

Research Governance Guidelines

Human Research Ethics Committees (HRECs) grant scientific and ethical approval for a research project. However, before the project can commence, each participating site must receive Site Specific Assessment (SSA) authorisation in line with NSW Health policy (PD 2010_056 *Authorisation to commence research in NSW Public Health Organisations*)

Why is Site Specific Assessment necessary?

Site Specific Assessment (SSA) ensures that the proposed research project complies with governance requirements at each particular site. The issues considered as part of the site specific assessment include:

- Do the site investigators have the necessary skills and credentialing to undertake the research?
- Are there adequate facilities and resources at the site?
- Is the project adequately funded?
- Have legislative requirements been met?
- Are there adequate indemnity and insurance arrangements in place for a clinical trial?
- Has scientific and ethical approval been granted by a HREC?

Who should make the Site Specific Assessment application?

Applications for Site Specific Assessment (SSA) should be made by the Principal Investigator i.e. the person responsible for the conduct and management of the research at Concord Hospital.

What is the procedure for submitting a Site Specific Assessment?

- 1) If the project was approved by the Sydney Local Health District HREC – CRGH and Concord Hospital is the only site:

The Principal Investigator (PI) – i.e. the person who created the NEAF or LNR form, should:

- Log on to the Australian Online Forms website: www.ethicsform.org/au.
- Open the ethics application form (NEAF or LNR form) for the project.
- Select the “SSA” tab.
- Some of the information from the ethics application form will automatically populate the SSA form.
- Once the SSA form is completed, click on the “Submission” tab, and print a copy of the form. Once original signatures have been obtained, the form and associated documents (see below) can be sent to the Research Governance Officer at any time.

- 2) If the project was approved by the Sydney Local Health District HREC – CRGH as a multi-site project and Concord Hospital is the Co-ordinating Site:

The Co-ordinating Investigator (CI) – i.e. the person who created the NEAF or LNR form, should:

- Log on to the Australian Online Forms website: www.ethicsform.org/au.
- Open the ethics application form (NEAF or LNR form) for the project.
- Select the “SSA” tab.
- Enter the number of sites for which SSAs need to be created for the project. (*More sites can be added at a later date if necessary*) Some of the information from the ethics application form will automatically populate your SSA form.
- SSAs can now be transferred to other participating sites for completion and submission to their own Research Governance Officers.
- Once the SSA form for Concord Hospital has been completed, click on the “Submission” tab, and print a copy of the form. Once original signatures have been obtained, the form can be sent to the CRGH Research Governance Officer at any time.

- 3) If the project was approved by the Sydney Local Health District HREC – CRGH as a multi-site project but Concord Hospital is not the Co-ordinating Site:

OR

The project was approved as a multi-site project by another Lead HREC and Concord Hospital is a participating site:

- The SSA form should be transferred to the Principal Investigator at CRGH by the Co-ordinating Investigator via the Ethics Form website.
- Once the SSA form for Concord Hospital has been completed, click on the “Submission” tab, and print a copy of the form. Once original signatures have been obtained, the form and associated documents (see below) can be sent to the Research Governance Officer at any time.

What other documents need to be submitted with the SSA?

All SSAs will need to be accompanied by:

- Site Specific Participant Information Sheet(s) and Consent Form(s) based on the approved Master Version(s)

If the Sydney Local Health District HREC – CRGH was not the Lead HREC then the following documents also need to be submitted:

- Copy of the approval letter from the HREC
- Copy of the ethics application form (NEAF or LNR form)
- Copies of approved Master Participant Information Sheet(s) and Consent Form(s)

- Copies of any other study-related documentation such as protocol, questionnaires etc.

For commercially-sponsored clinical trials:

All of the above, plus:

- Investigator's Brochure – **two copies** (one for the Research Office & one for the Clinical Trials Pharmacist)
- Protocol – **two copies** (one for the Research Office & one for the Clinical Trials Pharmacist)
- CTN form (if applicable) – **one original**
- Standard Medicines Australia Form of Indemnity – **three originals**
See <http://medicinesaustralia.com.au/issues-information/clinical-trials/indemnity-and-compensation-guidelines/>
- Standard Medicines Australia Clinical Trial Research Agreement (CTRA) for Commercially-Sponsored Trials – **at least two originals**

OR

Standard Medicines Australia Clinical Trial Research Agreement (CTRA) for Contract Research Organisations acting as the Local Sponsor – **at least two originals**

See <http://medicinesaustralia.com.au/issues-information/clinical-trials/clinical-trials-research-agreements>

- Certificate of Insurance – which names the commercial sponsor as insured under the relevant policy; covers the conduct of the relevant clinical trial in Australia; will be current for at least the period of the clinical trial; contains insurance cover for at least AUD20 million per occurrence and in the annual aggregate and does not contain an excess greater than AUD25,000 for each claim.

All legal documents should name "Sydney Local Health District" Level 11, KGV Building, Missenden Road, CAMPERDOWN NSW 2050. ABN: 17 520 269 052.

What should the local Participant Information Sheet and Consent Form contain?

The wording of the local Participant Information Sheet and Consent Form should be the same as that approved by the lead HREC for the Master Participant Information Sheet and Consent Form. However, the following variations are required:

- The local Participant Information Sheet must contain the name and contact details of the CRGH investigator.
- The local Participant Information Sheet must retain the name and contact details of the lead HREC.
- The local Participant Information Sheet must contain the following local information *"The conduct of this study at Concord Hospital has been authorised by the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study may contact the Research Governance Officer on 02 9767 5622 and quote protocol number xx/xx/xx"*.
- The local Participant Information Sheet must contain a footer which reads *"CRGH Version x dated xx/xx/20xx based on Master Version x dated xx/xx/20xx"*.

Who do I submit the SSA application to?

The Research Governance Officer, CRGH Research Office Building 75, Concord Hospital, Hospital Road, CONCORD NSW 2139. (Phone 02 9767 5622)

When should I submit my SSA application?

The SSA application may be submitted at any time during the submission process. There are no submission dates. Site authorisation will not be granted until final ethical approval for the research project has been granted by the relevant HREC.

Are there fees for making a SSA application?

The fee for a SSA application for a research project **with full industry sponsorship** is \$3 740.00 (including GST). There are no fees associated with research which is not commercially sponsored.

What is An Access Request form?

An approved research project which requires support from another NSW public hospital in the form of access to participants but does not involve the conduct of the research at that site, may not require a full Site Specific Assessment.

Instead, it may be possible to lodge an Access Request with the public health organisation using the Access Request Form available on the Online Forms website at <https://www.ethicsform.org/au>. The application should be accompanied by a written agreement from the relevant local staff who will provide the access required.

Examples of situations where this process might be used include:

- Recruitment of participants through posters, leaflets, handouts or letter of invitation (but not active enrolment)
- Distribution of surveys and questionnaires (but not collation and analysis of responses).
- Access to data or tissue held at the public health organisation (but not processing or analysis of the data or tissue).

Researchers should discuss their requirements with the Research Governance Officer on 02 9767 5622.

While the study is ongoing, what do I need to submit to the Research Governance Officer (RGO)?

If Concord Hospital is the Co-ordinating Site then amendments, annual reports etc will be sent to the SLHD HREC – CRGH and no extra documentation is required UNLESS a change is made to the Site Specific Participant Information Sheet and Consent Form. Where the project has been approved by another Lead HREC the following should be submitted to the RGO:

1. **Amendments** to an authorised research project should be submitted to the RGO, along with the approval letter from the Lead HREC and any associated documents.
2. Revised **Site Participant Information Sheets and Consent Forms** should be submitted to the RGO, with a copy of the Master Version which has been approved by the Lead HREC. A copy of the lead HREC approval letter is also requested.
3. **Adverse event reporting** – the CRGH principal investigator should report serious adverse events (SAEs) and suspected unexpected serious adverse

reactions (SUSARs) involving a Concord Hospital research participant to the lead HREC within 72 hours. The Principal Investigator will provide a copy of these reports to the CRGH Research Governance Officer (and to the Co-ordinating Investigator, if a multi-centre project).

You are *not* required to submit Quarterly or 6 monthly SUSAR line-listings to the RGO.

4. **Updated Investigator's Brochure or Annual Safety Report** (in the case of a clinical trial), should be submitted to the RGO. This should be accompanied by an acknowledgment letter from the Lead HREC.
5. A copy of the **annual report submitted to the lead HREC**. We will also request a status update on the study's progress at CRGH on the anniversary of the site authorisation of your project.
6. Protocol Violations (ie serious departures from the protocol which potentially affect the welfare or rights of the participant and affect the scientific soundness of the research plan) must be reported to the Lead HREC in a timely manner, *and a copy provided to the Research Governance Officer* (along with any responses from the Lead HREC). Examples of protocol violations include failure to obtain consent, enrolment of a participant who did not meet all inclusion/exclusion criteria; performing a study procedure not approved by the HREC; medication dispensing or dosing error etc.

Protocol deviations (i.e. minor alterations to the HREC-approved protocol which do not impact on the safety of the participants, do not affect the participant's willingness to continue in the study or the integrity of the study data) need *not* be reported to the Research Governance Officer

Abbreviations/Definitions

CI – Co-ordinating Investigator: the person who has overall responsibility for the research project and submits the project for ethical review. For single-centre research, Co-ordinating Investigator and Principal Investigator are synonymous.

CRGH – Concord Repatriation General Hospital

HREC – Human Research Ethics Committee

LNR – Low & Negligible Risk

NEAF – National Ethics Application Form

RGO – Research Governance Officer

SAE - Serious Adverse Event

SSA - Site Specific Assessment

SUSAR – Suspected Unexpected Serious Adverse Reaction