

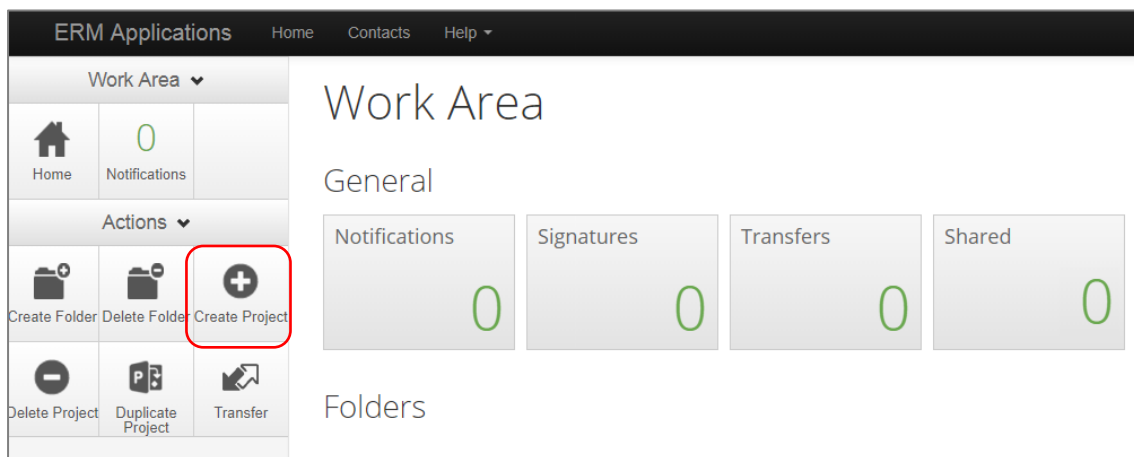
Create a Human Research Ethics Application (HREA) in ERM

Study Set Up: Create a HREA in ERM

To access ERM, login using your ERM email address and password - <https://au.forms.ethicalreviewmanager.com/>

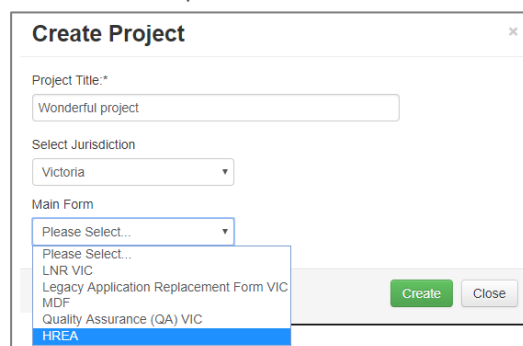
Steps

1. Select **Create Project**



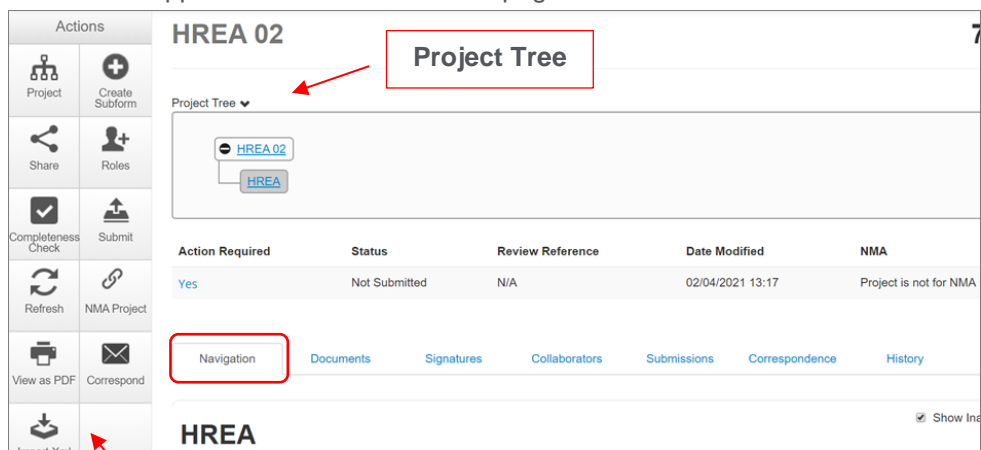
2. In the Create Project pop-up textbox:

- Enter the Project Title
- Select the jurisdiction where the application will be reviewed
- Select HREA from the Main Form options and select the **Create** button

A screenshot of the "Create Project" pop-up form. It has a title bar with "Create Project" and a close button. The form contains three sections: "Project Title:" with a text input field containing "Wonderful project"; "Select Jurisdiction" with a dropdown menu showing "Victoria"; and "Main Form" with a dropdown menu showing "Please Select...". A list of options is visible below the "Main Form" dropdown: "Please Select...", "LNR VIC", "Legacy Application Replacement Form VIC", "MDF", "Quality Assurance (QA) VIC", and "HREA" (highlighted in blue). At the bottom right of the form are "Create" and "Close" buttons.

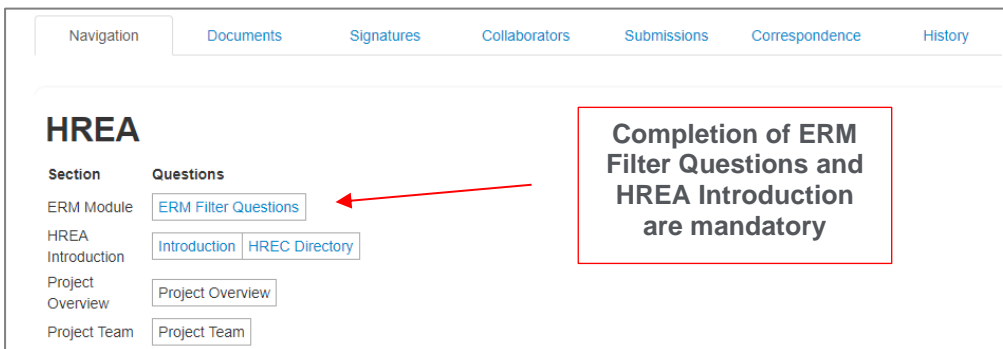
3. ERM opens the project in the Form Management Screen. The Project Tree will display the newly created project and HREA.

- Under the Navigation tab, enter information into the HREA form. There are seven tabs available. See **Tab Functions** table below & Applicant User Guide to ERM page 15.



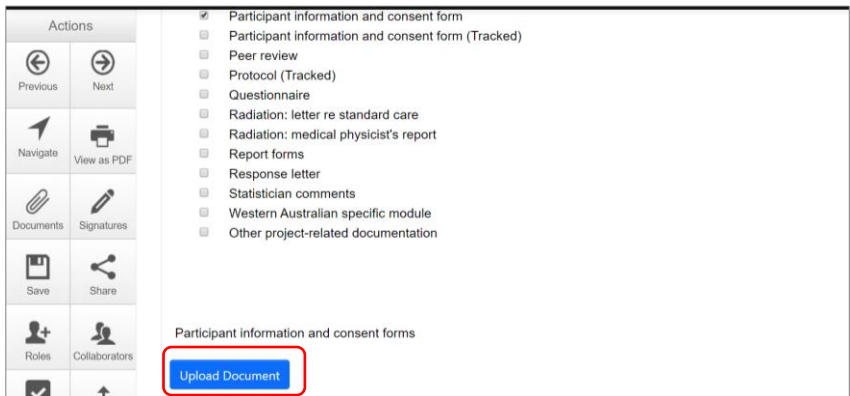
Actions pane displays the actions available from this screen

- Completion of the ERM Filter Questions and HREA Introduction are mandatory.



Completion of ERM Filter Questions and HREA Introduction are mandatory

- If the project involves a site in Victoria, a Victorian Specific Module (VSM) is required. See Section 6: Victorian Specific Module of the Applicant User Guide to ERM for more information.
- In Section1 Core Information page of the HREA, select the Acknowledge and Continue button located at the bottom of the page to open the rest of the HREA to complete the application. Continue to complete the form.
- Supporting documents e.g. protocol / PICF are uploaded in **Section 4** of the HREA. Press **Upload Document** button to raise a pop up to attach the selected document.



Documents - Participant information and consent form

Please attach your Participant information and consent form here:

Document Name	Version Date	Version
PICF main <input type="button" value="Browse"/>	01/05/2019	1

PICF main.docx

Attach the supporting document from your local drive

9. Once the HREA has been completed and all supporting documents have been uploaded, the HREA can be signed by the CPI/Researcher. There are three signature methods available. Electronic signatures are applied last. See page 26 of the Applicant User Guide to ERM for further information.

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

Tab Functions

Tab	Explanation
Navigation	The HREA is completed under the Navigation tab
Documents	Displays all supporting documents that have been uploaded within the HREA 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 HREA, and all signature requests
Collaborators	Displays members of the research team with access to the HREA; levels of access can be modified
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 HREA has been submitted, an archived version of the submission is available here.

Authorised by the Coordinating Office for Clinical Trial Research

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