



Northern Adelaide Local Health Network

Investigator Initiated Clinical Trials Submission Guidelines

(NALHN Sponsored)

NALHN Research Governance Office



Government
of South Australia

Health

Northern Adelaide
Local Health Network

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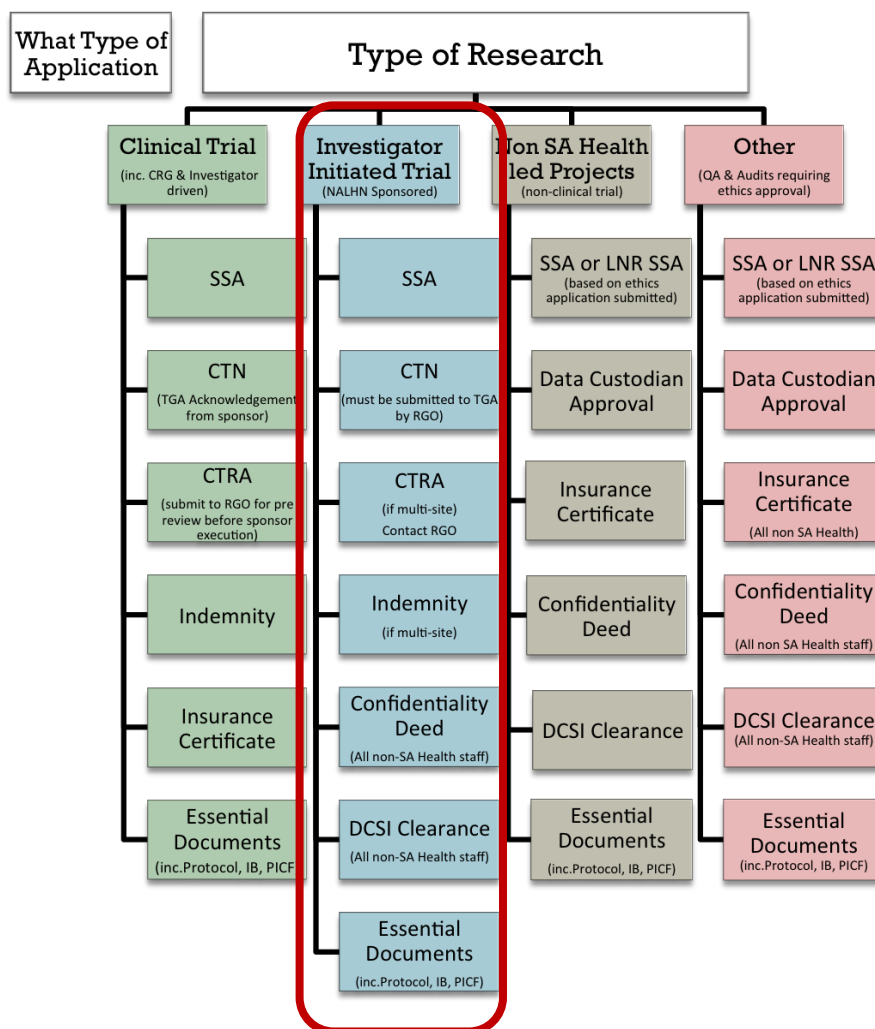
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Introduction

In accordance with the [SA Health Research Governance Directive](#), 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.

At a minimum, this will include a Site-Specific Assessment (either a full SSA or Low/Negligible Risk form), research protocol, Ethics approvals, and other supporting documents, depending on the type of study.

This guide relates to NALHN Sponsored Investigator Initiated Clinical Trials. In cases where NALHN is not the trial sponsor, please refer to the Clinical Trials (including Clinical Research Group and Investigator Driven Trials) Submission Guideline.



Site Specific Assessment - SSA

Advance Notice - Transitioning to the Research Gems process for NALHN

The current system, Online Forms, will no longer be available from the 31 October 2020. The new system, Research GEMS is due to go live in November 2020. The NALHN Research Secretariat has implemented an interim process for HREA and Site Specific Assessment (SSA) applications.

Please see the [Transitioning to Research GEMS fact sheet](#) to assist with your application.

The interim process for greater than low risk studies can be submitted using the temporary [Site Specific Assessment \(SSA\) form](#).

Helpful Hints

If you have any questions regarding the content of the SSA including how to answer specific questions in the application please review the:

- > [NALHN SSA Cover sheet](#)
- > [NALHN Specific – SSA Completion Guide](#) (useful question-by-question guidance)
- > [NALHN SSA Forms Page](#)

If you cannot find your answer in the guide please contact the RGO - healthnalhnrgo@sa.gov.au

Dual submission

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.

Clinical Trial Notification – CTN

For sponsor initiated clinical trials, please attach a copy of the eCTN to your SSA.

For investigator initiated clinical trials, the CTN must be submitted to the Therapeutic Goods Administration by the Research Governance Office (please refer to [fees schedule](#) for current fees).

Information on the Clinical Trial Notification/Clinical Trial Exemption schemes is available at <https://www.tga.gov.au/clinical-trials>

For sponsors submitting eCTNs for clinical trials being conducted at Lyell McEwin or Modbury Hospital the approving authority information is provided below:

Name of Approving Authority: Northern Adelaide Local Health Network Incorporated operating as Lyell McEwin Hospital (select appropriate site), or

Northern Adelaide Local Health Network Incorporated operating as Modbury Hospital

Approving Authority Contact Officer: Roy Sneddon

Position: Research Governance Officer

Contact Phone: +61 8 8182 9346

health.nalhrngo@sa.gov.au

Clinical Trial Research Agreement (CTRA)

If your project involves a medicine or device, you need to submit an agreement between the parties involved. This is required whether you are involved in a:

- > Collaborative Group project
- > Commercially Sponsored project
- > Contract Research Organisation or,
- > Project funded from a grant

[Medicines Australia Standard CTRA templates](#) are endorsed by SA Health and should be used wherever possible to avoid the need for legal review.

Amendments to Schedule 7 or Schedule 4 require SEBS approval. Please [Medicines Australia Standard CTRA templates](#) for further information.

Site Details for inclusion in the template (select appropriate site):

<p>Name of Institution: Northern Adelaide Local Health Network Incorporated, operating as Lyell McEwin Hospital Address: Haydown Road, Elizabeth Vale, South Australia 5112 ABN: 46 371 200 573</p>
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<p>Name of Institution: Northern Adelaide Local Health Network Incorporated, operating as Modbury Hospital Address: 41-69 Smart Road, Modbury, South Australia 5092 ABN: 46 371 200 573</p>
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Schedule 2:

Governance Fee

Research governance submission fees are payable to the Institution according to the [current fee schedule](#). The research governance office will invoice the sponsor directly.

Pharmacy Fees

Be aware that SA Health may require a separate pharmacy agreement. Please contact Health.LMHClinicalTrialsPharmacy@sa.gov.au

Payee

All payments listed in this schedule will be made by the Sponsor to Institution upon receipt of a tax invoice by direct credit.

Bank: Commonwealth Bank of Australia

Branch: 96 King William St, Adelaide

BSB: 065 266 Account Number: 10020646

Account Name: NALHN Oracle Operating

ABN: 46 371 200 573

Swift Code: CTBAAU2S

Note: The sponsor is responsible for study payments and must be the party in Schedule 2 that NALHN will invoice.

For information on how to negotiate the study budget for inclusion in the CTRA please review the [Finance Information](#).

Indemnity

[Medicines Australia Standard Indemnity templates](#) are endorsed by SA Health.

Site details for inclusion in the template (select appropriate site):

Northern Adelaide Local Health Network Incorporated, operating as Lyell McEwin Hospital (“the Indemnified Party”)

or

Northern Adelaide Local Health Network Incorporated, operating as Modbury Hospital (“the Indemnified Party”)

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 Sponsors:

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.

Essential Documents

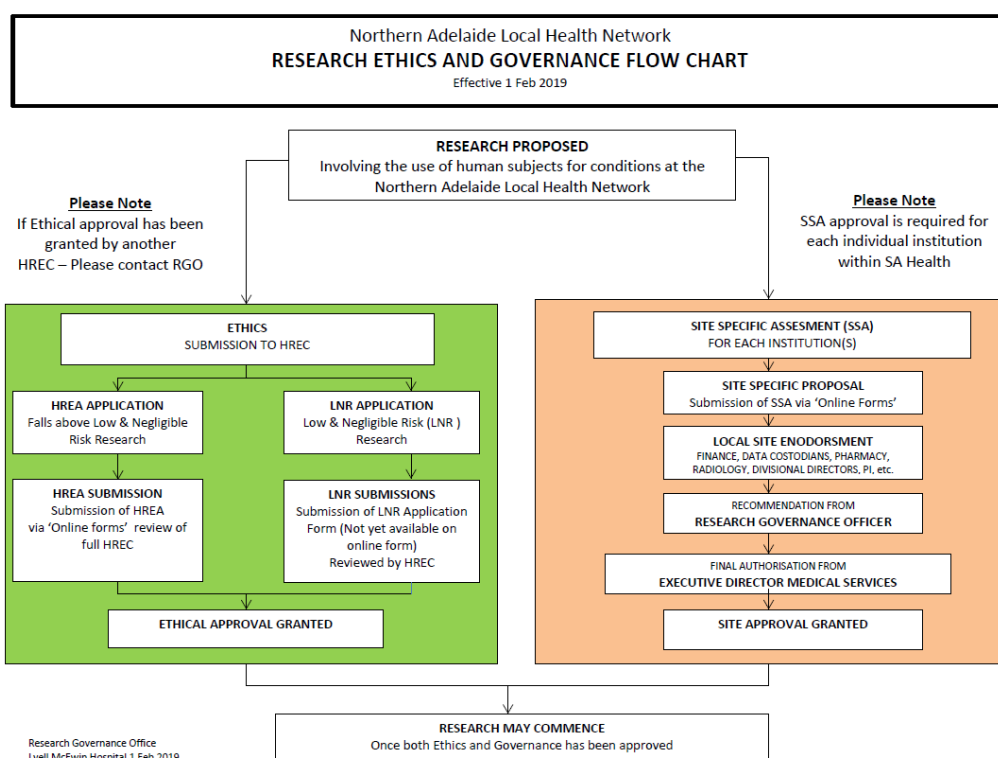
SSA Fee Form

[Research Governance Application – SSA Fee Form](#)

Human Research Ethics Committee (HREC)

A HREC Approval Letter and HREC Application Form need to be submitted with a SSA. These forms can be accessed on the [SA Health website](#).

NALHN does not have a Human Research Ethics Committee; however the Research Governance Office accepts HREC approvals from all registered National Mutual Acceptance HRECs.



Study Protocol

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

Investigator Brochure

Where the trial involves drugs and/or devices, the Trial Sponsor will provide the Investigator Brochure. Where devices are approved for use in Australia or internationally, an Instruction for Use (IFU) document could be submitted as a replacement for the investigator brochure.

The title, version and date listed on the Investigator Brochure should be listed in the research protocol and must match those listed on the HREC approval letter (including all future variations).

Please ensure that the filename is “IB_Version_Date”

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](#).

Good Clinical Practice Certificate

For Clinical Trials, it is mandatory for all NALHN researchers to provide a copy of their Good Clinical Practice Certificate (GCP).

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.

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.

Police clearances

<https://screening.sa.gov.au>

Under the Criminal and Relevant History Screening Policy Directive (2019) SA Health complies with the legal requirement that every person seeking to work (including researchers) under the [Child Safety \(Prohibited Persons\) Act 2016](#), [The Child Safety \(Prohibited Persons\) Regulations 2019](#), [The Children's Protection Law Reform \(Transitional Arrangements and Related Amendments\) Act 2017](#), and/or the [Aged Care Act 1997](#) undergo a criminal and relevant history screening assessment.

This applies whether or not the person is currently working in SA Health. Information on process, applications and Fees is available on the Department of Human Services [website](#).. The cost of the assessment is borne by prospective researcher.

Screening clearances must be provided with the SAA for all researchers on site (or who may potentially come in contact with identifiable information).

Confidentiality Agreement for non-SA Health Staff

[Confidentiality deed for non-NALHN employee](#)

Trial Coordinator Form

[Research Co-ordinator Authorisation Form](#)

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.

[Corporate Identity Policy](#)

[Social Media Policy](#)

SA Health Logos

It is an SA Health requirement that the institution logo is used – please insert the SA Health Logo in the Header of your Participant Information Sheet and Consent Form. The diameter of the circle must be a minimum of 1cm.



Other Contracts and Agreements

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

Next Steps

Signing

Before lodging your SSA application, you must obtain the necessary approvals from all of the various departments, units, divisions pertinent to your study. Further information about delegated signatories is available on the [“Who can sign my application?”](#) page.

Lodging your application

How to submit your application to the RGO

- > Follow the [completion guidelines](#)
- > Complete the [SSA Cover sheet](#) (helps to ensure your application is complete)
- > Email the cover sheet, SSA, and ALL supporting documents to healthnalhnrgo@sa.gov.au

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

Note that Online Forms does NOT notify us that you've submitted anything online. You need to email us.

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 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 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 Research Secretariat 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

For more information

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www.ausgoal.gov.au/creative-commons



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