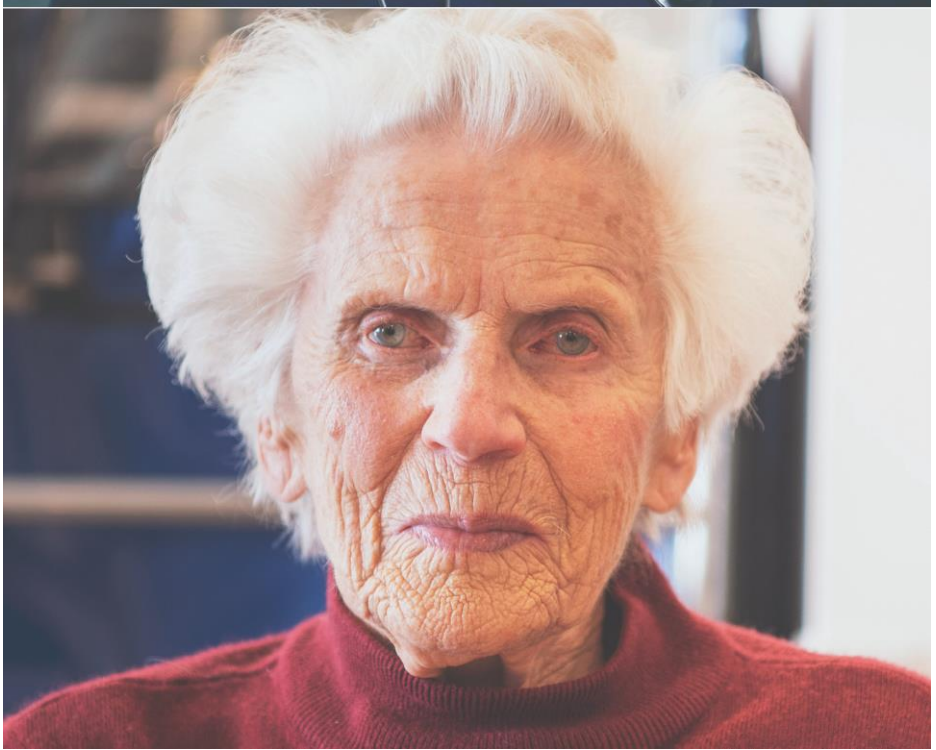

Government of South Australia

Health
Southern Adelaide
Local Health Network

Research Ethics Essentials

Publication Details

Publication title:

SALHN Ethics Essentials

Publisher: Office for Research

Table of Contents –

1. Ethics Overview

Human research can involve a wide range of methods and practices: it can be a retrospective audit, qualitative, quantitative or mixed; interventional, experimental or observational in nature; and involve various degrees of collaboration between researchers and participants. Each research project is shaped by the field to which the research question relates the research question itself, the desired outcome, and the context in which it is conducted.

To ensure that all medical research provides adequate protection to the participants involved and treats them in a fair and ethically acceptable manner, all Human Research Ethics Committees (HREC) and researchers follow ethical conventions and standards that outline how medical research is designed, reviewed and conducted.

There are 5 guiding ethical principles of research that provide a solid foundation for designing and conducting high quality research. Please read section 1 in The National Statement on Ethical Conduct in Human Research (2023) on how the below principles relate to your research.

1. Merit and Integrity
2. Justice.
3. Beneficence
4. Respect

Research Ethics addresses:

It is a requirement that all research conducted at South Australian public health institutions, or involving clients of South Australian public health institutions, including regional health services, hospitals, community health services, public health clinics and associated programs, complies with relevant polices and guidelines.

Every HREC in Australia is required to be properly constituted in accordance with section 5.1.30 of the National Statement, which prescribes its minimum size and composition, and the expertise necessary to address ethical issues.

The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC) is registered and accredited with the National Health and Medical Research Committee (NHMRC) and has National Mutual Acceptance (NMA) certification which enables the committee to undertake single ethical review and multi-site ethical review of research in South Australia, Victoria, New South Wales, Queensland and Western Australia.

As the lead (approving) HREC, the SAC HREC reviews ethics applications, amendments, and post approval documents within Southern Adelaide Local Health Network (SALHN) SA Health, Country Health, DASSA, Southern Mental Health and public health institutions Australia wide. The committee also reviews ethics applications for clinical research conducted by Flinders University.

The Southern Adelaide Local Health Network Office for Research (OfR) oversees research Ethics and governance and site authorisation of research in line with the SA Health Research Ethics and Governance Policy available on the SA Health website .

Research ethics is concerned with ensuring the research is well-designed and considered, with methodology that can meet the research aims and objectives, respect for all participants and that the benefits of the research outweigh any risks to participants.

Research governance is concerned with the quality, safety, privacy, risk management, financial management and ethical acceptability of research.

Research can only commence when both ethical approval (local or external) and site governance authorisation have been granted. Please refer to the Research Governance Essentials guide for more information on governance submissions.

The SALHN Office for Research email is: Health.SALHNOfficeforResearch@sa.gov.au

The Office for Research team are:

Executive Director of Research, Professor Andrew Bersten
Manager, Research Governance and Ethics, Simon Windsor: 08 8204 4507
Research Development Manager, Lauren Perry: 8204 5414
Nurse Consultant, Safety & Quality, Kathryn Zotti**:** 8204 6453
Project Officer, Dani Eley: 08 8204 6453

Research Ethics

- Dominic How, Executive Officer – Higher risk applications: 8204 6285
- Petrina Kasperski Ethics Officer – Low risk applications: 8204 7433

Research Governance

- Karen Saxty, Research Governance Officer: 8204 6139
- Research Governance Admin Officer: 8204 6453

Training Resources

The Office for Research has a Training Resources webpage, which provides resources for our staff and researchers who are looking to update their skill set.

- Ethics and Governance – a beginner's guide - 6 steps to get you on your way.
- A free Good Clinical Practice (GCP) training course - provides a certificate upon completion valid for 3 years
- National Statement training guide and quiz – provides an overview of each section and a quiz at the end to test your knowledge.

- A-CTEC Australia – Australian-Clinical Trials Education Centre is a not for profit, Australia wide, member-based education platform, hosting a suite of evidence- based, interactive clinical trials education opportunities suitable for a range of learning needs. A free GCP course is also available.
- Global Health Training Centre – free online courses to help increase your knowledge of research processes and methods. A certificate is issued if an 80% pass mark is reached.
- Research Governance Essentials – a guide for governance applications at SALHN and what is required with the Site-Specific Assessment (SSA) form or Low and Negligible Risk (LNR) application form.

Research Safety and Quality

All staff have a role to play in creating a safe and high-quality healthcare system when undertaking clinical trials or research at SALHN. They are responsible and accountable for their patients/participants safety, minimising risks to consumers and for continuously monitoring and improving the quality of the care provided.

An online 'Introduction to Safety and Quality' learning module has been developed to inform staff on how this relates to you.

The Office for Research has a webpage, which provides the channels in which all SALHN approved studies are monitored, plus self-monitoring tools for our researchers.

One very important component of any research study is for a set of Standard Operating Procedures to be available for all investigators. SOPs provide the research team with a consistent set of expectations and processes for completing common tasks and procedures and ensures consistency of service delivery.

Research.

It is also a requirement of Good Clinical Practice and the National Standard Operating Procedures for Clinical Trials, including Teletrials in Australia and the SALHN Clinical Trials Framework.

For more information and templates, please go to our webpage.

Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC)

The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC) is a team of approximately 40 volunteers with a wide range of medical, clinical and life skills and experience, who work together to provide ethical and scientific review for all human research involving human participants and tissue.

To ensure that all medical research provides adequate protection to the participants involved, and treats them in a fair and ethically acceptable manner, all HRECs follow ethical conventions and

standards that outline how medical research is designed, reviewed and conducted. In Australia, we use the National Statement on Ethical Conduct in Medical Research (2023). This is produced by the National Health and Medical Research Council (NHRMC), who are the peak body for supporting health and medical research.

The committee is a properly constituted Human Research Ethics Committee under the National Statement on Ethical Conduct in Human Research (2023).

Ethics and governance review pathways

SALHN has five review pathways:

1. Quality assurance / quality or service improvement / continuous improvement:
    - via Continuous Improvement Pathway
    - reviewed by the SALHN Office for Research
2. Low risk research
    - Via email using the study protocol and low risk form.
        - Do not submit your low-risk application via GEMs.
    - Reviewed out of session via the Expedited Review Panel
3. Higher risk research
    - Via GEMS using Human Research Ethics Application
    - Protocol template can be found here.
    - Reviewed at full committee.
    - Site Specific Assessment form
4. Authorised prescriber.
    - Via authorised prescriber form
    - Reviewed at full committee.
    - Governance submission not required.
    - Please contact the Office for Research if you would like to submit this type of application.
5. National Mutual Acceptance:
    - via a public health HREC
    - Governance at SALHN only
    - Site Specific Assessment form

Choosing the correct application form for your study can save significant time and will result in a faster review. If you are unsure which form to use, you are always welcome to contact the SALHN Office for Research.

All applications undergo a quality assurance review, to ensure all appropriate documents have been submitted, the application reads well, and all sections have been completed.

Incomplete applications or password protected documents will be returned.

Applications will not be assigned to the committee until a high-quality application is achieved.

Please refer to National Statement on Ethical Conduct in Human Research Section 3.1 for guidance on

the elements of research project design.

All protocol templates, participant information sheet templates and guidance documents can be found on our website.

Our staff are available to discuss your application, please email or ring to arrange a meeting.

The Office for Research recommend that all researchers obtain their Good Clinical Practice (GCP) certificate, to assist in their understanding and practice of conducting a successful and well organised research project.

SALHN Office for Research Fees

The SALHN Office for Research charges fees according to the SA Health Research Ethics and Governance Fees Schedule available here. There are three broad categories covered in the SA Health fees schedule:

1. Clinical Trials with Full Commercial Sponsorship
2. Non-Commercially Sponsored Clinical Trials / Cooperative Research Group (CRG)
3. Health and medical research projects (non – clinical trials)

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.

2. Ethical and Scientific review / application types

1. Quality assurance / quality improvement / continuous improvement

The Office for Research advises that any projects that are classified as Quality Assurance (QA) / Quality Improvement (QI), Service improvement, service design, continuous improvement or negligible risk projects may not require ethical review by the Southern Adelaide Clinical Human Research Ethics Committee.

An activity whose primary purpose is to monitor or improve the quality of service is considered Continuous Improvement, Quality Improvement, Service Improvement. The project must only occur within SALHN, by SALHN staff and data collected must remain within SALHN.

If the project is being conducted as part of / towards a degree or any part is external to SALHN, an ethics application is required.

The Continuous Improvement Unit facilitates improvement across the Southern Adelaide Local Health Network (SALHN). For support with your Continuous improvement activity, please contact the Continuous Improvement team.

Ph: 8204 6260 / HEALTH.SALHNContinuousImprovementUnit@sa.gov.au

Further information and the submission template can be found here.

All quality / service improvement projects conducted at SALHN are registered in the SALHN Quality Library. To register you project, click here.

3. Low risk research

As per the National Statement chapter 2.1 - low risk research is defined as...*the only foreseeable risk is no greater than discomfort. Research in which the risk for participants is greater than discomfort is not low risk research.*

This type of application is submitted via email using the Low-risk application form and protocol, which covers both ethical and governance considerations.

Please do not submit low risk applications via GEMS.

As a rule, low risk applications are reviewed out of session and do not go to full committee. The Chair of the SAC HREC will refer low risk applications to the full committee if they contain a request for waiver of consent involving active participation of participants, a vulnerable participant population, other identified issues, or are being submitted under NMA.

Triggers to identify your research as higher risk are:

- All interventions

- Your research involves Aboriginal / Torres Strait Islanders as participants.
- Your research involves participants with mental illness, cognitive or intellectual impairment, pregnant women, or their foetus.
- All requests for opt out or waiver of consent (involving active participation)
- Genetic testing
- Creating a databank, biobank, or registry
- Exploration of sensitive personal or cultural issues

The low risk ethics and governance forms can be found on our website.

4. Higher risk research

Human Research Ethics Form (HREA) form is used for higher risk applications and is submitted in two separate documents:

1. The HREA form ensures the project complies with the National Statement on the Ethical Conduct in Human Research and created electronically via the GEMS Research Management System.
2. The protocol (project description) provides the HREC with information on the design, objectives, methodology, rationale, recruitment, and consent and data management plan for the research.
3. The template and a submission guide are located on our website.
4. For any studies involving a device, SALHN Biomedical Engineering should be consulted. Please email SABMEFMC@sa.gov.au to discuss your device before submitting the ethics application.

Application tips for writing your application.

For a timely review and to meet current research ethics and governance requirements, please ensure you read through the below information. These are the most common items that are picked up in the quality assurance review, and result in the application being returned to the researcher.

General items

- Please treat your application as a piece of academic writing, taking into careful consideration readability, spelling, and grammar.
- You must provide a literature review, to demonstrate the originality and relevance of your research.
- Declare the funding source and amount.
- Fill out all sections of the HREA and protocol in a clear and concise manner, so anyone reading your application will be able to understand what your research project involves.
- If a section of the HREA or protocol does not apply to your study, rather than write N/A, explain why it isn't applicable.

- Please do not refer to participants as subjects.
- Please only use SA Health, University, or professional email address in the application.
- Please ensure additional documents are correctly named and have a version number and date in the footer i.e., PICF v2 dated 01.01.17.

Research Personnel

- All research activities conducted at SALHN must include a SALHN Principal Investigator (PI). The PI must have the experience and training to serve as PI. This means they have sufficient authority, relevant scientific knowledge, and the capacity to carry out or supervise all aspects of the study at the site. They must also be credentialled to work at the study site.
- If the PI is not a SALHN employee a SALHN Co-PI must be appointed.
- Listed investigators must complete their Good Clinical Practice certificate.
- The PI is ultimately responsible for the conduct of the study at the site, and for ensuring all annual reviews, amendments and safety reporting is submitted.
- Students must not be listed as PI.
- The site contact person is the person to liaise with SALHN OFR regarding ethics and governance.
- It is also important to list all non-SA Health staff and students who are working on the research at SALHN and to detail their involvement, particularly those having participant contact.
- Additional support staff can be documented on a 'Delegation of Responsibilities log'.

Access to SA Health Electronic Systems for Research purposes

- My Health Record data cannot be accessed for research and public health purposes.
- Governance authorisation is mandatory for access to SA Health electronic systems.
- Accessing data for clinical purposes is different to accessing data for research purposes. Even if you normally have access to this data in a clinical capacity, this does not automatically grant you access for research purposes.
- Data access for research purposes must be in compliant with the SA Health Research Ethics and Governance Policy and have appropriate authorisation before the project commences.
- Non-SA Health staff should not be granted access to SA Health electronic information.

systems that store identifiable patient records / data, without appropriate authorisation via Research Governance.

- Students can access patient records as part of their clinical placement agreement between SALHN and the University given they are under direct SALHN supervision and have undergone all the necessary SALHN requirements to undertake their placement.
    - The student must be logged on Placeright.
    - Students NOT on placement but assisting with a research project cannot access patient data.
- Where patient and other confidential health data is required for a specific project, a SA Health staff member must extract and de-identify the data before it is provided to the research investigators listed on the application.
- As part of your Governance application, you will be asked to provide approval from the relevant data custodian. Data cannot be accessed for research purposes until this approval has been granted. The SALHN data custodian for hard copy and electronic medical records at SALHN is Karen Saxty, Research Governance Officer

The data custodian reserves the right to refuse a request to supply data if the request cannot be met within the required timeframe or has other concerns about the request.

3. Writing your application - common ethical considerations

When reviewing ethics applications, there are a number of items that the committee commonly ask to the researchers to amend or add into the submission. These common items are explained below.

Recruitment and consent

The **recruitment method** must be compliant with the *Health Care Act 2008*.

When a researcher is not part of the team directly caring for the patient, there is no legal authority for those researchers (or anyone acting on their behalf of those researchers) to access a patient's medical records without appropriate consent to identify potential participants for clinical trials or other research projects.

If you are not part of the patient's clinical care team and need to access a patient's medical records to **pre-screen** for eligible participants, and you do not have prior patient consent to do so, you will need to apply for an exemption under 93(3)(f).

Please clearly state in the recruitment section in the protocol:

- Under s93(3)(f) of the *Health Care Act 2008*, we wish to apply for an exemption of patient consent to access their personal information for research purposes. In order to identify suitable participants for this research project, <*specify who or a title i.e., study coordinator*> will be required to access <*specify wha.t is being accessed*>, prior to obtaining consent from the patient.

.Please consider and address any **dependent relationships** between participant and researchers in the research and use the National Statement chapter 4.3 for guidance on how this will be managed.

Participants must be given enough time to read the information sheet, ask questions and provide their consent without feeling rushed or coerced into participating in the research.

Appropriate recruitment methods are:

- Letters or emails of invitation sent to patients.
- Posters in the waiting room, that advises they may be approached while waiting.
- Clinician mentions the research during the patient's appointment and gains the patient's consent for the researchers to contact them.
- Flyers and posters in key areas, that invite them to contact the researchers for more information.

Consumer engagement

Researcher are encouraged to consult with Consumer and Community groups with the design of their research. Consumer engagement in research is vital, as it will strengthen the research design and how it is conducted. Health care professionals and researchers have the expert knowledge about treatment and services, but they do not have the lived experience. By involving consumers in the research design and conduct, it can be tailored to suit and support the participants and produce high quality research.

More information on Consumer engagement can be found here.

Waiver of consent

In some research, requesting a waiver of consent is an appropriate method for researchers to access a patient's personal information or personal health information. Please refer to chapter 2.3 of the National Statement for guidance on this method.

If you are applying for a waiver of consent, you must use section 2.3.9 of the National Statement to justify why a waiver of consent is appropriate in the protocol. All applications requesting a waiver of consent, where there is active participation in the research are reviewed at full committee.

Conflicts of interest - researchers

Please declare all **conflicts of interests** and how they will be disclosed and managed. The conflicts may

be actual, potential, or perceived or personal, financial, or professional. It is important the conflicts are declared and information on. Please refer to the

National Statement chapter 5.6 for guidance and to your institutions policies on how to handle a conflict of interest.

Highly dependent, cognitive impairment, intellectual disability or a mental illness

If your research involves any of these patient groups, the committee ask you to read the National Statement chapters 4.4 and 4.5 for guidance on how to respectfully include these patients in your research.

If the participant is unable to provide consent for themselves, you will need a third-party consent participant information sheet and consent form. A link to the PICF template is on our website or go to the InFORMed website.

Children and young people

Ethics applications involving multiple sites, including Women's and Children's Health Network (WCHN), and where the primary research participants are children and young people, or where the project involves access to paediatric data primarily held by WCHN, must be submitted to the WCHN HREC for review as the lead HREC.

If the research is to be conducted at SALHN, a Site-Specific Assessment will be required as per SALHN governance requirements.

Aboriginal and Torres Strait Islander people

The South Australian Aboriginal Health Research Ethics Committee (AHREC) reviews all research applications where the focus is on a topic or disease/health burden identified as being of specific concern to Aboriginal and Torres Strait Islander people (based on 4.7 of the National Statement, 2023).

In addition to a research application having been submitted to and reviewed by any SA Health HREC, proposals are required to also be submitted to the AHREC if:

- The experience of Aboriginal and Torres Strait Islander people is an explicit focus of all or part of the research; or
- Data collection is explicitly directed at Aboriginal and Torres Strait Islander people; or
- Where it is proposed to separately identify Aboriginal and Torres Strait Islander people in the results; or
- The information has an impact on one or more Aboriginal and Torres Strait Islander communities; or

- The geographic location of the research is such that a significant number of the population. are likely to be of Aboriginal and Torres Strait Islander origin (based on 4.7.6 of the National Statement, 2023); or
- Where terms such as ‘resilience’; ‘well-being’; ‘cultural safely’; ‘cultural health’; and ‘language and culture’ are used in the description and design of the project indicating that the project has important health implications; or
- Aboriginal and Torres Strait Islander health funds are a source of funding.

Participant information sheets (National Statement 2023 2.2.6)

- Please use the InFORMED PICF templates, which are found on the Office for Research or InFORMed website.
- Please remove the first two instruction pages
- Please ensure the formatting is consistent and professional in appearance i.e., check spelling and grammar, line spacing, font, text colour.
- Please ensure the participants are provided with clear and concise information on what their participation involves.
- The PICF must be free of any jargon and all acronyms explained.
- Where the research will involve a variety of cultures then the committee may ask that the PICF be translated into the relevant language.
- For a multi-site application submit the ‘master’ PICF in a generic format to be used at all sites. The site specific will be reviewed in the governance process.
- Please write the PICF to a readability age of 12 years old.
- It is acceptable to remove any sections in the template that are not relevant to your study.
- The Office for Research contact details and a link to the PICF templates can be found on our website.

Data linkage and SA/NT data linkage research

Applicants who are seeking to access SA Health data held by SA NT DataLink or to conduct data linkage studies must submit to the SA Department for Health and Wellbeing HREC.

Appropriate retention of data

General Disposal Schedule No. 28 is for Clinical and Client-Related Records of Public Health Units in South Australia. Research and ethics records not only provide evidence of what research is conducted but how it is conducted with regards to subject recruitment, treatment and ethical conduct. The guidance recommends data should be destroyed after 15 years and before this occurs, researchers will need to seek approval as per Official Records Destruction Agency Process SALHN (SALHN staff only).

Publications

As a general principle, the findings of research funded with public money should be made available to the wider community to facilitate knowledge and understanding. Publication of research results irrespective of whether they are favourable or unfavourable is considered good ethical practice, promoting transparency and knowledge, and is supported by SA Health. For these purposes, a 'publication' can be a hard copy, electronic copy or online (internet) publication.

Project findings should also be appropriately communicated to research participants and the SALHN office for Research.

Biosafety, Chemical and Radiation Safety

All research that involves biosafety or radiation must comply with relevant requirements. If researchers are unsure of the biosafety requirements of their study, they should contact the Flinders University Institutional Biosafety Committee (IBC).

If the study protocol specifies that the study involves radiation beyond what is standard of care a radiation report must be provided. If the radiation is not above standard of care the PI must provide a letter confirming this. Research involving radiation must be conducted in accordance with the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code of Practice for the Exposure of Humans to Ionising Radiation for Research Purposes (2005) available here.

The South Australian Environmental Protection Agency (EPA) must also be notified in writing of the research before the research commences using the EPA Notification of a Research Study Involving Exposure of Humans to Ionising Radiation form.

4. Submitting your application

Submitting your application

There are two ways to submit your application.

1. Higher risk applications are created and submitted via GEMS Research Management System.
2. Low risk applications are submitted via email to the SALHN Office for Research.

Documents checklist

- HREA.
- Protocol.
- Low risk application form. / Site Specific Assessment form (SSA)

- A literature review to support your study.
- Participant Information/Consent Form (PICF).
- Victorian or Western Australian specific module for any of these sites that the SAC HREC is providing approval for.
- Project approvals from other HRECs.
- Aboriginal community approval (if applicable).
- Protocol and investigator brochure must be submitted for all clinical drug trials.
- Questionnaires or surveys being used in the study.
- Data collection tools.
- Patient facing documents.
- Recruitment advertisements such as flyers and posters.
- Relevant Head of Department (HOD) endorsement letter(s).
- Letter of support from Flinders Medical Centre pharmacy (if applicable).
- Radiation Safety Report (if applicable).
- Proof of registration with Australian Register of Therapeutic Goods.
- HREC indemnity form for multicentre trials.

Site Specific Assessment (Governance)

For all public health sites listed on your application, a separate Site-Specific Assessment (SSA) must also be lodged before the research project can begin at any public heath site listed in the application. Your research cannot commence until it has been authorised by the Chief Executive/delegate of the public health site where the project is to be undertaken.

If the research project is being conducted at a university, please contact the University's Governance Officer for institutional requirements.

In the case of SALHN applications, the Office for Research also encourages researchers to submit their Site-Specific Assessment forms at the same time as the ethics application for concurrent review. This will assist in reducing the amount of time it takes for full authorisation to be granted.

The SSA is created via the GEMS Research Management System.
For low-risk applications, the Low and Negligible Risk application form is used.

SAC HREC review of multicentre research.

There are two approaches for multicentre research applications to be submitted and reviewed:

1. SA Health single ethical review model.

2. National Mutual Acceptance (NMA) model.

SA Health single ethical review model

The Single Review Model applies to all multi-site research taking place within SA public health system. This model enables researchers to seek ethical and scientific approval through one HREC only (referred to as the lead committee). This approval will be accepted by all SA Health HRECs and institutions. The SAC HREC will accept ethics approval of the lead SA Health HREC for all research taking place within the SA Health public health system.

As a rule, the lead committee will be located at the institution of the CPI. The applicant will assume responsibility for submitting all required documentation in accordance with SA Health and local HREC requirements.

The SAC HREC is responsible for notifying the CPI of the outcome of the review. It is the CPIs responsibility to notify the outcome of this review to each of the other sites where the project is proposed to take place, via the Research Governance Officer associated with the site/s. For further information, please refer to the SA Health Research Ethics and Governance Policy

National Mutual Acceptance

National Mutual Acceptance (NMA) is the system of single scientific and ethical review of multi-centre human research projects across Australian jurisdictions (public health organisations only). All Australian states and territories participate in NMA (New South Wales, Queensland, Victoria, the ACT, Western Australia, South Australia, Tasmania, and Northern Territory).

SALHN accepts (subject to NHMRC HREC research category certification) SA Health HREC reviews and National Mutual Acceptance (NMA) single ethical review and Private HREC review. This means that you may be able to rely on ethics review from another site if they are under NMA or another accredited public health HREC in South Australia.

All research must have ethical approval prior to site authorisation.

SALHN accepts ethics review for commercially sponsored clinical trials from the Belberry HREC.

In SA, the ethics application and SSA must be completed via the GEMS Research Management System and be submitted to a lead HREC (NMA Certified) for review.

Exemptions

The following research proposals are excluded from consideration under these two review pathways in South Australia in accordance with Standard Principles for Operation:

- Phase 0 (first time in human) and Phase 1 clinical trials.
    - SALHN have specific Phase 1 requirements. Please contact the Office for Research to discuss your phase 1 trial.
- Human research proposals involving South Australian Aboriginal and Torres Strait Islander participants, or which have an Aboriginal health focus, for which applications will need to be reviewed by the SA Aboriginal Human Research Ethics Committee (AHREC) in addition to a NMA certified HREC.

6. Post approval monitoring and reporting

The SALHN Office for Research has a responsibility to monitor all research authorised to be conducted at a SALHN site. SALHN has produced monitoring and reporting guidelines to assist researchers in understanding their obligations.

Once you have received ethics and governance authorisation for your research project, there are mandatory reporting requirements you must adhere to Failure to do is a breach of a breach of the NHRMC Australian Code for the Responsible Conduct of Research R17, R22, the National Statement chapter 5.5 and the terms and conditions of the ethical approval for this study.

Failure to submit the required report may result in the ethics approval being withdrawn and the application closed.

Progress reports, extension requests, Discontinuation of research projects and final reports

It is the Chief Investigator's responsibility to ensure that all reports and amendments are submitted to the Office for Research. Reporting is an important part of your research project, as it provides the SAC HREC with an overview of the study progress and that it is progressing as approved.

- Progress report –is required annually for the life of the study, on the anniversary of the approval date.
    - Any study that does not submit a progress report by the due date will have their SAC HREC approval immediately and suspended. This is in line with section 3.15 of the SA Health Research Ethics Policy Directive which outlines "SA Health HRECs reserve the right to suspend activity on an approved research project should the CPI fail to observe the HRECs conditions of approval or any other reasonable requirement of the HREC. Grounds for suspending the activity on a project may include: • Failure to provide regular (at least annual) reports of progress".
    - Upon submission of a completed progress report, the SAC HREC approval will be reactivated, and the investigators may continue the study.

- Extension request – is required 1 month before the ethics expiry date.

- Final report – this is required to be submitted on completion of the research project. Copies of all publications or posters are to be provided to the SAC HREC when available.
    - Failure to submit a progress report or final report by the due date violates the terms and conditions of SAC HREC approval and will result in immediate suspension of the SAC HREC approval until a valid progress report or final report is submitted.
    - Submission of a valid progress report will continue the SAC HREC approval for the next 12 months, at which point a new progress report will be due.
- Discontinuation of research projects – this must be communicated via the Withdrawal of Research form as soon as possible
- The reporting templates are on our website and the competed report emailed to Health.SALHNofficeforresearch@sa.gov.au

If the research application was submitted via GEMS, please use GEMS to submit the report. Researchers will see a reminder on their GEMS dashboard when their progress report is due. If the application has any outstanding reports, they will not be able to submit an amendment.

The Office for Research also has a Research safety and quality webpage, which provides the channels in which all SALHN approved studies are monitored, plus self-monitoring tools for our researchers.

Safety reporting and protocol deviations / violations

The Monitoring and Reporting matrix can be found here. Researchers can filter by report type and state to understand what is required to be submitted to the HREC and/or RGO.

Depending on nature of your research project, you may need to submit Serious Adverse Event reports, protocol violations or Development Safety reports. These can be submitted via GEMS or via email on the appropriate template.

- Significant Safety Issue (SSI) / Urgent Safety Measure (USM) are reported to the lead HREC if they are definitely, probably or possibly related to the study, within 72 hours of the occurrence, unless the Principal Investigator considers immediate notification is necessary.
- Other safety reports required by the committee are Serious Unexpected Suspected Adverse Reactions (SUSARs), Adverse Events (AEs), Adverse Device Events (ADEs) and Data Monitoring Committee (DMC/IDMC) reports.
    - These are to be reported immediately if they have an impact on the safety of the study within SALHN or patients involved in SAC HREC approved research at other institutions, otherwise they are to be reported at least every six months.
- Protocol Violations or Deviations are only reported, where there is an impact on the participant's safety within 72 hours of the occurrence. The PI should acknowledge the Violation or Deviation and corrective action should be outlined.

- If there is no site impact, the violation / deviation does not need to be reported.

Notifications

Any other items, such as letters, insurance certificates and minor communications from sponsors or researchers can be submitted via email or GEMS for review by the Office for Research.

Amendments

Studies can change overtime and no matter how small the change is, and amendment is required to be submitted for review.

The amendment notification process is a requirement of continuing ethics approval and institutional authorisation and aims to eliminate immediate risks to participants or to assist in the viability of recruitment or other research administration.

Amendments can be submitted via email or via GEMS for review by the Office for Research.

- All relevant application documents will need to be updated, to reflect the current status of the research.
- Please use track changes to make all edits, so the committee can clearly see what has been changed.
- Investigator brochure and protocols:
  - Will need to be submitted with a clean and tracked version.
  - Will require a summary of changes.
- Please update the version number and date of all submitted documents in the document footer.
- Sub studies or significant changes to the study design will need to be submitted as a new application.

Amendments requiring SAC HREC approval, and SALHN research governance acknowledgement will be reviewed at the same time. The amendment cannot be incorporated into the study until the ethical approval has been granted by the committee, which will be a communicated in a formal letter via email.

Standard Operating Procedures (SOPs)

National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia—Based on the International Council for Harmonisation Guideline for Good clinical practice.

These National Standard Operating Procedures for Clinical Trials, including Teletrials have been developed to assist organisations engaged in conducting clinical trials in Australia to, wherever possible, standardise their procedures for key operations related to clinical trials and specifically teletrials. They have been developed for the National Mutual Acceptance (NMA) Scheme in Australia and to support a consistent approach to national implementation more broadly.

Standard operating procedures (SOPs) are important documents within all types of research, that provide researchers and their team with a useful tool to clearly outline the process for completing common tasks and procedures. SOPs set expectations on how the tasks are to be completed to ensure consistency of the task delivery.

This document will outline the purpose of the SOP, who is responsible for the task/s, the procedures, any contingency plans or corrective actions if the SOP cannot be followed and any supporting documents.

View the Standard Operating Procedure Template.

6. Reference Documents, policies and Resources

Polices and guidance documents to assist in your submission are:

- SA Health Research Ethics and Governance Policy 2023
- Access to Data for Research Purposes policy (2019)
- National Statement on Ethical Conduct in Human Research (NHMRC) (2023)
- Australian Code for the Responsible Conduct of Research (2018)
- Australian Clinical Trials: Researchers
- Access to Unapproved Therapeutic Goods - Clinical Trials in Australia (TGA)
- International Conference on Harmonisation / Good Clinical Practice Guidelines (ICHGCP Guidelines)
- Framework for Monitoring: Guidance for the National Approach to single ethical review of multi-centre research (NHMRC, 2012)
- SA Health Intellectual Property Policy (2017)
- Department of the Premier and Cabinet (2016), Information Privacy Principles
- SA Health Privacy Policy Directive (2023)

Document History

Custodian	SALHN Office for Research	
Document status	New document	
Key words	Research, Research Governance, Ethics, Human Research Ethics Committee (HREC), Clinical Trials, Audit Based Research, Monitoring, Education.	
Version control	**Amendment details**	**Start Date**
V1.0	Initial targeted launch for consultation	December 2018
V2.0	Final document incorporating consultation outcomes pending SALHN Authorisation	April 2019
2.1	Update to incorporate recent changes to submission documentation	Jan 2020
2.2	Update to incorporate introduction of GEMS	May 2021
3.0	Update to incorporate changes to audit applications and addition of new webpages.	Aug 2021
3.1	Update to incorporate training resources	Nov 2021
3.2	Update to progress and final reports	Feb 2022

3.3	Administration update	April 2023
3.5	Administration update	June 2023
3.6	Administration update re National Statement 2023 release	July 2023
3.7	Administration update	January 2024

Print Name: Simon Windsor, Manager, Research Governance & Ethics

Signature: 

Date: 25.01.2024

The signed version is retained by SALHN Office for Research.