Checklist SSA

ATTACH THIS CHECKLIST TO YOUR *HARD COPY* SUBMISSION.

Do not provide the hard copies as a rolling document.

(Each document is to be separate. Do not copy documents on the back of others. They must all be stapled or clipped separately.)

Item	Hard copies Attached (Tick)	Uploaded in ERM (Tick)
***Detailed Cover letter** addressed to the RGO signed by the Principal Investigator / Coordinator for SSA. • Listing documents with version & dates provided for SSA review. • Naming the actual site/s where the research is to occur in the CHHHS (in the cover letter).	**Mandatory** ☐	Mandatory ☐
*Initial Approval letter from the Ethics Committee (The site must be listed (e.g., Cairns Hospital). Also, any new HREC approval letters outlining amended current study documents if applicable.	Mandatory ☐	Mandatory ☐
* SSA including Signatures: • Ensure the *Principal Investigator* at CHHHS signs the SSA. • *Business Head of Department* (HoD) to sign at the end of the SSA. See *attachment* C. • *Chief Finance Officer* (CFO) to review the excel Budget Endorsement Request Form (*attachment D*). The CFO will provide a signed CFO Endorsement Memo which needs to be submitted to the RGO. Provide completed Budget Endorsement Request Form to the RGO and upload both documents at 9.6 in the SSA in ERM. If there are multi-sites in the CHHHS, please contact the RGO for advice regarding possible additional signatures for HoD.	Mandatory ☐	Mandatory ☐
*HREA (Human Research Ethics Application) as approved by the HREC.	Mandatory ☐	Mandatory ☐
*HREC approved study documentation including but not limited to: • Participant Information Sheets; Consent Forms; Study Tools; Questionnaires; Advertisements; Diaries; Surveys; Recruitment Posters; Collection data; flyers; case reports etc. • Ensure that Participant Info and Consent Forms (PICFs) are site specific if multi centre research. Contact RGO for advice. • Master copies of PICFs must also be provided if relevant for multi centre research.	Mandatory ☐	Mandatory ☐

• Clean & tracked version for Site Specific PICFs are required, cross referencing Master version in the footer. • All the study documents you provide must match the version and dates as listed in the HREC approval letter. Version control is essential.		
*Protocol/Study design (this is in addition to your SSA form)	Mandatory ☐	Mandatory ☐
Is this research a Clinical Trial? If yes, then you must provide evidence/Certificate that the Principal Investigator has completed Good Clinical Practice Training. GCP Certificate.	Mandatory ☐	Mandatory ☐

Some studies require additional documentation – see below.

Item	Attached (Tick)	Uploaded (Tick)
#If a waiver of consent has been granted by the HREC, please refer to the separate Checklist PHA (*Attachment E*) – you may require PHA approval. If accessing identifiable confidential Patient information - medical records, data bases, tissue samples etc without patient consent. If any identifiable patient data is being disclosed to non CHHHS employees, external organisations a PHA may be required. Check with PHA@health.qld.gov.au before you submit the SSA if in doubt. Contact the RGO if further advice is required.	☐	☐
#Research Funding Schedule (Budget)	☐	☐
#Indemnity Form (Medicines Australia Format)	☐	☐
#Insurance Certificate	☐	☐
#Clinical Trial Notification (CTN)	☐	☐

#**Do you need a research contract/agreement?** *This is applicable to all non-QLD Health applicants and partnerships between QH/CHHHS employees and external entities (E.g. CHHHS Principal Investigator and Uni of Q).* • Note contracts in standard unaltered Medicines Australia Format will not require local legal review. • A standard template available from the RGO is also available. This can also be utilised for Uni researcher /collaborations etc. • If you are a CHHHS employee but are doing the research as part of gaining a degree via a University or doing research that is not on behalf of QH/CHHHS you will need a research contract. Contact the RGO for advice. • If any of the researchers are from an external organisation you will need a contract. • If any data is going to an external organisation, you will need a contract. • If you are collaborating with an outside organisation regarding the research, you will need a contract. • Outside organisations includes universities, government departments, private organisations, not for profit organisations. Any entity that is not Queensland Health. You will need a contract. • Contact the RGO to organise a suitable contract/agreement. • The RGO will gain the signature for the Institution CHHHS Chief Executive on the contract.	☐	☐

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

Send all documents in **hard copy – printed documents** to Margaret Grasso, 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.