Cairns and Hinterland
Hospital and Health Service

SSA Submission Checklist

ATTACH THIS CHECKLIST TO YOUR *HARD COPY* SUBMISSION.

Do not provide the hard copies as a rolling document.

(Each document is to be printed separately. Each separate document can be printed back-to-back. All documents must be stapled. Clips can be used for large documents.)

Mandatory Documents	Hard Copy	Uploaded in ERM
➢ **Detailed Cover letter** addressed to the RGO signed by the PI or Project/Study Coordinator. • *Template available on request.*	☐	☐
➢ **HREC Approval letter/s** • Original and all amendment HREC approval letters outlining amended current study documents, CHHHS site.	☐	☐
➢ **Protocol**	Mandatory ☐	Mandatory ☐
➢ **SSA form** in hard copy including all signatures: • *Verified Budget Endorsement Request (BER) form* from the Research Senior Business Coordinator (Uploaded at Q9.5 on the SSA form). • *Financial Memo* from CFO Services (Upload at Q9.6 on the SSA form). • *Business Head of Department* (HoD) to sign the SSA form. • *Principal Investigator* at CHHHS signs the SSA form. If there are multiple sites within the CHHHS, contact the RGO regarding the relevant HoD signature/s.	☐	☐
➢ **Human Research Ethics Application (HREA)** as approved by the HREC.	☐	☐
➢ **HREC approved study documentation as listed on the ethics approval letter** including, but not limited to: • Participant Information Sheets and Consent Forms (PISCF), Study tools, Questionnaires, Surveys, Advertisements, Diaries, Recruitment posters / flyers, data collection tools, case report forms etc. All study documents must match the version and date as listed in the HREC approval letter. <u>For multi-centre/site research projects</u> • Only clean copies MASTER study documents are required for multi-centre research projects. • Site specific study documents (eg. PISCFs, recruitment poster/flyers, surveys, and questionnaires etc) may be required for multi-centre research. • Clean & tracked copies for Site Specific study documents are required, cross referencing Master version in the footer. • *Please contact RGO for advice on site specific documentation.* **Version control is essential for all study documents.**	☐	☐
➢ **Current CV for all investigators** *(CVs should be dated and remain current for 2 years)*	☐	☐

Some studies require additional documentation – see below.

Additional Documentation	Hardcopy	Uploaded in ERM
Does this study require a contract? ☐ Yes ☐ No If external entities are involved, a contract is required. - *Contact the RGO for advice & contract templates.*	☐	☐
Public Health Act (PHA) application and approval letter *(Please refer to the Checklist PHA (Attachment E) – you may require PHA approval.)*	☐	☐
Evidence of approval from the Data Custodian – Email **CHHHS-HIS@health.qld.gov.au** *(Required if a waiver of consent has been granted by a HREC and the access to data for research is being sought under Section 150 of the Hospital and Health Bords Act 2011[#])*	☐	☐
Research Funding Schedule / Agreement	☐	☐
Indemnity Form (Required for Clinical Trials) Click here for the Medicines Australia template	☐	☐
Insurance Certificate (Required for Clinical Trials)	☐	☐
Clinical Trial Notification (CTN)	☐	☐
Good Clinical Practice (GCP) Certificate - Required for Clinical Trials only. *(GCP certificate remain current for 3 years.)*	☐	☐

[#] Section 150 of the Hospital and Health Boards Act 2011 provides that a 'designated person' may disclose 'confidential information' to another' designated person' if the disclosure is for the purpose of 'evaluating, managing, monitoring or planning health services'.

Post a **hard (paper) copy** of the entire submission including all study documents in to:

Research Governance Officer
Level 7 William McCormack Place
5b Sheridan Street, Cairns QLD 4870.

The hard copy documents are utilised to review the submission, for the master file and for the Chief Executive to review and authorise the submission.