

Submitting a Site-Specific Application (SSA)

Barwon Health

Research Development Unit

March 2025



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Why do I
need an SSA?



Research Governance & the SSA

- Research governance can be defined as the broad range of regulations, principles and standards of good practice that exist to achieve, and continuously improve, research quality across all aspects of healthcare.
- The SSA form is the core document to manage the requirements of site governance assessment.
- The SSA form holds the information on how the project will be conducted at the site; it includes supporting documentation and essential signatures.

Why do I need an SSA?

- An SSA provides the details on how a research project will be run at the site
- Ethics (HREC) approval and Governance (SSA) authorisation may happen in parallel, but they are not the same thing.

Research Ethics vs Research Governance

- An SSA provides the details on how a research project will be run at the site
- Ethics approval and Governance authorisation may happen in parallel, but they are not the same thing.
- Governance (SSA) authorisation cannot be granted until Ethics (HREC) approval has been obtained.
- Read about the key differences here:

Ethics

- Reviewed by Human Research Ethics Committee (HREC)
- Considers ethical aspects of clinical trial or research
- Coordinating Principal Investigator (CPI) is responsible for application, communications and reporting
- Occurs once for a multi-site research project
- Undertaken at any organisation accredited under National Mutual Acceptance (NMA)
- Any delay impacts the SSA review

Research Governance/SSA

- Reviewed by site Research Governance Officer (RGO)
- Considers risk management, law, strategic alignment, finance, resources, management of research at site
- Site Principal Investigator (PI) is responsible for application, communications and reporting
- Occurs separately at every site participating in a multi-site research project
- Undertaken at the specific site where the research project is conducted
- Authorisation is dependent on ethics approval being granted

What HREC approval do I have?

- If you already have ethics (HREC) approval where the HREC is listed under the National Mutual Acceptance (NMA) scheme, you **do not** need to apply for ethics again at Barwon Health.
- If you don't have ethics (HREC) approval or the HREC approval you have is not listed under NMA, please contact the RDU office. You may need to apply for Barwon Health ethics (HREC) approval in parallel with your governance SSA application.

National Mutual Acceptance (NMA) Scheme



NMA allows multi-site research projects to take place in multiple public health services across different states and territories with one HREC review and approval



You may already have HREC approval for your trial under the National Mutual Acceptance (NMA) scheme or you might be applying for HREC approval at Barwon Health HREC



Not all HRECs are the same and it's important to check you have the correct approval for your project or clinical trial



More information can be found here

[National Mutual Acceptance - clinical trials and research](#)



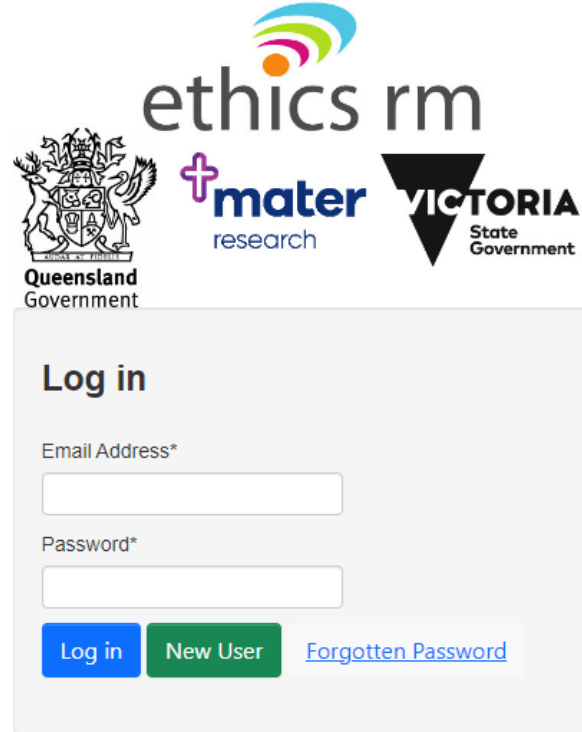
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What do I
need to
know to
start my SSA
Application?

SSA applications are completed in ERM

- ERM = Ethics Review Manager



The screenshot shows the login interface for the Ethics Review Manager (ERM). At the top, there are logos for the Queensland Government, Mater Research, and the Victorian State Government. The text 'ethics rm' is prominently displayed. Below the logos, the heading 'Log in' is centered. There are two input fields: 'Email Address*' and 'Password*'. At the bottom of the form, there are three buttons: a blue 'Log in' button, a green 'New User' button, and a blue link for 'Forgotten Password'.

ethics rm

Queensland Government

mater research

VICTORIA State Government

Log in

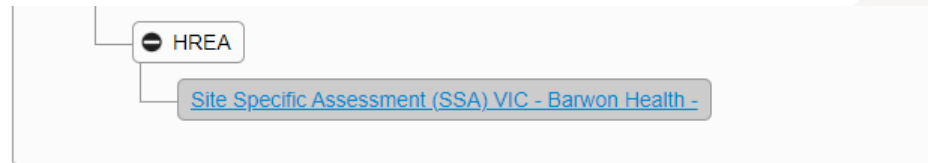
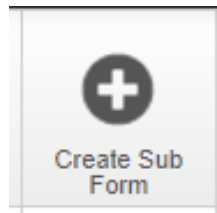
Email Address*

Password*

[Log in](#) [New User](#) [Forgotten Password](#)

Logging into ERM

- If you don't have an ERM account, you can make one with the following link by selecting new user
- [Login - ERM Applications \(ethicalreviewmanager.com\)](https://ethicalreviewmanager.com)
- To begin, make sure the project has been shared with you by the project owner. Then create the SSA form under the HREA tab by selecting 'create sub form, site specific assessment'.



Barwon Health Reference Number



A BH reference number is used to track your project

Please use this link to create the reference number which will go into your SSA application

[Barwon Health Research Reference Number Generator](#)

Research Project

1.1 Project title

1.2 Study type

Please Select...



1.3 Local reference number (optional)

HREC approval

- If you have external NMA HREC approval, you will need to upload the HREC approval letter and other relevant HREC amendment approval letters. This can be supplied to you by the project manager.
- If you have applied for ethics approval at Barwon Health, you can submit your SSA while the HREC approval is still pending so we can start working on governance authorisation for your project at the same time.

Ethics Review

1.5 Is this SSA form for a teletrial project?

- Yes
 No

1.6 What is the current status of the ethics application related to this SSA?

- Not yet approved by the HREC
 Approved by the HREC

Upload ethics approval letter

Upload Document



Who is the PI?

The site Principal Investigator (PI) is the person who has responsibility for the conduct of the clinical trial at the site.

Some of these duties include:

- Ensuring all appropriate approvals are in place to conduct the trial
- Complying with consent requirements
- Ensuring patients' welfare and that the necessary clinical care is provided for participants, including the reporting and management of adverse events
- Responsibility for co-investigators, clinical trial coordinators and research team

The site PI should be someone who has:

- An in-depth understanding of the protocol
- Clear oversight of the project at the site
- The scope of practice to act as the PI
- Undertaken Good Clinical Practice (GCP) training

Delegation

It's important to know who your team is going to be when you are submitting your SSA application. The Principal Investigator (PI) should be approved on the HREC application along with the site (Barwon Health).

The delegation log can be helpful to plan the structure of your team and to ensure all tasks are delegated appropriately.

The PI and all Associate Investigators (AIs) need their details entered into the SSA application and will need their CV, proof of professional registration and GCP uploaded depending on the type of project or trial.



Site Signature and Delegation of Responsibilities Log



Study Sponsor:		Principal Investigator:	
Protocol Study Number:		Study Site Number:	
Country:			

Complete upon assignment of site staff							To complete when staff exit the study	
Name	Signature <small>My signature below indicates that I accept the study task.</small>	Initials	Study Role	Study Task(s) <small>(Select from key)</small>	Start Date <small>(dd/mmm/yyyy)</small>	PI Signature	End Date <small>(dd/mmm/yyyy)</small>	PI Signature

INVESTIGATOR SITE COMMENTS (optional): *(all Comments must be signed and dated)*

Research Team Documents

Upload investigator CV

Upload Document

Upload evidence of current professional registration

Upload Document

Upload evidence of Good Clinical Practice (GCP) training

Upload Document

Upload any other documents relating to the site research team

Upload Document



PI & AI documents

What other documents do I need?

This depends on the type of project you are conducting.

Most applications will require:

- Protocol
- Insurance certificate
- Research Agreement

And sometimes:

- Indemnity

Research Agreements



Most likely the sponsor will provide you with the contract they wish to use, but if you need to find a template, the below templates are available on the [RDU website](#) or upon request to RDU@barwonhealth.org.au.

Data Share Agreement: When only data is being sent from or received by the organisation

Material Transfer Agreement: To be used when materials are being sent from or received by the organisation

Research Collaborative Agreement: For use with all non-clinical trials that involve access to participants and the transfer of data

CTRA (Clinical Trial Research Agreement): For use when you are conducting a clinical trial

Annexure A: For research being conducted in collaboration with Deakin University

Insurance & Indemnity



Insurance is required for all **clinical trials** that are commercially sponsored and collaborative group trials. Also, for investigator-initiated multi-centre **clinical trials** when the other party is a registered business or a university.

Insurance is **not** required for collaborative or investigator-initiated **clinical trials** when the other party is a health service or for **non-clinical trials**.

Indemnity is required for all commercially sponsored **clinical trials** and collaborative group **clinical trials** when the other party is a registered business.

The Research Development Unit can guide you to determine what your project requires.

Executing the research agreement

The research agreement will go through a signing process

When you are happy with the agreement it is signed

- By the Principal Investigator
- By the sponsor

After these two signatures have been obtained you are ready to attach your agreement to the SSA

- Then finally by the institution where it will be signed after review by the Chief Medical Officer.



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Supporting Departments

Supporting Departments



- It's important to discuss your project needs with any supporting departments prior to submitting your SSA
- For example, if your project needs support from trials pharmacy for blinded study medications these details would be negotiated, and when you have agreed on a plan these details are entered into the SSA

3.3(b) Supporting department(s) at this site

Department

Head of department

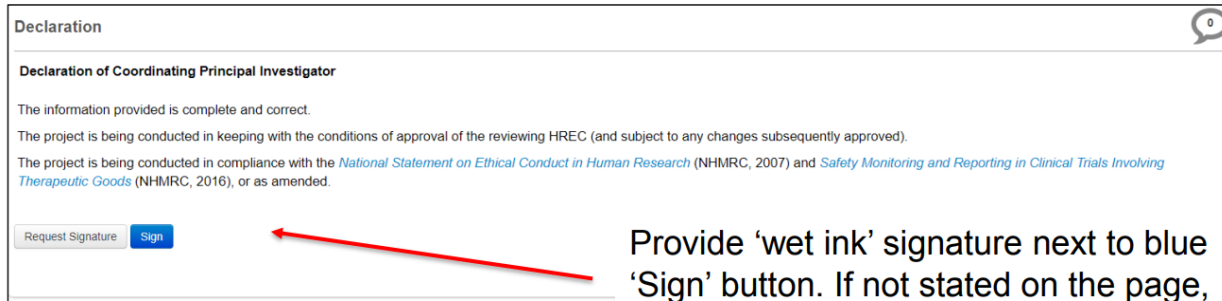
Location/campus

Add Another

3.3(c) Specify any conditions of the supporting department(s), including financial arrangements

Signatures

- The PI, AI's, Heads of supporting departments and the Head of the department where the research will occur are required to sign the SSA submission
- This occurs at the end of the form and can be completed by
 - printing out the SSA and getting a wet ink signature, then uploading this to the documents section
 - OR requesting electronic signatures through ERM



The screenshot shows a web form titled "Declaration" with a sub-heading "Declaration of Coordinating Principal Investigator". The form contains three lines of text: "The information provided is complete and correct.", "The project is being conducted in keeping with the conditions of approval of the reviewing HREC (and subject to any changes subsequently approved).", and "The project is being conducted in compliance with the [National Statement on Ethical Conduct in Human Research](#) (NHMRC, 2007) and [Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods](#) (NHMRC, 2016), or as amended." At the bottom left of the form, there are two buttons: "Request Signature" and "Sign". A red arrow points from the "Sign" button towards the right, towards the explanatory text.

Provide 'wet ink' signature next to blue 'Sign' button. If not stated on the page, clearly print signatory name/designation

Electronic Signatures



- Enter the email address the recipient uses for their ERM account login, and it will be sent to them for signature
- When you request signatures, the form will be locked and no further changes can be made
- After all signatories have signed the form, it then needs to be submitted for review. This will not happen automatically, you need to **log back in and hit the submit button**. You can check if you have submitted the form as below.

A screenshot of a web form titled "Request a signature". The form has a close button in the top right corner. Below the title, there is a prompt: "Enter the email address of the person you want to sign this form". There are two input fields: the first is labeled "Email Address" and the second is labeled "Enter a message (Optional, max 800 characters)". At the bottom right of the form, there are two buttons: a blue "Request" button and a grey "Close" button.

Action Required on Form	Status	Review Reference	Date Modified	NMA
Yes	Not Submitted	N/A	11/10/2024 07:40	Project is for NMA

Signatures

If you have forgotten to add something you can cancel the signatures and upload it, this will invalidate all signatures and the form will need to be re-signed, alternatively if it's only one additional form it can be added to the correspondence section of the SSA

Navigation	Documents	Signatures	Collaborators	Submissions	Correspondence	History
Signatures						
Type	Signatory Email		Signed Date		Validity	
Coordinating Principal Investigator	ima.testperson2@gmail.com		21/08/2019 15:17		Valid	
Signature Requests						
Type	Signatory Email	Requested Date	Status	Response Date	Action	
Coordinating Principal Investigator	ima.testperson2@gmail.com	21/08/2019 15:16	Signed	21/08/2019 15:17	<input type="button" value="Cancel"/>	

After submitting a form if something has been missed you can ask RDU to send the form back to you to add it, which will not require gaining signatures again.

Contact the RDU team

- Email RDU@barwonhealth.org.au
- Phone- 03 4215 3374

Biostatistician

Kabir Ahmad

Ph: 03 4215 3569

Ethics/HREA/QA

Richard Larsen

Ph: 03 4215 3371

Governance/SSA

Michelle Horton

Ph: 03 4215 3568

References

- Australian Commission on Safety and Quality in Health Care. (2024). *Fact sheet - roles and functions for site principal investigators*. Retrieved from [fact sheet - roles and functions for site principal investigators.docx \(live.com\)](#)
- State Government of Victoria. (2024). *Research governance and site specific assessment process and practice*. Retrieved from [Research-Governance-SSA-Process-and-Practice.-March-2024.pdf \(clinicaltrialsandresearch.vic.gov.au\)](#)
- Ethical Review Manager. (2024). *Help - ERM applications*. Retrieved from [Help - ERM Applications \(ethicalreviewmanager.com\)](#)