



## Checklist

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### Research governance documentation checklist

Date approved: 12/06/2020

Review due: 12/06/2022

### Purpose

The purpose of this checklist is to provide Researchers with the Site-Specific Approval (SSA) requirements of all Research Governance Submissions for the Sunshine Coast Hospital and Health Service (SCHHS).

The 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.

Detailed definitions for Site Specific approval requirements are available from the SCHHS Research Governance Checklist Guideline.

### Submission of research governance documentation

- As not all documents are relevant to each study, Researchers are encouraged to contact Research Governance at [SC-Research-Support@health.qld.gov.au](mailto:SC-Research-Support@health.qld.gov.au) prior to submission to discuss their study requirements.
- All documents should be provided electronically via ERM. The checklist highlights which documents also require hard copies. **When submitting hard copies please include this Checklist as an identifier and submit via:**

**Hand delivery:** Research Governance and Development Office, Lakeside Building, Level 1, Sunshine Coast University Hospital.

**Postal:** Research Governance and Development Office, Sunshine Coast University Hospital, 6 Doherty St, Birtinya, Qld 4575.

- All supporting documents should be uploaded to the ERM and should be appropriately named so that they can be easily identified, and include the application form, and HREC letters.
- Once all Research Governance requirements have been met, the RGO will submit hard copy documents to the Health Service Chief Executive with a recommendation to authorise the conduct of the study within the SCHHS.

### Research study project identifiers

Principal Investigator (PI) name:

PI or Site Coordinator Contact Number

PI or Site Coordinator Email Address

ERM Project ID Number

Study Title

Short Name (If applicable)

Is the principal investigator undertaking  
this study as a student?

Yes / No

Layman's description of the study

*(Copy from the LNR/HREA Application Form):*

## Research study checklist – Site-specific approval document requirements

	Document	Submission Format		Researcher Notes	Document included in submission		
	Document requirement	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"/>

	Document	Submission Format		Researcher Notes	Document included in submission		
	Document requirement	ERM	Hard Copy		Yes	No	N/A
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

Version	Prepared by	Endorsed by	Authorised by	Review due
1.0	Research Governance and Development Unit	Research Clinical Council	Manager Research	12/06/2022
<b>Supersedes:</b> N/A				
<b>Keywords:</b> research, governance, checklist, HREC, patient consent, information, withdrawal, approval, public health, clinical trials, human research, ethics				