

Victorian Specific Module (VSM) in ERM

OFFICIAL

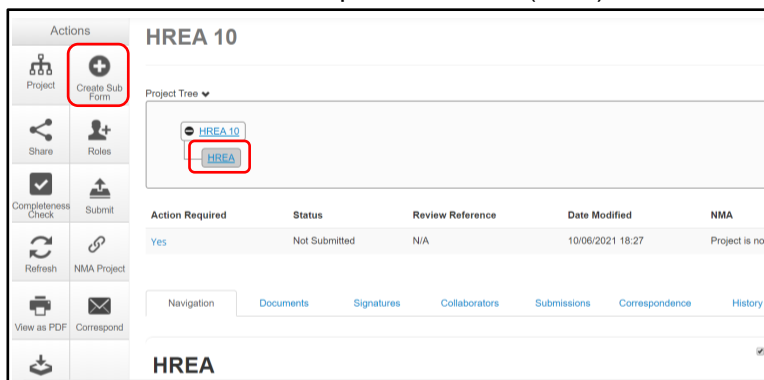
For each research project that utilises the Human Research Ethics Application (HREA) form and has a site in Victoria, the **Victorian Specific Module (VSM) must be completed and submitted to the reviewing Human Research Ethics Committee (HREC)** as part of the ethics application.

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

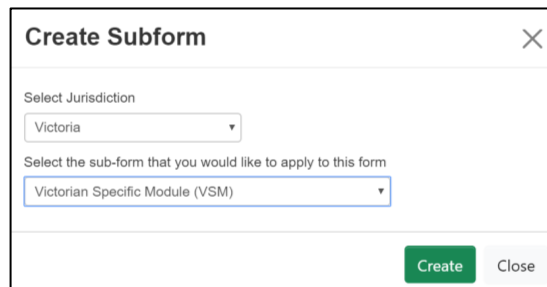
Instructions for Applicants

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.



Action Required	Status	Review Reference	Date Modified	NMA
Yes	Not Submitted	N/A	10/06/2021 18:27	Project is not



Create Subform


Select Jurisdiction
Victoria

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


Create Close

3. Complete all applicable sections of the VSM form.

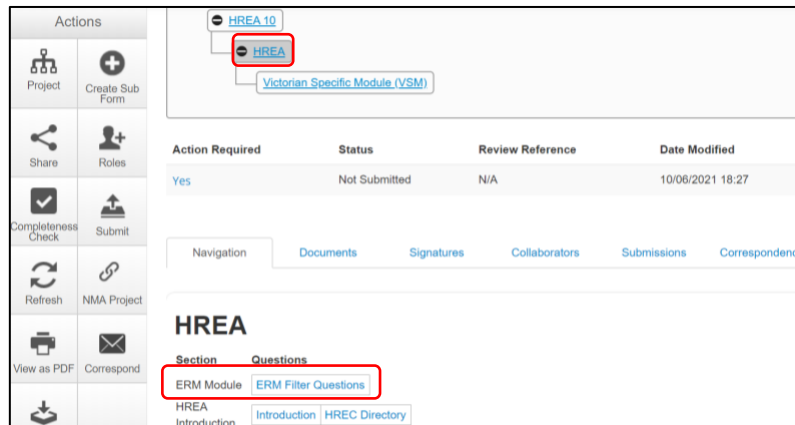
Victorian Specific Module (VSM) in ERM



The screenshot shows the ERM interface for a project named 'HREA 10'. On the left, there is a sidebar with various actions like Project, Duplicate Form, Delete Form, Share, Transfer Form, Completeness Check, Submit, Refresh, NMA Project, and View as PDF. The main area displays a 'Project Tree' with a hierarchy: HREA 10 > HREA > Victorian Specific Module (VSM). Below the tree is a table with columns: Action Required, Status, Review Reference, and Date Modified. The table contains one row: Action Required: Yes, Status: Not Submitted, Review Reference: N/A, Date Modified: 14/06/2021 17:29. At the bottom, there are navigation tabs: Navigation, Documents, Signatures, Collaborators, Submissions, and Correspondence.

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 ERM interface for a project named 'HREA'. The 'Project Tree' shows a hierarchy: HREA 10 > HREA > Victorian Specific Module (VSM). Below the tree is a table with columns: Action Required, Status, Review Reference, and Date Modified. The table contains one row: Action Required: Yes, Status: Not Submitted, Review Reference: N/A, Date Modified: 10/06/2021 18:27. Below the table are navigation tabs: Navigation, Documents, Signatures, Collaborators, Submissions, and Correspondence. The main area displays the 'HREA' section with a sub-section 'ERM Module' highlighted. Below the section are links for 'Introduction' and 'HREC Directory'.

6. Upload the PDF of the VSM.



The screenshot shows the ERM interface for a project named 'HREA'. The main area displays the 'Victorian Specific Module' form. The form contains a question: 'Will this ethics application involve a site or data in Victoria?' with radio buttons for 'Yes' and 'No'. Below the question is a section titled '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'. Below the checkboxes is a note: '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.' Below the note is a section titled 'Victorian Specific Module' with a blue 'Upload Document' button highlighted.

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:

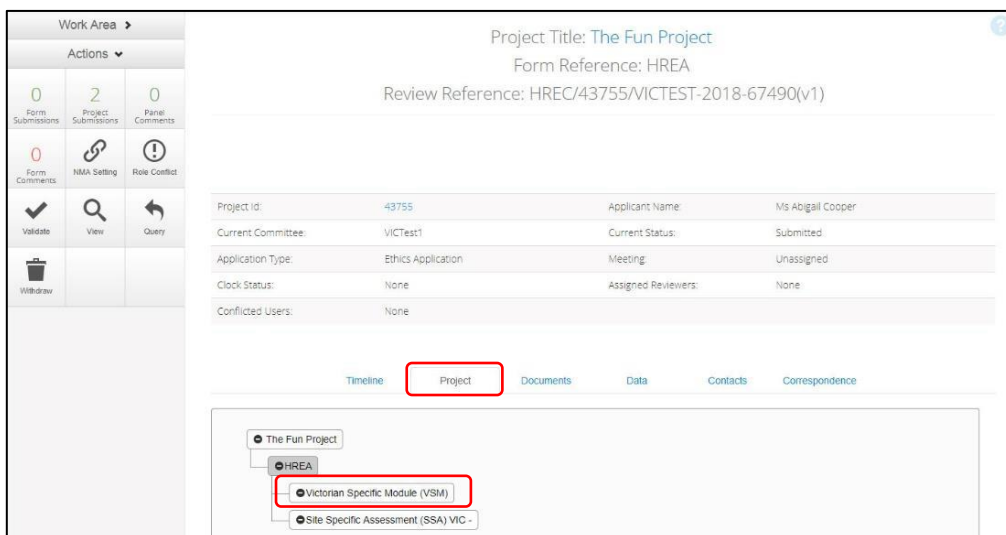
9. Uploading the VSM (step 6 above) means that it is a **supporting document** for the HREA. All supporting documents are visible for the research governance/SSA application(s) associated with the HREA. This is of particular importance for a multi-site project.
10. Submitting the VSM (step 8 above) allows 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

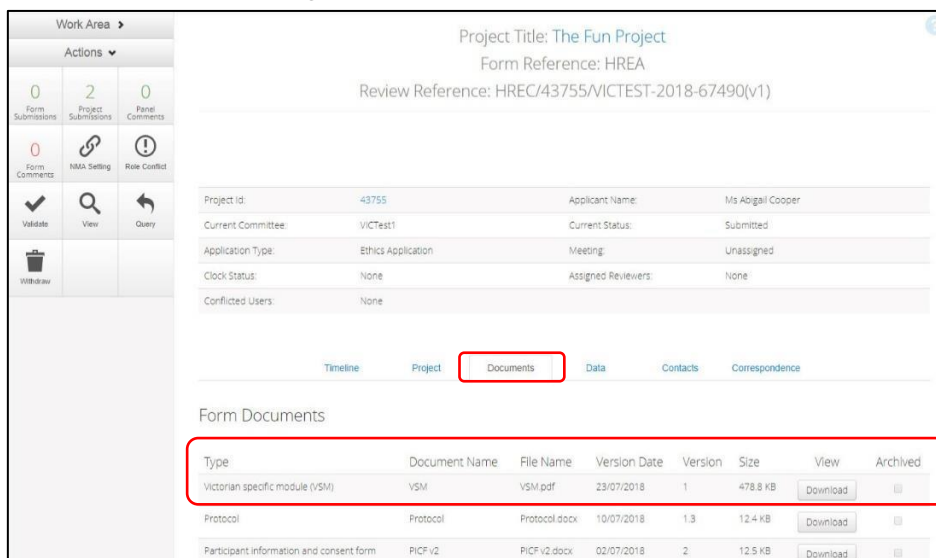
If the applicant has completed steps 6-8 above, the VSM appears in your ERM account as **both** an ethics sub-form of the HREA **and** a supporting document for the HREA.

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.



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).



To receive this document in another format, phone 0408 274 054, using the National Relay Service 13 36 77 if required, or [email Coordinating Office for Clinical Trial Research <multisite.ethics@health.vic.gov.au>](mailto:multisite.ethics@health.vic.gov.au).

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