Northern Adelaide Local Health Network

Quality Assurance and Audits Submission Guidelines

Government of South Australia

Health
Northern Adelaide
Local Health Network

CONTENTS

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 /quality improvement 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/Quality Improvement

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.

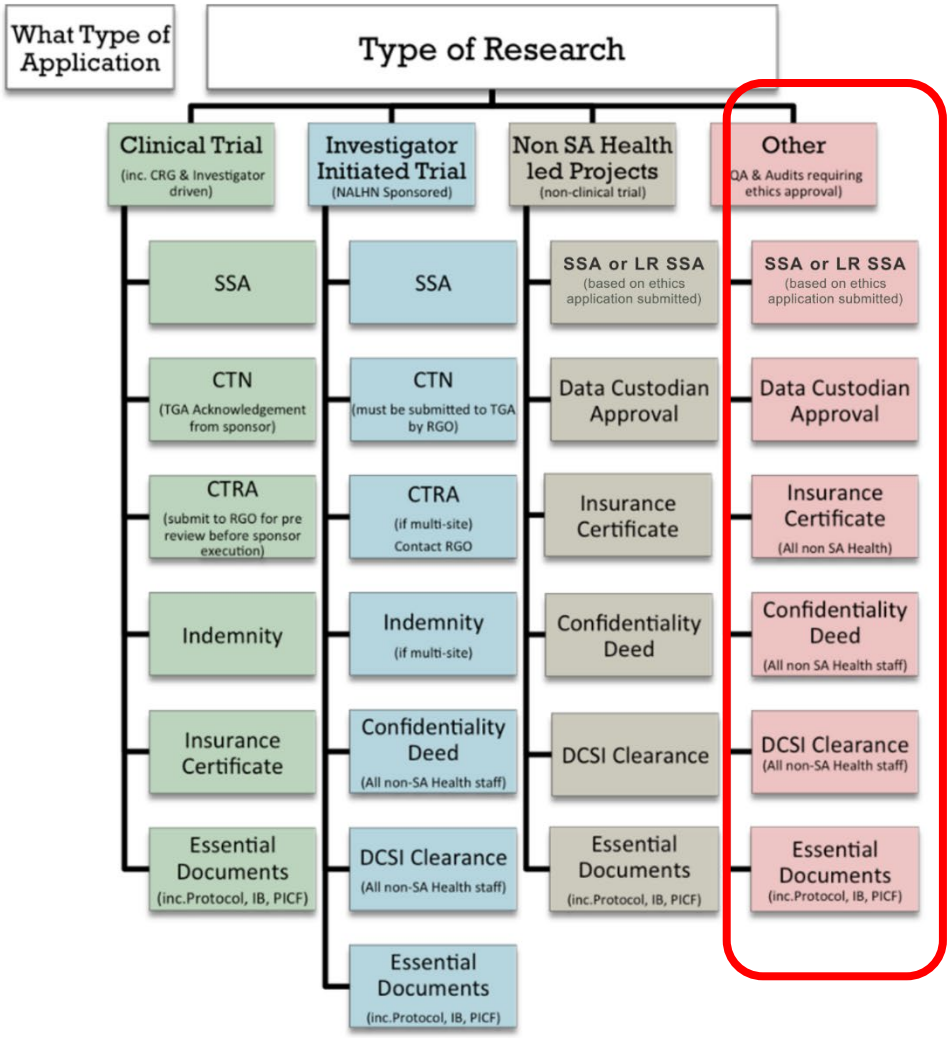
All Other Audits

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 Risk form), research protocol, Ethics approvals, and other supporting documents, depending on the type of study.

WHAT DEFINES A QUALITY ASSURANCE /QUALITY IMPROVEMENT /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 DOCUEMENTS TO BE SUBMITTED TO HREC/RGO

- Study Plan Abstract /Protocol: See link
  Fully signed Low Risk 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 RISK

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

The NHMRC National Statement on Ethical Conduct in Human Research (2023) defines low risk research as research, including some types of clinical trials, in which the only foreseeable risk is no greater than discomfort. Accordingly, research in which the risk for participants or others is greater than discomfort is not low risk research. Research in this category is considered higher risk research and carries risk of harm. Higher risk research requires review by an HREC

Figure1: Risk profiles of research (from the NHMRC 2023)

Lower risk		**Higher risk** (Individual, group, community, societal or global)	
Minimal	**Low**	**Greater than low**	**High**
No risk of harm or discomfort; potential for minor burden or inconvenience*	No risk of harm; risk of discomfort (+/- foreseeable burden)	Risk of harm (+/- foreseeable burden)	Risk of significant harm (+/- foreseeable burden)

The National Statement provides that Institutions are responsible for establishing procedures for the ethical review of human research. That review can be undertaken at various levels, according to the degree of risk involved in the research (see Chapter 2.1: Risk and benefit and Chapter 5.1: Governance responsibilities of institutions). Research with a greater than low level of risk (as defined in Chapter 2.1) must be reviewed by an HREC. Research involving no more than low risk may be reviewed under other processes described in 5.1.10 to 5.1.14. Institutions may also determine that some human research is exempt from ethics review (see 5.1.15 and 5.1.18

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

There are 3 types of Low Risk application.

1. There are NO triggers for ethical review, or you already have HREC approval
   - You can just use the Low Risk application form for the governance process
2. YES there are triggers for ethical review (SALHN, CALHN, NALHN sites only)
   - You can use the Low Risk application form
   - Refer to the Low Risk Research Protocol Guidelines
   - Make sure that you highlight in the Low Risk 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 healthnalhnrgo@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.

Waiver of consent

Before deciding to waive the requirement for consent (other than in the case of research aiming to expose illegal activity), an HREC or other review body must be satisfied that the project meets all requirements of Chapter 2.3.10 of the NHMRC National Statement on Ethical Conduct in Human Research (2018) (incorporating all changes) as set out below.

Please address clearly Points (a-i) within the NAHMRC National Statement on Ethical Conduct in Human Research 2018, points 2.3.10 . Please include an introduction sentence to the waiver, stating what type of waiver is being requested (for example Pre-screening for eligibility or retrospective medical records looking at years from XXXX to XXXX) and who will be accessing the medical records.

a) involvement in the research carries no more than low risk (see paragraphs 2.1.6 and 2.1.7, page 18) to participants

b) the benefits from the research justify any risks of harm associated with not seeking consent

c) it is impracticable to obtain consent.

d) there is no known or likely reason for thinking that participants would not have consented if they had been asked

e) there is sufficient protection of their privacy

f) there is an adequate plan to protect the confidentiality of data

g) in case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media)

h) the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled

i) the waiver is not prohibited by State, federal, or international law.

New Data Collection (REDCap)

(Research Electronic Data Capture) REDCap is the NALHN mandatory method of building and managing investigator-initiated research data bases and surveys. REDCap, a robust web-based survey and data collection tool, available to NALHN. It is designed to simplify and streamline the process of creating and managing surveys for research studies. quality improvement initiatives. and other data collection projects.

For further information: see link

(Note that NALHN REDCAP is now mandatory for data management of research studies undertaken at NALHN).

Data and Sample Management

Data storage during the study

– State whether data collected will be de-identified, re-identifiable, identifiable but confidential or anonymous.
– How will data be de-identified and who will be responsible for this?

– Outline how data re-identification will occur (e.g. enrolment log).

– Outline which investigator(s) will have access to de-identified data and/or identifiable data.

–Where will data be stored and how will it be secured?

– Who will have access to the data?

Data storage post project completion

– What format will data be stored in?

– Where will data be stored?

– ho will have access to the data and for what purpose?

– What strategies will be put in place to ensure data security?

– How long will data be stored, who will be responsible for its disposal, how will disposal occur?

Please note: Data must be stored at the institution that owns the study results. If data is identifiable, it must be stored at NALHN unless consented.

Sample management.

– Where will they be stored during and after the project?

– Will samples be identifiable, de-identified or re-identifiable?

–Which institution owns the samples?

–Which Institution will be responsible for analysing samples?

–How long will samples be stored, who will be responsible for its disposal, how will disposal occur?

Budget process

For investigator-initiated projects supported by in-kind support at NALHN, a summary of the project's required resources and hours must be provided. The Divisional Business Consultant and Divisional Director must also approve the summary of the In Kind budget.

Publication

– Outline the authorship and publication policy.

– What is the plan for reporting, publishing or otherwise disseminating the outputs/outcomes of the research?

– Will participants in the research be informed of the study findings?

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 Low Risk application 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 Low Risk Protocol Guidelines

The Study Protocol and the Low Risk 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/Quality Improvement /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, its 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 Low 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 Low Risk 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/Low Risk applications.

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.

Government of South Australia
Health
Northern Adelaide Local Health Network

Government of South Australia
Health
Northern Adelaide Local Health Network

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

Please be aware of the below three step process for Low Risk: -

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 for Greater than low risk applications, (SSA), dual submission are not supported for Low Risk applications. 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 Low Risk/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 Low Risk/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
NALHN Research Office
Lyell McEwin Hospital
Level 2 Entrance to the Library
Haydown Road
ELIZABETH VALE SA 5112
(08) 8182 9346
email: healthNALHNRGO@sa.gov.au
sahealth.sa.gov.au/nalhn

Government of South Australia
Health
Northern Adelaide
Local Health Network