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.)

Item	Hard copies Attached (Tick)	Uploaded in ERM (Tick)
➢ **Detailed Cover letter** * addressed to the RGO signed by the PI or Project/Study Coordinator. • *Template available on request.*	Mandatory ☐	Mandatory ☐
➢ **HREC Approval letter/s** * • Original and all amendment HREC approval letters outlining amended current study documents, CHHHS site.	Mandatory ☐	Mandatory ☐
➢ **Protocol** *	Mandatory ☐	Mandatory ☐
➢ **SSA form** * in hard copy including all signatures: • *Principal Investigator* at CHHHS signs the SSA as PI. • *Business Head of Department* (HoD) to sign the SSA. • *Financial Memo* from CFO Services. If multi-sites in the CHHHS, contact the RGO regarding HoD signature/s	Mandatory ☐	Mandatory ☐
➢ **Human Research Ethics Application (HREA)** * as approved by the HREC.	Mandatory ☐	Mandatory ☐
➢ **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 research projects</u> • Site specific study documents (eg. PISCFs, recruitment poster/flyers, surveys, and questionnaires etc) may be required for multi-centre research. • Only clean copies MASTER study documents are required for multi-centre research projects. • 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.**	Mandatory as applicable ☐	Mandatory as applicable ☐

Some studies require additional documentation – see below.

Item	Attached Hardcopy (Tick)	Uploaded (Tick)
# Does this study require a contract? ☐ Yes ☐ No If external entities are involved, a contract is required. - *Contact the RGO for advice & contract templates.*	Mandatory if applicable ☐	Mandatory if applicable ☐
# If a waiver of consent has been granted by the HREC, please refer to the Checklist PHA (*Attachment E*) – you may require PHA approval.	☐	☐
# Research Funding Schedule / Agreement	☐	☐
# Indemnity Form (Medicines Australia template)	☐	☐
# Insurance Certificate	☐	☐
# Clinical Trial Notification (CTN)	☐	☐
# Is this research a Clinical Trial? ☐ Yes ☐ No If yes, provide a certificate that all investigators have completed Good Clinical Practice Training (GCP Certificate).	Mandatory If clinical trial ☐	Mandatory If clinical trial ☐

* Mandatory for all research.
# Must be provided if relevant to your research.

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.