# Research Governance Checklist Guideline

## Purpose

The purpose of this guideline is to provide researchers who are new to submitting Site-Specific Approvals (SSA) for research studies with detailed definitions of the requirements listed in the *Research Governance Checklist*.

## Scope

The Research Governance Checklist may be submitted in lieu of a cover letter and can be used to ensure all approval requirements have been considered and captured prior to submission with Research governance.

## Guidelines

Identify which of the criteria below are applicable to your study.

### 1. Checklist or Cover Letter

The checklist (or a cover letter) provides a summary of all relevant documents required for the submission.

### 2. SSA Form

The SSA form must include the signatures of all Mackay Hospital and Health Service (MHHS) investigators, contact persons, business manager or finance delegate, heads of departments / supporting departments and the Service Group director.

- The **name, date and position** of the signatory are required.
- **Signatures:** MHHS preference is for wet ink signatures using our template letter of support. *Sponsored Clinical Trials **MUST** have wet ink signatures.*
- **Electronic signatures** are permitted, however if the document is altered in any way after electronic signatures are provided, they with need to be obtained again.

| Signature | When required |
|---|---|
| Head of Department | For any research conducted in their financial jurisdiction. Typically, the Manager or Director of the Principal Investigator's employing department. |
| Head of Supporting Department | For any other departments contributing to a study where there is a financial implication / consideration (i.e., in-kind activity). |
| Service Group Director | To approve any department involvement within their Service Group. |
| Business Manager | For the service group, needs to sign off on the budget for the research. |
| Clinical Information Services Director | Needs to give approval for the use of patient information in research. *(Not required if they have signed the Public Health Application form)* |
| Pathology Director | If results or data are required from Pathology Queensland, including results obtained within the patient's medical records*. |
| Radiology/Medical Imaging Director | If patient radiology data is required for use in research. |

**Research that requires standard of care bloods via ieMR for data collection **doesn't** require Pathology sign off*

## 3. Budget Template / Information

All applications must include a budget which details all funding sources including:

- in-kind contribution made by the MHHS (if any)
- which MHHS costs will be covered by an external funding body (e.g., grant)
- research governance review fees (if commercially sponsored)

The budget must include signatures from the Principal Investigator and relevant business manager.
A copy of the MHHS budget template can be obtained by contacting MKY-RGO@health.qld.gov.au.

## 4. Protocol

If more than one version of the Protocol has been approved by the Human Research Ethics Committee (HREC), provide the most recent **approved** version listed in HREC approval correspondence supplied.

## 5. Patient Information, Consent and Withdrawal Form (PICF)

Participant Information, Consent and Withdrawal Forms (PICFs) must be submitted when the research team is seeking participant consent. The PICF version provided must match the most recent HREC approval letter.

| Form Type | Explanation |
|---|---|
| **Master PICF** | The Master PICF is the version which has been approved by Ethics (HREC).<br>For single-site studies, the Master PICF and the Site Specific PICF are the same.<br>For multi-site projects, the HREC normally approves a Master PICF and Site Specific PICFs are generated for each site involved in the research. |
| **Site Specific PICF** | Where a Site Specific PICF is being provided, a tracked version showing changes from the Master PICF, along with a clean copy are required.<br>For single-site projects, the Site Specific PICF should be the same version as the Master approved by the HREC.<br>For multi-site projects, a Site Specific PICF should be created based on the most recent HREC approved master version. Site Specific PICF should contain:<br>• the site version and date.<br>• the version and date of the Master PICF which it is based on.<br>• details of the Site Principal Investigator.<br>• details of MHHS Research Governance Officer should participants have any concerns about the project.<br>• the MHHS/Queensland Government logo on the front page, to validate endorsement from Queensland Health and the Health Service. |

## 6. Research Agreements

A research agreement is required for all research in which an external organisation is involved. This includes sponsored, collaborative and student (e.g., Research Higher Degree) research.

Research Governance Officer review/approval of the Research Agreement is required prior to obtaining signatures.

- The Medical Technology Association of Australia template agreements are preferred for all device trials.
- The Medicines Australia template agreements are preferred for all clinical drug or other trials (e.g., trials of psychological support interventions).

All commercially sponsored research will incur a processing fee from the Research Governance Office, which needs to be outlined in the Research Agreement, the current schedule of fees is available on QHEPs.

## 7. Indemnity Forms

The Medicines Australia Standard Form of Indemnity is required for all commercially sponsored clinical research. If unsure of the Party details required, discuss with Research Governance Office prior to obtaining signatures.

## 8. HREA Application Form

All SSA applications should contain the Human Research Ethics application (HREA) form submitted to the governing HREC for approval. The HREC submission code or Ethical Review Manager (ERM) number and date of the HREC application must match the version on the HREC approval letter.

## 9. All HREC Documents, Approval Letter and HREC Communications

The original HREC approval letter should be included in the SSA submission uploaded to ERM. If amendments to the study occur following original approval, all HREC amendment approval letters should also be uploaded.

Other items approved by HREC may include - material supplied to participants or promotional material.

## 10. Approval Correspondence

Where appropriate, any correspondence from HREC which reflects the history of the project i.e., Requests for further information from HREC and responses, and amendments, should be provided in the ERM SSA submission.

## 11. Master PICF

See: 5. Patient Information, Consent and Withdrawal Form (PICF).

## 12. Data Collection

Data collection forms / questionnaires approved by the HREC should be included in the governance submission via ERM.

## 13. Funding Information

If a study has external funding, i.e., a Grant or sponsor; include the funding approval letter or agreement.

## 14. Investigator CVs

Provide a current CV of each Investigator at the site (refer to SSA form for list of site investigators).

## 15. Insurance Certificate

Insurance Certificates are required for all projects involving external parties. For commercially sponsored research, insurance details or a current insurance certificate must be included in the Schedule of the Agreement.

## 16. Investigator Brochure

An Investigator brochure and product information are required for all drug and/or device trials.

## 17. PHA Application and Approval

A Public Health Act (PHA) application form **and** approval letter may be required in research where **patient consent** is NOT obtained for some / all aspects of the study.

If the study involves use or disclosure of identifiable or potentially re-identifiable patient information where disclosure will occur with or between non-designated persons, approval under the *Public Health Act 2005 (Qld)* is required. Further information to assist with your application is available via the Public Health Act application and SSB website.

## 18. QCAT Application and Approval

A Queensland Civil and Administrative Tribunal (QCAT) application form **and** approval letter are required for clinical and/or interventional research where patients have impaired capacity to consent, and the project meets the definition of Clinical Research under *the Guardianship and Administration Act 2000* (Qld).

## 19. Pathology Queensland Approval and Quote

A Pathology Queensland application for service form must be completed where Pathology Queensland are providing a service e.g., preparing/accessing tissue samples, taking/processing bloods. The Pathology Queensland approval form and quote can be used to evidence Pathology Department approval for the SSA form.

## 20. Forensic & Scientific Services Approval

Forensic and Scientific Services (FSS) approval is required for studies accessing coronial material.

## 21. Agreement, Collaboration or Other Engagement with a Foreign Entity

The Foreign Arrangements Scheme ensures that arrangements between State or Territory governments (and their entities) and foreign entities do not adversely affect Australia's foreign relations and are not inconsistent with Australia's foreign policy. The Scheme creates an 'approval' process for arrangements known as 'core foreign arrangements' and a 'notification' process for arrangements known as 'non-core foreign arrangements' to ensure compliance with *Australia's Foreign Relations (State and Territory Arrangements) Act 2020* (Cth).

## 22. Other supporting documents

If appropriate to the study, other approvals may be required, consult with Research Governance for details.

## 23. Clinical Trials Notification (CTN)

The Clinical Trials Notification (CTN) form is lodged online. Once notification is complete, the approval letter should be submitted with the SSA. If CTN lodgement occurs after governance authorisation is issued, the CTN approval should be submitted as a post-authorisation notification in ERM.

# Document approval

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| **Authorised by** | Nursing Director, Research Support Unit | **Approval date** | 24/02/2025 |
| | A/Executive Director Medical Services | | 25/02/2025 |
| **Author** | Research Governance Officer | **Next review due** | 25/02/2028 |