# Create a Human Research Ethics Application (HREA) in ERM



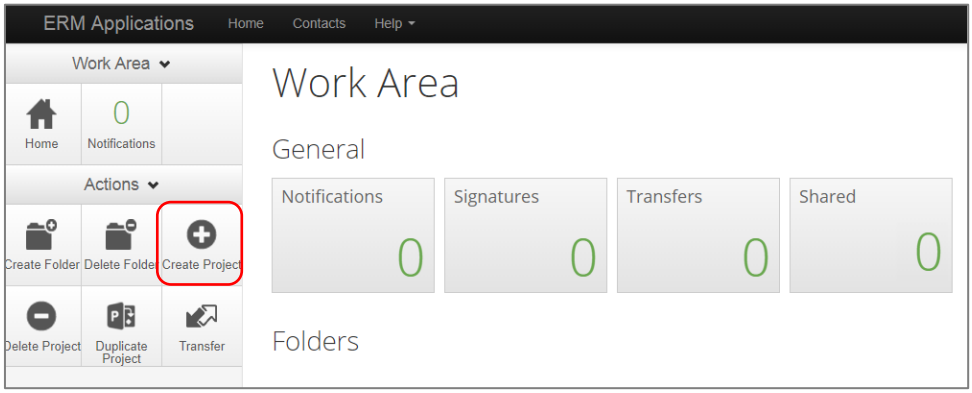
## Study Set Up:  Create a HREA in ERM

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

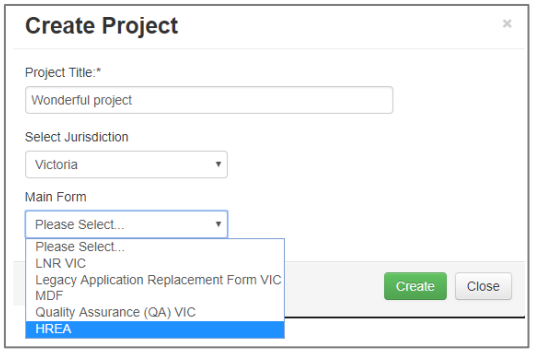
## Steps

1. Select **Create Project** 

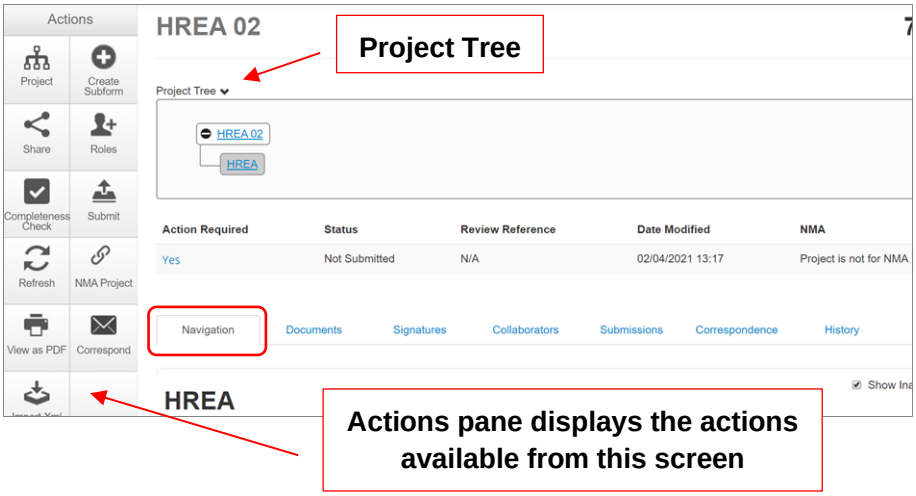
button under the Actions pane



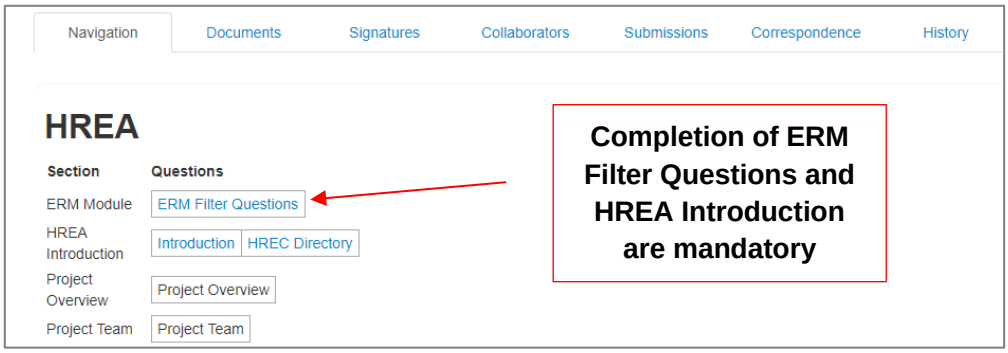

2. In the Create Project pop-up textbox:
    - Enter the Project Title
    - Select the jurisdiction where the application will be reviewed
    - Select HREA from the Main Form options and select the **Create** button



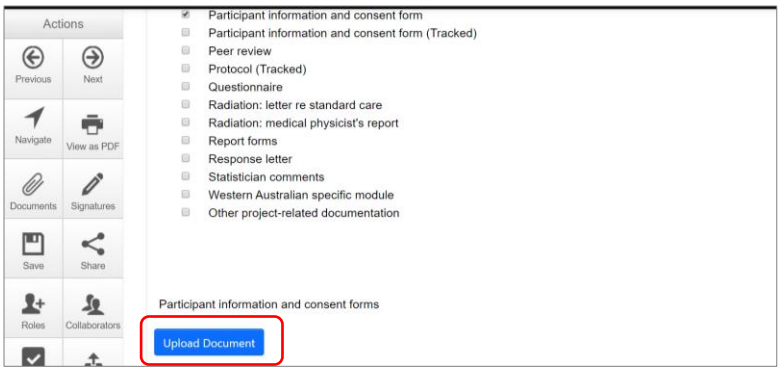
3. ERM opens the project in the Form Management Screen. The Project Tree will display the newly created project and HREA.
4. Under the Navigation tab, enter information into the HREA form. There are seven tabs available. See **Tab Functions** table below & Applicant User Guide to ERM page 15.

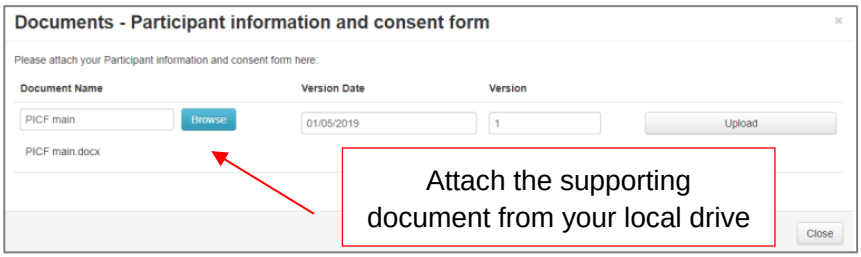



5. Completion of the ERM Filter Questions and HREA Introduction are mandatory.

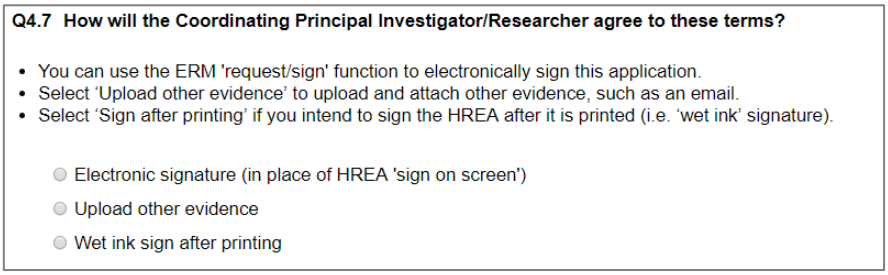



6. If the project involves a site in Victoria, a Victorian Specific Module (VSM) is required.
   See Section 6: Victorian Specific Module of the Applicant User Guide to ERM for more information.
7. In Section 1 Core Information page of the HREA, select the Acknowledge and Continue button located at the bottom of the page to open the rest of the HREA to complete the application. Continue to complete the form.
8. 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.






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.




**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<br>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. |