

ERM GUIDE #1: Submitting a New Project on ERM

Purpose: This guide provides step-by-step instructions to submit a new application via ERM to the Austin Health Human Research Ethics Committee.

1. Ensure that all your study documents under the 'Ethics Package' are ready. Visit our website for a list of these documents:
 - High Risk (HREC): [single site submission](#) or [multi-site submission](#).
 - Low Risk (CRRC): [single site submission](#) or [multi-site submission](#).

Note:

- For help in document naming, please refer to this [guide](#) (accessible via HUB only).
- For Austin Health single site studies, the Office for Research encourages submission of the 'Governance Package' along with the 'Ethics Package' if it is ready.
- For multi-site studies, please submit your 'Governance Package' after ethics approval letter has been issued. Refer to 'Submitting a Governance Application on ERM' guide for Governance Submission.

2. Log into your [ERM](#) account and it will direct you to the main Work Area.

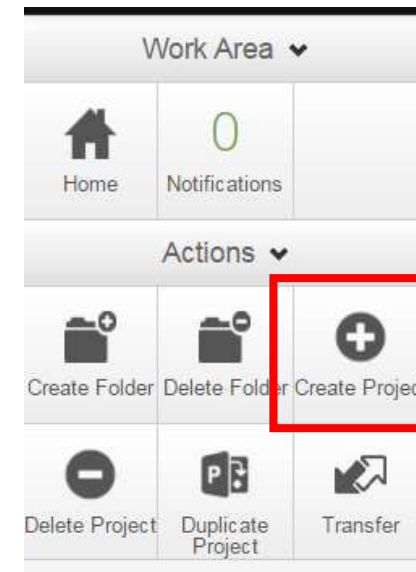
Note: If you have used 'Online Forms' before, the same login account details can be used for ERM. If you are a new user, Create an account on ERM.

3. Click on **'Create Project'** on the 'Actions' panel.

Note: When a project is created, a 'Review Reference' will be issued in the format 'HREC/12345/Austin-2019-123456(v1).

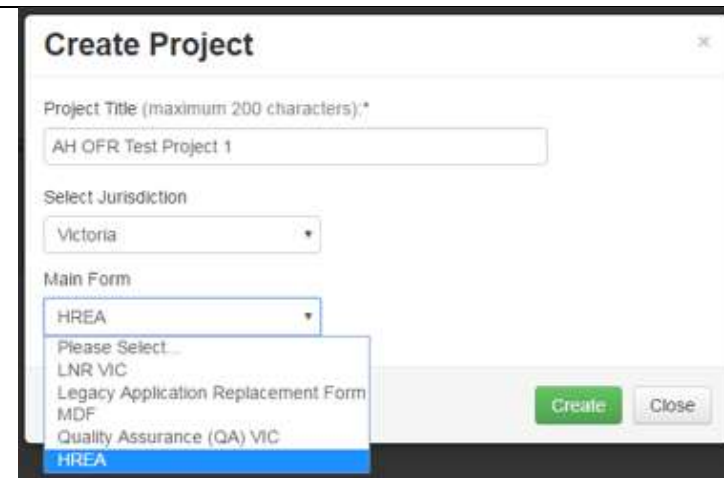


Therefore, the HREC reference number for your project will be 'HREC/12345/Austin-2019'.

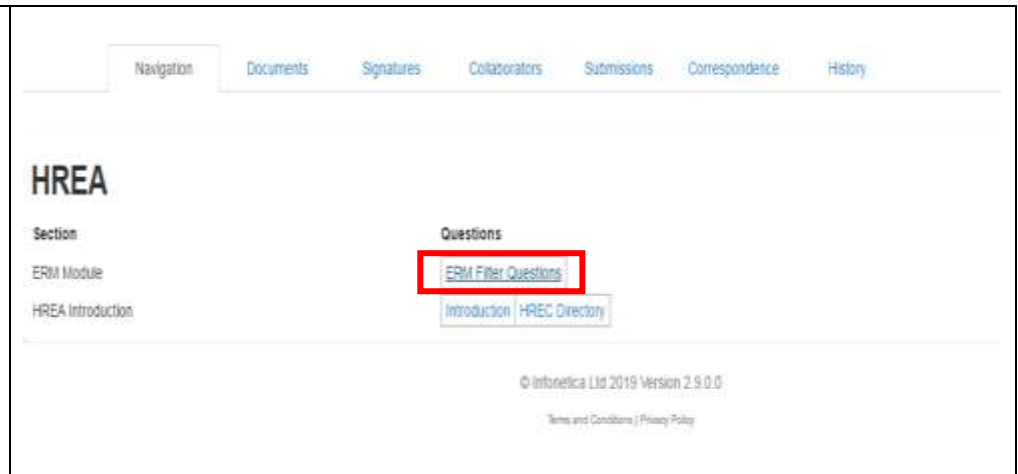


4. Enter your **Full Project Title** as prompted.
 Select **'Victoria'** as the Jurisdiction.
 Select **'HREA'** under Main Form.
 Click **'Create'**.


Note: Completion of the HREA is mandatory for both low and high risk projects being submitted to Austin Health.



5. Start filling out the online application by clicking on **'ERM Filter Questions'** under the heading 'Questions' in the middle of the page.



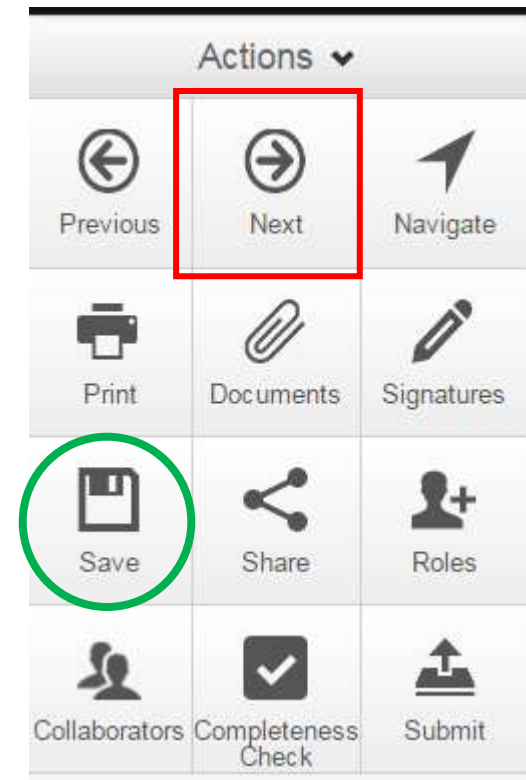
6. Answer the questions as prompted.


Click on the  icon if you require guidance to complete any question.

Note: Select **'Austin Health – Austin Health Human Research Ethics Committee'** as the committee for your ethics application submission.

7. Click on **'Next'** on the left 'Actions' panel to go to the next question page.

Note: If you would like to save changes or complete your application at another time, click on **'Save'** (circled in green) as you work through the questions. This action will save the form in a draft format.



8. For the section 'Project Team', select  at the end of the question to add subsequent investigators as required.

9. For Question **Q 4.3**, select **'Austin Health – Austin Health Human Research Ethics Committee'**.

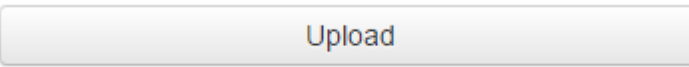
10. To upload a document in Section 4:

- a. Select the document type to be uploaded (e.g. advertising material, PICF etc.)
If the document category is no available for your document, select 'Other'.

- b. Click  under the document type.

- c. Click on  and select the respective documents.

- d. Enter the version date and version number.

- e. Select 

11. For question Q4.5, select:

- a. **'Greater than low risk review pathway'** for high-risk projects for HREC review.

or

- b. **'Negligible risk review pathway'** for low or negligible risk projects for CRRC review.



12. Provide signatures of Principal Investigators and Associate Investigators where prompted.

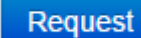
Note: Ensure that your submission is ready before requesting for signatures. **When signatures are requested, this will lock the application. Unlocking the application will invalidate signatures and you will have to request for them again.**


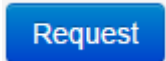
Depending on the type of signatures (electronic signatures only, wet-ink signatures only or mix signatures) you will be obtaining, please refer to the instructions below:

Scenario #1: Electronic Signatures only

- a. Enter the name of Principal Investigator (PI) or any other investigators in the respective 'Declaration' section.
- b. Select the **'electronic signature'** option.

- c. If you are the PI, select . Enter your ERM login details and select .

- d. If you are not the project PI, select . Enter the PI's email address and select .
- e. Repeat the above step for any other investigators in the respective 'Declaration' section (if required).
- f. Once signatures are obtained, **please continue to step 13-15 of this guide.**

Scenario #2: Wet Ink Signatures only

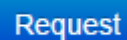
- a. Enter the name of respective investigators (Principal Investigator, Associate Investigator or others).
- b. Select the 'Wet ink signature after printing' option.
- c. **Continue with step 13 to 15 of this guide (submitting your HREA). ONCE DONE, PLEASE FOLLOW PART 'D-F' INSTRUCTIONS BELOW.**
- d. Print your HREA by selecting 'Print' on the 'Actions' Panel. This will print out your submitted HREA with the relevant submission review reference
- e. Obtain wet ink signature from the relevant investigator on the appropriate HREA declaration section.
- f. Scan the signed page and submit to ethics@austin.org.au along with project reference details.

Scenario #3: Electronic AND Wet Ink Signatures

- a. Enter the name of the investigators in the respective sections.
- b. Select the 'wet ink signature after printing' or 'electronic signature' option for all investigators. **Do not request for signatures until either one of the options are chosen for the investigators.**
- c. For investigators signing through electronic signature, go to their Declaration section.

- d. If you are the listed investigator in that section, select . Enter your ERM login details and select .

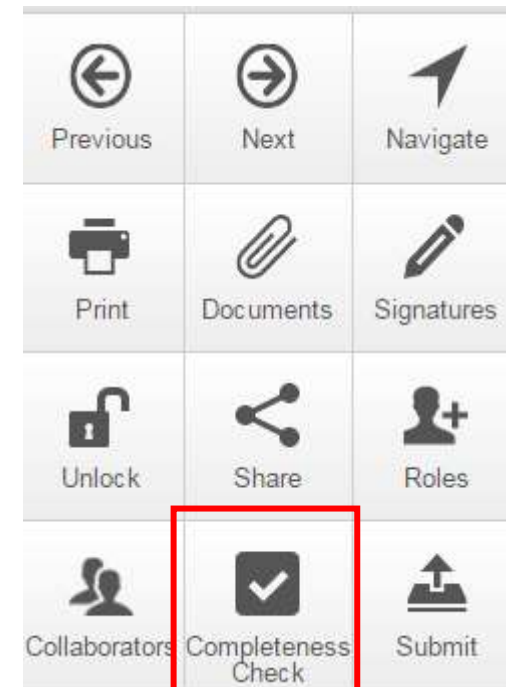
- e. If you are not the listed investigator, select . Enter the Investigator's email address and select



- f. Repeat the above step for any other investigators using electronic signatures.

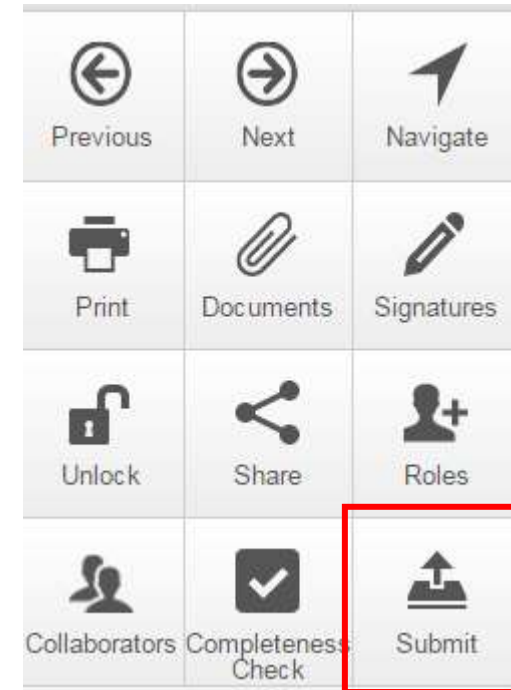
- g. Once signatures are obtained, **please continue to step 13 to 15 of this guide. ONCE DONE, PLEASE FOLLOW PART ‘H-J’ INSTRUCTIONS BELOW.**
- h. Print your HREA by selecting **‘Print’** on the ‘Actions’ Panel. This will print out your submitted HREA with the relevant submission review reference
- i. Obtain wet ink signature from the relevant investigators on the appropriate HREA declaration section.
- j. Scan the signed page and submit to ethics@austin.org.au along with project reference details.

13. To check if you have completed all the questions, click on **‘Completeness Check’** on the ‘Actions’ Panel.



14. Submit your HREA by clicking on **'Submit'** on the left 'Actions' panel.

Note: If this step is not performed, the submission will not go through the system. Once submitted, your application will be locked. If you wish to modify the application, please contact the Office for Research.



15. Once submitted, a 'success page' will appear as below:

Form Submitted

Thank you for submitting your form.

What happens now?

- Use the form's **History** tab to check its progress. If you have shared the application using **Share Roles** with the research team and sponsor, they can also check the **History**.
- The reviewing organisation's research office will contact you by email if anything further is required.
- Use the **Correspondence** button if you need to contact the reviewing organisation's research office.

Forgotten something?

- Use the **Recall** [or **Withdraw**] button to take back your application. Check the history before doing so, you should not recall the application if they have started to process your submission.

If you recall, you can make updates to the application and sign it again. Please remember to re-submit when ready!

Home

16. After ERM submission, please notify us by submitting an electronic copy of your submission to ethics@austin.org.au with the subject line 'New Project Submission: HREC/xxxxx/Austin-2019'. Please include a copy of the submitted HREA and attach study documents in PDF format.

For any other ERM-specific questions, visit the [FAQ](#) section.

For ERM technical assistance, please contact helpdesk@infonetica.net.

For queries on the submission process, please contact ethics@austin.org.au.