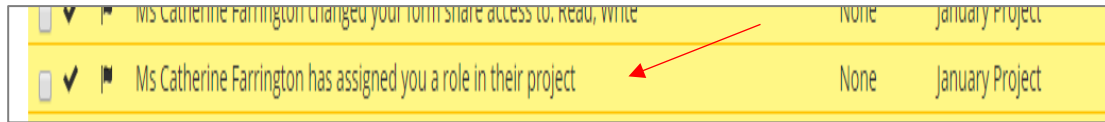
Accept access

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

- From the **Work Area** the collaborator selects **Notifications** tile

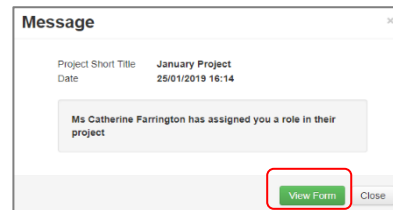


- Select the Message title to open the message




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

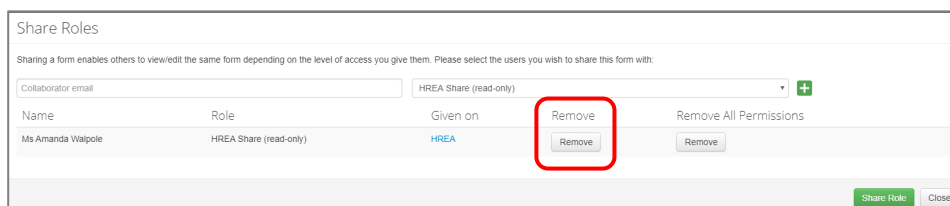
Select **View Form**



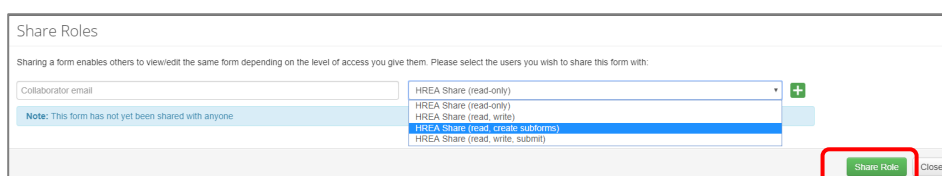
- The project and form will be displayed. Supporting documents attached to the form can also be viewed
- The collaborator can edit and submit sub-forms e.g. the SSA for their site depending on the level of access assigned by the project owner

Manage access

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



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



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

Applying Signatures

Declaration

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

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

Signatures

The HREA form questions / information must be complete, 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 Signature / Sign' function to electronically sign the declaration within the application using ERM




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

The HREA form owner may request signatures as follows:

1. To use Wet ink signature

- Select Wet ink sign after printing

- 'Wet ink sign after printing' creates a signature section (at bottom of screen)

- Using the **Print** button  from the Actions Pane, print this section and obtain the signature from the CPI / PI. Save to your local drive as a pdf
- Navigate to last section of the HREA to find 
- Upload** then opens **Q 4.2** to attach the Declaration page
- Select **'Yes'** to other relevant documents and select **'Other project-related documentation'**
- Select **Upload document**  to attach the signature document to the HREA
- The uploaded signature document will be displayed with the document and file name and versions

☒ 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 ERM email address and message and select **Request**

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

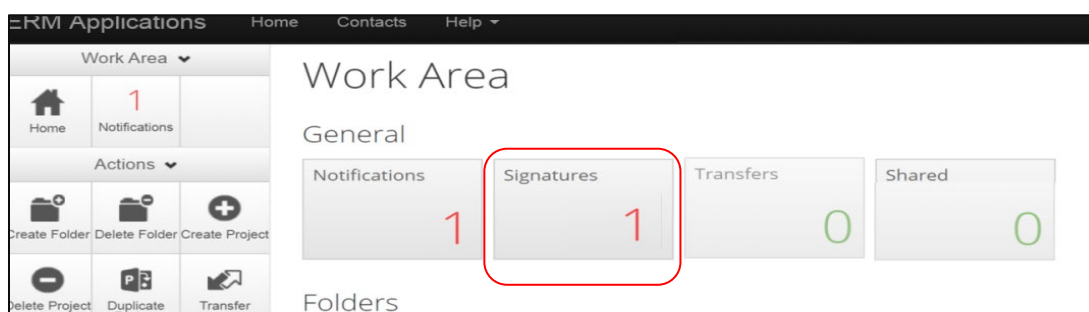
You have received a signature request from Ms Jane Citizen with a message.

Could you please sign this HREA?

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

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



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



- New requests are highlighted

Requested Date 12/12/2018 15:38

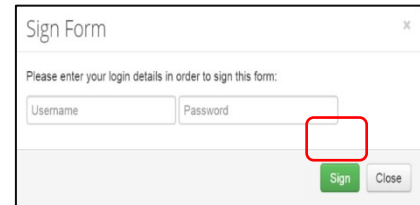
Type	Project Title	Requesting User	Message	Requested Date	Response Date	Status	Action
Co-ordinating Principal Investigator/Researcher	October 22	Ms Catherine Farrington	Can you please sign the HREA	12/12/2018 15:38		Requested	View Form
Head of Supporting Department	October 24	Ms Catherine Farrington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

Work Area

Home

13

Notifications

Signatures

Search Signatures

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 15:55	Signed	View PDF
Head of Supporting Department	October 24	Ms Catherine Farrington		19/11/2018 12:20		Invalidated	View Form

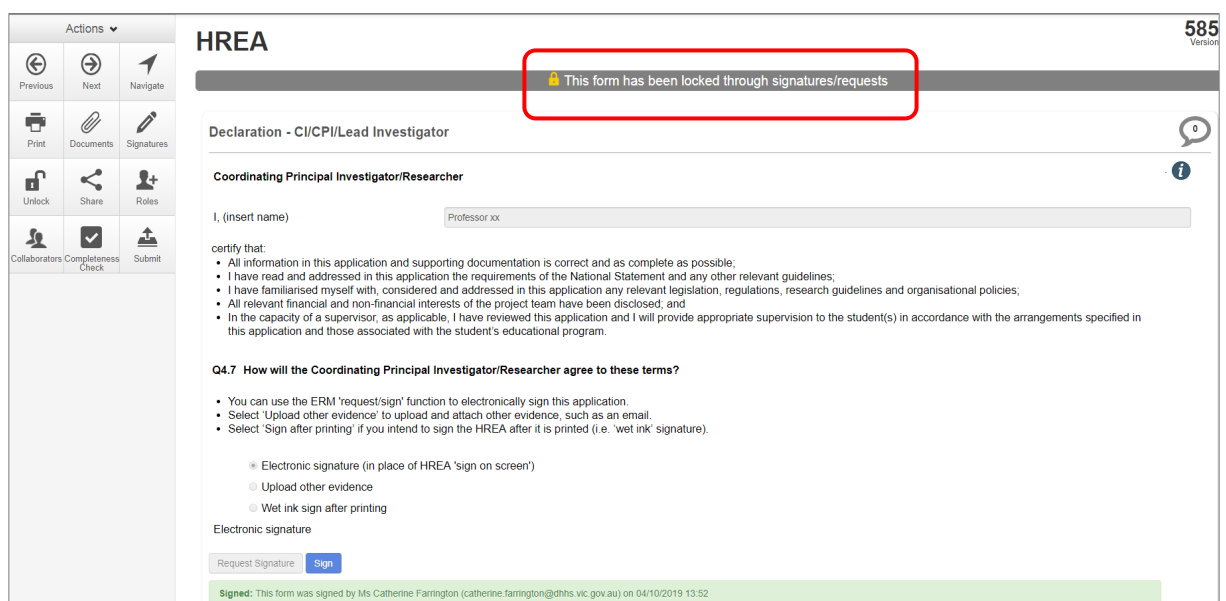
- The applicant receives an email notification indicating the signature request has been accepted by the signatory i.e. the form has been signed

See advice on acceptance of electronic signatures using ERM on the [Clinical trial research](#) webpage

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

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

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



HREA 585 Version

Actions

- Previous
- Next
- Navigate
- Print
- Documents
- Signatures
- Unlock
- Share
- Roles
- Collaborators
- Completeness Check
- Submit

Declaration - CI/CPI/Lead Investigator

Coordinating Principal Investigator/Researcher

I, (insert name)

certify that:

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


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

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

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

Electronic signature

Signed: This form was signed by Ms Catherine Farrington (catherine.farrington@dhhs.vic.gov.au) on 04/10/2019 13:52

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

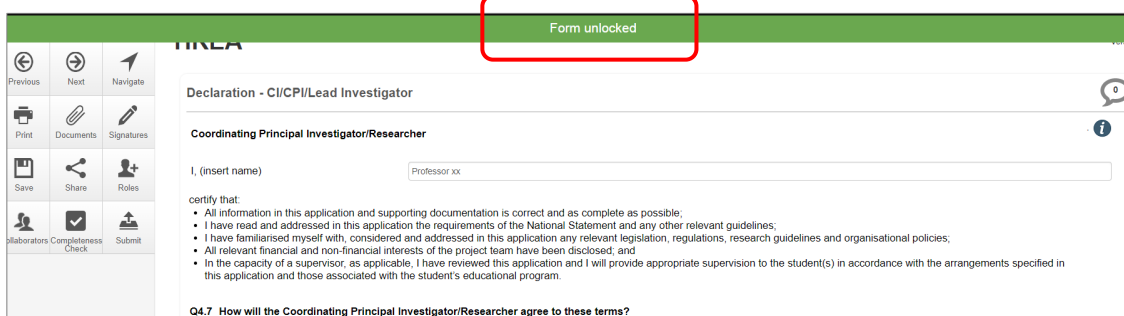


Unlock Form

Performing this action will invalidate any signatures on the form. Are you sure?

Confirm **Cancel**

- The form is unlocked for editing



The screenshot shows the top of the form with a green header bar. A red rectangle highlights a green button labeled "Form unlocked" in the top right corner of the header. Below the header, the form content is visible, including a "Declaration - CI/CPI/Lead Investigator" section and a "Coordinating Principal Investigator/Researcher" section with a text input field.

- Complete the edits in the form
- Repeat the signatory process for electronic signatures from research team members
- 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.

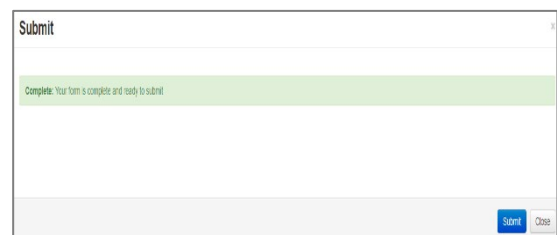
For the initial application submission ensure the form is complete and all **documents are uploaded and signatures completed**.

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

Submission

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


- Select the **Submit**  button



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



Application type	HREC - the HREA
ERM Project ID	46664
Organisation/hospital code	VICTEST
Year	2018- year of submission
Submission number	154992 - submission version number
Version number	v1

- Following the submission, a unique identification code is generated.
It is composed of six parts - e.g. HREC/46664/VICTEST-2018-154992(v1)

- The **Form Status**  of the application becomes Submitted

Recall an application

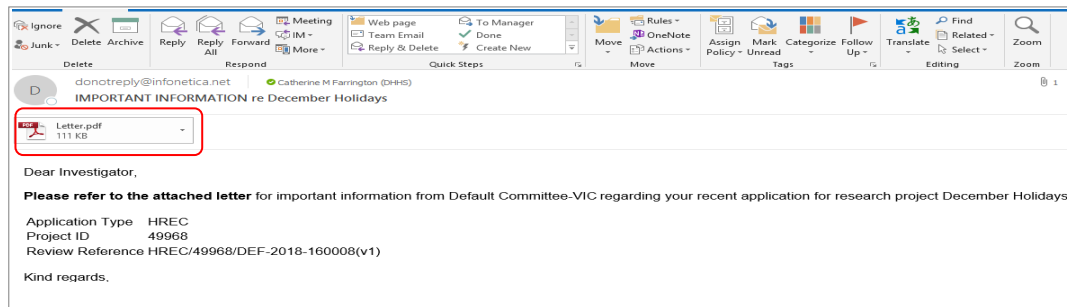
Any changes made to the submission will INVALIDATE all electronic signatures and will require all signature requests again

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



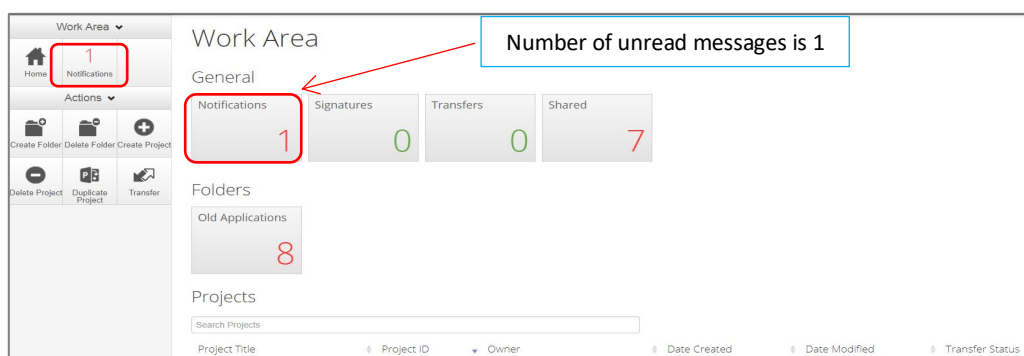
- A 'Query – Ethics Application' letter (pdf) from the Research Office will include details for further information to be provided via ERM



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

To access the Query

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



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

Notifications

Search

Start End

Display 100 notifications

Please note that only the specified number of notifications will show after searching.

[Search](#)

Message	Attachment	Project Short Title	Time
✓ Your January Project has been upgraded	None	January Project	14/02/2019 ✕
✓ Dr Bernice Davies has requested a signature from you	None	February Project	07/02/2019 ✕
✓ Your form has been signed by Ms Abigail Cooper	None	Jan Project	07/02/2019 ✕
✓ Dr Bernice Davies changed your form share access to: Read, Write, Submit	None	March Project	04/02/2019 ✕
✓ Dr Bernice Davies has assigned you a role in their project	None	February Project	01/02/2019 ✕
✓ Information is required regarding your application. Please refer to the attached letter.		New Years Eve	14/01/2019 ✕

- 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

Message

Project Short Title **New Years Eve**

Date **14/01/2019 1:18 PM**

Information is required regarding your application. Please refer to the attached letter.

[View Form](#) [Close](#)

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

Work Area

Home 1 Notifications

Actions

Project 3 Reviewer Comments

Share Roles Consistency Check

Submit Refresh MMA Project

Print Correspond Import Xsl

December Holidays

Project Tree

December Holidays

HREA

Form Status Review Reference Application Type Date Modified NMA

Queried N/A Ethics Application 13/12/2018 14:25 Project is not for NMA

Navigation Documents Signatures Collaborators Submissions Correspondence History

HREA

Section

ERM Module

HREA Introduction

Project Overview

Project Team

Disclosure of Interests

Restrictions

Evaluations

Location

Methods

Participants

Questions

ERM Filter Questions

Introduction HREC Directory

Project Overview

Project Team

Disclosure of Interests

Restrictions

Evaluations

Location

Methods

Participants

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

Overall Reviewer Panel Comments

Supporting document requiring edits

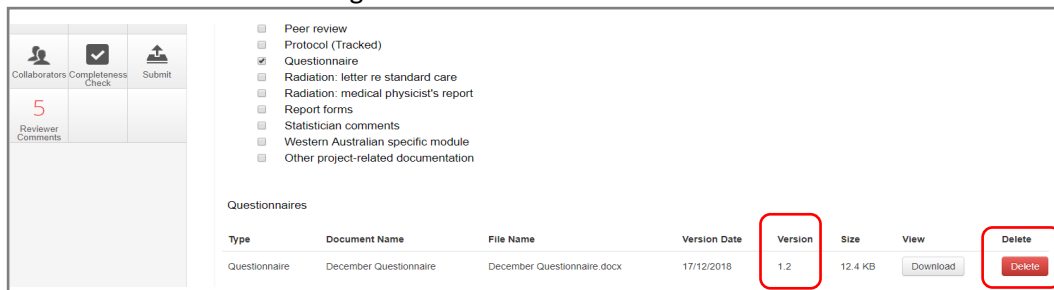
Previous Comments

Comment	Date Added	Submission
Please edit the questionnaire.	14/12/2018 at 09:16 AM	Latest Submission
This application will not be reviewed until you provide a protocol.	14/12/2018 at 09:15 AM	Latest Submission
This project requires a participant information and consent form. Please provide it.	14/12/2018 at 09:14 AM	Latest Submission

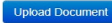
[Close](#)

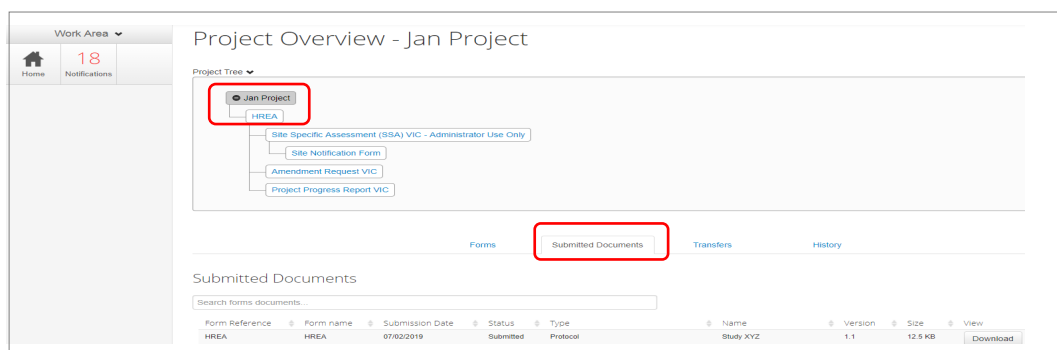
- Select a comment to be directed to the relevant section in the form i.e. to **Q 4.2 Are there any other relevant documents associated with conducting your research project?**
- As the query requires a new version of a document, the original version should be deleted, and the new version uploaded into the form. Deleted/previous document versions are automatically archived. See [Archived documents](#) for further information on how to access archived documents.

- **Delete**  to delete the original version



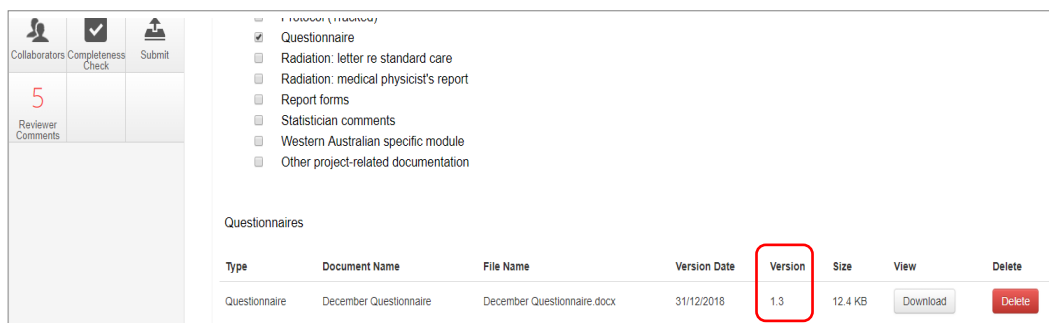
Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Questionnaire	December Questionnaire	December Questionnaire.docx	17/12/2018	1.2	12.4 KB	Download	Delete

- 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



Form Reference	Form name	Submission Date	Status	Type	Name	Version	Size	View
HREA	HREA	07/02/2019	Submitted	Protocol	Study XYZ	1.1	12.5 KB	Download

- The HREA now includes the latest version ready for resubmission



Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Questionnaire	December Questionnaire	December Questionnaire.docx	31/12/2018	1.3	12.4 KB	Download	Delete

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

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

- Once the revisions / additions have been completed, the form and / or supporting documents can be resubmitted
- The system will automatically search for a completed electronic signature if 'Electronic signature' was selected in **Q 4.7** of the HREA in the previous submission
- If the CPI is not required to complete the Declaration page, proceed to **Q 4.7** of the HREA

- Select **Wet ink sign after printing**. This will reset the signature method to enable the system to resubmit the application

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

The CPI signs. For minor changes the Research Office has all signatures on the initial submission
Other Investigators to sign if a substantial change or required by local policy

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

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



Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Participant information and consent form	PICF's Dec 2017	PICF's Dec 2017.docx	01/12/2018	1.1	474.6 KB	Download	Delete

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Questionnaire	December Questionnaire	December Questionnaire.docx	31/12/2018	1.3	12.4 KB	Download	Delete

- 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

Dear Investigator,

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

Application Type HREC
Project ID 49968
Review Reference HREC/49968/DEF-2018-160883(v2)

Kind regards,

- A 'Request For Further Information' letter (pdf) from the HREC will include details for further information to be provided via ERM
- The form is **unlocked** to allow the applicant to complete the requests as outlined in the attached letter


Respond to a request for further information from the Ethics Committee

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

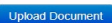
- A **Message** box will be displayed allowing the user to view the form
Press **View Form** [View Form](#) to be directed to the relevant form

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


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

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

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Protocol	December Holidays protocol	December Holidays protocol.docx	01/12/2018	1.1	11.5 KB	Download	Delete

- 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

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Protocol	December Holidays protocol	December Holidays protocol.docx	31/12/2018	1.2	11.5 KB	Download	Delete

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

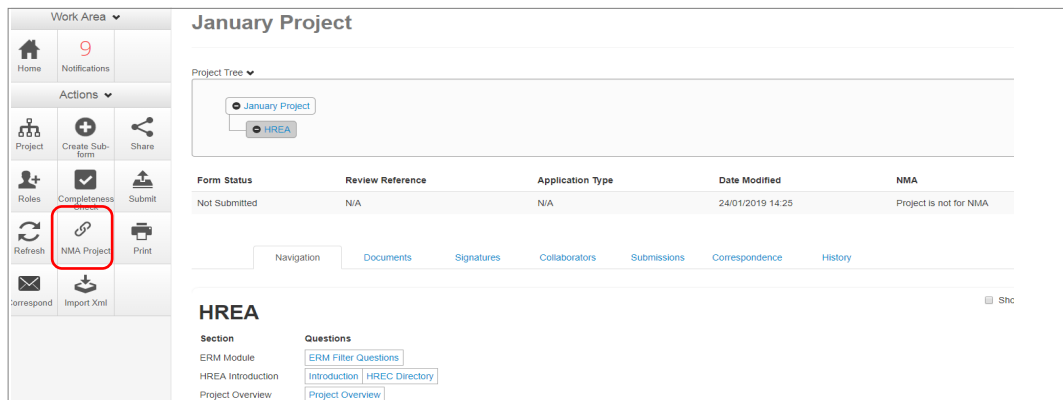
NMA is a national system for mutual acceptance of scientific and ethical review of multi-centre human research projects conducted in publicly funded health services across jurisdictions.

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?**

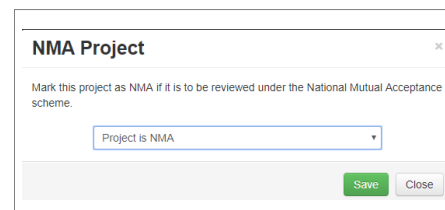
- Navigate  back to the **Actions** pane and select **NMA Project**



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** from the drop-down list

Select **Save**




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

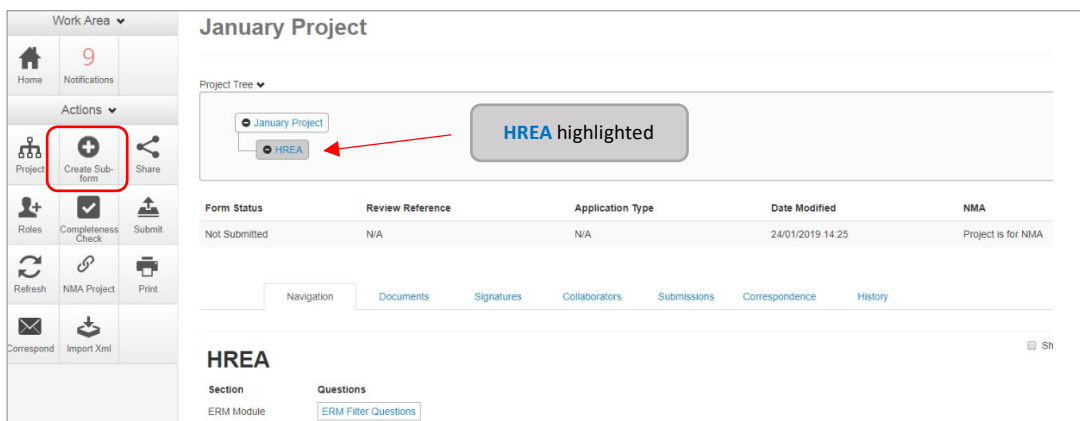
Section 6: Victorian Specific Module (VSM)

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

The VSM is submitted to the reviewing HREC as part of the ethics application.

In ERM:

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



Work Area

Home 9 Notifications

Actions

Project Create Sub-form Share

Roles Completeness Check Submit

Refresh NMA Project Print

Correspond Import Xml

January Project

Project Tree

January Project

HREA highlighted

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

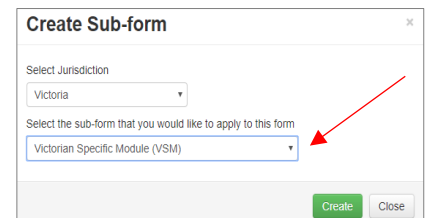
Navigation Documents Signatures Collaborators Submissions Correspondence History

HREA

Section ERM Module

Questions ERM Filter Questions

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



Create Sub-form

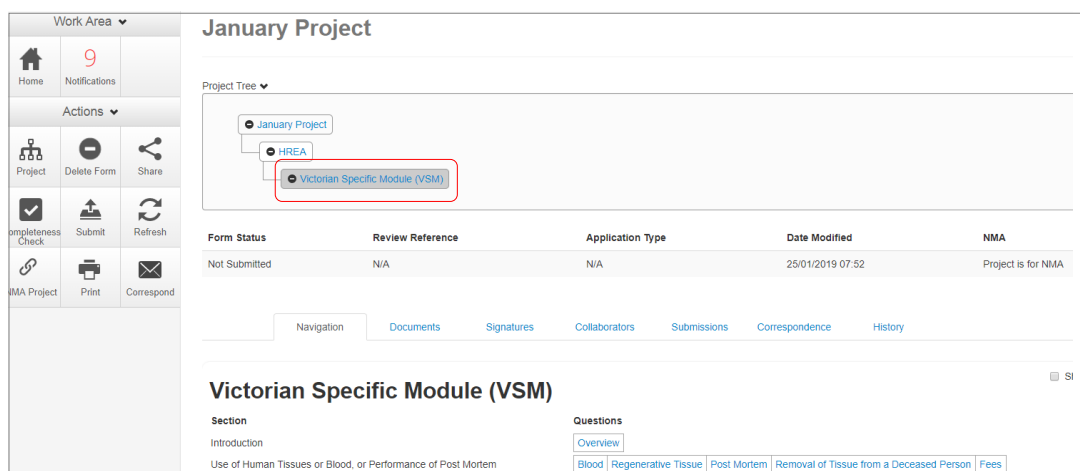
Select Jurisdiction

Victoria

Select the sub-form that you would like to apply to this form

Victorian Specific Module (VSM)

Create Close



Work Area

Home 9 Notifications

Actions

Project Delete Form Share

Completeness Check Submit Refresh

NMA Project Print Correspond

January Project

Project Tree

January Project

HREA

Victorian Specific Module (VSM)

Form Status	Review Reference	Application Type	Date Modified	NMA
Not Submitted	N/A	N/A	25/01/2019 07:52	Project is for NMA

Navigation Documents Signatures Collaborators Submissions Correspondence History


Victorian Specific Module (VSM)

Section Introduction

Use of Human Tissues or Blood, or Performance of Post Mortem

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 (highlight in Project Tree) and go to the [ERM Filter Questions](#) section

January Project

Project Tree

- January Project
 - HREA**
 - Victorian Specific Module (VSM)

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

HREA

Section: ERM Module | Questions: [ERM Filter Questions](#)

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

Actions: Previous, Next, Navigate, Print, Documents, Signatures, Save, Share, Roles, Collaborators, Completeness Check, Submit

Is the Coordinating Principal Investigator the contact person for this application?

☒ Yes
☐ No

A multi-site application must be shared with the Principal Investigator (or their delegate) at each site included in the ethics application.

Have you shared this form with colleagues at each site?

☐ Yes

Will this ethics application involve a site in Victoria?

☒ Yes
☐ No

Select the features that are applicable to this research project:

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

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

Victorian Specific Module

Upload Document

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

Actions: Previous, Next, Navigate, Print, Documents, Signatures, Save, Share, Roles, Collaborators, Completeness Check, Submit

Have you shared this form with colleagues at each site?

☐ Yes

Will this ethics application involve a site in Victoria?

☒ Yes
☐ No

Select the features that are applicable to this research project:

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

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

Victorian Specific Module

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Victorian specific module (VSM)	VSM January 2019	VSM January 2019.docx	01/01/2019	1.1	80.8 KB	Download	Delete

- When the HREA is complete and all supporting documents are uploaded (including the VSM) and signatures obtained, **Submit** the HREA
- Return to the VSM in the Project Tree and **Submit** the VSM
- If edits to the VSM are requested by the reviewing HREC, the Research Office will unlock the form
- Complete the edits and select **Submit**

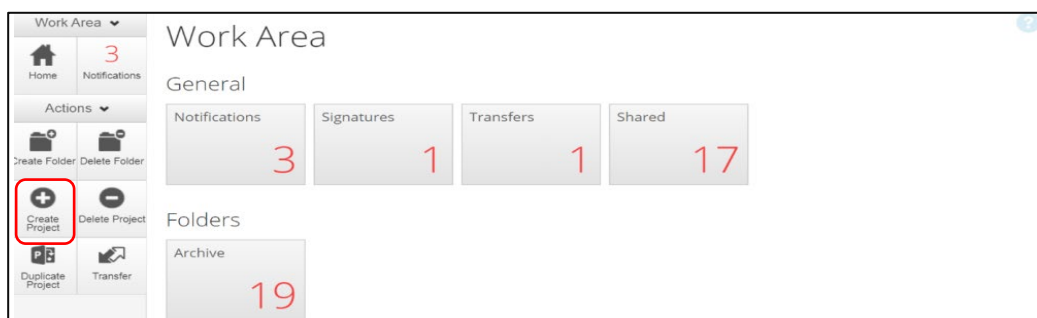
Section 7: Victorian Low and Negligible Risk Application (LNR VIC)

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

Create Project

Project Title (maximum 200 characters):*

LNR January

Select Jurisdiction

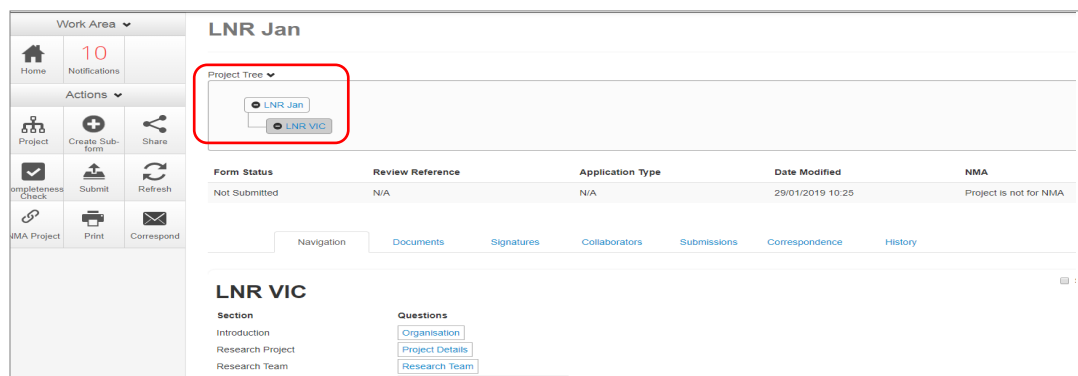
Victoria

Main Form

LNR VIC

Create Close

- 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 into 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

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

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

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

- 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](#) and to manage 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 screenshot shows the 'LNR VIC' form interface. On the left is an 'Actions' sidebar with icons for Previous, Next, Navigate, Print, Documents, Signatures, Save, Share, Collaborators, Completeness Check, and Submit. The main content area is titled 'LNR VIC' and contains a 'Statement' section. Under 'Statement', there is a 'Declaration of Coordinating Principal Investigator' section. It includes a list of statements to certify, such as 'All information is correct and as complete as possible' and 'I have had access to and read the National Statement on Ethical Conduct in Human Research (NHMRC, 2007)'. At the bottom of this section are two buttons: 'Request Signature' and 'Sign'. A red arrow points to the 'Sign' button, and a text box next to it states 'Signature required by CPI for multisite application'.

This screenshot shows the 'LNR VIC' form interface, similar to the one above but for a single site application. The 'Statement' section contains a 'Declaration of Principal Investigator' section. It includes a list of statements to certify, such as 'All information is correct and as complete as possible' and 'I have had access to and read the National Statement on Ethical Conduct in Human Research (NHMRC, 2007)'. At the bottom of this section are two buttons: 'Request Signature' and 'Sign'. A red arrow points to the 'Sign' button, and a text box next to it states 'Signature required by PI for single site application'. In the top right corner of the form, it says '5018 Version'.



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

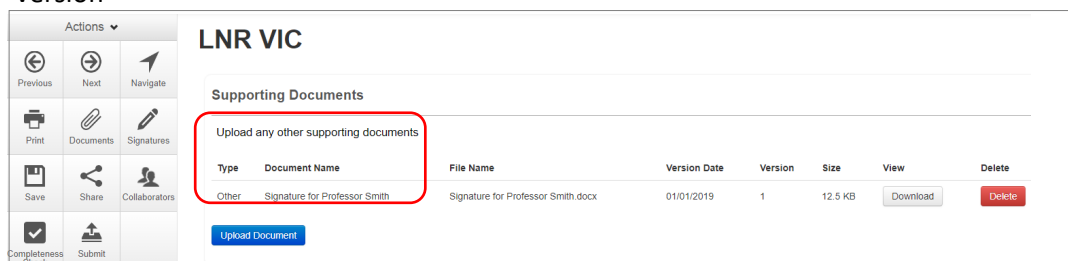
The signatory must have an **ERM** account to provide an electronic signature

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





Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Other	Signature for Professor Smith	Signature for Professor Smith.docx	01/01/2019	1	12.5 KB	Download	Delete

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 ERM email address and select **Request**




- The signatory will receive an email notification for a signature, a message and a link to ERM Log In page
- The signatory logs in to ERM

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

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

Type	Project Title	Requesting User	Message	Requested Date	Response Date	Status	Action
Principal Investigator	LNR December	Ms Catherine Farrington	Can you please sign this LNR form so I can submit	24/12/2018 10:52		Requested	View Form


- 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

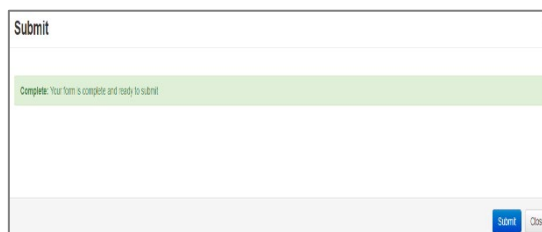
Section 8: Submission and Review Process – LNR VIC

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
- Following submission, a unique identification code is generated.
It is composed of six parts – e.g. LNR/61791/DEF-2020-202467 (v1)

Application type	LNR
ERM Project ID	61791
Organisation/hospital code	DEF
Year	2020- year of submission
Submission number	202467 - submission version number
Version number	v1

Recall an application

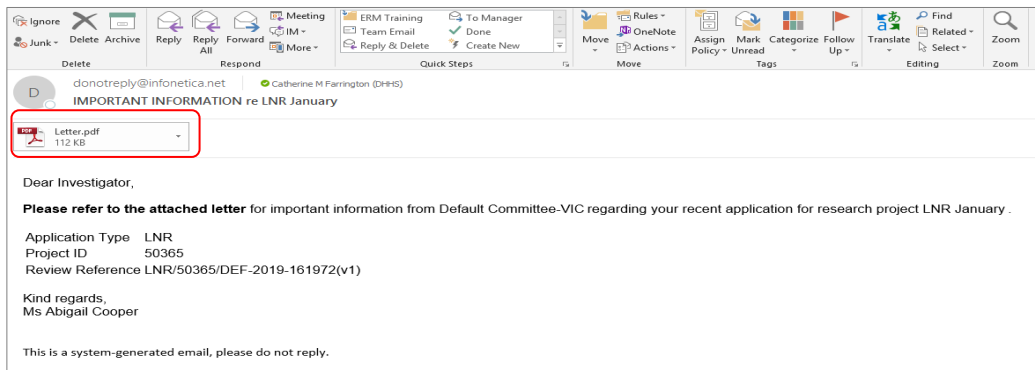
**Any changes made to the submission will INVALIDATE all electronic signatures
and will require all signature requests again**

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

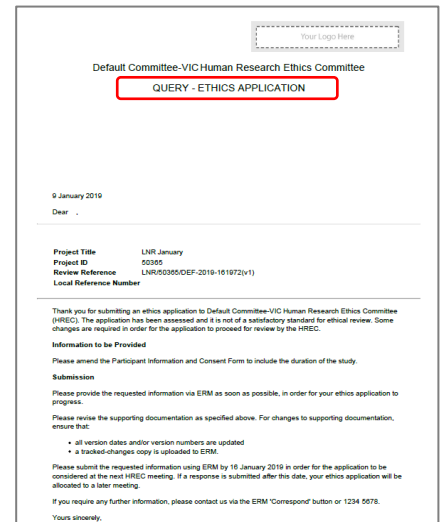
Responding to a Query from the Research Office

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



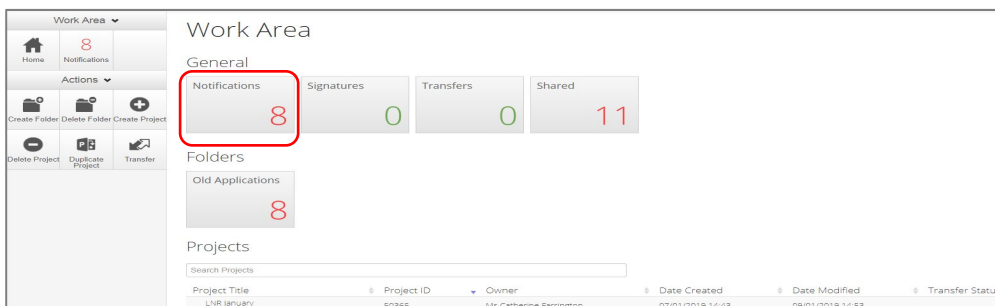
- A 'QUERY-ETHICS APPLICATION' letter (pdf) from the Research Office will include details for further information to be provided via ERM



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

To access the Query

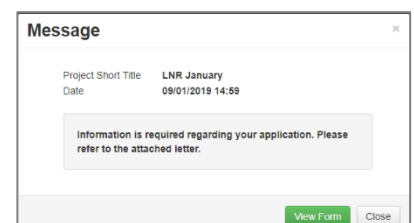
- In the Work Area, click on the **Notifications** tile



- Select the Message title to open and view the message

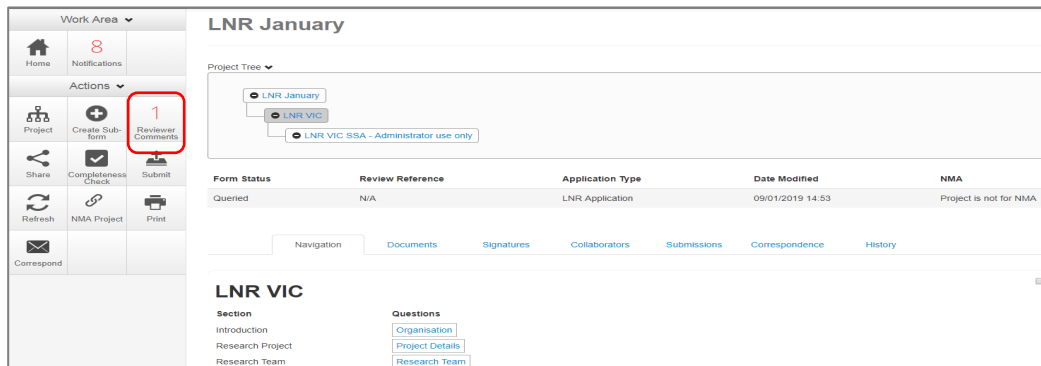


- A **Message** box will be displayed allowing the user to view the form
- Press **View Form** to be directed to the relevant form

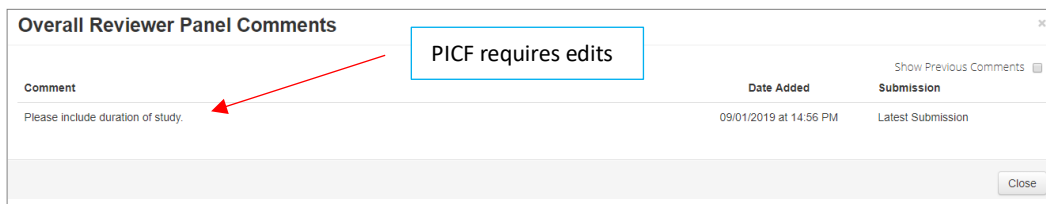


- The LNR VIC form will open under the **Navigation** tab.


Select **Reviewers Comments**  under the Actions pane

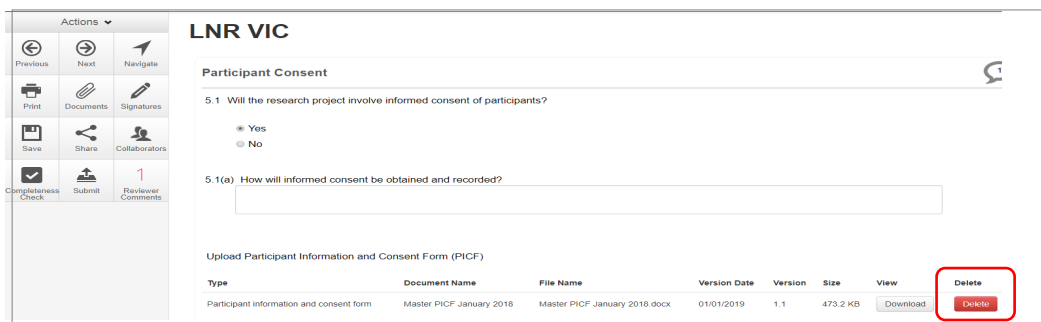



- A text box will be displayed of the **Overall Reviewer Panel Comments**

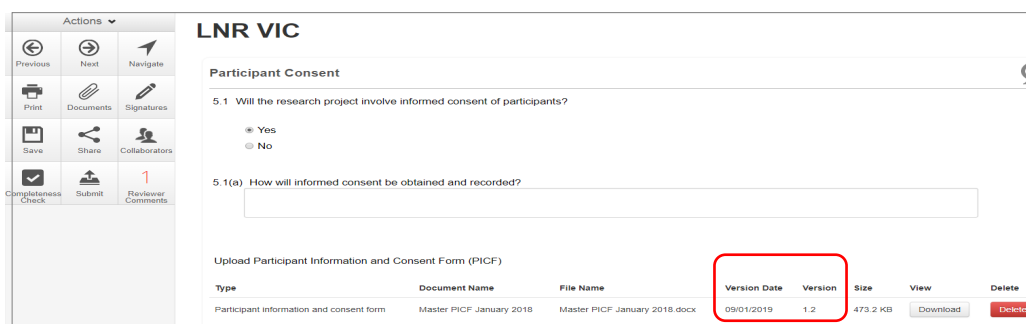


- Select the comment to be directed to the relevant section in the form i.e. to **Participant Consent Q 5.1**
- As the query requires a new version of a **document**, the original version should be deleted, and the new version uploaded into the form. Previous document versions are automatically archived.


- 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



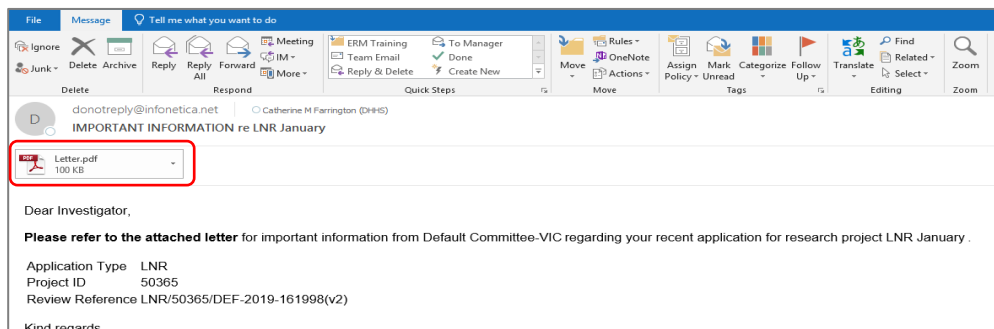
- Continue to complete other queries if instructed in the **Overall Reviewer Panel Comments**
- Once the revisions / additions have been completed, the form and / or supporting documents can be resubmitted

- Select the **Submit**  button under the **Actions** pane to resubmit the revised application
- 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

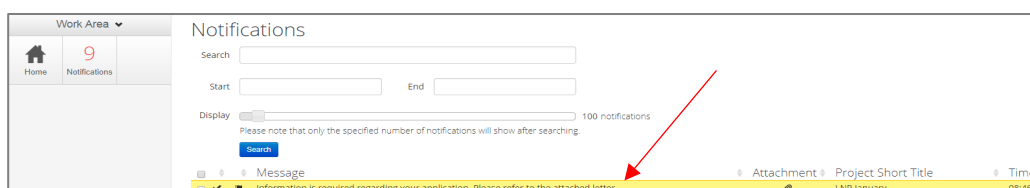
- The applicant is advised via an ERM email of important information regarding the application




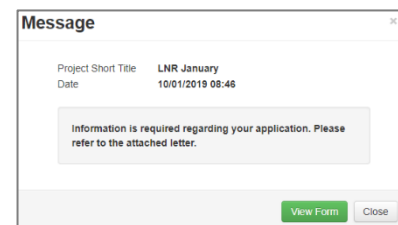
- A 'REQUEST FOR FURTHER INFORMATION' letter (pdf) from the HREC will include requests for further information to be provided via ERM
- The form is **unlocked** to allow the applicant to complete the requests as outlined in the attached letter

Respond to a request for further information from the Ethics Committee

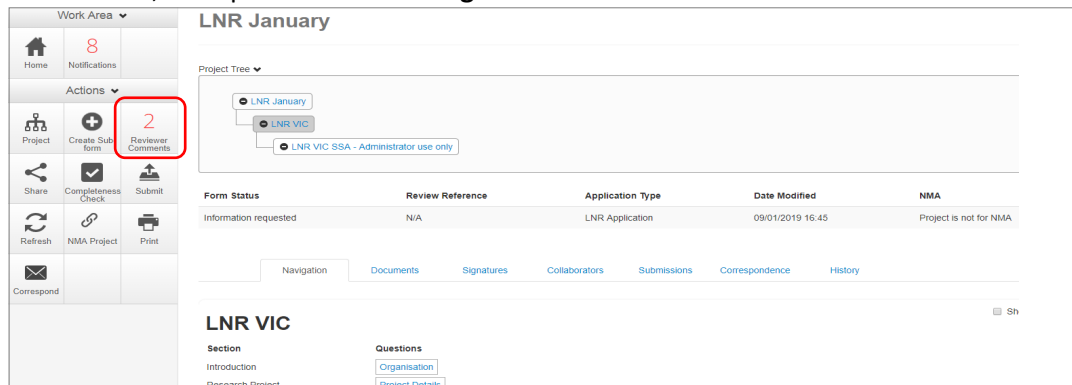
- Depending on the request, the applicant can amend the LNR VIC form and add new documents
- Log in to ERM account
- In the Work Area, click on the **Notifications** tile
- Select the Message title to open and view the message



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



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



Work Area

Home 8 Notifications

Actions

Project Create Sub-form Reviewer Comments

Share Completeness Check Submit

Refresh NMA Project Print

Correspond

LNR January

Project Tree

- LNR January
 - LNR VIC
 - LNR VIC SSA - Administrator use only

Form Status	Review Reference	Application Type	Date Modified	NMA
Information requested	N/A	LNR Application	09/01/2019 16:45	Project is not for NMA

Navigation Documents Signatures Collaborators Submissions Correspondence History

LNR VIC

Section

- Introduction
- Research Project

Questions


- Organisation
- Project Details

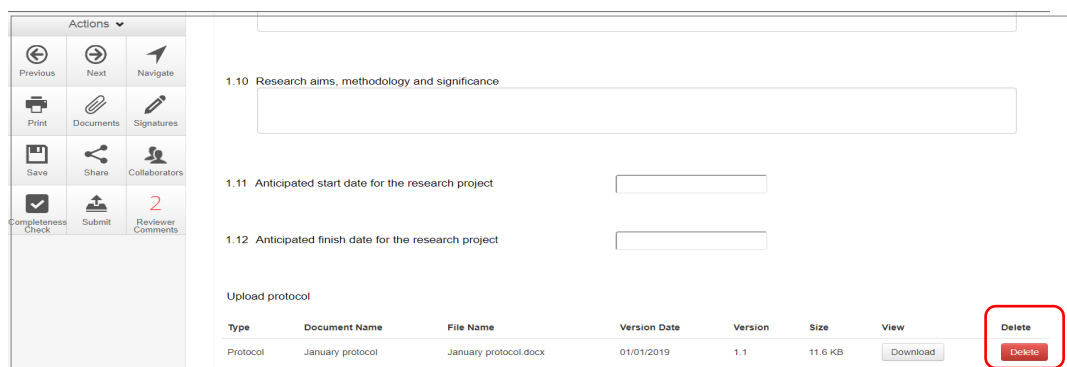
- Select **Reviewers Comments**  under the Action pane
- A text box will be displayed of the **Overall Reviewer Panel Comments**

Overall Reviewer Panel Comments

Comment	Date Added	Submission
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

[Show Previous](#)

- 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 into the form. Previous document versions are automatically archived.
- Select **Delete**  to delete the original version



Actions

Previous Next Navigate

Print Documents Signatures

Save Share Collaborators

Completeness Check Submit Reviewer Comments


1.10 Research aims, methodology and significance

1.11 Anticipated start date for the research project

1.12 Anticipated finish date for the research project

Upload protocol

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Protocol	January protocol	January protocol.docx	01/01/2019	1.1	11.6 KB	Download	Delete

- 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

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Protocol	January protocol	January protocol.docx	10/01/2019	1.2	11.6 KB	Download	Delete


- 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?

- The CPI/PI signs - for minor changes the Research Office has all signatures on the initial submission
- Other investigators to sign - if a substantial change or required by local policy

Check with other 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

The screenshot shows the 'Jan Project' interface. On the left, the 'Actions' pane contains a 'Create Sub-form' button (a plus icon in a circle) which is highlighted with a red box. In the main area, the 'Project Tree' shows 'Jan Project' and 'HREA', with 'HREA' also highlighted by a red box. Below the tree is a table with columns: Form Status, Review Reference, Application Type, Date Modified, and NMA. The table contains one row: 'Not Submitted', 'N/A', 'N/A', '30/01/2019 12:13', and 'Project is not for NMA'. At the bottom, there are tabs for 'Navigation', 'Documents', 'Signatures', 'Collaborators', 'Submissions', 'Correspondence', and 'History'. The 'HREA' section is visible, showing 'Section' (ERM Module) and 'Questions' (ERM Filter Questions, Introduction, HREC Directory).

- 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 a close button. Inside, there is a 'Select Jurisdiction' dropdown menu with 'Victoria' selected. Below it is a 'Select the sub-form that you would like to apply to this form' dropdown menu with 'Site Specific Assessment (SSA) VIC' selected. At the bottom right, there are 'Create' and 'Close' buttons. A red arrow points from the 'Create' button in the previous screenshot to this dialog box.

- The Project Tree will display the newly created SSA

The screenshot shows the 'Jan Project' interface after creating the SSA. The 'Project Tree' now includes 'Jan Project', 'HREA', and 'Site Specific Assessment (SSA) VIC -', with the new SSA highlighted by a red box. The table below the tree is the same as before. The 'Site Specific Assessment (SSA) VIC' section is now the active view, showing 'Section' (Introduction) and 'Questions' (Information, Project, Location, Ethics Review, Site Addition). The 'Information' question is selected, showing a link to 'Site Specific Assessment (SSA) VIC - Information'.

- 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.

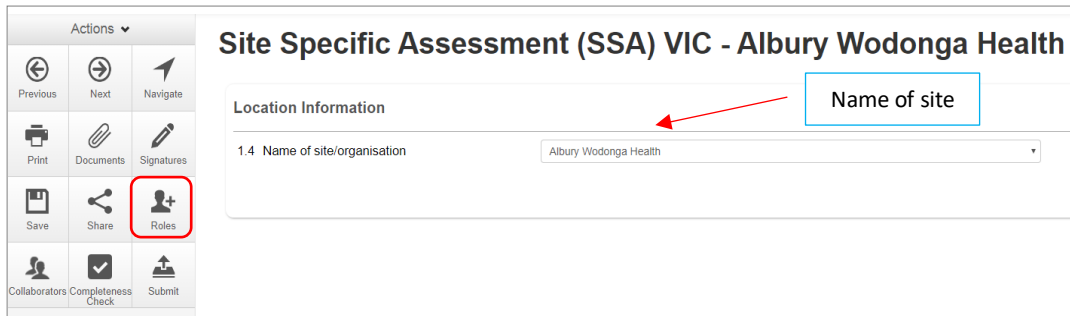
The creation and management of site SSAs in **ERM** should be determined by the CPI / delegate.

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 and becomes the SSA form owner
- The HREA / SSA owner may start the SSA then assign responsibility for its completion and submission to the site PI
- 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

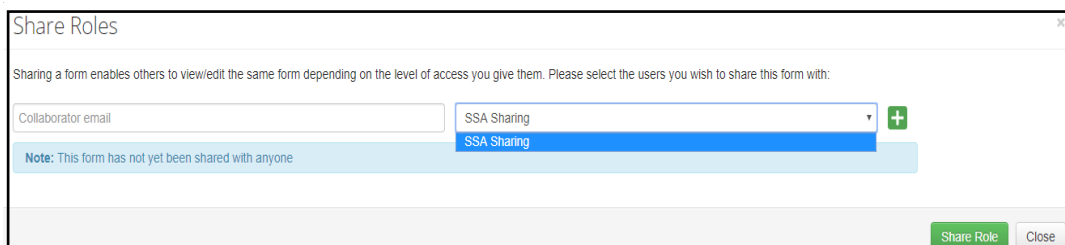



- A **Share Roles** text box will be displayed

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

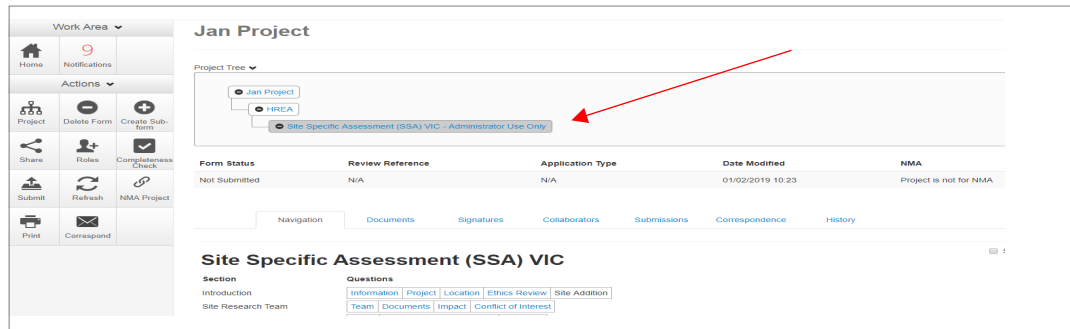
This level of access includes all of the following:

- 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



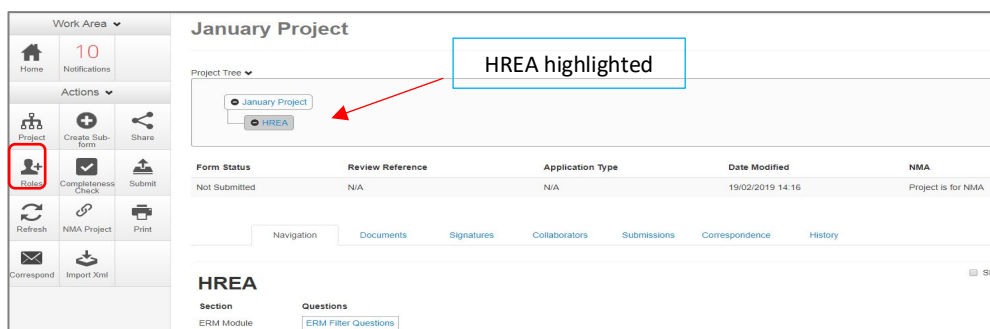
- Using **Roles +** allows the collaborator to also view the HREA form and supporting documents. All documents uploaded to the ethics application by the CPI are automatically available when the CPI has shared the SSA (using Roles +) with the site PI

- Complete the SSA form

(ii) Assigning Role to Site PI

- The HREA is allocated to the PI/delegate using **Roles +** allowing the PI access to the HREA to create their own SSA

- The HREA project owner selects the **Roles +** 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)**

Share Roles

Sharing a form enables others to view/edit the same form depending on the level of access you give them. Please select the users you wish to share this form with:

Collaborator email

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**

Create Sub-form

Select Jurisdiction

Victoria

Select the sub-form that you would like to apply to this form

Site Specific Assessment (SSA) VIC

Create

Close

- The SSA will be displayed in the Project Tree



- Complete the SSA form



Upload Documents

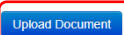
All site specific supporting documents are uploaded to the SSA when completing the relevant question in the form. See table below for examples of document types.

Section	Questions (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

Upload participant information and consent form (PICF)							
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		



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

Form Status	Review Reference	Application Type	Date Modified	NMA
Not Submitted	N/A	N/A	01/02/2019 14:07	Project is for NMA

Type	Document Name	File Name	Version Date	Version	Size	View
Curriculum vitae	Dr Jones CV	Dr Jones CV.docx	01/02/2018	1	12.5 KB	Download
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

Site Specific Assessment (SSA) VIC -

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.

- 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

Site Specific Assessment (SSA) VIC -

Signature of Head of Supporting Department

- A supporting department is any department that is providing support or services to the research project, but which does not have any member(s) on the research team.
- A Head of Supporting Department may delegate responsibility to an appropriate staff member.

Who is providing signature?

- ☒ Head of Supporting Department
- ☐ Head of Supporting Department's Delegate

Name

Department

Declaration by Head of Supporting Department

I certify that:

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

Signatures

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



Any change to the SSA form will invalidate signatures.

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


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

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


To use Wet ink signature

- 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

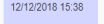

- Navigate to Section 'Other Documents' of the SSA to find [Other Documents](#)
- **Other Documents** opens to **Q 7.1** of the SSA form to attach the signature document
- Select **Upload Document**  to attach the signature document from your local drive to the SSA form
- Other supporting documents can also be uploaded in this section


To request an Electronic Signature

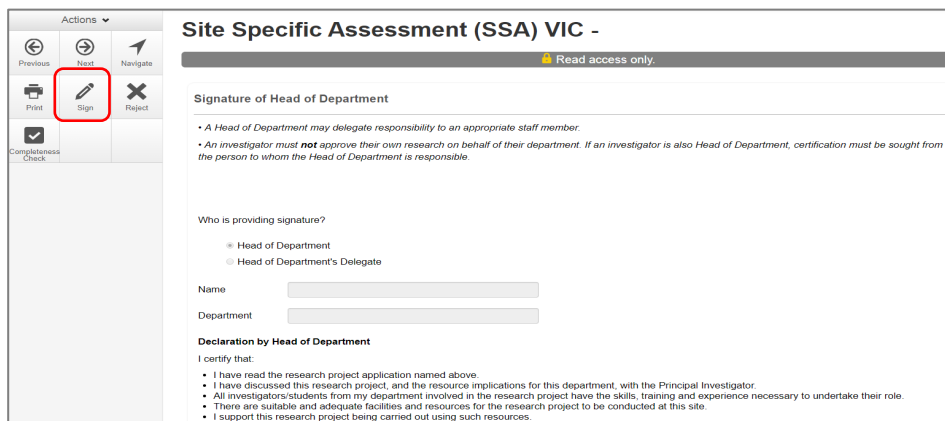
- To request an electronic signature from the Head of Department, Supporting Head of Department or Principal Investigator select **Request Signature**  button


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

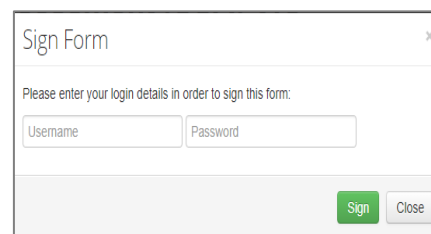
- The requested signatory will receive an email notification for a signature
- The signatory logs into ERM
- From the **Work Area** the signatory selects **Signatures** tile to open the request

- 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



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




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

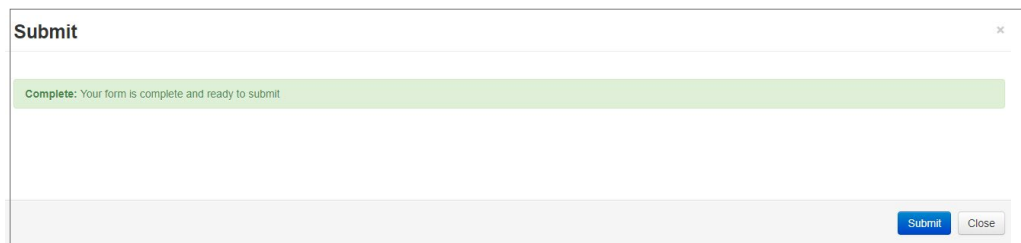
Section 10: Submission and Review Process – SSA


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

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

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





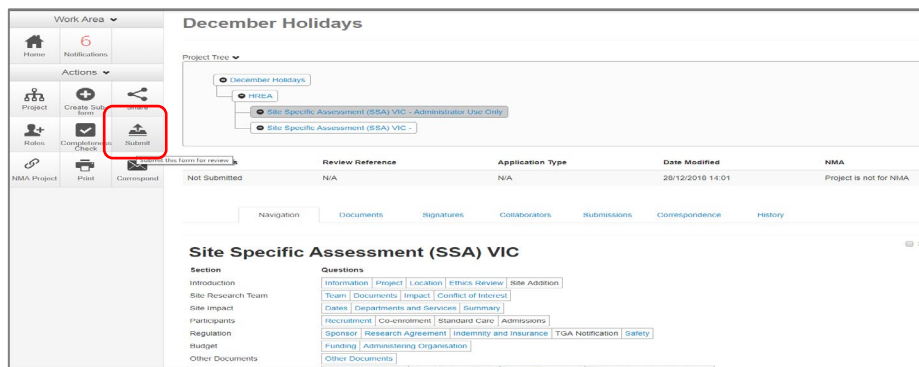
- Select the **Submit**  button
- The system will automatically submit the application to the site/organisation selected in **Q 1.4** of the SSA
- Following the submission, a unique identification code is generated.
It is composed of six parts - e.g. SSA/60889/VICTEST-2020-201446(v1)

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

Recall an application

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

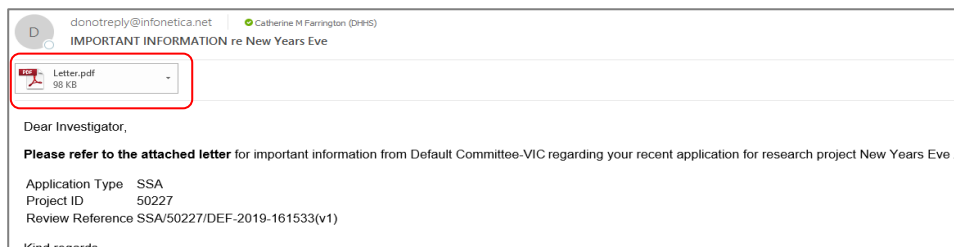
- Once the SSA application has been submitted, a recall option becomes available
- The form can be recalled **until** the submission is actioned by the Research Office
- This action removes the submitted application from the Research Office's ERM account
- Select the **Recall**  button under the Actions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



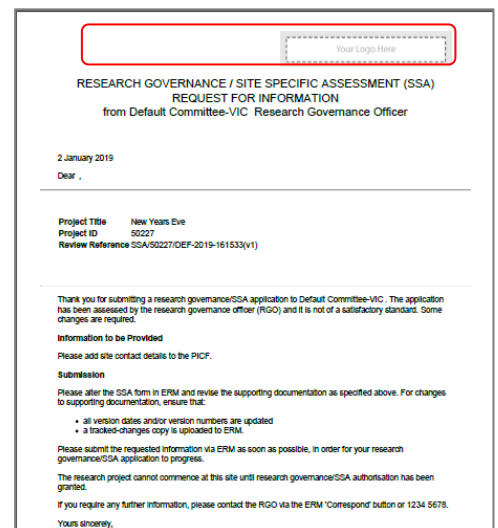
Responding to a Query from the Research Office

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



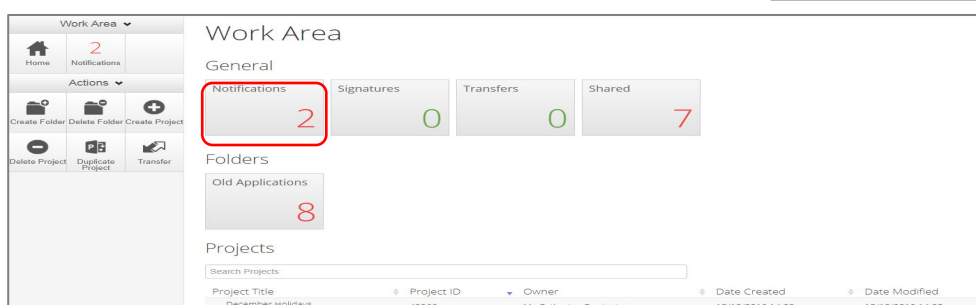
- A 'REQUEST FOR INFORMATION' letter (pdf) from the Research Office will include details for further information to be provided via ERM



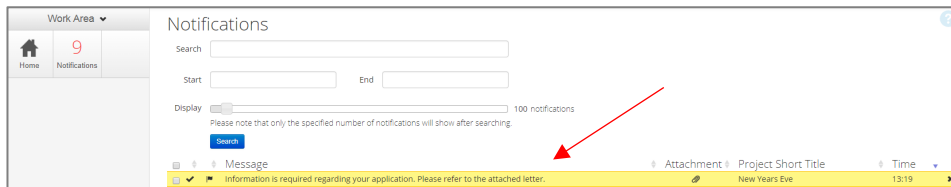
- The form will be **unlocked** to allow the applicant to complete the revisions / additions as requested


To access the Query

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



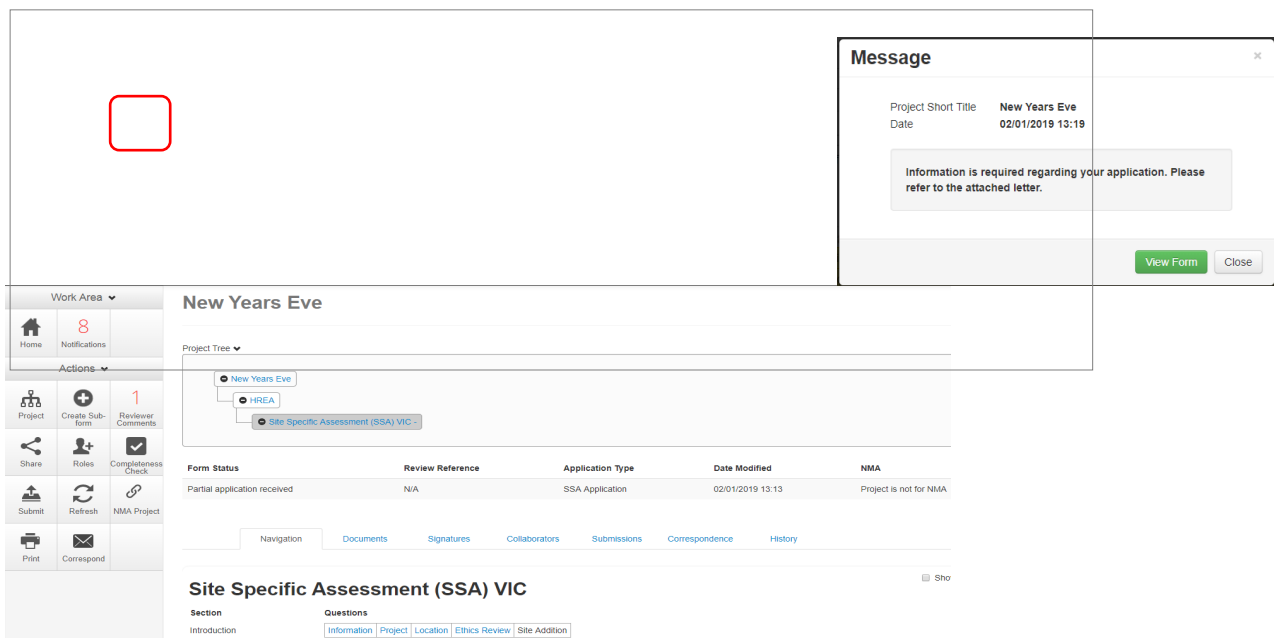
- Select the Message title to open and view the message



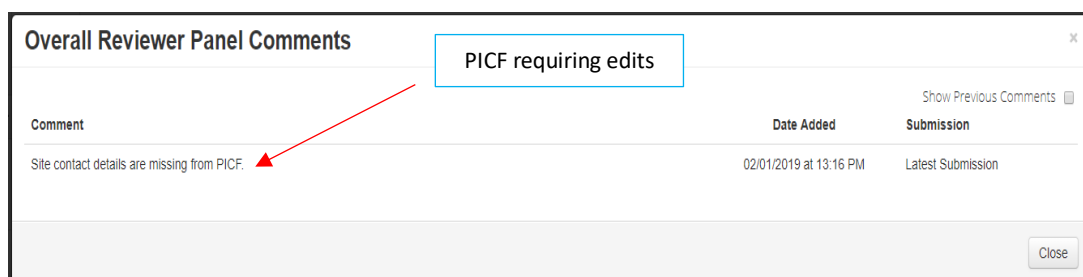
- A **Message** box will be displayed allowing the user to view the form
- Press **View Form**  to be directed to the relevant form


- 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, e.g. 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

Site Specific Assessment (SSA) VIC -

Participant Details

4.1 What does the research project involve at this site?

☒ Recruitment of participants
☐ Access to records
☐ Use of samples

4.1(a) Target number of participants at this site

4.1(b) Recruitment procedure at this site
 Include information about any dependent or unequal relationships, and participant reimbursement.

Upload participant information and consent form (PICF)

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Participant information and consent form	PICF's Dec 2017(site specific version)	PICF's Dec 2017(site specific version).docx	31/12/2018	1.1	269.6 KB	Download	Delete

- 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

Site Specific Assessment (SSA) VIC -

Participant Details

4.1 What does the research project involve at this site?

☒ Recruitment of participants
☐ Access to records
☐ Use of samples

4.1(a) Target number of participants at this site

4.1(b) Recruitment procedure at this site
 Include information about any dependent or unequal relationships, and participant reimbursement.

Upload participant information and consent form (PICF)

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Participant information and consent form	PICF's Dec 2017(site specific version)	PICF's Dec 2017(site specific version).docx	01/01/2019	1.2	269.6 KB	Download	Delete

- 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

New Years Eve

Project Tree

- New Years Eve
 - HREA
 - Site Specific Assessment (SSA) VIC -

Form Status	Review Reference	Application Type	Date Modified	NMA
Partial application received	N/A	SSA Application	02/01/2019 13:13	Project is not for NMA

Site Specific Assessment (SSA) VIC

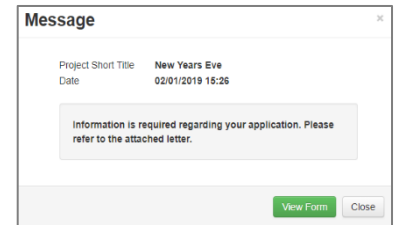
Section: Introduction | Questions: Information | Project | Location | Ethics Review | Site Addition

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

RGO Review Request

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

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



donotreply@infonetica.net Catherine M Farrington (DrHIS)
IMPORTANT INFORMATION re New Years Eve



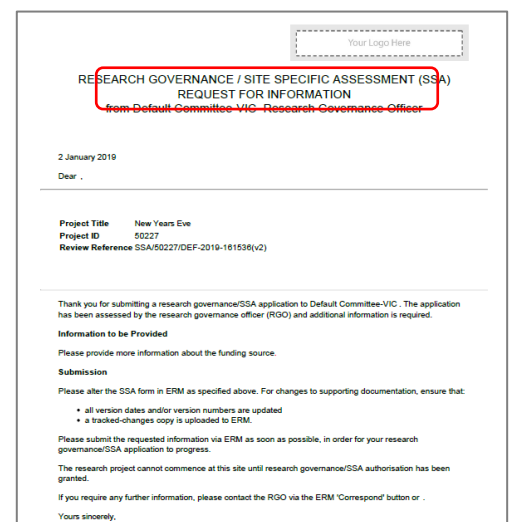
Dear Investigator,

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

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

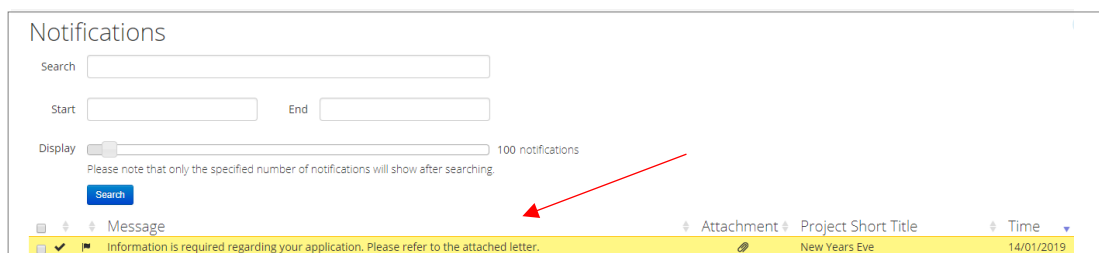
Kind regards,

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





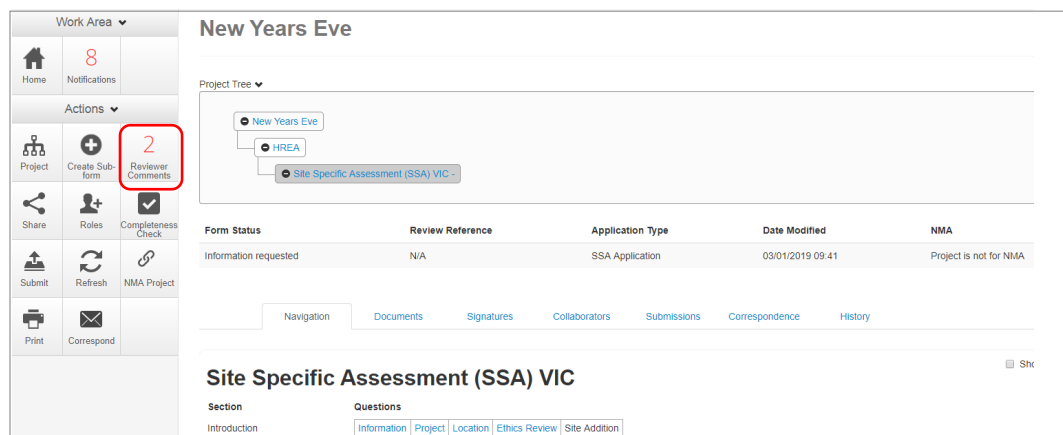
Respond to a request for further information from the RGO

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



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

- Press **View Form**  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



Work Area ▾

Home 8 Notifications

Actions ▾

Project Create Sub-form Reviewers Comments 2

Share Roles Completeness Check

Submit Refresh NMA Project

Print Correspond

New Years Eve

Project Tree ▾

- New Years Eve
- HREA
- Site Specific Assessment (SSA) VIC -

Form Status	Review Reference	Application Type	Date Modified	NMA
Information requested	N/A	SSA Application	03/01/2019 09:41	Project is not for NMA

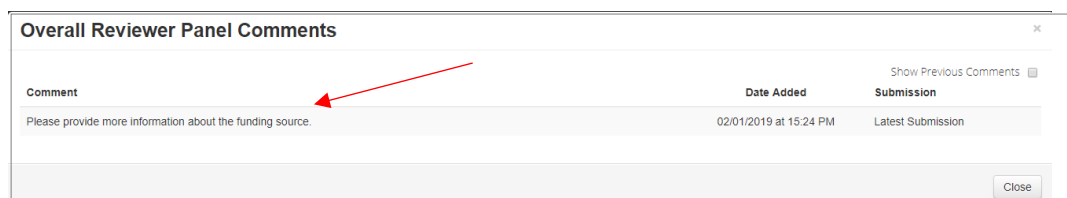
Navigation Documents Signatures Collaborators Submissions Correspondence History

Site Specific Assessment (SSA) VIC

Section Questions

Introduction Information Project Location Ethics Review Site Addition

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



Overall Reviewer Panel Comments

Comment

Please provide more information about the funding source.

Date Added 02/01/2019 at 15:24 PM

Submission Latest Submission

Show Previous Comments

Close

- 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**



Actions ▾

Previous Next Navigate

Print Documents Signatures

Save Share Roles

Collaborators Completeness Check Submit

Reviewers Comments 2

Site Specific Assessment (SSA) VIC -

Funding

6.1 Type(s) of funding

- ☐ Commercially sponsored
- ☐ Sponsored, other (e.g. collaborative group)
- ☐ External (e.g. NHMRC)
- ☐ Internal/Departmental
- ☒ Other

Other funding

Source Philanthropic funds raised from 2018 charity event


AUS 1000000

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

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

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

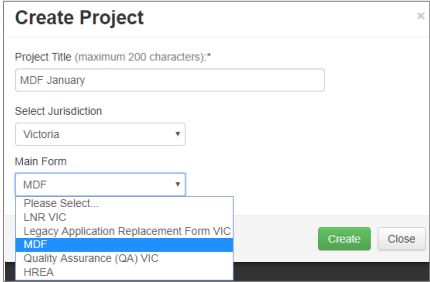
Section 11: Minimal Dataset Form (MDF)

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

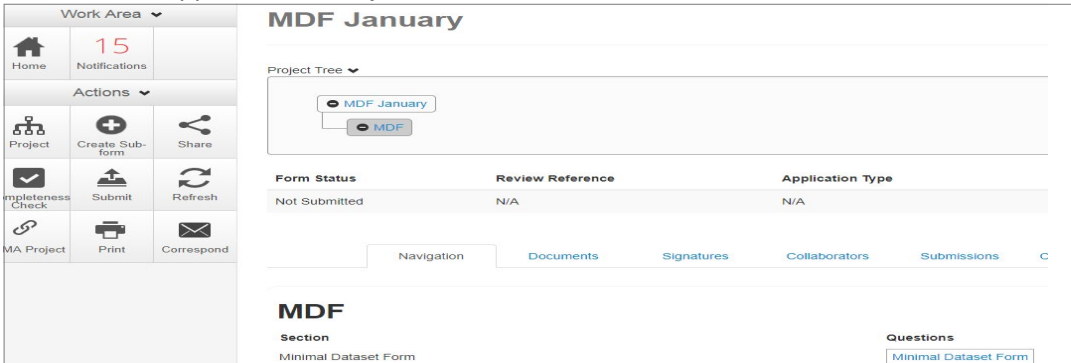
- Enter the Project Title, jurisdiction and select **MDF** from the Main Form drop-down list
Select **Create** button



The 'Create Project' dialog box contains the following fields and options:

- Project Title (maximum 200 characters):*** MDF January
- Select Jurisdiction:** Victoria
- Main Form:** A dropdown menu with 'MDF' selected. The dropdown list is open, showing options: 'Please Select...', 'LNR VIC', 'Legacy Application Replacement Form VIC', 'MDF' (highlighted), 'Quality Assurance (QA) VIC', and 'HREA'.
- Buttons:** 'Create' and 'Close'.

- The MDF will appear in the Project Tree





The screenshot shows the ERM interface with the 'MDF January' project selected in the Project Tree. The main content area displays the 'MDF' form details:

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

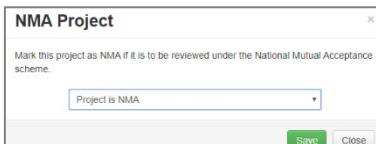
Below the table are tabs for 'Navigation', 'Documents', 'Signatures', 'Collaborators', and 'Submissions'. The 'MDF' section is titled 'Minimal Dataset Form'.

- Complete the questions in the MDF
- Enter the unique ethics reference number indicating where the ethics application was reviewed and approved e.g. HREC/19/CAL/123

- Select the **Navigate**  button to move back to the Project Tree and select the **NMA Project**  button under the Actions pane

- A **NMA Project** text box is displayed

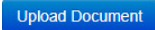
- Select 'Project is NMA' and **Save** 

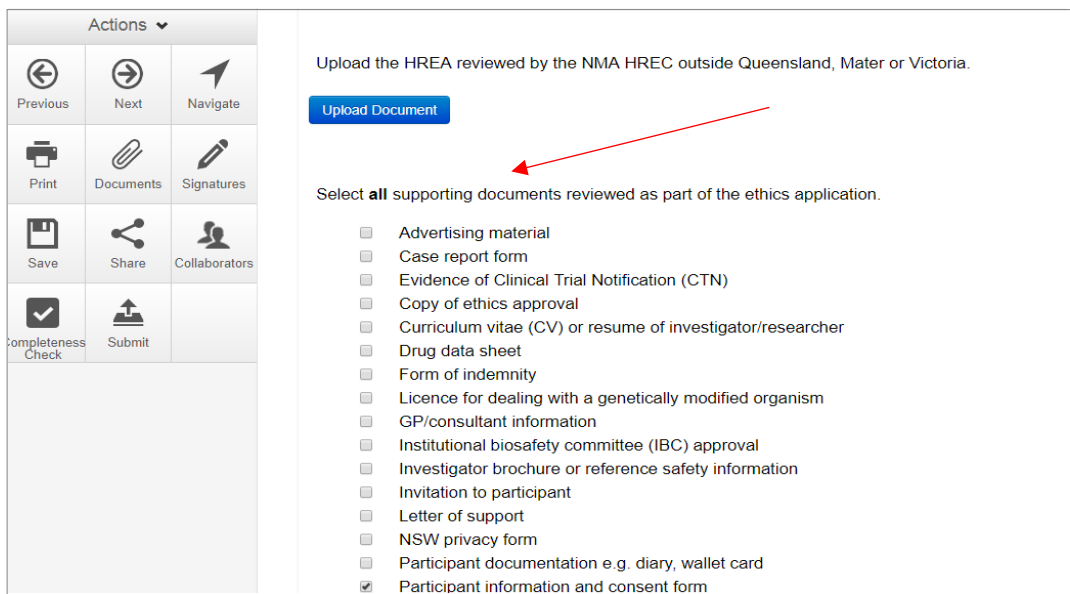


The 'NMA Project' dialog box contains the following fields and options:

- Text:** 'Mark this project as NMA if it is to be reviewed under the National Mutual Acceptance scheme.'
- Field:** 'Project is NMA' with a dropdown arrow.
- Buttons:** 'Save' and 'Close'.

For further information on NMA see [NMA research governance/SSA application](#) on the **Clinical trials and research** webpage

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



Upload the HREA reviewed by the NMA HREC outside Queensland, Mater or Victoria.

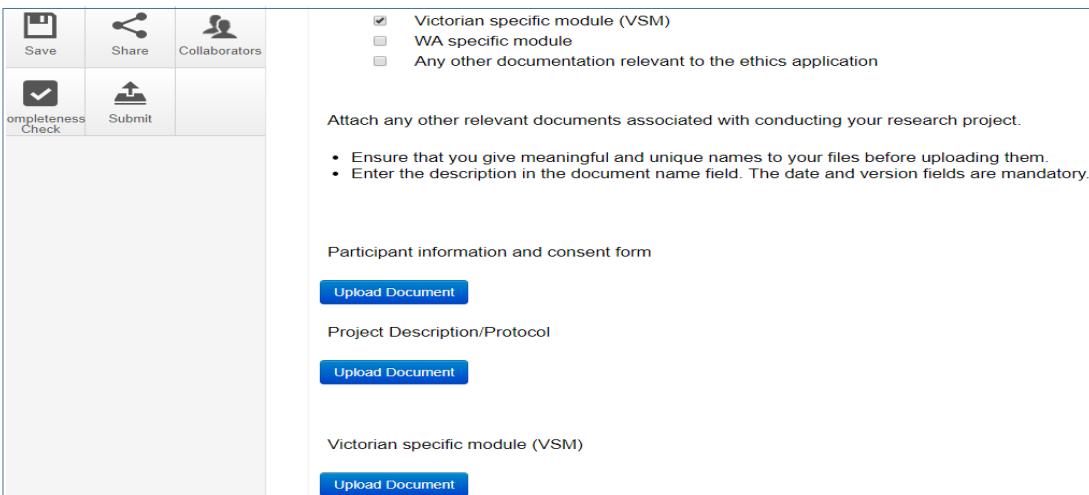
Upload Document

Select **all** supporting documents reviewed as part of the ethics application.

- ☐ 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 (VSM) is selected if a VSM was submitted as part of the ethics application. The CPI should provide a copy of the WORD document of the VSM that was submitted to the reviewing HREC.



☒ Victorian specific module (VSM)

☐ WA specific module

☐ Any other documentation relevant to the ethics application

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

- 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.

Participant information and consent form


Upload Document

Project Description/Protocol

Upload Document

Victorian specific module (VSM)

Upload Document

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

Work Area

Home 15 Notifications

Actions

Project Create Sub-form Share

Completeness Check Submit Refresh

MA Project Print Correspond

MDF January

Project Tree

MDF January

MDF

Form Status Not Submitted

Review Reference N/A

Application Type N/A

Navigation Documents Signatures Collaborators Submissions C

MDF

Section Minimal Dataset Form

Questions Minimal Dataset Form

- Select the jurisdiction and Site Specific Assessment (SSA)
Select **Create** button

Create Sub-form

Select Jurisdiction

Victoria

Select the sub-form that you would like to apply to this form

Site Specific Assessment (SSA) VIC

Create Close

- 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) ERM email address and select SSA Sharing
Select **Share Role**

Share Roles

Sharing a form enables others to view/edit the same form depending on the level of access you give them. Please select the users you wish to share this form with:

Collaborator email

SSA Sharing

Note: This form has not yet been shared with anyone

Share Role Close


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

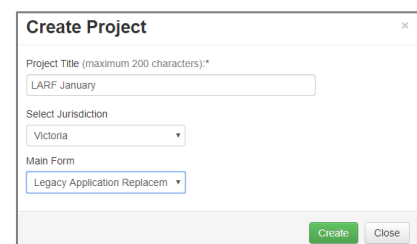
Section 12: Legacy Application Replacement Form (LARF)

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



Create Project

Project Title (maximum 200 characters):*

LARF January

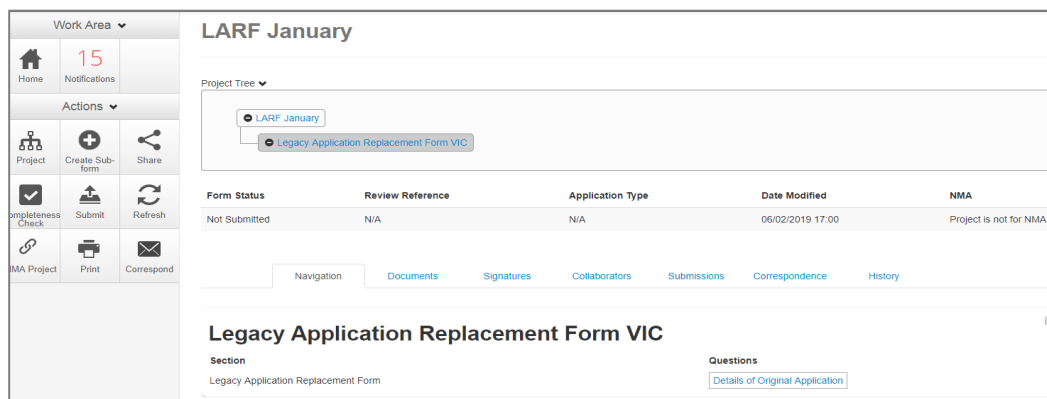
Select Jurisdiction

Victoria

Main Form

Legacy Application Replacem

Create Close



Work Area ▾

Home 15 Notifications

Actions ▾

Project Create Sub-form Share

Completeness Check Submit Refresh

MA Project Print Correspond

LARF January

Project Tree ▾

- LARF January
- Legacy Application Replacement Form VIC


Form Status	Review Reference	Application Type	Date Modified	NMA
Not Submitted	N/A	N/A	06/02/2019 17:00	Project is not for NMA

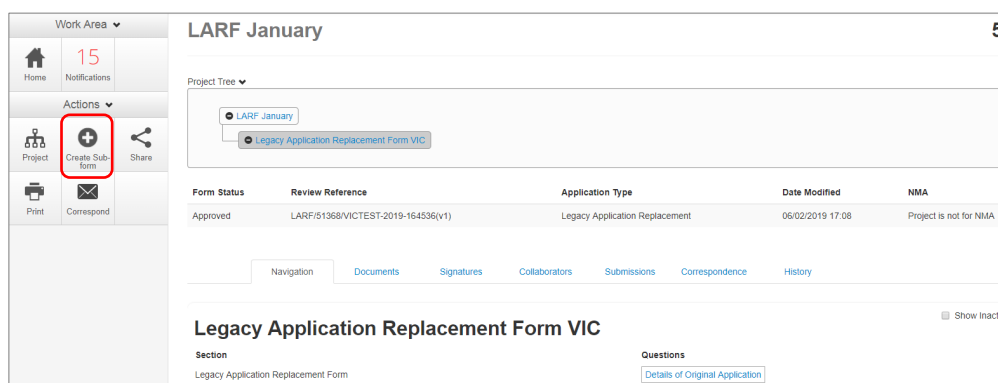
Navigation Documents Signatures Collaborators Submissions Correspondence History

Legacy Application Replacement Form VIC

Section Legacy Application Replacement Form

Questions [Details of Original Application](#)

- 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



Work Area ▾

Home 15 Notifications

Actions ▾

Project **Create Sub-form** Share

Print Correspond

LARF January

Project Tree ▾

- LARF January
- Legacy Application Replacement Form VIC

Form Status	Review Reference	Application Type	Date Modified	NMA
Approved	LARF/51368/VICTEST-2019-164536(v1)	Legacy Application Replacement	06/02/2019 17:08	Project is not for NMA

Navigation Documents Signatures Collaborators Submissions Correspondence History


Legacy Application Replacement Form VIC

Section Legacy Application Replacement Form

Questions [Details of Original Application](#)


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

Select **Create**



Create Sub-form ✕
Select the sub-form that you would like to apply to this form

Create Close

- 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**

Share Roles ✕
Sharing a form enables others to view/edit the same form depending on the level of access you give them. Please select the users you wish to share this form with:
 +

Note: This form has not yet been shared with anyone

Share Role Close

- 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 the following types of projects:

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

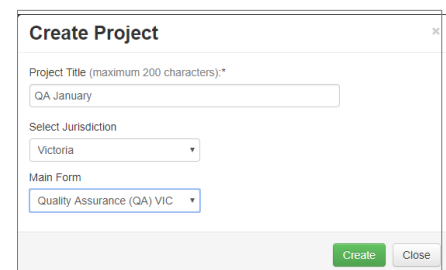
Consult with the organisation's Research Office before creating the QA application. The Research Office will advise whether the QA form is the right choice for the project.


- The applicant logs into ERM

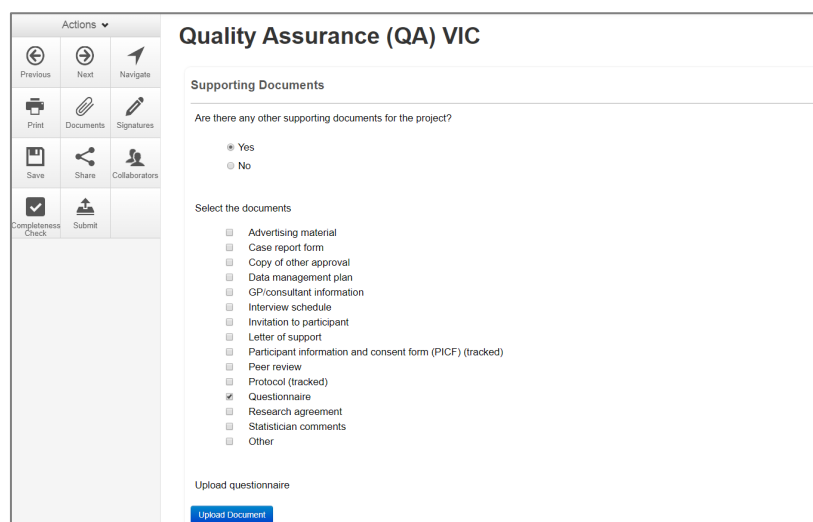
- Select **Create Project**  button under the Actions pane to create a new Main Form

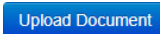

- Enter the Project Title, jurisdiction and select **Quality Assurance (QA) VIC** from the main form drop-down list

Select **Create**



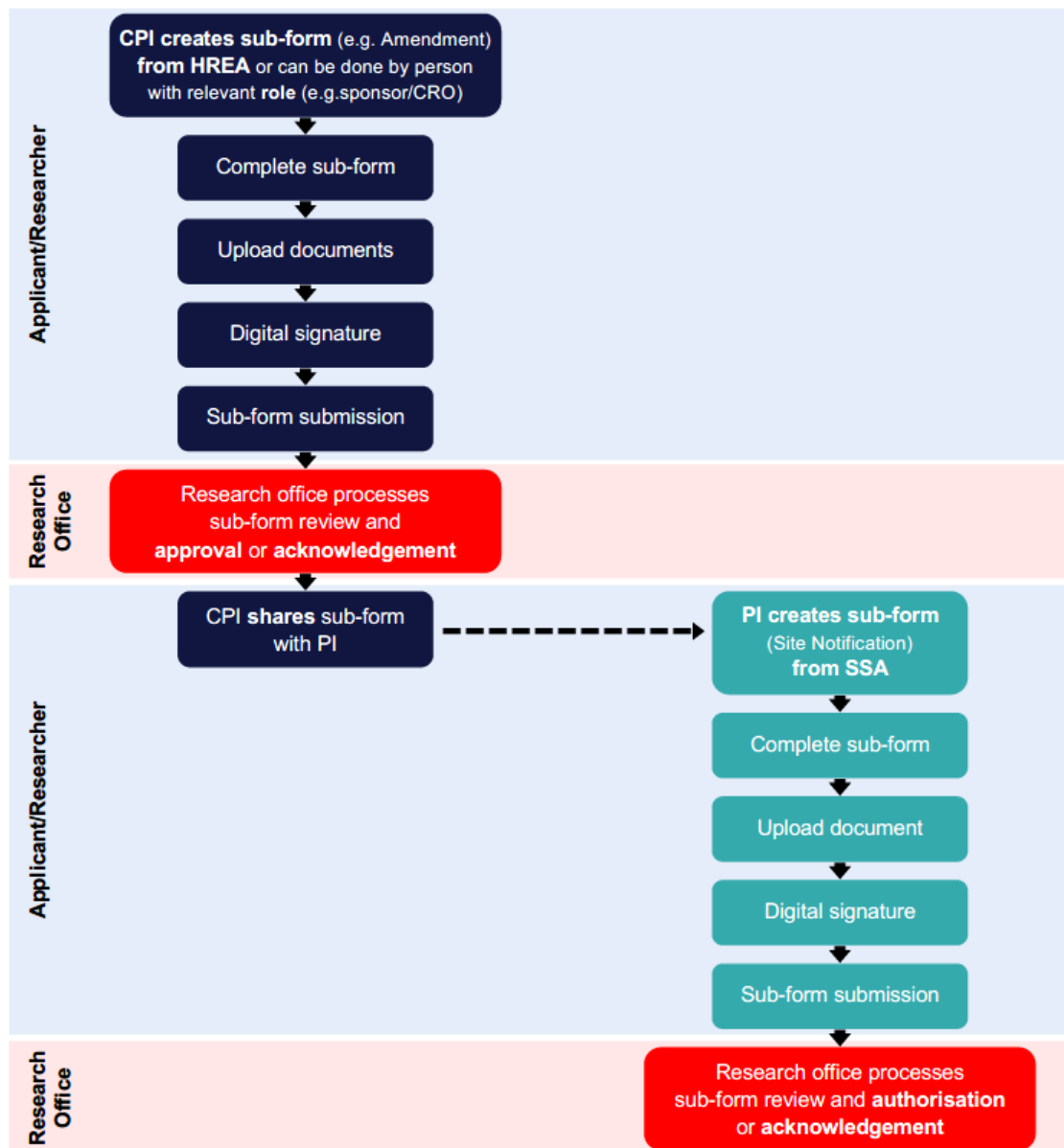
- The QA form will appear under the Project Tree
- Complete the questions in the QA form
- The **Supporting Documents**  section will enable supporting documents e.g. a Questionnaire to be uploaded into the application



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

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.

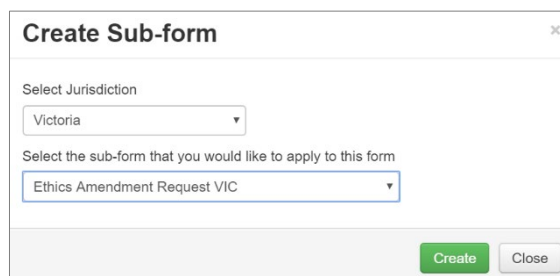
Sub-forms for post approval

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

Create a Sub-form

- The CPI / delegate logs in to ERM
- Select the project title to display the project under the Project Tree and highlight the HREA
- Select **Create Sub-form**  button under the Actions pane to create a new sub-form
- Select the jurisdiction and the sub-form e.g. Ethics Amendment Request VIC

Select **Create**



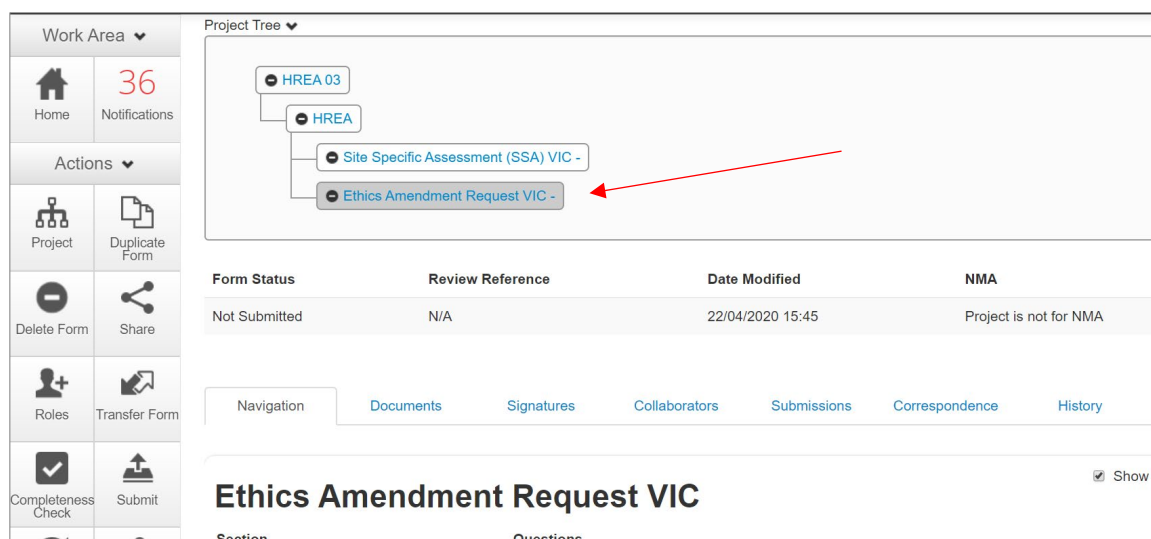
Create Sub-form

Select Jurisdiction
Victoria

Select the sub-form that you would like to apply to this form
Ethics Amendment Request VIC

Create Close

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



The screenshot shows the ERM interface. On the left is a sidebar with 'Work Area' containing Home, Notifications (36), and Actions. The Actions pane includes Project, Duplicate Form, Delete Form, Share, Roles, Transfer Form, Completeness Check, and Submit. The main area shows the 'Project Tree' with a hierarchy: HREA 03, HREA, Site Specific Assessment (SSA) VIC -, and Ethics Amendment Request VIC -. A red arrow points to the 'Ethics Amendment Request VIC -' node. Below the tree is a table with columns: Form Status, Review Reference, Date Modified, and NMA. The table shows one entry: Not Submitted, N/A, 22/04/2020 15:45, Project is not for NMA. At the bottom, there are tabs for Navigation, Documents, Signatures, Collaborators, Submissions, Correspondence, and History. The main content area is titled 'Ethics Amendment Request VIC' and has a 'Show I' checkbox.

Form Status	Review Reference	Date Modified	NMA
Not Submitted	N/A	22/04/2020 15:45	Project is not for NMA

Complete a Sub-form – Ethics Amendment Request

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

Amendment Request VIC

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

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)

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

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. Ethics Amendment Request in the Project Tree

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

- Select **Share Role**

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

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

Amendment Request VIC

Declaration

Declaration of Coordinating Principal Investigator

The information provided is complete and correct.

The project is being conducted in keeping with the conditions of approval of the reviewing HREC (and subject to any changes subsequently approved).

The project is being conducted in compliance with the [National Statement on Ethical Conduct in Human Research](#) (NHMRC, 2007) and [Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods](#) (NHMRC, 2016), or as amended.

Request Signature **Sign**

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

- Enter the signatory's ERM email address and message

Select **Request**

Request a signature

Enter the email address of the person you want to sign this form

Email Address

Can you please sign the amendment form

Request **Close**

- 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

ERM Applications Home Contacts Help

Work Area

Home 1 Notifications

Actions

Create Folder Delete Folder Create Project

Delete Project Duplicate Project Transfer

Work Area

General

Notifications 1 **Signatures 1** Transfers 0 Shared 0

Folders

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

Signatures

Search Signatures

Type	Project Title	Requesting User	Message	Requested Date	Response Date	Status	Action
Principal Investigator	LNR December	Ms Catherine Farrington	Can you please sign this LNR form so I can submit	24/12/2018 10:52		Requested	View Form

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

Amendment Request VIC

Actions

Previous Next Navigate

Print **Sign** Reject

Completeness Check

Amendment Request VIC

Read access only.

Guidance

Amendment

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

This Amendment Request must be completed and submitted to the reviewing HREC or ethics review body.


An amendment to a research project may also impact research governance/site specific assessment (SSA). The Research Governance Officer (RGO) at each affected site must be notified of the amendment by the site Principal Investigator (PI), in order to determine if research governance/SSA amendment is required.

An amendment must not be implemented at a site until the HREC or ethics review body has granted approval of the amendment **and** (if applicable) the site RGO has granted authorisation of research governance/SSA amendment.

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



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

Select **Sign**  button

A screenshot of a 'Sign Form' dialog box. The title bar says 'Sign Form' with a close button (X). The main text says 'Please enter your login details in order to sign this form:'. Below this are two input fields: 'Username' and 'Password'. At the bottom right, there are two buttons: a green 'Sign' button and a grey 'Close' 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).

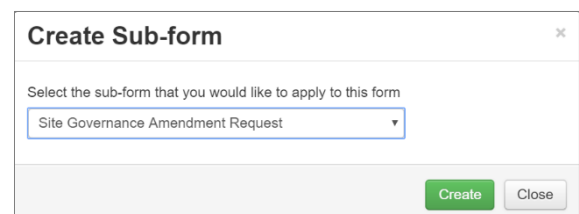
Sub-forms for post authorisation

- Complaint Report
- Non-serious Breach / Deviation Report
- Site Audit Report
- Site Governance Amendment Request
 - To notify the RGO of an amendment that has been approved by the reviewing ethics committee **or**
 - To notify the RGO of a governance-only amendment that does not require ethical approval
- Site Notification Form
- Site Progress Report

Create a Sub-form

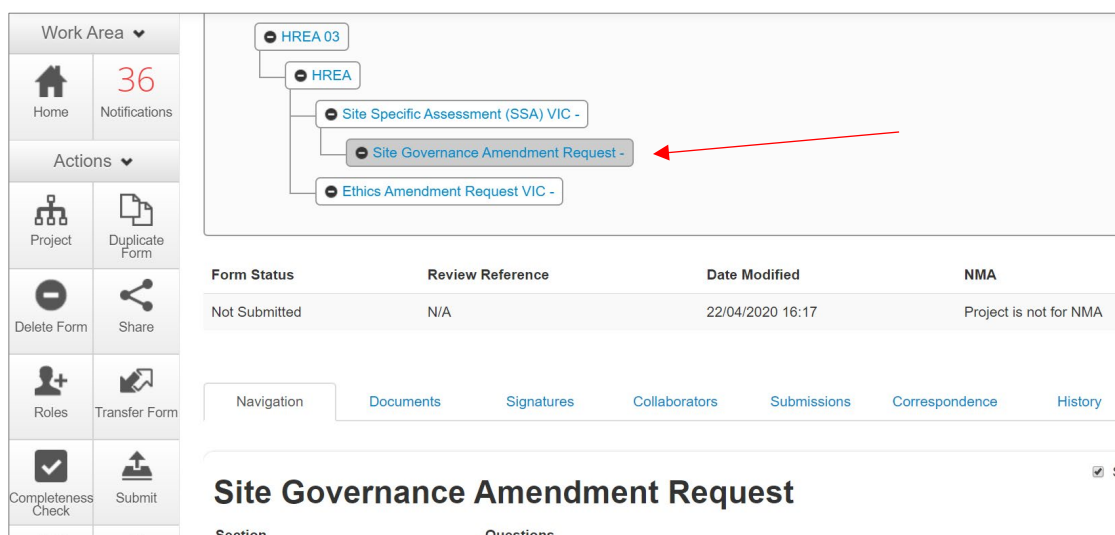
- The PI / delegate logs in to ERM
- Select the project title to display the project under the Project Tree and highlight the SSA for your organisation

- Select **Create Sub-form**  button under the Actions pane to create a new sub-form e.g. Site Governance Amendment Request
Select **Create**



The 'Create Sub-form' dialog box has a title bar with a close button. The main content area contains the text 'Select the sub-form that you would like to apply to this form' above a dropdown menu. The dropdown menu is currently set to 'Site Governance Amendment Request'. At the bottom right, there are two buttons: a green 'Create' button and a grey 'Close' button.

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



The screenshot shows the ERM interface. On the left is a sidebar with a 'Work Area' dropdown and various action buttons: Home, Notifications (36), Project, Duplicate Form, Delete Form, Share, Roles, Transfer Form, Completeness Check, and Submit. The main area displays a 'Project Tree' with a hierarchy: HREA 03, HREA, Site Specific Assessment (SSA) VIC -, Site Governance Amendment Request - (highlighted with a red arrow), and Ethics Amendment Request VIC -. Below the tree is a table with the following data:

Form Status	Review Reference	Date Modified	NMA
Not Submitted	N/A	22/04/2020 16:17	Project is not for NMA

At the bottom, there is a navigation bar with tabs: Navigation, Documents, Signatures, Collaborators, Submissions, Correspondence, and History. The main content area is titled 'Site Governance Amendment Request' and has a 'Section' and 'Questions' header.

Complete a Sub-form – Site Governance Amendment Request


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

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

- In the Project Tree, select the Ethics Amendment Request VIC form
- From the **Documents** tab, the amendment submission can be downloaded by selecting the **Print**



button under the **Actions** pane and saved to your local drive

- Associated documents can be downloaded by selecting **Download**  and saved to your local drive


Form Status	Review Reference	Date Modified	NMA	63445
Not Submitted	N/A	22/04/2020 18:05	Project is not 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	PICF Master December 2019	PICF Master December 2019.docx	31/12/2019	1	11.9 KB	Download
Protocol	December Holidays protocol	December Holidays protocol.docx	31/12/2019	1	11.5 KB	Download

Download All as Pdf

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- Return to the Site Governance Amendment Request form in the Project Tree
- Upload a copy of the:
 - Ethics Amendment Request to the reviewing ethics committee (PDF copy of the amendment submission)
 - Amendment approval from the reviewing ethics committee (PDF copy of amendment approval letter/certificate)
- Other documents if relevant, e.g. the protocol, Master PICF and Site PICF can be uploaded in the [Amended Documents](#) section under Documents

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

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

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

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

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

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 Governance Amendment Request in the Project Tree

Work Area ▾

Home 36 Notifications

Actions ▾

Project Duplicate Form

Delete Form Share

Roles Transfer Form

Completeness Check Submit

HREA 03

HREA

Site Specific Assessment (SSA) VIC -

Site Governance Amendment Request -

Ethics Amendment Request VIC -

Form Status	Review Reference	Date Modified	NMA
Not Submitted	N/A	22/04/2020 16:17	Project is not for NMA

Navigation Documents Signatures Collaborators Submissions Correspondence History

Site Governance Amendment Request

Section Questions

- Select **Roles +** button under the Action pane
- Enter the collaborator's ERM email address and select **Post Approval/Authorisation Subform**

Share Roles

Sharing a form enables others to view/edit the same form depending on the level of access you give them. Please select the users you wish to share this form with:

Collaborator email

Post Approval/Authorisation Subforms +

Name Role Given on Remove Remove All Permissions

- Other collaborators can be added by selecting **+** button
- Select **Share Role** **Share Role**
- The collaborator receives an email notification on their assigned role in the project
- The collaborator at the site can view the Site Governance Amendment Request 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 the **Request Signature** **Request Signature** button

Actions ▾

Previous Next

Navigate Print

Documents Signatures

Save Share

Request Signature

Site Governance Amendment Request - 01/04/2020

Declaration

Declaration of Principal Investigator

The information provided is complete and correct.

The project is being conducted in keeping with the conditions of approval of the reviewing HREC (and subject to any changes subsequently approved).

The project is being conducted in compliance with the [National Statement on Ethical Conduct in Human Research](#) (NHMRC, 2007) and [Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods](#) (NHMRC, 2016), or as amended.

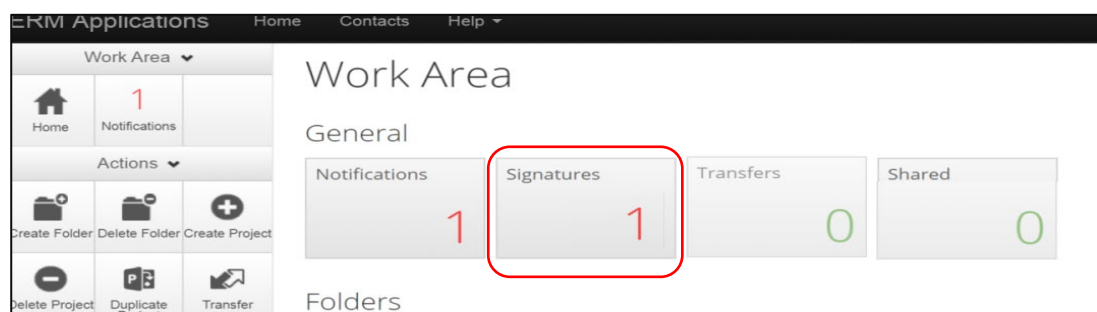
Request Signature **Sign**

- 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



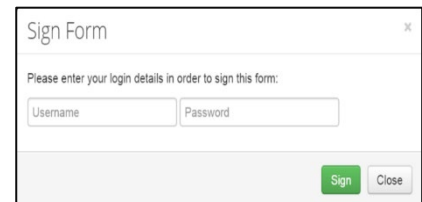
- New requests are highlighted. Select **View Form**  to review the Site Governance Amendment Request form

- 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

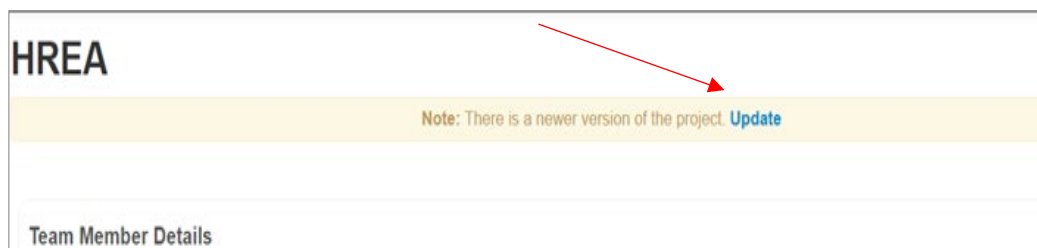
Project Update

A notification to update a project will appear when there has been a modification to a form or a process within ERM. This ensures access to the most recent version of forms used in ERM.

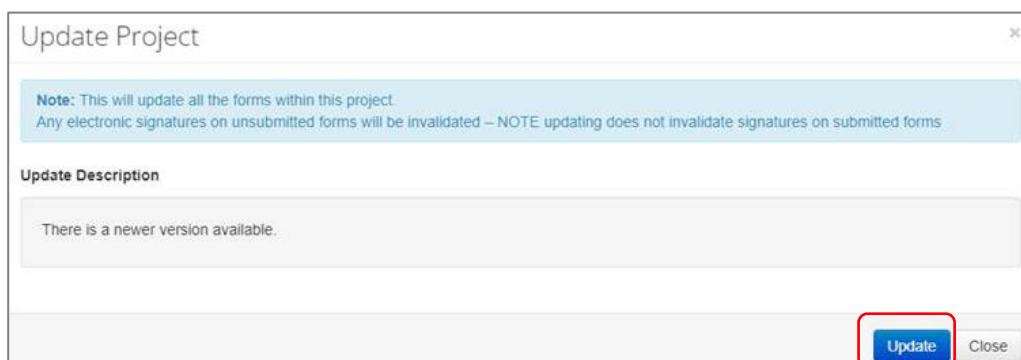
- Only the project owner may update a project
- Approved forms retain the version they were approved in
- Forms and sub-forms that have been submitted or under review will also be updated
- Forms with electronic signatures applied but not submitted should be **updated after submission** otherwise updating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

How to update to a newer version

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



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



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

Notifications

Search

Start End

Display 100 notifications

Please note that only the specified number of notifications will show after searching.

Message	Attachment	Project Sho
✓ Your May HREA has been upgraded	None	May HREA

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

Message

Project Short Title
Date 17/02/2020 10:56

Your has been upgraded

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

Note: There is a newer version of the project. (Please contact the project owner to update this form).

When should the project be updated?

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

What are the steps in a multi-site project?

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

How to find the form version

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

Cancel a Signature

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

- Move to the Signatures tab and select the **Cancel** Cancel button under the **Action** heading

The screenshot shows the ERM interface for project 'HREA 30'. The left sidebar contains navigation icons. The main content area shows the 'Signatures' tab selected. A table lists signature requests, with one entry for 'amanda.waipole@dhhs.vic.gov.au' with a status of 'Requested'. The 'Action' column for this entry has a 'Cancel' button highlighted with a red box.

- The form is now unlocked and signatures invalidated. The **Status** has changed from Requested to Recalled
- The signatory will also receive a notification email regarding the signature cancellation
- If a Principal Investigator has signed Sign their own form directly, their signature can also be cancelled
- To cancel the signature, open the relevant form at any question and select the **Unlock** button under the Actions pane

The screenshot shows the 'Site Specific Assessment (SSA) VIC - Administrator Use Only' form. A message at the top states 'This form has been locked through signatures/requests'. The 'Actions' pane on the left contains an 'Unlock' button highlighted with a red box. The main form area contains 'Site Dates' with two questions: '3.1 Anticipated start date for the research project at this site' and '3.2 Anticipated finish date for the research project at this site'.

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

Changing jobs

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

If a project owner is leaving the project permanently, the project should be transferred to another collaborator in the research team.

Transfer a Project

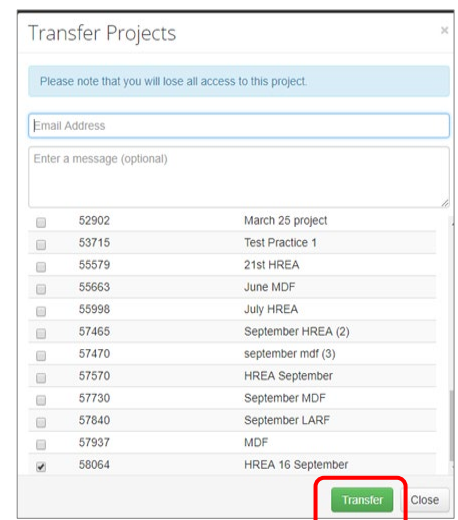
The project owner can use the **Transfer** function to permanently transfer a project to another ERM user. This may be when a Sponsor creates an HREA application then transfers it permanently to the CPI or when the project owner intends to leave the project and transfers project responsibilities to another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

If the current project owner is unable to be contacted, contact [Infonetica Helpdesk](#) for further assistance to permanently transfer a project.



- From the Work Area, select the **Transfer** button from the Actions pane
- A **Transfer Projects** text box is displayed noting loss of future access to the project
- The project owner enters the ensuing project owner's ERM email address

- Enter a message to the new project owner (optional)
- Select the correct project from the list
- Select **Transfer** button
- All forms are locked pending the transfer
- The new project owner will receive an email notification regarding the transfer of the project

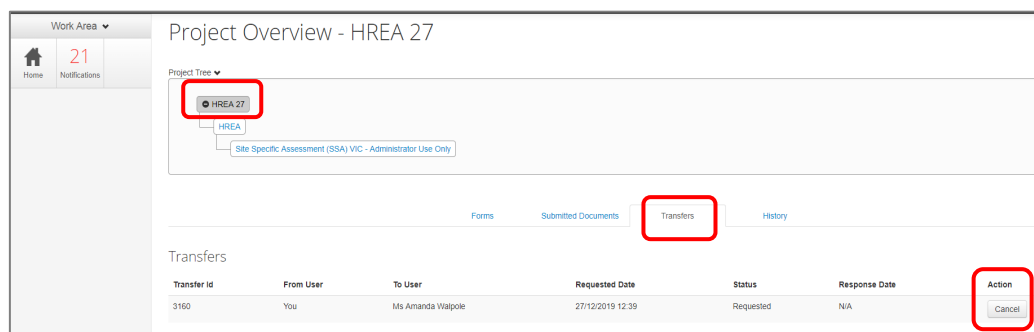


Project ID	Project Name
<input type="checkbox"/> 52902	March 25 project
<input type="checkbox"/> 53715	Test Practice 1
<input type="checkbox"/> 55579	21st HREA
<input type="checkbox"/> 55663	June MDF
<input type="checkbox"/> 55998	July HREA
<input type="checkbox"/> 57465	September HREA (2)
<input type="checkbox"/> 57470	september mdf (3)
<input type="checkbox"/> 57570	HREA September
<input type="checkbox"/> 57730	September MDF
<input type="checkbox"/> 57840	September LARF
<input type="checkbox"/> 57937	MDF
<input checked="" type="checkbox"/> 58064	HREA 16 September

Cancel a transfer request

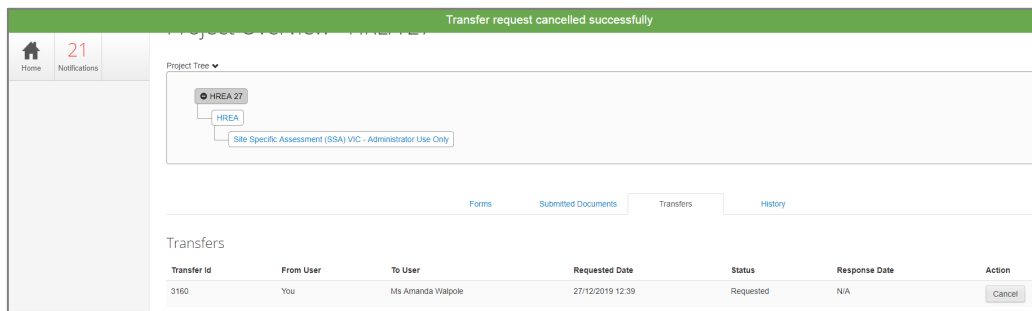
The project owner can cancel the transfer request if the request has **not** been accepted by the new project owner.

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



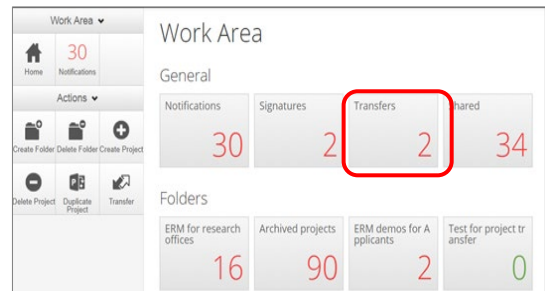
Transfer Id	From User	To User	Requested Date	Status	Response Date	Action
3160	You	Ms Amanda Walpole	27/12/2019 12:35	Requested	N/A	Cancel


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

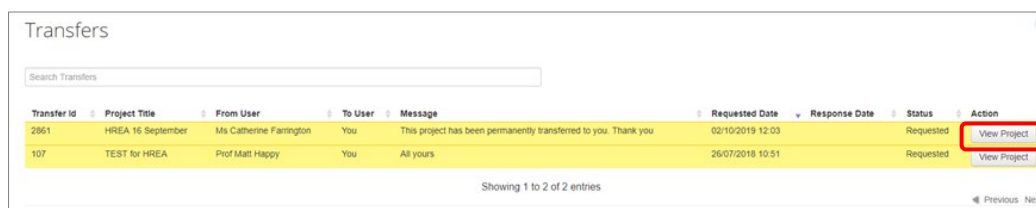


Accept a transfer

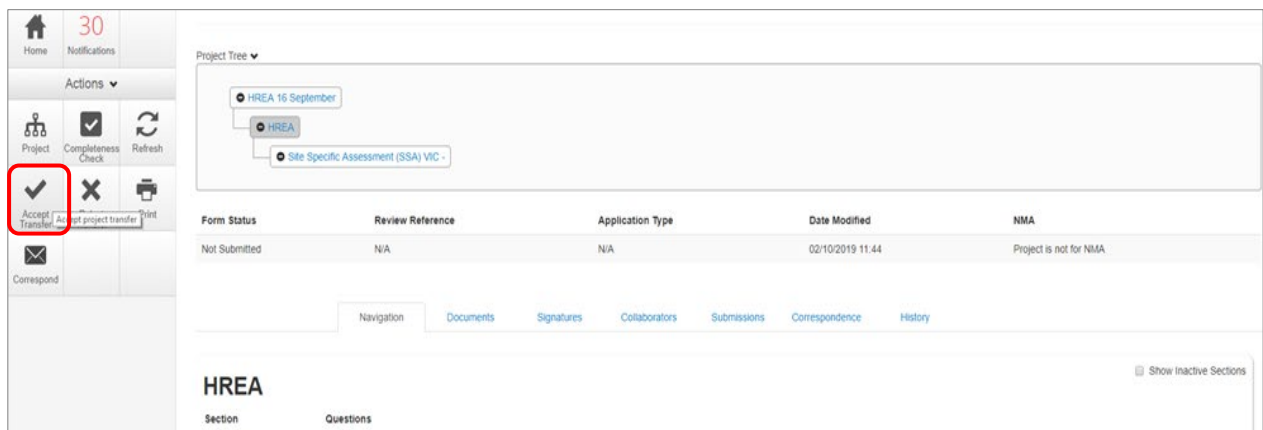
- The new project owner will receive an email notification to log into their ERM account
- In the Work Area, select the **Transfers** tile



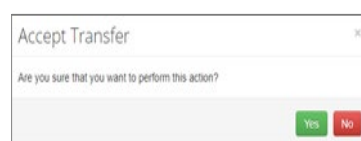
- A list of all transfers will be displayed. In the relevant message line, select **View Project**  to open the project as read only



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



- An **Accept Transfer** text box is displayed
- Select **Yes** to accept the transfer



Form Status	Review Reference	Application Type	Date Modified	NMA
Information requested	N/A	Ethics Application	17/04/2019 14:25	Project is not for NMA


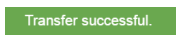
- Ownership of the project is transferred including all sub-forms e.g. SSAs and associated documents. The new owner can access the project from their Work Area.
- The new owner can assign other research members pre-defined levels of access to the project and forms



Transfer a Sub form

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

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

Form Status	Review Reference	Date Modified	NMA
Not Submitted	N/A	23/01/2020 10:29	Project is not for NMA

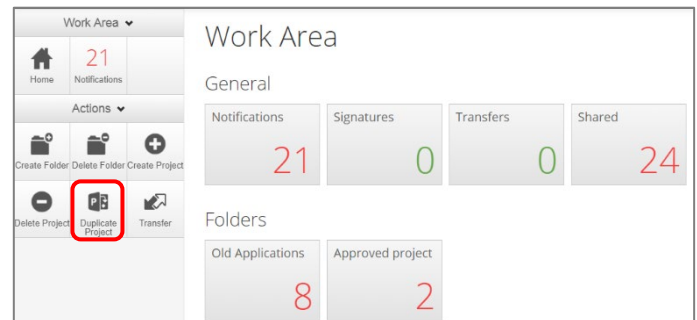
- Select **Transfer Form**  button under the Actions pane
- A **Transfer Form To Another User** text box will be displayed
- Select the **Transfer Sub Forms** checkbox to include other subforms that are associated with the form e.g. a Site Progress Report
- Select **Transfer**
- A **Transfer successful**  message will be displayed at the top of the screen.
- The collaborator will receive an email notification informing them of the transfer with a link to ERM and becomes the new form owner including the owner of any associated subforms
- The new form owner is shown under the **Collaborators** tab

- The new form owner can assign other collaborators access to the form using the **Share**  function
- The collaborators can only view the HREA if the Project Owner assigns access from the HREA using the **Roles +**  function

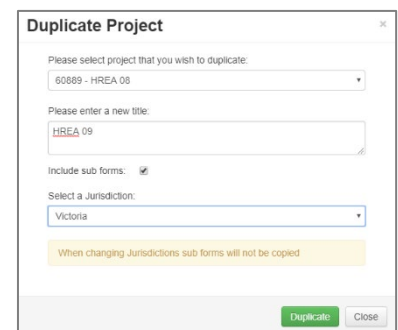
Duplicate a Project

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

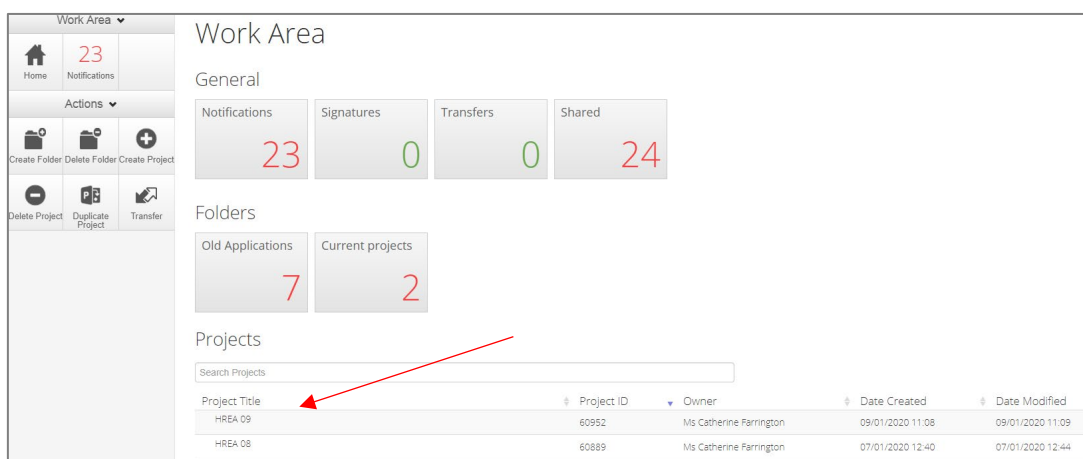
- From the Work Area select **Duplicate Project**



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



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



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

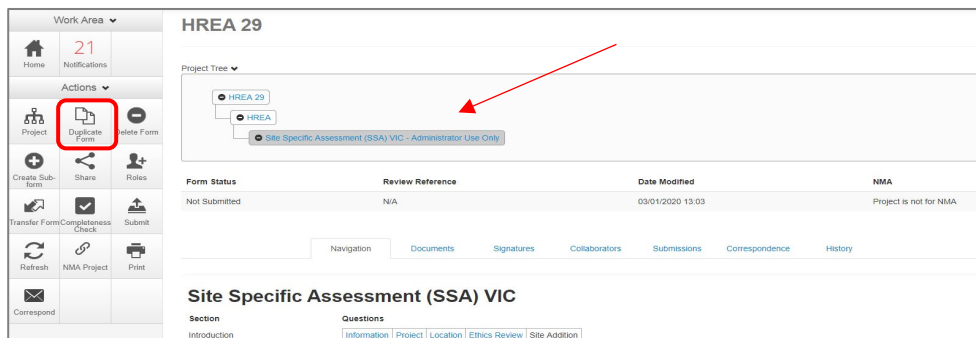
- Upload supporting documents and assign other members of the research team pre-defined levels of access to the duplicated project using the **Roles +** or **Share** function.

Duplicate a Form

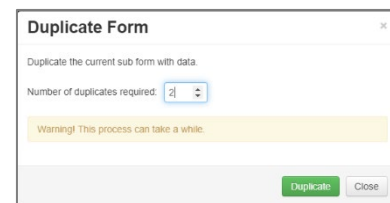
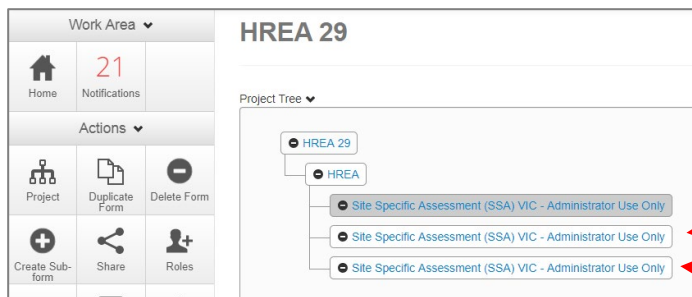
Subforms can be duplicated using a similar duplicate function and can be useful for duplicating SSAs. The duplicate function will copy all answers in the form but **not** copy documents e.g. site PICFs, signatures and permissions assigned to the original subform. As the SSA site/organisation name will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

- In the Project Tree highlight the subform to be duplicated

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



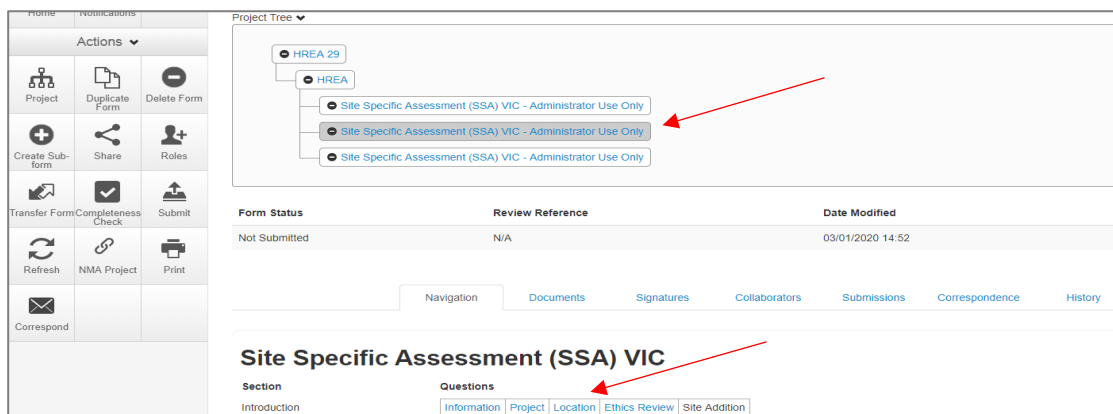
- A **Duplicate Form** textbox will be displayed
- Select number of duplicates required e.g. 2
- Select **Duplicate**
- The duplicated subforms will be displayed in the Project Tree

Duplicate SSA

Duplicate SSA

- Select the duplicate SSA then select the **Location** [Location](#) hyperlink to be directed to **Q 1.4 Name** of site/organisation



- Select the relevant site/organisation name from the drop-down list

Actions

Previous Next Navigate

Print Documents Signatures

1.4 Name of site/organisation Albury Wodonga Health

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

Work Area

Home Notifications

Actions

Project Duplicate Form Delete Form

Create Sub-form Share Roles

HREA 29

Project Tree

HREA 29

HREA

Site Specific Assessment (SSA) VIC - Administrator Use Only

Site Specific Assessment (SSA) VIC - Albury Wodonga Health

Site Specific Assessment (SSA) VIC - Administrator Use Only

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

Delete a Form

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

- In the Project Tree highlight the subform which needs to be deleted

- Select the **Delete Form** button under the Action pane

Work Area

Home Notifications

Actions

Project Duplicate Form Delete Form

Create Sub-form Share Roles

Transfer Form Completeness Check Submit

Refresh NMA Project Print

Correspond

HREA 27

Project Tree

HREA 27

HREA

Site Specific Assessment (SSA) VIC - Administrator Use Only

Form Status	Review Reference	Date Modified	NMA
Not Submitted	N/A	27/12/2019 14:26	Project is not for NMA

Navigation Documents Signatures Collaborators Submissions Correspondence History

Site Specific Assessment (SSA) VIC

Section Questions

Introduction Information Project Location Ethics Review Site Addition

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

Delete Form

Delete form Site Specific Assessment (SSA) VIC?

Delete Close

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

- If the form has been signed by the signatory, open the form and select the **Unlock** button under the Actions pane.



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

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



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

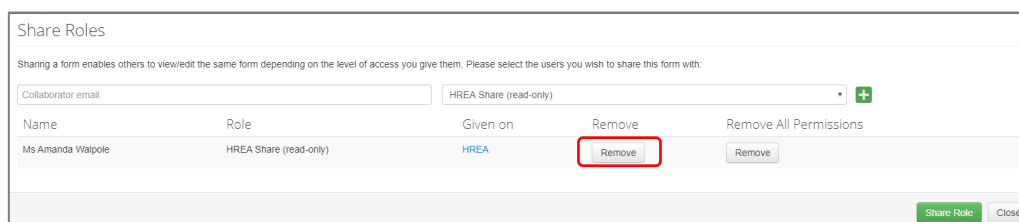
Edit Roles and Share

A collaborator's level of access to a form can be changed in two ways depending on whether

Roles +  or **Share**  has been used to assign access.

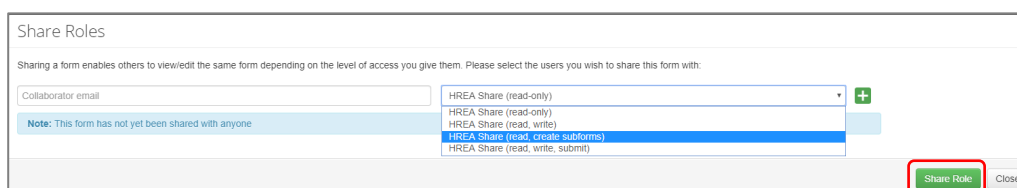
Roles +

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



Name	Role	Given on	Remove	Remove All Permissions
Ms Amanda Walpole	HREA Share (read-only)	HREA	Remove	Remove

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



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

Share

- Highlight the relevant form in the Project Tree and move to the **Collaborators** tab
- Select the **Edit Permissions** button to modify the collaborator's access level

The screenshot shows the ERM interface with the 'Collaborators' tab selected. The 'Edit Permissions' button is highlighted with a red box. The interface includes a sidebar with various actions like Project, Create Sub-form, Share, Roles, Completeness Check, Submit, Refresh, NMA Project, Print, Correspond, and Import Xml. The main area displays a table of collaborators with columns for Name, Access, and Edit Permissions.

Name	Access	Edit Permissions
Ms Abigail Cooper	Read, Write, Submit, Share, Create all sub forms, Receive notifications	Edit Permissions
Ms Catherine Farrington	Project Owner and Form Owner	Edit Permissions

- An **Edit Permissions** textbox will be displayed. Deselect the permissions and select **Save**
- The collaborator will receive a message in the **Notifications** tile (under the Work Area) informing them of the change in their access level.

Collaborators

The form owner can use the **Collaborators** action button to edit permissions for each collaborator only if the access level is assigned through the **Share** action

- Select the **Collaborators** action button

The screenshot shows the ERM interface with the 'Collaborators' action button highlighted with a red box. The interface includes a sidebar with various actions like Previous, Next, Navigate, Print, Documents, Signatures, Save, Share, Roles, and Collaborators. The main area displays a form for adding collaborators with fields for Title, First Name, Surname/family name, and Email Address.

- A list of current collaborators for the form will be displayed

Select **Edit Permissions**

The screenshot shows the 'Collaborators' dialog box with a list of current collaborators. The 'Edit Permissions' button is highlighted with a red box. The dialog box includes a table of collaborators with columns for Name, Access, and Edit Permissions.

Name	Access	Edit Permissions
Ms Catherine Farrington	Project Owner and Form Owner	Edit Permissions
Ms Amanda Walpole	Read, Write, Submit, Share, Create all sub forms, Receive notifications	Edit Permissions

- Deselect or select the new levels of access
- Select **Save**

The screenshot shows the 'Edit Permissions - Ms Amanda Walpole' dialog box. The 'Save' button is highlighted with a green box. The dialog box includes a list of permissions with checkboxes for Read, Write, Submit, Share, Create all sub forms, and Receive notifications.

Contacts

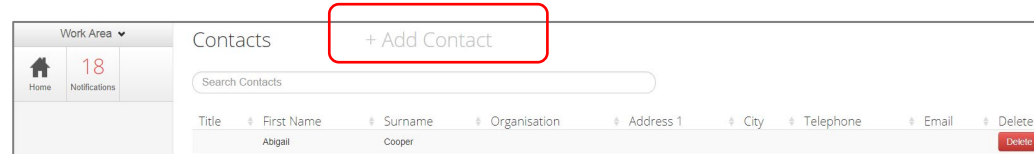
The **Contacts** area can be used to save and edit contact details for project team members. Details saved in **Contacts** can be used to populate all ERM forms.

Add a Contact

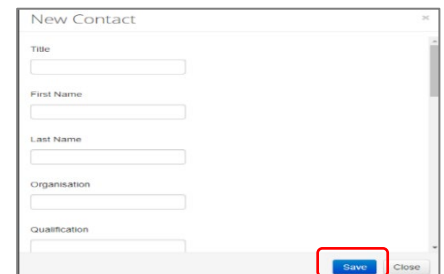
- Select **Contacts** above Work Area



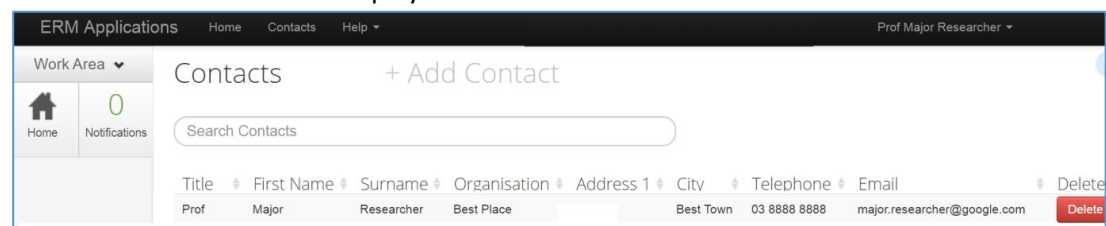
- Select **+ Add Contact**



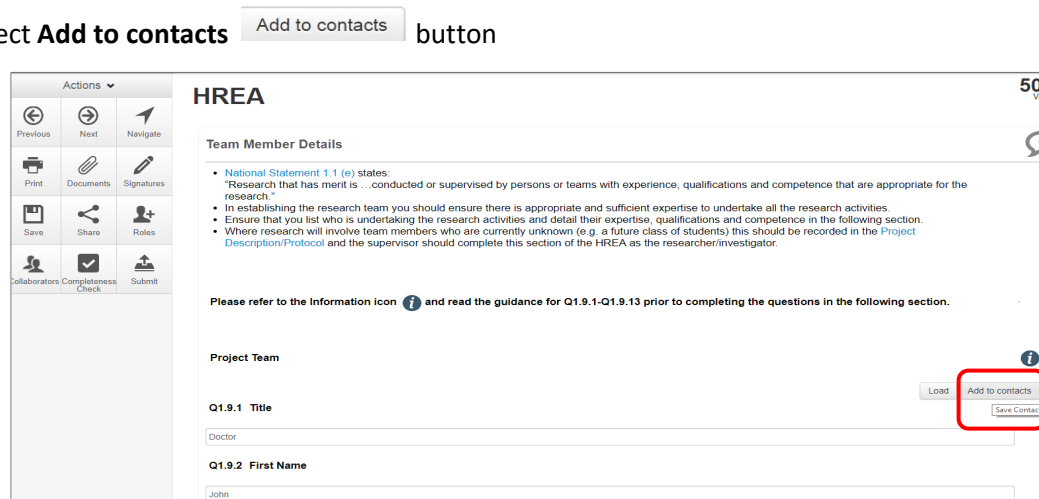
- A **New Contact** textbox will be displayed to enter the new details
- Select **Save** button



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




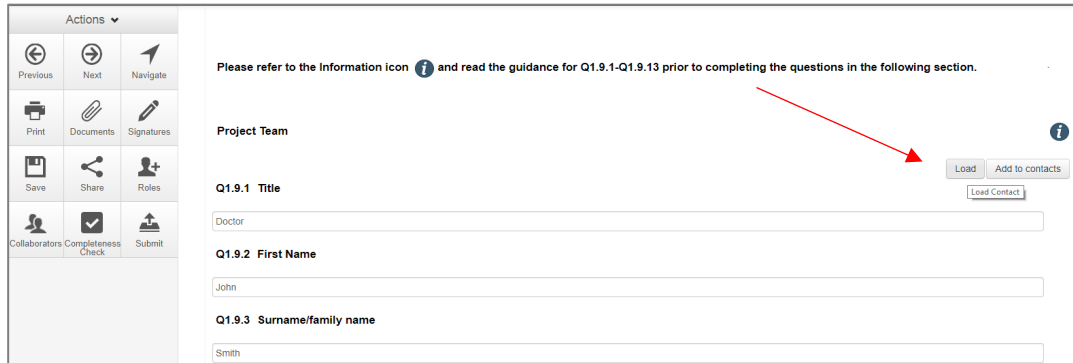
- Contacts can also be added when completing a form
- Select **Add to contacts** button



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

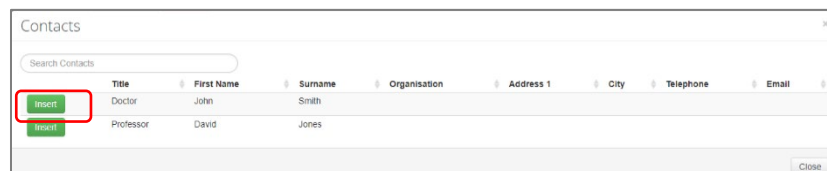
Insert Contact in a form

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



The screenshot shows a form titled 'Project Team' with fields for 'Q1.9.1 Title', 'Q1.9.2 First Name', and 'Q1.9.3 Surname/family name'. The 'Load' button is highlighted with a red arrow. The 'Actions' pane on the left contains various icons for navigation and document management.

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



The screenshot shows the 'Contacts' dialog box with a table of contacts. The 'insert' button is highlighted with a red box. The table has columns for Title, First Name, Surname, Organisation, Address 1, City, Telephone, and Email.

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

- Contact details will be successfully loaded into the form




The screenshot shows the form with the contact details loaded into the fields: 'Q1.9.1 Title' is 'Professor', 'Q1.9.2 First Name' is 'David', and 'Q1.9.3 Surname/family name' is 'Jones'. The 'Load' button is highlighted with a red arrow.

Correspondence

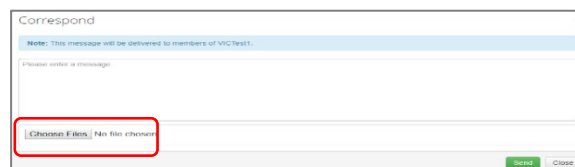
To the Research Office

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

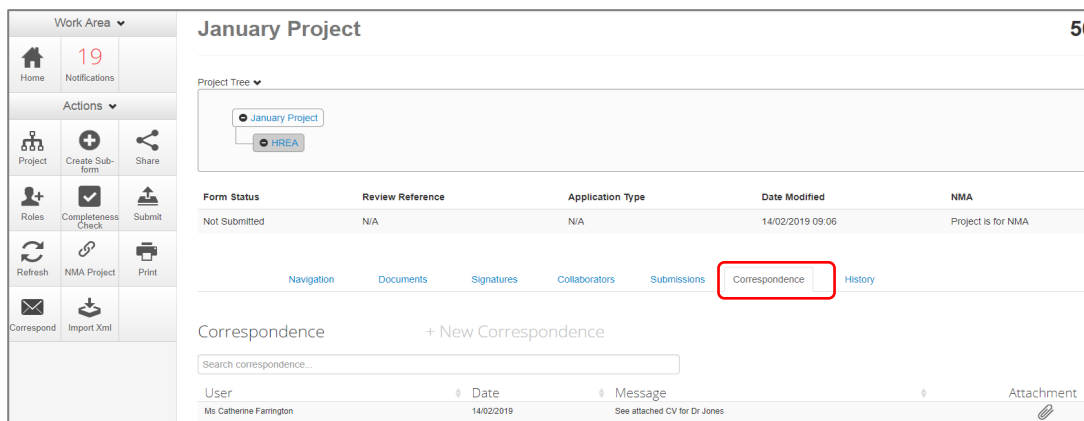
Correspond must **not** be used to respond to a query or information request.

Select the **Correspond**  button from the Actions pane to open communication with the designated Research Office.

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

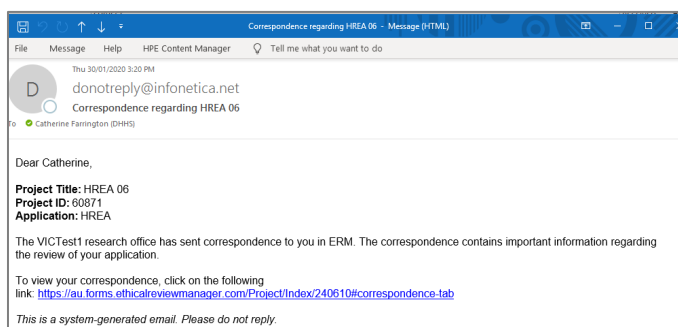


- A record of the correspondence can be accessed in the **Correspondence** tab

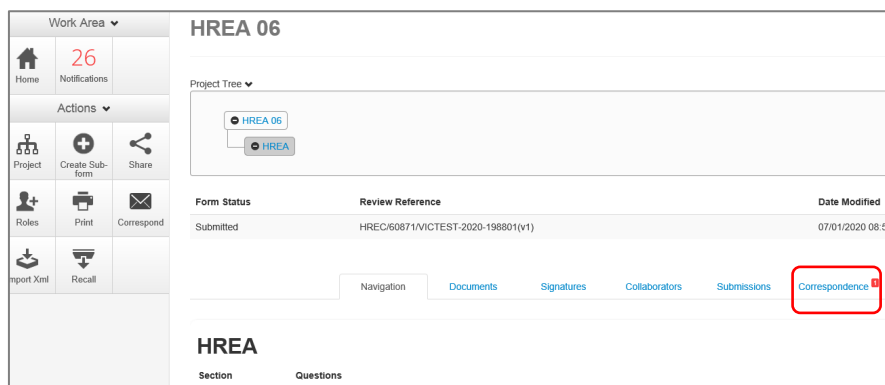


From the Research Office

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



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



- Select the relevant message

Work Area ▾

Home 26 Notifications

Actions ▾

Project Create Sub-form Share

Roles Print Correspond

Import Xml Recall

HREA 06

Project Tree ▾

- HREA 06
- HREA

Form Status	Review Reference	Date Modified
Submitted	HREC/60871/VICTEST-2020-198801(v1)	07/01/2020 08:53

Navigation Documents Signatures Collaborators Submissions Correspondence

Correspondence

+ New Correspondence

Search correspondence...

User	Date	Message
Review user	30/01/2020	Hi Catherine, Thanks for submitting your application. It lo...

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

Correspondence Message


Date 30/01/2020 2:19 PM

Hi Catherine,
Thanks for submitting your application. It looks great! The committee are really looking forward to reviewing it at their meeting!
from your friendly research office

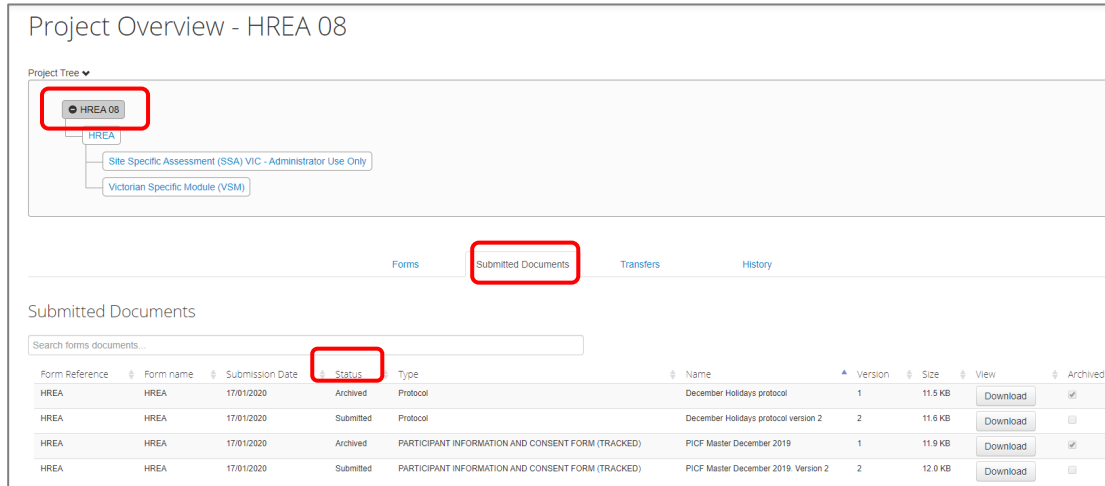
Note: No correspondence attachments

Close

Archived documents


When an application requires resubmission with new document versions, deleted  documents are automatically archived in ERM. Archived documents can be accessed in the Project Overview screen

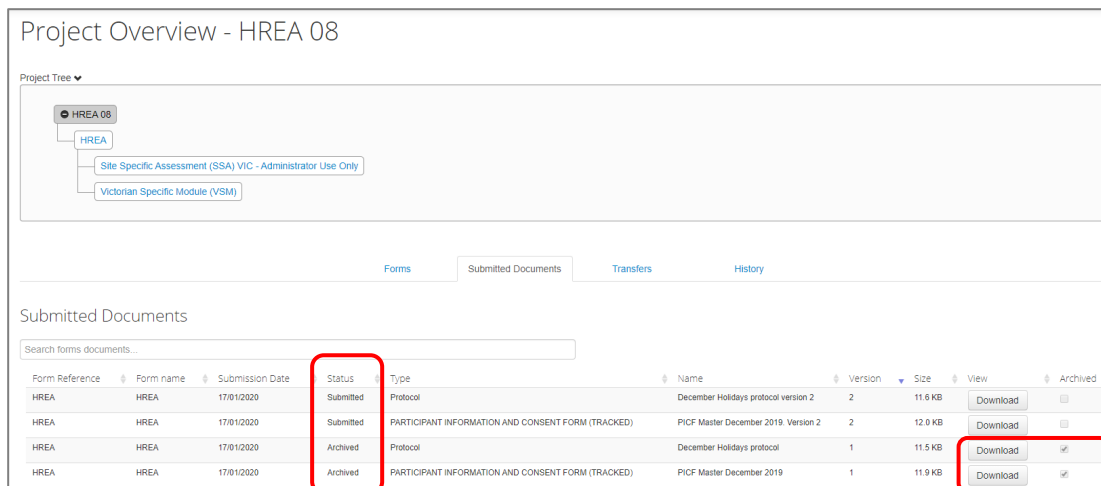
- Highlight the project title in the Project Tree and move to the **Submitted Documents** tab



The screenshot shows the 'Project Overview - HREA 08' interface. In the 'Project Tree' on the left, 'HREA 08' is highlighted with a red box. Below the tree, the 'Submitted Documents' tab is selected and highlighted with a red box. The 'Submitted Documents' section contains a search bar and a table of documents.

Form Reference	Form name	Submission Date	Status	Type	Name	Version	Size	View	Archived
HREA	HREA	17/01/2020	Archived	Protocol	December Holidays protocol	1	11.5 KB	Download	<input checked="" type="checkbox"/>
HREA	HREA	17/01/2020	Submitted	Protocol	December Holidays protocol version 2	2	11.6 KB	Download	<input type="checkbox"/>
HREA	HREA	17/01/2020	Archived	PARTICIPANT INFORMATION AND CONSENT FORM (TRACKED)	PICF Master December 2019	1	11.9 KB	Download	<input checked="" type="checkbox"/>
HREA	HREA	17/01/2020	Submitted	PARTICIPANT INFORMATION AND CONSENT FORM (TRACKED)	PICF Master December 2019, Version 2	2	12.0 KB	Download	<input type="checkbox"/>

- The **Status** for current document versions is Submitted and previous/deleted versions are now Archived
- When the application has been approved, the **Status** of the submitted documents is Approved
- Select **Download**  button to view an archived document




The screenshot shows the 'Project Overview - HREA 08' interface. The 'Submitted Documents' tab is selected. A red box highlights the 'Status' column in the table, showing 'Submitted', 'Archived', and 'Archived' entries.

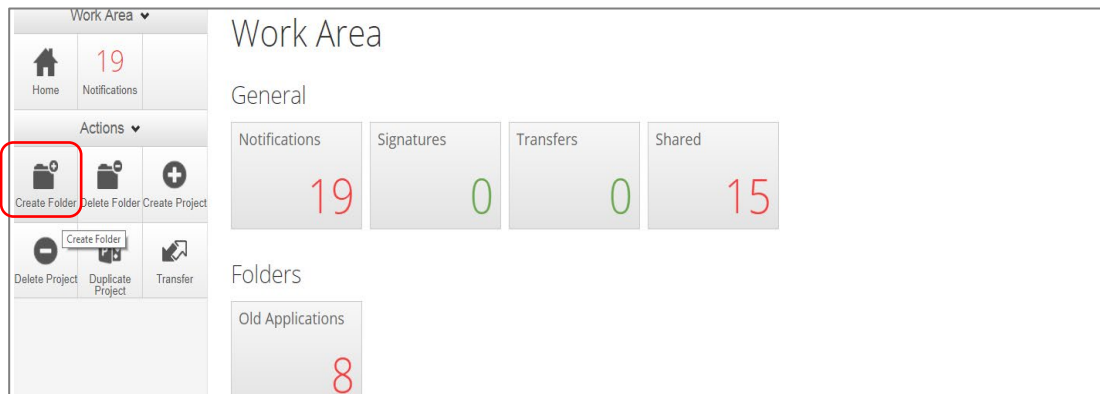
Form Reference	Form name	Submission Date	Status	Type	Name	Version	Size	View	Archived
HREA	HREA	17/01/2020	Submitted	Protocol	December Holidays protocol version 2	2	11.6 KB	Download	<input type="checkbox"/>
HREA	HREA	17/01/2020	Submitted	PARTICIPANT INFORMATION AND CONSENT FORM (TRACKED)	PICF Master December 2019, Version 2	2	12.0 KB	Download	<input type="checkbox"/>
HREA	HREA	17/01/2020	Archived	Protocol	December Holidays protocol	1	11.5 KB	Download	<input checked="" type="checkbox"/>
HREA	HREA	17/01/2020	Archived	PARTICIPANT INFORMATION AND CONSENT FORM (TRACKED)	PICF Master December 2019	1	11.9 KB	Download	<input checked="" type="checkbox"/>

- Other collaborators with assigned access can also view archived documents

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**

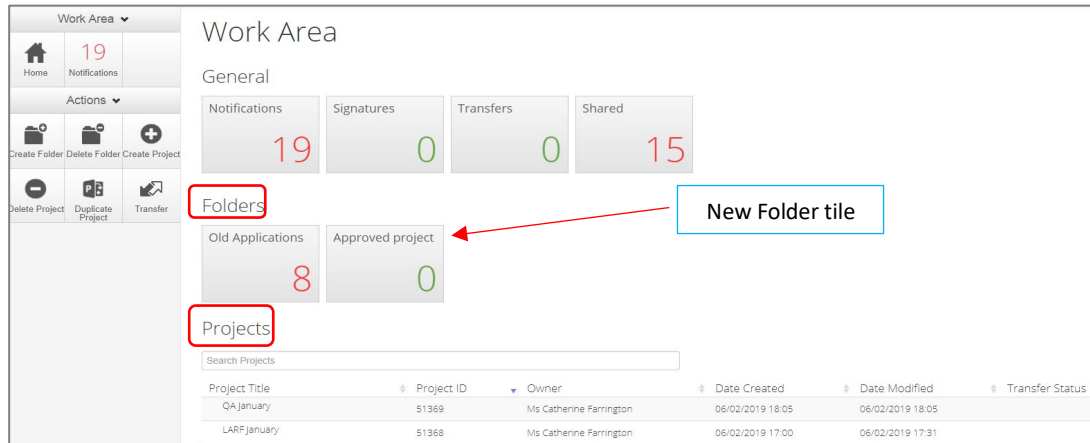
Create Folder

Folder Title (maximum 40 characters):*

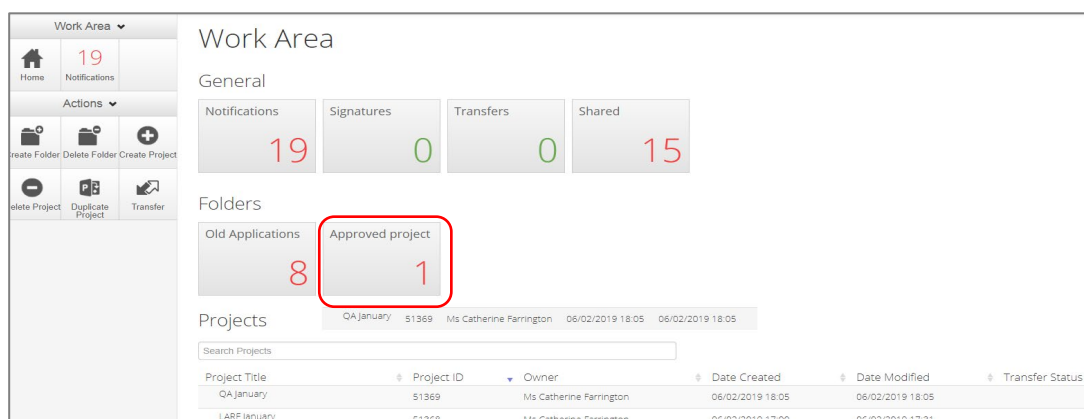
Approved projects

Create Close

- 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

Approved project Projects

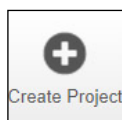
Search Projects

Project Title	Project ID	Owner	Date Created	Date Modified
QA January	51369	Ms Catherine Farrington	06/02/2019 6:05:20 PM	06/02/2019 6:05:22 PM
MDF January	51345	Ms Catherine Farrington	06/02/2019 12:13:53 PM	06/02/2019 12:30:53 PM

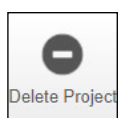
Showing 1 to 2 of 2 entries

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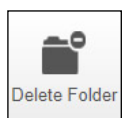
Other Folder Actions



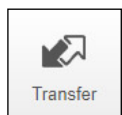
Create a new project



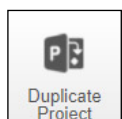
Delete a project (only possible if the main form has **not** been submitted via ERM)



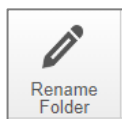
Delete a folder (only empty folders can be deleted)



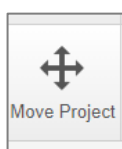
Permanent transfer of a project to another user e.g. Sponsor creates the HREA and transfers it permanently to the CPI



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



Rename the tiles under **Folders** and enter a new name for the tile



Move a Project filed in **Folders** to the **Work Area**. The Project will be listed with other current projects under **Project Title**

Submission to non ERM Research Offices

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

- Leave the last question in the ERM Filter Questions section (*Select the Committee that your ethics application will be submitted to*) blank
- Leave **Q 4.3** (*Select the Organisation that hosts the HREC*) blank



- Select the **Print** button under the Actions pane to generate a pdf of the form. Save the document to your local drive

Do not select Submit.

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