

Applicant user guide to ERM

Ethical Review Manager (ERM)

Coordinating Office for Clinical Trial Research

Department of Jobs, Precincts and Regions



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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).
CTA	Clinical Trial Approval scheme (scheme's previous name Clinical Trial Exemption (CTX))
CTN	Clinical Trial Notification scheme
CTRA	Clinical Trial Research Agreement
CV	Curriculum Vitae
FDA	Food and Drug Administration (in USA)
GCP	Good Clinical Practice
HREA	Human Research Ethics Application
HREC	Human Research Ethics Committee that has been certified under the NHMRC National Certification Scheme, and be a Certified Reviewing HREC under the NMA scheme
IB	Investigator Brochure
ICH-GCP	International Conference on Harmonisation – Good Clinical Practice
LARF	Legacy Application Replacement Form
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, Northern Territory, Queensland, South Australia, Tasmania, Victoria and Western Australia participate in NMA
PI	Principal Investigator. Responsible for the project at a site
PICF	Participant Information Consent Form
QA	Quality Assurance application
RGO	Research Governance Officer
SSA	Site Specific Assessment
VSM	Victorian Specific Module

1 Introduction

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

1.1 About ERM

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

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

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

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

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

Who uses Ethical Review Manager (ERM)

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

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

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

1.2 Create an account

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

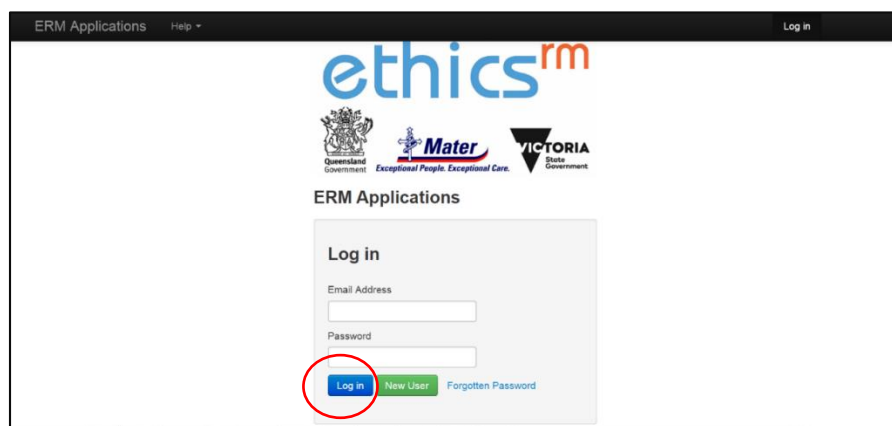
To Log in:

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

For users with no previous Online Forms account:

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

Log in

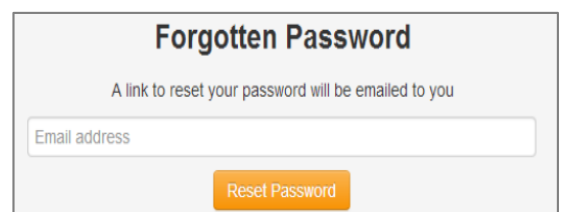


1. Enter your email address and password
2. Select **Log in**

Forgotten password

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

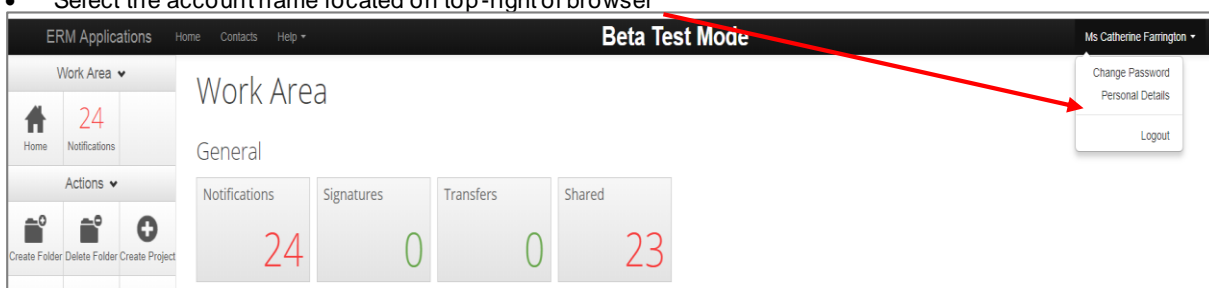
- Select **Forgotten Password**
- Enter the email address of the account to be signed into
- Select **Reset Password**
- An email will be sent with a link to change the password. Enter the new password and select **Reset Password**
- A Message box will be displayed confirming the password change
- Select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



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

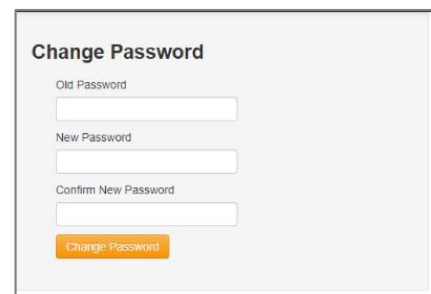
Changing password

- 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

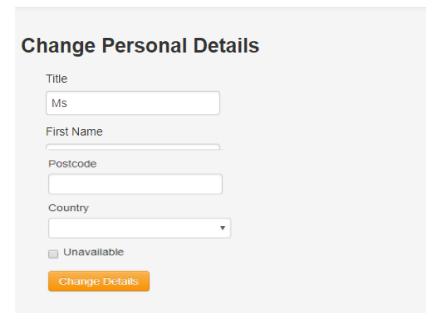
New Password

Confirm New Password

[Change Password](#)

Changing personal details

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



Change Personal Details

Title

First Name

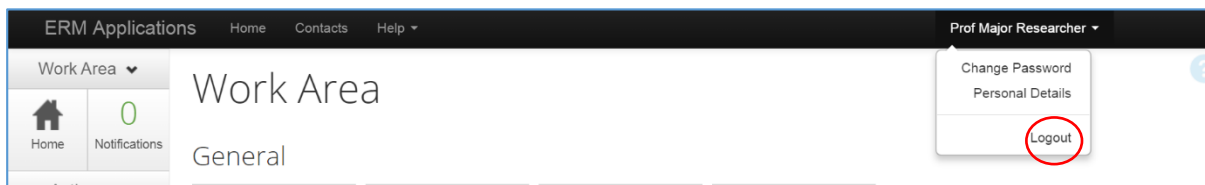
Postcode

Country

☐ Unavailable

[Change Details](#)

Log out



ERM Applications Home Contacts Help

Prof Major Researcher

Work Area

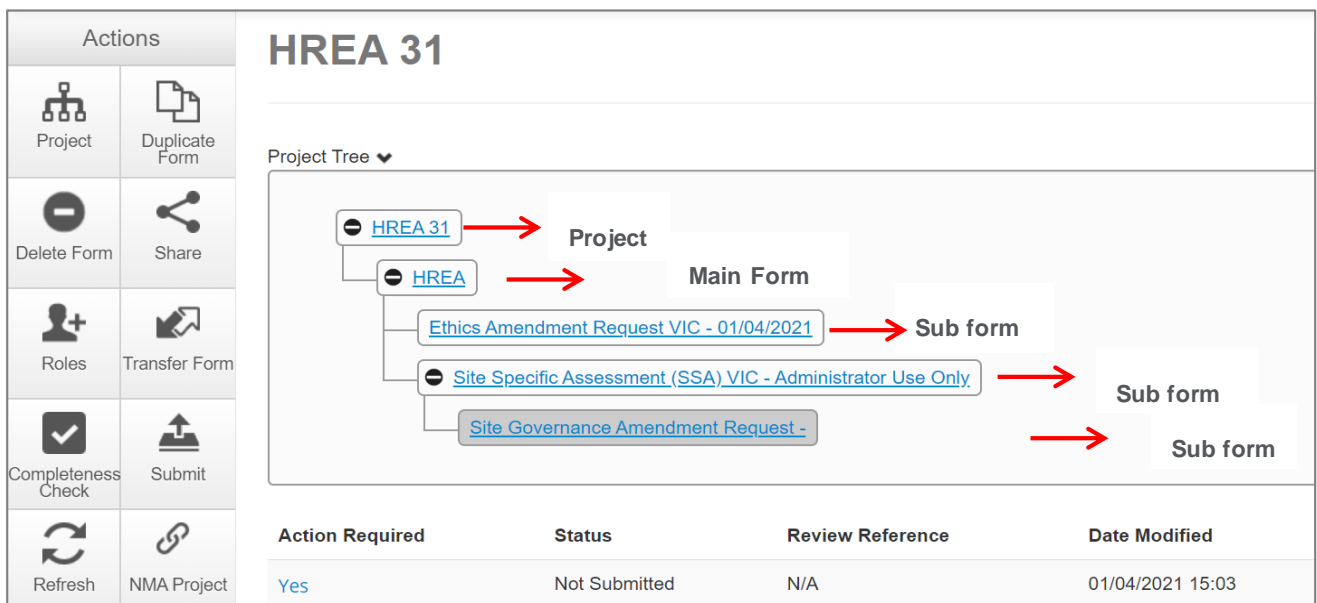
Home Notifications

General

Change Password
Personal Details
Logout

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

1.3 ERM forms



HREA 31

Project Tree

- HREA 31 → Project
- HREA → Main Form
 - Ethics Amendment Request VIC - 01/04/2021 → Sub form
 - Site Specific Assessment (SSA) VIC - Administrator Use Only → Sub form
 - Site Governance Amendment Request - → Sub form

Action Required	Status	Review Reference	Date Modified
Yes	Not Submitted	N/A	01/04/2021 15:03

- ERM is based on **forms**. The applicant creates a **project** and a **main form** simultaneously
- From the **main form**, the applicant can create **sub-forms** e.g. Ethics Amendment Request, SSA form.

- From some sub-forms (SSA and LNR VIC SSA) further sub-forms can be created e.g. Site Governance Amendment Request, Site Progress Report and Site Notification Form
- A summary of the forms available in ERM is displayed in the tables below.

Main forms

There is only one main form for each project.

Form	Description
Human Research Ethics Application (HREA)	Ethics application form
Victorian Low/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

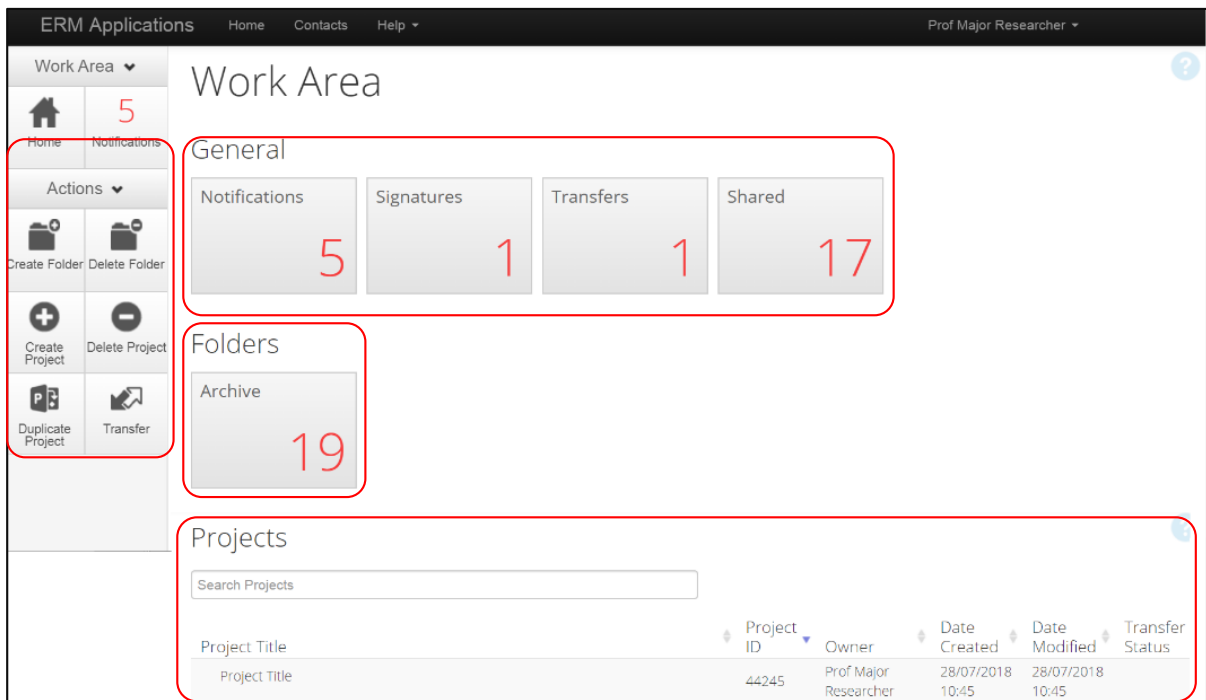
Suspected Breach Report	Report a suspected breach to the reviewing ethics committee
Project Progress Report	Report to the reviewing ethics committee on the progress of a research project (at least annually, may be more frequent if requested)
Site Closure Report	For a multi-site project, report the closure 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

2 Work Area

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



2.1 Actions

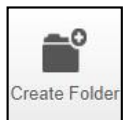
There are six action buttons under the Actions pane



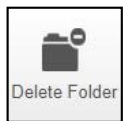
Create a new project



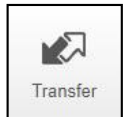
Delete a project (only possible if the main form has **not** been submitted via ERM)



Create a bespoke folder for storage of projects



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



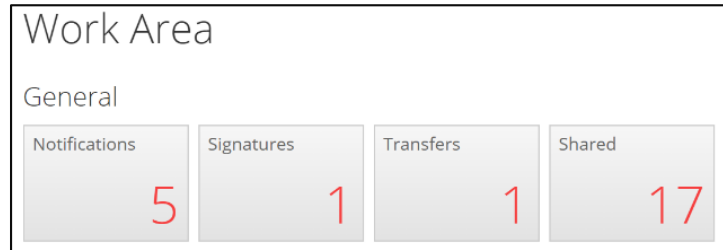
Permanently transfer a project to a colleague



Duplicate an existing project

2.2 General

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



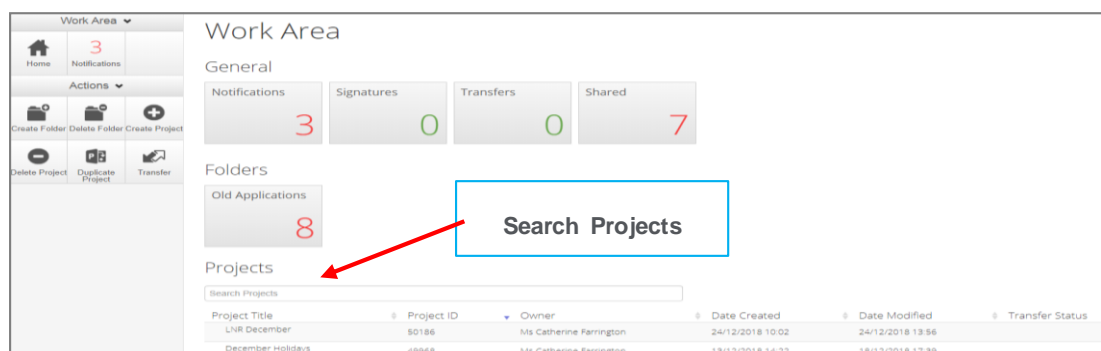
- Notifications**
- Contain messages that are sent to the user from the Research Office:
 - o queries or request for information regarding an application
 - o Approval letters
 - Messages automatically generated by ERM e.g. form updates
 - Messages from other research team members/collaborators
 - o 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

2.3 Folders

Displays bespoke folders for storage of projects.

2.4 Projects

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



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

Action Required	Status	Review Reference	Date Modified
Yes	Not Submitted	N/A	01/04/2021 15:03

2.5 Actions pane

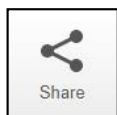
There are eleven possible action buttons available under the Action pane on the left side of the screen. The actions are listed below:



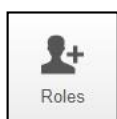
Go to the Project overview



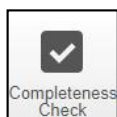
Create a Sub-form from the main form e.g. SSA



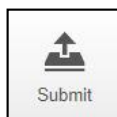
Enable collaborators to view, edit and manage the form



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 for printing or save as soft copy



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

2.6 Form status bar

The Form status bar has five columns which displays the current activity of the form

Action Required - if any actions are required by the user

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

Status - indicates the status of the form

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

Review Reference – unique identification code

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

① ② ③ ④ ⑤ ⑥
e.g. HREC/74950/VICTEST-2021-257683(v1)

	Component	Description	Examples
1	Application type	Identifies the type of application form	HREA, LNR VIC, MDF, SSA
2	ERM Project ID	The unique identification number for the research project	74950
3	Organisation/hospital code	The organisation/hospital to which this form was submitted	Austin, RCH, VICTEST
4	Year	Year of submission	Can change when a new form version is submitted in the following year
5	Submission number	System identifier for the particular submission of this form	257683
6	Version number	Version number to track submission history	v1 to v2 to v3

Application Type - Identifies the type of application/form submitted

- Ethics Application (the HREA)
- 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.

2.7 Tab functions

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

The screenshot displays the ERM application interface. On the left is an 'Actions' sidebar with icons for Project, Create Subform, Share, Roles, Completeness Check, Submit, Refresh, NMA Project, View as PDF, and Correspond. The main area shows a 'Project Tree' with a hierarchy: HREA31 (expanded) -> HREA -> Ethics Amendment Request VIC - 01/04/2021 -> Site Specific Assessment (SSA) VIC - Administrator Use Only (expanded) -> Site Governance Amendment Request -.

Below the Project Tree is a table with the following data:

Action Required	Status	Review Reference	Date Modified	NMA
Yes	Not Submitted	N/A	31/03/2021 14:05	Project is for NMA

At the bottom, there is a navigation bar with seven tabs: Navigation, Documents, Signatures, Collaborators, Submissions, Correspondence, and History. The 'Navigation' tab is currently selected and highlighted with a red border.

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

Each tab is described below:

Navigation

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

Documents

- The Documents tab displays current supporting documents that have been uploaded into a form. The details displayed indicate the document type, name, file name, version date and number
- A column of checkboxes allows documents to be selected or deselected
- Select any combination of documents to either open as a PDF in a new browser using the **View Selected** button or download as a ZIP file using the **Download Selected** button
- A **Search Bar** is available to filter documents and find specific documents types e.g. PICFs

Actions

Project Tree

69893

Project: The Banana Project

Action Required	Status	Review Reference	Date Modified	NMA
No	Approved	HREC/69893/VICTEST-2020-237181(v2)	15/10/2020 14:31	Project is not for NMA

Navigation Documents Signatures Collaborators Submissions Correspondence History

Documents

Search Bar

Search Document

Type	Document Name	File Name	Version Date	Version	Size
<input checked="" type="checkbox"/> Victorian specific module (VSM)	VSM	VSM.pdf	15/10/2020	1	203.3 KB
<input checked="" type="checkbox"/> Protocol	Protocol	Protocol.docx	13/10/2020	1.3	12.4 KB
<input checked="" type="checkbox"/> Questionnaire	Questionnaire	Questionnaire.docx	12/10/2020	1b	11.4 KB
<input checked="" type="checkbox"/> Participant information and consent form	PICF v2	PICF v2.docx	15/10/2020	2	12.5 KB
<input checked="" type="checkbox"/> PARTICIPANT INFORMATION AND CONSENT FORM (TRACKED)	PICF v2 (with changes)	PICF v2 (with changes).docx	15/10/2020	2 (tracked)	12.4 KB
<input checked="" type="checkbox"/> Form	Form	Form.pdf			

Showing 1 to 6 of 6 entries

View Selected Download Selected

Signature

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

Signatures

Type	Signatory Email	Signed Date	Validity
Co-ordinating Principal Investigator/Researcher	major.researcher101010@gmail.com	17/10/2020 16:11	Valid
Co-ordinating Principal Investigator/Researcher	major.researcher101010@gmail.com	17/10/2020 15:38	Invalid
Co-ordinating Principal Investigator/Researcher	major.researcher101010@gmail.com	17/10/2020 15:11	Invalid
Co-ordinating Principal Investigator/Researcher	major.researcher101010@gmail.com	17/10/2020 14:44	Invalid

Signature Requests

Type	Signatory Email	Requested Date	Status	Response Date	Action
Co-ordinating Principal Investigator/Researcher	major.researcher101010@gmail.com	17/10/2020 16:00	Signed	17/10/2020 16:11	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 their email will be displayed

Collaborators

Name	Access
Prof Ann Researcher	Read, Write, Submit, Share, Create all sub forms, Receive notifications
Prof M. Happy	major.researcher101010@gmail.com

Edit Permissions

Edit Permissions

Edit Permissions

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

Submissions

- Displays the Review Reference e.g. HREC/72733/VICTEST-2021-246469(v3)
- Displays the current status of the application form e.g. Approved
- The Committee that will/has reviewed the application e.g. VICTest1
- Select **View as PDF** action button to view, download or print the pdf from a new browser tab as required

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Actions

Project Create Subform

5 Reviewer Comments Share

Roles View as PDF

Correspond Import Xml

Action Required	Status	Review Reference	Date Modified	NMA
No	Approved	HREC/72733/VICTEST-2021-246469(v3)	05/01/2021 11:57	Project is for NMA

Navigation Documents Signatures Collaborators Submissions Correspondence History

Submissions

Review Reference	Date	Status	Committee	Pdf
HREC/72733/VICTEST-2021-246469(v3)	05/01/2021	Approved	VICTest1	View as PDF
HREC/72733/VICTEST-2020-246311(v2)	31/12/2020	Archived	VICTest1	View as PDF

Correspondence

- Displays a record of the communication between the user and the reviewing organisation's research office
- It has no write/send message function
- Use the **Correspond** button under the Actions pane to write and send a message to the Research Office only after a form has been submitted

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Actions

Project Create Subform

Share Roles

View as PDF Correspond

Import Xml Recall

HREA 31 HREA

Action Required	Status	Review Reference	Date Modified	NMA
No	Submitted	HREC/74950/VICTEST-2021-257683(v1)	02/04/2021 12:19	Project is for NM

Navigation Documents Signatures Collaborators Submissions Correspondence History

Correspondence + New Correspondence

Search correspondence...

User	Date	Message	Attachment
Ms Catherine Farrington	02/04/2021	CPI CV pending	

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

Actions

Project Create Subform Share

Roles Completeness Check Submit

Refresh NView as PDF Print

Correspond Import Xml

Site Notification Form Amendment Request

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

Navigation Documents Signatures Collaborators Submissions Correspondence History

Form History

Search history...

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

2.8 ERM Reference Numbers

Project ID:

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

Review Reference:

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

The screenshot shows the ERM interface. At the top, the title 'HREA 31' is displayed. To the right, the 'Project ID' is highlighted with a blue box and a red arrow pointing to the value '74950'. Below this, the 'Project Tree' shows a hierarchy with 'HREA 31' and 'HREA'. A red arrow points from the 'Review Reference' label to a red box containing 'HREC/74950/VICTEST-2021-257683(v1)'. Below this, a table shows the submission details: 'Action Required' (No), 'Status' (Submitted), 'Review Reference' (HREC/74950/VICTEST-2021-257683(v1)), 'Date Modified' (02/04/2021 12:19), and 'NMA' (Project is for NMA). At the bottom, there is a navigation bar with tabs: 'Navigation', 'Documents', 'Signatures', 'Collaborators', 'Submissions', 'Correspondence', and 'History'. The 'HREA' logo is at the bottom left, and a 'Show Inactive Section' checkbox is at the bottom right.

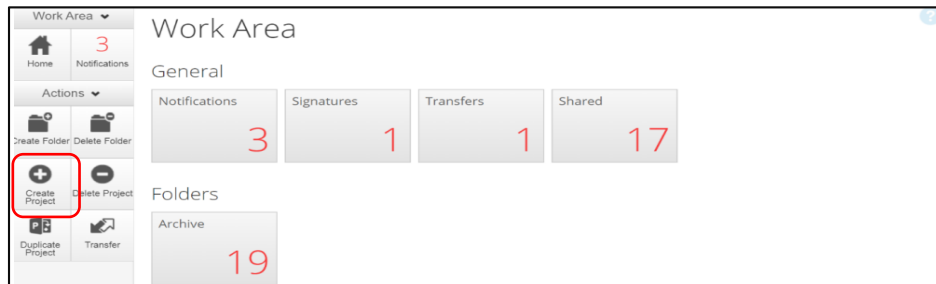
- Composed of six parts - ① ② ③ ④ ⑤ ⑥
e.g. HREC/74950/VICTEST-2021-257683(v1)

	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	74950
③	Organisation/hospital code	The organisation/hospital to which this form was submitted	VICTEST
④	Year	Year of submission	2021
⑤	Submission number	Identifies the particular submission (version) of this form	257683
⑥	Version number	Version number	v1

3 The HREA form

3.1 Create a HREA

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



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

Create Project

Project Title (maximum 200 characters):*

January Project

Select Jurisdiction

Victoria

Main Form

HREA

Create Close

HREA 02

Project Tree

Project Tree

HREA 02

HREA

Project Title

Action Required	Status	Review Reference	Date Modified	NMA
Yes	Not Submitted	N/A	02/04/2021 13:17	Project is not for NMA

Navigation Documents Signatures Collaborators Submissions Correspondence History

HREA

Show In

3.2 Complete the HREA

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

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

3.3 Import a HREA

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

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

- Click on the **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.

3.4 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

Actions

Previous

Next

Navigate

View as PDF

Documents

Signatures

Save

Share

HREA

Attachments

Q4.1 Attach the [Project Description/Protocol](#) to your HREA. *

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

Upload Document

- Press **Upload Document**

Upload Document

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

Actions

Previous

Next

Navigate

View as PDF

Documents

Signatures

Save

Share

Roles

Collaborators

Completeness

Submit

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,
 - data management plans (see National Statement Chapter 3.1),
 - ethically defensible plans for the communication of research findings or results to participants (see National Statement Chapters 3.1, 3.2 and 3.3, as appropriate, for guidance on the content of ethically defensible plans),
 - 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.
- The document name field is editable. Enter the description in the document name field. The date and version fields are

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

- Press **Upload Document**

Upload Document

 to attach the selected Supporting Document from your local drive

☒ 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

- 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	Download	Delete
Upload Document							

Participant information and consent forms

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Participant information and consent form	PICFs Dec 2017	PICFs Dec 2017.docx	31/12/2017	1.3	474.6 KB	Download	Delete
Upload Document							

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

Project

Create Subform

Share

Roles

Completeness Check

Submit

Refresh

NMA Project

View as PDF

Correspond

Action Required

Status

Review Reference

Date Modified

NMA

75001 ?

Yes

Not Submitted

N/A

02/04/2021 13:39

Project is not for NMA

Navigation

Documents

Signatures

Collaborators

Submissions

Correspondence

History

Documents

Search Document

Type	Document Name	File Name	Version Date	Version	Size
<input checked="" type="checkbox"/> Protocol	December Holidays protocol	December Holidays protocol.docx	01/12/2020	1	11.5 KB
<input checked="" type="checkbox"/> Participant information and consent form	PICF Master December 2020	PICF Master December 2020.docx	01/12/2020	1	12.2 KB
<input checked="" type="checkbox"/> Form	Form	Form.pdf			

Showing 1 to 3 of 3 entries

View Selected

Download Selected

3.5 Assign access to the HREA

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

Project

Create Subform

Share

Roles

Completeness Check

Submit

Refresh

NMA Project

View as PDF

Correspond

Project Tree

HREA 02

HREA

Action Required

Status

Review Reference

Date Modified

NMA

Yes

Not Submitted

N/A

02/04/2021 13:39

Project is not

Navigation

Documents

Signatures

Collaborators

Submissions

Correspondence

History

HREA

Section

Questions

ERM Module

ERM Filter Questions

Applicant user guide to ERM. April 2021

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VICTORIA
State Government

Jobs,
Precincts
and Regions

- 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


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

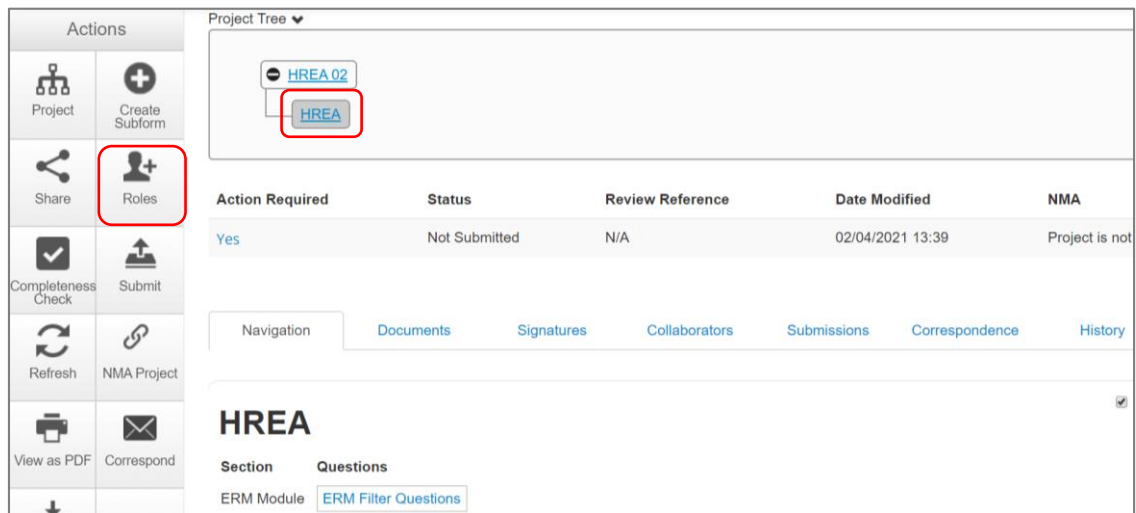
If the collaborator does not have an ERM account

- 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



The screenshot shows the ERM interface. On the left, the 'Actions' pane contains a grid of icons. The 'Roles +' icon, which shows a person with a plus sign, is highlighted with a red box. In the 'Project Tree' on the right, the 'HREA' folder is also highlighted with a red box. Below the Project Tree, there is a table with columns: Action Required, Status, Review Reference, Date Modified, and NMA. The table contains one row with the following data: Action Required: Yes, Status: Not Submitted, Review Reference: N/A, Date Modified: 02/04/2021 13:39, NMA: Project is not. Below the table, there is a navigation bar with tabs: Navigation, Documents, Signatures, Collaborators, Submissions, Correspondence, and History. The 'HREA' form is displayed below the navigation bar, with a 'Section' dropdown set to 'ERM Module' and a 'Questions' section with a link to 'ERM Filter Questions'.

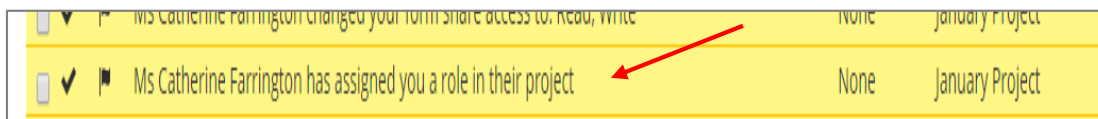
Accept access

- 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



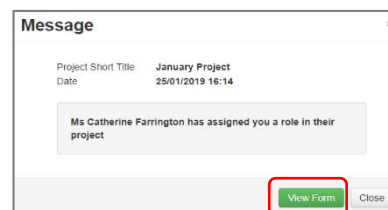
The screenshot shows the 'Work Area' interface. On the left, there is a 'Work Area' sidebar with a 'Home' button and a 'Notifications' button with a red '1' next to it. Below the sidebar, there is a grid of tiles. The 'Notifications' tile is highlighted with a red box and has a red '1' next to it. Other tiles include 'Signatures' (with a red '1'), 'Transfers' (with a green '0'), and 'Shared' (with a green '0').

- Select the Message title to open the message



The screenshot shows a list of messages. The first message is highlighted in yellow and has a red arrow pointing to it. The message text is: 'Ms Catherine Farrington has assigned you a role in their project'. The message is from 'None' and is dated 'January Project'.


- A **Message** text box will be displayed
Select **View Form**



The screenshot shows a 'Message' dialog box. It contains the following information: Project Short Title: January Project, Date: 25/01/2019 16:14. The message text is: 'Ms Catherine Farrington has assigned you a role in their project'. At the bottom right, there is a 'View Form' button highlighted with a red box and a 'Close' button.

- 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

3.6 Applying signatures

Declaration

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

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

Signatures

The HREA form questions / information must be complete, 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 screenshot shows the ERM application form interface. On the left is a sidebar titled 'Actions' with icons for Previous, Next, Navigate, View as PDF, Documents, Signatures, Save, Share, Roles, Collaborators, Completeness Check, and Submit. The main content area has a header 'I, (insert name)' followed by a 'certify that:' section with a list of statements. Below this is a section titled 'Q4.7 How will the Coordinating Principal Investigator/Researcher agree to these terms?' with a list of options. The 'Signatures' section is highlighted with a red box, showing three radio button options: 'Electronic signature (in place of HREA 'sign on screen')', 'Upload other evidence', and 'Wet ink sign after printing'.




The HREA form owner may request signatures as follows:

1. To use Wet ink signature

- Select Wet ink sign after printing



The screenshot shows the HREA form for the 'Coordinating Principal Investigator/Researcher'. It includes a name field, a 'certify that:' section, and a 'Q4.7 How will the Coordinating Principal Investigator/Researcher agree to these terms?' section. The 'Signatures' section is highlighted with a red box, showing three radio button options: 'Electronic signature (in place of HREA 'sign on screen')', 'Upload other evidence', and 'Wet ink sign after printing'. The 'Wet ink sign after printing' option is selected. Below the options are fields for 'Sign here:' and 'Date:'.

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

- Using the **View as PDF**  action button, custom print the page and obtain the signature from the CPI / PI. Save to your local drive as a pdf
- Navigate to last section of the HREA to find 
- Upload** 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		

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

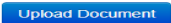
- Select 'Upload other evidence'


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





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

☐ 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		

3. To request an Electronic Signature

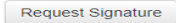

- Select **Electronic signature** and a   button will appear

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

- To request an electronic signature from the Coordinating Principal Investigator / Principal Investigator, select

Request Signature

Request Signature

button

- The system performs a completeness check to highlight any incomplete sections that need to be completed. Each incomplete item will be displayed as a link to the relevant section

- When all required sections of the HREA have been completed select **Request Signature**

Request Signature

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

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

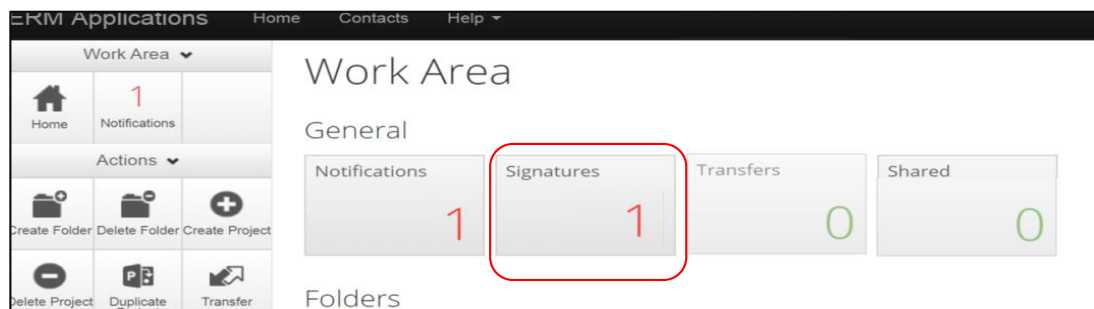
You have received a signature request from Ms Jane Citizen with a message.

Could you please sign this HREA?

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

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

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



- New requests 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

View Form

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

Sign

Actions

Previous Next

Navigate View as PDF

Sign Reject

Completeness Check

HREA 75001 Version: Be

Read access only.

ERM Filter Questions

In which jurisdiction will your ethics application be submitted for review?

☐ Queensland Health
☒ Victoria
☐ Mater

Project Title CHANGES TO THIS FIELD WILL UPDATE THE TITLE FOR THE ENTIRE PROJECT

HREA 02

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

Sign Form

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

Username Password

Sign Close

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

Signatures

Search Signatures

Type	Project Title	Project ID	Requesting User	Message	Requested Date	Response Date	Status	Action
Co-ordinating Principal Investigator/Researcher	HREA 02	75001	Ms Catherine Farrington	Please sign the HREA	02/04/2021 14:50	02/04/2021 14:55	Signed	PDF being Generated
Head of Supporting Department	HREA 16	67040	Ms Catherine	TESTING A FORM	20/07/2020	20/07/2020	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

Actions

Previous Next

Navigate View as PDF

Documents Signatures

Unlock Share

HREA 7

This form has been locked through signatures/requests

Declaration - CI/CPI/Lead Investigator

Coordinating Principal Investigator/Researcher

I, (insert name)

certify that:

- 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



button under the Actions pane

Unlock Form

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

Confirm

Cancel

- The form is unlocked for editing

Form unlocked

Previous

Next

Navigate

View as PDF

Documents

Signatures

Save

Share

Roles

Collaborators

DECLARATION

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

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


4 Submission and review process – HREA

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

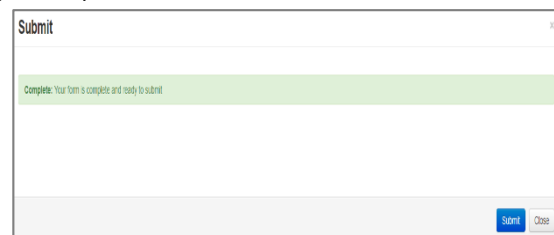
For the initial application submission ensure the form is complete and all **documents are uploaded and signatures completed**.

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

4.1 Submission

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


- Select the **Submit**  button



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



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

- Following the submission, a unique identification code is generated.
It is composed of six parts - e.g. HREC/74950/VICTEST-2021-257683(v1)

- The **Form Status**  of the application 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.

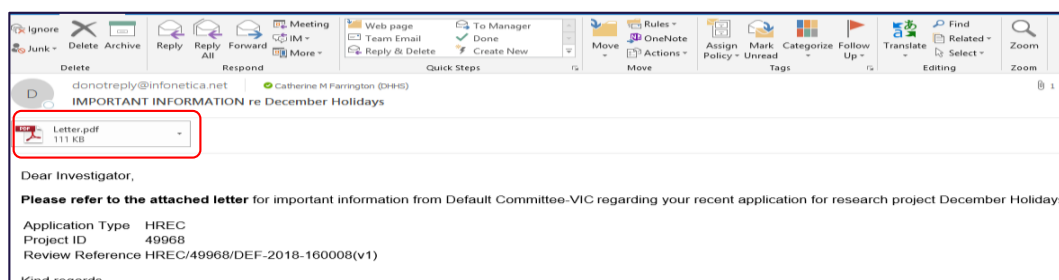
4.2 Responding to a query from the Research Office

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

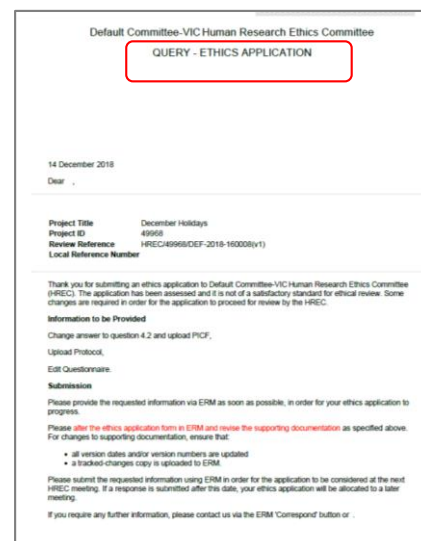
The form Status has changed from 'Submitted' to 'Queried' -

Action Required	Status	Review Reference	Date Modified	NMA
Yes	Queried	HREC/74950/VICTEST-2021-257691(v3)	02/04/2021 17:15	Project is for NMA

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

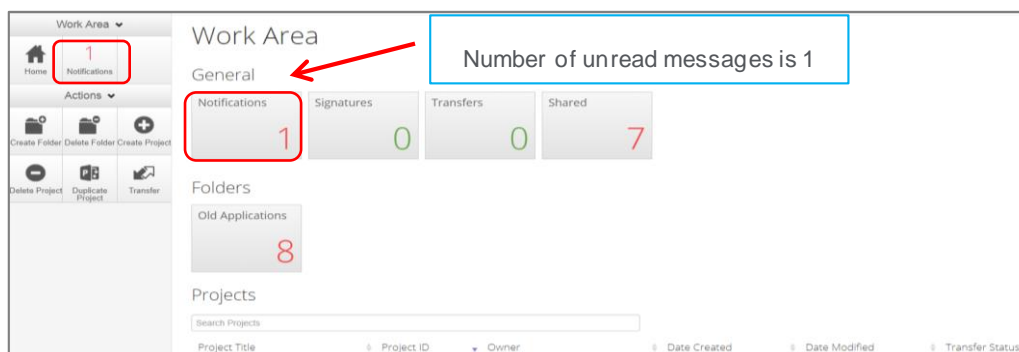


- A 'Query – Ethics Application' letter (pdf) from the Research Office will include details for further information to be provided via ERM



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 3 Reviewer Comments

Project Tree

- December Holidays

Form Status	Review Reference	Application Type	Date Modified	NMA
Quarried	N/A	Ethics Application	13/12/2018 14:25	Project is not for NMA

Navigation Documents Signatures Collaborators Submissions Correspondence History

HREA

Section

- PDMA Module
- HREA Introduction
- Project Overview
- Project Team
- Disclosure of Interests
- Restrictions
- Evaluations
- Location
- Methods
- Participants

Questions

- PDMA 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

Comment

Please edit the questionnaire.

This application will not be reviewed until you provide a protocol.

This project requires a participant information and consent form. Please provide it.

Date Added	Submission
14/12/2018 at 09:16 AM	Latest Submission
14/12/2018 at 09:15 AM	Latest Submission
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** [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	12.9 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

The screenshot shows the ERM system interface. On the left, the 'Actions' pane is visible with the 'Submit' button highlighted. The main area displays a list of documents and questionnaires.

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

4.3 Ethics Committee review request

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

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

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

The screenshot shows an email from donotreply@infonetica.net to Catherine M Farrington (DHHS). The email subject is 'IMPORTANT INFORMATION re December Holidays'. The email body contains the following text:

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

Respond to a request for further information from the Ethics Committee

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

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

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

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

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

Overall Reviewer Panel Comments

Comment	Date Added	Submission
The questionnaire is too complex. Please simplify it so that participants will be able to understand	17/12/2018 at 13:46 PM	Latest Submission
The protocol is nice but needs more detail about the methodology.	17/12/2018 at 13:46 PM	Latest Submission

Close

- 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

Actions

Previous Next

Navigate View as PDF

Documents Signatures

Save Share

Attachments

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

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

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Protocol	December Holidays protocol	December Holidays protocol.docx	01/12/2020	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

Actions

Previous Next

Navigate View as PDF

Documents Signatures

Save Share

Attachments

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

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

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Protocol	December Holidays protocol version 2 (clean)	December Holidays protocol version 2 (clean).docx	31/12/2020	2	14.2 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.

5 National Mutual Acceptance (NMA) applications

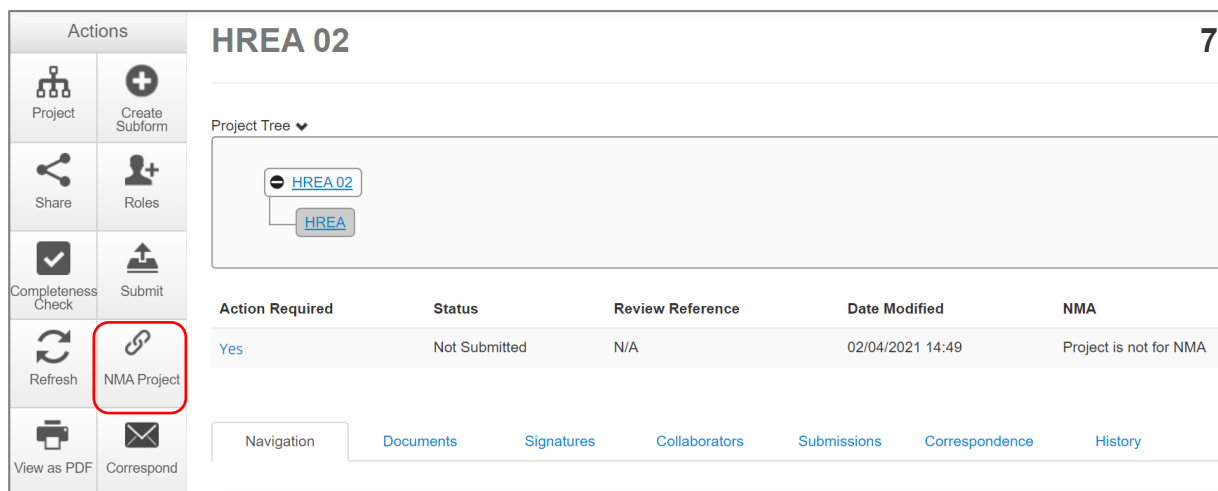
NMA is a national system for mutual acceptance of scientific and ethical review of multi-centre human research projects conducted in publicly funded health services across jurisdictions.

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

If 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?**

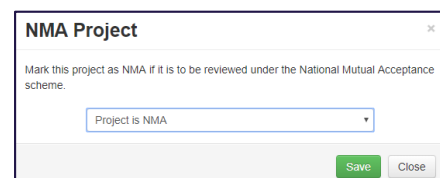
- Navigate  back to the **Actions** pane and select **NMA Project**



Action Required	Status	Review Reference	Date Modified	NMA
Yes	Not Submitted	N/A	02/04/2021 14:49	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'

6 Victorian Specific Module

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

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

In ERM:

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

Action Required	Status	Review Reference	Date Modified	NMA
Yes	Not Submitted	N/A	02/04/2021 17:38	Project is for NMA

- 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

Select Jurisdiction
Victoria

Select the sub-form that you would like to apply to this form
Victorian Specific Module (VSM)

Create Close

Action Required	Status	Review Reference	Date Modified	NMA
Yes	Not Submitted	N/A	02/04/2021 17:47	Project is for NMA

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

Victorian Specific Module (VSM)

Blood

3.1(a) Will the research involve the collection of blood from an adult?

☒ Yes
☐ No

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

HREA

Section: **Questions**

ERM Module: **ERM Filter Questions**

HREA: **Introduction** | **HREC Directory**

Action Required	Status	Review Reference	Date Modified	NMA
Yes	Not Submitted	N/A	02/04/2021 17:38	Project is for NMA

Navigation: Documents Signatures Collaborators Submissions Correspondence History

75

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

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

☒ Yes
☐ No

Select the features that are applicable to this research project:

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

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

Victorian Specific Module

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Victorian specific module (VSM)	VSM	VSM.pdf	02/04/2021	1	226.6 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**

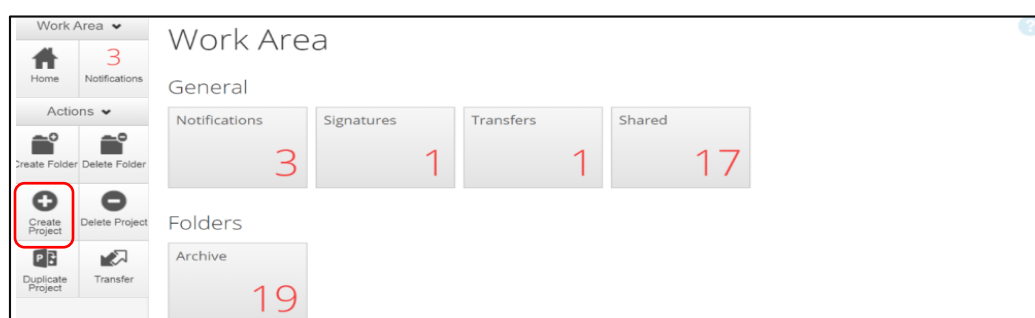
7 Victorian Low and Negligible Risk application (LNR VIC)

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.

7.1 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

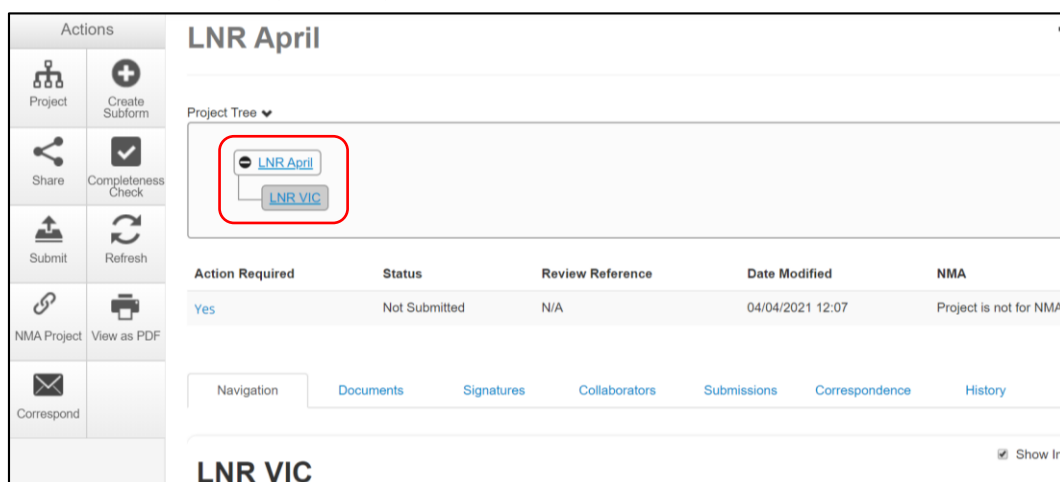
Victoria

Main Form

LNR VIC

Create Close



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

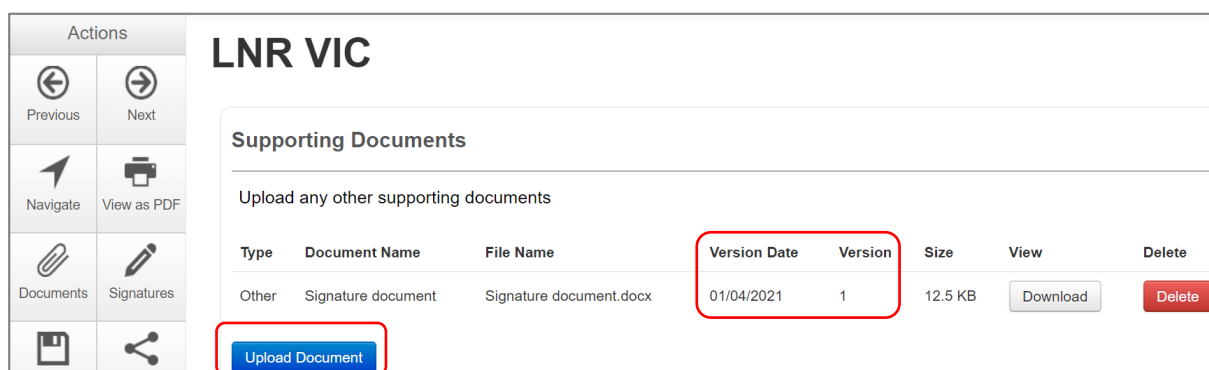


7.2 Complete the LNR VIC

- 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

7.3 Upload documents

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




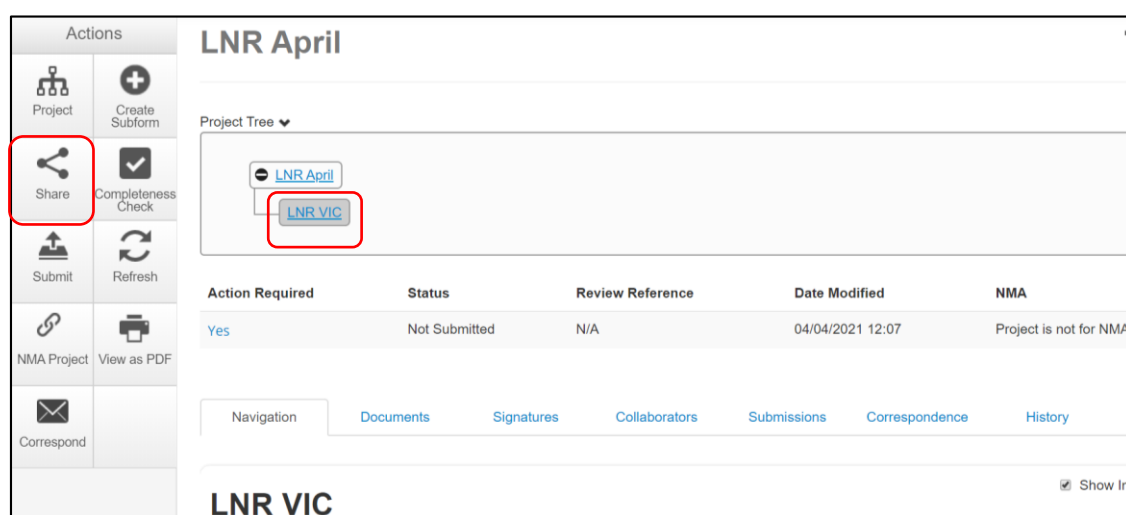
Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Other	Signature document	Signature document.docx	01/04/2021	1	12.5 KB	Download	Delete

7.4 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 **Share** function, the project owner assigns other collaborators specific levels of access to the LNR VIC form.

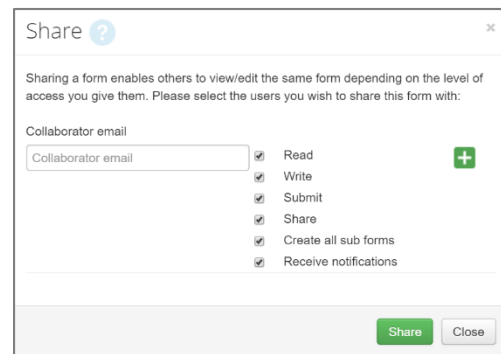
- Select the **Share**  button under the Actions pane



Action Required	Status	Review Reference	Date Modified	NMA
Yes	Not Submitted	N/A	04/04/2021 12:07	Project is not for NMA

- A **Share** textbox will be displayed. Enter the collaborator's ERM email address and select the checkboxes to assign the level of access

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




Share ?

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

Collaborator email

Read ☒ Write ☒ Submit ☒ Share ☒ Create all sub forms ☒ Receive notifications ☒



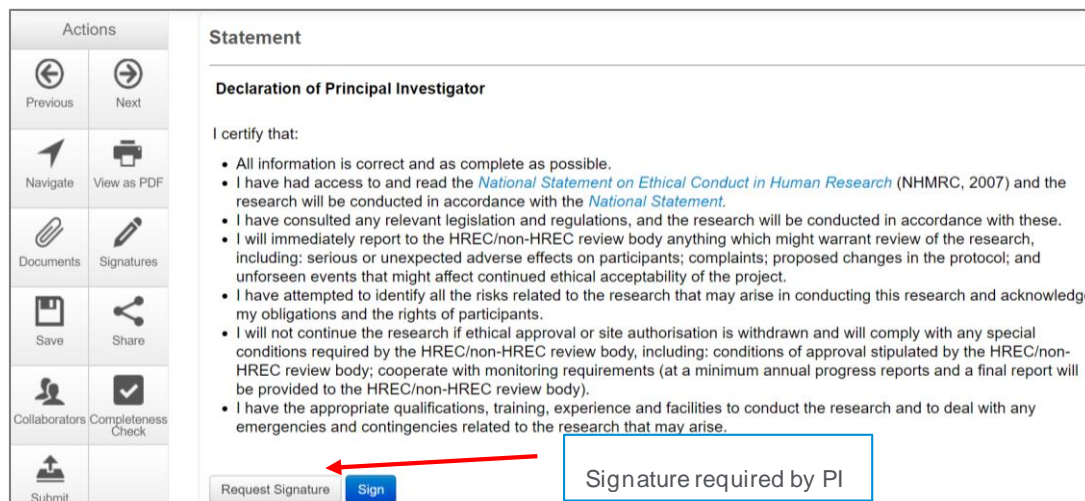
Share **Close**

7.5 Applying signatures

Declaration

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

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



Actions

Previous Next

Navigate View as PDF

Documents Signatures

Save Share

Collaborators Completeness Check

Submit

Statement

Declaration of Principal Investigator

I certify that:

- All information is correct and as complete as possible.
- I have had access to and read the [National Statement on Ethical Conduct in Human Research](#) (NHMRC, 2007) and the research will be conducted in accordance with the [National Statement](#).
- I have consulted any relevant legislation and regulations, and the research will be conducted in accordance with these.
- I will immediately report to the HREC/non-HREC review body anything which might warrant review of the research, including: serious or unexpected adverse effects on participants; complaints; proposed changes in the protocol; and unforeseen events that might affect continued ethical acceptability of the project.
- I have attempted to identify all the risks related to the research that may arise in conducting this research and acknowledge my obligations and the rights of participants.
- I will not continue the research if ethical approval or site authorisation is withdrawn and will comply with any special conditions required by the HREC/non-HREC review body, including: conditions of approval stipulated by the HREC/non-HREC review body; cooperate with monitoring requirements (at a minimum annual progress reports and a final report will be provided to the HREC/non-HREC review body).
- I have the appropriate qualifications, training, experience and facilities to conduct the research and to deal with any emergencies and contingencies related to the research that may arise.

Request Signature **Sign**

Signature required by PI



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**

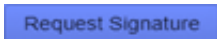
- Using the **View as PDF**  button from the Actions pane, custom print the Declaration page and obtain the signature from the PI. Scan and save to your local drive as a pdf
- Navigate to last section of the LNR VIC to find the Supporting Documents hyperlink [Supporting Documents](#)
- **Supporting Documents**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

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

- Navigate to last section of the LNR VIC to find the Supporting Documents hyperlink [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**



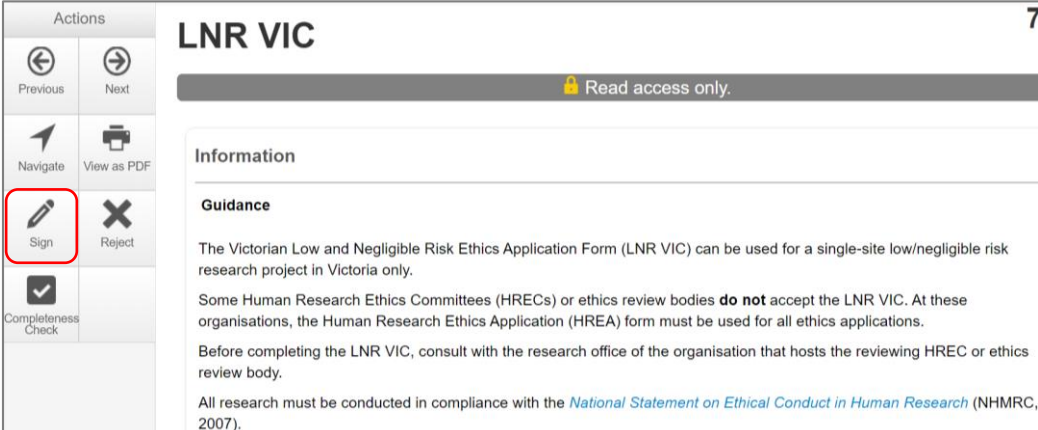
- Enter the signatory's ERM email address and select **Request**
- The signatory will receive an email notification for a signature, a message and a link to ERM Log In page
- The signatory logs in to ERM
- From the **Work Area** the signatory selects **Signatures** tile to open the request

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

Signatures

Type	Project Title	Project ID	Requesting User	Message	Requested Date	Response Date	Status	Action
Principal Investigator	LNR April	75014	Ms Catherine Farrington	Please sign the LNR form	04/04/2021 13:27		Requested	View Form
Co-ordinating Principal Investigator/Researcher	HREA 02	75001	Ms Catherine Farrington	Please sign the HREA	02/04/2021 14:50	02/04/2021 14:55	Invalidated	View Form

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




The screenshot displays the LNR VIC application form. On the left, the 'Actions' pane includes buttons for 'Previous', 'Next', 'Navigate', 'View as PDF', 'Sign' (highlighted with a red box), 'Reject', and 'Completeness Check'. The main content area features the title 'LNR VIC' and a 'Read access only' status. Below this, the 'Information' section contains 'Guidance' text explaining the form's purpose and usage.

- 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

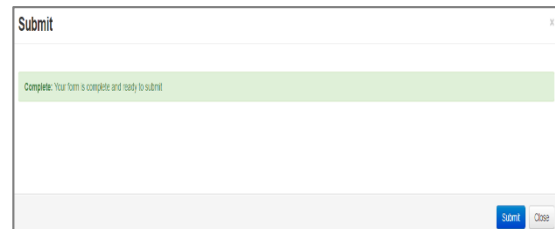
8 Submission and review process – LNR VIC

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

8.1 Submission

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

- Select the **Submit**  button





- The system will automatically submit the application to the 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

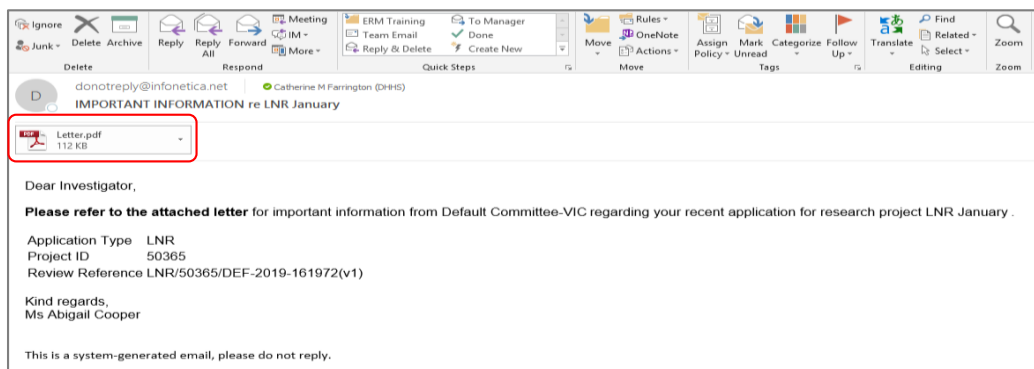
**Any changes made to the submission will INVALIDATE all electronic signatures
and will require all signature requests again**

- 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

8.2 Responding to a query from the Research Office

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

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



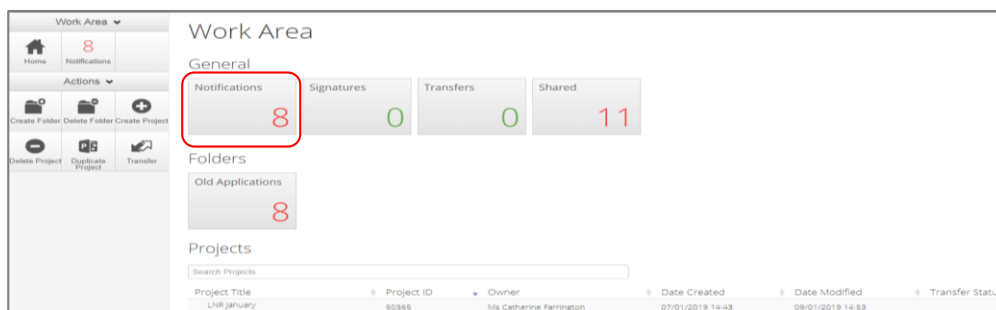
- A 'QUERY-ETHICS APPLICATION' letter (pdf) from the Research Office will include details for further information to be provided via ERM



- 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

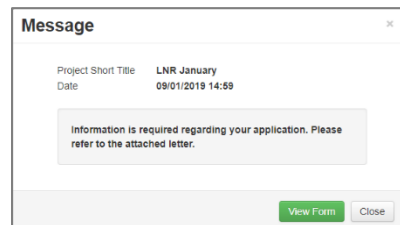


- Select the Message title to open and view the message



- 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 Action pane

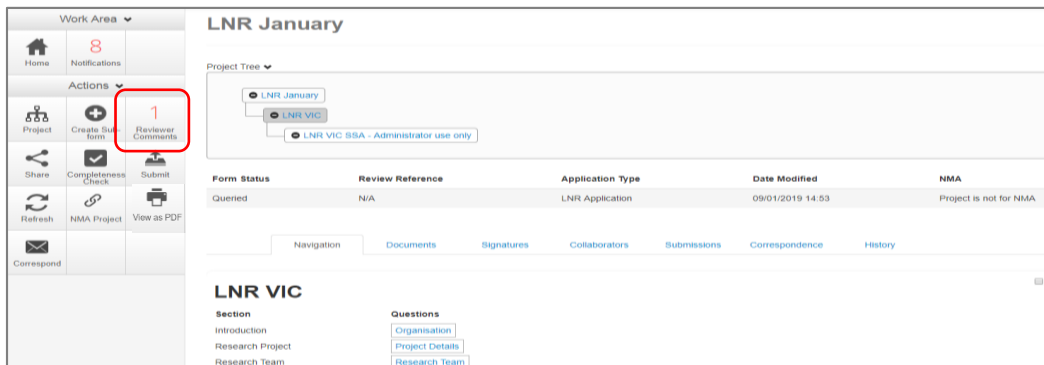


Message

Project Short Title: LNR January
Date: 09/01/2019 14:59

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

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



Work Area: LNR January

Project Tree: LNR January, LNR VIC, LNR VIC SSA - Administrator use only

Form Status: Queried, Review Reference: N/A, Application Type: LNR Application, Date Modified: 09/01/2019 14:53, NMA: Project is not for NMA

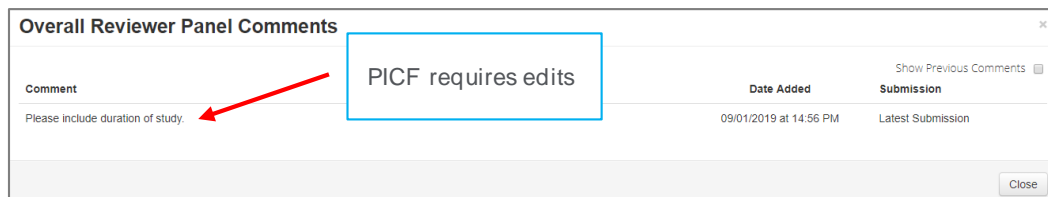
Navigation: Documents, Signatures, Collaborators, Submissions, Correspondence, History

LNR VIC

Section: Introduction, Research Project, Research Team

Questions: Organisation, Project Details, Research Team

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



Overall Reviewer Panel Comments

Comment: Please include duration of study.

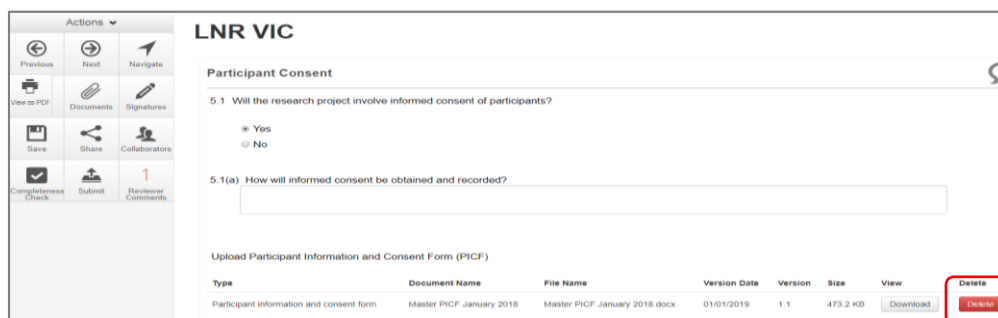
PICF requires edits

Date Added: 09/01/2019 at 14:56 PM, Submission: Latest Submission

[Show Previous Comments](#) [Close](#)

- 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



LNR VIC

Participant Consent

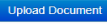
5.1 Will the research project involve informed consent of participants?

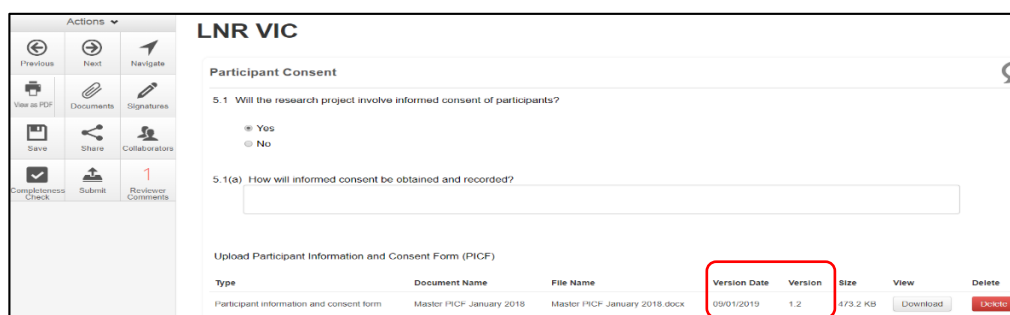
☒ Yes ☐ No

5.1(a) How will informed consent be obtained and recorded?

Upload Participant Information 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	01/01/2019	1.1	473.2 KB	Download	Delete

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



LNR VIC

Participant Consent

5.1 Will the research project involve informed consent of participants?


☒ Yes ☐ No

5.1(a) How will informed consent be obtained and recorded?

Upload Participant Information 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	09/01/2019	1.2	473.2 KB	Download	Delete

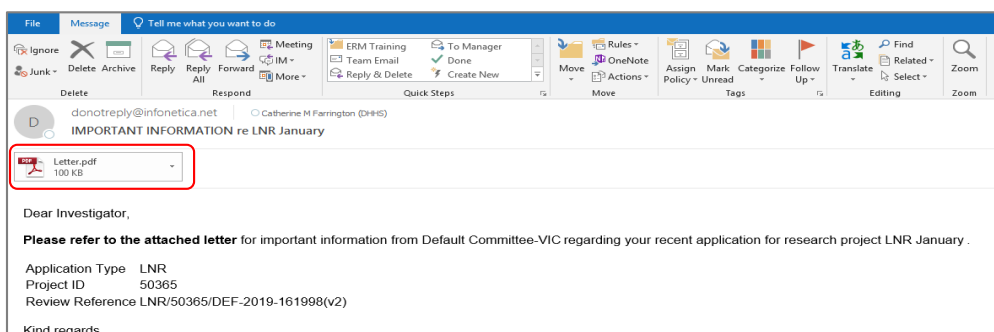
- Continue to complete other queries if instructed in the **Overall Reviewer Panel Comments**
- Once the revisions/additions have been completed, the form and / or supporting documents can be resubmitted

- Select 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.

8.3 Ethics Committee review request

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

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

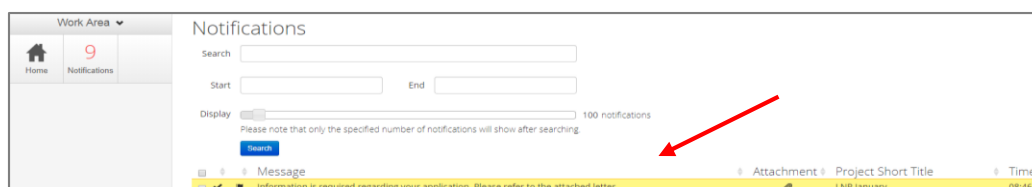



- A 'REQUEST FOR FURTHER INFORMATION' letter (pdf) from the HREC will include requests for further information to be provided via ERM
- The form is **unlocked** to allow the applicant to complete the requests as outlined in the attached letter



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

Message

Project Short Title

LNR January

Date

10/01/2019 08:46

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

View Form

Close

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

Work Area

Home

8

Notifications

Actions

Project

Create Sub-form

Share

Refresh

Correspond

2

Reviewer Comments

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

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

Actions

Previous

Next

Navigate

View as PDF

Documents

Signatures

Save

Share

Collaborators

2

Reviewer Comments

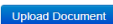
1.10 Research aims, methodology and significance

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 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.

9 Site Specific Assessment (SSA)

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

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

9.1 Create a SSA

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

The screenshot shows the 'HREA 31' interface. On the left, the 'Actions' pane has a 'Create Sub-form' button highlighted with a red box. In the 'Project Tree' on the right, 'HREA 31' is highlighted with a red box. Below the Project Tree is a table with the following data:

Action Required	Status	Review Reference	Date Modified	NMA
Yes	Queried	HREC/74950/VICTEST-2021-257691(v3)	02/04/2021 17:15	Project is for NMA

At the bottom, there is a navigation bar with tabs: Navigation, Documents, Signatures, Collaborators, Submissions, Correspondence, and History. The 'HREA' label is at the bottom left, and a 'Show Inactive' checkbox is at the bottom right.

- 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 'Select Jurisdiction' dropdown menu with 'Victoria' selected. Below it, there 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.

- The Project Tree will display the newly created SSA

The screenshot shows the 'Site Specific Assessment (SSA) VIC' interface. On the left, the 'Actions' pane has a 'Create Sub-form' button highlighted with a red box. In the 'Project Tree' on the right, 'Site Specific Assessment (SSA) VIC' is highlighted with a red box. Below the Project Tree is a table with the following data:

Action Required	Status	Review Reference	Date Modified	NMA
Yes	Not Submitted	N/A	04/04/2021 14:59	Project is for NMA

At the bottom, there is a navigation bar with tabs: Navigation, Documents, Signatures, Collaborators, Submissions, Correspondence, and History. The 'Site Specific Assessment (SSA) VIC' label is at the bottom left, and a 'Show Inactive' checkbox is at the bottom right.

- Information from the HREA will not automatically populate the SSA


9.2 Creating SSAs for sites

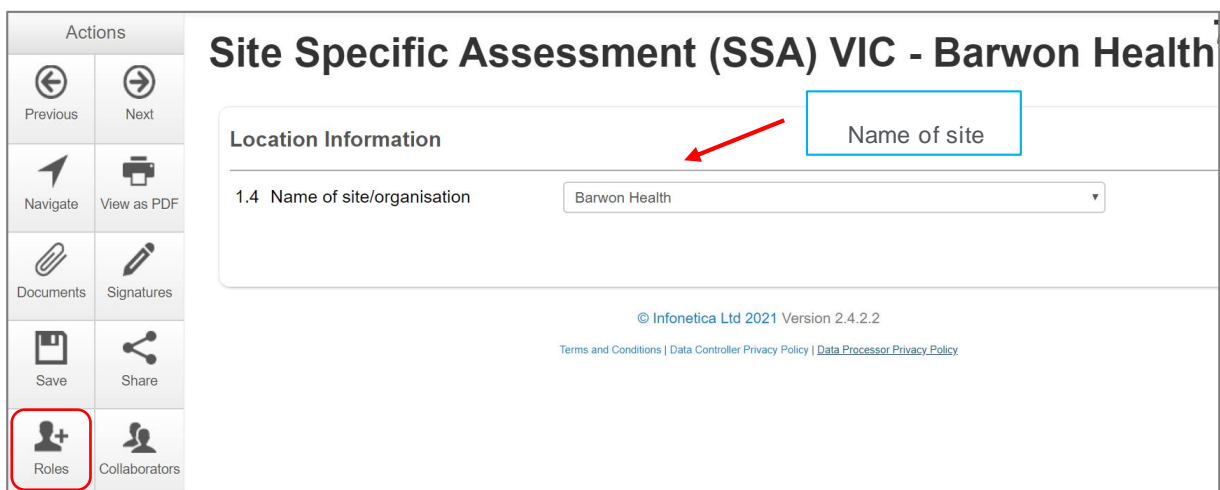
The SSA for a site is created by either the **HREA (or LNR VIC)** project owner or by assigning this role to the site PI.

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
- Highlight the SSA in the Project Tree
- In the **Introduction** section of the SSA form, complete question **Q 1.4** to enter the name of the site/organisation
- Select **Roles+**  button under the Actions pane



Site Specific Assessment (SSA) VIC - Barwon Health

Location Information

1.4 Name of site/organisation Barwon Health

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Terms and Conditions | Data Controller Privacy Policy | Data Processor Privacy Policy

Actions

Previous Next

Navigate View as PDF

Documents Signatures

Save Share

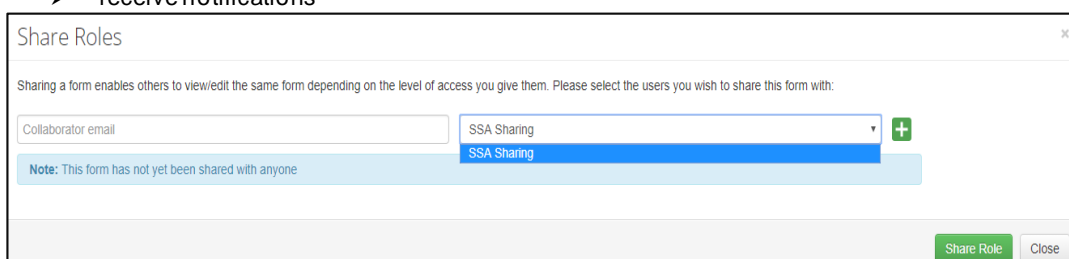
Roles Collaborators

- 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




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

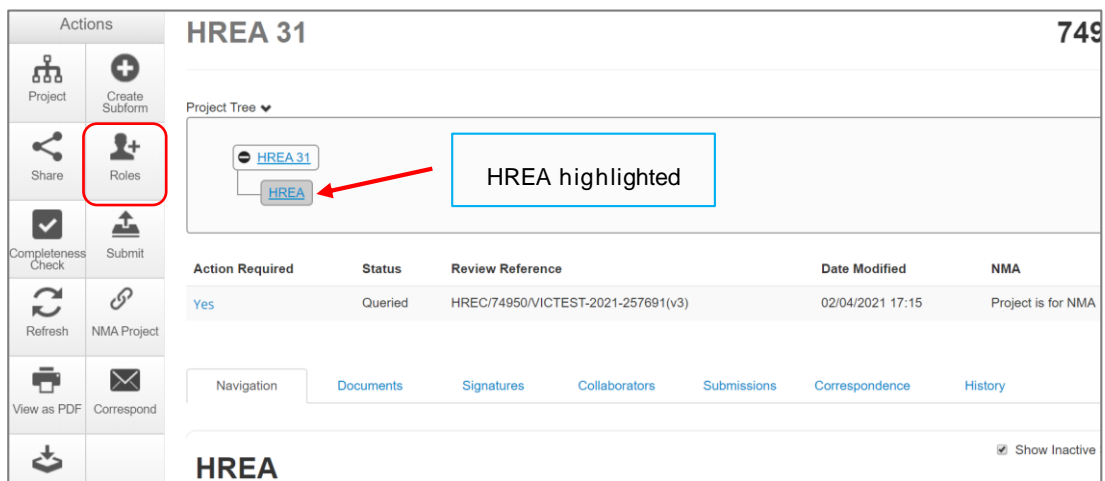
Share Role Close

- 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
- The collaborator can continue to complete the SSA form

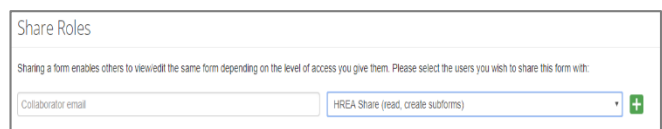
(ii) Assigning Role to Site PI


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

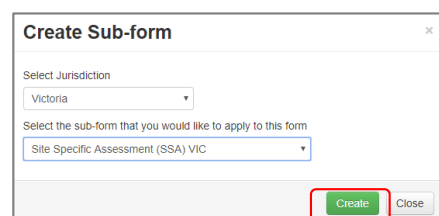


Action Required	Status	Review Reference	Date Modified	NMA
Yes	Queried	HREC/74950/VICTEST-2021-257691(v3)	02/04/2021 17:15	Project is for NMA

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



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



- The SSA will be displayed in the Project Tree

- Complete the SSA form

9.3 Upload documents

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

Section	Questions (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 **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
Participant information and consent form	PICF Site December 2020	PICF Site December 2020.docx	01/12/2020	1	12.2 KB	Download	Delete

- Documents will be displayed under the **Documents** tab and can be viewed or downloaded individually or together

- Select the checkbox for each corresponding document or all documents can be selected at once

Action Required	Status	Review Reference	Date Modified	NMA
Yes	Not Submitted	N/A	04/04/2021 15:46	Project is for NMA

Type	Document Name	File Name	Version Date	Version
<input checked="" type="checkbox"/> Participant information and consent form	PICF Site December 2020	PICF Site December 2020.docx	01/12/2020	1
<input checked="" type="checkbox"/> Curriculum vitae	Dr Jones CV	Dr Jones CV.docx	01/12/2020	1
<input checked="" type="checkbox"/> Evidence of GCP training	Dr Jones GCP Certificate	Dr Jones GCP Certificate.docx	01/12/2020	1
<input checked="" type="checkbox"/> Form	Form	Form.pdf		

- Select the **View Selected** button to open the document as a PDF in a new browser

or select the **Download Selected** button to download as ZIP file

9.4 Assign access to the SSA form

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

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

9.5 Applying signatures

Declaration

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

Site Specific Assessment (SSA) VIC - Administrator Use Only

Signature of Principal Investigator

Declaration by Principal Investigator

I certify that:

- The information in this form is truthful and accurate to the best of my knowledge and belief, and I take full responsibility at this site.
- I will only start this research project after obtaining authorisation from the site and approval from the responsible Human Research Ethics Committee (HREC).
- I accept responsibility for the conduct of this research project according to the principles of the *National Statement on Ethical Conduct in Research* (NHMRC, 2007).
- I undertake to conduct this research project in accordance with the protocols and procedures as approved by the HREC and the ethical and research arrangements of the organisation(s) involved.
- I undertake to conduct this research in accordance with relevant legislation and regulations.
- I agree to comply with the requirements of adverse or unexpected event reporting as stipulated by the HREC and in accordance with *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* (NHMRC, 2016).
- I will adhere to the conditions of approval stipulated by the HREC and will cooperate with HREC monitoring requirements.
- I will inform the HREC and the research governance officer if the research project ceases before the expected date.
- I will discontinue the research if the HREC withdraws ethical approval.
- I will adhere to the conditions of authorisation stipulated by the authorising authority at the site where I am Principal Investigator.
- I will discontinue the research if the authorising authority withdraws authorisation at the site where I am Principal Investigator.
- I understand and agree that study files and documents and research records and data may be subject to inspection by the HREC, research governance officer, sponsor or an independent body for audit and monitoring purposes.
- I understand that information relating to this research and about me as a researcher will be held by the HREC, research governance officer, and on Ethics Review Manager (ERM). I understand that this information will be used for reporting purposes and managed according to the principles established in the *Privacy Act 1988* (Cth) and relevant laws in the States and Territories of Australia.

Request Signature Sign

Signature required by PI

- 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 investigator/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.

Request Signature Sign

- 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.

Request Signature Sign

Signatures

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



Any change to the SSA form will invalidate signatures.

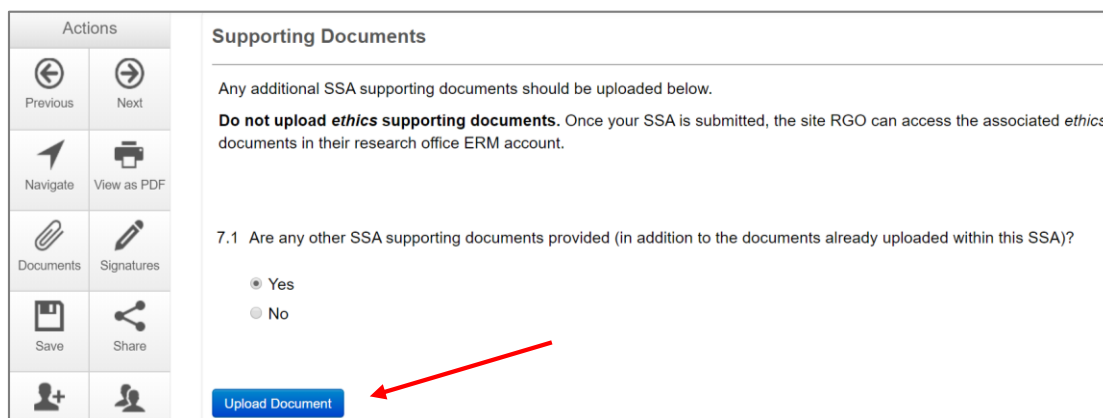
Using a combination of signature methods e.g. wet ink signatures, attaching other evidence, electronic signatures should be sought LAST as the form will be locked once electronic signature requests have been made. Multiple electronic signatures can occur.

* 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 **View as PDF**  button from the Actions Pane, custom print the relevant Declaration page and obtain the signature from the PI /Head of Department /Supporting Head of Department. Scan and save to your local drive as a PDF
- Navigate to Section **Other Documents** of the SSA to find [Other Documents](#)
- Other Documents** opens to **Q 7.1** of the SSA form to attach the Declaration page
- Select **Upload document**  to upload the Declaration page from your local drive to the SSA form



Actions

Previous Next

Navigate View as PDF

Documents Signatures

Save Share

Roles Collaborators

Completeness Submit


Supporting Documents

Any additional SSA supporting documents should be uploaded below.

Do not upload *ethics* supporting documents. Once your SSA is submitted, the site RGO can access the associated *ethics* documents in their research office ERM account.

7.1 Are any other SSA supporting documents provided (in addition to the documents already uploaded within this SSA)?

☒ Yes
☐ No

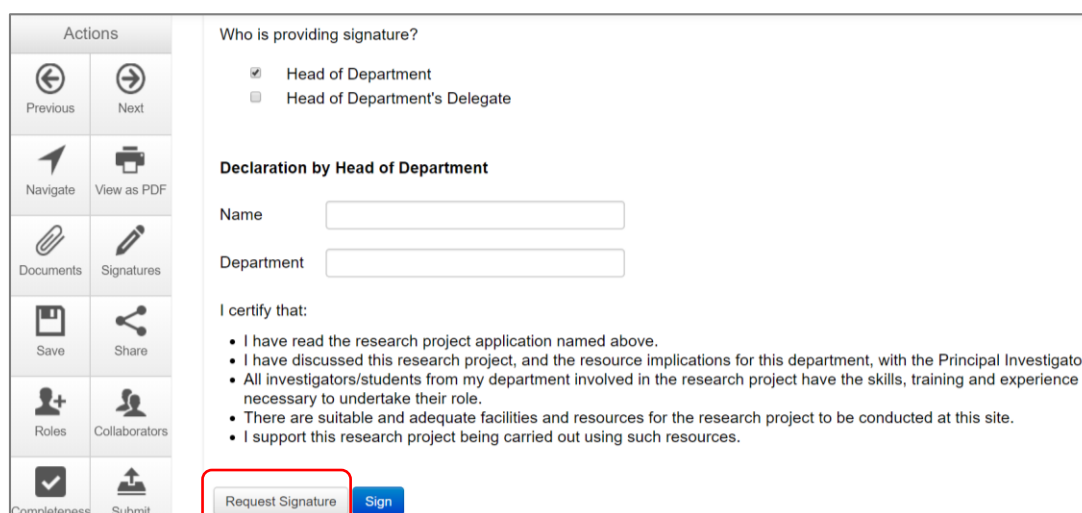


To attach other evidence to indicate agreement

- 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 upload 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



Actions

Previous Next

Navigate View as PDF

Documents Signatures

Save Share

Roles Collaborators

Completeness Submit

Who is providing signature?

☒ Head of Department
☐ Head of Department's Delegate

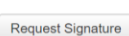

Declaration by Head of Department

Name

Department

I certify that:

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

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

Request a signature

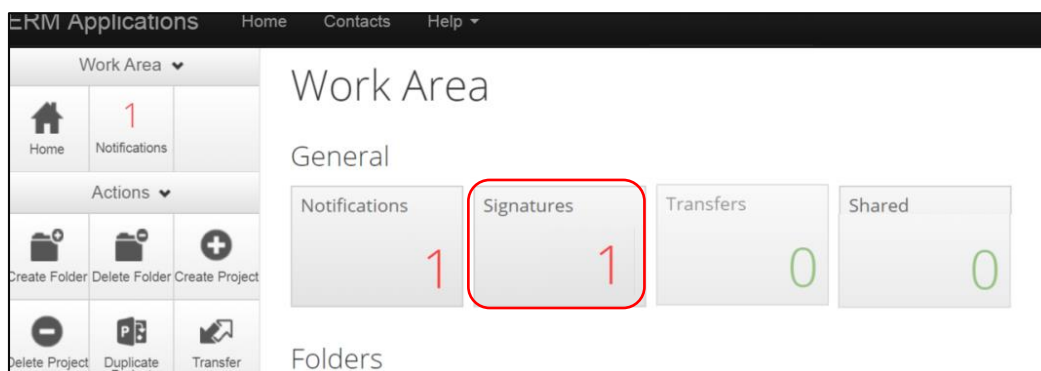
Enter the email address of the person you want to sign this form

Email Address

Enter a message (Optional, max 800 characters)

RequestClose

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



- New requests are highlighted

Type	Project Title	Project ID	Requesting User	Message	Requested Date	Response Date	Status	Action
Head of Department	HREA 31	74950	Ms Catherine Farrington	Please sign the SSA form	04/04/2021 16:59		Requested	View Form
Principal Investigator	LNR April	75014	Ms Catherine Farrington	Please sign the LNR form	04/04/2021 13:27	04/04/2021 13:30	Signed	View PDF
Co-ordinating Principal Investigator/Researcher	HREA 02	75001	Ms Catherine Farrington	Please sign the HREA	02/04/2021 14:50	02/04/2021 14:55	Invalidated	View Form

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

Actions

Project

Completeness Check

NMA Project

Sign

Reject

View as PDF

Correspond

Project Tree

HREA 31

HREA

Site Specific Assessment (SSA) VIC - Administrator Use Only

Action Required	Status	Review Reference	Date Modified	NMA
Yes	Not Submitted	N/A	04/04/2021 17:16	Project

Navigation

Documents

Signatures

Collaborators

Submissions

Correspondence

History

Site Specific Assessment (SSA) VIC

Section

Questions

Introduction

Information

Project

Location

Ethics Review

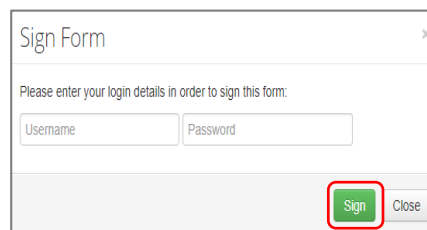
Site Addition

- The ethics application (**HREA**) can be viewed if the HREA owner has used **Roles +** from the SSA level to share the form with the signatory

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

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

Select **Sign**  button



The image shows a 'Sign Form' dialog box. It has a title bar with 'Sign Form' and a close button. Below the title bar, it says 'Please enter your login details in order to sign this form:'. There are two input fields: 'Username' and 'Password'. At the bottom right, there are two buttons: 'Sign' (highlighted with a red rectangle) and 'Close'.

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

10 Submission and review process – SSA form

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

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

10.1 Submission

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

The screenshot shows the SSA form interface. On the left, the 'Actions' pane contains several icons: Project, Duplicate Form, Create Subform, Share, Roles, Transfer Form, Completeness Check, Submit (highlighted with a red box), NMA Project, View as PDF, and an envelope icon. The main area displays a 'Project Tree' with 'HREA 31' and 'HREA' as parent nodes, and 'Site Specific Assessment (SSA) VIC - Administrator Use Only' as a child node. Below the tree is a table with columns: Action Required, Status, Review Reference, Date Modified, and NMA. The table contains one row with values: Yes, Not Submitted, N/A, 04/04/2021 17:16, and Project is 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 Specific Assessment (SSA) VIC' and has a 'Show Inactive' checkbox. Below the title, there is a 'Section' dropdown and a 'Questions' section with tabs: Introduction, Information, Project, Location, Ethics Review, and Site Addition.

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



The screenshot shows a 'Submit' dialog box. It has a title bar with 'Submit' and a close button. The main area contains a green message: 'Complete: Your form is complete and ready to submit'. At the bottom right, there are 'Submit' and 'Close' buttons.

- 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

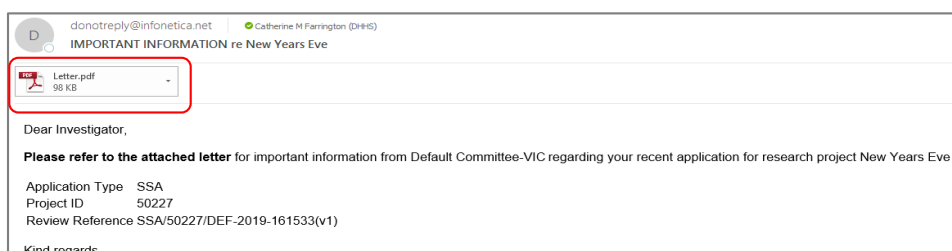
10.2 Responding to a query from the Research Office

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

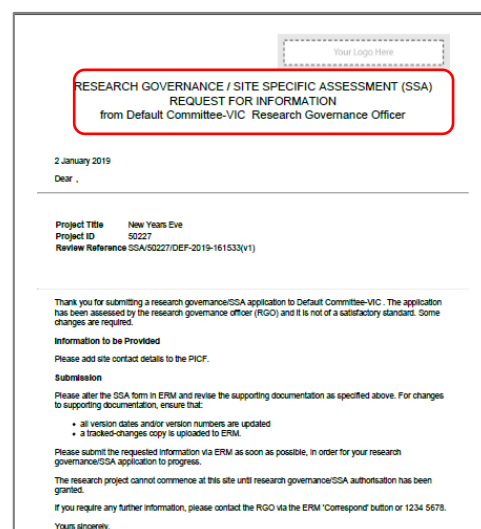
The form Status has changed from 'Submitted' to 'Partial application received' indicating the application is incomplete.

Action Required	Status	Review Reference	Date Modified	NMA
Yes	Partial application received	SSA/74950/VICTEST-2021-257728(v1)	05/04/2021 13:00	Project is for NMA

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



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



To access the query

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

- Select the Message title to open and view the message

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


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

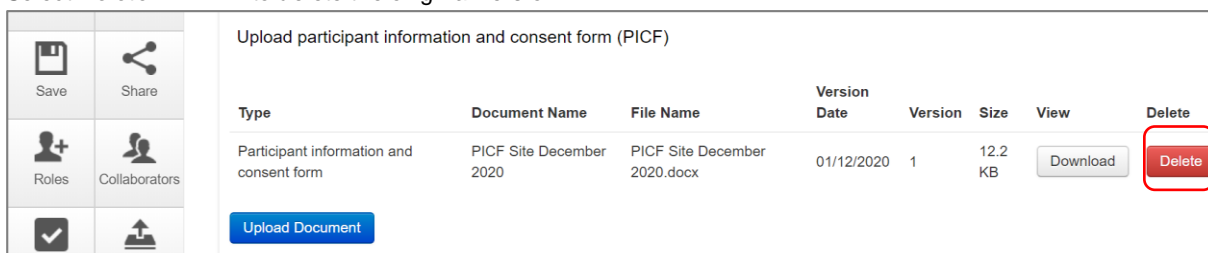
- Select **Reviewers Comments** under the Action pane

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

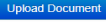
- Select the comment to be directed to the relevant section in the SSA form, e.g. to **Q 4.1 Participant Details**

- 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



Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Participant information and consent form	PICF Site December 2020	PICF Site December 2020.docx	01/12/2020	1	12.2 KB	Download	Delete

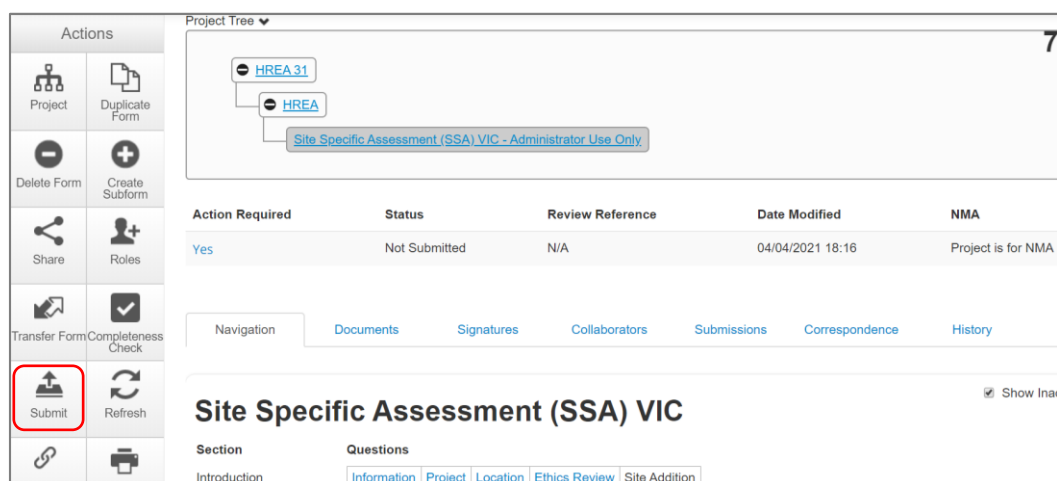
- Select **Upload Document**  to upload the revised (new) version of the document with the correct version number and date
- The SSA form now includes the latest version ready for resubmission



Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Participant information and consent form	PICF Site December 2020	PICF Site December 2020.docx	31/12/2020	2	12.2 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



Actions

- Project
- Duplicate Form
- Delete Form
- Create Subform
- Share
- Roles
- Transfer Form
- Completeness Check
- Submit**
- Refresh

Project Tree

- HREA 31
 - HREA
 - Site Specific Assessment (SSA) VIC - Administrator Use Only

Action Required	Status	Review Reference	Date Modified	NMA
Yes	Not Submitted	N/A	04/04/2021 18:16	Project is for NMA

Navigation

- Documents
- Signatures
- Collaborators
- Submissions
- Correspondence
- History

Site Specific Assessment (SSA) VIC

Section

- Introduction
- 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

10.3 RGO review request

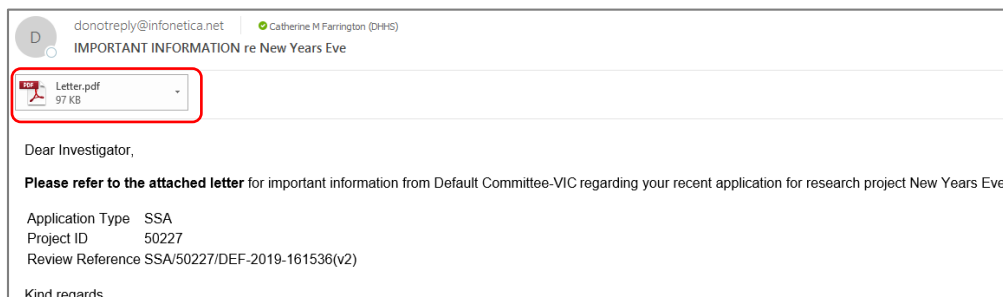
Clarification or requests for further information from the RGO to the applicant must be managed through ERM.

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

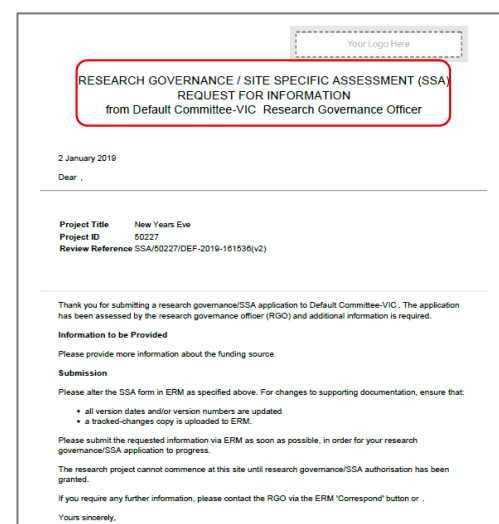
The form Status has changed from 'Submitted' to 'Information requested' -

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

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

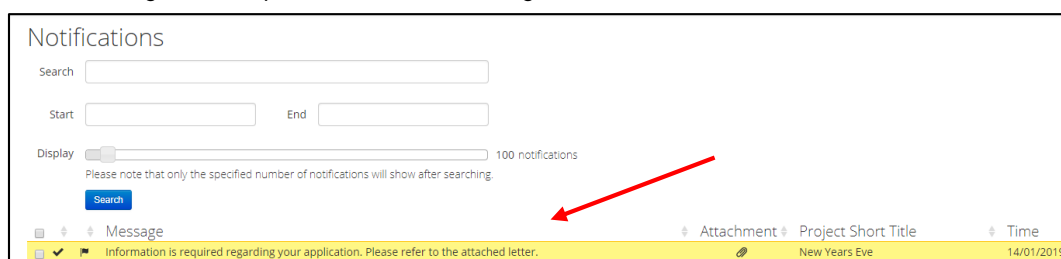


- A 'REQUEST FOR INFORMATION' letter (pdf) from the RGO will include requests for further information to be provided via ERM





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

Message

Project Short Title: **New Years Eve**
Date: **02/01/2019 18:26**

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

View Form Close

Work Area

Home

8 Notifications

Actions

Project

Create Sub-form

Share

Submit

View as PDF

Reviewer Comments

Roles

Refresh

Correspond

Completeness Check

NMA Project

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

Date Added

Submission

Show Previous Comments

Please provide more information about the funding source.
02/01/2019 at 15:24 PM
Latest Submission

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**

Previous

Next

Navigate

View as PDF

Documents

Signatures

Save

Share

Roles

Collaborators

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 2020 charity event

AUS

100000


per year

- 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.

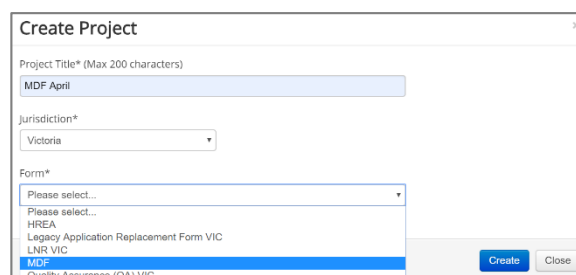
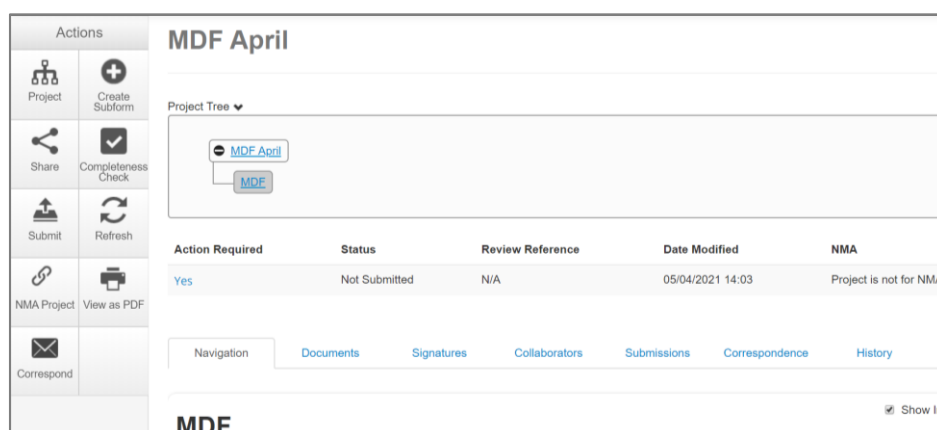
11 Minimal Dataset Form (MDF)

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



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

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

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

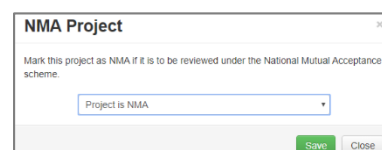



- Complete the questions in the MDF
- Enter the unique ethics reference number indicating where the ethics application was reviewed and approved e.g. HREC/19/CAL/123


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

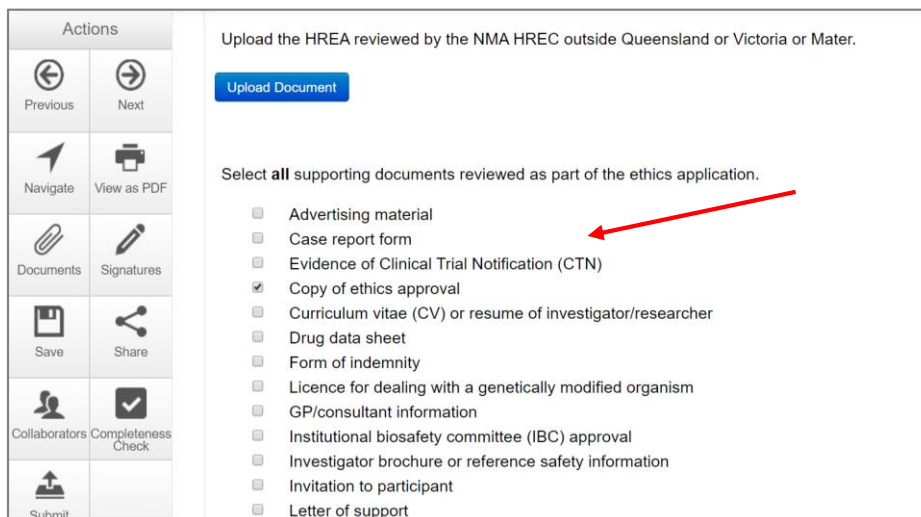
- A **NMA Project** text box is displayed

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



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 or Victoria or Mater.

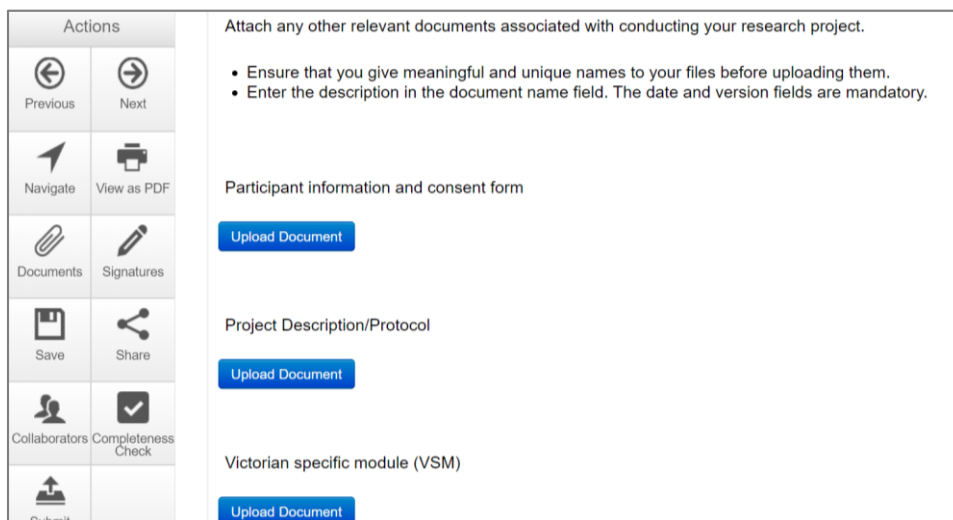
Upload Document

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

- 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.



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

MDF April

Project Tree

- MDF April
 - MDE

Action Required	Status	Review Reference	Date Modified	NMA
Yes	Not Submitted	N/A	05/04/2021 14:03	Project is not for NMA

Navigation: Documents Signatures Collaborators Submissions Correspondence History

MDF

- 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.


12 Legacy Application Replacement Form (LARF)

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

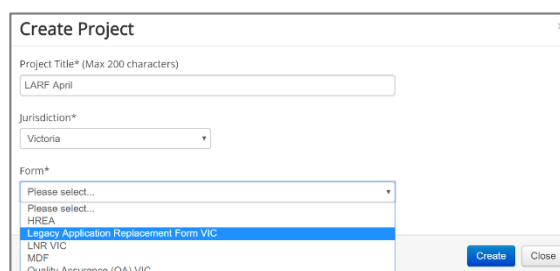
The LARF is not an ethics application form; it is a proxy form that allows sub-forms e.g. post approval forms to be created in ERM. Only **one** LARF is required for the research application.

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

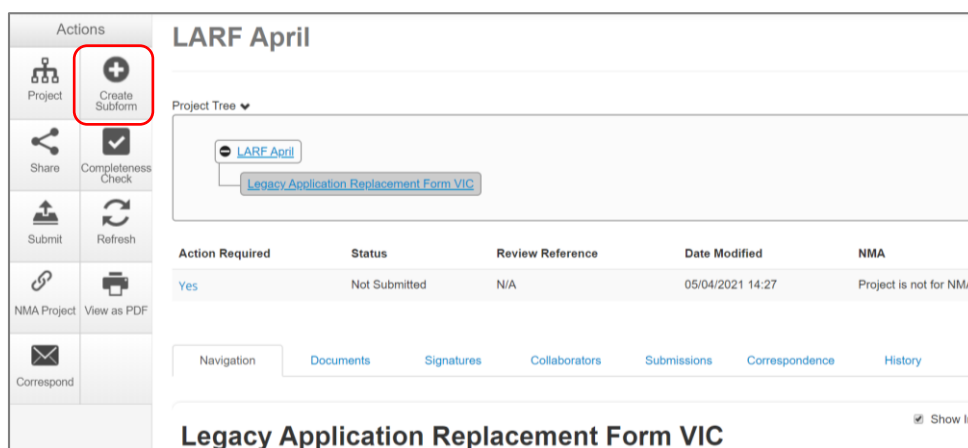
- The CPI / delegate logs onto ERM


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

Select **Create** button

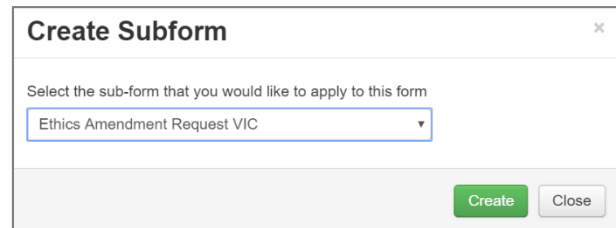


- The LARF will appear under the Project Tree




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

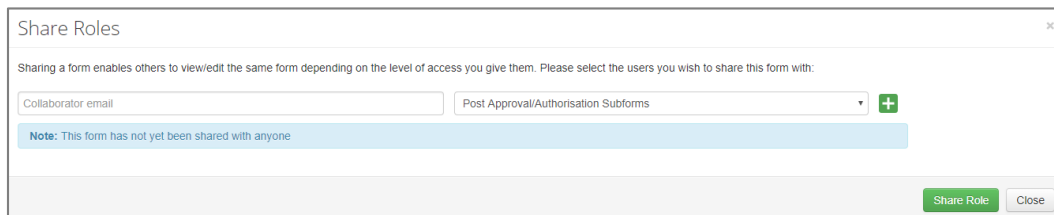
Select **Create**



The 'Create Subform' 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' followed by a dropdown menu showing 'Ethics Amendment Request VIC'. At the bottom right, there are two buttons: 'Create' (green) and 'Close' (grey).

- 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**



The 'Share Roles' dialog box has a title bar with a close button. The main content area contains the text '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:'. Below this is a text input field for 'Collaborator email' and a dropdown menu for 'Post Approval/Authorisation Subforms' with a green plus icon to its right. A blue note box states 'Note: This form has not yet been shared with anyone'. At the bottom right, there are two buttons: 'Share Role' (green) and 'Close' (grey).

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

13 Quality Assurance (QA) Application Form

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

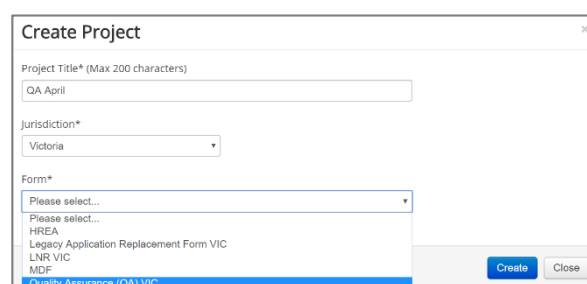
- clinical audit
- quality assurance
- evaluation activities
- a project that involves the potential for no more than negligible risk

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.

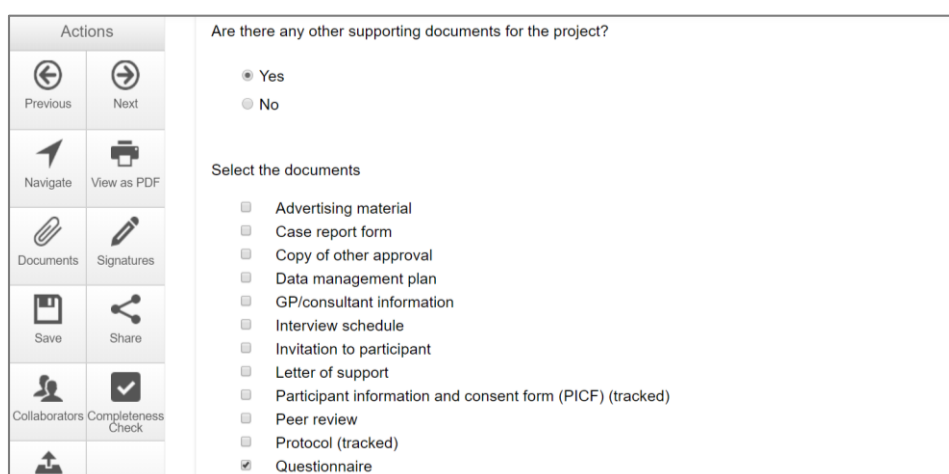
- The applicant logs into ERM



- 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** [Supporting Documents](#) section will enable supporting documents e.g. a Questionnaire to be uploaded into the application

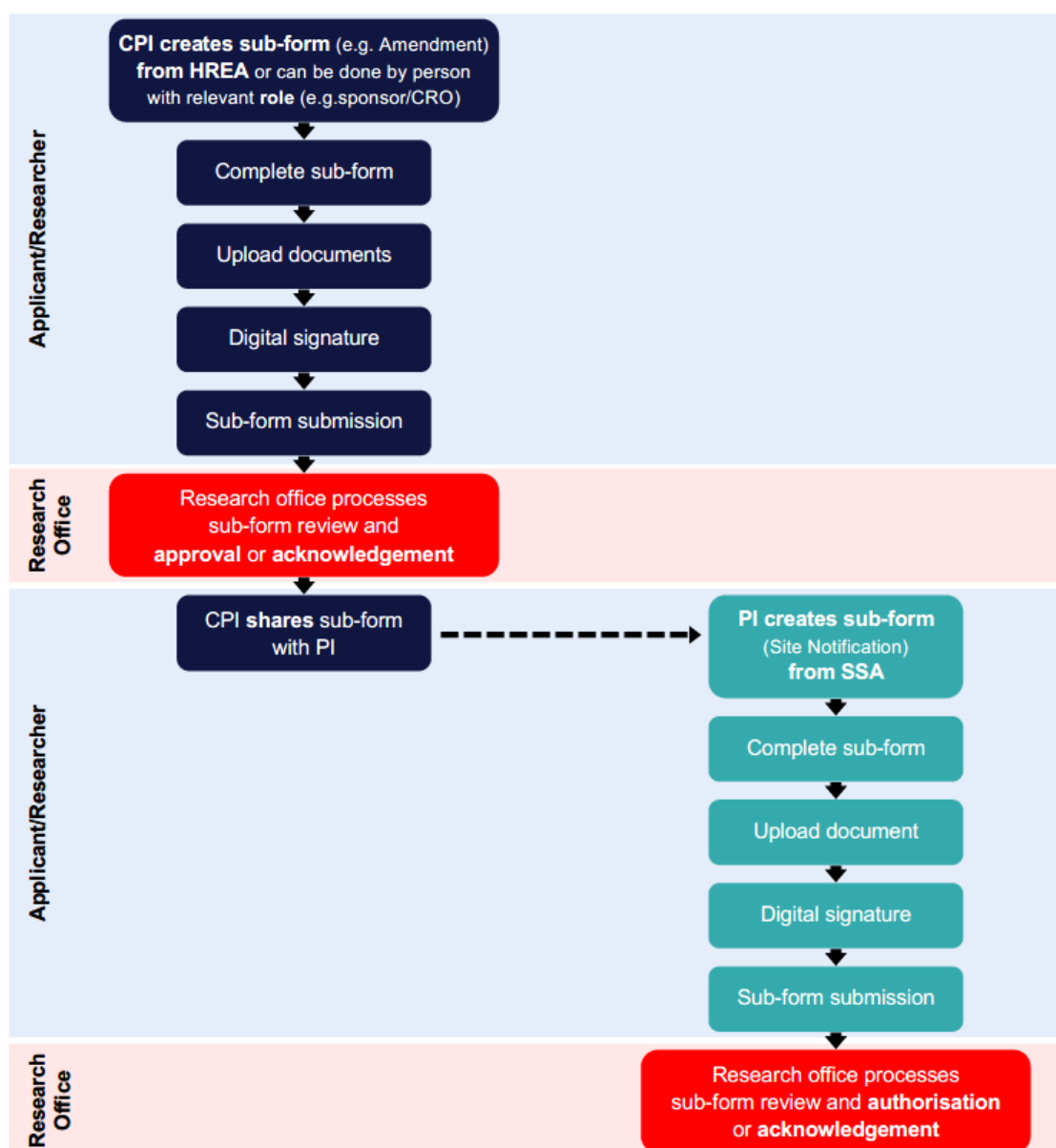


- Select **Upload Document** 
- Select **Submit**  button under the Actions pane to submit the application to the reviewing organisation.

14 Post Approval

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.

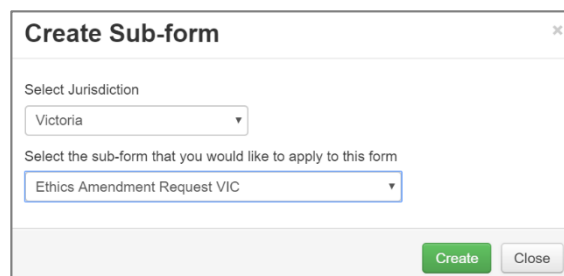
In ERM, Post Approval forms are created as sub-forms from the original ethics application (HREA) to request amendments and provide information / reports relating to the research project as required by the reviewing HREC.

Sub-forms for post approval

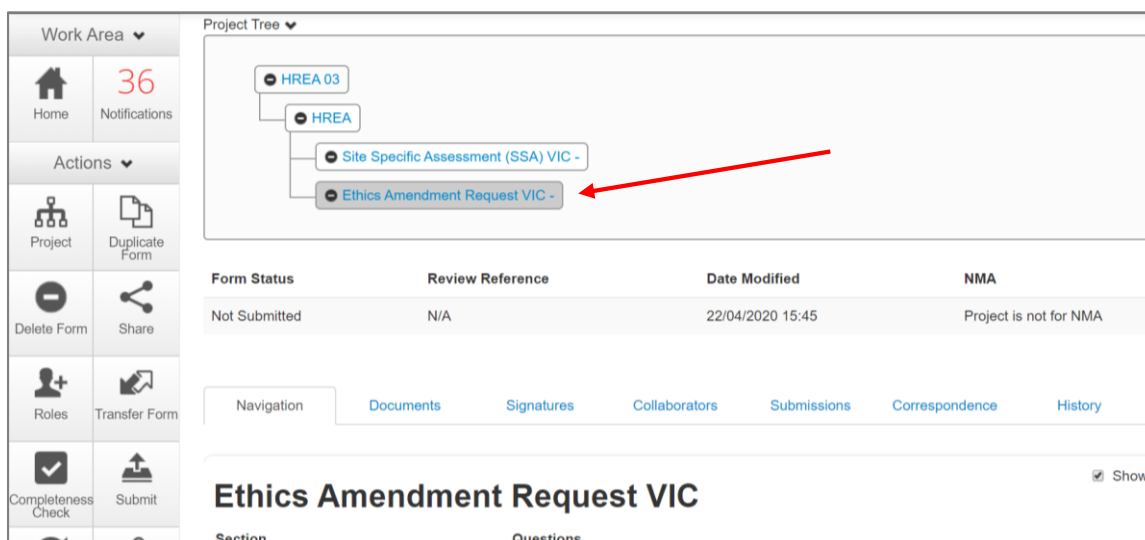
- Ethics Amendment Request
- Project Notification Form
- Project Progress Report
- Project Final Report
- Site Closure Report
- Safety Report
- Annual Safety Report
- Serious Breach Report
- Suspected Breach Report

14.1 Create a sub-form

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



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



14.2 Complete a sub-form – Ethics Amendment request

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

The screenshot shows the 'Actions' sidebar on the left with icons for Previous, Next, Navigate, View as PDF, Documents, Signatures, Save, Share, Roles, Collaborators, Completeness, and Submit. The main form area contains the following sections:

- Participant information and consent forms (PICFs) to be uploaded**
 - ☐ PICF with tracked changes
 - ☒ PICF (clean version)
- Upload amended PICF (clean version)**
 - [Upload Document](#)
- Protocol type(s) to be uploaded**
 - ☐ Protocol with tracked changes
 - ☒ Protocol (clean version)
- 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

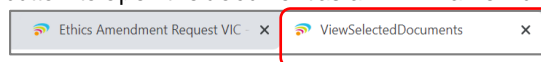
The screenshot shows the document list table in the form. The table has columns: Type, Document Name, File Name, Version Date, Version, Size, View, and Delete. Two documents are listed:

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Participant information and consent form	PICF Master 31 December 2020. Version 2 (clean)	PICF Master 31 December 2020. Version 2 (clean).docx	31/12/2020	2	18.5 KB	Download	Delete
Protocol	December Holidays protocol version 2 (clean)	December Holidays protocol version 2 (clean).docx	01/12/2020	2	14.2 KB	Download	Delete

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

Type	Document Name	File Name	Version Date	Version	Size
<input checked="" type="checkbox"/> Participant information and consent form	PICF Master 31 December 2020. Version 2 (clean)	PICF Master 31 December 2020. Version 2 (clean).docx	31/12/2020	2	18.5 KB
<input checked="" type="checkbox"/> Protocol	December Holidays protocol version 2 (clean)	December Holidays protocol version 2 (clean).docx	01/12/2020	2	14.2 KB
<input checked="" type="checkbox"/> Form	Form	Form.pdf			

- Select the **View Selected** button to open the document as a PDF in a new browser



or select the **Download Selected** button to download as ZIP file

14.3 Allowing others to access post approval forms

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

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

- Select **Roles +** 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**

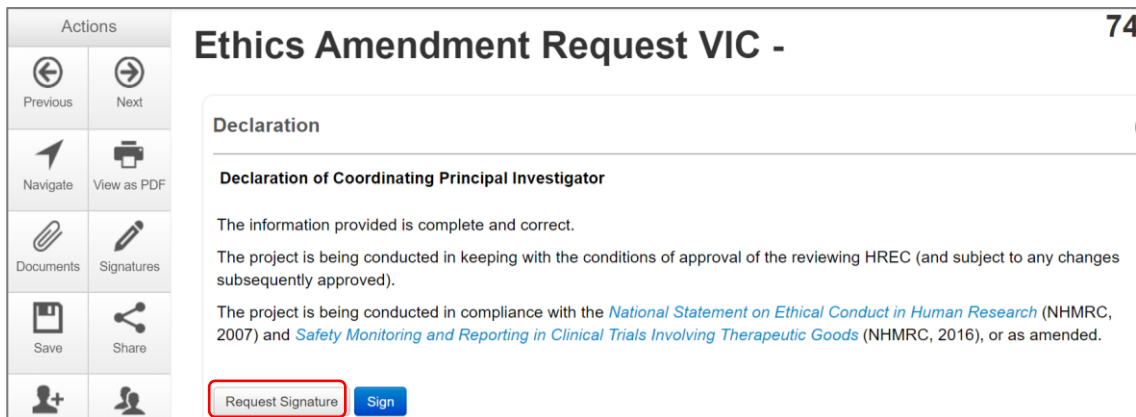
Name	Role	Given on	Remove	Remove All Permissions
Dr Bernice Davies	SSA Sharing	Site Specific Assessment (SSA) VIC - Administrator Use Only	Remove	Remove

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

14.4 Applying signatures

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

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



Ethics Amendment Request VIC - 74

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

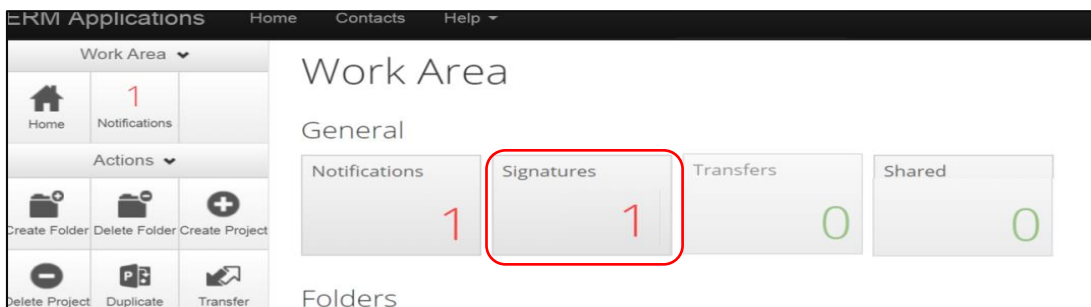
Enter the email address of the person you want to sign this form

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

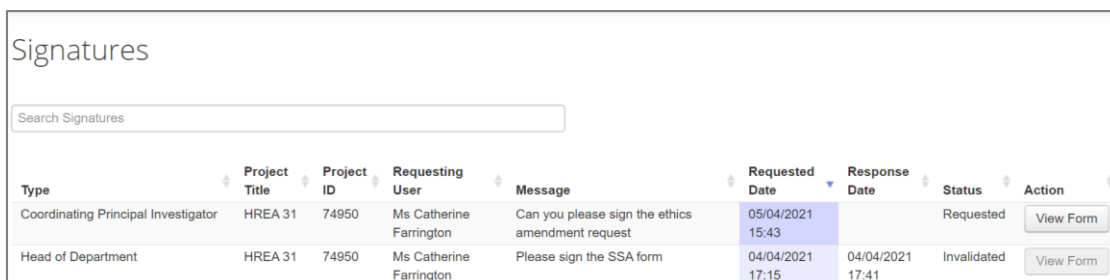
Work Area

General

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

Folders

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




Signatures

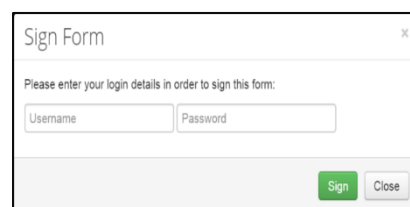
Search Signatures

Type	Project Title	Project ID	Requesting User	Message	Requested Date	Response Date	Status	Action
Coordinating Principal Investigator	HREA 31	74950	Ms Catherine Farrington	Can you please sign the ethics amendment request	05/04/2021 15:43		Requested	View Form
Head of Department	HREA 31	74950	Ms Catherine Farrington	Please sign the SSA form	04/04/2021 17:15	04/04/2021 17:41	Invalidated	View Form

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





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



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

14.5 Submission and review

- Navigate to the Actions pane and select the **Submit**  button
- The system performs a completeness check to highlight any incomplete sections. If complete the form is ready to be submitted
- Select **Submit**  button
- The post approval form will be received by the reviewing organisation's Research Office.
How to respond to queries and requests from the Research Office is described in [Submission and Review Process](#)

15 Post Authorisation

15.1 Create a sub-form

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

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

Sub-forms for post authorisation

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

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**



Create Sub-form

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

Site Governance Amendment Request

Create

Close

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

Work Area

Home

Notifications

36

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

15.2 Complete a sub-form – Site Governance Amendment request

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

- (i)** If the amendment request was submitted to an ethics committee in Victoria, ensure the Ethics Amendment Request form owner (CPI / delegate) has assigned the site PI/ delegate access to the ethics amendment submission and documents. See [Allowing others to access post approval forms](#)
- In the Project Tree, select the Ethics Amendment Request VIC form
 - Working under the **Documents** tab select **View Selected** button to open selected documents e.g. Ethics Amendment Request form, Master PICF as a PDF in a new browser or select **Download Selected** to download the Ethics Amendment Request form and selected documents e.g. Master PICF as a zip file, and save to your local drive
 - Return to the Site Governance Amendment Request form in the Project Tree
 - Upload a copy of the:
 - Ethics Amendment Request to the reviewing ethics committee (PDF copy of the amendment form that was saved from the zip file)
 - Amendment approval from the reviewing ethics committee (PDF copy of amendment approval letter/certificate)
 - Other documents if relevant, e.g. the protocol and Site PICF are uploaded in the following documents page or the [Amended Documents](#) section

The screenshot shows the 'Site Governance Amendment Request - 74' form. On the left is an 'Actions' sidebar with icons for Previous, Next, Navigate, View as PDF, Documents, Signatures, Save, Share, Roles, Collaborators, and a checkmark icon. The main content area is titled 'Documents' and contains the following text: 'Are there any amended documents to be provided to the site RGO?'. Below this are two radio buttons: 'Yes' (selected) and 'No'. Further down, it asks 'Which documents are amended?' and lists several items with checkboxes: Protocol, Participant information sheet and consent form(s) (checked), Investigator brochure, Research agreement, Certificate of insurance, and Other.

- Select **Upload Document** [Upload Document](#) to upload the relevant documents from your local drive
 - Specify the version and date
 - Continue to complete the form
- (ii)** If the amendment request was submitted to an ethics committee outside of Victoria, the **Minimal Dataset Form** (MDF) is used to enable the Site Governance Amendment Request form to be completed
- In the Project Tree, select the site SSA for your organisation
 - Select the **Create Sub-form** action to create a Site Governance Amendment Request form

The screenshot shows the ERM interface. On the left is an 'Actions' panel with icons for Project, Duplicate Form, Delete Form, Share, Roles, Transfer Form, Completeness Check, Submit, Refresh, NMA Project, and a printer icon. The main area displays the 'Project Tree' with a hierarchy: MDF April, MDF, Site Specific Assessment (SSA) VIC - Barwon Health, and Site Governance Amendment Request - (highlighted with a red arrow). Below the tree is a table with the following data:

Action Required	Status	Review Reference	Date Modified	NMA
Yes	Not Submitted	N/A	05/04/2021 16:11	Project is not for NMA

Below the table is a navigation bar with tabs: Navigation, Documents, Signatures, Collaborators, Submissions, Correspondence, and History. The main title 'Site Governance Amendment Request' is at the bottom, with a 'Show In' dropdown on the right.

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

15.3 Allowing others to access post authorisation forms

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

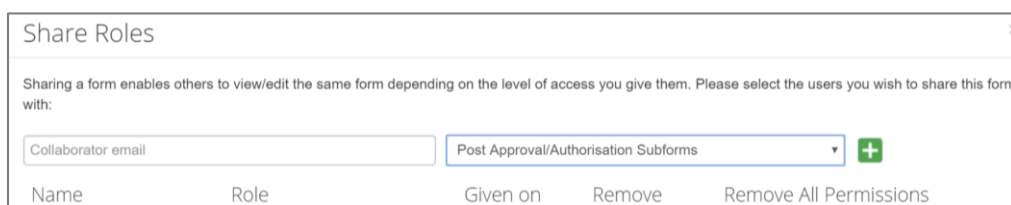
- Highlight the post authorisation form e.g. Site Governance Amendment Request in the Project Tree

This screenshot is similar to the previous one but highlights the 'Roles' button in the 'Actions' panel with a red box. The 'Project Tree' shows a different hierarchy: HREA 03, HREA, Site Specific Assessment (SSA) VIC -, Site Governance Amendment Request - (highlighted with a red arrow), and Ethics Amendment Request VIC -. The table below has the following data:

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

The main title 'Site Governance Amendment Request' is at the bottom, with a 'Section' dropdown on the left and a 'Questions' section below it.

- 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 +

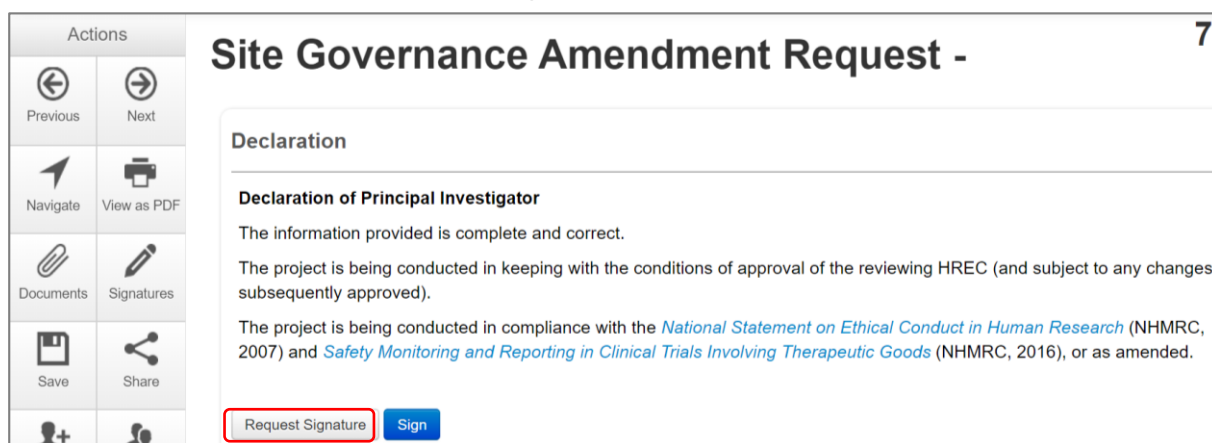
Name	Role	Given on	Remove	Remove All Permissions
------	------	----------	--------	------------------------

- 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

15.4 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	📄 View as PDF
📎 Documents	✍ Signatures
💾 Save	🔗 Share
👤+	👤

Site Governance Amendment Request - 74

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**



Request a signature

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


Email Address:

Can you please sign the Site Governance Amendment Request 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 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

15.5 Submission and review

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

- Select **Submit**  button

- The post authorisation form will be received by the organisation's RGO.

How to respond to queries and requests from the RGO is described in [Submission and review process – SSA form](#)

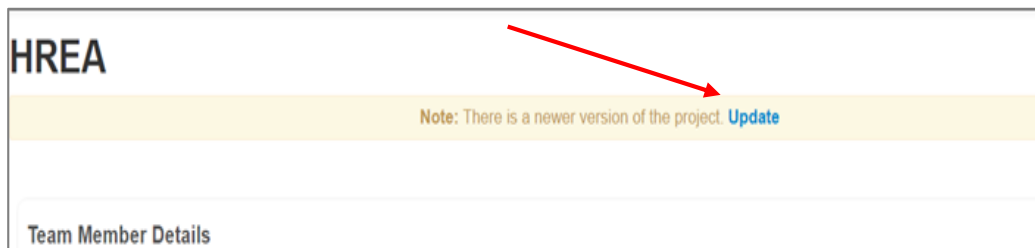
16 Other ERM features

16.1 Project update

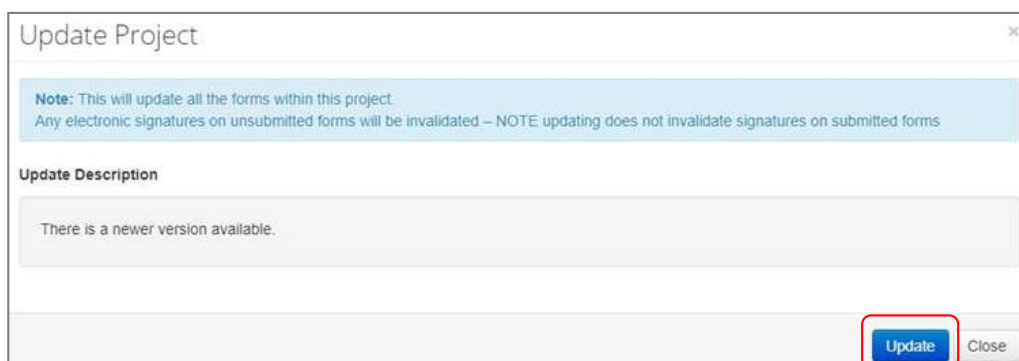
- Only the project owner may update a project
- Approved forms retain the version they were approved in
- Forms and sub-forms that have been submitted or under review will also be updated
- Forms with electronic signatures applied but not submitted should be **updated after submission** otherwise updating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

How to update to a newer version

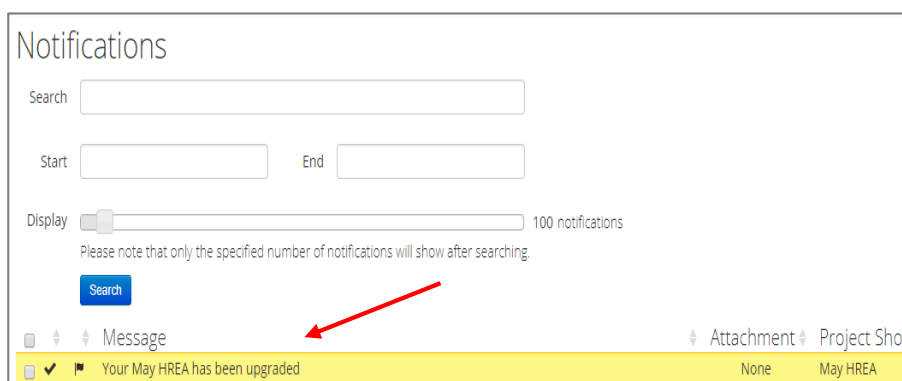
- Print and save a copy of any unsubmitted forms before the project is updated to ensure no data is lost
- The **Update** prompt is viewed by the project owner at the top of the form
- The project owner clicks on the **Update** link



- A pop-up message displays information about electronic signatures on unsubmitted forms which will be invalidated if a project is updated
- 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

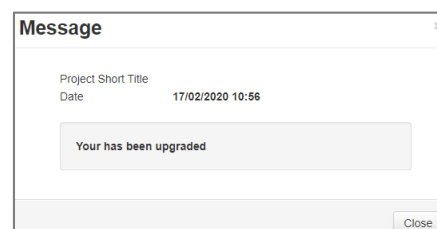
Display 100 notifications

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

☐ ☒ ☐ Message

☒ ☐ 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

16.2 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** button under the **Action** heading

Action Required	Status	Review Reference	Date Modified	NMA
Yes	Not Submitted	N/A	05/04/2021 16:23	Project is for NMA

Type	Signatory Email	Requested Date	Status	Response Date	Action
Principal Investigator	amanda.walpole@dhhs.vic.gov.au	05/04/2021 16:23	Requested		Cancel

- 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

Ethics Amendment Request VIC - 74

Actions

- Previous
- Next
- Navigate
- View as PDF
- Documents
- Signatures
- Unlock**
- Share
- Roles
- Collaborators

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

Signed: This form was signed by Ms Amanda Walpole (amanda.walpole@dhhs.vic.gov.au) on 05/04/2021 3:45 PM

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

16.3 Changing jobs

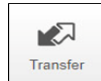
If an applicant changes jobs or moves to another organisation but remains a collaborator on certain projects, the applicant can continue to access their projects in ERM but will need to have their ERM account details updated. Contact [Infonetica Helpdesk](#) to update the account details and email.

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

16.4 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

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

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

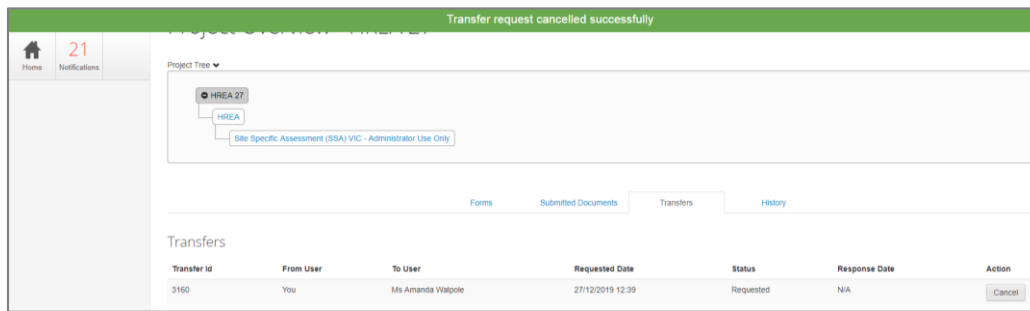
Cancel a transfer request

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

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

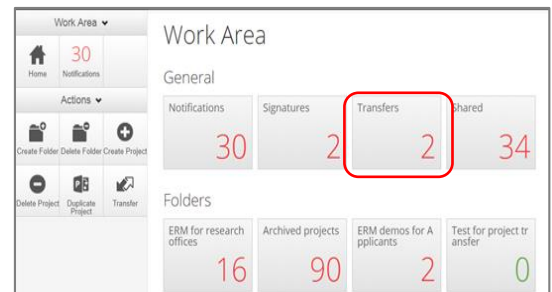
Transfer id	From User	To User	Requested Date	Status	Response Date	Action
3160	You	Ms Amanda Walpole	27/12/2019 12:39	Requested	N/A	Cancel

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

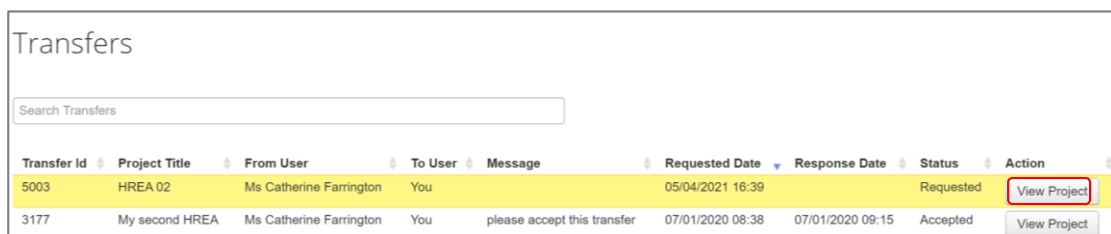


Accept a transfer

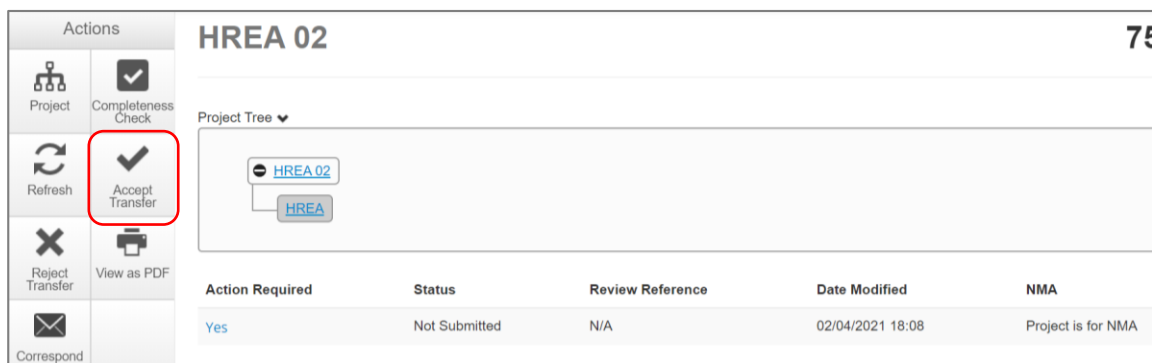
- The new project owner will receive an email notification to log into their ERM account
- In the Work Area, select the **Transfers** tile



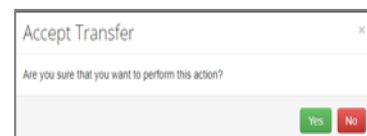
- A list of all transfers will be displayed. In the relevant message line, select **View Project** [View Project](#) to open the project as read only



- 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

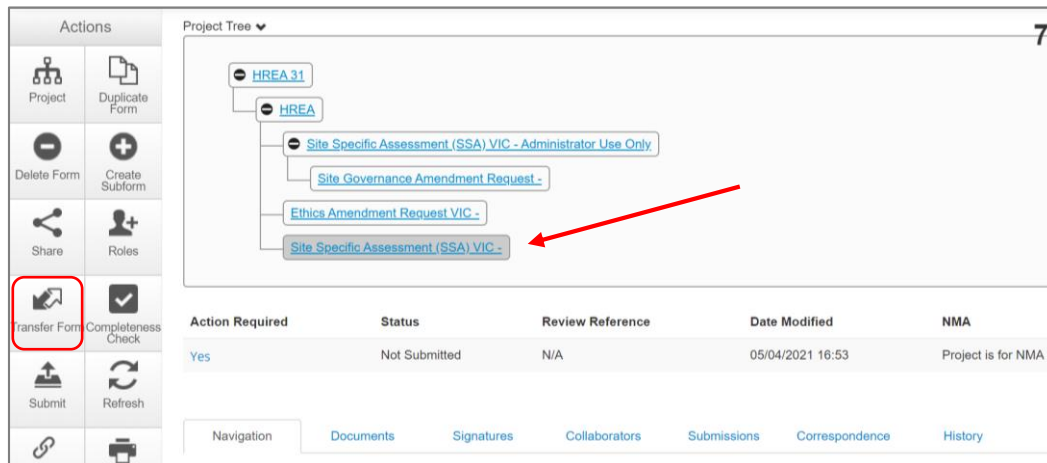





- Ownership of the project is transferred including all sub-forms e.g. SSAs and associated documents. The new owner can access the project from their Work Area.
- The new owner can assign other research members pre-defined levels of access to the project and forms


16.5 Transfer a sub-form

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

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



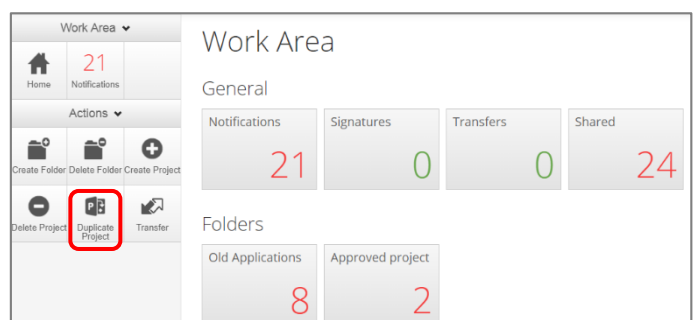
- Select **Transfer Form**  button under the Actions pane
- A **Transfer Form To Another User** text box will be displayed
- Select the **Transfer Sub Forms** checkbox to include other subforms that are associated with the form e.g. a Site Progress Report
- Select **Transfer**
- A **Transfer successful**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

Roles +  function

16.6 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**

Project Title	Project ID	Owner	Date Created	Date Modified
HREA 09	60952	Ms Catherine Farrington	09/01/2020 11:08	09/01/2020 11:09
HREA 08	60889	Ms Catherine Farrington	07/01/2020 12:40	07/01/2020 12:44

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


16.7 Duplicate a form

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

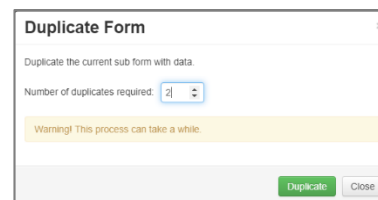
The duplicate function will copy all answers in the form but **not** copy documents e.g. site PICFs, signatures and permissions assigned to the original subform. As the SSA site/organisation name will also be duplicated it is important to amend these details for each duplicated SSA.

- In the Project Tree highlight the subform to be duplicated

Action Required	Status	Review Reference	Date Modified	NMA
Yes	Not Submitted	N/A	05/04/2021 16:53	Project is for NMA

- 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



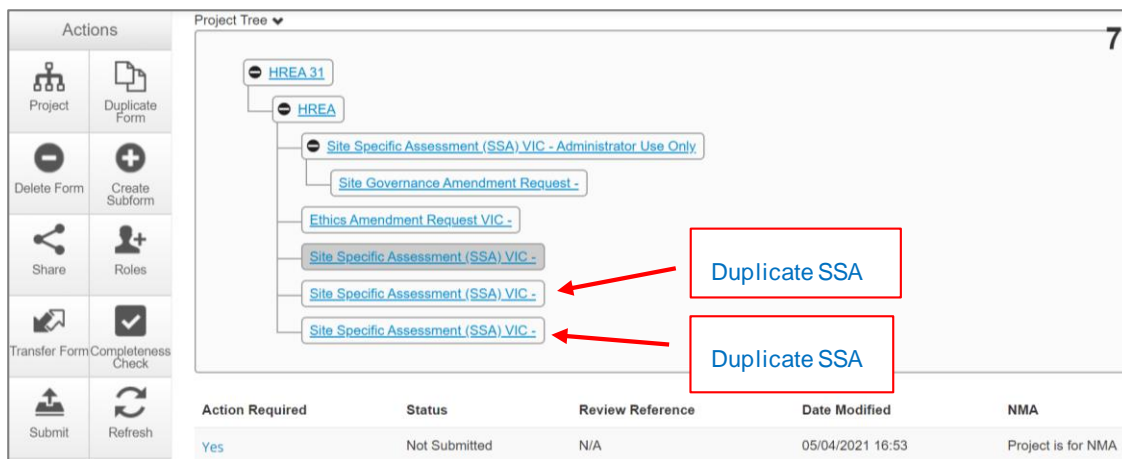
Duplicate Form

Duplicate the current sub form with data.

Number of duplicates required:

Warning! This process can take a while.

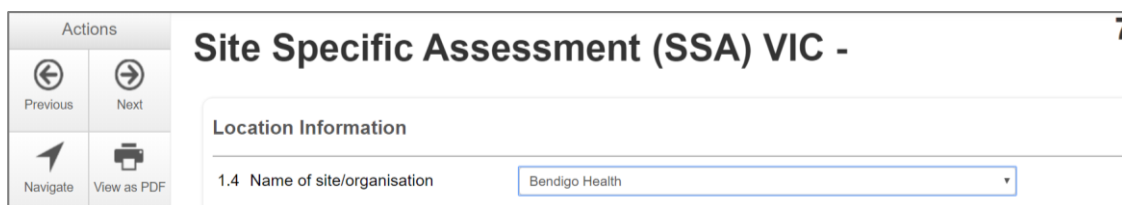
Duplicate **Close**



The screenshot shows the 'Actions' pane on the left with the 'Duplicate Form' button highlighted. The 'Project Tree' on the right shows a hierarchy starting with 'HREA 31' and 'HREA'. Under 'HREA', there are several subforms, including 'Site Specific Assessment (SSA) VIC - Administrator Use Only', 'Site Governance Amendment Request -', 'Ethics Amendment Request VIC -', and three instances of 'Site Specific Assessment (SSA) VIC -'. Two red arrows point to the last two instances of 'Site Specific Assessment (SSA) VIC -', with labels 'Duplicate SSA' and 'Duplicate SSA' respectively. Below the Project Tree is a table with the following data:

Action Required	Status	Review Reference	Date Modified	NMA
Yes	Not Submitted	N/A	05/04/2021 16:53	Project is for NMA

- Select the duplicate SSA in the Project Tree 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

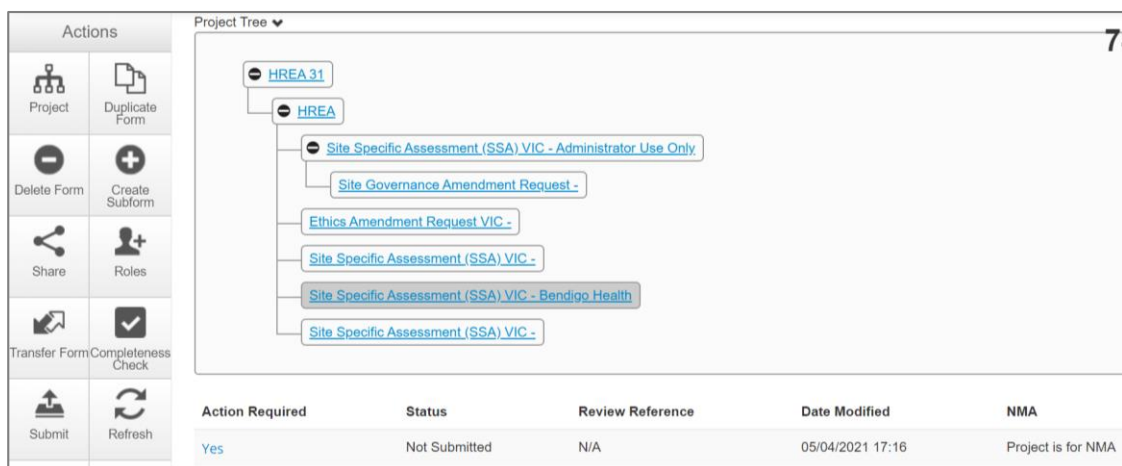


Site Specific Assessment (SSA) VIC -

Location Information

1.4 Name of site/organisation

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



The screenshot shows the 'Actions' pane on the left. The 'Project Tree' on the right shows the same hierarchy as before, but the last instance of 'Site Specific Assessment (SSA) VIC -' is now labeled 'Site Specific Assessment (SSA) VIC - Bendigo Health'. Below the Project Tree is a table with the following data:

Action Required	Status	Review Reference	Date Modified	NMA
Yes	Not Submitted	N/A	05/04/2021 17:16	Project is for NMA

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

16.8 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

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

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

- 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.

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

16.9 Edit access permissions using Roles and Share

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



Share  has been used to assign access.

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

Actions	Action Required	Status	Review Reference	Date Modified	NMA
Project	Yes	Not Submitted	N/A	03/02/2021 12:56	Project is not for NMA
Share	Navigation Documents Signatures Collaborators Submissions Correspondence History				
Completeness Check	Collaborators				
Submit	Name	Access	Edit Permissions		
NMA Project	Prof Ann Researcher	Read	Edit Permissions		
View as PDF	Prof M. Happy	Project Owner and Form Owner	Edit Permissions		
	Ms Victoria Trainer	Read, Create all sub forms, Receive notifications	Edit Permissions		

Share action used

Roles + action used

Roles +

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

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

Share Role Close

- 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**

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-only)

Note: This form has not yet been shared with anyone

HREA Share (read-only)

HREA Share (read, write)

HREA Share (read, create subforms)

HREA Share (read, write, submit)

Share Role Close

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

Share

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

Edit Permissions - Prof Ann Researcher

Read

Write

Submit

Share

Create all sub forms

Receive notifications

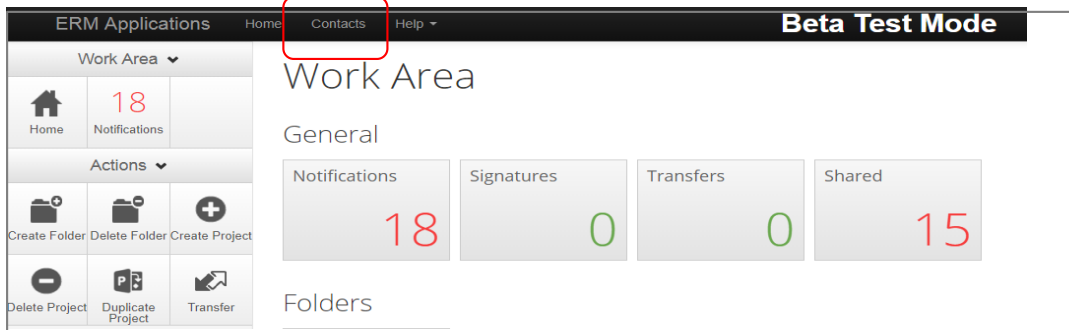
Save Close

16.10 Contacts

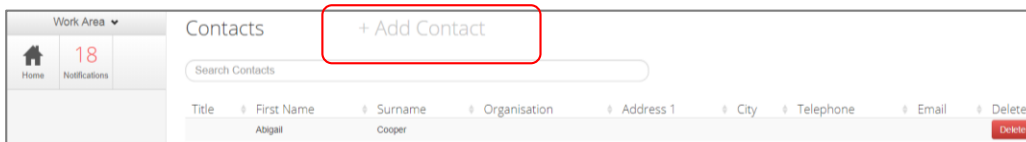
The **Contacts** area can be used to save and edit contact details for project team members. Details saved in **Contacts** can be used to populate all ERM forms.

Add a Contact

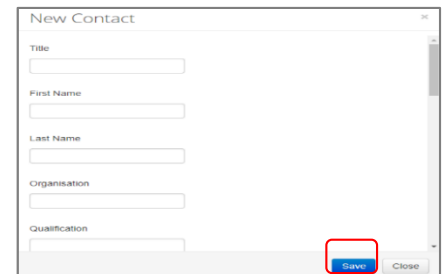
- Select **Contacts** above Work Area



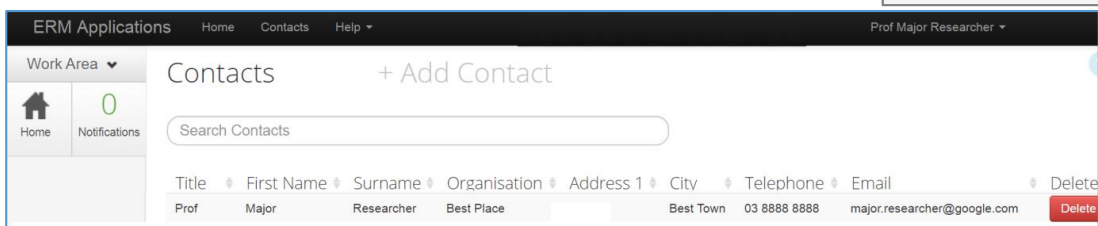
- Select **+ Add Contact**



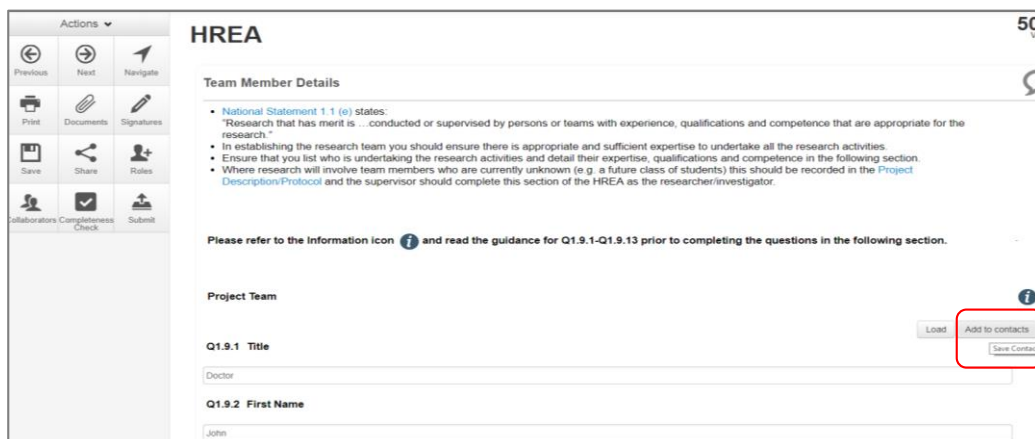
- A **New Contact** textbox will be displayed to enter the new details
- Select **Save** button



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




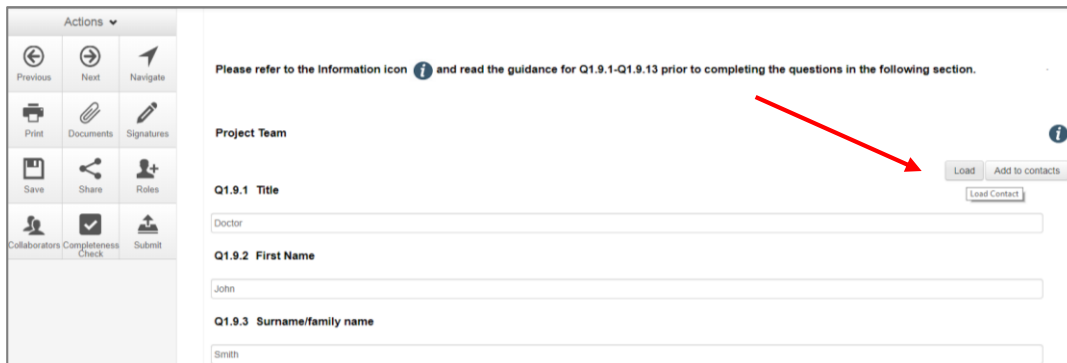
- Contacts can also be added when completing a form
- Select **Add to contacts** button



- 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




Actions

Previous Next Navigate

Print Documents Signatures

Save Share Roles

Collaborators Completeness Check Submit

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

Project Team

Q1.9.1 Title

Doctor

Q1.9.2 First Name

John

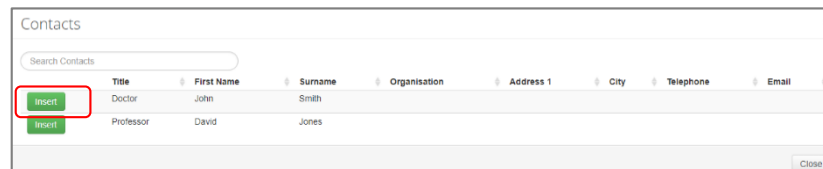
Q1.9.3 Surname/family name

Smith

Load Add to contacts

Load Contact

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



Contacts

Search Contacts

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

insert insert

Close

- Contact details will be successfully loaded into the form



Actions

Previous Next Navigate

Print Documents Signatures

Save Share Roles

Collaborators Completeness Check Submit

Add Another Remove

Project Team

Q1.9.1 Title

Professor

Q1.9.2 First Name

David

Q1.9.3 Surname/family name

Jones

Q1.9.4 Email Address


Load Add to contacts

16.11 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.

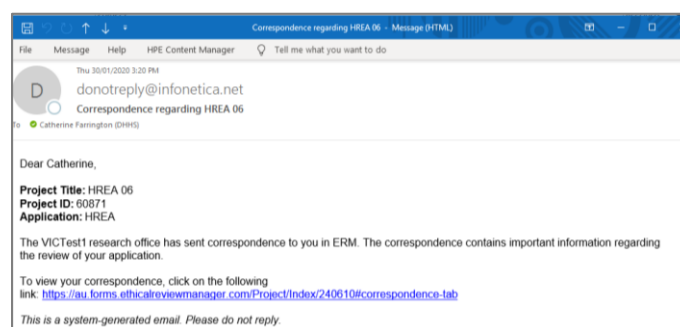
- A **Correspond** text box will display where the message will be delivered to

- 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	HREC60871/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 is...

- 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

16.12 Archived documents

When an application requires resubmission with new document versions, deleted Delete 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

Project Overview - HREA 08

Project Tree ▾

- HREA 08
- HREA
- Site Specific Assessment (SSA) VIC - Administrator Use Only
- Victorian Specific Module (VSM)

Forms Submitted Documents Transfers History

Submitted Documents

Search forms 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	✓
HREA	HREA	17/01/2020	Submitted	Protocol	December Holidays protocol version 2	2	11.6 KB	Download	□
HREA	HREA	17/01/2020	Archived	PARTICIPANT INFORMATION AND CONSENT FORM (TRACKED)	PICF Master December 2019	1	11.9 KB	Download	✓
HREA	HREA	17/01/2020	Submitted	PARTICIPANT INFORMATION AND CONSENT FORM (TRACKED)	PICF Master December 2019, Version 2	2	12.0 KB	Download	□

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

Project Overview - HREA 08

Project Tree

- HREA 08
 - HREA
 - Site Specific Assessment (SSA) VIC - Administrator Use Only
 - Victorian Specific Module (VSM)

Forms Submitted Documents Transfers History

Submitted Documents

Search forms documents:

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	
HREA	HREA	17/01/2020	Submitted	PARTICIPANT INFORMATION AND CONSENT FORM (TRACKED)	PICF Master December 2019, Version 2	2	12.6 KB	Download	
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

16.13 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

Work Area

Home Notifications

19

Actions

Create Folder Delete Folder Create Project

19 0 0 15

General

Notifications Signatures Transfers Shared

Folders

Old Applications

8

- A **Create Folder** text box will be displayed
Enter Folder title e.g. Approved project
- Select **Create**
- A new Folder tile (Approved project) is displayed in the Work Area under **Folders**

Create Folder

Folder Title (maximum 40 characters):*

Approved projects

Create Close

Work Area

Home Notifications

19

Actions

Create Folder Delete Folder Create Project

19 0 0 15

General

Notifications Signatures Transfers Shared

Folders

Old Applications Approved project

8 0

Projects

Search Projects

Project Title	Project ID	Owner	Date Created	Date Modified	Transfer Status
QA January	51369	Ms Catherine Farrington	06/02/2019 18:05	06/02/2019 18:05	
LARF January	51368	Ms Catherine Farrington	06/02/2019 17:00	06/02/2019 17:31	

- 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

The screenshot shows the 'Work Area' dashboard. On the left is a sidebar with navigation icons: Home (19 notifications), Actions (Create Folder, Delete Folder, Create Project, Delete Project, Duplicate Project, Transfer), and a 'Rename Folder' icon. The main area has a 'General' section with four tiles: Notifications (19), Signatures (0), Transfers (0), and Shared (15). Below this is a 'Folders' section with two tiles: 'Old Applications' (8) and 'Approved project' (1), which is highlighted with a red box. At the bottom is a 'Projects' section with a search bar and a table of projects.

Project Title	Project ID	Owner	Date Created	Date Modified	Transfer Status
QA January	51369	Ms Catherine Farrington	06/02/2019 18:05	06/02/2019 18:05	
LARF January	51368	Ms Catherine Farrington	06/02/2019 17:00	06/02/2019 17:31	

- Select a project to display the application and associated forms

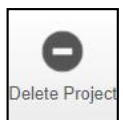
The screenshot shows the 'Approved project Projects' view. It features a search bar and a table of projects. A red arrow points to the 'QA January' project in the table. Below the table, it says 'Showing 1 to 2 of 2 entries'. At the bottom, there is a copyright notice: '© Infonetica Ltd 2019 Version 2.0.5.1' and a link to 'Terms and Conditions | Privacy Policy'.

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

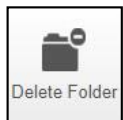
Other Folder Actions



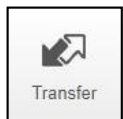
Create a new project



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



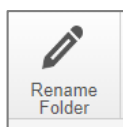
Delete a folder (only empty folders can be deleted)



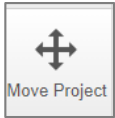
Permanent transfer of a project to another user e.g. Sponsor creates the HREA and transfers it permanently to the CPI



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**

16.14 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 **View as PDF**  button under the Actions pane to generate a pdf of the form. Save the document to your local drive

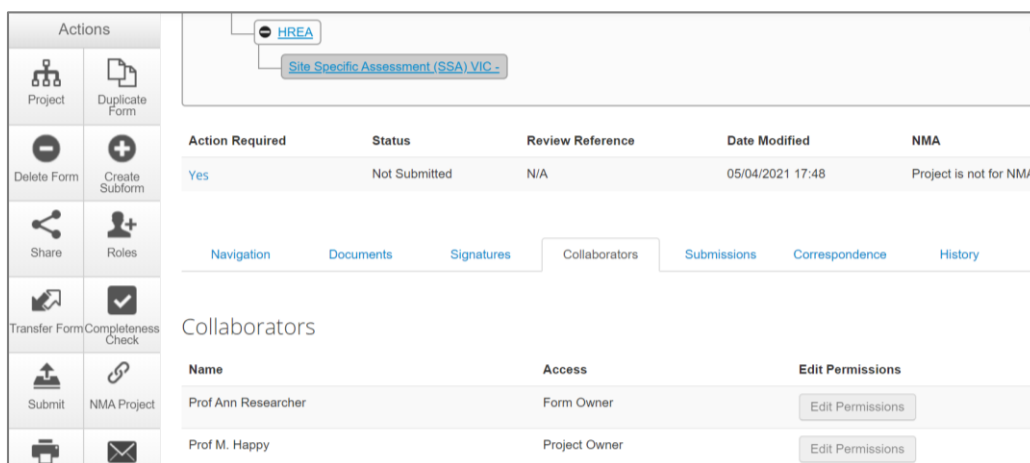
Do not select Submit.

16.15 How to identify the Project Owner

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

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

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



Action Required	Status	Review Reference	Date Modified	NMA
Yes	Not Submitted	N/A	05/04/2021 17:48	Project is not for NMA

Name	Access	Edit Permissions
Prof Ann Researcher	Form Owner	Edit Permissions
Prof M. Happy	Project Owner	Edit Permissions

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

17 Help

To access ERM

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

For assistance

Infonetica Helpdesk:

02 9037 8404

helpdesk@infonetica.net

Coordinating Office for Clinical Trial Research:

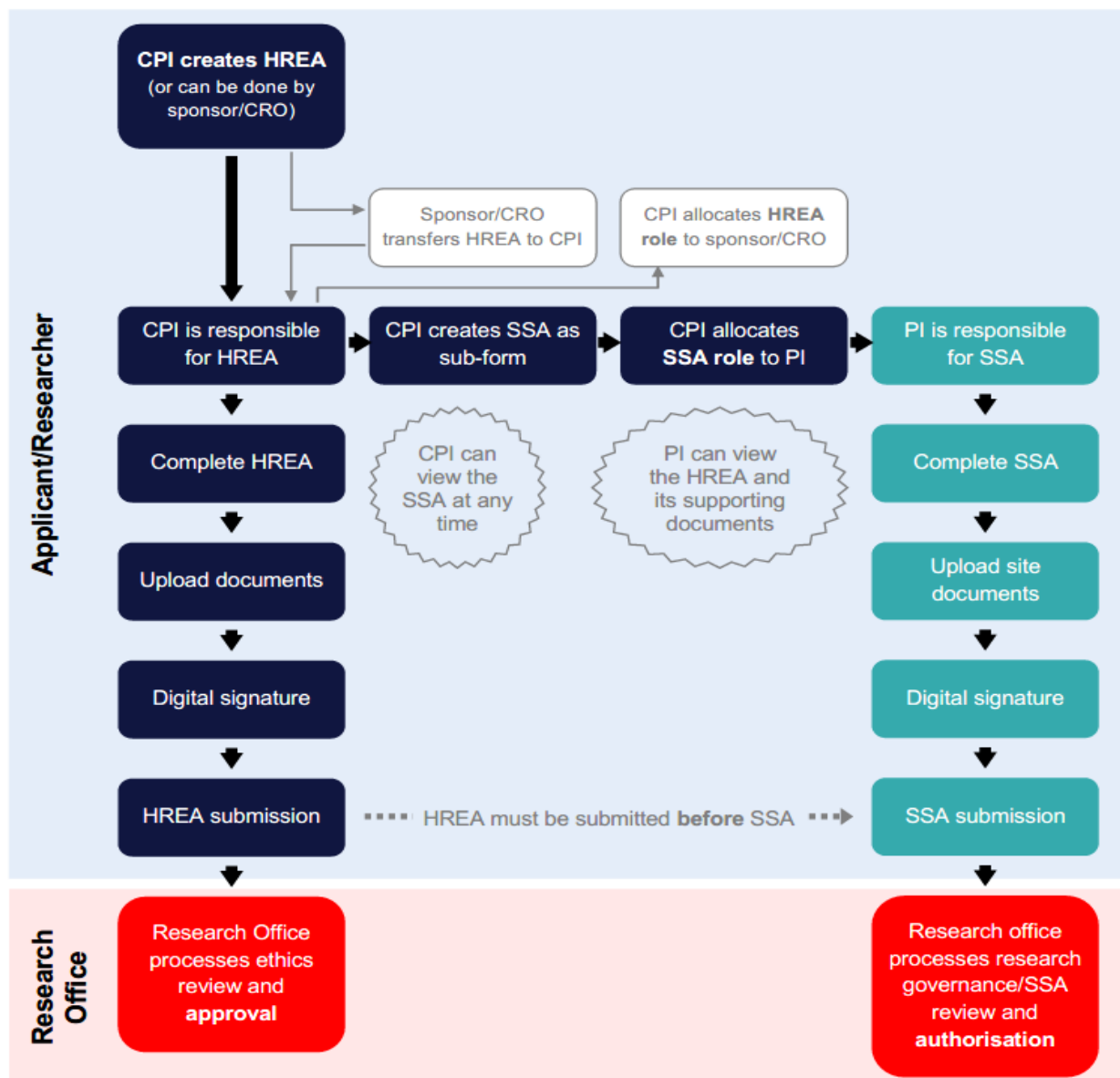
0408 274 054

multisite.ethics@ecodev.vic.gov.au

Appendix 1: Application process flow

Ethical Review Manager (ERM)

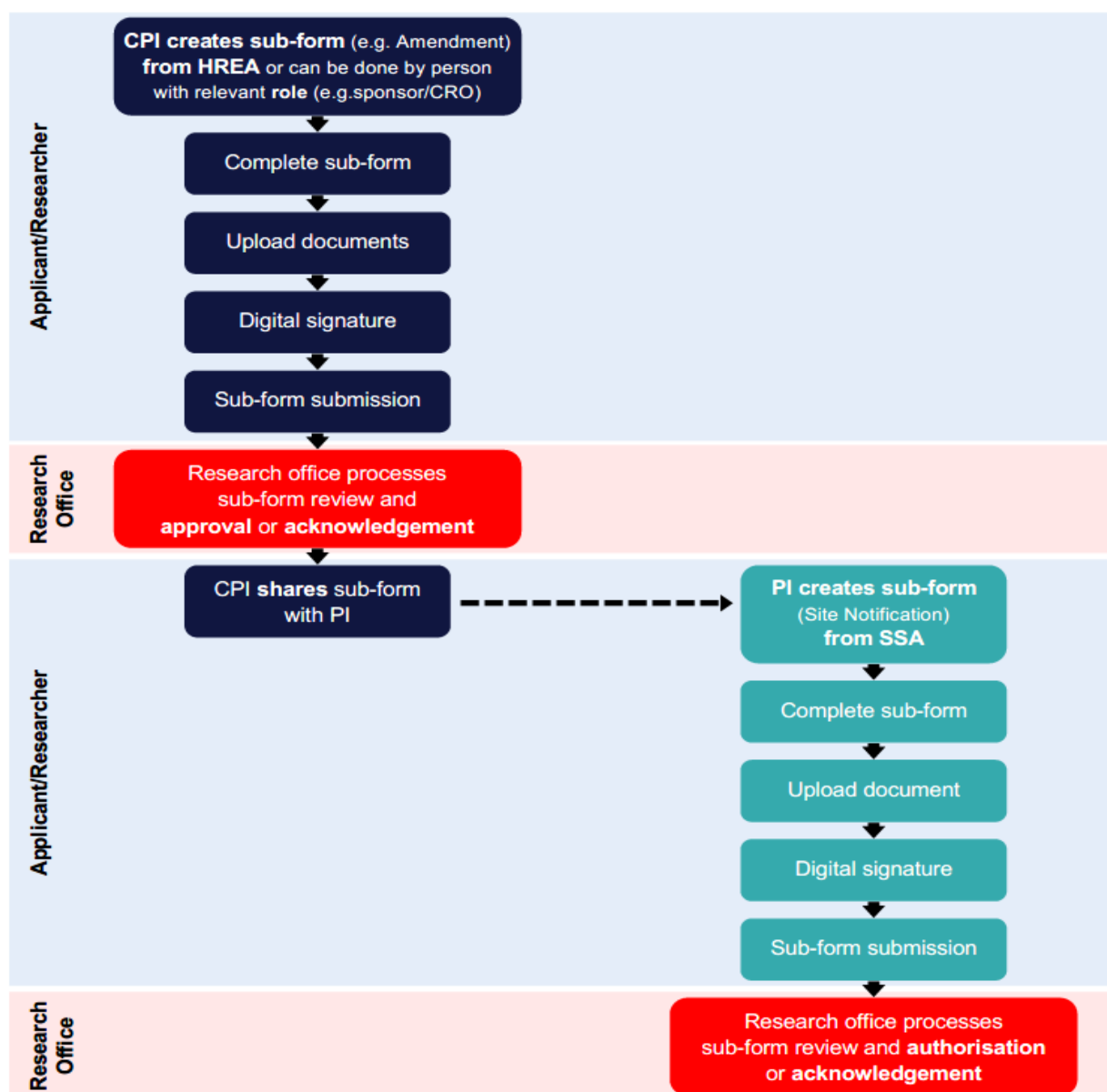
Ethics and Research Governance/SSA



Appendix 2: Post approval & post authorisation chart

Ethical Review Manager (ERM)

Post-approval and Post-authorisation



Authorised by the Coordinating Office for Clinical Trial Research, Medical Research
Department of Jobs, Precincts and Regions
121 Exhibition Street Melbourne Victoria 3000
Telephone 0408 274 054

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