# SCHHS Checklist of Research Governance Documents

The purpose of this checklist is to assist researchers in the preparation of documents for research governance approval.

**THE CHECKLIST MAY BE SUBMITTED IN LIEU OF A COVER LETTER**
**HOWEVER**
**EITHER A *COVER LETTER* OR THE *CHECKLIST* ARE REQUIRED**

- This checklist should be used in conjunction with the Checklist in the Site Specific Application (SSA) Form located in the on-line forms: https://au.ethicsform.org/SignIn.aspx.

- Not all documents are relevant for each study. Researchers should contact the SCHHS Research Governance Office at SC-Research-Governance@health.qld.gov.au to discuss their study and the requirements in order to facilitate approval.

- A legend with explanatory notes has been provided at the end of the Checklist to assist researchers with understanding the requirements for submission. Researchers should refer to the legend when completing the checklist.

- Documents are required in both electronic and hard copy format (with the exception of Investigator Brochures which can be submitted electronically only, where required).

- Documents may be submitted electronically either as email attachments or on a USB (USBs will not be returned). Email submissions should include the HREC number and short title of the study in the subject line to allow identification of the project. Electronic documents should be appropriately named so that they can be easily identified (e.g. use the document name in the checklist below).

- Once all Research Governance requirements have been met, the Research Governance Officer will submit hard copy documents to the Health Service Chief Executive with a recommendation to approve the conduct of the study within the SCHHS.

**A cover letter or the checklist (below) should be completed and submitted with your study documents to:**

**E-mail**: SC-Research-Governance@health.qld.gov.au
**Hand delivery:** Sunshine Coast University Hospital, SCHHS Research Offices, Lakeside Building, Level 1
**Postal**: Sunshine Coast University Hospital, PO Box 5340, SUNSHINE COAST MC Qld 4560
**Phone**: 07 5202 2991

## Research Governance Checklist:

Principal Investigator name:

Principal Investigator or Site Coordinator contact details (name/telephone/email):

HREC Number:

Study title:

Short name (if applicable):

Is the principal investigator undertaking this study as a student?

Layman's description of the study (copied from the LNR/HREA Application Form):

| Document | Format | Researcher Notes * | Yes | No | N/A |
|---|---|---|---|---|---|
| Checklist or coverletter | Hard copy and Electronic | | ☐ | | |
| SSA form | Hard copy and Electronic | | ☐ | | |
| Budget Template / Information | Hard copy and Electronic | | ☐ | | |
| HREA/LNR Application Form | Hard copy and Electronic | | ☐ | | |
| HREC approval letter | Hard copy and Electronic | | ☐ | | |
| Approval Correspondence | Hard copy and Electronic | | ☐ | ☐ | ☐ |
| Protocol | Hard copy and Electronic | | ☐ | ☐ | ☐ |
| Master PICF | Hard copy and Electronic | | ☐ | ☐ | ☐ |
| Site Specific PICF | Hard copy and Electronic | | ☐ | ☐ | ☐ |
| Data collection | Hard copy and Electronic | | ☐ | ☐ | ☐ |
| Funding information | Hard copy and Electronic | | ☐ | ☐ | ☐ |
| Investigator CVs | Hard copy and Electronic | | ☐ | ☐ | ☐ |
| Agreements** | Hard copy and Electronic | | ☐ | ☐ | ☐ |
| Indemnity forms** | Hard copy and Electronic | | ☐ | ☐ | ☐ |
| Insurance Certificates** | Hard copy and Electronic | | ☐ | ☐ | ☐ |
| Investigator brochure | Electronic | | ☐ | ☐ | ☐ |
| PHA Application and Approval | Hard copy and Electronic | | ☐ | ☐ | ☐ |
| QCAT Application and Approval | Hard copy and Electronic | | ☐ | ☐ | ☐ |
| Pathology Queensland Approval and Quote | Hard copy and Electronic | | ☐ | ☐ | ☐ |
| Forensic and Scientific Services Approval | Hard copy and Electronic | | ☐ | ☐ | ☐ |
| Other HREC approved documents *** | Hard copy and Electronic | | ☐ | ☐ | ☐ |
| Other supporting documents | Hard copy and Electronic | | ☐ | ☐ | ☐ |
| CTN | Hard copy and Electronic | | ☐ | ☐ | ☐ |

## Legend and Explanatory Notes:

| Document | Explanatory Notes |
|---|---|
| Checklist or coverletter | The above checklist or a coverletter is required to identify the relevant documents and information associated with the governance submission |
| SSA form | SSA form must contain a submission code (located in the bottom right corner of the document). The SSA form must also contain the signatures of all investigators, contact person, finance delegate, and heads of departments/supporting departments/Service Group director. The name and position of the signatory are required. Electronic signatures are permitted.<br><br>*The budget section of the SSA is no longer required. However, a separate budget template should be provided (refer to Budget Template/Information below).* |
| Budget Template / Information | Where possible the SCHHS research budget template should be used. The budget must include a signature from the relevant finance delegate. A copy of the SCHHS budget template can be obtained by contacting the Research Governance and Development Office (SC-Research-Support@health.qld.gov.au).<br><br>All applications must include a budget irrespective of the source of funding, the value of the in-kind contribution made by the SCHHS (if any), and the extent to which SCHHS costs will be covered by an external funding body (eg grant).<br><br>For commercially sponsored clinical trials, the budget should also include the research governance review fee. |
| HREA/LNR Application Form | All applications should contain the Human Research Ethics Committee (HREC) application form submitted to the governing HREC for approval.<br><br>The HREC submission code and date of the HREC application form must match the version information on the HREC approval letter. |
| HREC approval letter | The original HREC approval letter should be included in the governance submission. Where amendments to the study have occurred following the original approval, all HREC amendment approval letters should also be included. |
| Approval Correspondence | Other correspondence from HREC which reflects the history of the project, discussion between the investigator and HREC (in particular requests for further information from the HREC and the responses), and any amendments made to the project should also be provided to the Research Governance Officer. |
| Protocol | If more than one version of the Protocol has been approved by the HREC, provide the most recent approved version. |
| Master PICF | Participant Information, Consent and Revocation Forms (PICFs) must be submitted for research projects in which the research team is seeking participant consent. The version details must match the most recent HREC approval letter.<br><br>For single-site studies, the Master PICF will be the same as the Site Specific PICF (refer to below).<br><br>For multi-site projects, the HREC will normally approve a Master PICF from which Site Specific PICFs will be generated for each site involved in the research. |
| Site Specific PICF | For single-site projects, the Site Specific PICF should be the same as the PICF approved by the HREC.<br><br>For multi-site projects, a Site Specific PICF should be created based on the most recent HREC approved master version. Site Specific PICF should contain<br>• the site version and date<br>• the version and date of the Master PICF which it is based on<br>• details of the Site Principal Investigator<br>• details of SCHHS Research Governance Office should the participants have any concerns about the project<br>• the SCHHS/Queensland Government logo on the front page, to demonstrate to the participants that the research project has received Queensland Health endorsement.<br>Where a Site Specific PICF is being provided, a tracked version showing changes from the Master PICF, along with a clean copy are required. |
| Data collection | Data collection forms / questionnaires approved by the HREC should be included in the governance submission |
| Funding information | Where applicable, please include funding information, including but not limited to grant approval letter and grant agreement. |
| Investigator CVs | CV of each Investigator at the site (refer to SSA form for list of site investigators). |

| Document | Explanatory Notes |
|---|---|
| Agreements** | A research agreement is required for all research in which an external organisation is involved in the research. This includes sponsored, collaborative and student (e.g. Research Higher Degree) research. Research Governance Office review/approval of the Research Agreement is required prior to obtaining signatures.<br><br>The Medical Technology Association of Australia template agreements are preferred for all device trials. The Medicines Australia template agreements are preferred for all clinical drug or other trials. |
| Indemnity forms** | The Medicines Australia Standard Form of Indemnity is required for all commercially sponsored clinical research.<br><br>Party details must be correctly included. Researchers should discuss with the Research Governance Office prior to obtaining signatures if unsure of the required details. |
| Insurance Certificates** | Insurance Certificates are required for all projects involving external parties, in particular commercially sponsored research |
| Investigator brochure | Investigator brochure and product information are required for all drug and/or device trials |
| PHA Application and Approval | Public Health Act (PHA) application form **and** approval letter may be required for research where patient consent is not obtained for some or all aspects of the research. Please contact Research Governance Office for further information. |
| QCAT Application and Approval | Queensland Civil and Administrative Tribunal (QCAT) application form **and** approval letter are required for clinical and/or interventional research where patients have impaired capacity to consent (usually a Person Responsible PICF is used), and the research project meets the definition of Clinical Research under *the Guardianship and Administration Act 2000* (Qld). |
| Pathology Queensland Approval and Quote | Pathology Queensland Approval Form **and** Quote are required where studies require access/services of Pathology Queensland. |
| Forensic and Scientific Services Approval | Forensic and Scientific Services (FSS) approval is required where studies require access to coronial material held by Queensland Health FSS |
| Other HREC approved documents *** | All other material approved by the HREC and relevant to the site. This may include any other material supplied to participants (e.g. identification cards and diaries) or recruitment/promotional material (e.g. advertisement material such as posters) |
| Other supporting documents | Depending on the study, other documents may be required. This can include: Radiation Safety Report, NHMRC Cellular Therapies Advisory Committee (CTAC), NHMRC Embryo Research Licensing Committee, and Institutional Biosafety Committee documents |
| CTN | Clinical Trials Notification (CTN) form is lodged online. Once the notification process has been completed, the approval letter should be submitted to the Research Governance Office at the address above. The CTN lodgement may occur after governance authorisation for the study has been issued. |

**KEY**:
* Where necessary, researchers can provide additional information relevant to a document type in this column (for example if the study involves multiple PICF).

** It is recommended that researchers discuss their project with the Research Governance Office as early as possible, particularly where non-Queensland Health collaborators are involved. Advice can be given as to whether or not a research agreement and indemnity form may be required. Where these documents are required, hard copies are to be submitted in triplicate.

*** The Human Research Ethics Committee (HREC) approval letter will generally include a list of documents that have been approved (including the version number and date of the document). You will need to submit all of the documents listed in this letter for Research Governance approval. Please ensure that the versions of documents submitted are the same version number and date as that approved by the HREC.