

Northern Adelaide Local Health Network
**Quality Assurance
and Audits
Submission Guidelines**



Government
of South Australia

Health
Northern Adelaide
Local Health Network



CONTENTS

CONTENTS2

INTRODUCTION4

GENERAL GUIDE4

 Routine Quality Assurance4

 Ad Hoc Audits.....4

 All Other Audits.....4

WHAT DEFINES A QUALITY ASSURANCE /AUDIT PROJECT?5

QA DOCUMENTS TO BE SUBMITTED TO HREC/RGO6

SITE SPECIFIC ASSESSMENT (SSA)7

LOW/NEGLIGIBLE RISK (LNR)7

INSURANCE8

 SA Health Employees8

 Dual Employment8

 Non- SA Health Employees8

 Third Party Sponsor8

ESSENTIAL DOCUMENTS9

 Governance Fee Form9

 Human Research Ethics Committee (HREC)9

 Study Protocol and LNR Protocol Guidelines10

 Participant Information Sheet and Consent Form11

 Investigator CV and GCP11

 Police Clearances / Confidentiality Deeds12

 SA Health Logos.....12

 Other Contracts and Agreements13

NEXT STEP14

 Signing14

 Lodging your application14

 Contact Us15





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 or (Executive Director of Medical Services) before commencing. This includes quality assurance and audit projects.

The most common issue involving Quality Assurance (QA) activity is confusion over the terminology. Terms such as 'peer review', 'quality assurance', 'quality improvement', 'quality activities', 'quality studies' and 'audit' are often used interchangeably and frequently incorrectly.

As a result, researchers may inadvertently be undertaking a research project that has been misidentified as QA and breaches NALHN'S obligations under the [Australian Code of Responsible Conduct of Research \(2018\)](#). Therefore, all QA activity should be registered with the NALHN Research Office for review.

As a general guide, researchers can consider the following

GENERAL GUIDE

Routine Quality Assurance

Routinely collected retrospective review of existing data for maintaining internal compliance with standards. This activity will be managed at a departmental level and does not require HREC approval or registration with the RGO.

If and when findings from the activity warrant publication, the investigator should submit to both the HREC and RGO an abstract and an approval letter/email from the Head of Department confirming that this activity is part of normal business. The HREC will provide a letter of acknowledgement sufficient to meet the publisher's requirements.

Ad Hoc Audits

These are the review of existing data to check compliance with standards or assess existing standard care and are submitted to the Safety & Quality Improvement Register. Any ongoing support will be provided by the SQRM.

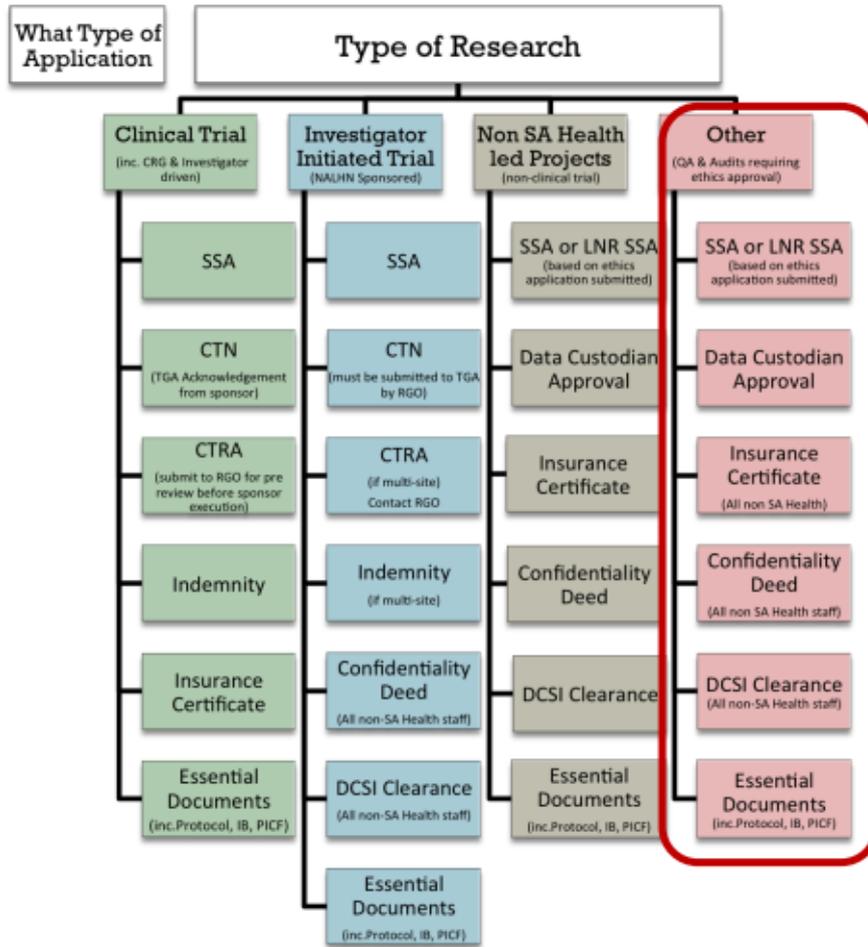
If and when findings from the activity warrant publication, the investigator should submit to both the HREC and RGO an abstract and an approval letter/email from the SQRM confirming that this activity is approved. The HREC will provide a letter of acknowledgement sufficient to meet the publisher's requirements.

All Other Audits

ALL other Audit activity, retrospective review of existing data, student projects, surveys etc may be considered as research activity and the following guideline applies.

The following information is based on the National Health & Medical Research Council's document [Ethical Considerations in Quality Assurance and Evaluation Activities](#)

This guide relates to Quality Assurance and Audits Submission that may require Human Research Ethics Approval.



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.

WHAT DEFINES A QUALITY ASSURANCE /AUDIT PROJECT?

It is critical when preparing your research protocol that you clearly identify why the project should be considered QA, and the researcher should address the NHMRC criteria in the protocol. This will allow the HREC and RGO to quickly assess and approve the project. If a protocol fails to address this, the project will be assessed as any other research project and may face delays.

The NHMRC states that:

“An activity where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation is a QA activity...”

Irrespective of whether an activity is called research or QA or evaluation, those conducting the activity must consider whether the people involved (e.g. participants, staff or the community) will be exposed to any risk, burden, inconvenience or possible breach of their privacy”

The NHMRC suggests that the following are activities which do not require ethical review (but still require Governance oversight):

- “The data being collected and analysed is coincidental to standard operating procedures with standard equipment and/or protocols;
- The data is being collected and analysed expressly for the purpose of maintaining standards or identifying areas for improvement in the environment from which the data was obtained;
- The data being collected and analysed is not linked to individuals; and
- None of the triggers for consideration of ethical review... are present”

The NHMRC document defines the “triggers for ethical review” as:

- “Where the activity potentially infringes the privacy or professional reputation of participants, providers or organisations.
- Secondary use of data - using data or analysis from QA or evaluation activities for another purpose
- Gathering information about the participant beyond that which is collected routinely. Information may include biospecimens or additional investigations
- Testing of non-standard (innovative) protocols or equipment
- Comparison of cohorts
- Randomisation or the use of control groups or placebos.
- Targeted analysis of data involving minority/vulnerable groups whose data is to be separated out of that data collected or analysed as part of the main QA/evaluation activity.”

Other aspects which would suggest that the activity might need further review include:

- The purpose is not principally to review or improve the quality of a service
- Where contact with patients identified through a data searching process is required
- Where consent from patients, volunteers or other health professionals is required
- The completion of questionnaires which are not part of standard care
- The use of data which is not available within the researcher’s own domain
- Collection of highly sensitive information.
- The comparison of performance of individual health care professionals, departments or institutions.
- Where the research may possibly infringe Australian Privacy Principles
- Where publication or presentation may directly or indirectly identify an individual

Documents should be submitted to the Research Governance Office and HREC for initial review. If the project is subsequently deemed to be research other documents may be required.

QA DOCUMENTS TO BE SUBMITTED TO HREC/RGO

- Study Plan Abstract /Protocol:
Fully signed LNR form
- Any supporting documents (eg. Copies of questionnaires, scripts etc), email approvals from Medical Records, Divisional Business Consultant etc



SITE SPECIFIC ASSESSMENT (SSA)

Submission Guidelines – Full Site-Specific Assessment (SSA)

QA projects rarely require the full Governance and Ethics Management System (GEMS) process – but some researchers (particularly for multi-site projects) prefer this.

Please see the SA Health Research *Governance and Ethics Management System*, [Research GEMS](#) with a link to the [user guides](#) for step-by-step instructions on how to navigate the Research GEMS system.

LOW/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](#) 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)

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 3 types of LNR application.

1. There are NO triggers for ethical review, or you already have HREC approval
 - You can just use the LNR application form for the governance process
2. YES there are triggers for ethical review (SALHN, CALHN, NALHN sites only)
 - You can use the LNR application form
 - Refer to the Low/Negligible Risk Research Ethics and Governance Application Guidelines
 - Make sure that you highlight in the LNR form what triggers for ethical review that you want HREC to check. This makes it easier for the HREC to assess your claim.

For example:-

“Whilst we believe the study to be a QA Audit activity, there is a comparison of cohorts (see highlighted on page # of the protocol) that may trigger ethical review, and we are seeking confirmation from the HREC Chair”

3. For studies involving other SA Health or public health sites submission is via the Governance and Ethics Management System (GEMS).

Please see the SA Health Research *Governance and Ethics Management System*, [Research GEMS](#) with a link to the [user guides](#) for step-by-step instructions on how to navigate the Research GEMS system.

Contact us at healthnalhngo@sa.gov.au or (08) 8182 9346 to discuss which method is most suitable for 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 all research PROJECTS (including QA activity) sponsored by a third party, 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.

ESSENTIAL DOCUMENTS

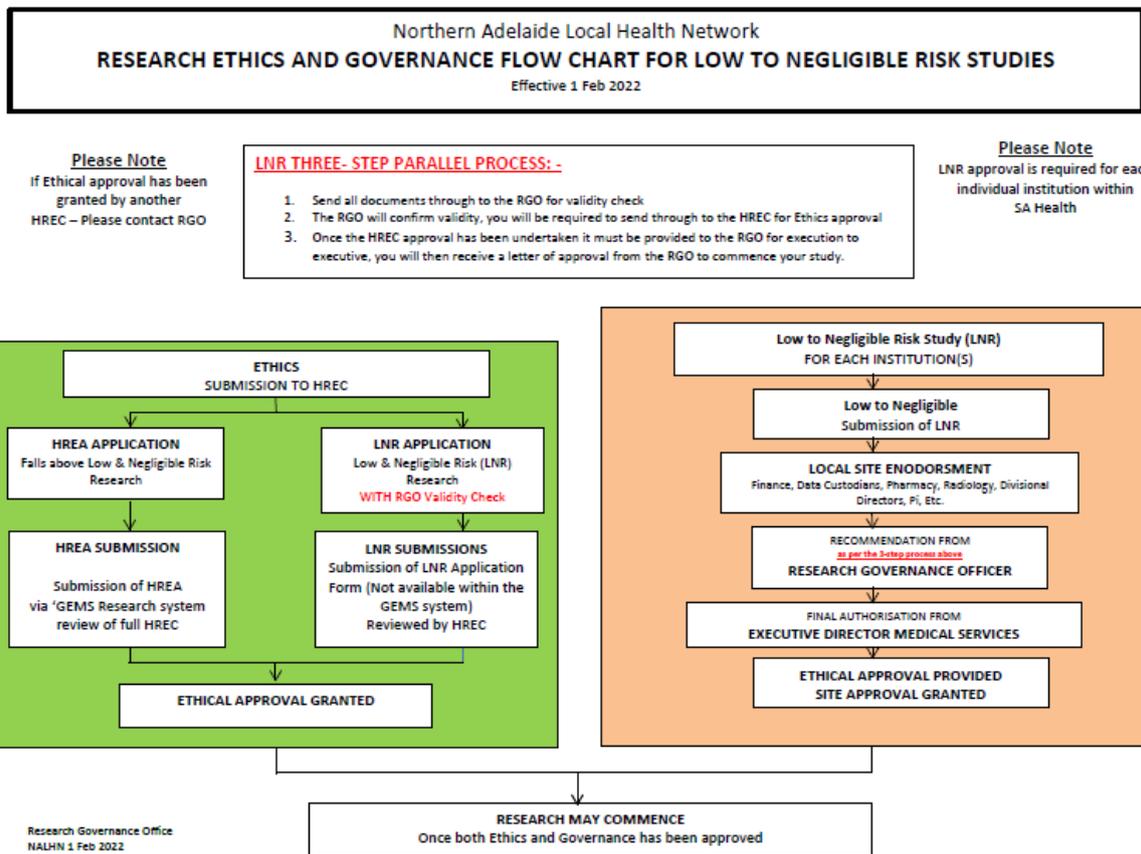
Governance Fee Form

QA projects do not in themselves incur a Governance Fee, however where a third party contract is required, a contract review fee may be charged – see [SA Health Research Governance Fee Schedule](#)

Human Research Ethics Committee (HREC)

Where the study includes a trigger for ethical review, a HREC Approval Letter and HREC Application Form (this will probably be the LNR form) need to be submitted with a QA governance application.

NALHN does not have a Human Research Ethics Committee; however, the Research Governance Office accepts HREC approvals from all registered National Mutual Acceptance HRECs. National Mutual Acceptance HRECs information is available on the [SA Health website](#).





Study Protocol and LNR Protocol Guidelines

The [Study Protocol](#) and the [LNR Study Protocol guideline](#) form are an essential document for both the HREC and the RGO. It should address the NHMRC criteria for QA projects and should include the following headings:

1. Title (include the words Quality Assurance/Audit in the title)
2. Sponsor Name
3. Investigator details/qualifications
4. Introduction
5. Background
6. Purpose of project

- (a) Aims
- (b) Objectives
- (c) Hypotheses

7. Study Design

Participants (Types of patients, date range, health care professional etc.)

- (a) Inclusion criteria
- (b) Exclusion criteria
- (c) Recruitment
- (d) Informed Consent
- (e) Methodology
- (f) Description of Data
- (g) Data Collection
- (h) Tissue Samples
- (i) Existing Guidelines or Standard of Care
- (j) Analysis

Existing Data (for example Sunrise, Departmental Records, etc) – noting whether the data is identifiable or de-identified, and whether the patients have provided consent to access the data, or a waiver to access the data is requested

New Data Collection (for example patient surveys about their care)

8. Data Security and Confidentiality Issues
9. Publications
10. Ethical Considerations. (Issues which may need special consideration).
11. Consumer and Community Engagement
12. Protocol Deviations
13. Serious Breaches
14. Safety Considerations
15. References
16. Attachments



Participant Information Sheet and Consent Form

Patient consent - When consent to involvement in the project is required, it probably not considered a QA. However, where a patient is being surveyed on their perceptions of the quality of their care or a health care professional is being asked about their attitudes to a type of treatment (unless sensitive information is included), it may be considered by HREC as negligible risk. This type of information should be expressly stated in the protocol.

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 CV and GCP

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

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. For LNR studies this is only required by the NALHN site Principal Investigator (PIs) to ensure that the Australia Code for the Responsible Conduct of Research has been accepted.

See links for GCP training

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



Police Clearances / Confidentiality Deeds

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

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

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/LNR. 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 STEP

Signing

Before lodging your QA governance 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 : healthnalhnrgo@sa.gov.au

Lodging your application

How to submit your application to the RGO

Import/Export permits

- Follow the completion Guidelines
- Complete the SSA/LNR Cover sheet (helps to ensure your application is complete)
- Email the cover sheet SSA/LNR application , and ALL supporting documents to healthnalhnrgo@sa.gov.au

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

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

Feel free to contact me should you have any other queries.

Hard copies are not required

Note that if you are using the Governance and Ethics Management System (GEMS) your application is reviewed and processed it its completeness within GEMS. The project must not commence until you receive a letter of authorisation from the RGO.

NALHN supports dual submission of ethics and governance. While LNR/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 LNR/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 LNR/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 08 8182 9346 or healthNALHNrgo@sa.gov.au



For more information

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