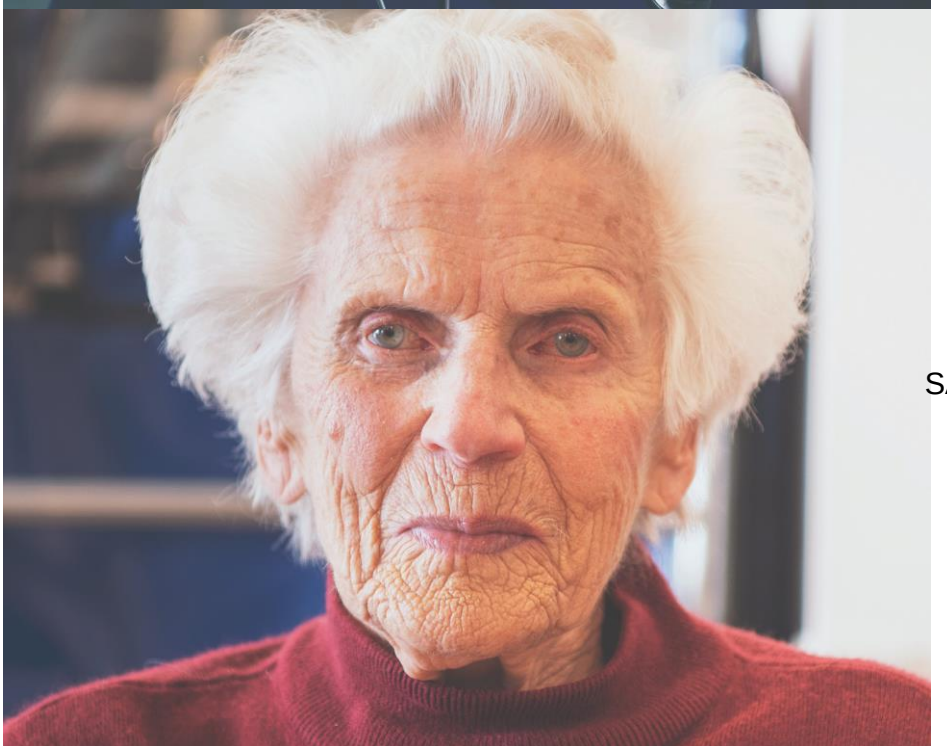

Government of South Australia

Health
Southern Adelaide
Local Health Network

Research Governance Essentials

Publication Details

Publication title:

SALHN Research Governance Essentials

Published: 2025

Publisher: Research Hub

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National Clinical Trials Governance Framework

Evidence-based practice and Clinical Trials at the Southern Adelaide Local Health Network (SALHN) ensure our consumers have access to innovative treatments and interventions aimed at improving the overall standard of medical care we provide. This integration of research and routine health service provision has been supported in the Australian Commission on Safety and Quality in Health Care National Clinical Trials Governance Framework (NCTGF) as part of the Australian Health Service Safety and Quality Accreditation Scheme (AHSSQA). At the SALHN a Clinical Trials Framework has been designed to assist all staff as well as our clinical trial workforce in making decisions regarding safety, quality and integrity when designing, conducting, recording, and reporting all clinical trials and research.

More information can be found here [National Clinical Trials Governance Framework] and Contact the SALHN Research Hub to access the current SALHN Clinical Trial Framework: Health.SALHNOfficeforResearch@sa.gov.au or 8204 6061.

Data Governance Framework

SALHN has established a Data Governance Framework to guide safe and appropriate use of SALHN's data. Through this framework, we aim to uphold data privacy, security, and integrity while fostering a culture of collaboration and innovation.

This Data Governance Framework is applicable to anyone wanting to create a new SALHN data asset or access SALHN data for secondary use such as research, analytics, performance management, and improving patient experience.

As part of this Data Governance Framework, a data management plan must be submitted with all SSA applications.

The template can be found on the Governance webpage.

The Data Governance Framework can be found on the SALHN Intranet.

Governance Overview

Governance encompasses a system by which a health organisation has established a set of relationships and responsibilities between its executive, workforce and stakeholders such as patients and consumers, ('*The Australian Commission on Safety and Quality in Health Care', 2020*). Research governance refers to these requirements (legislation, policy, procedures etc.) to ensure the institution is accountable for the research conducted under their auspices.

Research Governance addresses:

- The protection of research participants as well as the privacy and confidentiality of their data.
- Financial probity of research and the use of SALHN resources
- Legal, regulatory and Institutional risk management
- Promotes good research culture and monitoring of research and publications.

The SALHN Research Hub oversees research governance and site authorisation of research in line with the SA Health Research Governance Policy Directive available here. Research can only commence when both ethical approval (local or external) and site governance authorisation have been granted.

All resources and templates can be found on our webpages:

- Higher risk research
- Lower risk research
- Research Governance
- Continuous Improvement
- Post approval
- Training resources
- Safety and Quality

Governance application forms

1. Site Specific Assessment Form – Higher Risk and Low Risk) studies

These are completed on the Research GEMS website which can be located at https://gems.sahealth.sa.gov.au. Guides on how to submit the form are readily available on the Site.

2. Access to SALHN data for SA Health initiatives

As part of our commitment to data governance and ensuring the responsible use of information, we have implemented this Data Access Request Form to facilitate Data Custodian approval for SA Health initiatives that require data extraction, that includes SALHN data but does not involve SALHN investigators or onsite activity.

This form is on the Governance webpage and is submitted by email to the SALHN Research Hub.

Ethical and Scientific review

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

Applicants who are seeking to access SA Health data held by SA NT DataLink to conduct data linkage studies must submit to the SA Department for Health and Wellbeing Human Research Ethics Committee | SA Health.

The following research proposals are excluded from consideration under NMA in South Australia in accordance with Standard Principles for Operation:

- Phase 0 (first time in human) and Phase 1 clinical trials - these must be reviewed by the local (SA Health) HREC responsible for the public health organisation where the clinical trial is taking place.
- 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.

Under NMA, in SA the ethics and/or governance application must be completed via Research GEMS. Please review the user guides for step-by-step instructions on how to navigate the Research GEMS system.

The SALHN PI is responsible for the SALHN SSA submission and will provide all relevant HREC approved documents as part of the SSA submission to the Research Governance Officer via Research GEMS.

Following the RGO application review, you will be notified via GEMS of any items that need to be addressed. If the RGO does not receive a response within 30 days after receipt and you have not requested an extension, your application will be withdrawn from GEMs and you will need to submit a new application.

Research Hub Fees

The SALHN Research Hub 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. Contract Review

To define clinical trials we acknowledge the following the World Health Organisation definition: For the purposes of registration, a clinical trial is any research study prospectively assigning human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. This definition includes Phase I to Phase IV trials.

Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, devices, cells and other biological products, surgical procedures, radiologic procedures, behavioural treatments, diagnostic tools, process-of-care changes, preventive care, etc.

Site Specific Review

When the application is reviewed, the Research Governance Officer will be looking at the below criteria. This review forms part of the recommendation to the CEO for site authorisation. A brief description of the information required is included under each heading.

1. Research Personnel

All research activities conducted at SALHN must include a 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. The PI is ultimately responsible for the conduct of the study at the site.

- Unqualified students must not be listed as PI.
- If the PI is not a SALHN employee a SALHN Co-PI must be appointed. Please contact the SALHN Research Hub (RH) for the required Co-PI form.

The site contact person is the person to liaise with SALHN Research Hub regarding ethics and governance. The experience and training for all researchers involved in the research at SALHN must be listed in the SSA.

Delegation log

All research staff that are performing a function i.e. consenting, interviews, assessments can be registered on a ‘Delegation of Responsibilities log’ and would not need to be listed as an investigator in the protocol.

The investigators who have responsibility for the study i.e. Chief Investigator, Site / Principal Investigator, SALHN staff accessing medical records are listed in the ethics and governance application as investigators, detailing their study activity and responsibilities.

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. Additional support staff can be documented on a

The SALHN Research Governance Officer must be notified of any changes to Investigators.

- If the PI is changed, the reviewing HREC must also be notified.
- No changes to research personnel should be implemented prior to receiving authorisation from the SALHN CEO/Delegate and approval from the relevant HREC.

All researchers must have a Good Clinical Practice Certificate before they can be involved in a research study at SALHN. Free training is available at Victorian Clinical Trials Education Centre, which has an aim to build the capacity and capability of the clinical trials workforce through easy access to world-class education and training opportunities, at no cost to the end user.

Delegation Log

All research staff that are performing a function i.e. consenting, interviews, assessments can be registered on a ''Delegation of Responsibilities log', and would not need to be listed as an investigator in the protocol.

The investigators who have responsibility for the study i.e. Chief Investigator, Site / Principal Investigator, SALHN staff accessing medical records **are** listed in the ethics and governance application. A template can be found on our Safety and Quality page.

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.

2. SALHN credentialing

SALHN must ensure all clinicians, contractors, visiting private practitioners, volunteers and students are credentialed. If any of the investigators listed on the application are working at SALHN in a clinical capacity, they must have up-to-date credentialing within SALHN. If the credentialing details are out of date, we will request evidence of renewal and the study will not proceed until evidence of renewal has been provided. SALHN Clinical Governance Unit manage staff credentialling, you can contact the team on 8204 3949.

3. Non-SA Health researchers and Criminal & Relevant History Screening

Non-SA Health staff coming on site at SALHN as part of a research study must provide a SALHN confidentiality deed and National Police Certificate (NPC).

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 approach is compliant with the South Australian Health Criminal and Relevant History Screening Policy Directive available here.

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.
- A SALHN confidentiality deed will need to be signed by all non-SA Health staff viewing confidential information.

4. Divisional and Departmental Approval

The Head of Department and the Divisional Director within SALHN must authorise the application.

It is a potential conflict of interest for the principal investigator to also sign on behalf of the department. In the case that the PI is also the head of department, the person to whom the head of department reports to must sign the SSA. Where the Director is the PI then an equivalent will be identified with the SALHN Research Hub.

All SALHN departments or divisions involved in the research must endorse the research being conducted within their department by endorsing the study via the Research GEMS website or via email. This includes departments not actively involved in the research but may experience some impact from the conduct of the research.

5. Access to SA Health Data

The SALHN Data Management Framework must be adhered to for all research applications, and a Data Management Plan is required as part of the SSA application.

Non-SA Health staff will not be granted access to SA Health electronic information systems that store identifiable patient records / data.

Where patient and other confidential health data is required for a specific project, the preferred mechanism is for SA Health staff to extract and de-identify the data for the PI. This work does however give rise to time and resource cost considerations. Please note on 30th January 2023 SALHN Medical Records ceased routine supply of historical paper case notes.

Access to any data for research purposes must have appropriate authorisation. 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.

As part of your SSA application you will be asked to provide approval from the relevant data custodian. The data custodian must endorse the SSA. The SALHN data custodian for electronic medical records is the Executive Director, SALHN Research Strategy.

My Health Record data cannot be accessed for research and public health purposes.

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 listed on the Place Right system.
- Students NOT on placement but assisting with a research project cannot access electronic SA health systems.

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.

Monitoring and Reporting requirements

The SALHN Research Hub is required to monitor and to conduct post authorisation audits to ensure researchers are following International Conference on Harmonisation Good Clinical Practice (ICH GCP) principles and ensure the conduct of the study is consistent with authorisation.

If your research unit is selected for a site monitoring visit you will be contacted well in advance and be provided an audit plan. At SALHN all approved studies will be monitored by the Office for Research via the below channels:

- Annual report and (where applicable) safety report – as part of the Terms and Conditions of research study authorisation, all researchers are required to submit to the Research Hub an annual report that reflects site activity (this is in addition to HREC annual reporting)
- Desk top audit
- Risk register
- Participant feedback
- Providing templates for researchers to self-monitor

More details can be found on our SALHN Research Web page Research Safety and Quality at SALHN

1. Complaints process

In accordance with the *SA Health Research Ethics and Governance Policy (2023)*; all complaints can be made in writing to the Research Hub. To arrange a confidential appointment, please email Health.SALHNOfficeforResearch@sa.gov.au or phone (08) 8204 6139.

2. Data breaches at SALHN

All major data breaches containing personal information must be notified to the Privacy Committee of South Australia via email: privacy@sa.gov.au in accordance with the Personal Information Data Breaches Guideline**.**

The report to the Privacy Committee may also include the remedial action and steps put in place to prevent a similar breach occurring in future, depending on the breach.

A ‘‘PCSA Privacy Breach Notification Template’ has been developed to assist managers and investigators with making a notification.

3. Safety Learning System (SLS) Reporting at SALHN

All participant or staff safety events or privacy breaches, e.g., inappropriate access to or unlawful disclosure of personal information, occurring at SALHN must be recorded i(by a SALHN staff member) n the incident module of SLS in accordance with the SA Health Policy Directive. This will ensure a formal record of the breach and any remedial action to be implemented where relevant. Detail of actions taken, and notifications made, should be included in the manager response.

Intellectual Property

Intellectual Property can be described as the genesis of an outcome that is new, non-obvious (involve an inventive step) and useful (able to be made or used in an industry). An inventive step means that the invention is not an obvious thing to do for someone with knowledge and experience in the technological field of the invention.

The potential development of new intellectual property must be outlined in the SSA form. If an agreement is required, then the owner of the IP should be declared in the agreement. Any IP arrangements should be made in line with the SA Department of Premier and Cabinet Intellectual Property Policy.

Insurance and Indemnity

All research studies hosted by SA Health organisations involving SA Health or external staff must have appropriate insurance and indemnity arrangements. Further information regarding insurance and indemnity in research can be found in the SA Health Legal Governance and Insurance Services (LGIS) guidance document located here.

The SALHN Research Governance Officer will work with the investigators to ensure proper arrangements are in place prior to governance authorisation and will involve the following scenarios:

1. SA Health Employees

SA Health employees conducting a research study in the capacity of their employment with SA Health are automatically covered by SA Health insurance when approval from a SA Health HREC or NMA HREC has been obtained.

2. Collaborative institutions involved in investigator led studies.

For research study collaborations undertaken at SALHN among staff, patients, data etc. involve non-SA Health employees; the PI must provide appropriate insurance documentation on behalf of the non-SA Health organisation. Appropriate insurance documentation includes written confirmation of insurance approval from the non-SA Health organisation for the research study confirming that the researchers would be covered as part of their involvement in the research study.

3. Students

Indemnity insurance for students involved in research studies conducted at a SALHN site are assessed as follows:

- SALHN initiated:

If the student is involved in a SA Health initiated research project/clinical trial and working under the supervision of a principal investigator who is an SA Health employee conducting research as part of their SA Health employment, no evidence of insurance is required.

- Flinders University / Academic initiated:

If the student/university employee is the person conducting the research, then evidence of indemnity from the university is required. An email from the university confirms cover for the research, including the title of the specific project, would be considered sufficient evidence of insurance.

4. Commercially sponsored clinical trials

For commercially sponsored clinical trials, the sponsor must supply evidence of their insurance cover. A sponsor's insurance cover must indemnify SALHN. The Medicines Australia *'Form of Indemnity for Clinical Trials – Standard'* agreement must be submitted to the SALHN Research Governance Officer.

If the Southern Adelaide Clinical Human Research Ethics committee (SAC HREC) is reviewing a commercially sponsored clinical trial at sites outside of SALHN, the sponsor must indemnify the HREC by submitting a HREC Review Only Medicines Australia Form of Indemnity for Clinical Trials. Collaborative Research Group (CRG) studies are exempt from this.

Biosafety, Chemical and Radiation Safety

All research involving 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 the study involves radiation beyond what is **standard of care** a radiation report must be provided to the HREC and SALHN Research Governance Officer. 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 found here.

Investigational Drugs – SA Pharmacy

The FMC Pharmacy Department is part of SA Pharmacy, a state-wide clinical support service that is governed by Central Adelaide Local Health Network (CALHN). In accordance with the Investigational and Clinical Trial Drugs Within SALHN procedure - Pharmacy SALHN, any research proposals (SSA and Clinical Trial Research Agreements) involving investigational drugs, must be approved by SA Pharmacy. This indicates FMC Pharmacy Department are aware of the research and have provided approval for the dispensing methodology and or provided a quote to manage, store, and/or dispense the investigational drug(s).

All dispensing must be performed through the FMC Pharmacy Department, unless otherwise approved by the Director of Pharmacy or Pharmacy delegate at FMC. Investigators of non-sponsored studies (such as

grants) that have pharmacy involvement are encouraged to discuss their requirements with pharmacy prior to submitting their grant application.

Clinical Trial Notification scheme - Clinical trials involving therapeutic goods

As detailed on the Therapeutic Goods Administration of Australia (TGA) clinical trials website, the following avenues provide for the importation into and/or supply in Australia of 'unapproved' therapeutic goods for use in a clinical trial.

Clinical trials that do not involve 'unapproved' therapeutic goods are not subject to requirements of the CTN or CTA schemes. It is the responsibility of the Australian clinical trial sponsor to determine whether a product is considered an 'unapproved' therapeutic good

CTN's are submitted via their online submission portal. Where SALHN is not the CTN sponsor of the clinical trial, it is the responsibility of the study sponsor to submit the application and pay the submission fee. SALHN requires that the CTN form must not be submitted to the TGA online portal until both ethical approval and research governance authorisation have been granted.

In some circumstances such as investigator initiated clinical trials, SALHN will agree to act as 'CTN sponsor' for the clinical trial. A researcher must apply to the Research Governance Officer in order for SALHN to agree to act as CTN sponsor.

In the event SALHN agrees to act as CTN sponsor, any relevant agreements (if any) must be in writing first to clarify the obligations SALHN undertakes in its role as sponsor for a particular study and to determine how the TGA submission fee will be paid by the group or reimbursed to SALHN (as the case may be).

SALHN also require researchers to provide all relevant information to be entered into the online CTN form and to provide the Research Governance Officer with a copy of the TGA notification letter as soon as practicable. The Research Governance Officer will liaise with the Research Team regarding management of the CTN process for their study. TGA also charge a fee for lodging a CTN which must be paid for by the local research unit out of the Special Purpose Fund (SPF). The SALHN Research Hub cannot pay the CTN fee.

The online CTN files "Approving Authority Details' for SALHN are as follows:

Table 1 – SALHN CTN registration details

Name of approving authority:	Southern Adelaide Local Health Network Inc. ABN 14 227 133 467
Approving authority contact:	Dr Kerrie Mahon
Position:	Chief Executive Officer
Contact phone:	08 8204 6061
Contact email:	***Health.SALHNOfficeforResearch@sa.gov.au***

If the SAC HREC is the reviewing HREC, the details are:

HREC Name: Southern Adelaide Clinical Human Research Ethics Committee
HREC Code: EC00188
HREC Contact Officer: Sam Button
Position: Executive Officer
Contact Phone: 08 8204 6285
Contact Email: Health.SALHNOfficeforResearch@sa.gov.au

Finance

All Research proposals (SSA's) will have the financial impact to SALHN reviewed and approved.

This will be obtained on your behalf by the Research Governance Officer. When completing an SSA, relevant funding and costing details will need to be completed, describing the study costs, in kind costs and any costs to SALHN.

A supporting study budget and/or a Clinical Trial Research Agreement should be uploaded with the application. This should list all activities related to the study with a cost attributed to each - see Figure 1 for more details. All funding (external and in kind) related to the study must be accurately reported. Please contact the SALHN Research Hub for a copy of the budget template.

If funds are being paid into SALHN for clinical trials, funding grants, research activities, or for SALHN services, the funds must be paid into the nominated SALHN bank account approved by SA Health and administered through a SPF. Budgets must be in Australian dollars ($AUD).

Figure 1 Resource categories to consider when negotiating a research budget.

SALHN guidelines for Research Agreements

All research projects involving an SA Health organisation and one or more external parties must be supported by an approved research agreement prior to commencing.

This should clearly outline the responsibilities of each party such as funding (or no funding), services provided by each party and expectations in relation to intellectual property, publications etc.

Agreements should be in writing and may take various forms, including a legal contract, an exchange of letters, or a research management plan agreed by all parties or representatives of all parties.

If the SA Health organisation proposes to delegate or sub-contract specific responsibilities within the research project to a third party, this must also be formalised within an appropriate agreement that outlines the scope and responsibilities of the third party, and provides the SA Health organisation with appropriate

assurances the third party has the relevant expertise to undertake the research activities, as well as conforming with any standard SA Health requirements such as insurance and indemnity requirements.

The SALHN CEO / Delegate is the only person authorised to sign contracts on behalf of SALHN.

Do not edit the body of the standard agreement. Any non-standard agreements (not on an approved template) will need to be reviewed by the SALHN legal representative prior to signing.

SALHN only accept Medicines Australia agreements or Crown Solicitors Office agreements, available via the Research Governance Officer.

The SALHN institutional details should be as follows:

Institution: **SOUTHERN ADELAIDE LOCAL HEALTH NETWORK INC** (ABN 14 227 133 467) of Flinders Drive, Bedford Park SA 5042 ('SALHN')

Contact for notices should be the Principal Investigator.

- The SALHN ABN should always be included (14 227 133 467)
- The SALHN address is Flinders Drive, Bedford Park, SA 5042
- The following SALHN banking details must be included in Schedule 2:

BANK	**Australia and New Zealand Banking**	**BSB**	**015-101**
		ACCOUNT	**38568775**
ACCOUNT NAME	**SOUTHERN ADELAIDE LOCAL HEALTH NETWORK INC. SALHN ORACLE OPERATING**		
ABN	**14 227 133 467**	**SWIFT**	**ANZBAU3MX**
BRANCH ADDRESS	**18/83 Pirie Street, Adelaide, SA 5000**		

- The protocol name must be correct and consistent across all documents
- The sponsor must be an Australian entity.
- The Principal Investigator should be named in the Schedule 1. The Principal Investigator may sign the agreement, but this is not required.
- The Schedule 2 must contain the provision for the payment of Ethics and Governances fees in line with SA Health Research Ethics and Governance Review Fees Schedule
- Any amendment to the standard agreement must be made using the Special Conditions Schedule via SEBS Committee using SEBS /NACTA Review Template. A copy of the SEBS/NACTA approval must be provided.
- SALHN studies should not raise any invoices for parties based outside of Australia or in foreign currencies (A$, AUD only).

Legal templates and forms

Types of legal templates are as follows:

1. SALHN Confidentiality Deed

Non-SA Health staff coming on site as part of a research study must provide a SALHN confidentiality deed and National Police Certificate (NPC) if they are working with adults. 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 a NPC.

Contact the SALHN Research Hub to access the current document: Health.SALHNOfficeforResearch@sa.gov.au or 8204 6061.

2. Material transfer agreement (MTA) or Data Transfer Agreement (DTA)

An MTA or DTA is a contract governing the transfer of tangible research materials or data between two organizations, when the recipient intends to use it for his or her own research purposes. The MTA/DTA defines the rights of the provider and the recipient with respect to the materials and any derivatives. Contact the SALHN Research Hub to access the current document: Health.SALHNOfficeforResearch@sa.gov.au or 8204 6061.

3. Non-Disclosure Agreement (NDA) or Confidentiality Disclosure Agreement (CDA)

On each occasion that confidential information is proposed to be exchanged by SALHN an NDA should be executed. An NDA will:

- Provide certainty in relation to the terms upon which information is being exchanged.
- Provide a clear basis to seek redress for any breach of confidence.
- Ensure that an application for a Patent is not undermined.
- Ensure there is no reduction in the potential value of Intellectual Property.

There are two standard NDA forms that can be used, namely:

- A mutual NDA is to be used if both parties are likely to disclose confidential information to each other.
- A single NDA is used if only the other party is providing confidential information to SALHN, for example, if a clinical trial is being considered and the other party wishes to share the protocol.

The process to enter into the NDA is:

- Include relevant details in the standard document.
- Have the document signed by persons with authority from SALHN.

The Process for the Release of Confidential Information:

- All confidential documents to be released should be given a title, marked as confidential, and include page numbers.
- A receipt should be requested or provided for any documents exchanged.
- A list of confidential material exchanged should be kept by SALHN researchers.

4. Memorandum of Understanding / Lease agreements

If your research involves a third party that is conducting activities at a SALHN site (Office space, Laboratory, access to patients etc.) you may be required to formalise these arrangements prior to any study authorisation.

5. Clinical Trial Research Agreement (CTRA) Guidelines

Each clinical trial to be conducted at SALHN and sponsored by a third party must be governed by a written agreement clarifying the obligations and responsibilities of the parties involved in the trial.

SALHN will only accept CTRAs that use the standard agreement templates developed by Medicines Australia. The documents are freely available on the Medicines Australia website found here. The CTRA should be submitted along with the SSA and must be reviewed by the SALHN Research Hub prior to execution by SALHN.

6. Grants

Each year SALHN administers the SALHN Enquiry grant round. The Research Hub should be consulted if you are looking to get a letter of support from SALHN. SALHN Staff are required to either be reimbursed for grant funded work or declare in-kind support using a budget and appropriate governance submission. SALHN staff can also contribute to research at external organisations. To explain the SALHN contribution and attain endorsement for the project please contact the Research Hub as soon as possible.

7. Research Collaboration Agreements (RCA)

SA Health have developed a template that should be used for all research collaborations that require a significant exchange of services across institutions. This could include; database administration, funding and staff. Please contact the Research Hub for a copy of the current template.

8. Non-standard agreements

Sometimes an institution will provide a copy of an agreement that is not an SA Health approved template listed above. These need to be consulted with the SALHN legal representative and will incur an extra cost for review.

Study management

Studies can change over time The SALHN Research Hub has a responsibility to monitor all research authorised to be conducted at a SALHN site. SALHN has produced monitoring and reporting guidelines available here to assist researchers in understanding their obligations. The Research Hub is also an independent contact for feedback or complaints for participants are enrolled in studies. Please review the SALHN contact details for Participant Information and Consent Forms guidance to ensure you present participants the appropriate contact details. It is important each research team has a compliant management process in place.

Participant Information and Consent Form amendments / Third party consent

There is currently there is no legal mechanism in place for a ‘family member’ to consent an individual into a study. As per SA Legislation, only a SACAT approved guardian or an individual appointed under an Advanced Care Directive can consent to medical research on behalf of another individual.

To manage changes to the PICF for multicentre studies we require the Project Amendment be submitted via GEMS. This should include a copy of the HREC approval letter, a copy of the master PICF approved by the HREC and the SALHN site specific PICF. The PICF changes should be tracked from the previous version. The clean site-specific version should be representative of what potential participants will receive. Applicants will receive and should file the Research Governance Officer approval email.

All SALHN patients being recruited at a SALHN site by SALHN staff will need to have their details entered into the SUNRISE Electronic Medical Record system (see Clinical Trial Reference Guide for Clinical Trials). The SALHN RGO will add a barcode to all Site PICF’s for this purpose. Once consented, these PICF’s can be uploaded to SUNRISE EMR.

Study and Contract Amendments (Grants and Agreements)

Research projects routinely change over time. It is often necessary to introduce an agreement to ongoing study or to amend previous agreements. This may be due to a change to arrangements or modification to the funding of a study (i.e. a new grant).

A Contract Amendment Form is available on our SALHN Research website. This should be completed before submitting any new contracts to an authorised study for signing. Ensure you have made reference to the original agreement and why the changes were necessary. All contract amendments should be submitted by the SALHN PI or their coordinating team. If the changes have impacted the study budget, the amendment needs to be reviewed by the SALHN Corporate Finance Manager before they can be signed. This can be done by emailing the Contract Amendment Form and agreement to Health.SALHNFinanceBusinessAdvisoryService@sa.gov.au . Administrative changes can be emailed directly to the Research Hub on: Health.SALHNOfficeforresearch@sa.gov.au .

Contract amendments for third party sponsored clinical trials will be charged a contract review fee as per the SA Health Research Ethics and Governance Fees Schedule available here.

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 in Figure 4 recommends data should be destroyed after 15 years. even though data retention is 15 years, they can't just destroy without the appropriate approvals in line with State records legislation as per Official Records Destruction Agency Process SALHN (SALHN staff only).

Table 2 - Research and Ethics General Disposal Schedule No. 28 - Appropriate retention of data

6 RESEARCH AND ETHICS					
6.8.1	Data Management	All research data, including electronic data.	**TEMPORARY** Destroy 15 years after research completed or last contact, whichever is later	• Statistical Packages • Survey Forms • Databases • Spreadsheets	• *Data must be recorded in a durable and appropriately referenced format and comply with relevant privacy protocols. Ref. Section 2.1 of* Australian Code for the Responsible Conduct of Research *(NH&MRC, Australian Research Council and Universities Australia)*
6.17.1	Research Practice Activities	Records relating to the actual practice or performance of research, including clinical trials sponsored by pharmaceutical companies.	**TEMPORARY** Destroy 15 years after research project completed	• Results • Notes • Samples & Specimens • Application form • Completed questionnaires • Signed consent forms • Adverse events • Research reports • Data	• *National Health and Medical Research Council* • *Australian Code for the Responsible Conduct of Research 2.1.1* • *NOTE: the disposal action of "15 years after project completed" is a minimum requirement. Where pharmaceutical company sponsors stipulate longer retention, researchers may adhere to such*

Publications

As a general principle, the findings of research funded with public funding 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 Research Hub.

Reference Documents and Resources

SALHN Data Management Framework (2024)
SA Health Research Ethics and Governance Policy (2023)
Australian Code for the Responsible Conduct of Research (2018)
Australian Clinical Trials.gov.au/researchers
National Statement on Ethical Conduct in Human Research (NHMRC) (2023)
Clinical trials | Therapeutic Goods Administration (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 (2017)SA Health Privacy Policy Framework (2017)

SALHN Research Hub Contact Details

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Researchers are encouraged to discuss their studies in person.

We aim to provide an open-door approach promotes easily accessible advice and produces a culture of collaboration. To deliver on objective, we can now offer the following three opportunities for face-to-face/video meetings, by appointment to discuss your research:

1. External: Our staff can visit your office to fit into your schedule
2. Internal: via drop-in session on Wednesday mornings 10am – 12pm / by appointment
3. Virtual: We can meet via MS Teams by appointment

If you have any suggestions, complaints or feedback on this document please contact the Research Hub.

To schedule a meeting; please email Health.SALHNOfficeforResearch@sa.gov.au or call (08) 8204 6061 and provide detail on the nature of the meeting (i.e. ethics and/or governance).

Document History

Custodian	SALHN Research Hub	
Document status	New document	
Key words	Research, Research Governance, Human Research Ethics Committee (HREC), Clinical Trials, 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
V3.0	Reduce volume of information and added information on Research GEMS and policy updates	February 2021
V4.0	Update hard copy medical Records Data custodian details as well as recruitment and financial requirements	July 2021
V5	Application form details modified to include the LNR pathway (Access Request form no longer in use). New CEO details added	July 2021
V6	Hyperlink update, CEO, National Clinical Trials Governance Framework, Victorian Clinical Trials Education Centre, Hard copy records, Honorary Research Affiliate: Sunrise EMR Access - and Access Audit Request Form, Data breaches reporting requirements.	February 2023
V7	Hyperlink update	January 2024
V8	Finance details updated Monitoring and Reporting details added Agreement details expanded to include Research Collaboration Agreements and Data transfer agreements	February 2024
V9	SALHN BANKING DETAILS updated	August 2024
V9.1	Addition of DMP	Mar 2025

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Signature: 

Date: **24.03.2025**

The signed version is retained by SALHN Research Hub.