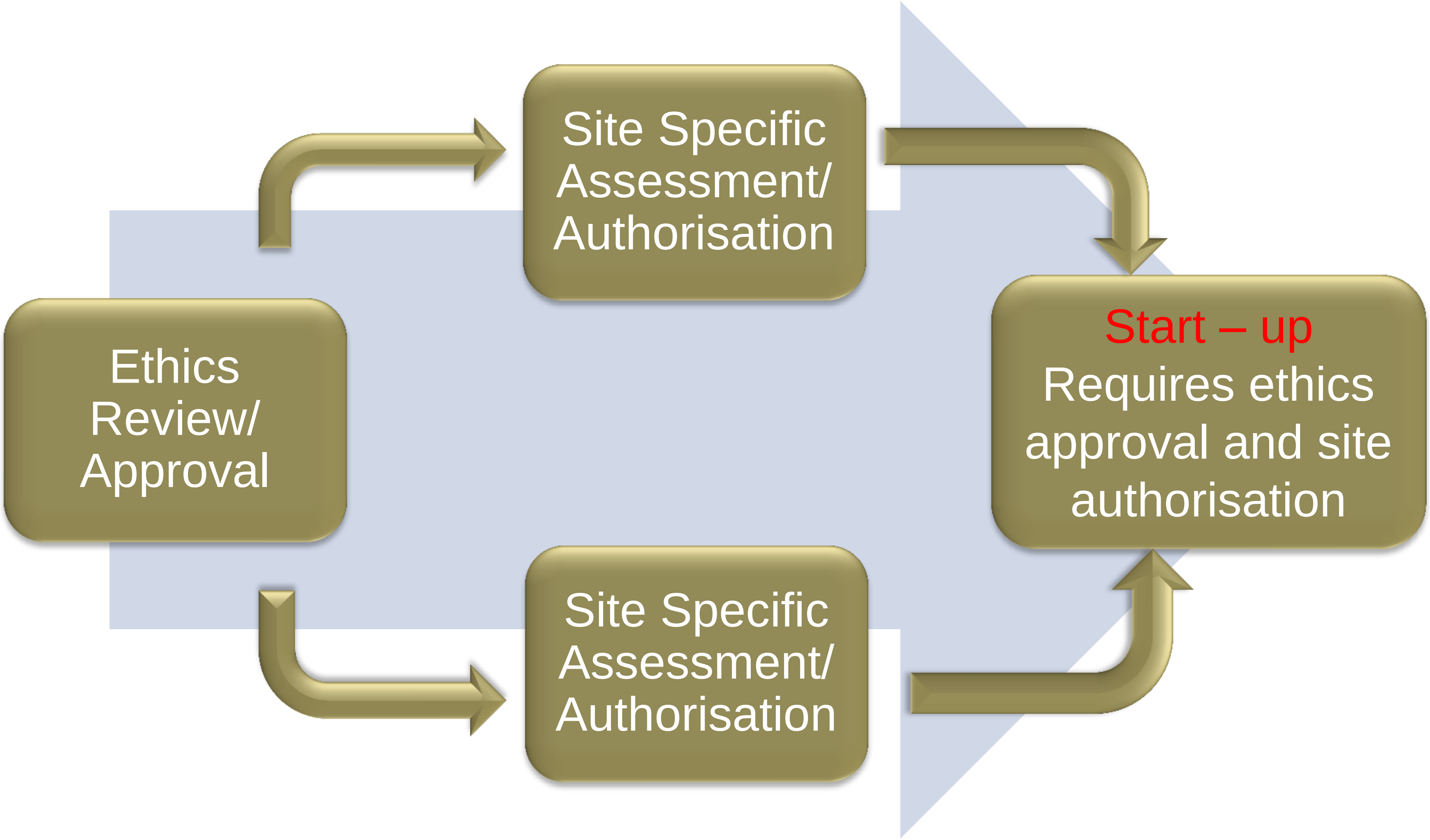
ERM for Applicants & Sponsors

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

This presentation describes the Victorian processes

Victoria State Government | Health and Human Services

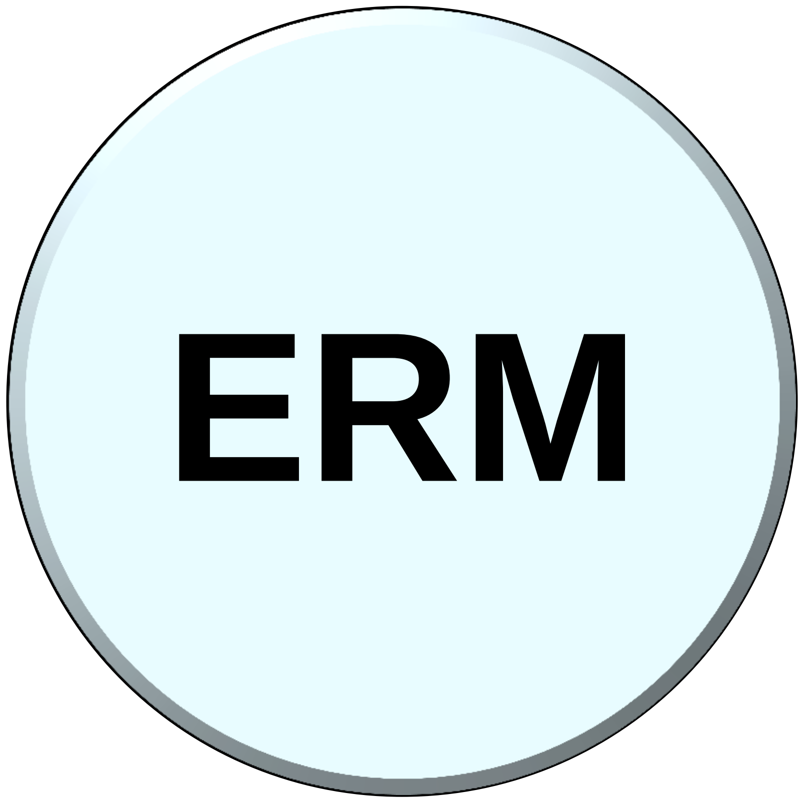
Recap of single ethical review for multi-site research



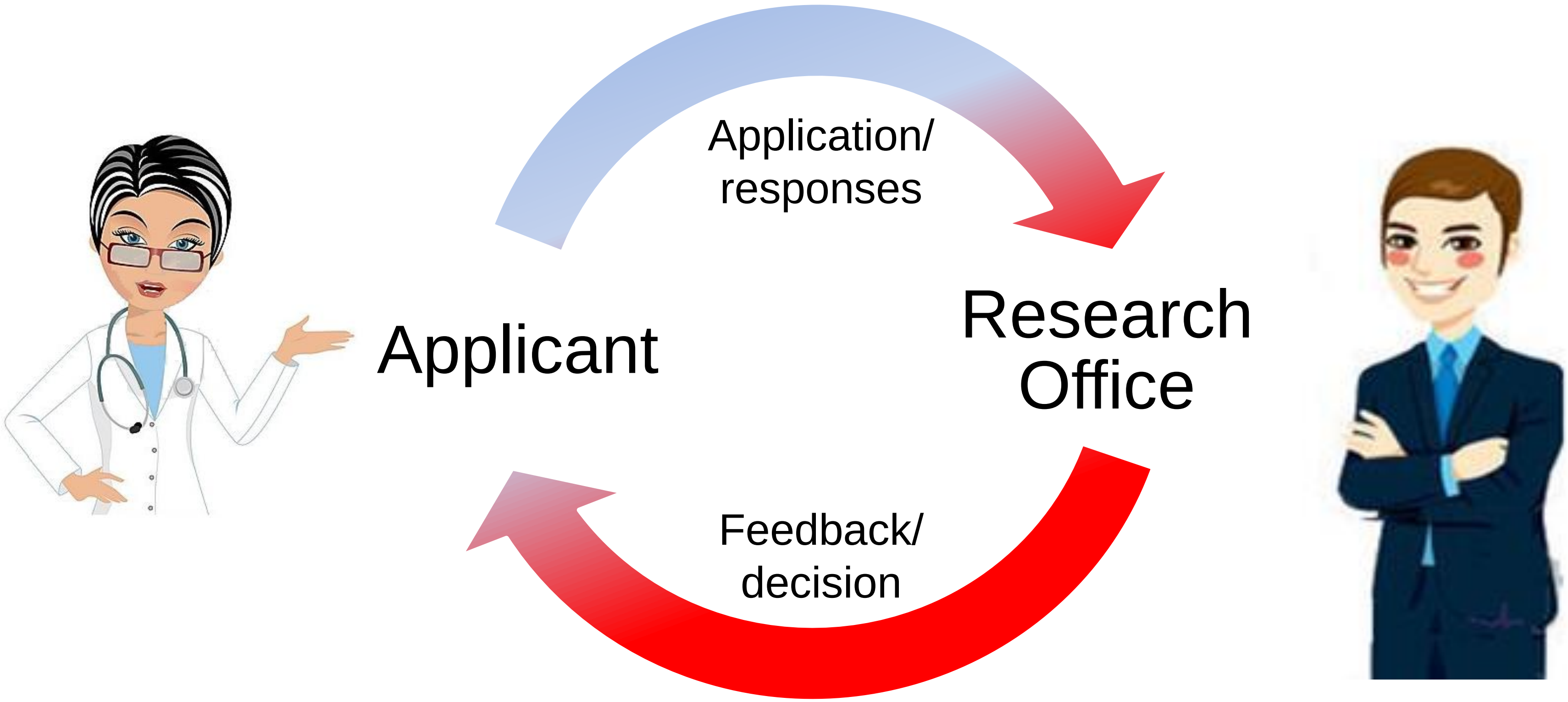
This talk covers

- **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

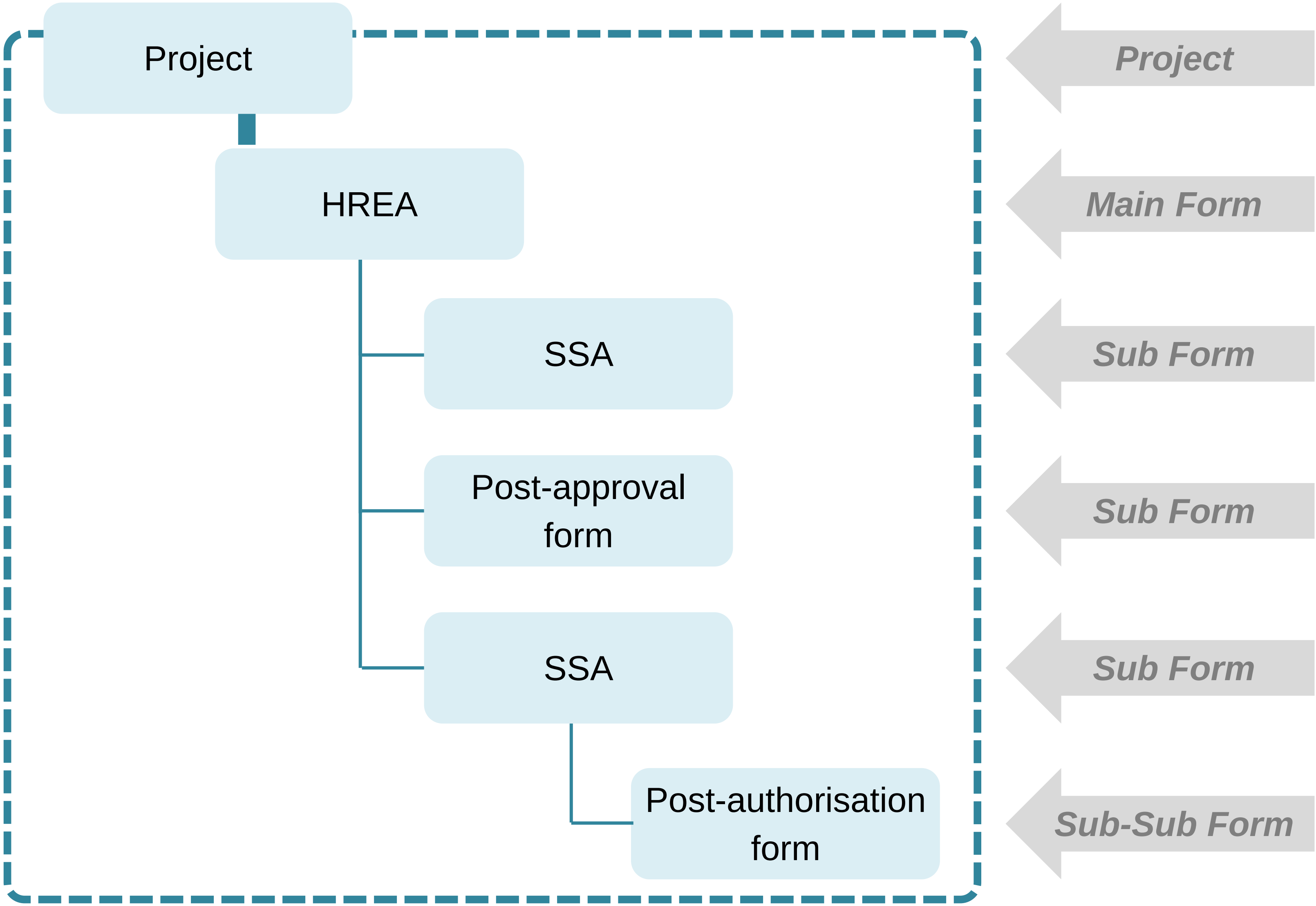


ERM links Research Applicants to the Research Office



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)	• Complaint report • Non serious breach/ deviation report • Site audit report • Site notification form • Site progress report
	Victorian Specific Module (VSM	
HREA (Post approval)	• 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	• Complaint report • Non serious breach/ deviation report • Site audit report • Site notification form • Site progress report
LNR (Post approval)	• 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

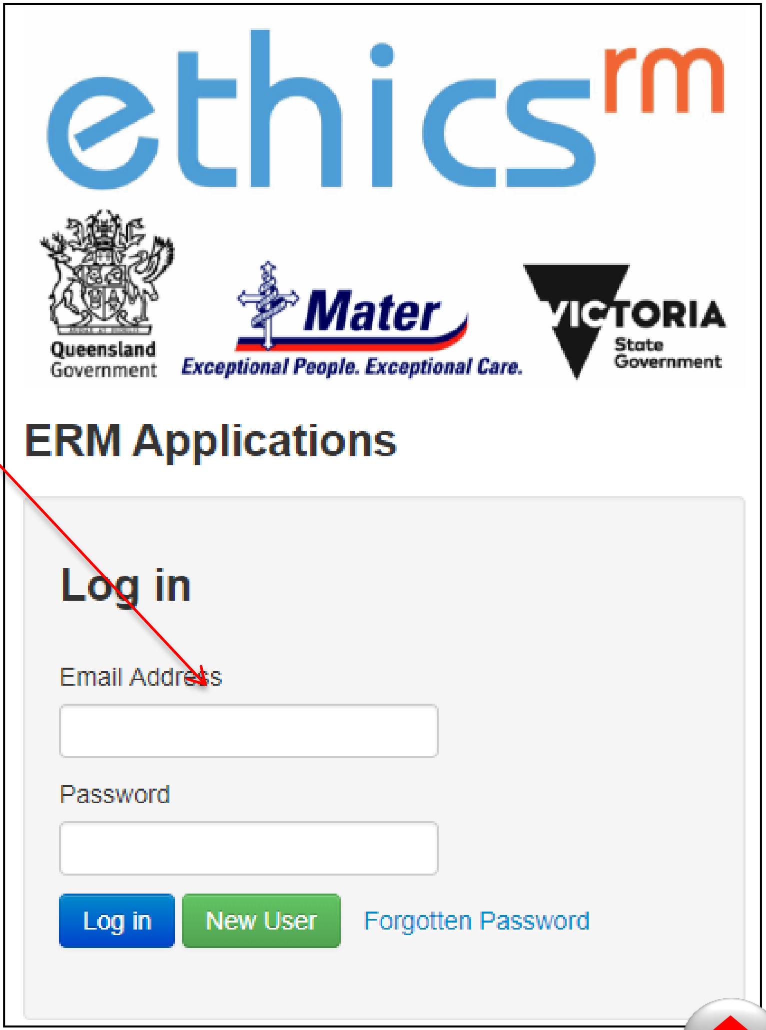
- ERM review reference
- Contacts
- Collaborators
- Correspondence
- Notifications
- Documents
- Completeness check
- Signatures
- Submission

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)



ERM Review Reference (1)

Review Reference is allocated on form submission.

It is composed of six parts :

HREC/46877/VICTEST-2018-153794(v2)

1 2 3 4 5 6

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)

This is most important as it is the key to identifying an applications . Use this number when communicating.

Organisation code

Year

Submission number (Updates with submission)

Version number (Updates with submission)

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.

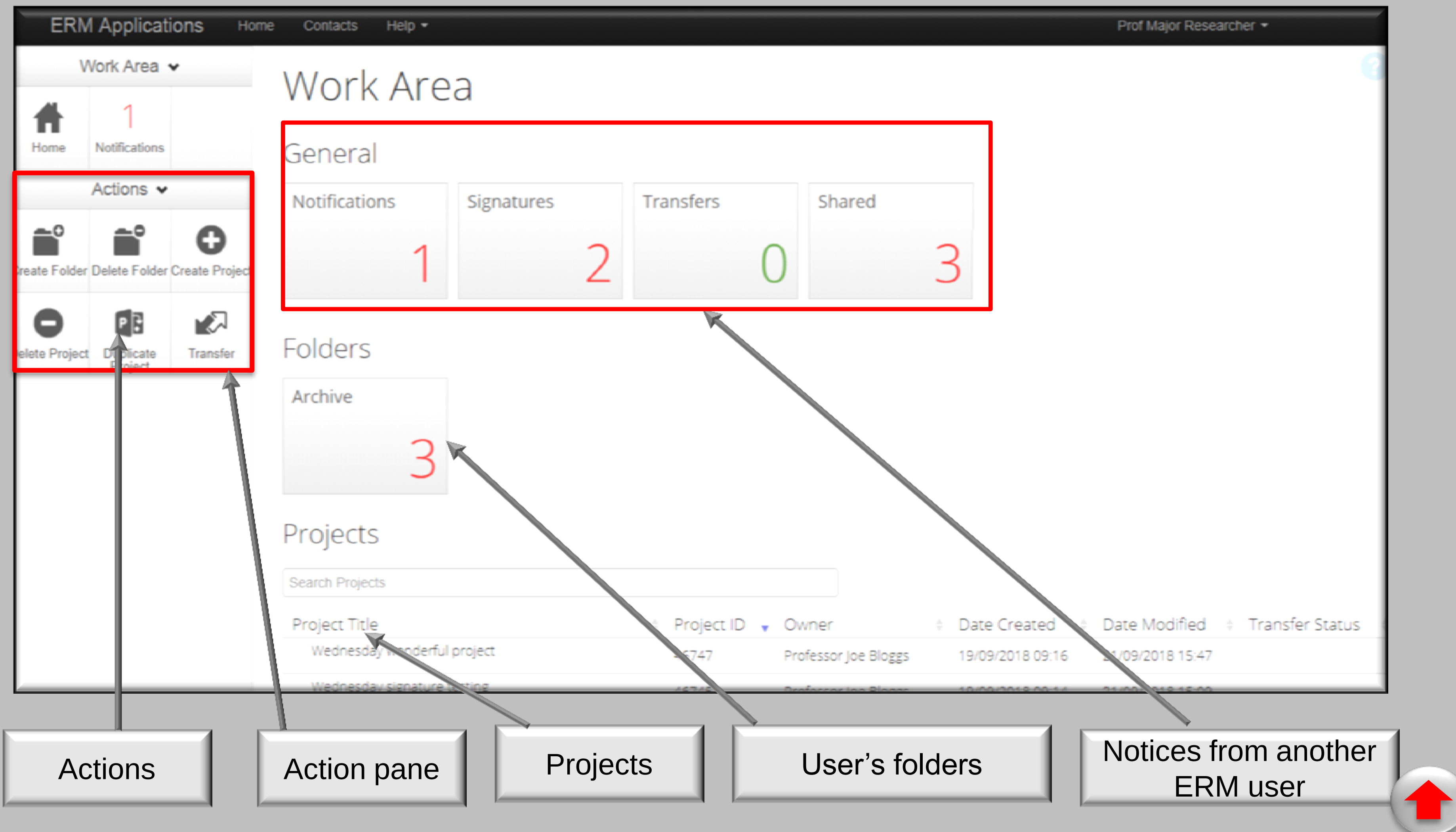
- Notifications
- Signatures
- Transfers
- Shared

Folders (user may create own folders)

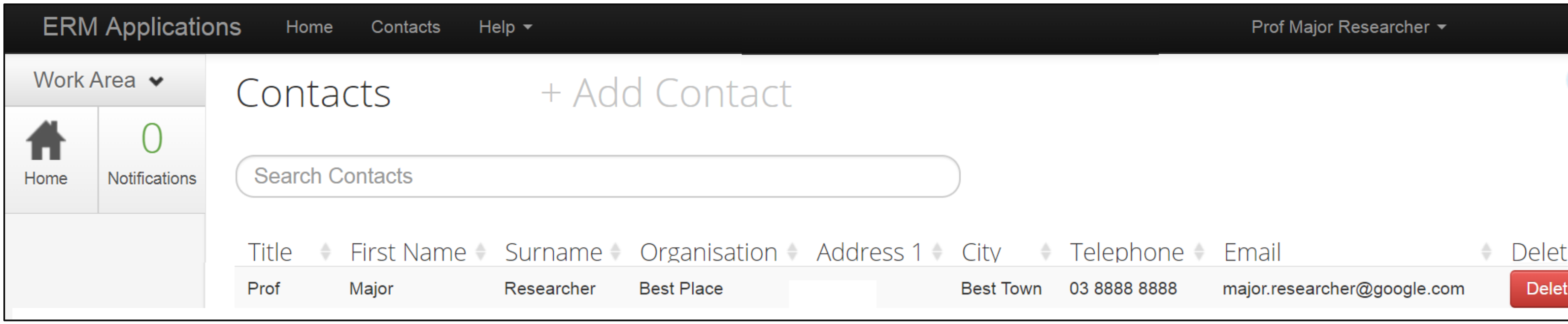
Projects (either created by or shared to this account)

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

Work Area explained



Contacts



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

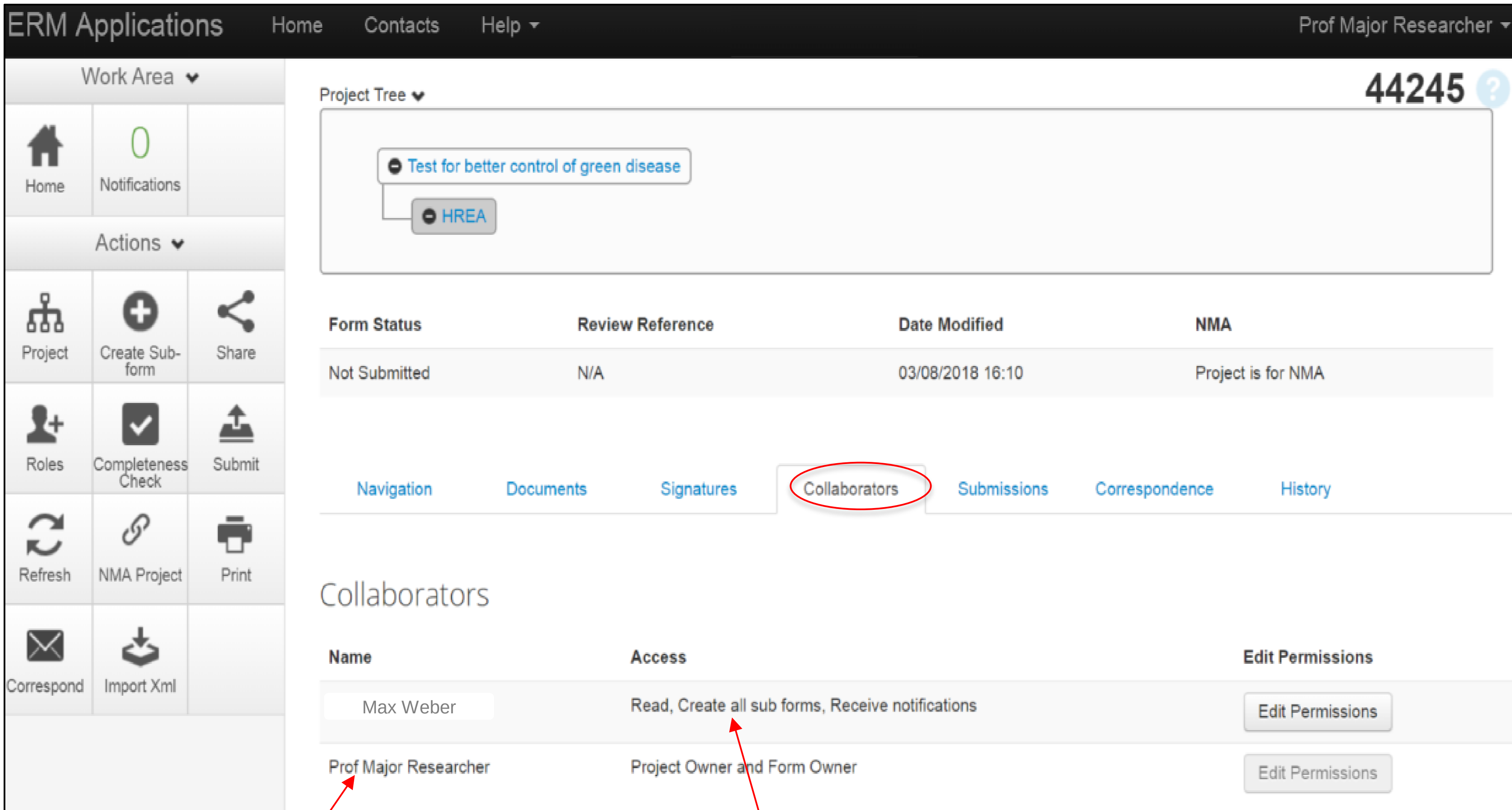
ERM gives the form owner the option to make the contents of the form available to others (e.g. sponsors or colleagues).

Allocate **<u>Role</u>** 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)

<u>Permanent</u> transfer of project to another user.
E.g. Sponsor creates HREA but then transfers it to the CPI.
CPI (form owner) manages it thereafter

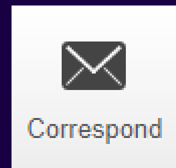
Use the ‘Collaborator’ tab to view all collaborators on the highlighted form

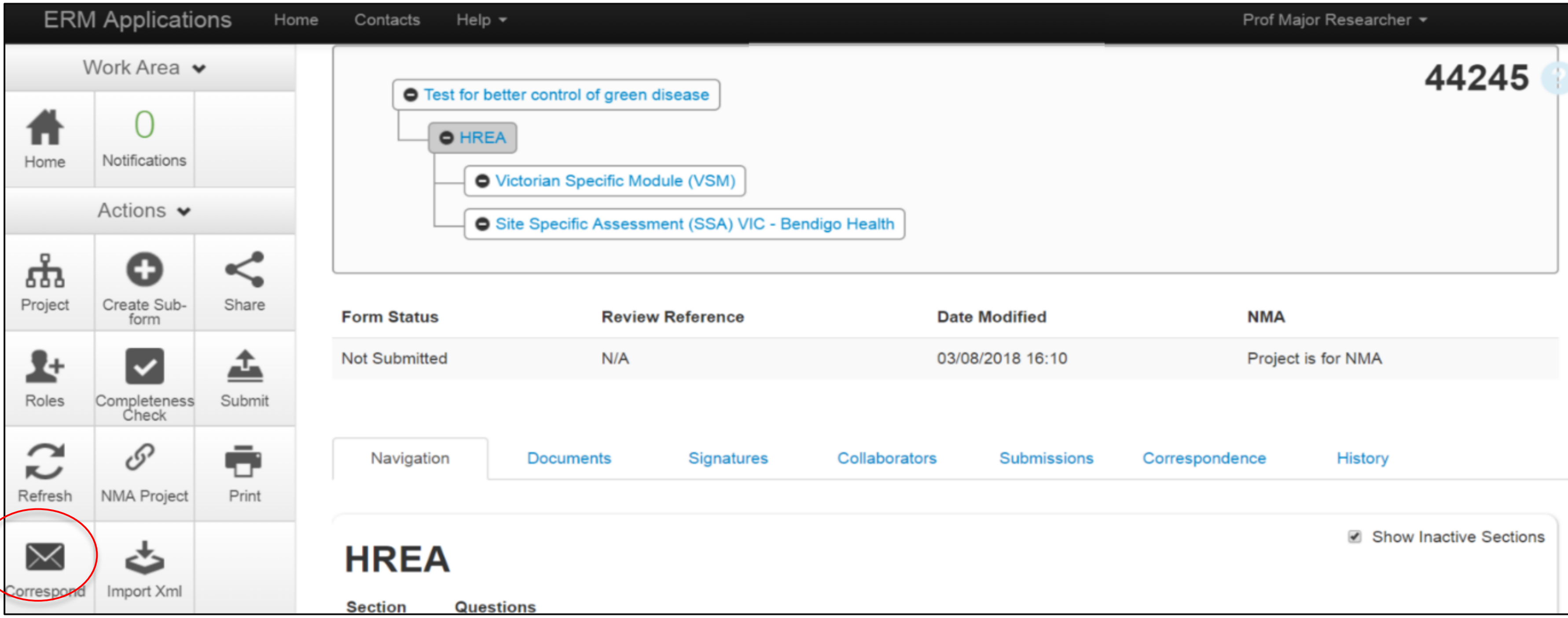


Project owner

Collaborator

Correspondence





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

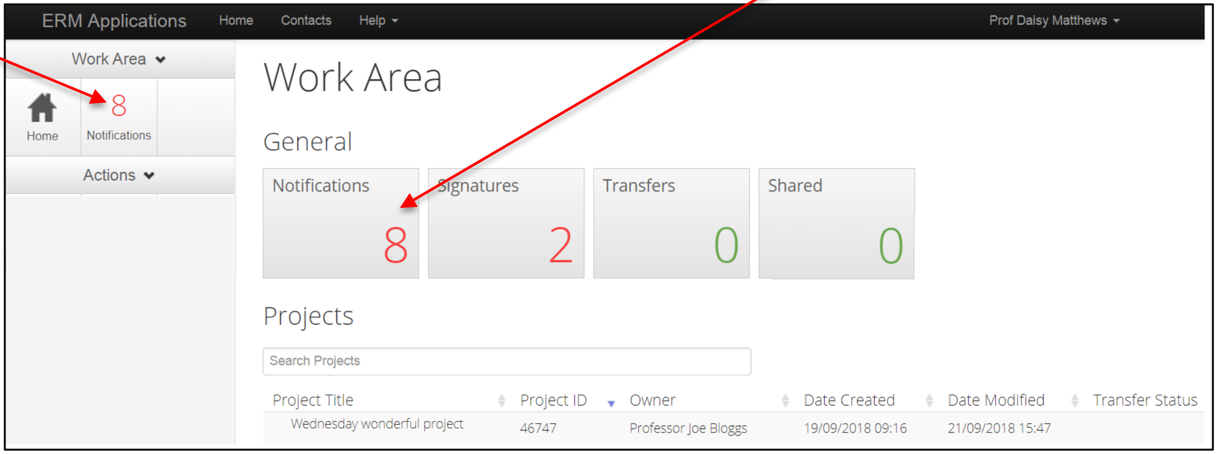
Tip : the research office must be selected before correspondence is initiated.

Notifications

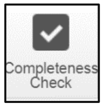
An ERM user is notified when there is:

- 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.



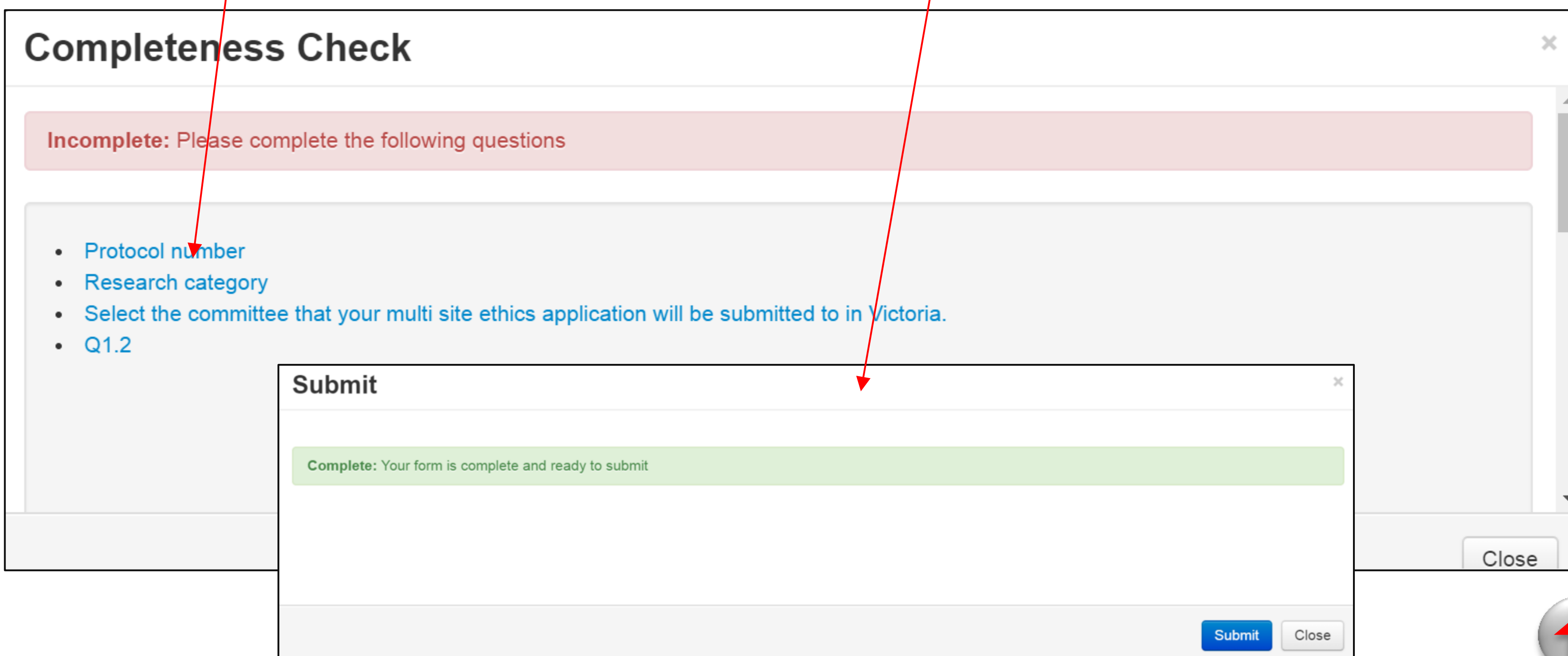
Completeness check



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



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.

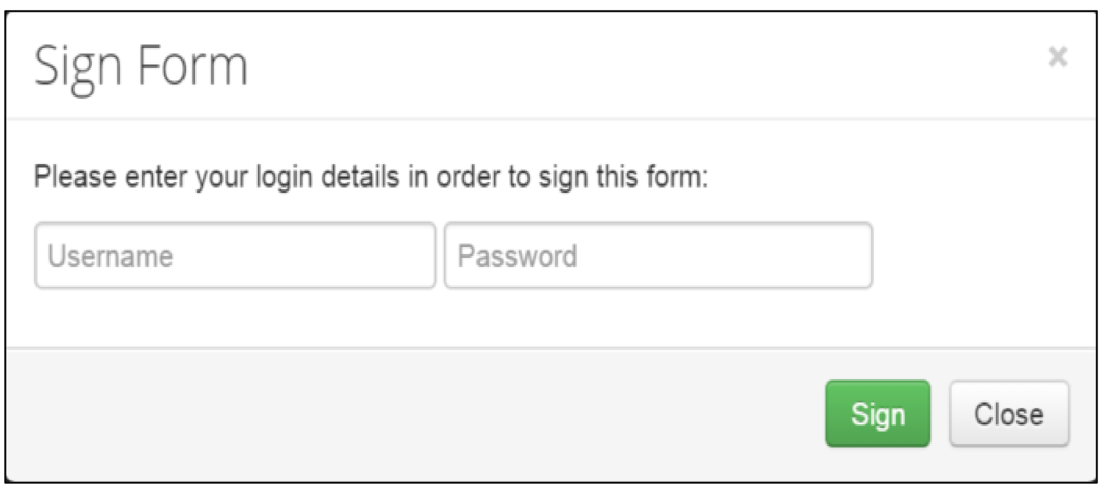
Note : Signatories must have a ERM account to provide an electronic signature

Signatures : Signatory

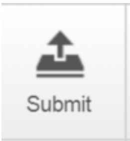
Signatory advised by email that a notification has been received.

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.



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

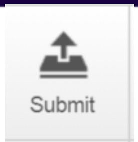
Research office may request further information

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

Form owner addresses review queries.

Submission and review process

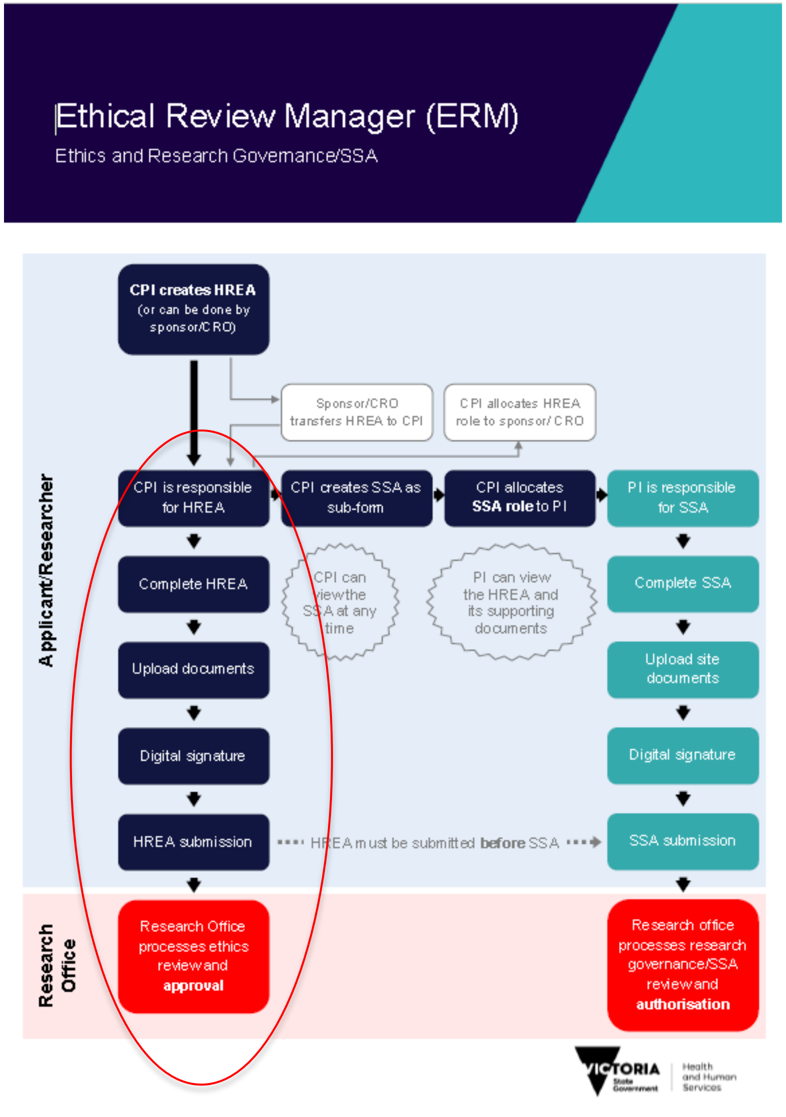
Amended form is submitted to the research office, using the 'Submit' button from the Actions panel



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



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).

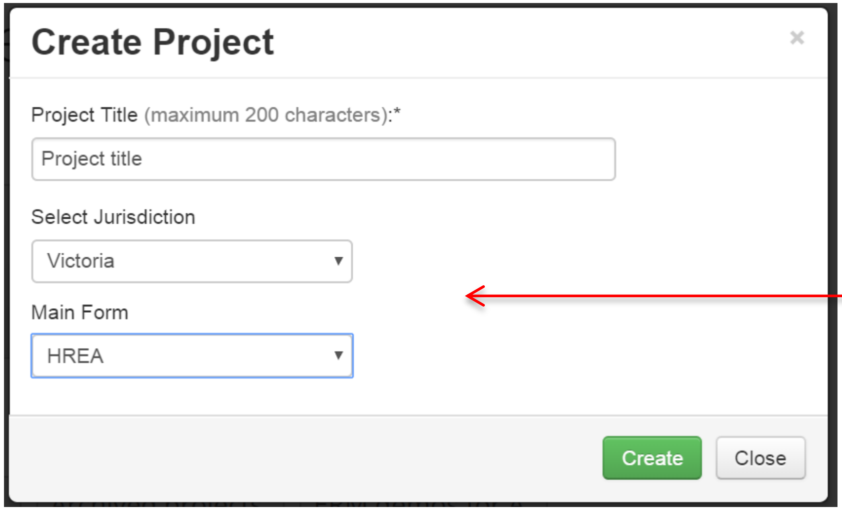
We will first look at the ethics process.

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.

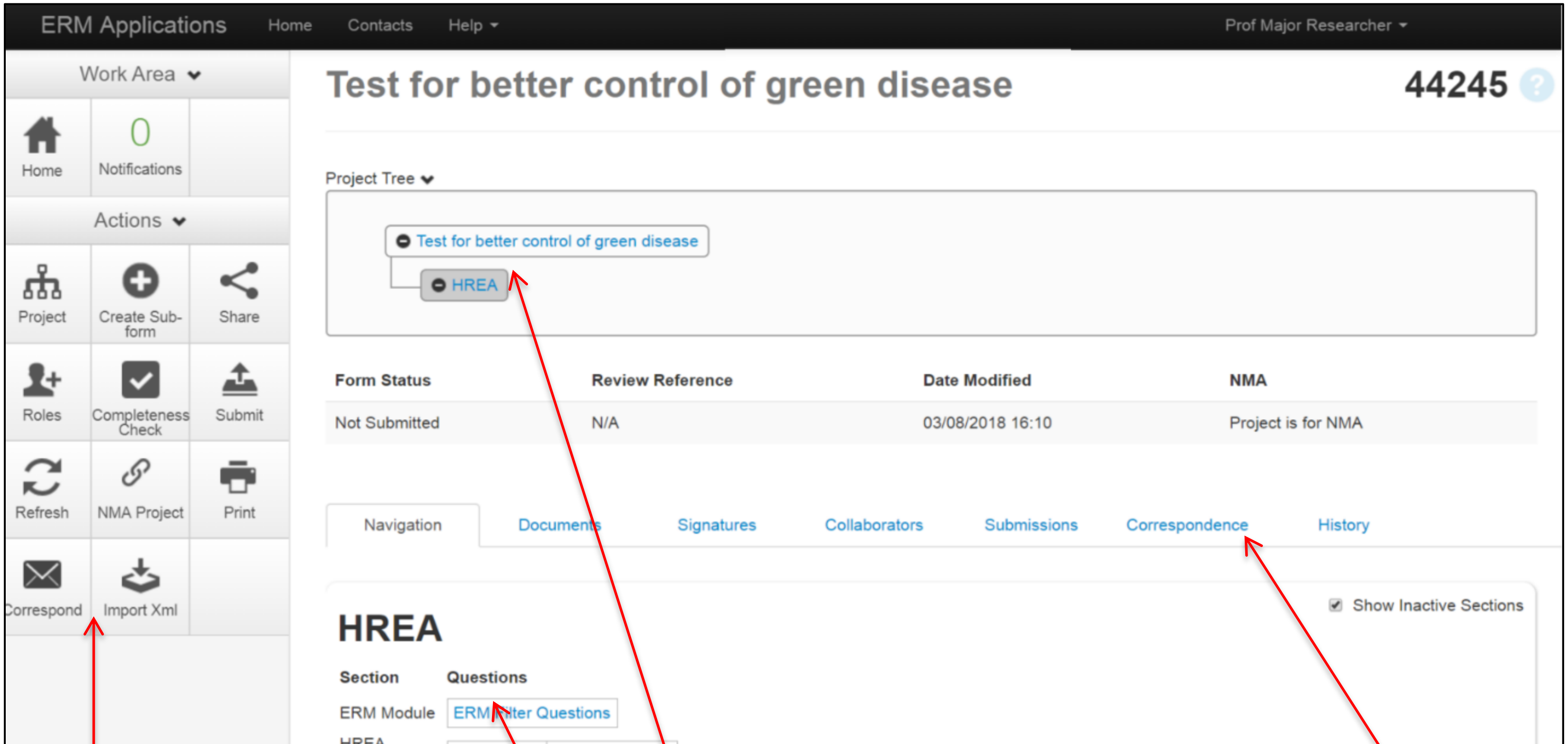
Enter project title and jurisdiction (Victoria) and a main form.



The available main forms are: :

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

Main form screen



Project tree

Function tabs

Actions

HREA form

Complete the HREA Form

Using the ERM functions previously discussed, the form owner:

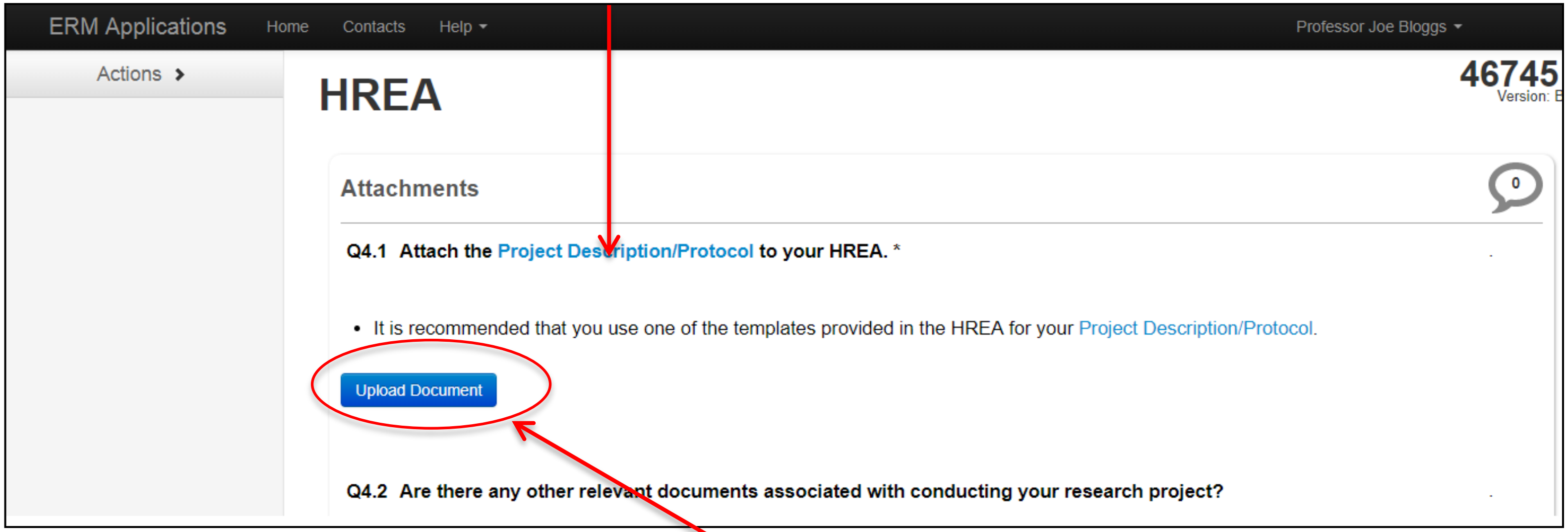
- Completes the form
  - (*Note: The Filter section and Acknowledgement of the HREA <u>must</u> be completed before continuing with the rest of the application*.)
- Chooses collaborators
- Checks for completeness
- Adds documents
- Acquires signatures
  - (*Note: Form is now finalised or locked)*

Add documents

Upload Document

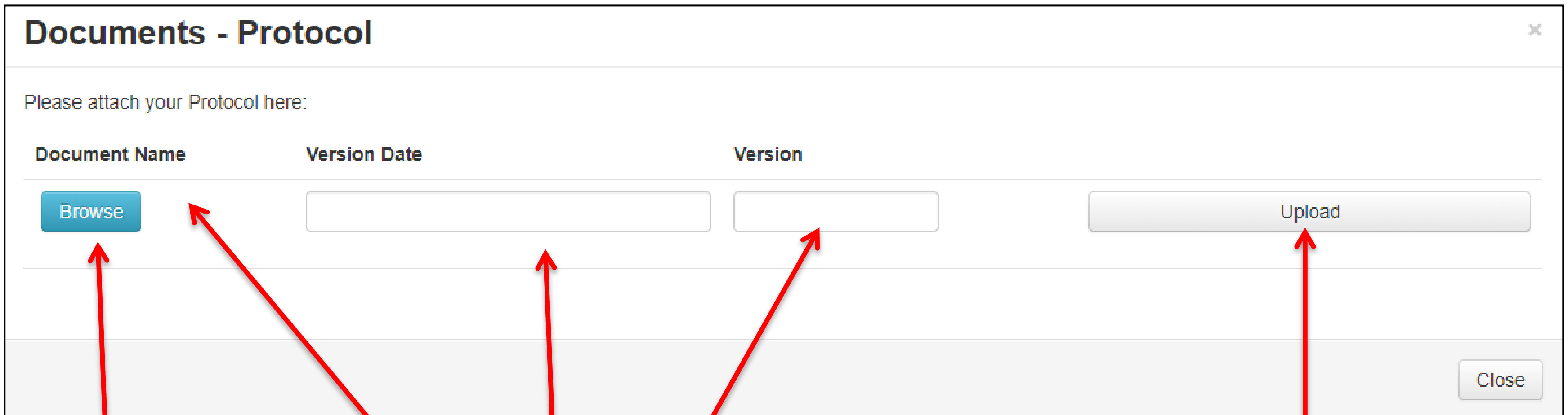
Specific documents are added to designated questions within a form.

In this example, the protocol is to be uploaded.



Selecting the ‘Upload Document’ icon raises a pop up form .

Document pop up form

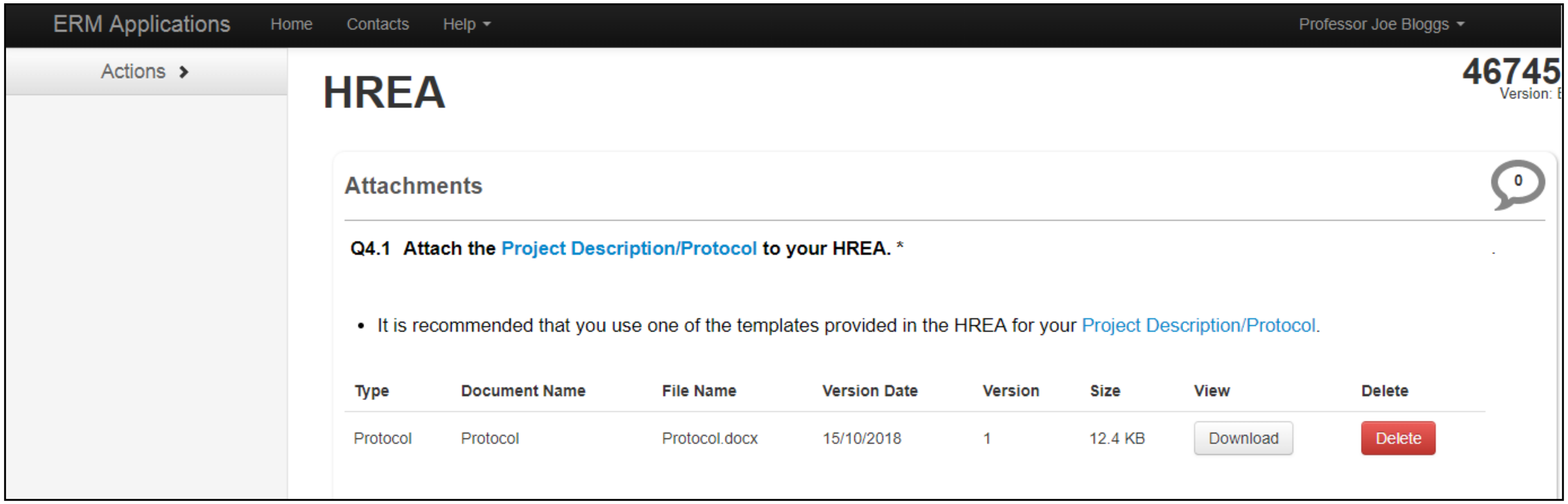


Locate the document

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

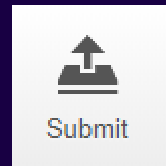


The document is now embedded in the form and can be downloaded from the form and the ‘Documents’ function tab.

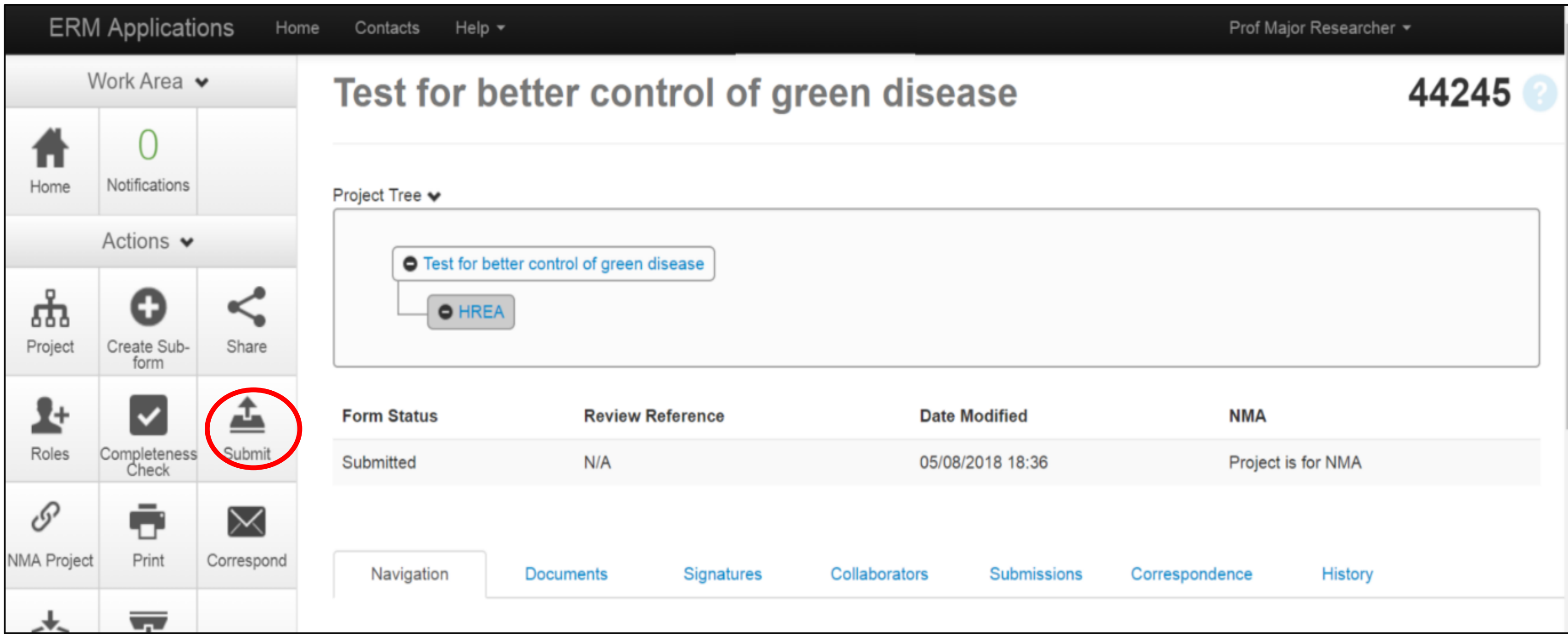
More than one document of the same type may be added (e.g. a PICF for the main study and another for a sub study).

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

Submission

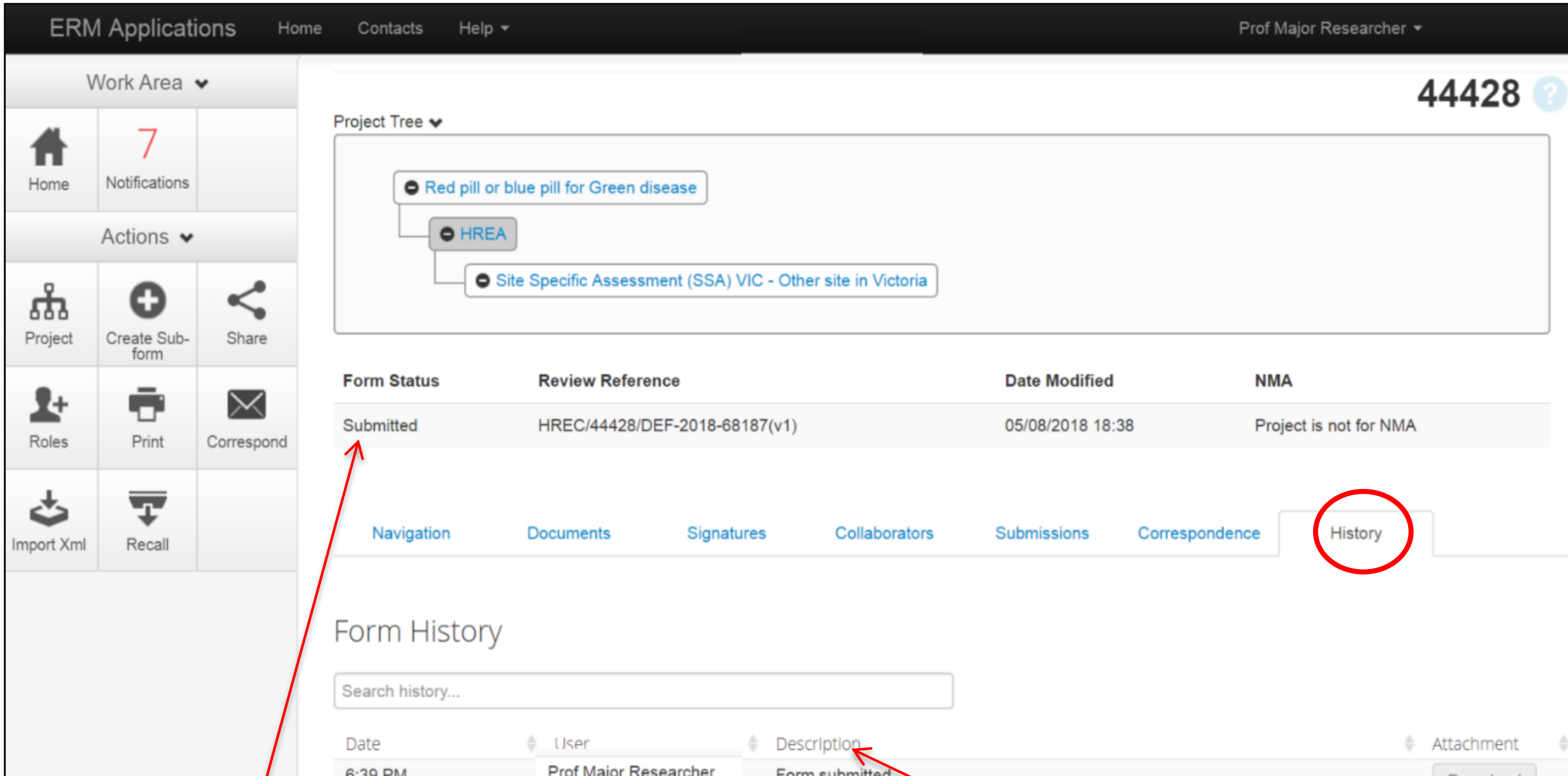


The form owner selects the ‘Submit’ button from the Action Pane.



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



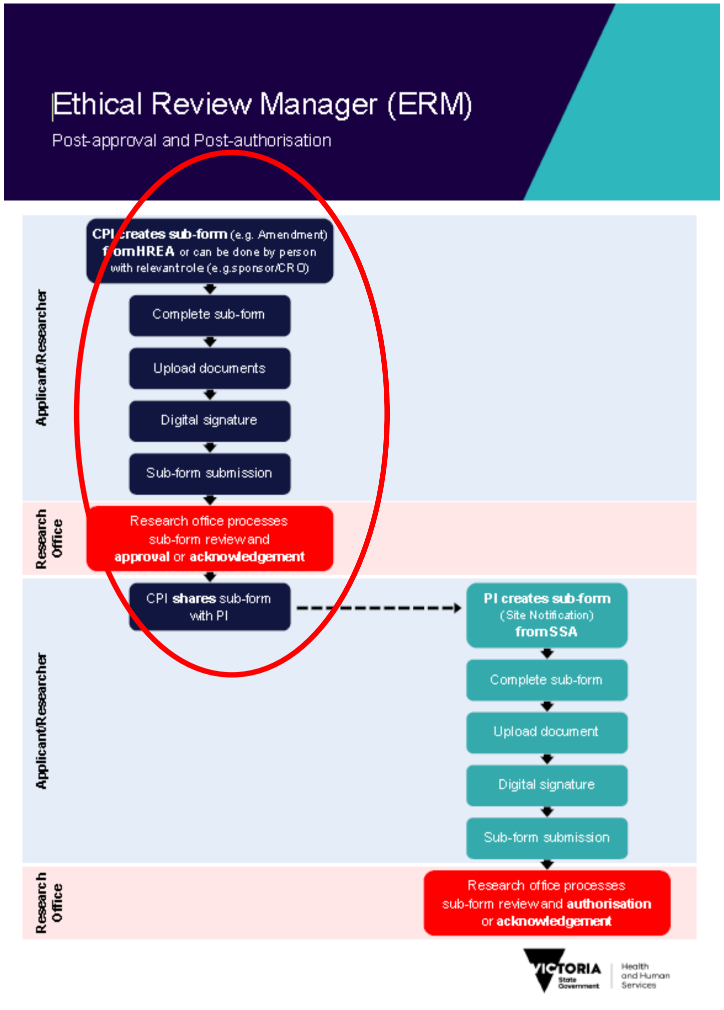
Change of form status

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)



Congratulations! Your project is approved!

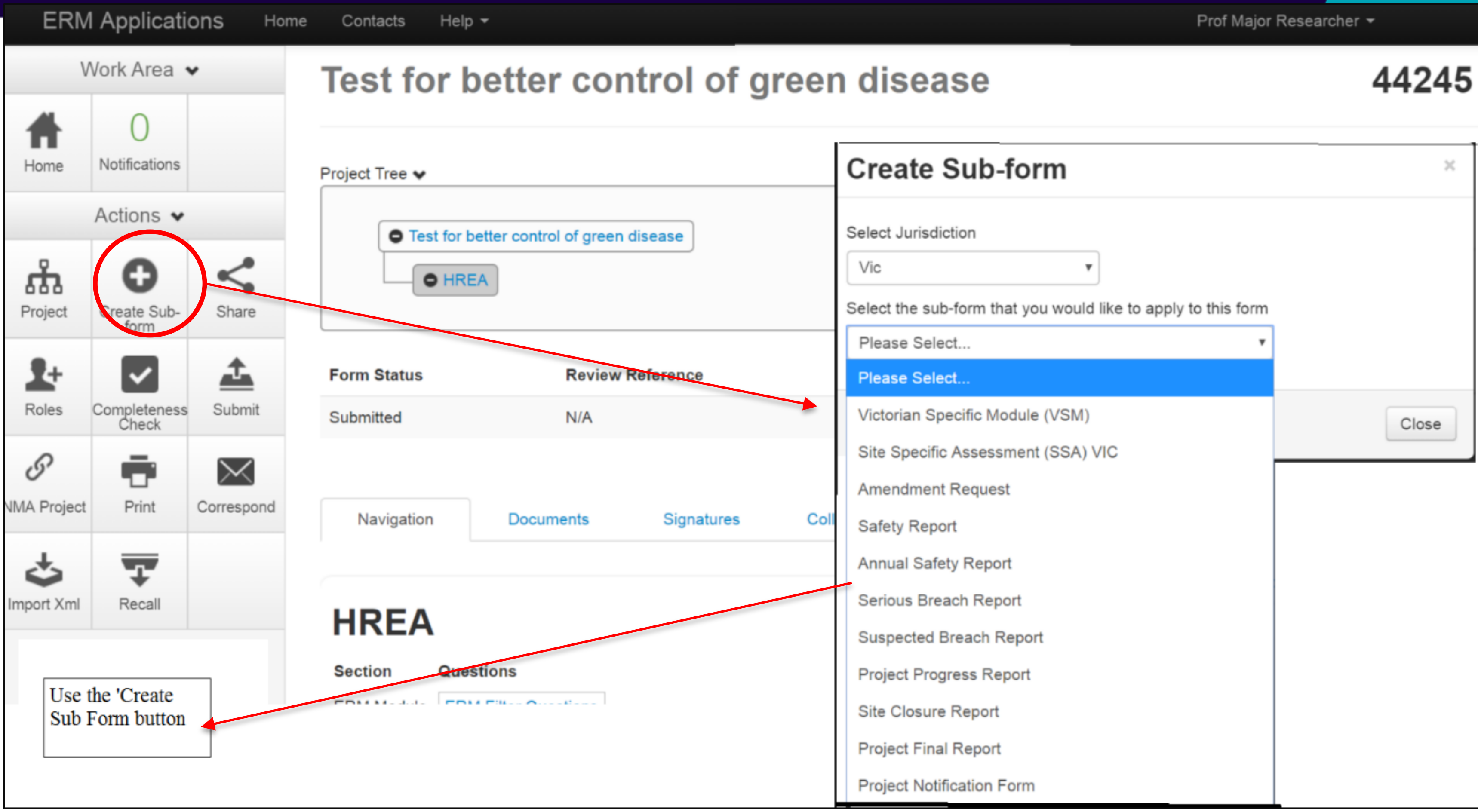
The Human Research Ethics Application (HREA) is now an “anchor” for the project to allow creation of post approval sub forms:

- 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



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

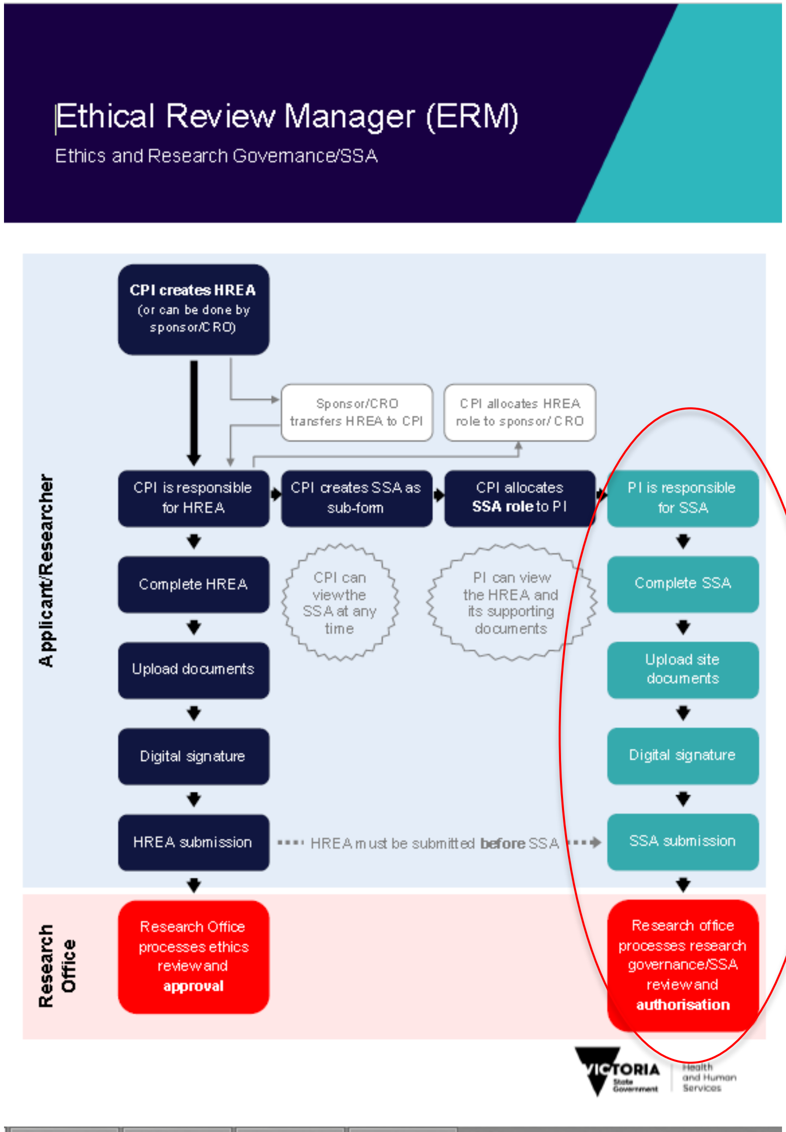
- Sub form is submitted to research office for review
- Reviewer may request further information
- Sub form owner responds to queries and submits updated sub form to research office
- Application from research office returned with a decision

Site Specific Application (SSA)

The SSA is a **<u>sub form</u>** of the HREA.

The HREA and SSA forms are linked electronically.

SSA initial application



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.

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

1

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

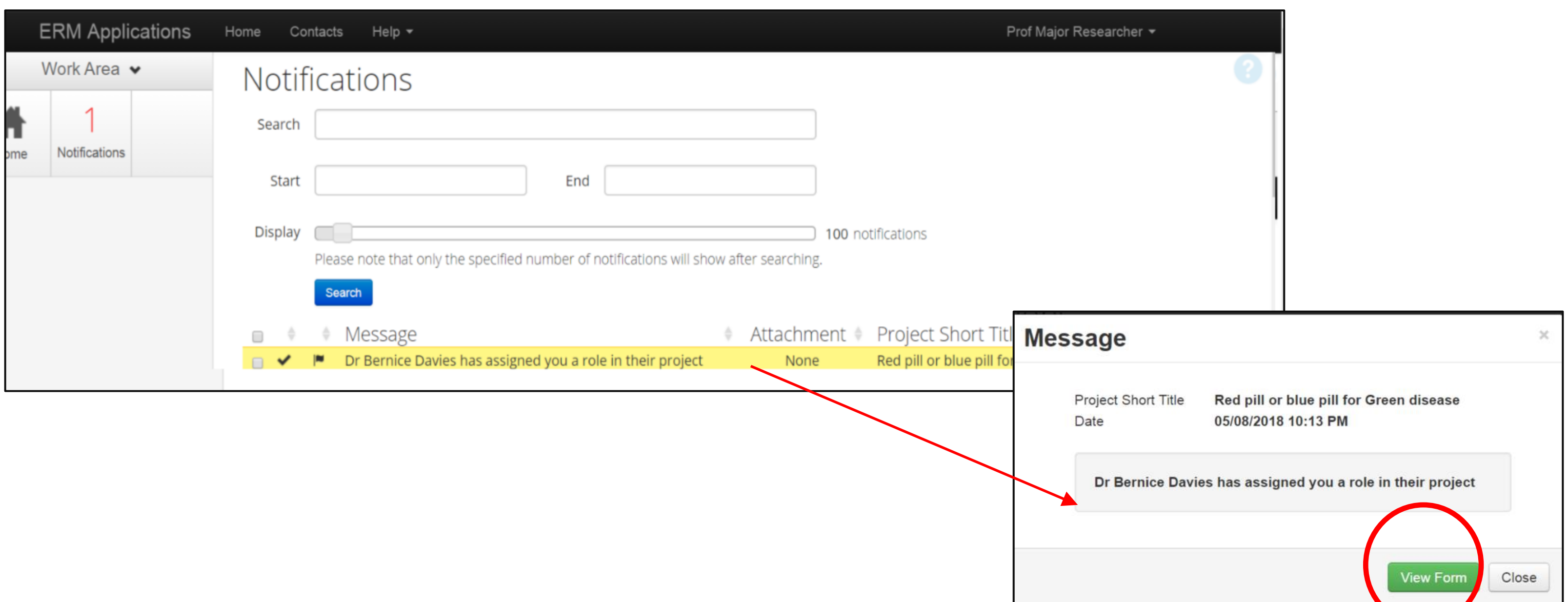
3

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

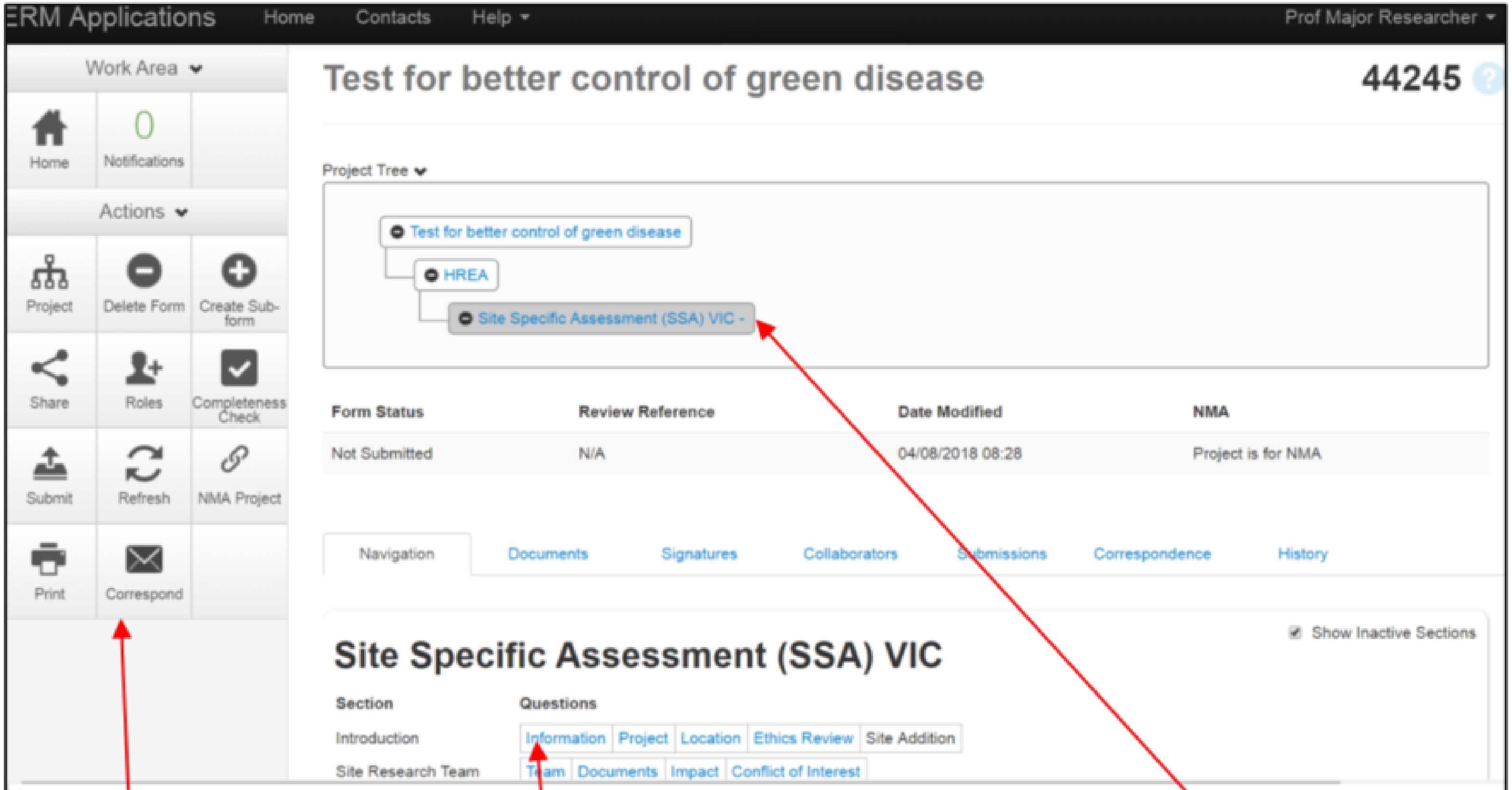
2) Accept the SSA from the HREA owner

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

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



The SSA screen is similar to the HREA screen



Available actions

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

Project tree includes the HREA and the SSA

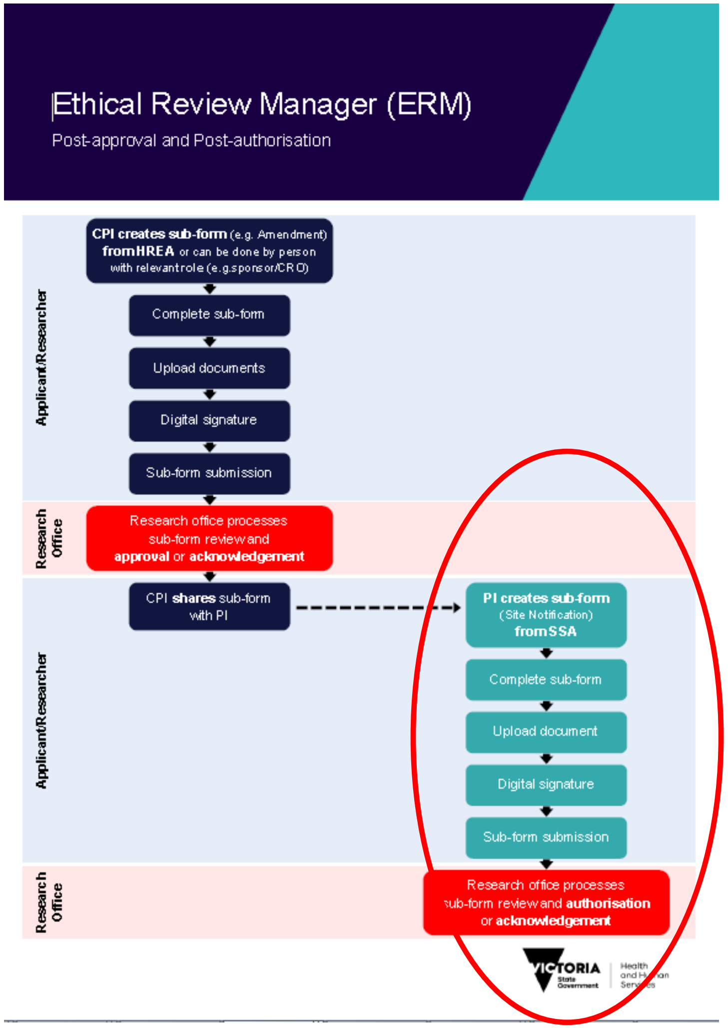
SSA processes (Completion and submission)

- 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



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:

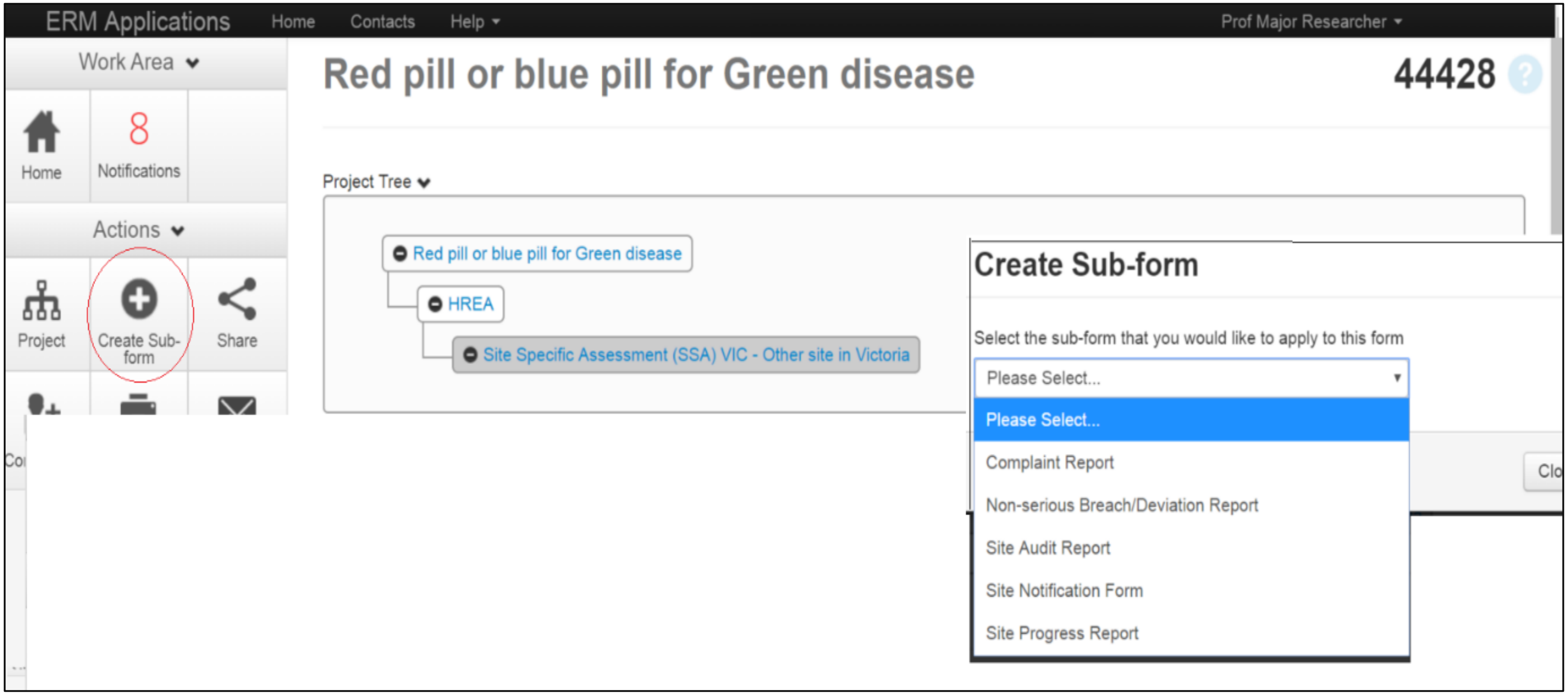
- Complaint report
- Non serious breach/ deviation report
- Site audit report
- Site notification form
- Site progress report

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



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:

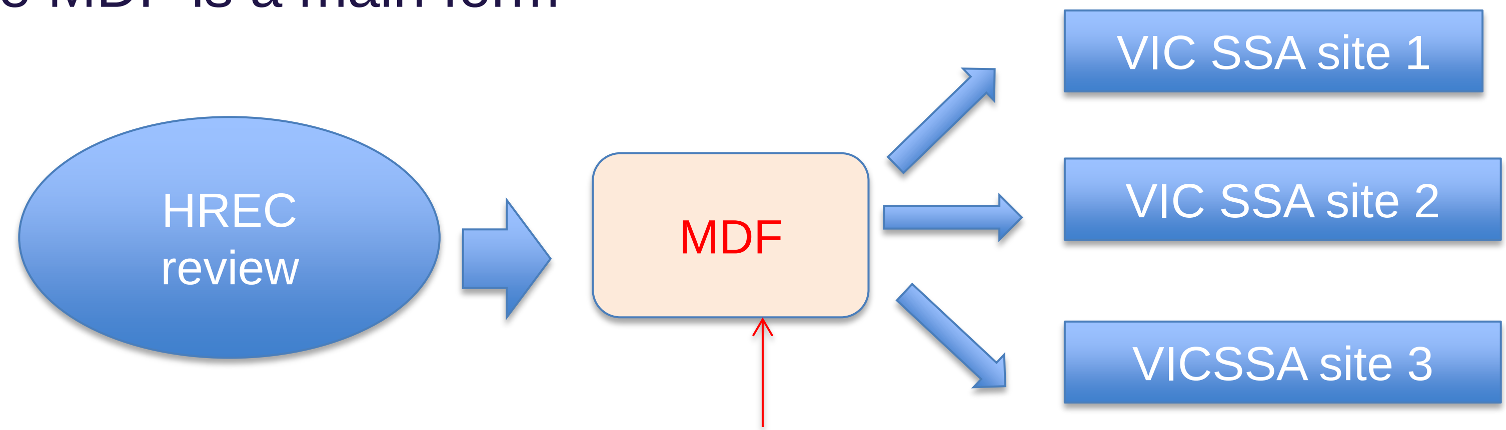
- Print the VSM and save it as a PDF.
- Open the HREA, upload the V

M 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