

ERM GUIDE #4: Submitting a Site Specific Assessment (SSA) on ERM

Purpose: This guide provides step-by-step instructions to submit a site specific governance application via ERM to the Austin Health Research Governance Office.

1. Ensure that all your study documents under the 'Governance Package' are ready.
Visit our website for a list of these documents:
 - Where ethics approval is granted by an external HREC: [external HREC submission](#).
 - Where ethics approval is granted by Austin Health Human Research Ethics Committee
 - 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](#).
- 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, please create an account on ERM.

3. Click on the respective project under the 'Projects' list.

Projects

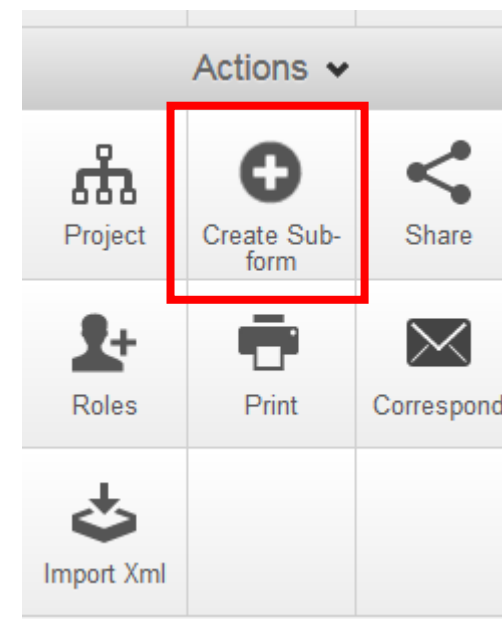
Project Title	Project ID
AH OFR Test Project 1	50399

4. Click on '**Create Sub-form**' on the 'Actions' panel. Select 'Victoria' as the jurisdiction and 'Site Specific Assessment (SSA) Vic' as the sub-form.

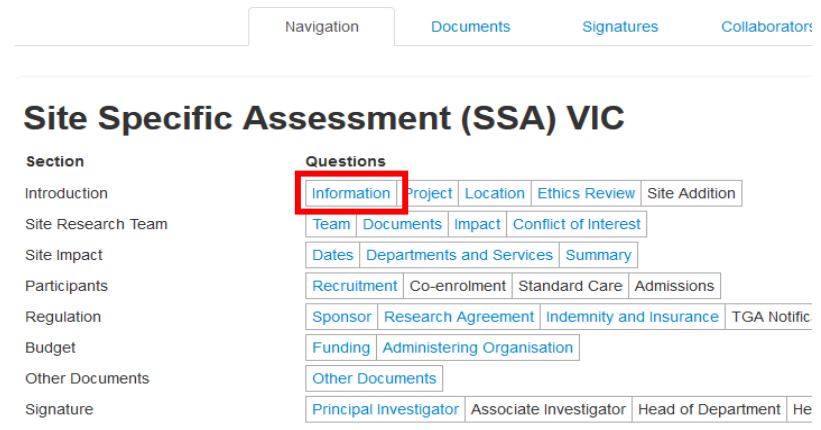
Note: When a SSA is created, a 'Review Reference' will be issued in the format 'SSA/12345/Austin-2019-123456(v1).

ERM Project ID	Year application submitted	Submission code and version - changes every submission
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Therefore, the SSA reference number for your project will be 'SSA/12345/Austin-2019'.

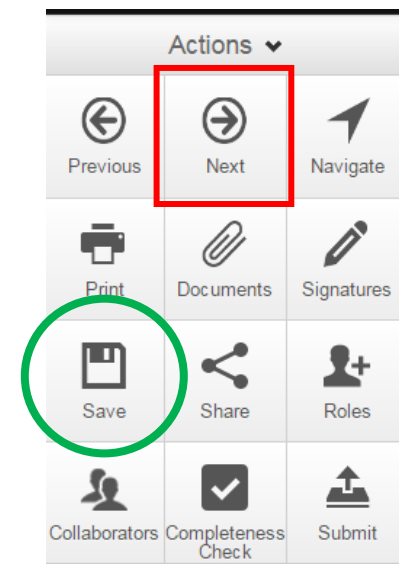


5. Start filling out the online application by clicking on **'Information'** under the heading 'Questions' in the middle of the page.




6. Click on **'Next'** on the '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.



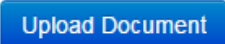


7. Click on **'Next'** on the 'Actions' panel to go to the next question page.

8. Answer the questions as prompted.

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

Note: Select 'Austin Health' as the 'Name of Site/Organisation'. Ensure all investigators at Austin Health are listed in the Project Team.

10. Under the section 'Research Team Documents', upload the investigators' CV and GCP training certificate:

- a. Click .
- b. Click on  and select the CV and GCP training certificate.
- c. Enter the version date and version number.
- d. Select .
- e. Repeat as necessary.

11. Upload the Participant Information Sheet/Consent Form (PICF) when prompted by following the above steps.

12. For question 7.1, select 'yes' and upload all other documents (e.g. HREC approval letter, protocol, flyers etc).

For a full list of documents required, visit our website for a list of these documents:





- Where ethics approval is granted by an external HREC: [external HREC submission](#).
- Where ethics approval is granted by Austin Health Human Research Ethics Committee
 - High Risk (HREC): [single site submission](#) or [multi-site submission](#).
 - Low Risk (CRRC): [single site submission](#) or [multi-site submission](#).

13. Provide signatures of Principal Investigator, Associate Investigators and Head of Department 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. If you are the PI, select  . Enter your ERM login details and select  .
- b. If you are not the project PI, select  . Enter the PI's email address and select  .
- c. Repeat the above step for any other investigators/HOD in the respective 'Declaration' section (if required).
- d. Once signatures are obtained, **please continue to step 14-17 of this guide.**

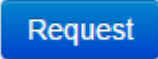
Scenario #2: Wet Ink Signatures only

- a. **Continue with step 14 to 16 of this guide (submitting your SSA). ONCE DONE, PLEASE FOLLOW PART 'B-D' INSTRUCTIONS BELOW.**
- b. Print your SSA by selecting '**Print**' on the 'Actions' Panel. This will print out your submitted SSA with the relevant submission review reference
- c. Obtain wet ink signature from the relevant investigators on the appropriate SSA declaration section.
- d. Scan the signed page and submit according to step 17.

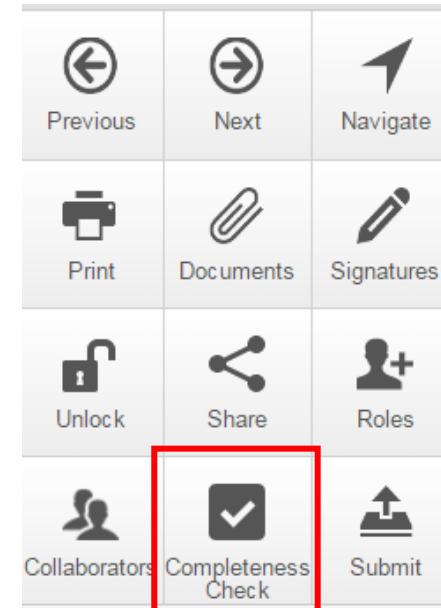
Scenario #3: Electronic AND Wet Ink Signatures

- a. For investigators signing through electronic signature, go to their Declaration section.
- b. If you are the listed investigator in that section, select  . Enter your ERM login details and select  .

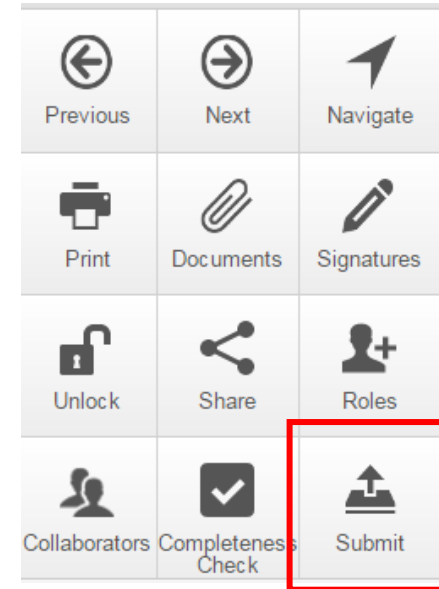
Request Signature

- c. If you are not the listed investigator, select  . Enter the Investigator’s email address and select
- d. Repeat the above step for any other investigators using electronic signatures.
- e. Once electronic signatures are obtained, **please continue to step 14 to 16 of this guide.**
ONCE DONE, PLEASE FOLLOW PART ‘F-H’ INSTRUCTIONS BELOW.
- f. Print your SSA by selecting ‘Print’ on the ‘Actions’ Panel. This will print out your submitted SSA with the relevant submission review reference
- g. Obtain wet ink signature from the relevant investigators on the appropriate SSA declaration section.
- h. Scan the signed page and submit according to step 17.

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



15. Submit your SSA by clicking on **'Submit'** on the 'Actions' panel.



16. 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](#)

17. After ERM submission, please notify us by submitting an electronic copy of your submission to ethics@austin.org.au (single site studies) or rgo@austin.org.au (multi-site studies). Please submit the SSA in PDF format and attach the relevant study documents. If your study requires a PICF, please submit this in WORD format. Please use the subject line 'SSA Submission for <HREC Reference Number>.

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.