Guideline

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Research governance checklist

Research Governance and Development Unit

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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.

Guideline

To identify which of the criteria below are applicable to your study, see the Applicability Matrix. in Appendix 1.

1. Checklist or Cover Letter

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

2. SSA form with all required Signatures

The SSA form must include the signatures of all 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: SCHHS preference is for wet ink signatures using our template letter of support which can be obtained by contacting SC-Research-Support@health.qld.gov.au . *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 are required for use in research.

Research that requires standard of care bloods via ieMR for data collection **does not 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 SCHHS (if any),
- Which SCHHS 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 SCHHS budget template can be obtained by contacting the Research Governance and Development Office at SC-Research-Support@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 PICF version which has been approved by Ethics (HREC) **For single-site studies**, The Master PICF and the Site Specific PICF will be the same. **For multi-site projects**, HREC normally approve 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. **For single-site projects**, the Site Specific PICF should be the same version as the Master approved by the HREC. **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 – The site version and date – The version and date of the master PICF which it is based on – Details of the site principal investigator – Details of SCHHS research governance officer should participants have any concerns about the project – Details of the SCHHS patient liaison officer for complaints – The SCHHS/ 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/LNR Application Form

All SSA **applications** should contain the Human Research Ethics Committee (HREC) application form submitted to the governing HREC for approval. The HREC submission code or ERM number and date of the HREC application form 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.

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. Contact the Research Governance Office for further information regarding legislative requirements.

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 Approval Form **and** Quote are required where Pathology Queensland are providing a service e.g. preparing/accessing tissue samples, taking/processing bloods. A 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. Other HREC approved documents

Any other supporting HREC documents not provided as part of previous sections.

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.

References and further reading

Primary legislation, policy, standards or other authority

Public Health Act 2005

National Safety and Quality Health Service (NSQHS) Standards 2nd ed – Clinical governance

Forms and other related or supporting documents

001591-a1 Research governance schedule of fees

001591-a2 Research governance checklist

Consultation

Key stakeholders who contributed to and/ or reviewed this version include:

Research Clinical Council

Director Research

Research Governance and Development Unit

Compliance is addressed by

Reporting mechanism: Reporting to the Research clinical council.

Key indicators and/ or outcomes: 100% compliance.

Document approval

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1.0	Research Governance and Development Unit	Research Clinical Council	Manager, Research	12/06/2022
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Appendix 1– Applicability matrix

Category	HREC Approval	SCHHS SSA	Public Health Act (2005) Approval	Budget on RGDU Template	Medicines Australia Clinical Trial Research Agreement (March '17)	Medicines Australia Indemnity Standard Form (Oct '12)	Collaborative Research Agreement	USC Facility Access Agreement
QUALITY IMPROVEMENT/CLINICAL AUDIT								
All internal SCHHS staff	✗	✗	✗	✗	✗	✗	✗	✗
SCHHS staff **PLUS** student on placement as recognised part of course	✗	✗	✗	✗	✗	✗	✗	✓
SCHHS staff **PLUS** student **NOT** on placement as recognised part of course	✓	✓	*	✗	✗	✗	✓	✗
SCHHS staff **PLUS** other external party/person	✓	✓	*	✗	✗	✗	✓	✗
RESEARCH								
SCHHS Investigator-led **Clinical Trial** SCHHS only site	✓	✓	✗	✓	✗	✗	✗	✗
SCHHS Investigator-led **Clinical Trial** SCHHS plus other sites	✓	✓	✗	✓	✗	✗	✓	✗
Clinical Trail - led by other site (non-commercial)	✓	✓	✗	✓	#	✗	✓	✗
Clinical Trial - Commercially sponsored	✓	✓	✗	✓	✓	✓	✗	✗
Research study - SCHHS staff only, SCHHS site only	✓	✓	^	✓	✗	✗	✗	✗
Research study - SCHHS staff only, SCHHS plus other sites	✓	✓	^	✓	✗	✗	✓	✗
Research study - SCHHS staff **PLUS** student on placement as recognised part of their course, SCHHS site only	✓	✓	<	✓	✗	✗	✗	✓
Research study - SCHHS staff **PLUS** student on placement as recognised part of their course, SCHHS plus other sites	✓	✓	<	✓	✗	✗	✓	✓
Research study - SCHHS staff **PLUS** student **NOT** on placement as recognised part of their course, SCHHS only	✓	✓	>	✓	✗	✗	✓	✓
Research study - SCHHS staff **PLUS** student **NOT** on placement as recognised part of their course, SCHHS plus other sites	✓	✓	>	✓	✗	✗	✓	✓
Research study - SCHHS staff **PLUS** other external party/person	✓	✓	>	✓	✗	✗	✓	✓
RESEARCH HIGHER DEGREE STUDENTS								
Masters or PhD Student	✓	✓	*	✓	✗	✗	✓	✓

*	HREC must specify student position and activities (credentialing may be required) PHA if consent for data access cannot be obtained directly from participant(s) Budget required is utilising SCHHS resources (incl 'in-kind' time of staff) CRA to ensure student is insured by their institution and their involvement is authorised Student cannot access ieMR directly. IF PhD student is also a SCHHS staff member, all data access must be conducted as part of their normal duties (as applicable) in SCHHS work time.
#	At least one of either CTRA or CRA required
^	PHA if consent for data access cannot be obtained directly from participant(s)
<	PHA if consent for data access cannot be obtained directly from participant(s) USC FFA - if student is USC
>	PHA if consent for data access cannot be obtained directly from participant(s) CRA to ensure external person is insured by their institution and their involvement is authorised, or they have other insurance in place External person cannot access ieMR directly