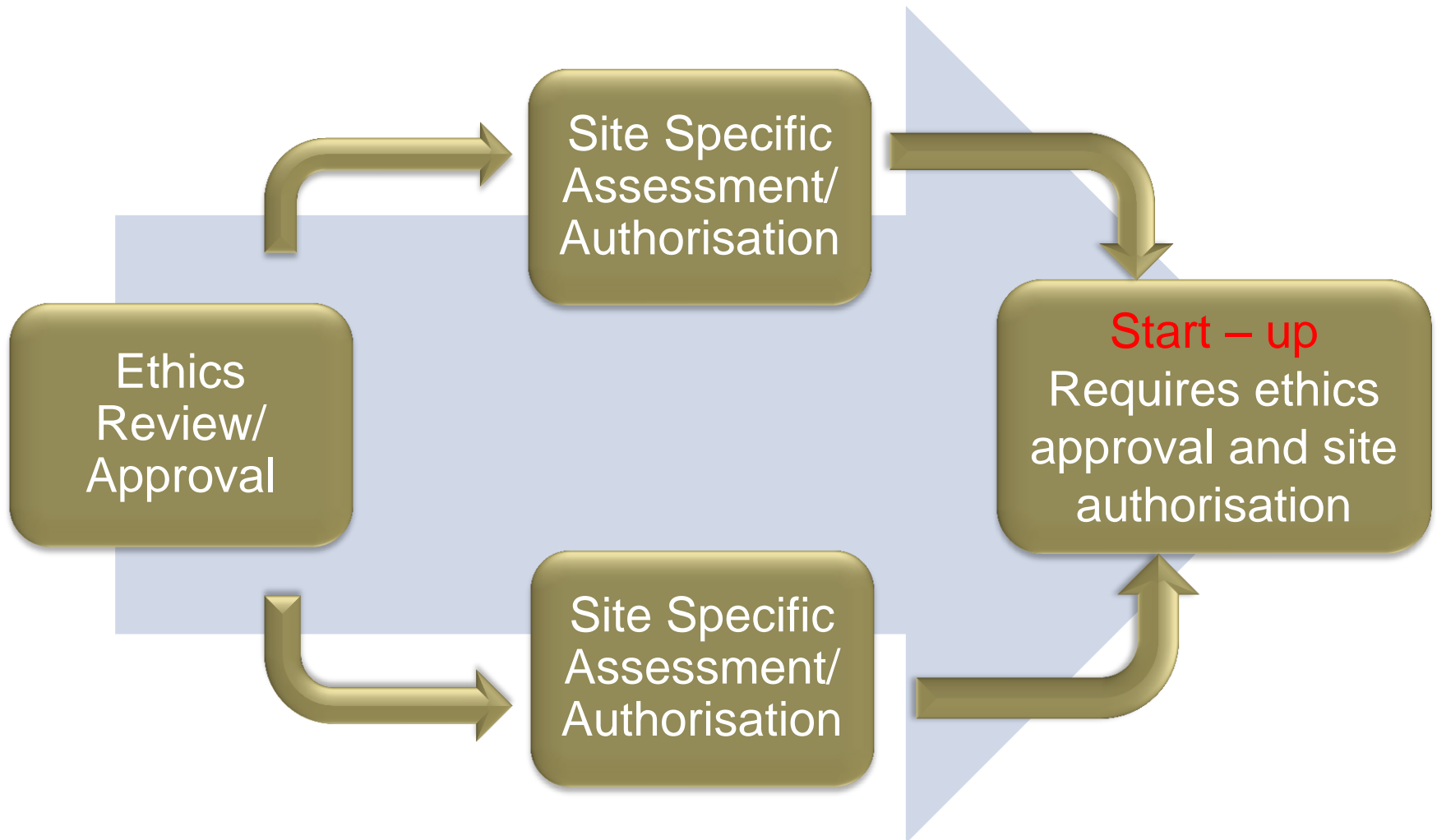


ERM for Applicants & Sponsors

ERM replaced Online Forms in Victoria and Queensland on 16 July 2018

This presentation describes the Victorian processes

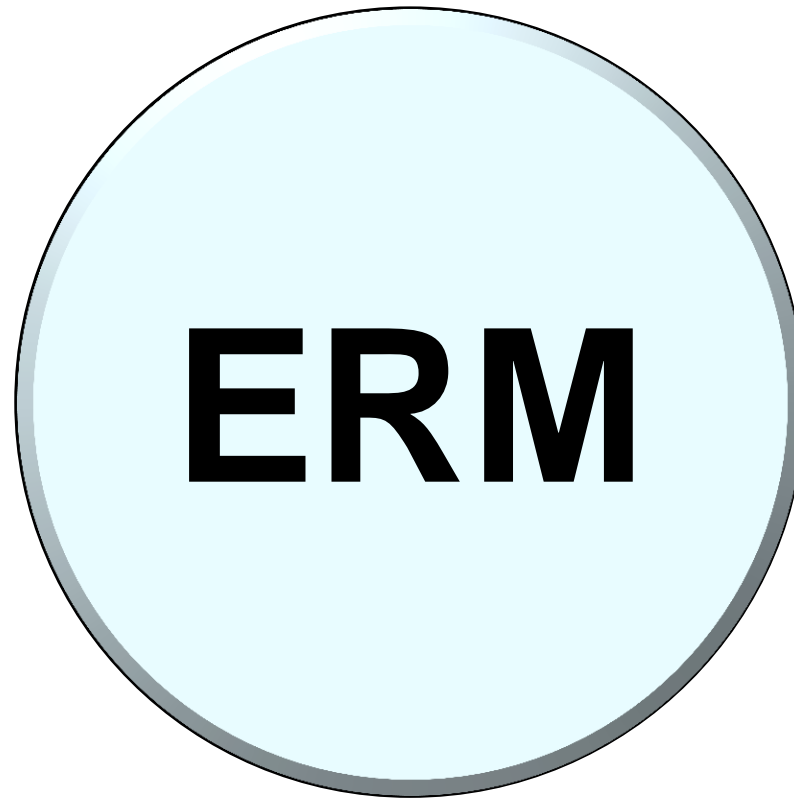
Recap of single ethical review for multi-site research



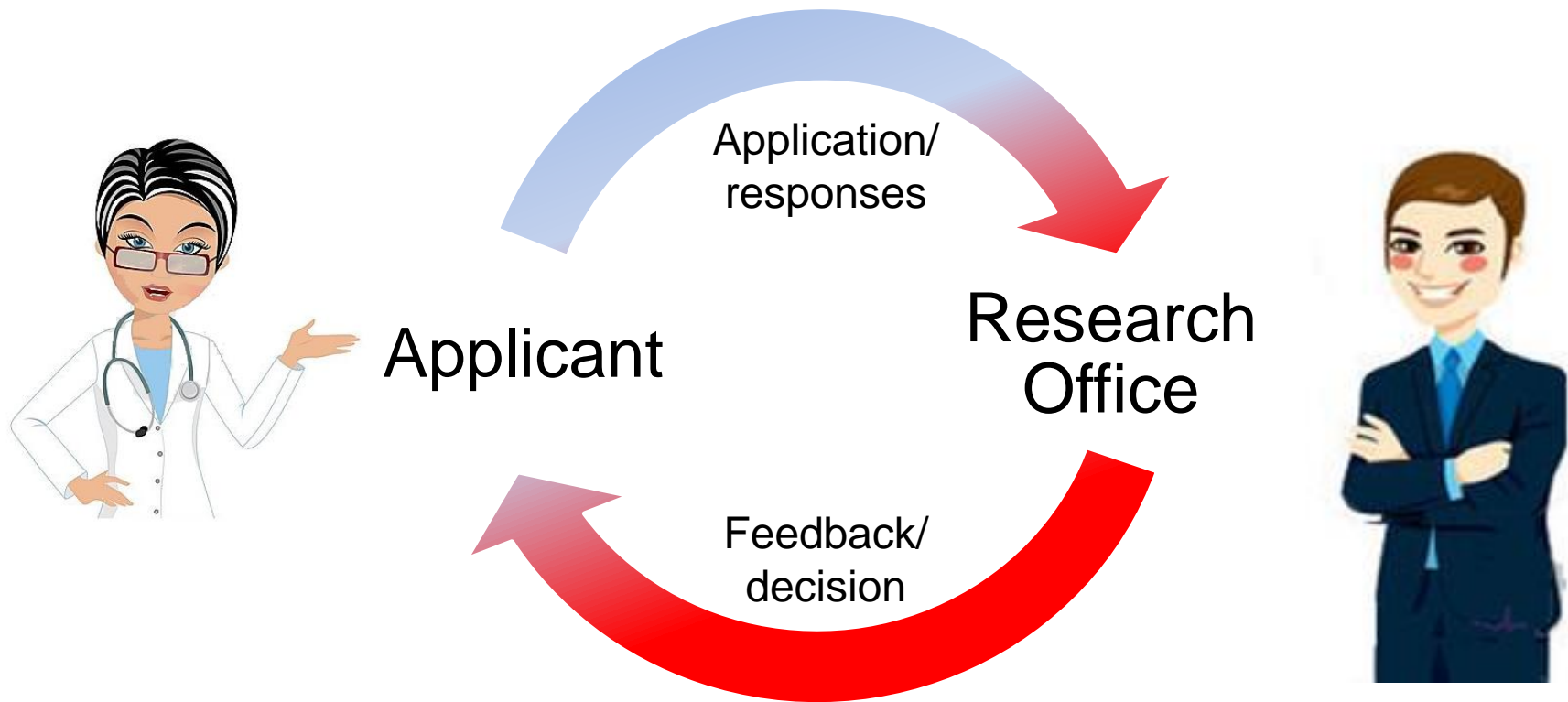
This talk covers

- **General information about ERM**
- **Features of ERM**
- **Overview of**
 - initial ethics and governance applications
 - post approval and post authorisation processes
 - Victoria Specific Module (VSM)
 - Minimal Data Set (MDF)
- **ERM live**

ERM information flow

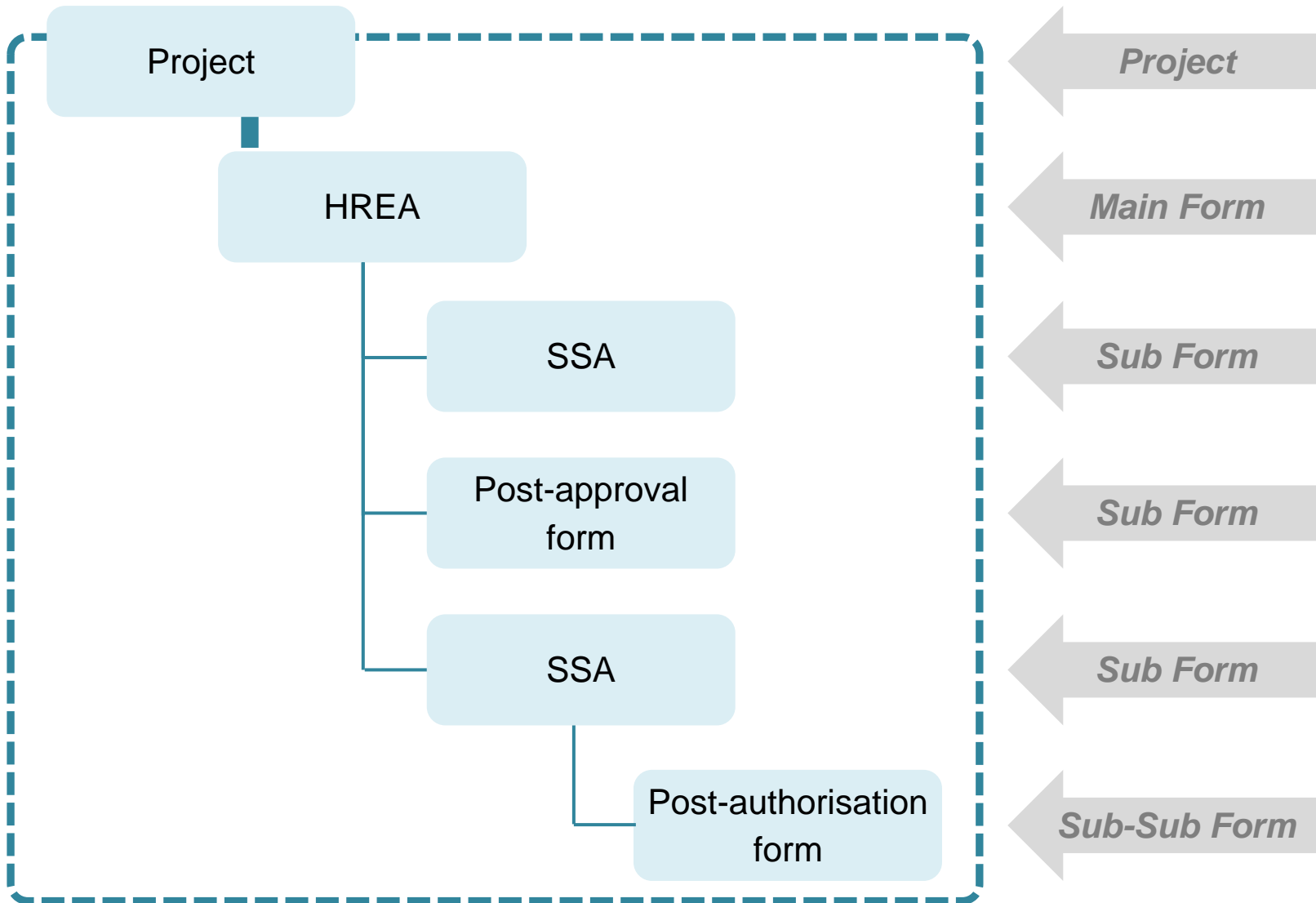


ERM links Research Applicants to the Research Office



The system is totally electronic (i.e. application, documents, signatures, correspondence) between Applicant and Research Office

ERM Form Relationships



Summary of the forms in ERM

Main Forms	Sub –forms	Sub-sub forms (Post- Authorisation)
HREA (Initial application)	Site Specific Application (SSA)	<ul style="list-style-type: none"> Complaint report Non serious breach/ deviation report Site audit report Site notification form Site progress report
HREA (Post approval)	Victorian Specific Module (VSM) <ul style="list-style-type: none"> Safety report Annual safety report Serious breach report Suspected breach report Project progress report Site closure report Project final report Project notification report 	
LNR VIC (Initial application)	LNR VIC SSA	<ul style="list-style-type: none"> Complaint report Non serious breach/ deviation report Site audit report Site notification form Site progress report
LNR (Post approval)	<ul style="list-style-type: none"> Amendment request Safety Report Serious Breach Report Suspected Beach Report Project Progress Report Site Closure Report Project Final Report Project Notification Forms 	
Legacy Application Replacement Form MDF Quality Assurance (QA) Vic		

Features in ERM

You should be familiar with these ERM features

- [ERM review reference](#)
- [Contacts](#)
- [Collaborators](#)
- [Correspondence](#)
- [Notifications](#)
- [Documents](#)
- [Completeness check](#)
- [Signatures](#)
- [Submission](#)



Your registered email in ERM

Your registered email is:

- Used for logging into ERM.
- The key method for communications using ERM.

(Always use the one email address)

ethics^{rm}

Queensland Government *Mater* Exceptional People. Exceptional Care. VICTORIA State Government

ERM Applications

Log in

Email Address

Password

[Log in](#) [New User](#) [Forgotten Password](#)



ERM Review Reference (1)

**Review Reference is allocated on form submission.
It is composed of six parts :**



- 1. Application type :** Identifies the type of application form.
- 2. Project ID :** The **unique identification** number for the research project.
- 3. Organisation code :** The organisation that form was submitted to.
- 4. Year:** Year of submission.
- 5. Submission number:** Identifies the particular submission (version) of this form.
- 6. Version number:** Version number (updates with each submission).



ERM Review Reference (2) project example

In this example, project involves an ethics application (HREA), SSA and an amendment which is reported to the site RGO.

Form	Review reference
HREA	HREC/46877/VICTEST-2018-153794(v2)
SSA	SSA/46877/DEF-2018-154181(v1)
Post Approval (Amendment)	AM/46877/VICTEST-2018-154186(v1)
Post Authorisation (Site notification)	S.OTHER/46877/DEF-2018-154188(v1)

Application type (Form specific)	Project ID (Stays the same)	Organisation code	Year	Submission number (Updates with submission)	Version number (Updates with submission)
	This is most important as it is the key to identifying an applications . Use this number when communicating.				



Work area

The work area is your dashboard.

The General area displays alerts. When the number is red, this denotes new alerts which have not yet been read.

- Notifications
- Signatures
- Transfers
- Shared

Folders (user may create own folders)

Projects (either created by or shared to this account)

Actions (left hand menu) that can be undertaken from this screen



Work Area explained

The screenshot shows the 'Work Area' interface in ERM Applications. The top navigation bar includes 'ERM Applications', 'Home', 'Contacts', and 'Help', with the user 'Prof Major Researcher' logged in. The 'Work Area' dropdown menu is open, showing 'Home' (1 notification) and 'Actions' (6 items: Create Folder, Delete Folder, Create Project, Delete Project, Duplicate Project, Transfer). A red box highlights the 'Actions' menu and the 'General' section of the main content area. The 'General' section contains four cards: 'Notifications' (1), 'Signatures' (2), 'Transfers' (0), and 'Shared' (3). Below this is the 'Folders' section with an 'Archive' card (3). The 'Projects' section features a search bar and a table with columns: Project Title, Project ID, Owner, Date Created, Date Modified, and Transfer Status. The table lists two projects: 'Wednesday wonderful project' and 'Wednesday signature project'. Arrows point from labels at the bottom to these elements: 'Actions' points to the 'Actions' menu; 'Action pane' points to the 'General' section; 'Projects' points to the 'Projects' table; 'User's folders' points to the 'Archive' card; and 'Notices from another ERM user' points to the 'Notifications' card.

Actions

Action pane

Projects

User's folders

Notices from another ERM user



Contacts

ERM Applications Home Contacts Help Prof Major Researcher

Work Area

Home Notifications 0

Contacts + Add Contact

Search Contacts

Title	First Name	Surname	Organisation	Address 1	City	Telephone	Email	Delete
Prof	Major	Researcher	Best Place		Best Town	03 8888 8888	major.researcher@google.com	Delete

Select 'Contacts'

Select 'Add Contact'

Save details that have been entered into the application form

Note: Contacts may be also edited or deleted from 'Contacts'

Inserting a contact into a form

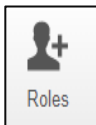
Select 'Load' to open a pop-up of 'Contacts'

Choose the appropriate personnel and select the green 'Insert' button to add the details to the form

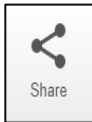


Collaborators

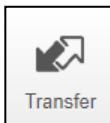
ERM gives the form owner the option to make the contents of the form available to others (e.g. sponsors or colleagues).



Allocate **Role** to user. Allows user to access a sub form and its main form (e.g use for SSA so that SSA user can view the HREA)



Share attributes for user in that form only (i.e. if SSA shared the new user can't see HREA)



Permanent transfer of project to another user.

E.g. Sponsor creates HREA but then transfers it to the CPI.
CPI (form owner) manages it thereafter



Use the 'Collaborator' tab to view all collaborators on the highlighted form

The screenshot displays the ERM Applications interface. At the top, there are navigation links for Home, Contacts, and Help, and a user profile for Prof Major Researcher. The main content area shows a 'Project Tree' with a selected form titled 'Test for better control of green disease' under the 'HREA' project. Below this is a table with columns for Form Status, Review Reference, Date Modified, and NMA. The 'Collaborators' tab is highlighted in red, showing a list of users with their names, access levels, and edit permission buttons.

Form Status	Review Reference	Date Modified	NMA
Not Submitted	N/A	03/08/2018 16:10	Project is for NMA

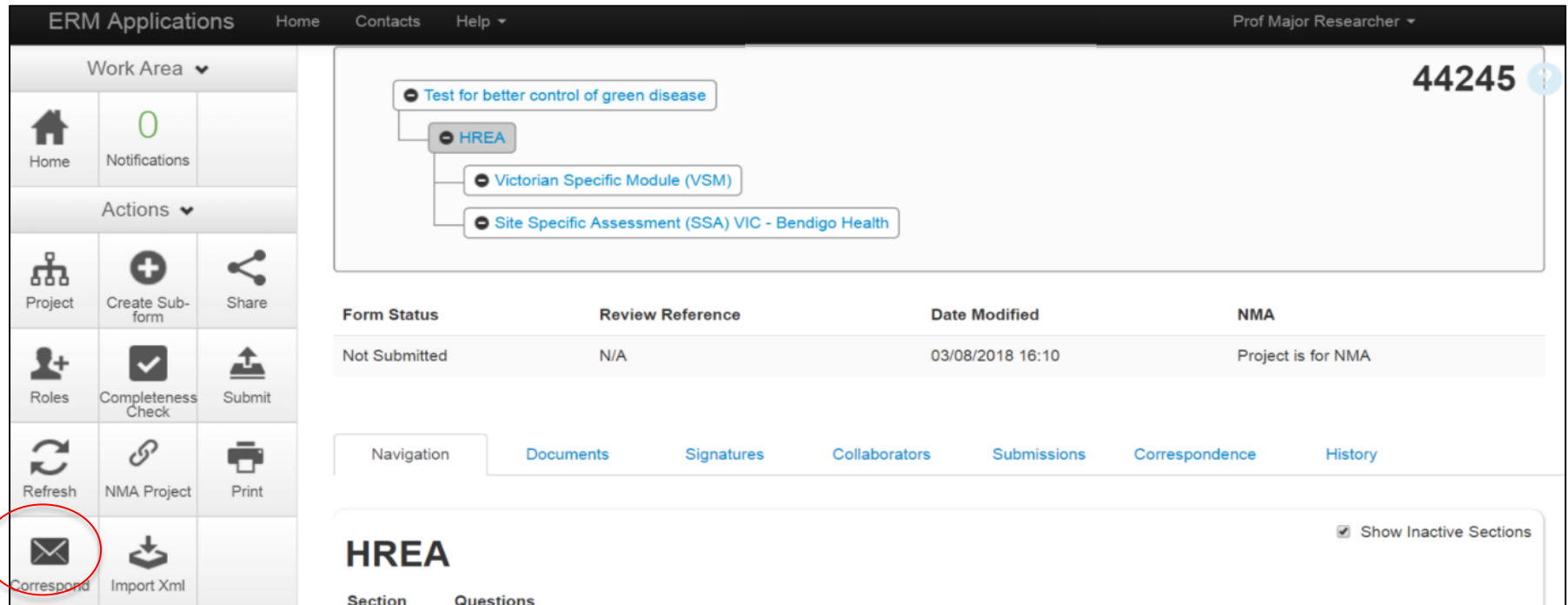
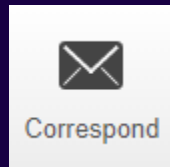
Name	Access	Edit Permissions
Max Weber	Read, Create all sub forms, Receive notifications	Edit Permissions
Prof Major Researcher	Project Owner and Form Owner	Edit Permissions

Project owner

Collaborator



Correspondence



The screenshot shows the ERM Applications interface. The top navigation bar includes 'Home', 'Contacts', and 'Help'. The user is identified as 'Prof Major Researcher'. The main content area displays a form titled 'Test for better control of green disease' with a notification count of 44245. The form structure includes sections for 'HREA', 'Victorian Specific Module (VSM)', and 'Site Specific Assessment (SSA) VIC - Bendigo Health'. Below the form is a table with columns for 'Form Status', 'Review Reference', 'Date Modified', and 'NMA'. The 'Form Status' is 'Not Submitted', 'Review Reference' is 'N/A', 'Date Modified' is '03/08/2018 16:10', and 'NMA' is 'Project is for NMA'. A navigation bar at the bottom includes 'Navigation', 'Documents', 'Signatures', 'Collaborators', 'Submissions', 'Correspondence', and 'History'. The 'Correspondence' button is highlighted with a red circle in the Action pane on the left.

Form Status	Review Reference	Date Modified	NMA
Not Submitted	N/A	03/08/2018 16:10	Project is for NMA

ERM allows a form owner to communicate directly with the research office. Select the 'Correspondence' button from the Action pane to start.

Tip : the research office must be selected before correspondence is initiated.



Notifications

An ERM user is notified when there is:

- Advice from Research Office
- Status change of a form that the user owns or collaborates on.
- A request from another user (eg to sign).

To open, select 'Notifications' from the 'Work Area' screen or 'Work Area' pane.

The screenshot displays the 'Work Area' interface for ERM Applications. The top navigation bar includes 'ERM Applications', 'Home', 'Contacts', and 'Help'. The user profile 'Prof Daisy Matthews' is visible in the top right. The left sidebar shows 'Work Area' with a dropdown menu containing 'Home' and 'Notifications' (highlighted with a red arrow and the number 8). Below the sidebar, the 'Actions' dropdown is visible. The main content area features a 'Work Area' header and a 'General' section with four cards: 'Notifications' (8), 'Signatures' (2), 'Transfers' (0), and 'Shared' (0). Below this is a 'Projects' section with a search bar and a table of project data.

Project Title	Project ID	Owner	Date Created	Date Modified	Transfer Status
Wednesday wonderful project	46747	Professor Joe Bloggs	19/09/2018 09:16	21/09/2018 15:47	



Completeness check



The 'Completeness Check' icon displays any sections that are incomplete. The check can be initiated at any time during form completion by selecting 'Completeness Check' icon.

Link to incomplete fields

All fields completed

Completeness Check [x]

Incomplete: Please complete the following questions

- [Protocol number](#)
- [Research category](#)
- [Select the committee that your multi site ethics application will be submitted to in Victoria.](#)
- [Q1.2](#)

Submit [x]

Complete: Your form is complete and ready to submit

[Close]

[Submit] [Close]



Documents

Adding documents

Documents are uploaded in specific sections inside the form.

Click on the blue 'Upload Document' button and follow the prompts. (For multiple types of the same document, click on the 'Upload Document' button multiple times).

The Document Name can be modified by overwriting it before the upload.

Tip: If the review body has asked you to amend your document, you can delete the document and upload the latest document. Be sure to revise the date and version of the document.



Signatures : Requestor

The Signature pages requires the signatories to electronically sign the form and confirm they agree to the declaration.

Request a signature ×

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

Note : Signatories must have a ERM account to provide an electronic signature

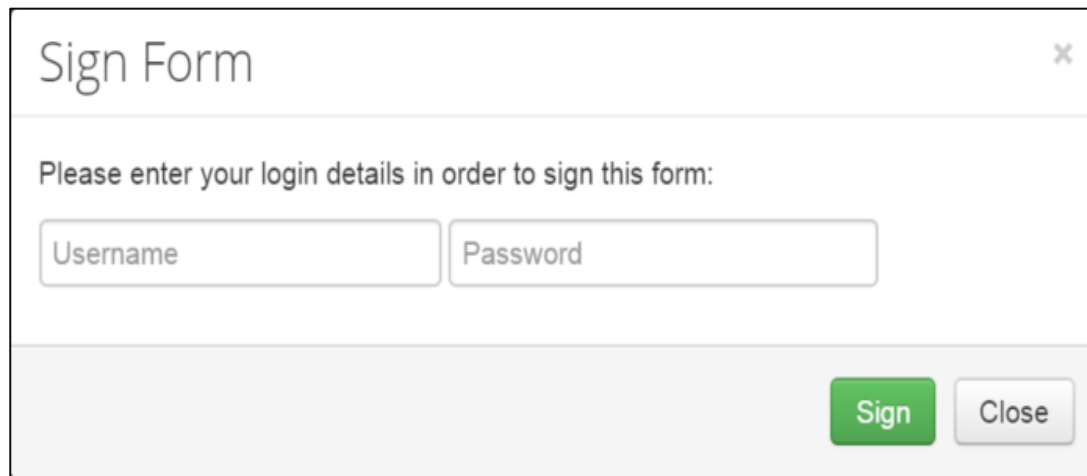


Signatures : Signatory

Signatory advised by email that a notification has been received.

Opens ERM account, selects the relevant notification which opens the form.

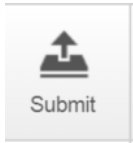
When the signatory is satisfied with the project, select the 'Sign' button, which raises the 'Sign Form' pop up.



The image shows a screenshot of a 'Sign Form' pop-up window. The window has a title bar with the text 'Sign Form' and a close button (an 'x' icon) in the top right corner. Below the title bar, there is a message: 'Please enter your login details in order to sign this form:'. Underneath this message, there are two input fields: one labeled 'Username' and one labeled 'Password'. At the bottom right of the form, there are two buttons: a green 'Sign' button and a grey 'Close' button.



Submission and review process



Form is submitted to research office, using the 'Submit' button from the Actions panel.

Form is received/ processed by research office

Research office may request further information

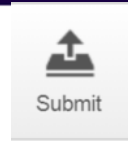
Form owner is notified by email. Logs onto ERM and selects message in 'Notifications'

Form owner addresses review queries.



Submission and review process

Amended form is submitted to the research office, using the 'Submit' button from the Actions panel



Form is received/ processed by research office.

Form owner is notified by email to log onto ERM. Logs onto ERM and selects relevant message in 'Notifications.'



ERM initial application

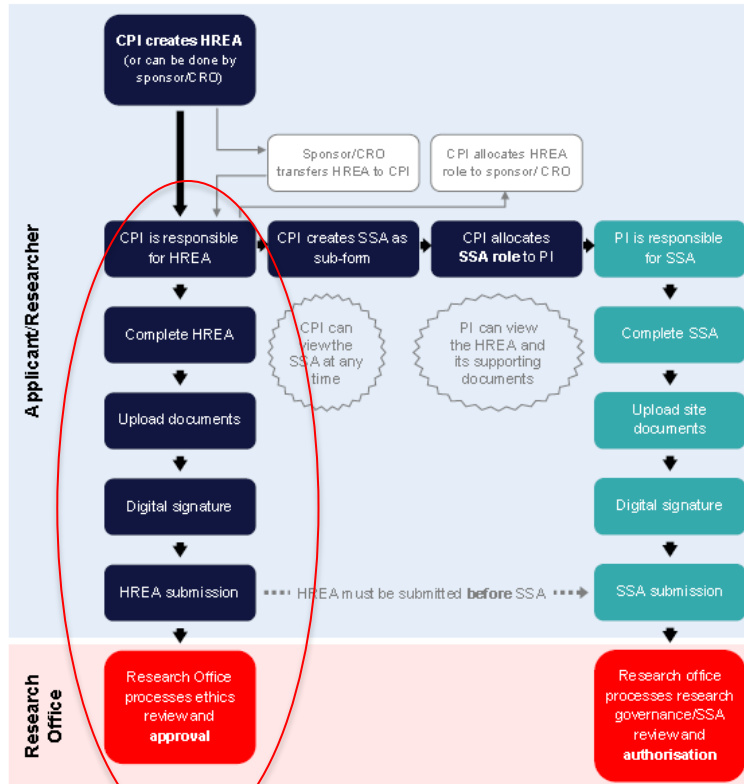
Ethical Review Manager (ERM)

Ethics and Research Governance/SSA

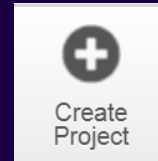
This is an overview of the initial application process. It shows two activities:

1. Creation of the ethics form (vertical).
2. Generation and sharing of the SSA (horizontal).

We will first look at the ethics process.



Create main form : HREA



Go to the Work Area and select the 'Create project' button from the Action pane.

This raises a 'Create Project' pop up screen.

Enter project title and jurisdiction (Victoria) and a main form.

A screenshot of a web-based "Create Project" dialog box. The dialog has a title bar with "Create Project" and a close button (X). Below the title bar, there are three input fields: a text box for "Project Title (maximum 200 characters):*" containing "Project title", a dropdown menu for "Select Jurisdiction" with "Victoria" selected, and another dropdown menu for "Main Form" with "HREA" selected. At the bottom right, there are two buttons: a green "Create" button and a grey "Close" button. A red arrow points from the "Main Form" dropdown in the dialog to the list of main forms in the adjacent text box.

The available main forms are: :

- LNR VIC
- Legacy Application Replacement Form
- MDF
- Quality Assurance (QA) Vic
- HREA



Main form screen

ERM Applications Home Contacts Help Prof Major Researcher

Work Area

Home Notifications

Actions

Project Create Sub-form Share

Roles Completeness Check Submit

Refresh NMA Project Print

Correspond Import Xml

Test for better control of green disease 44245

Project Tree

- Test for better control of green disease
 - HREA

Form Status	Review Reference	Date Modified	NMA
Not Submitted	N/A	03/08/2018 16:10	Project is for NMA

Navigation Documents Signatures Collaborators Submissions Correspondence History

HREA

Section Questions

ERM Module

HREA

Show Inactive Sections

Actions

Project tree

HREA form

Function tabs



Complete the HREA Form

Using the ERM functions previously discussed, the form owner:

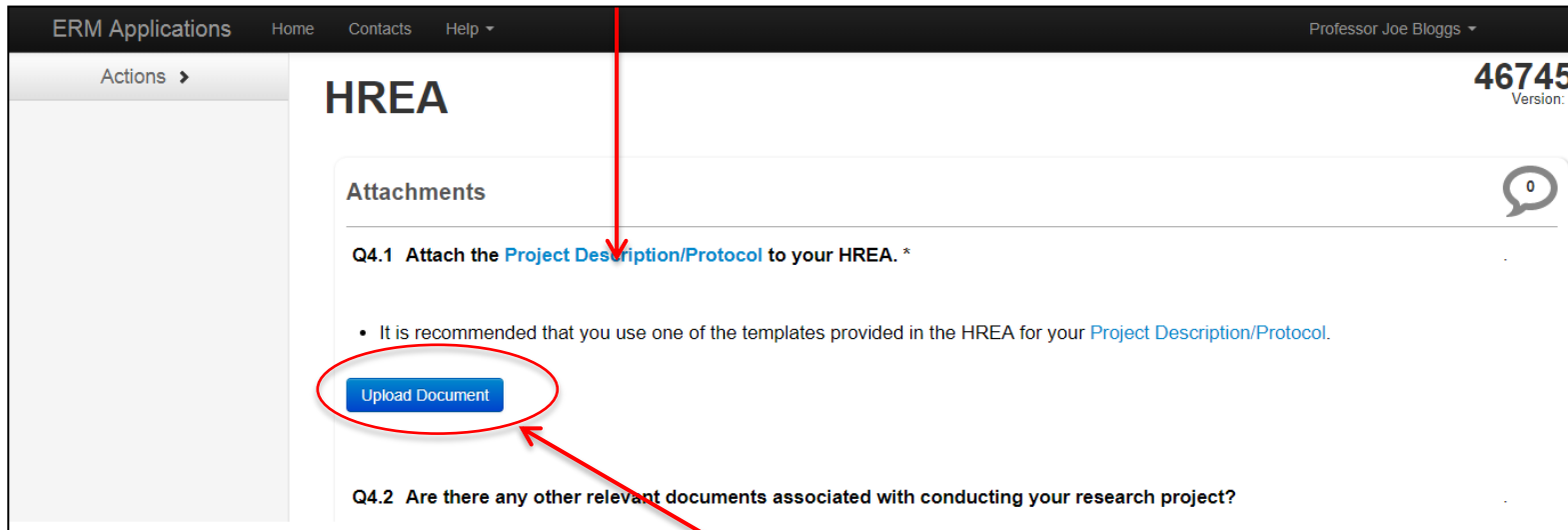
- Completes the form
 - *(Note: The Filter section and Acknowledgement of the HREA must be completed before continuing with the rest of the application.)*
- Chooses collaborators
- Checks for completeness
- Adds documents
- Acquires signatures
 - *(Note: Form is now finalised or locked)*



Add documents

Upload Document

Specific documents are added to designated questions within a form.
In this example, the protocol is to be uploaded.



The screenshot displays the 'ERM Applications' interface for an 'HREA' form. The top navigation bar includes 'Home', 'Contacts', and 'Help'. The user is identified as 'Professor Joe Bloggs'. The form title is 'HREA' with a version number '46745'. The 'Attachments' section contains a question: 'Q4.1 Attach the Project Description/Protocol to your HREA. *'. Below the question, a note states: 'It is recommended that you use one of the templates provided in the HREA for your Project Description/Protocol.' A blue 'Upload Document' button is circled in red. Below this, question 'Q4.2 Are there any other relevant documents associated with conducting your research project?' is visible. A red arrow points from the 'Upload Document' button to the text 'protocol' in the preceding paragraph.

Selecting the 'Upload Document' icon raises a pop up form .



Document pop up form

The screenshot shows a window titled "Documents - Protocol" with a close button in the top right corner. Below the title bar, the text "Please attach your Protocol here:" is displayed. The form contains three columns: "Document Name", "Version Date", and "Version". Under "Document Name" is a blue "Browse" button. Under "Version Date" is a dropdown menu. Under "Version" is a text input field. To the right of these fields is a large grey "Upload" button. A "Close" button is located in the bottom right corner of the window. Four red arrows point from the text below to the "Browse", "Version Date", "Version", and "Upload" buttons.

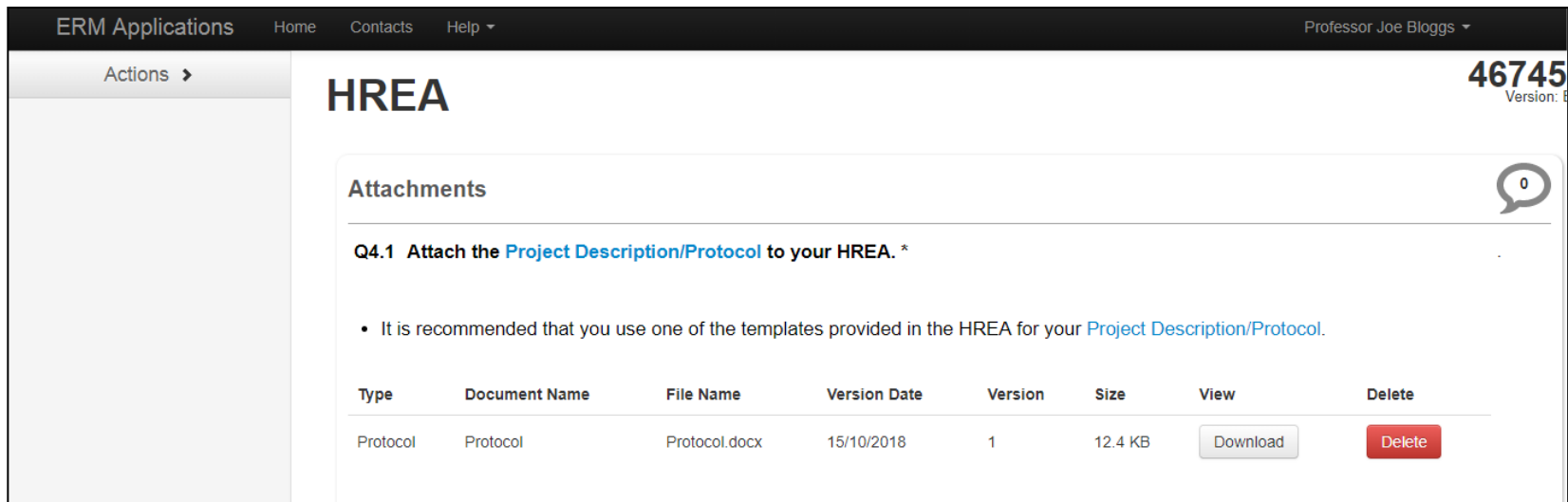
Locate the document

Enter the key identifiers:
Document name (Can be overwritten)
Version date (from dropdown)
Version (can enter number or text)

Select 'Upload' to add the document. This completes the process



Uploaded documents



The screenshot shows the HREA application interface. At the top, there is a navigation bar with 'ERM Applications', 'Home', 'Contacts', and 'Help'. The user 'Professor Joe Bloggs' is logged in. The main header displays 'HREA' and the number '46745' with 'Version: 1.0' below it. A sidebar on the left contains an 'Actions' menu. The main content area is titled 'Attachments' and includes a message: 'Q4.1 Attach the Project Description/Protocol to your HREA. *'. Below this, a note states: 'It is recommended that you use one of the templates provided in the HREA for your Project Description/Protocol.' A table lists the uploaded document:

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Protocol	Protocol	Protocol.docx	15/10/2018	1	12.4 KB	Download	Delete

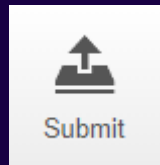
The document is now embedded in the form and can be downloaded from the form and the 'Documents' function tab.

More than one document of the same type may be added (e.g. a PICF for the main study and another for a sub study).

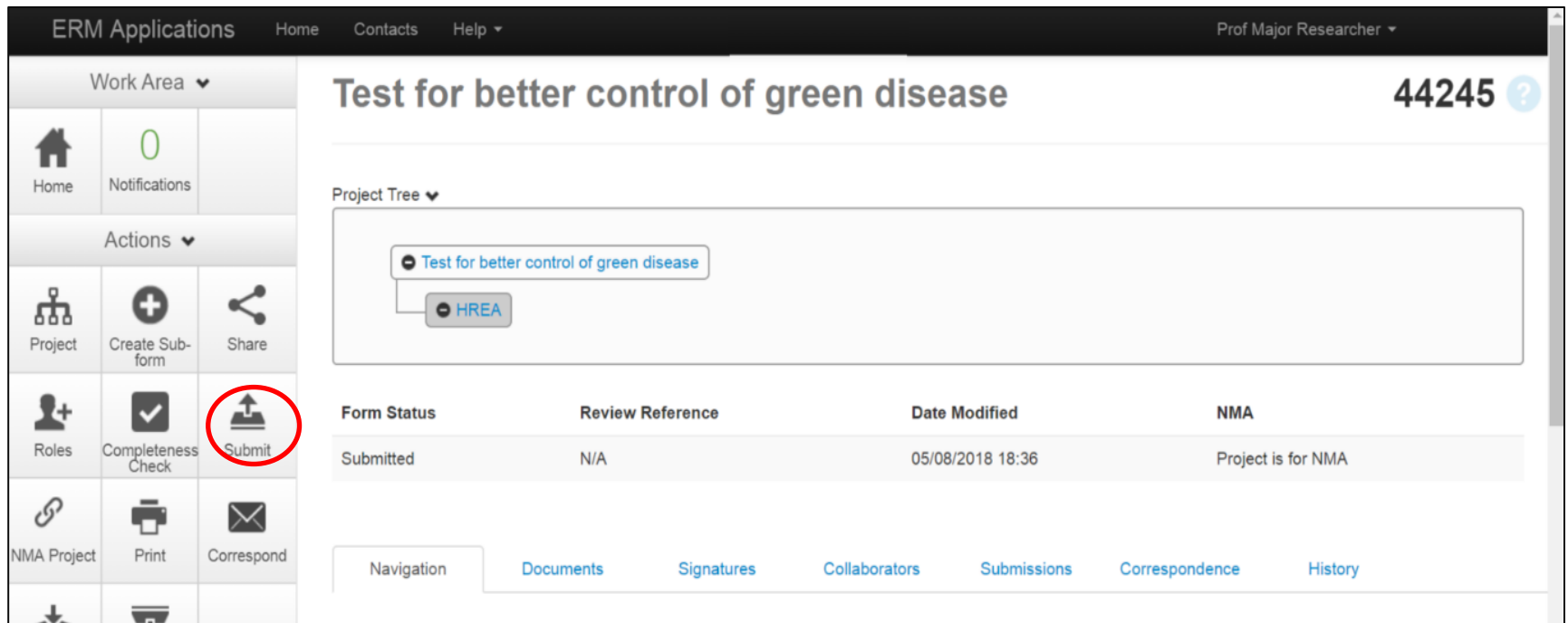
Delete any superfluous documents (e.g. not the latest version)



Submission



The form owner selects the 'Submit' button from the Action Pane.

A screenshot of the ERM Applications web interface. The top navigation bar includes "ERM Applications", "Home", "Contacts", "Help", and a user profile "Prof Major Researcher". The main content area is titled "Test for better control of green disease" with a form ID "44245". A "Project Tree" shows a hierarchy with "Test for better control of green disease" and "HREA". Below this is a table with columns: "Form Status", "Review Reference", "Date Modified", and "NMA". The table contains one row: "Submitted", "N/A", "05/08/2018 18:36", and "Project is for NMA". At the bottom, there is a "Navigation" bar with links for "Documents", "Signatures", "Collaborators", "Submissions", "Correspondence", and "History". On the left side, there is an "Actions" pane with icons for "Project", "Create Sub-form", "Share", "Roles", "Completeness Check", and "Submit". The "Submit" icon, which is a document with an upward arrow, is circled in red.

This will raise a pop up of a pre-submission completeness check. You must have a 'green line' in the Completeness check before submission takes place.



Project is submitted

The screenshot displays the ERM Applications interface. At the top, the user is identified as 'Prof Major Researcher' with a user ID of '44428'. The main content area shows a 'Project Tree' with a hierarchy: 'Red pill or blue pill for Green disease' (parent), 'HREA' (child), and 'Site Specific Assessment (SSA) VIC - Other site in Victoria' (child). Below the tree is a table with the following data:

Form Status	Review Reference	Date Modified	NMA
Submitted	HREC/44428/DEF-2018-68187(v1)	05/08/2018 18:38	Project is not for NMA

Below the table is a navigation bar with tabs: 'Navigation', 'Documents', 'Signatures', 'Collaborators', 'Submissions', 'Correspondence', and 'History'. The 'History' tab is circled in red. Below the navigation bar is the 'Form History' section, which includes a search bar and a table with the following data:

Date	User	Description	Attachment
6:39 PM	Prof Major Researcher	Form submitted	Download

Change of form status

New entry into project history



Review process

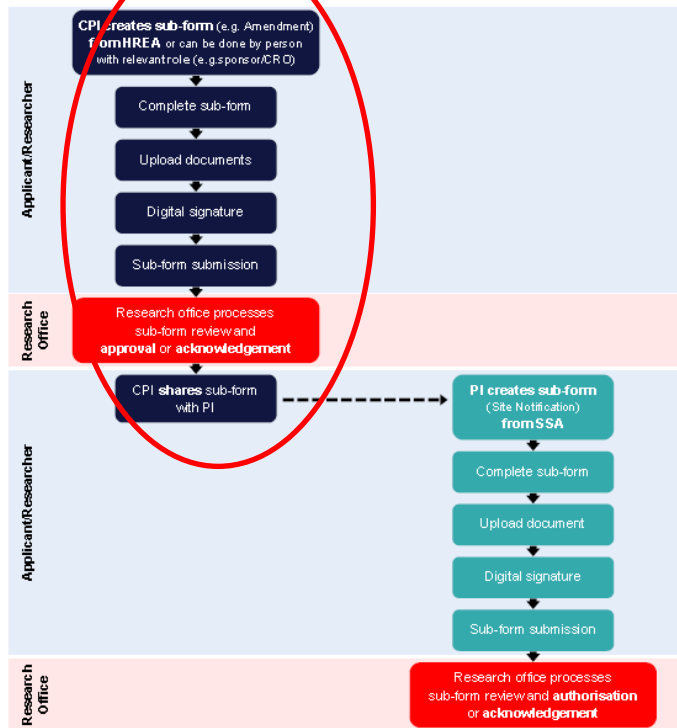
- Form is submitted to research office for review
- Reviewer may request further information
- Form owner responds to queries
- Resubmission to research office
- Applications returned from review body with a decision



Post Ethics (1)

Ethical Review Manager (ERM)

Post-approval and Post-authorisation



Congratulations! Your project is approved!

The Human Research Ethics Application (HREA) is now an “anchor” for the project to allow creation of post approval sub forms:

- Safety report
- Amendment form
- Annual safety report
- Serious breach report
- Suspected breach report
- Project progress report
- Site closure report
- Project final report
- Project notification report



Post Ethics (2)

- Go to ERM
- Select the relevant project
- Select the HREA form
- Select the 'Create sub form' button from the Actions menu
- Select the desired sub form



Post Ethics (3) Select the desired sub form

The screenshot displays the ERM Applications web interface. At the top, the navigation bar includes 'ERM Applications', 'Home', 'Contacts', 'Help', and the user profile 'Prof Major Researcher'. The main header shows the project title 'Test for better control of green disease' and the ID '44245'. On the left, a sidebar contains a 'Work Area' menu with icons for Home, Notifications, Project, Roles, NMA Project, and Import Xml. Below this is an 'Actions' menu with icons for Create Sub-form (circled in red), Share, Roles, Completeness Check, Submit, Print, Correspond, and Recall. A red arrow points from the 'Create Sub-form' icon to a dialog box titled 'Create Sub-form'. The dialog box has a 'Select Jurisdiction' dropdown set to 'Vic' and a list of sub-forms to choose from. A red arrow also points from a text box at the bottom left to the 'Create Sub-form' icon. The main content area shows a 'Project Tree' with 'Test for better control of green disease' and 'HREA' nodes, and a 'Form Status' table.

ERM Applications Home Contacts Help Prof Major Researcher

Work Area

Home Notifications

Actions

Project Create Sub-form Share

Roles Completeness Check Submit

NMA Project Print Correspond

Import Xml Recall

Test for better control of green disease 44245

Project Tree

- Test for better control of green disease
- HREA

Form Status Review Reference

Submitted	N/A
-----------	-----

Navigation Documents Signatures Col

HREA

Section Questions

Use the 'Create Sub Form button'

Create Sub-form

Select Jurisdiction

Vic

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

- Please Select...
- Please Select...
- Victorian Specific Module (VSM)
- Site Specific Assessment (SSA) VIC
- Amendment Request
- Safety Report
- Annual Safety Report
- Serious Breach Report
- Suspected Breach Report
- Project Progress Report
- Site Closure Report
- Project Final Report
- Project Notification Form

Close



Post Ethics (4) Complete sub form

- Navigate the sub form
- Add documents
- Completeness check
- Collect Signatures (Form now finalised/ locked)
- Collaborators
- Submit to research office (same ethics committee which undertook initial review)



Post Ethics (5) Review process of sub form

- Sub form is submitted to research office for review
- Reviewer may request further information
- Sub form owner responds to queries and submits updated sub form to research office
- Application from research office returned with a decision



Site Specific Application (SSA)

The SSA is a sub form of the HREA.

The HREA and SSA forms are linked electronically.



SSA initial application

Ethical Review Manager (ERM)

Ethics and Research Governance/SSA

This is an overview of the initial application process.

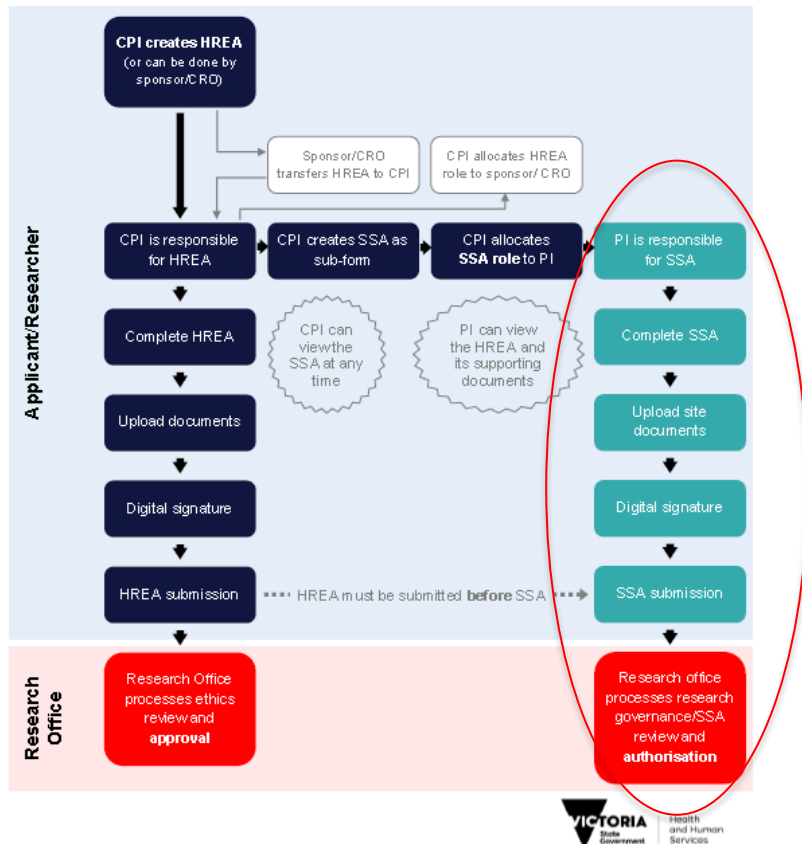
It shows two activities:

- Creation of the ethics form (vertical).
- Generation and sharing of the SSA (horizontal).

We will now discuss the second process.

There are two processes in which a user accesses the SSA

- 1) The user creates the SSA from the HREA
- 2) Allocation of an SSA from an HREA owner.



Create the SSA as a Sub Form from the HREA (1)

HREA owner opens ERM and selects the relevant project.

- Ensure the HREA is highlighted
- Select 'Create Sub Form'
- This raises a pop up box to
 - Select jurisdiction (Victoria)
 - Select the desired sub form
 - Click on the green 'Create' button.



Create the SSA as a Sub Form from the HREA (2)

Select the project for which the SSA is to be created
From the HREA, select the 'Create Sub Form' button.



The screenshot displays the ERM Applications interface. The top navigation bar includes 'Home', 'Contacts', and 'Help'. The user is identified as 'Prof Major Researcher'. The main content area shows a project titled 'Test for better control of green disease' with ID '44245'. Below this, a 'Project Tree' shows a hierarchy with 'Test for better control of green disease' as the parent and 'HREA' as a child. In the left-hand 'Actions' menu, the 'Create Sub-form' button is circled in red. At the bottom, a table provides details about the form's status and submission.

Form Status	Review Reference	Date Modified	NMA
Not Submitted	N/A	03/08/2018 16:10	Project is for NMA



Create the SSA as a Sub Form from the HREA (3)

1

Create Sub-form

Select Jurisdiction

Vic

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

Please Select...

Close

3

Selecting the form raises a green 'Create' button
Click on the 'Create' button. This opens the SSA.

2

Select required sub-form. In this case it is the SSA:

- Victorian Specific Module (VSM)
- **Site Specific Application (SSA)**
- Safety report
- Annual safety report
- Serious breach report
- Suspected breach report
- Project progress report
- Site closure report
- Project final report
- Project notification report



2) Accept the SSA from the HREA owner

PI (or delegate) receives an email advising they need to log onto ERM

PI (or delegate) logs onto ERM, and selects 'Notifications'

The screenshot displays the ERM Applications web interface. The top navigation bar includes 'ERM Applications', 'Home', 'Contacts', and 'Help'. The user is logged in as 'Prof Major Researcher'. The main content area is titled 'Notifications' and features a search bar, 'Start' and 'End' date pickers, and a 'Display' slider set to 100 notifications. A 'Search' button is located below the search filters. A notification is listed in a table with columns for 'Message', 'Attachment', and 'Project Short Title'. The notification text is 'Dr Bernice Davies has assigned you a role in their project'. A red arrow points from this notification to a detailed 'Message' dialog box. The dialog box shows the 'Project Short Title' as 'Red pill or blue pill for Green disease' and the 'Date' as '05/08/2018 10:13 PM'. The message content is 'Dr Bernice Davies has assigned you a role in their project'. At the bottom of the dialog box, the 'View Form' button is circled in red.



The SSA screen is similar to the HREA screen

The screenshot displays the ERM Applications interface. At the top, there is a navigation bar with 'Home', 'Contacts', and 'Help' menus, and a user profile for 'Prof Major Researcher'. The main content area is titled 'Test for better control of green disease' with a reference number '44245'. A 'Project Tree' on the left shows a hierarchy: 'Test for better control of green disease' -> 'HREA' -> 'Site Specific Assessment (SSA) VIC -'. Below this is a table with columns: 'Form Status', 'Review Reference', 'Date Modified', and 'NMA'. The table contains one row: 'Not Submitted', 'N/A', '04/08/2018 08:28', and 'Project is for NMA'. A navigation bar below the table includes 'Documents', 'Signatures', 'Collaborators', 'Submissions', 'Correspondence', and 'History'. The main section is titled 'Site Specific Assessment (SSA) VIC' and has a 'Show Inactive Sections' checkbox. Under 'Section', there are tabs for 'Introduction' and 'Site Research Team'. Under 'Questions', there are tabs for 'Information', 'Project', 'Location', 'Ethics Review', and 'Site Addition'. The 'Information' tab is selected.

Available actions

Select the relevant section of the SSA to enter data into the form

Project tree includes the HREA and the SSA



SSA processes (Completion and submission)

- Navigate
- Add documents
- Completeness check
- Collect Signatures (Form now locked)
- Collaborators
- Submit to RGO

- SSA is reviewed
- Possible request for further information from reviewers
- Respond to queries
- Amended SSA is submitted to RGO

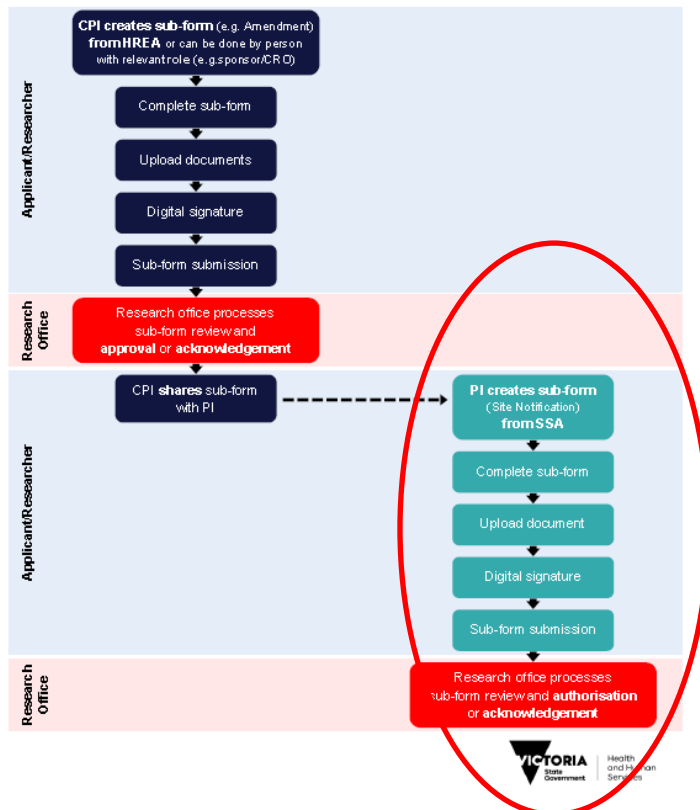
- SSA returned with a decision



Post SSA Authorisation: sub forms

Ethical Review Manager (ERM)

Post-approval and Post-authorisation



Congratulations! Your project is authorised

The Site Specific Application (SSA) is now an “anchor” for the site governance to allow creation of post authorisation sub sub forms:

- Complaint report
- Non serious breach/ deviation report
- Site audit report
- Site notification form
- Site progress report



Create sub form from SSA

- Go to ERM
- Select the relevant project (ensure the SSA is highlighted)
- Select 'Create Sub Form'
- This raises a pop up box of available sub forms
- Select the desired sub form
- Selection of the form raises the green 'Create' button
- Click on the green 'Create' button



Create sub form from SSA

The screenshot displays the ERM Applications interface. At the top, the navigation bar includes 'ERM Applications', 'Home', 'Contacts', and 'Help', with the user 'Prof Major Researcher' logged in. The main header shows the project title 'Red pill or blue pill for Green disease' and the ID '44428'. The 'Project Tree' on the left contains three items: 'Red pill or blue pill for Green disease', 'HREA', and 'Site Specific Assessment (SSA) VIC - Other site in Victoria'. The 'Actions' menu on the left has the 'Create Sub-form' icon circled in red. A 'Create Sub-form' dialog box is open on the right, prompting the user to 'Select the sub-form that you would like to apply to this form'. The dialog lists several options: 'Please Select...', 'Please Select...' (highlighted), 'Complaint Report', 'Non-serious Breach/Deviation Report', 'Site Audit Report', 'Site Notification Form', and 'Site Progress Report'.



Post authorisation sub forms: (completion and submission)

- Navigate the sub form
- Add documents
- Completeness check
- Collect signatures (Form now finalised/locked)
- Collaborators
- Submit to RGO for consideration

- Sub form is reviewed.
- Possible request for further information from reviewers
- If required sub form owner responds to queries and submits amended application to RGO.

- Application returned with a decision



Other Forms

Victoria Specific Module (VSM)

Minimal Data Set (MDF)



Victorian Specific Module (VSM)

The VSM is a component of ethical deliberations when there is at least one site in Victoria (See HREA filter question)

Sub form of the HREA

When you have completed all applicable sections of the VSM:

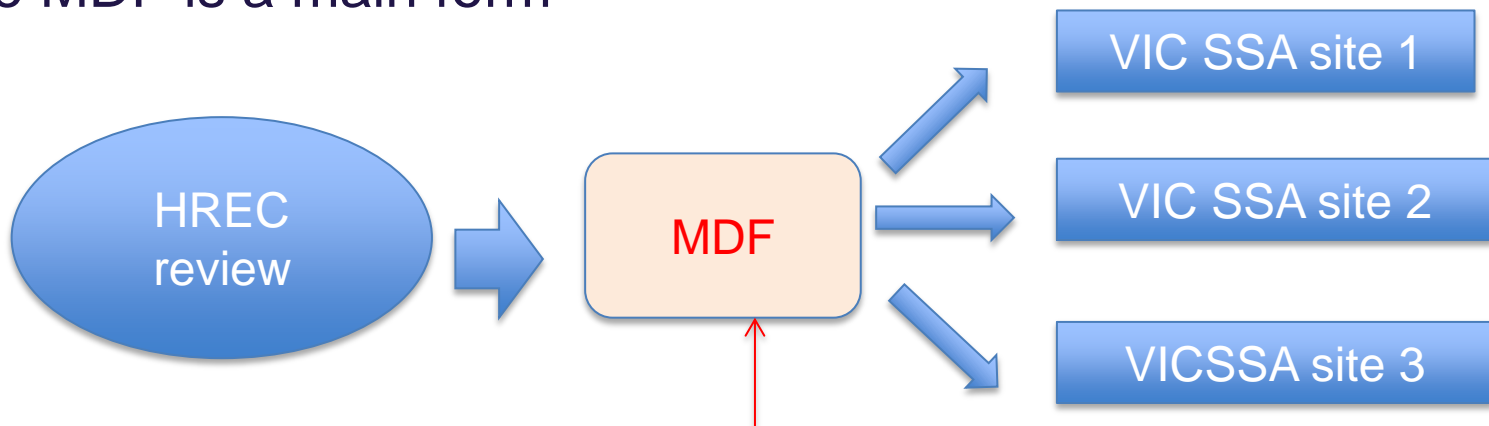
- Print the VSM and save it as a PDF.
- Open the HREA, upload the VSM pdf in the pre-HREA filter question.
- Complete the HREA (including supporting documents) & sign it electronically
- Submit the VSM to the reviewing HREC.



Minimal Dataset Form (MDF)

This is a “proxy” form to link the HREC review in a state using a different research system and to create SSA/s for Victorian sites

The MDF is a main form



Complete the information in the MDF.

Upload the ethics form, documents and HREC approval letter (if available).

Submit (This is a system action, so it does not go to a specific research office).

Create the SSAs as sub forms of the MDF. Use Roles+ to share the SSAs.



How to use the MDF

The CPI logs onto ERM

- CPI selects “Create Project” and selects Minimal Data Form (MDF)
- Uploads HREA & supporting documents. Submit.
- The CPI then creates a SSA
- The CPI allocates SSA to PI (using Roles+)
- The site PI uses ERM to complete the SSA, upload site documents, electronically sign the form and submit it to the site research governance officer (RGO).



Wet signatures

While it is not optimal, a signatory might need to use a 'wet signature' in place of the electronic. The signatory signs on a printed page which is then scanned.

HREA

If the form is not locked, the signature may be added into the signature block.

SSA

If the form is not locked, the signature may be added into q 7.1 'Supporting documents'.

Note: If the form is locked, use 'Correspondence' to provide the research office with relevant signatures.



Further information

To access ERM:

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

For assistance:

Infonetica

- 02 9037 8404
- helpdesk@infonetica.net

Coordinating Office

- 03 9096 7394
- Multisite.ethics@DHHS.vic.gov.au

Further information: [May 2018 E-bulletin](#)