

Site Specific Assessment (SSA) application checklist

Documentation required for the submission of a new SSA at a facility within Metro North:

No.	Description	No. of Copies	Check (☑) for Yes
Mandatory			
1.	Cover letter signed by the Principal Investigator, containing a brief description of the proposed study.	1 hard copy 1 file on USB or CD	
2.	Site Specific Assessment form (signed) (Please note: there are costs associated with all research, whether actual or in-kind. The budget must be completed for all studies and signed-off by either the relevant departmental Business Manager or hospital Director of Finance).	1 hard copy 1 file on USB or CD	
3.	HREC approval letter and HREC comment/responses	1 hard copy 1 file on USB or CD	
4.	HREA (signed)	1 hard copy 1 file on USB or CD	
5.	Protocol (and Protocol amendments, if any, with a copy of HREC amendment approval letters)	1 hard copy 1 file on USB or CD	
6.	Curriculum Vitae (signed and dated, maximum of 2 pages) - if not already held on file within the past 2 years.	1 hard copy 1 file on USB or CD	
No.	Description	No. of Copies	Yes / No / N/A
Mandatory (If applicable)			
7.	PICF (master and site-specific)	1 hard copy 1 file on USB or CD	
8.	Signed Public Health Act (PHA) application & approval letter	1 hard copy 1 file on USB or CD	
9.	Clinical Trial Notification (CTN) (obtained after HREC approval) (Print screen of completed CTN showing TGA number)	1 hard copy 1 file on USB or CD	
10.	Research related study tools (questionnaires, advertisements, diaries completed etc)	1 hard copy 1 file on USB or CD	
11.	Research Agreement (if there are any entities external to Queensland Health involved in the research eg. commercial sponsor, university, other academic research organisation, a research agreement must accompany the SSA. For commercially sponsored clinical trials, the standard Medicines Australia CTRA should be used)	3 hard copies	

12.	Pharmacy quote	1 hard copy 1 file on USB or CD	
13.	Radiology quote	1 hard copy 1 file on USB or CD	
14.	Queensland Civil and Administrative Tribunal (QCAT) approval (for studies involving participants without the capacity to consent)	1 printed copy 1 file on USB or CD	
15.	Medicines Australia Standard Form of Indemnity (for commercially sponsored clinical trials)	3 printed copies	
16.	Insurance certificate (current)	1 hard copy 1 file on USB or CD	
17.	Pathology Queensland quote and approval (including Pathology Queensland Laboratory Declaration)	1 hard copy 1 file on USB or CD	
18.	Funding approval letters and/or agreements	1 hard copy 1 file on USB or CD	
19.	Investigator brochure (for clinical trials)	1 hard copy 1 file on USB or CD	
20.	Radiation safety report	1 hard copy 1 file on USB or CD	
21.	Any other quotes for services related to the research e.g..Biosafety approval	1 hard copy 1 file on USB or CD	

* If the study has been approved by the TPCH HREC, then documents that have already been reviewed by the HREC do not need to be re-submitted with the SSA application.

SSA submissions can be made at any time with the relevant Research Governance Office.

For further information, please use the contact details below:

Research Governance Officers

The Prince Charles Hospital	Royal Brisbane and Women's Hospital
Research Ethics and Governance Unit Ascar Yu Email: RGOTPCH@health.qld.gov.au Phone: (07) 3139 4407	Research Governance Office Jacqueline Robinson Email: RBWH-RGO@health.qld.gov.au Phone: (07) 3646 8579

Redcliffe, Caboolture & Kilcoy Hospital, Community, Indigenous Subacute Services
Research Governance Office Vanessa Constable Email: RCRGO@health.qld.gov.au Phone: (07) 3883 7243

Date	Version	Custodian
11/2015	1.0	Research Governance Officers, The Prince Charles Hospital, Royal Brisbane and Women's Hospital and Redcliffe, Caboolture & Kilcoy Hospital, Community, Indigenous Subacute Services
13/09/2017	2.0	Research Governance Officers, The Prince Charles Hospital, Royal Brisbane and Women's Hospital and Redcliffe, Caboolture & Kilcoy Hospital, Community, Indigenous Subacute Services