


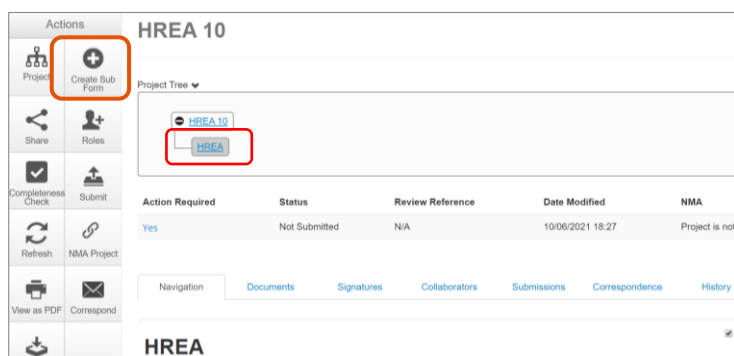
Victorian Specific Module (VSM) in ERM

For each research project that utilises the Human Research Ethics Application (HREA) form and has a site in Victoria, the **Victorian Specific Module (VSM) must be completed and submitted to the reviewing Human Research Ethics Committee (HREC)** as part of the ethics application.

The VSM is mandatory when the HREA is used. It addresses Victorian legislative requirements.

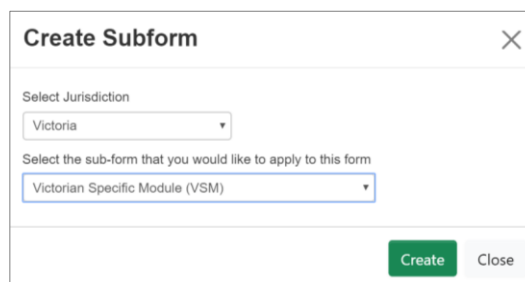
Instructions for Applicants

1. In ERM, select **Create Project**  and choose Main Form = HREA.
2. Create the Victorian Specific Module (VSM) as a sub-form of the HREA.



The screenshot shows the ERM interface for a project named 'HREA 10'. In the 'Actions' panel on the left, the 'Create Sub Form' button is highlighted with a red box. In the 'Project Tree' on the right, the 'HREA' sub-form 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	10/06/2021 18:27	Project is not



The 'Create Subform' dialog box is shown with a red arrow pointing from the 'Create Sub Form' button in the previous screenshot. The 'Select Jurisdiction' dropdown is set to 'Victoria'. The 'Select the sub-form that you would like to apply to this form' dropdown is set to 'Victorian Specific Module (VSM)'. There are 'Create' and 'Close' buttons at the bottom right.

3. Complete all applicable sections of the VSM form.

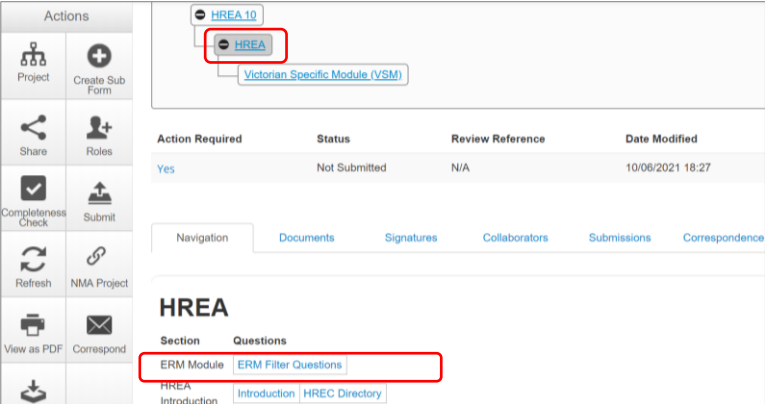


The screenshot shows the ERM interface for a project named 'HREA 10'. In the 'Project Tree' on the right, the 'Victorian Specific Module (VSM)' sub-form is highlighted with a red box. Below the project tree is a table with the following data:

Action Required	Status	Review Reference	Date Modified
Yes	Not Submitted	N/A	14/06/2021 17:29

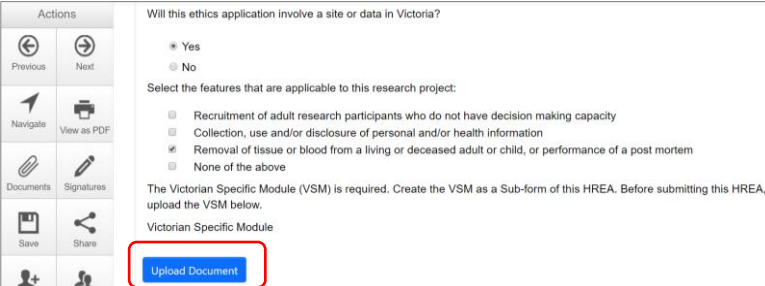
4. In the VSM, select **View as PDF**  This generates a PDF which can be saved to your local drive.

5. Return to the HREA and go to the pre-HREA section **ERM Module**.




The screenshot shows the HREA interface. On the left is an 'Actions' sidebar with icons for Project, Create Sub Form, Share, Roles, Completeness Check, Submit, Refresh, NMA Project, View as PDF, and Correspond. The main area shows a tree view with 'HREA 10' expanded to show 'HREA' and 'Victorian Specific Module (VSM)'. Below this is a table with columns: Action Required, Status, Review Reference, and Date Modified. The table contains one row: Yes, Not Submitted, N/A, 10/06/2021 18:27. Below the table are tabs for Navigation, Documents, Signatures, Collaborators, Submissions, and Correspondence. The 'HREA' section is active, showing 'Section' and 'Questions' tabs. Under 'Section', 'ERM Module' and 'ERM Filter Questions' are listed, with 'ERM Module' highlighted by a red box. Under 'Questions', 'HREA Introduction' and 'HREC Directory' are listed.

6. Upload the PDF of the VSM.



The screenshot shows a form titled 'Will this ethics application involve a site or data in Victoria?'. It has radio buttons for 'Yes' and 'No'. Below this is a section 'Select the features that are applicable to this research project:' with checkboxes for 'Recruitment of adult research participants who do not have decision making capacity', 'Collection, use and/or disclosure of personal and/or health information', 'Removal of tissue or blood from a living or deceased adult or child, or performance of a post mortem', and 'None of the above'. The 'Removal of tissue...' checkbox is checked. Below this is a text box: '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.' Underneath is a section 'Victorian Specific Module' with an 'Upload Document' button highlighted by a red box.

7. When the HREA is complete, all its supporting documents have been uploaded (including the VSM) and electronic signature(s) have been applied, **Submit**  the HREA.

8. Highlight the VSM form in the project tree and **Submit**  the VSM.

It is important to **complete steps 1-8** as:

- Uploading the VSM (step 6 above) means that it is a **supporting document** for the HREA. All supporting documents are visible for the research governance/SSA application(s) associated with the HREA. This is of particular importance for a multi-site project.
- Submitting the VSM (step 8 above) allows the Research Office and HREC to have direct access to the data within the VSM. This assists the HREC to fulfil their requirements under Victorian legislation.

Information for Research Offices

If the applicant has completed steps 6-8 above, the VSM appears in your ERM account as **both** an ethics sub-form of the HREA **and** a supporting document for the HREA.

It is important for the VSM to be in two places:

1. **The VSM being a sub-form of the HREA** means that all of the data in the VSM form is reportable. The data can be used to compile the annual report to the Victorian Health Complaints Commissioner.

Work Area >

Actions

0 Farm Submissions | 2 Project Submissions | 0 Panel Comments

0 Farm Comments | NMA Setting | Role Conflict

Validate | View | Query

Withdraw

Project Title: The Fun Project
Form Reference: HREA
Review Reference: HREC/43755/VICTEST-2018-67490(v1)

Project Id:	43755	Applicant Name:	Ms Abigail Cooper
Current Committee:	VICTest1	Current Status:	Submitted
Application Type:	Ethics Application	Meeting:	Unassigned
Clock Status:	None	Assigned Reviewers:	None
Conflicted Users:	None		

Timeline | **Project** | Documents | Data | Contacts | Correspondence

- The Fun Project
 - HREA
 - Victorian Specific Module (VSM)**
 - Site Specific Assessment (SSA) VIC -

2. **The VSM being a supporting document for the HREA** means that, for research governance/SSA, the VSM is visible as an ethics supporting document (this is of particular importance for sites in a multi-site project).

Work Area >

Actions

0 Farm Submissions | 2 Project Submissions | 0 Panel Comments

0 Farm Comments | NMA Setting | Role Conflict

Validate | View | Query

Withdraw

Project Title: The Fun Project
Form Reference: HREA
Review Reference: HREC/43755/VICTEST-2018-67490(v1)

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Conflicted Users:	None		

Timeline | Project | **Documents** | Data | Contacts | Correspondence

Form Documents

Type	Document Name	File Name	Version Date	Version	Size	View	Archived
Victorian specific module (VSM)	VSM	VSM.pdf	23/07/2018	1	478.8 KB	Download	
Protocol	Protocol	Protocol.docx	10/07/2018	1.3	12.4 KB	Download	
Participant information and consent form	PICF v2	PICF v2.docx	02/07/2018	2	12.5 KB	Download	

Authorised by the Coordinating Office for Clinical Trial Research

Department of Jobs, Precincts and Regions
121 Exhibition Street Melbourne Victoria 3000
Telephone 0408 274 054

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This document is also available in an accessible format at multisite.ethics@ecodev.vic.gov.au