

Queensland Health sites all require a Researcher Governance authorisation by way of a Site-Specific Assessment Application form, this enables a complete and comprehensive review of the research projects and its conduct at any of the facilities within the Mackay Hospital and Health Service catchment and as part of this review the following are considered:

- Financial management
- Risk management
- Contracts
- Indemnity
- Insurance
- Institutional policy
- Research conduct
- Legislative compliance
- Regulations
- Guidelines
- Codes of Conduct

Prior to commencing your Site-Specific Assessment (SSA) Application Form

1. A certified HREC approval is required, both Ethics applications and SSA applications are completed via the [Online Forms](#) website.
2. All documentation is completed (refer to the MHHS Research Governance and Ethics Checklist)
3. If your project is a multi-centre project, you will need to complete an SSA for each site. Contact the Research Governance Officer (RGO) at each site to understand their requirements.

Research Governance Officers for each HHS throughout Queensland is available at:

https://www.health.qld.gov.au/_data/assets/pdf_file/0028/624763/rgo-submit-locn.pdf

What is Site Specific Assessment (SSA)?

The Site Specific Assessment application form is a document that allows a researcher and prospective site to understand the details of the project, which may include departments involved, staff required, appropriate departmental support availability, additional tests proposed, project plan timelines, costs associated with the project, sponsorship/funding arrangements, feasibility, risk, insurance, data collection and maintenance, expected outcomes and aims of the project and proposed final result/publication and audience. As part of the SSA submission a number of supporting documentation is also to be submitted to the local Research Governance Officer at each site; each site has similar requirements with respect to the documentation associated with projects however there are a number of other factors considered specific to the Hospital and Health Service that may also need to be addressed.

Documentation

When you submit your SSA application please send a hard copy of all documentation in full, and upload your documents as per the checklist on the SSA online application.

Mackay Hospital and Health Service

- All of the documents listed on your HREC approval letter must be uploaded again to your SSA application submission; the documents will not transfer from your ethics application to your SSA. To ensure all documents required are attached please refer to the Site-Specific Assessment Submission checklist.
- If your project is a Multi-Centre project, each HHS and site within the HHS will need to be listed. To ensure all resources and capabilities required for the success of your project are available and considered.
- Please ensure that all budget and finance sections of the SSA are completed. This includes all in kind costs as well as funded costs.

Site Contact Person

If you are not from this health service, it is mandatory that you contact and nominate local site contact person to obtain the necessary signatures for you. It is not the RGO's role to obtain these signatures for you. The site contact person may also consent to assist you with your research project including distribution of questionnaires, study materials if there is minimal work involved; however as the investigator it is your responsibility to manage these tasks.

Site Finance Management

On the SSA application you must outline any/all possible costs associated with your research project. This could include additional imaging, pathology, time required for a Phlebotomist to draw blood, your time to collect the data, printing costs for documents or paperwork associated with the project i.e. Participant Information and Consent Forms etc. For additional information or possible costs to consider see the Budget Template document available on the MIRI website. If your project/trial requires detailed cost information and budget workup as there are costs associated with outpatient appointments, patient admissions, imaging, radiology, pathology etc. please contact the site RGO for further assistance.

Finance Authorisation

The RGO will arrange this signature but you are required to add the Executive Director of Finance, Procurement and Infrastructure to the SSA application:

Validation

An application must be complete, with all signatures and documentation provided before it is considered valid. Once an application is valid, it will be sent to the Chief Executive or delegate for authorisation, then to the MHHS Solicitor for legal review of the Research Agreement, once the legal review is complete the Chief Executive reviews and signs which initiates the execution of the agreement. The time period allocation from the point an application is considered valid up until the final signature and authorisation letter is received is 21 working days. Please make allowance for this process in your project plan/timelines and expect this time frame as the timeframe for all processing purposes.

Registration of your Project

As part of the SSA authorisation, it is a requirement for all projects to be registered on the following two sites:

<http://au.researchweb.org/is/jcu/hrr/miri-current-research>

<http://access.health.qld.gov.au/DORA/view/search.aspx>

Please ensure this is completed upon receiving your Site-Specific Assessment, Research Governance authorisation.

Signatures

It is important that you have all the necessary signatures obtained when you submit your SSA. Obtaining these signatures is the researcher's responsibility. This includes all investigators, all head of department, any additional researchers/supervisors/mentors. The MHHS Research Governance Officer will ensure all Executive level signatures are obtained and will in addition assist any Principle/Coordinating Investigators based at another location requiring Head of Department contact information and signatures. All Researchers/Investigators based at any of the sites within the Mackay Hospital and Health Service will be expected to obtain these signatures prior to submitting the SSA application.

Reporting Requirements

Please ensure all reporting timeframes are adhered to and completed as/before due dates:

- Notification of Project Commencement
- Progress Reporting (Minimum 12 monthly)
- Final Report
- Publication Information/Data Collection finalisation and Analysis
- Adverse Event Notifications (Serious/Local etc.