

Low/Negligible Risk Research Ethics and Governance Application Guidelines

A human research project cannot commence at a site within Central Adelaide Local Health Network (including Royal Adelaide Hospital and The Queen Elizabeth Hospital) without having both ethics and governance approval.

Human ethics review is conducted in accordance with the NHMRC National Statement on Ethical Conduct in Human Research (2007). The National Statement provides that institutions may have ethical review processes other than full committee review for low/negligible risk studies.¹ Within CALHN this alternative process is review by the relevant Human Research Ethics Committee (HREC) Chairperson, followed by endorsement at a committee meeting.

Research governance is a framework through which institutions are accountable for the research they allow to be conducted under their auspices. Research must be conducted according to ethical principles, guidelines for responsible research conduct, legislation and regulations. Research governance is about responsibility and about managing the quality, safety, privacy, risk, finances and ethical acceptability of research.

For further information please refer to the [SA Health Research Governance Policy](#) and the [SA Health Research Ethics Operational Policy](#).

The LNR Ethics and Governance Application Form

The LNR Ethics and Governance Application (LNR EGA) Form replaces both the previous LNR Ethics Application form and the LNR Site Specific Assessment (SSA) application form for low or negligible risk research conducted at CALHN sites. The aim of the LNR EGA Form is to provide sufficient detail about a low/negligible risk research project to enable ethical review and governance assessment to occur concurrently.

When the LNR EGA Form should be used

The LNR EGA Form should be used for governance and ethical review of research projects that involves only low or negligible risk to participants. In the first instance it will be used for studies primarily conducted within CALHN sites, however if your study is a multi-centre study within South Australia please contact the Research Office to discuss the project and we will work with you to ensure governance review is efficient.

The NHMRC National Statement on Ethical Conduct in Human Research (2007) defines low risk research as “research where the only foreseeable risk is one of discomfort”. Discomfort may include minor side-effects of medication, discomfort related to measuring blood pressure or anxiety induced by an interview. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.

The National Statement describes research as negligible risk where “there is no foreseeable risk of harm or discomfort; and any foreseeable risk is not more than inconvenience.”

Note: There are several types of human research which require full ethics committee review, even though they may have few tangible risks. These research types are listed in Section 3 and Chapter 4 of the National Statement.

A copy of the National Statement can be found [here](#).

Following receipt of an application, the Chairperson of the relevant HREC may deem that an application involves more than low risk, or is not appropriate for the alternative review process, and refer it for ethical review by the full committee. Further information or additional documents may then be required.

The LNR EGA form may also be used to apply for governance approval of studies at CALHN sites that have received human ethics approval from another SA Health HREC, or animal ethics approval.

Audit and quality assurance studies

The LNR EGA form should not be used for audit or quality assurance studies. Audit and quality assurance studies are defined in the NHMRC Ethical Considerations in Quality Assurance and Evaluation Activities (2014)ⁱⁱ as activities “where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation.”

The NHMRC National Statement suggests that “oversight of quality assurance/evaluation activities is required but ethical review is not necessary.” Unless it is very clear the activity is quality assurance, it is highly recommended that a determination on the nature of the activity be made by the HREC Chairperson.

An application for this determination can be made by submitting a Study Plan and any associated documents, including data collection spreadsheet via email.

CALHNResearchLNR@sa.gov.au.

Further information

Guidelines to ethical considerations for LNR research and Audit/Quality Assurance studies, and a non-exhaustive list of the classes of study protocols that may be eligible for expedited ethical review are available on each of the CALHN HREC websites.

<https://www.rahresearchfund.com.au/rah-research-institute/for-researchers/>

<http://www.basilhetzelinstitute.com.au/research/information-for-researchers/>

Completing the LNR EGA Form

An electronic copy of the LNR EGA Form Responses must be typed. Hand written responses will not be accepted.

To assist the expedient review of applications, researchers are advised to discuss their application with the Researcher Support Officer prior to submission.

Email: CALHNResearchLNR@sa.gov.au

Project full title

This must be the same as the title on the Study Protocol.

Principal Investigator

This section must be completed for the **lead** Investigator. Details of all other Investigators and their role in the project must be provided in the Study Protocol.

Reviewing HREC

Select CALHN HREC if you require the CALHN HREC Chairperson to review your study. If CALHN is being added as a site then the reviewing ethics committee may be another HREC within South Australia, and a copy of the ethics application and approval letter must be attached with the application form.

Other Committee approvals

Some research projects require approval such as animal ethics, institutional biosafety or radiation safety. Where applicable these approval letters / reports must be included as attachments to the application. If HREC approval is required for other Committee approvals, this should be advised in the ‘Additional information’ section of the LNR EGA Form

Type of application

“The expression ‘low risk research’ describes research in which the only foreseeable risk is one of discomfort. Research in which the risk for participants is more serious than discomfort is not low risk.

“The expression ‘negligible risk research’ describes research in which there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience.”

The ‘Access Request’ checkbox in the LNR EGA Form may be used in the following cases:

1. Where there is participant recruitment at the site through distribution of posters, leaflets, handouts, and letters of invitation (but not recruitment through direct contact with potential participants or enrolment).
2. Where surveys and questionnaires are distributed through CALHN personnel (but not collation and analysis of responses at the CALHN site).
3. Where there is access being requested for data or tissue held at CALHN (but not processing or analysis at the CALHN site).

SA Health sites involved in the study

All SA Health sites at which the study will be conducted must be listed. CALHN sites include: Basil Hetzel Institute, The Queen Elizabeth Hospital, SA Pathology, Hanson Institute, Royal Adelaide Hospital, Hampstead Rehabilitation Centre and Eleanor Harrauld Building.

Only one LNR application is required for all CALHN sites.

If the study is being conducted at a University or SAHMRI, the section can be completed as ‘Nil’.

Non SA Health sites involved in the study

All non SA Health organisations and locations that will be involved in the study, e.g. University, SAHMRI, an interstate public or private organisation etc. must be listed.

If the study is being conducted by just CALHN employees at CALHN sites, this section can be completed as ‘Nil’.

Conflict of interest

Declarations of conflicts of interest are required by the NHMRC. In the event of a conflict, details must be provided in the Study Protocol.

Data

For both existing and new data collection, the application must indicate whether participant consent will be obtained prior to access or collection.

Further details about data access and collection, including participant consent processes, must be provided in the Study Protocol.

Tissue/samples

If access to existing tissue/samples is required for the study, whether participant consent has been obtained must be reported on the LNR EGA Form.

Where existing samples are held outside of the Principal Investigators’ department, approval from the person or department responsible for authorising access must be attached to the application. If HREC approval is required prior to seeking this approval, this must be indicated in the ‘Additional information’ section of the LNR EGA Form.

Further details about the tissue/sample source and access must be provided in the Study Protocol.

New sample collection

Where new tissue/samples will be collected as part of the study, whether participant consent will be sought must be reported on the LNR EGA Form.

Further details about tissue/sample collection, including whether collection is within the Principal Investigator’s standard of care/employment must be provided in the Study Protocol.

Peer review

Peer review is defined as an “impartial and independent assessment of research by others working in the same or a related field”. Some studies have undergone a peer review process prior to the ethics and governance application, for example as part of a grant application. If applicable, details of the reviewing organisation must be reported on the LNR EGA Form, and review comments attached to the application.

Funding

Details of funding for the study must be reported on the LNR EGA Form.

In-kind support: report details of the number of personnel and hours of support, including all investigators and research assistants. Approval from the appropriate unit Business Manager must also be provided.

Internal department funding: report details of the source, the amount of funding, and CALHN cost centre.

External source funding (either to or from a CALHN site): provide details of the external organisation, the amount of funding and, where appropriate, CALHN cost centre.

Budget

If funds are to be paid to or from CALHN, an approved budget must be submitted for review. The budget must report the actual costs incurred to undertake the research at each site within CALHN, including salaries for research personnel (investigators and research assistants), consumables and equipment. The actual funds that will be paid to or by each CALHN site must be specified in the budget.

Note: funding and budget details are not required if the study will be conducted outside of CALHN, and no CALHN staff or resources will be involved.

CALHN Research Finance must sight and consider the project budget and any associated costs to the site(s) before giving authorisation. A copy of the project budget and evidence of authorisation must be provided with the LNR EGA Form.

Research Finance email: Health.CALHNResearchFinance@sa.gov.au

Agreement

If funds are to be paid to or from a CALHN site, an agreement must be in place.

Possible agreements include collaborations with a third party, corporate sponsorship, service agreements, material transfers, or grants. A copy of the agreement must be attached to the application.

Non SA Health investigators

All researchers working on an SA Health site that are not SA Health employees must have a signed Confidentiality Deed and current police check. If these have not been previously submitted to the Research Office, they must be submitted with the LNR application.

Where these documents have been completed as part of an induction process, an email from the appropriate HR/Admin/Laboratory Manager in the CALHN Department confirming that the Investigators have completed these requirements may instead be submitted with the application.

Insurance/indemnity

All research projects hosted by SA Health institutions involving SA Health or external staff must have appropriate insurance and indemnity prior to the project commencing.

Indemnity for projects undertaken by SA Health researchers within the capacity of their employment is automatically provided through SA Health’s corporate insurance arrangements. No further documentation is required.

If an SA Health employee has dual employment with a University or SAHMRI or another organisation, or is also a university student, and is conducting a research project outside of their SA Health employment capacity, indemnity must be provided by the University or other institution. For wholly private or commercially sponsored studies, indemnity must be provided by the researcher's institution or sponsor. In both these circumstances a copy of a certificate of currency for the indemnity must be provided with the LNR EGA form. Further information is available from Legal Governance and Insurance Services.

Legal Governance and Insurance Services email: Health.LGISResearchTrials@sa.gov.au

CV

A copy of a current brief CV (approximately 1-2 pages) for all researchers and students involved in the study must be registered with the Research Office. It should contain information about the researcher's relevant qualifications, training and experience. If a CV has not been submitted within the previous 12 months it must be provided with the LNR application. For studies involving animal ethics approval, the appropriate training completion reference number for each researcher is sufficient.

Study Protocol

The Study Protocol is the most important part of the application. It provides comprehensive detail about the research project.

The protocol should provide information about the investigators conducting the research; the purpose and aims of the study; participant recruitment; methodology/procedures; data collection, analysis and storage; and any ethical considerations pertinent to the study.

The LNR application must include all recruitment flyers, information brochures, participant information sheets and consent forms and any other documentation relevant to the study. Each document should be clearly labelled and given a version number. The version number, revision date, page number and total number of pages of each document must be included in the document footer.

Guides to drafting to the following are available from the Research Office:

- LNR Study Protocol
- Participant Information and Consent forms.

Advertisements and flyers

All advertising material (flyers, posters, brochures etc) must be reviewed and approved by CALHN Media and Communications once ethics approval has been obtained.

Email: HealthCALHNCommunications@sa.gov.au

Declarations by investigators and head/s of department

Declarations must be completed by all research personnel involved in the study and all head/s of department (or facility, location or service) involved in hosting the project.

For multi-site studies, declarations must be completed for the lead site (the site conducting ethical review) for each participating site. Before submitting an application for review of a multi-site study, please contact the Research Office.

Email: CALHNResearchLNR@sa.gov.au

Submission documents checklist

- LNR EGA Form – completed and all signatures obtained
- Where applicable
 - Other Committee approvals
 - Data access approval
 - Tissue/sample access approval
 - Peer review comments
 - Budget
 - Agreement
- Non SA Health researchers (if not previously submitted)
 - Confirmation from Admin/HR/Laboratory Manager of approval to be on site
 - Insurance/indemnity confirmation
- 1-2 page CVs for each Investigator (if not previously submitted)
- Study Protocol
 - Attach all Participant Information and Consent Forms, recruitment flyers, questionnaires etc. as separate documents.

Submitting the LNR Application

Following completion, the LNR EGA declarations must be signed by all investigators and heads of department. The signed completed LNR EGA Form and all attachments must then be sent by email to the Research Office.

Email: CALHNResearchLNR@sa.gov.au

What happens next?

The Research Office will assess whether the application is valid (complete) and ready for review. If the application is valid it will be sent to both the Researcher Support Officer and the HREC Chairperson.

The Researcher Support Officer will examine the application from a governance perspective and may request additional information or changes to the documentation.

The chairperson of the relevant HREC will conduct ethical and scientific review of the study.

When the ethical and governance reviews are complete, the Research Office will make a recommendation as to whether the project should be authorised, not authorised, or requires Chief Executive/delegate consideration.

Following consideration, the Research Office will notify the Principal Investigator in writing whether or not the project is authorised for commencement at the site.

For multi SA Local Health Network site studies, following project authorisation at the lead site, the LNR EGA Form and all attachments (including all Appendices) must be submitted to the appropriate Research Governance Officer for review. For further details consult the Researcher Support Officer.

LNR ethics approval from other SA Health Human Research Ethics Committees

The CALHN HREC has mutual acceptance arrangements for LNR ethics approval with other SA public health system HRECs. However governance authorisation is still required for research conducted on CALHN sites. A LNR EGA Form and all attachments must still be submitted via email and a copy of the SA Health HREC approval must be included.

Contacts

CALHN Research Office

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ⁱ Paragraphs 5.1.18 to 5.1.23, NHMRC National Statement on Ethical Conduct in Human Research (2007).
ⁱⁱ Section 1, NHMRC Ethical Considerations in Quality Assurance and Evaluation Activities (2014).