

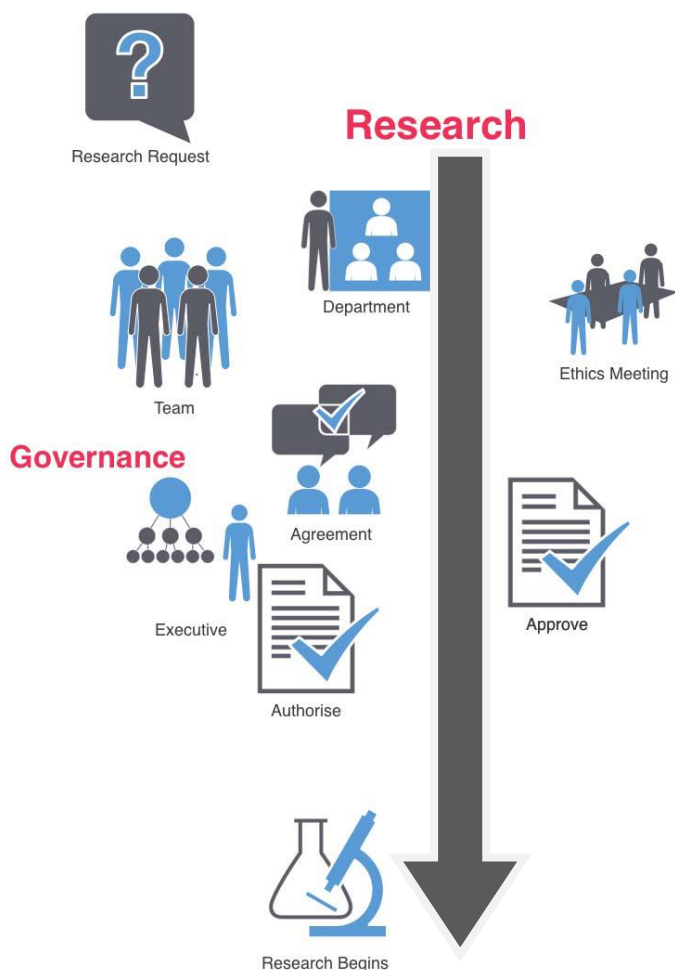
Research Governance Process v1.0

Fact Sheet 1

Background

Research Governance is a local institutional due diligence assessment common to all HHS's. It encompasses the assessment of legal, financial, regulatory and contractual issues related to research activity undertaken at any HHS site. Accordingly, all research undertaken at SCHHS needs to undergo Site Specific Assessment (SSA) research governance review. The general review process required prior to commencement of a research study is outline below:

Research Governance Review (RGR)



General Information

RGR is **separate from the ethical review** conducted by a Human Research Ethics Committee (HREC).

RGR is based on the information provided in the **SSA** submitted by the responsible investigator about their proposed research project.

The RGR is required by the HHS to confirm research:

- **Appropriateness**
- **Fit with HHS strategy**
- **Available resourcing**
- **Expertise and experience of proposed researchers**
- **Legal and conduct compliance**
- **Contractual requirements**
- **Co-ordination of monitoring**
- **HREC approval requirements**

It is the responsibility of individual researchers to provide the information required by the Research Governance team to adequately assess research projects.

A checklist, shown on the following page, that outlines all the potential documents required for Research Governance Review can also be found on the SCHHS Research website containing additional detailed explanatory notes to assist researchers with understanding the requirements for submission https://www.health.qld.gov.au/_data/assets/pdf_file/0020/163118/research-gov-checklist.pdf

If you are unsure about any of the information provided in this fact sheet, please contact the

Research Office P: 07 5202 2991

E: SC-Research-Support@health.qld.gov.au

Not all documents are relevant for each study

Researchers should contact the SCHHS Research Office to discuss their study and the requirements to facilitate approval at sc-research-governance@health.qld.gov.au

All documents to be submitted through the Ethics Review Manager (ERM) online system at <https://au.forms.ethicalreviewmanager.com>

In addition to submitting documents via the ERM system, the Research Governance Officer may require some documents to be submitted in hard copy, as identified on the checklist.

A cover letter or the above checklist should be completed and submitted with your study documents in ERM.

For documents that require hand delivery: SCHHS Research Offices, Level 1, Lakeside Building, SCUH.

Research Study Checklist – Site Specific Approval Document Requirements

	Document	Submission Format		Researcher Notes	Document included in submission		
		ERM	Hard Copy		Yes	No	N/A
1	Checklist or cover letter	✓			<input type="checkbox"/>		
2	SSA form with all required signatures	✓			<input type="checkbox"/>		
3	Budget on the SCHHS template with all the required signatures	✓			<input type="checkbox"/>		
4	Protocol	✓			<input type="checkbox"/>		
5	Site Specific PICF	✓			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	Research Agreements	✓	✓		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	Indemnity forms	✓	✓		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	HREA/LNR Application Form	✓			<input type="checkbox"/>		
9	All HREC documents, approval letter and HREC communications.	✓			<input type="checkbox"/>		
10	Approval Correspondence	✓			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11	Master PICF	✓			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12	Data collection	✓			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13	Funding information	✓			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14	Investigator CVs	✓			<input type="checkbox"/>		
15	Insurance Certificates	✓			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16	Investigator brochure	✓			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17	PHA Application and Approval	✓			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18	QCAT Application and Approval	✓			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19	Pathology Queensland Approval and Quote	✓			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20	Forensic and Scientific Services Approval	✓			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21	Other HREC approved documents	✓			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22	Other supporting documents	✓			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23	CTN	✓			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Document approval

Approved by	Manager Research	Approval date	21/07/2020
Author	Clinical Research and Development Unit	Next review due	31/07/2023
Keywords	Research Governance Review (RGR), Site Specific Assessment (SSA), checklist		