

SSA Submission Requirements

All documents must be provided to the RGO in Hard Copy.

If the research is a Clinical Trial, evidence/GCP Certificate must be provided outlining that the Principal Investigator has done Good Clinical Practice (GCP) Training. A GCP Certificate is valid for three years.

SSAs are a separate process to the Ethics approval process

- The Ethics approval process is a peer review of your research submission by a Human Research Ethics Committee (HREC). This is why you complete a HREA (the HREC reviews your ethics application with the following question in mind: *Is the research ethical?*) with a view to granting ethical approval.
- The Research Governance process is the Chief Executive's (CE) endorsement that your ethically approved research is now authorised to be conducted at a CHHHS site. Completing the SSA is the Research Governance process (*is the CE of the institution satisfied the research can commence at the CHHHS site?*).

Site Specific Assessment (SSA)

- If you intend to conduct research at a Queensland Health (QH) Site, you will need to complete an SSA in Ethics Review Manager (ERM). The link to ERM is: <https://au.forms.ethicalreviewmanager.com>
- **For technical advice regarding the ERM system, please contact: HIIRO helpdesk support team: Information Officer Research 07 3082 0629**
ERMhelpdesksupport@health.qld.gov.au
- The Researcher User Guide for ERM can be found [here](#), along with the ERM training schedule and presentation. These resources have been provided by The Health Innovation, Investment and Research Office (HIIRO).
- When completing your SSA press option 1 to proceed. (Option 2 requires specific approval by the Research Governance Officer (RGO)
What is the purpose of this form?
 - Option 1, To submit a NEW Site-Specific Assessment Form

You will need to create and complete an SSA sub-form, upload all HREC approved documents as outlined in the HREC approval letter and upload any other documentation, including the contract if relevant. Once completed, please submit the SSA form by pressing the submit button which is located in the Actions pane on the left-hand side of the screen. Please note that documents uploaded for the Ethics application in ERM do not transfer over into the SSA application – the documents will need to be uploaded again.

Please ensure you obtain all the required signatures along with the required documentation, before you send the **hard copy** of the SSA application to the Research Governance Officer (RGO).

Contracts – Research Collaboration Agreement (RCA)

For any researchers who are requiring a contract discuss with the RGO before or whilst preparing your SSA. **All contracts and indemnity forms will be presented to the Chief Executive by the RGO for execution.** The researcher is not to send any documentation directly to the CE's office. All documentation is to be provided to the RGO who will gain the CE's signature when the SSA is in order for authorisation.

Documentation

When you submit your SSA application, be sure to compile a detailed cover letter to the RGO, listing all the documents you are presenting with versions and dates of study documents provided and list the relevant site/s in the CHHHS.

Provide one hard copy of your SSA submission including the ethically approved HREA and any additional approved documentation (including your HREC approval letter).

Present your submission as a full set or suite of documents, ensuring you also upload all of your documents to the online form (in the SSA section of ERM) including PHA approvals, contracts, indemnities, insurance certificates if applicable to your research. Ensure the versions and dates of the documents for the SSA application are the same as outlined in the HREC approval letter.

The HREC approval letter must state the site/s that you are requesting to conduct the research at (e.g., CHHHS, Cairns Hospital etc). Use the Checklist SSA (*provided as attachment B*) to ensure you have sent and uploaded all the required documentation.

For studies approved by the FNQ HREC: The hard copy documents on an ethics file are not copied or transferred to the SSA file by the Ethics Administrator or RGO. The Master Ethics hard copy file is a separate file that is kept by the HREC Coordinator. Copies of the documents you gained ethical approval for are the documents you attach, upload, and include with your SSA (including your HREC approval letter). It is the researcher's responsibility to provide all the ethically approved documentation again to the RGO, as your hard copy documentation creates the Master Site Specific Assessment (SSA) file. This is provided to the CE by the RGO when requesting authorisation for your project.

Documents uploaded in ERM for the ethics application do not transfer over to the SSA application in ERM and must be uploaded again by the researcher in ERM. This includes the HREA.

More than one site in the Cairns & Hinterland Hospital & Health Service?

Please contact the RGO for advice before you proceed. Signatories from the various sites will/may be required or a letter/email of support from the DoN or Medical Superintendent of each site for regional areas. However, you will only need to do one SSA for the CHHHS regardless of how many sites are nominated for this jurisdiction.

Finance

- **[New process for SSA submissions submitted from 1 October 2021.](#)**

To assist you with providing the correct details regarding your budget for the CFO a pre review is now carried out by the Research Senior Business Coordinator (SBC). Prior to CFO review, send a PDF of the draft SSA; completed excel Budget Endorsement Request Form and contract (if applicable) to the Senior Business Coordinator CHHHS_Research_Business@health.qld.gov.au for pre review before progressing to the HoD signature and CFO. You will then receive a **verification email** of budget details from the SBC to provide to the HoD and CFO.

Signatures - Mandatory

- Towards the end of the SSA form there is a place for the Head of Department (HoD) to sign. The relevant business HoD is outlined on the excel SSA HoD Signatories List (*attachment C*) that is attached for you. The Clinical Head of the Department is **not** the relevant signature. The HoDs do not perform electronic signatures in ERM, only wet ink on a SSA pdf.
- Also attached is an excel Budget Endorsement Request Form (*attachment D*) that is required by the SBC and Chief Finance Officer (CFO) to review the SSA application. The CFO will then provide you with a signed

CFO Endorsement Memo giving financial endorsement for the project. Upload the completed excel Budget Endorsement Request Form (D) and CFO Endorsement Memo at **9.6** in the SSA in ERM.

- c) The PI must also sign the SSA form where required towards the end of the form.

Obtaining the above signatures is the researcher's responsibility.

If you are not from this Health Service, advise your nominated **local site contact person** to obtain the necessary signatures for you if you are unable to do so.

The RGO recommends your valid SSA to the CE for authorisation of the SSA application. Once the SSA has been validated you will receive a letter from the RGO and when authorised by the CE, an authorisation letter signed by the CE, is provided to the researcher/s by the RGO. The RGO will gain the CE's signature on contracts and indemnities at the time of authorisation. It is preferred that contracts are signed by the other party first. The average timeframe in the CHHHS for authorisation by the CE from receipt of a **valid** application is 7 -10 business days approximately.

Validation

An application must be complete, with all signatures and documentation provided before it can be validated. Once an application has been validated, you will receive a letter advising you of this, relevant paperwork will then be sent to the CE for authorisation. The time period specified by HIRO Brisbane for an RGO to process a **validated** application is **25 days**.

Please allow yourself plenty of time for this process, as applications cannot be expedited. The day your SSA arrives in the office of the RGO or the day you press submit in ERM is not when the 25-day clock starts. Once the submitted SSA is complete and correct is when the application is "validated" and then the clock commences within the ERM system.

Mandatory Documents

- **SSA Cover letter addressed to the RGO** (listing local sites and documents provided with the SSA for review). *Please include the version number and date for each study document in your cover letter.*
- **SSA Form** with a reference number printed in the bottom left-hand corner of the SSA. If there is no reference number on the SSA form it is still in **draft** form and not submitted in ERM.
- **Copy of HREA** as approved by the HREC.
- **Copy of HREC approval letter/s** (outlining the nominated CHHHS site/s).
- **All HREC approved documents** that will be used for the research project (e.g., protocol or study plan, consent forms, information sheets etc). The version numbers of these documents are cross-referenced with your HREC approval letter. The document versions need to match those outlined in the HREC approval letter. The version and date should be outlined in the footer of the document.
- If multi-site research, you may need Site Specific documents – e.g., PICFs. These are created from the Master approved by the HREC. Ask the RGO for advice regarding creating Site Specific documents for the CHHHS.
- For researchers who are not CHHHS employees, a **study agreement** may also be required (e.g., a student deed for JCU students) - if no JCU supervisors are listed as investigators, or a collaborative research agreement. A contract is also required where CHHHS employees and external researchers are involved e.g., CHHHS and JCU are investigators; CHHHS and Uni of NSW are investigators etc. Or an outside entity with no local investigators.

- The RGO can provide you with details concerning JCU research agreement requirements and a relevant template/s for other University Research Agreements. If you are a CHHHS employee but are doing research as part of a post graduate degree, then you will require a research agreement.
- The RGO can provide you with relevant QH legally approved Research Agreement template if there are any external parties involved with the research or multi external parties are involved.
- The RGO can provide you with a relevant QH legally approved Research Agreement template if there are no CHHHS investigators with all investigators being external to the CHHHS.
- A **PHA approval letter** must be provided (after you gain a waiver of consent from the HREC in your approval letter) if you are accessing confidential patient data, databases, tissue without approved written participant consent. If any external entity to CHHHS can view identifiable confidential data – a PHA approval will be required. See the Checklist PHA provided as *attachment E*.
- However, if you are “Designated Person” (and you have gained a waiver of consent from the HREC) you can access confidential patient data under the Hospital and Health Board’s Act 2011 without gaining a PHA. But if any external entity including a researcher who is not a CHHHS employee is part of the research, collaboration with an external organisation e.g., University, then you must gain a PHA approval. A “Designated Person” is a CHHHS employee.

Please Note:

- Any study amendments, new HREC approvals, up-versioned documents, annual/final reports, safety reports/notifications etc. also needed to be uploaded to the ERM database for the entire duration of the study before sending to the RGO to process. This is done via the Post Approval Notification (PAN) tab in ERM. The researcher must initiate the process by creating a PAN. The RGO cannot acknowledge or authorise anything until the researcher submits the PAN in ERM.

If you have any problems uploading your documents, please contact the [ERM Helpdesk](#) Phone: 07 30820629

A hard copy of all documents must be provided to the RGO for review and processing of the SSA to begin.

When couriering documents or via Australia Post, please send completed SSAs with supporting documents to:

Margaret Grasso, Research Governance Officer
Research Ethics and Governance Unit, Queensland Health
Level 7 William McCormack Place, 5b Sheridan Street, Cairns QLD, 4870

Phone: (07) 4226 5512

NB: Please ensure the address is displayed exactly as stated here to ensure your SSA is delivered to the correct area on Level 7. The building contains staff from many different government departments, and it can confuse the delivery drivers when they attempt to deliver parcels if all the above information isn’t provided on the con-note/address sticker.