



Northern Adelaide Local Health Network
**Other Research Projects
Submission Guidelines**
(NOT CLINICAL TRIALS)



Government
of South Australia

Health
Northern Adelaide
Local Health Network



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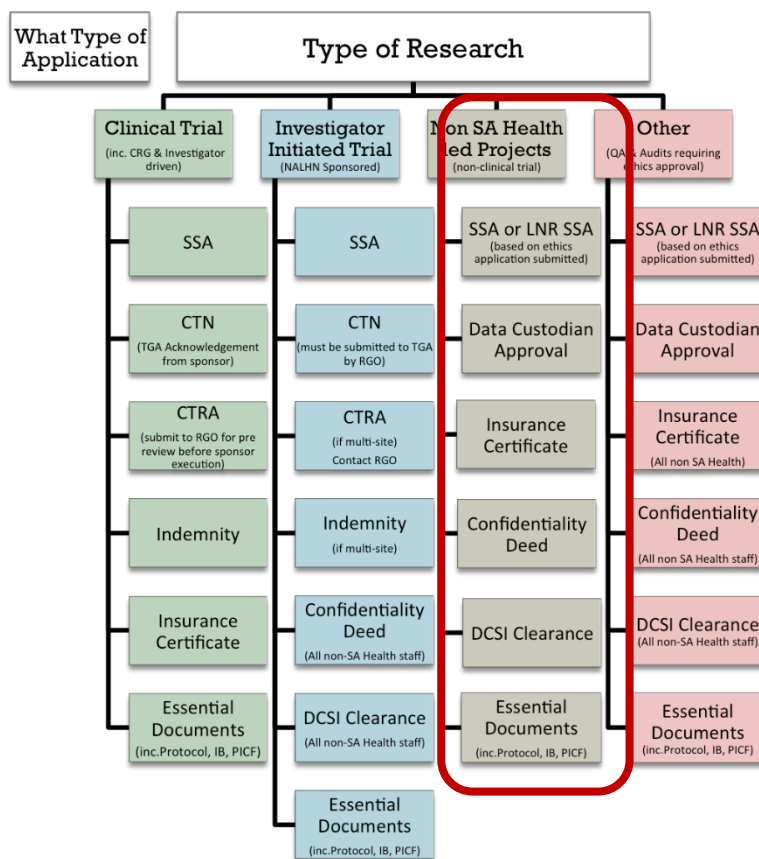
INTRODUCTION

In accordance with the, [SA Health Research Ethics and Governance Policy](#) all research within the Northern Adelaide Local Health Network (NALHN) requires authorisation of the delegated officer (Executive Director of Medical Services) before commencing. The Research Governance Office is keen to discuss your project proposals with you at an early stage wherever possible and is here to help navigate the necessary paperwork needed to lodge a research application.

While clinical trials have clearly defined governance guidelines, all research projects irrespective of their level of complexity must be registered with the Research Governance Office. Please refer to the [clinical trials guidelines](#) and [investigator initiated guidelines](#) for details.

Similarly [Quality Assurance and Audits Submission Guidelines](#) projects have specific definitions and rules in their separate guideline.

For all other projects the following guideline will assist researchers in navigating the NALHN research governance process.





SITE SPECIFIC ASSESSMENTS (SSA)

Research that involves a risk of harm is considered **more** than low risk research. See link to the [National Statement on Ethical Conduct in Human Research \(2007 Updated 2018\) paragraphs 5.1.19 to 5.1.23](#)

Site Specific Assessment Form – **Greater than low risk studies** are now required to be completed on the Research Governance and Ethics Management System (**GEMS**) website which can be located at, [Research GEMS](#) . Please review the [user guides](#) for step-by-step instructions on how to navigate the Research GEMS.

GEMS is designed to enable a more consistent and streamlined process for research applicants who wish to conduct research within SA Health.

Research GEMS allows researchers to:

- complete their Human Research Ethics Application and Site-Specific Assessment forms
- monitor approval progress and
- submit post approval monitoring to their local Research Office.

All SA Health sites are now accepting new applications for ethics and site assessments through Research GEMS. All Current studies have been migrated into the system and can be accessed through the Research GEMS web-based platform.

Feel Free to contact the NALHN Research Office for further guidance or support healthnalhnrgo@sa.gov.au

Technical Support – GEMS

Please review the [user guides](#) for step-by-step instructions on how to navigate the Research GEMS system or contact the NALHN Research Office on phone: 818-29346 or email :healthnalhnrgo@sa.gov.au for further guidance or support.

Helpful Hints

[Frequently Asked Questions regarding GEMS](#)

[Completing the site application part C: Department and Services guide](#)

Dual Submissions

Site assessment and ethical review may occur in parallel. However, the decision to authorise or not authorise the commencement of a research project at the site can only be made once the HREC has approved the project.



LOW TO NEGLIGIBLE RISK (LNR)

The Low/Negligible Risk form is an abridged site -specific assessment that may be used for studies that meet the Low/Negligible Risk criteria:

The NHMRC [National Statement on Ethical Conduct in Human Research \(2018\)](#) 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 on Ethical Conduct in Human Research](#), provides that institutions may have ethical review processes other than full committee review for low/negligible risk studies (see 5.1.18 – 5.1.23)

Low & Negligible Risk Application Form (LNR) – this form is used for expedited ethics and governance review of research studies that are considered low and negligible risk according to the [National Statement \(2018\)](#).

Formal determination of whether a study is low/negligible risk and/or is eligible for expedited review is made by the Chair of the Ethics Committee upon receipt of an application. Low and Negligible Risk (LNR) Studies require both ethical approval from the relevant HREC and governance authorisation to commence at SA Health sites.

There Are three Types of LNR applications: -

1. The [LNR form](#) is available on our [NALHN Research web page](#). If your application has already achieved ethics approval by an [National Mutual Accepted HREC](#) please ensure to advise on your application. Refer to the [Low/Negligible Risk Research Ethics and Governance Application Guidelines](#)
2. For studies involving other SA Health or public health sites submission is via GEMS system
3. You already have HREC approval

To assist with the LNR expedited process please ensure to provide as much detail as possible: -

e.g. Referral site only, recruiting at the site through the distribution of posters, will there be non- SA Health staff accessing site, provide details of leaflets, handouts, surveys and questionnaires, advising use of data or tissues held at NALHN.

Contact us at healthnalhnrngo@sa.gov.au or (08) 8182 9346 to discuss any queries that you may regarding your project.

INSURANCE

The Principal Investigator (PI) is responsible for confirming the insurance and indemnity arrangement for the research project. The PI must provide all required supporting documentation to the RGO. This generally includes copies of the relevant insurance certificates PLUS an email from the partnering organisation confirming that this study is covered by the insurance.

Any changes to insurance (including annual renewal) must be lodged with the RGO for ratification.

Please be aware that some projects will require Legal Governance and Insurance Services (LGIS) to review and approve insurance, and this can delay the processing of your SSA.



SA Health Employees

SA Health employees conducting a research project in the capacity of their employment with SA Health are covered by SA Health insurance where approval from a SA Health HREC or National Mutual Acceptance (NMA) HREC has been obtained. No further supporting documentation is required.

Dual Employment

If the researcher is an SA Health Employee, but has dual employment with a University or South Australian Health and Medical Research Institute (SAHMRI) or another organisation, or is also a university student, and is conducting a research trial/project in the capacity of their non SA Health employment, or as part of their private studies, indemnity must be provided by the University or SAHMRI and/or third party sponsor.

Non-SA Health Employees

Conducting research at an SA Health organisation that involve SA Health patients, staff, resources or data to support the project, the PI must provide appropriate insurance documentation from the non-SA Health organisation. Appropriate insurance documentation includes current insurance certificate/s and written insurance approval from the organisation. These requirements include research projects conducted by staff and students of academic institutions, such as Universities.

Third Party Sponsor

For clinical research TRIALS with third party sponsors it is a requirement that the Sponsor indemnifies the trial and provides evidence of indemnity, by way of Certificate of Currency (this is in addition to SA Health and/or non-SA Health insurance cover).

For research PROJECTS sponsored by a third party, including commercially sponsored clinical trials, the sponsor must supply evidence of its insurance cover. A sponsor's insurance cover must as a minimum identify the local site, investigator and research staff, and participants involved in the research project. For all commercially sponsored clinical trials, the 'Medicines Australia Form of Indemnity for Clinical Trials – Standard' must also be submitted

NALHN Credentialling

NALHN must ensure all staff, contractors, visiting private practitioners, volunteers and students are credentialed. If any of the investigators listed on the application are working at NALHN in clinical capacity, they must have up-to-date credentialling within NALHN. If the credentialling details are out of date, we will request evidence of renewal and the study will not proceed.

NALHN Credentialling Officer- Telephone 08 82821699 or email
Megan Glowik health.nalhncredentialling@sa.gov.au



ESSENTIAL DOCUMENTS

SSA Fee Form

The NALHN Office for Research charges fees according to the SA Health Research Ethics and Governance Fees Schedule available here. Please see the SA Health Fee Form –[SA Health Research Governance Fee Schedule](#)

Within the SA Health fees schedule there are three categories that are covered:

1. Clinical Trials with Full Commercial Sponsorship
2. Non-Commercially Sponsored Clinical Trials / Cooperative Research Group (CRG)
3. Contract Review

To define clinical trials, we acknowledge the following the [World Health Organisation definition](#):

A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes

Human Research Ethics Committee (HREC)

NALHN does not have a Human Research Ethics Committee; however, the Research Governance Office will accept any National Mutual Accepted HREC ethics with a Site-Specific Assessment form. NMA Ethics committees can be located on the [SA Health website](#).

Study Protocol

The [Study Protocol](#) is an essential document for both the HREC and the RGO.

For LNR studies please see the [LNR Protocol Guideline](#) form for both the HREC and the RGO.

Participant Information Sheets and Consent Forms (PISCF)

NALHN endorses use of the [NHMRC standardised PICFs](#) which are designed for three categories of participants identified by the National Statement:

When completing the Master PISCF and Site Specific PISCF please refer to the [Participant Information Sheets and Consent Forms fact sheet](#).

Investigator CVs

Investigators should provide a current copy of their Professional/Academic CV. Please ensure that the CV details relevant research experience, academic qualifications and publications.

GOOD CLINICAL PRACTICE CERTIFICATE

As part of the implementation of the National Clinical Trials Governance Framework and the Therapeutic Goods Administration (TGA) GCP Inspection Audits, investigators will be required to undertake GCP training and subsequent refresher training to meet compliance as mandated by SA Health.

The various Health Networks are working with SA Health towards ensuring that all staff involved in **any clinical research** (not only those involved in the design and conduct of clinical trials) undertake GCP training and hold a current certificate in GCP. This includes principal investigators, associate investigators, trial managers/coordinators and research nurses etc.



To ensure NALHN is compliant with the minimum training requirements, all staff (NALHN, SAHMRI, University etc) involved with undertaking any clinical research at NALHN must undertake GCP training. Evidence of GCP training will be part of the research ethics and research governance approval processes.

Certificates are kept on file in the Research Governance Office, so if you have provided a certificate within the past two years, you do not need to provide it with every new SSA application.

Further information can be found on the [Therapeutic Goods Administration](#) website.

- [Global Health Network Training Centre](#)
- [Syneos Health \(formerly INC Research\)](#)

Please note: This is interim advice and further information will be provided when available from SA Health

Police Clearances

Non-SA Health staff coming on site as part of a research study must provide a NALHN confidentiality deed and National Police Certificate (NPC) if they are working with adults at NALHN. If the study involves participants under the age of 18, child-related employment screening through the Department of Human Services (DHS) must be provided in place of an NPC. This is to be in compliance with the South Australian Health Criminal and Relevant History Screening Policy Directive available [Criminal and Relevant History Screening](#). There are numerous options for a police check online via accredited agencies. As a way to ensure compliance, screening and confidentiality are standard conditions on our governance authorisation:

- It is the responsibility of the Principal Investigator to ensure any non-SA Health personnel who conducts or monitors research meets SA Health screening requirements as per the SA Health Criminal & Relevant History Screening Policy Directive before they access any SA Health site. The cost of any such screening is the responsibility of the individual accessing the site or their employer. [Working with children check](#)

Confidentiality Agreement for non- SA Health Staff

A [NALHN confidentiality deed](#) will need to be signed by all non-SA Health staff that will require access to SA Health data.

Radiation Safety Report / Standard of Care Declaration by PI

[Standard of Care Radiation Letter Template](#)

Research involving gene technology and related therapies, drugs and/or ionising radiation may require specific notification, registration or licence requirements. Please refer to the SA Health Research Ethics Operational Policy Directive.

All research involving any form of radiation must comply with relevant National and State legislation, organisational policies and procedures, and codes and standards of practice provided by the NHMRC and the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).

Evidence of these requirements (including the HREC approval) should be attached to the SSA to permit the RGO to assess whether the appropriate processes and documents have been completed by the applicant.

Advertising

All advertisements including the SA Health Logo, and all radio/television/press/social media advertising must be first approved by the NALHN Communications Department:

HEALTH.NorthernCommunication@sa.gov.au

Evidence of approval from Media and Communications must be included with your SSA/LNR.

[Corporate Identity Policy](#)

https://www.sahealth.sa.gov.au/wps/wcm/connect/ddbe6580462bc31e8967896dc301fde5/Directive_Corporate%2BIdentity_Nov2014.pdf?MOD=AJPERES&CACHE=NONE&CONTENTCACHE=NONE

[Social Media Policy](#)

<https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/contact+us/social+media+policy+terms+and+conditions+of+use>

SA Health Logos



Other Contracts and Amendments

It is essential that any third-party agreements be negotiated and presented for signing at the same time as the researcher lodges the SSA.

The NALHN Executive Director of Medical Service / or nominated delegate is the only person authorised to sign contracts on behalf of NALHN. Do not edit the body of the standard agreement. Any non-standard agreements (not on an approved template) will need to be reviewed by a legal representative prior to signing.

These commonly include:

- Collaboration agreements with Universities/Medical Research Institutes/Hospitals
- Funding agreements
- Material Transfer Agreements (MTAs)
- Multi-Institution Agreements (MIAs)
- Intellectual Property Deeds
- Moral Rights declarations
- Service agreements
- Import/Export permits
- Student scholarship agreements
- Sanctioned Country clearances

Researchers should be aware that contract negotiations may take months, so these should be discussed with the NALHN Research Office at the earliest opportunity.



NEXT STEPS

Signing

There are two types of sign off

Low to Negligible Risk Studies (LNR) and *Greater than Low Risk Studies (GEMS-SSA)*

1. Before lodging your **LNR application**, you must obtain the necessary approvals from all of the various departments, units, divisions pertinent to your study. For further information about delegated signatories please contact the NALHN Research Office email : healthnalhnrngo@sa.gov.au

Please be aware of the below three step parallel process for LNR submissions: -

1. Send all documents through to the RGO for validity check
2. The RGO will confirm validity, you will be required to send through to the HREC for Ethics approval
3. Once the HREC approval has been undertaken it must be provided to the RGO for execution to executive, you will then receive a letter of approval from the RGO to commence your study.

No study is to commence at the NALHN sites without the NALHN RGO final letter of approval

2. If your application is **Greater than Low Risk** and will be submitted via [Research GEMS](#), please ensure to include the all of the various departments, units, divisions pertinent to your study- Head of Unit, Divisional Director, Business Consultant, etc. If your study is cross divisional, we will also require both divisions to note their support. See helpful hint - [Completing the site application part C: Department and Services guide](#)

Feel free to contact the Research Secretariat- PH: 08 81829346 or email healthnalhnrngo@sa.gov.au should you have any other queries.



Lodging your application

How to submit your applications: -

- > Follow the above **Low to Negligible pathway** or the **Greater than Low Risk - GEMS (SSA)** submission pathway
- > Complete the required steps / forms (for your process to be managed with promptness it helps to ensure your application is provided in complete form)
- > Low to Negligible Risk (LNRs)- Email the cover sheet, LNR, and ALL supporting documents to healthnalhnrngo@sa.gov.au for validation check (this step is required prior to submitting to the HREC)
- > Greater than Low Risk (SSA) – Follow the GEMS system process as listed above.

Hard copies are not required (except for CTRA and Medicines Australia Indemnity forms)

Note that if your submission is being managed via GEMS you will need to ensure that the CTRA and Medicines Australia Indemnity forms are provided to the NALHN Research Office via email healthnalhnrngo@sa.gov.au

NOTE CONTRACTS are not managed via GEMS. You need to email these to us. healthnalhnrngo@sa.gov.au

Once submitted, your application is reviewed by the RGO for final authorisation by the CEO/delegate. The project must **not commence until you receive a letter of authorisation from the RGO.**

NALHN supports dual submission of ethics and governance. While SSAs/LNRs can be submitted at any time before the project commences, dual submission allows the governance and ethical review to occur in parallel. **Your HREC approval is not sufficient to start the study.** A final endorsement letter will be provided for the SSA/LNRs only where HREC approval is obtained and the letter provided to the RGO.

Partially completed (unsigned/invalid) applications will be returned to the applicant. If you have not submitted an application within 3 months of receiving ethical approval, the RGO will contact the Principal Investigator for clarification. Please contact the RGO if you anticipate a lengthy delay in submitting an SSA.



CONTACT US

The team at the NALHN Research Office are happy to assist you in navigating the necessary documents and processes outlined in this guide, and to give advice on project-specific information.

Contact us on +61 8 8182 9346 or healthNALHNrgo@sa.gov.au



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