Central Adelaide
Local Health Network

Research Governance Framework and Guidelines

Government of South Australia
Health
Central Adelaide
Local Health Network

Contents

1. Purpose

Central Adelaide Local Health Network Inc. (CALHN) is committed to supporting research conducted in accordance with, ethical principles, and guidelines for responsible research conduct, legislation and regulations. It acknowledges the role that research plays in informing clinical practice and health in our community.

Core components of appropriate research conduct, as outlined by the NHMRC Australian Code for the Responsible Conduct of Research, are sound research management and research governance.

Responsibility for ensuring research governance requirements falls principally to the institution that hosts the research and the researchers who conduct health and medical research.

To address this, CALHN has developed a Research Governance Framework for all research involving human participants to ensure compliance with these requirements.

This Research Governance Framework provides guidance to researchers, both those employed by CALHN and external researchers seeking access to CALHN sites, data and/or staff.

2. Scope

The CALHN Research Governance Framework applies to researchers involved in the conduct of ethically approved health and medical research that is conducted at a CALHN site; and/or involves the use of samples/data/records or other material held and managed by CALHN.

The Framework applies equally to employees of CALHN and external researchers who are undertaking research at a CALHN site.

3. NHMRC Principles of Responsible Research Conduct as Outlined in The Code

The following principles (P1–P8) are the hallmarks of responsible research conduct:

P1 Honesty in the development, undertaking and reporting of research

P2 Rigour in the development, undertaking and reporting of research

P3 Transparency in declaring interests and reporting research methodology, data and findings

P4 Fairness in the treatment of others

P5 Respect for research participants, the wider community, animals and the environment

P6 Recognition of the right of Aboriginal and Torres Strait Islander peoples to be engaged in research that affects or is of particular significance to them

P7 Accountability for the development, undertaking and reporting of research

P8 Promotion of responsible research practices

4. Institutional and Researcher Responsibilities

4.1 Institutional Responsibilities

The responsible conduct of research is underpinned by the research culture of CALHN
CALHN has an obligation to encourage and support responsible research conduct and adheres to the specific institutional responsibilities outline in the Code.

- Establish and maintain good governance and management practices for responsible research conduct.
- Identify and comply with relevant laws, regulations, guidelines and policies related to the conduct of research.
- Develop and maintain the currency and ready availability of a suite of policies and procedures, which ensure that institutional practices are consistent with the principles and responsibilities of the Code.
- Provide ongoing training and education that promotes and supports responsible research conduct for all researchers and those in other relevant roles.
- Ensure supervisors of research trainees have the appropriate skills, qualifications and resources.
- Identify and train Research Integrity Advisors who assist in the promotion and fostering of responsible research conduct and provide advice to those with concerns about potential breaches of the Code.
- Support the responsible dissemination of research findings. Where necessary, take action to correct the record in a timely manner.
- Provide access to facilities for the safe and secure storage and management of research data, records and primary materials and, where possible and appropriate, allow access and reference.
- Facilitate the prevention and detection of potential breaches of the Code.
- Provide mechanisms to receive concerns or complaints about potential breaches of the Code. Investigate and resolve potential breaches of the Code.
- Ensure that the process for managing and investigating concerns or complaints about potential breaches of the Code is timely, effective and in accord with procedural fairness.
- Support the welfare of all parties involved in an investigation of a potential breach of the Code. Base findings of investigations on the balance of probabilities and ensure any actions are commensurate with the seriousness of the breach.

4.2 Researcher Responsibilities

Researchers will uphold the principles of responsible research conduct in all aspects of their research as outline in the Code

- Support a culture of responsible research conduct at their institution and in their field of practice.
- Provide guidance and mentorship on responsible research conduct to other researchers or research trainees under their supervision and, where appropriate, monitor their conduct. Undertake and promote education and training in responsible research conduct.
- Comply with the relevant laws, regulations, disciplinary standards, ethics guidelines and institutional policies related to responsible research conduct. Ensure that appropriate approvals are obtained prior to the commencement of research, and that conditions of any approvals are adhered to during the course of research.
- Ensure that the ethics principles of research merit and integrity, justice, beneficence and respect are applied to human research.

- Engage with Aboriginal and Torres Strait Islander peoples and respect their legal rights and local laws, customs and protocols.
- Ensure that the 3Rs (Replacement, Reduction and Refinement) are considered at all stages of research involving animals and minimise the impacts on animals used in research and in so doing support the welfare and wellbeing of these animals.
- Adopt methods appropriate to the aims of the research and ensure that conclusions are justified by the results.
- Retain clear, accurate, secure and complete records of all research including research data and primary materials. Where possible and appropriate, allow access and reference to these by interested parties.
- Disseminate research findings responsibly, accurately and broadly. Where necessary, take action to correct the record in a timely manner.
- Disclose and manage actual, potential or perceived conflicts of interest.
- Ensure that authors of research outputs are all those, and only those, who have made a significant intellectual or scholarly contribution to the research and its output, and that they agree to be listed as an author.
- Acknowledge those who have contributed to the research.
- Cite and acknowledge other relevant work appropriately and accurately.
- Participate in peer review in a way that is fair, rigorous and timely and maintains the confidentiality of the content.
- Report suspected breaches of the Code to the relevant institution and/or authority.

5. Research Project Consideration

All human research conducted within CALHN must, before it commences, establish its compliance with the requirements of the *National Statement on Ethical Conduct in Human Research* (2007, updated 2018) and be reviewed by a NHMRC certified Human Research Ethics Committee such as the CALHN HREC.

In order to conduct the research in CALHN, it is also a requirement that the research project is reviewed by the CALHN Research Office where the team considers the legal compliance, financial management, accountability and risk management associated with the project.

Approval for the proposed project is required by the appropriate heads of departments / directorates and CALHN Executive (or delegate).

5.1 Protocol

A well thought out study protocol is essential for a high quality research project. All research projects, including low and negligible risk research studies, require a protocol. It is also advisable to have a written project plan for audits.

5.2 Ethical Review

5.2.1 Low and Negligible Risk Research

The National Statement on Ethical Conduct in Human Research provides that institutions may have ethical review processes other than full committee review for low/negligible risk studies. Within CALHN, this alternative process is review by the relevant HREC Chairperson, followed by endorsement at a committee meeting.

Following receipt of an application, the Chairperson of the relevant HREC may deem that an application involves more than low risk, or is not appropriate for the alternative review process, and refer it for ethical review by the full committee.

CALHN is a participant in the state-wide provision of single ethical and scientific review of multi-centre low and negligible risk research. Further, the same review process is utilized for low and negligible risk research only to be conducted in CALHN.

Such projects are reviewed via an ethics and governance application process as per the CALHN Guidelines for Low and Negligible Risk Research Ethics and Governance

5.2.2 High Risk Research

For research projects involving higher risk interventions, and those that require notification or review by the Therapeutic Goods Association (TGA) CTN or CTX studies, CALHN requires that the research studies be reviewed by a certified HREC.

Such projects are reviewed via a HREA and SSA application process as per the CALHN Guidelines

5.2.3 Multi-centre Ethical Review

National Mutual Acceptance (NMA) supports the single scientific and ethical review of multi-centre human research projects across participating Australian jurisdictions (public health organisations).

CALHN HREC (EC00192) is certified by the NHMRC to undertake review in the categories of research outlined below:

- Clinical trials phase I, II, III, IV
- Clinical trials drugs and devices
- Clinical trials surgery
- Clinical interventional research other than clinical trials
- Population health and/or public health
- Qualitative research
- Mental health

In accordance with the Standard Principles for Operation National Mutual Acceptance of Single Ethical and Scientific Review of Multi-centre Human Research Projects, organisations are required to accept the approval of a NHMRC Certified HREC for a project submitted under NMA without requiring further ethical and scientific review.

5.2.4 Quality Assurance and Audit Studies

The NHMRC National Statement on Ethical Conduct in Human Research and the document Ethical Considerations in Quality Assurance and Evaluation Activities suggest “oversight of the activity is required, but ethical review is not necessary”. Unless it is very clear that the activity is clearly quality assurance, it is recommended that a determination on the nature of the activity be made through application to the Research Office. This determination will be made out of session by the Human Research Ethics Committee (HREC) Chairperson or delegate and written confirmation of this decision will be provided.

5.3 Monitoring Requirements

Under the National Statement on Ethical Conduct in Human Research, it is a responsibility of the organisation hosting the research to monitor the conduct of approved research.

Within CALHN this function is undertaken by the Human Research Ethics Committee (HREC) and/or Research Governance Office (RGO) that has provided the ethical and/or research governance approval for the project.

- Research monitoring may include:
- Review of annual reports from researchers
- Review of reports from independent agencies (e.g. data and safety monitoring boards)
- Review of safety reports
- Audits of research records, e.g. consent documentation
- Interviews or review of written feedback from research participants

The level of monitoring that is undertaken should correspond to the risk profile of the project. The principal investigator has a significant responsibility to monitor the research over the course of the project, and advise the Institution, via the HREC or RGO, of matters that may impact the ethical and scientific acceptability of the project, or site (research governance) acceptance of the project.
NMA applicants, HRECs and RGOs should refer to the NMA Monitoring and Reporting Framework available on the SA Health website for further guidance.

5.4 Research Project Authorisation

Research projects to be conducted by CALHN staff, whether they have undergone full or expedited HREC review, must undergo site specific assessment before authorisation can be granted.

The purpose of site specific assessment is to enable CALHN to ensure that the proposed research project complies with minimum governance requirements and consider whether the project should be conducted at the proposed CALHN site or by the CALHN researcher.

Site specific assessment is a separate process to ethical and scientific review of a research project. The decision of the HREC is not dependent on the decision by the CALHN delegate regarding authorisation.

CALHN must be satisfied that, based on the information provided in the application, the research project meets the following conditions:

- The investigators have the necessary skills, training and experience to undertake their role, and where necessary, appropriate training and supervision have been arranged;
- There are suitable and adequate facilities and resources for the project to be conducted at the site as proposed, and they are available for the duration of the project;
- The project has been costed appropriately and there are sufficient funds to cover the costs of conducting research at the site;
- Any legislative requirements, including notification, registration and licence application requirements have been addressed;
- Adequate indemnity and insurance arrangements are in place for clinical trials.
- If the project is a clinical trial or a funded collaboration, there is a written agreement clarifying the obligations, responsibilities and rights of the parties involved in the study.
- Research documents to be used at the site comply with requirements of CALHN (e.g. use of site logo, format, provision of site contact details, specific wording to be used in participant information sheets)

- There is ethical and scientific approval for the project and research documents, in line with SA Health Research Ethics Operational Policy 2013 (D0262).

Projects submitted to the CALHN HREC for full committee review require a Full SSA application form to be completed.
Projects submitted for expedited HREC review require an Ethics and Governance Application form to be completed together with a complete Protocol

The Principal Investigator must receive support via a declaration from their Head of the department and declarations of support from the heads of any additional supporting departments. Examples of supporting departments include pharmacy, pathology, medical imaging, medical records and treatment units providing care. Where the project requires access to data from specific collections held at a SA Health site, the Principal Investigator must obtain a declaration of support from an appropriate authority for data provision in the form. The authority is generally the data custodian who is responsible for the management of that data collection.

The completed form and supporting declarations and documents must be submitted to CALHN Research Office as per the Guidelines.

6. Supervision of Research Trainees

It is important that trainees (and research staff) are provided with induction, formal training and continuing education, including training appropriate to their discipline, and research ethics and governance.

Every research trainee, whether part of CALHN or from elsewhere, must have an appropriately qualified supervisor allocated to them.

Research Supervisors must ensure that training in research conduct, both formal and practical, is commenced as soon as possible in the career of a researcher. It should include research methods, ethics, confidentiality, data storage and records retention, occupational health and safety, environmental protection, regulation and governance.

Department or Unit Heads are responsible for and must establish clear lines of responsibilities and standards of supervision and mentorship.

The Research Supervisor must seek to ensure the validity of research data obtained by a research trainee under his/her supervision. Supervisors must also take responsibility for overseeing all stages of the research process, including developing a hypothesis or research objective, preparing applications for funding, selecting methods for research and data collection and recording, and summarising, analysing and reporting findings in appropriate forums and to the media. They should also ensure that research trainees receive appropriate credit for their work.

Research trainees should understand that research requires dedication and accountability. They must demonstrate a professional attitude to their research, play an active role in maintaining an appropriate schedule of meetings with their supervisor and complete induction and training as soon as possible.

7. Management of Research Data and Primary Materials

CALHN is committed to maximising the benefits from publically funded research, including by ensuring greater access to research data.

Effective data management is an important part of ensuring open access to publicly funded research data. Data management planning from the beginning of a research project helps to outline how data will be collected, formatted, described, stored and shared throughout, and beyond, the project lifecycle.

The requirement for data management plans is consistent with the responsibilities outlined in the Code, which in addition to management of research data and primary materials by researchers, includes management of data ownership, storage, retention and "appropriate access…by the research community".

Research projects that involve more than one organisation should have an agreement that covers the principles of storage, access and retention of research data and primary materials within each organisation.

Research data and primary materials remain the property of CALHN both during and following completion of the research project, unless subject to a third party agreement.

A range of resources, including information and guides on the elements of data management and data management planning, can be found on the Australian National Data Service (ANDS) website. ANDS also offers assistance to institutions in relation to ARC and NHMRC data management requirements.

7.1 Data Storage

Researchers must:

- Maintain a catalogue of all research data in a durable, indexed and easily accessible form
- Maintain full, accurate and legible records of research methods and data sources, including approvals granted, during and after the research process
- Ensure that research data and primary materials (including laboratory notebooks and electronic data) are kept in safe and secure storage even when not in use
- Ensure that research data is available should questions arise, or for use by other researchers unless prevented by ethical, privacy or confidentiality matters
- Ensure that data is recorded in a form that is adequate for verification of research results

Wherever possible, original data (and materials or samples) should be retained in the research department, laboratory or unit in which they were generated. If required, individual researchers can hold copies of the data for their own use. Retention solely by an individual researcher is not permitted, as it may not protect the researcher or CALHN in the event that the veracity of the data is questioned.

Where research material is not kept within the Department, a written record of the location of data must be retained by the researcher and Department Head.

Where a researcher moves from CALHN, original data must remain at CALHN, unless a written agreement is reached with the new organisation that covers ownership and storage of research data.

When data is obtained from limited access databases (or an external database), or via a contractual arrangement, written indication of the location of the original data, or key information regarding the database from which it was collected, must be retained by the researcher and Department Head.

If research results are challenged, all relevant data and materials must be kept until the matter is resolved.

Department Heads are responsible for ensuring that a register of all databases (paper, electronic, audiotape, audio visual or photographic) created and existing in their department is kept. There must be a co-ordinator of the register appointed who must ensure that the register is kept up-to-date.

7.2 Primary Materials Storage

Information about primary materials storage location, security, confidentiality and access must be provided in the study protocol and/or ethics application form.

If researchers intend to establish a biobank, this must be made clear in the study protocol and ethics application form.

A biobank is defined as a collection of biomaterials (e.g. blood, urine, tissue samples) linked to relevant personal and health information, and held specifically for non-diagnostic purposes such as research. Biobanked specimens and data, and the research they enable, make a significant contribution to increasing the understanding, detection, prevention, diagnosis, treatment and cure of complex diseases.

Department Heads are responsible for ensuring that a register of all biobanks created and existing in their department is kept. There must be a co-ordinator of the biobank appointed who must ensure that the biobank is kept up-to-date and maintained appropriately.

SA Health Guidance Document for Human Research Biobanks and Associated Data

7.3 Data Retention and Disposal

Research data, primary material, and registers of the material and data, must be kept for five years from the date of publication, or a period stipulated by the funding agency or publisher, whichever is the longer.

For most clinical trials, research data must be retained for 15 years. However retention for a longer period may be necessary.

Research into gene therapy and associated areas, and any work that may have community or heritage value, must retain the data permanently.

Short-term research projects for assessment purposes only, such as student research projects, must held for a minimum of 12 months after the completion of the project.

The General Disposal Schedule no.28 for South Australian Clinical and Client-Related Records of Public Health Units (2014) provides guidelines for the retention and destruction of records in a health context and covers research explicitly in several respects (Refer Section 6 Research and Ethics).

When the specified period of retention has finished, researchers have a responsibility to dispose of data and material in a secure and safe manner.

The destruction of research data must only be authorised by the Department Head.
A record of approval for destruction must be recorded on the departmental register and notification of the destruction should be forwarded to the CALHN Research Office.

8. Privacy

CALHN supports the importance of privacy and requires researchers to respect the privacy and confidentiality of patients and participants of research studies. All research involving the use of personal health information must abide by the Privacy Act 1998 (Cth) and the SA Health Privacy Policy Directive 2017.

8.1 Consent

Consent to collect, use and store a person's personal information should be obtained wherever possible.

The key elements of consent are:
- The participant is adequately informed before giving consent
- The participant gives voluntary consent
- The consent is current and specific
- The participant has the capacity to understand and communicate their consent
- It provides authority to handle personal information in a particular way

When collecting data, researchers should provide clear and comprehensive information about:
- The form in which the data will be stored (identifiable, re-identifiable, non-identifiable)
- The purposes for which the data will be used and/or disclosed
- Whether they require specific, extended or unspecified consent for future research

Extended or unspecified consent may need to include permission to enter the original data or tissue into a databank or Biobank. When unspecified consent is sought, its terms and implications should be clearly explained to potential participants and clearly recorded.

Participant consent forms contain identifiable data. Original consent forms must be filed in patients' case notes where applicable or kept in a lockable filing cabinet, in a secure office with controlled access, in the department in which the research is conducted, and separately from the collected research data for that project. Data stored in an identifiable form cannot be used in research that is exempt from ethical review.

Researchers and databank coordinators must observe participant confidentiality agreements and take every precaution to prevent the data being used in a way that the participants did not consent to.

All restrictions on the use of participants' data should be recorded.

8.2 Confidentiality

Researchers given access to confidential information must maintain the privacy, confidentiality and cultural sensitivities of participants. Confidential information must be used responsibly and only be used in ways agreed with those who provided it. Researchers must ensure that the privacy of participants is safeguarded at all times.

A breach of confidentiality may constitute research misconduct. A database trustee must report a breach of confidentiality to the Department Head and to the CALHN Research Office as soon as it becomes known.

9. Publication and Dissemination of Research

Dissemination of research findings is an important part of the research process, passing on the benefits to other researchers, professional practitioners and the wider community.

There are many ways of disseminating research findings. Formal publication of the results of research most commonly takes place in refereed academic journals or books, but this is not always the case. This section applies to all forms of dissemination of research findings including non-refereed publications such as web pages and social media, conferences and seminar presentations.

CALHN is committed to promoting an environment of honesty, integrity, accuracy and responsibility in the dissemination of research by

- Ensuring that researchers are made aware of the nature and scope of confidentiality agreements;
- Protecting the intellectual property rights of CALHN, researchers, research trainees and sponsors of the research, as appropriate;
- Ensuring that sponsors of research understand the importance of publication in research and do not delay publication beyond the time needed to protect intellectual property and other relevant interests;
- Ensuring that researchers are aware of contractual arrangements that restrict, delay or limit publication;
- Making every effort in acknowledging funding bodies, partner institutions and sponsors involved in collaborative research.
- Assisting researchers in effective communication through media by the provision of advice and guidance through the CALHN Communications Unit

Researchers must make reasonable steps to ensure that published reports, statistics and public statements about research activities are complete, accurate and unambiguous, and where applicable, include negative findings and results contrary to their hypotheses.

If a researcher becomes aware of misleading or inaccurate statements about their research, they must attempt to correct the record as soon as possible.

Accuracy is essential in describing the state of publication, sources of research funding and awards conferred, and where any of these relate to more than one researcher. Disclosure of any potential conflicts of interest must be included.

Publication based on the same set/s or subset/s of data is not acceptable, except where there is full cross-referencing within the publication e.g. in a series of closely related work, or where a project grew out of a preliminary publication, however this must be fully acknowledged.

Discussing research findings in the public arena should not occur until the findings have been through peer review. When discussing the outcomes of a research project, researchers must explain the status of the project e.g.: still in progress or finalised.

Publication activities must take into account restrictions relating to intellectual property or culturally sensitive data.

Researchers must register clinical trials on a public trials registry www.clinicaltrials.gov or www.anzctr.org.au at or before the time of first patient enrolment to promote access to information about clinical trials

9.1 Authorship

CALHN seeks to ensure that authors of research outputs are consistent with the requirements of the *Australian Code for the Responsible Conduct of Research*

The outcomes of research may be disseminated in a variety of ways but enduring forms, such as journal articles, are particularly important and to be an author for such a form is meritorious. To be named as an author, a researcher must have made a substantial scholarly contribution to the work and take responsibility for at least that part of the work they contributed.

Discussions regarding authorship should be held early in the planning process to determine who will be credited as authors, contributors and who will be acknowledged.

The order of authorship should also be decided and recorded in a signed document. This should be reviewed and updated periodically.

Authorship must be based on substantial contributions in a combination of:

- Conception and design of the project
- Analysis and interpretation of research data
- Drafting significant parts of the work or critically revising it so as to contribute to the interpretation

Authorship must not be offered solely on the Individuals position or profession and does not depend on whether the contribution was paid for or voluntary.

Researchers must ensure that all those who have contributed to the research, facilities or materials, including CALHN and partner institutions or sponsors, are properly acknowledged as contributors.

Each publication must have a responsible author. In research conducted by groups, individuals should be identified as co-authors if they meet the above criteria. Each author must take responsibility for their contribution. No author must be excluded without their express permission, in writing. All authors must witness the version of the paper submitted for publication and provide their consent to the publication in writing.

A written acknowledgement of authorship and order of authors, must be placed on file in the department of the responsible author at the time of submission of the research output for publication. It must remain in safe keeping in that department and be a version with original hand-written signatures.

Where disputes arise, researchers should endeavour to resolve the dispute based on the criteria for authorship in this document. Attempts should be made to resolve conflicts between authors of a work at the local level.

Where researchers are unable to resolve the dispute themselves, they may seek the advice from the CALHN Research Director, Head of Department or University Postgraduate Coordinator (for higher degree students). Disputes involving co-authors from other institutions are to be handled by the institution of the corresponding author.

10. Peer Review

Peer review - the impartial and independent assessment of research by others working in the same or a related field - is a valuable mechanism for maintaining research standards of excellence and integrity. The University seeks to support and encourage researchers to participate in responsible peer review.

Peer review is the impartial and independent assessment of research by others working in the same, or a related field. Peer review is considered an essential element of research quality assurance. It supports standards of excellence and integrity.

Peer review may also assist in identifying deviations from the principles of the Australian Code for the Responsible Conduct of Research. As reviewers do not have access to all relevant information, they cannot be solely responsible for ensuring research integrity.

CALHN recognises the importance of the peer review process and encourages and supports researchers to participate in the process.

Researchers participating in the review process must:

- Act in confidence,
- Declare all conflicts of interest,
- Not permit personal prejudice to influence the process,
- Not introduce considerations that are not relevant to the review criteria,
- Not take advantage of knowledge obtained during the process,
- Ensure that they are informed about, and comply with, the criteria to be applied,
- Not agree to participate in peer review outside their area of expertise,
- Give proper consideration to research that challenges or changes accepted ways of thinking, and
- Be fair and timely in their review

Researchers applying for research support or submitting papers for publication must not approach any peer reviewer in an attempt to influence the decision making process.

Supervising researchers have a responsibility to assist trainee researchers in developing the necessary skills for peer review and understanding their obligation to participate.

11. Conflicts of Interest

CALHN is committed to ensuring that interests of any kind are dealt with consistently, transparently and with rigour. This is to ensure that where a material personal interest arises, the individual will not be in a position to influence, or perceive to influence, the proper performance of the researcher. The perception of an interest is as important as any actual interest.

A conflict of interest may affect a researcher's integrity, compromise the research process and governance.

Researchers, board and committee members must disclose any actual, potential or perceived conflict of interest as soon as it becomes apparent. When invited to join a committee or board, researchers should review current activities for actual or potential conflicts and bring those conflicts to the attention of those running the board or committee.

Researchers should maintain records of their own activities that may lead to conflicts, for example:

- Consultancies
- Membership of committees
- Boards of directors
- Advisory groups, or selection committees
- Financial delegations
- Receipts of cash
- Services or equipment from outside bodies to support research activities

Relevant financial interests that must be considered for disclosure include but is not limited to:

- Research funding or other funding from an entity with an interest in the project
- Equity interest in a publicly or non-publicly traded entity (for example, stock, stock option, or other ownership interest)
- Income from intellectual property rights (for example, patents or royalties)
- Consultancies; and/or gifts or gratuities, including travel, honoraria, meals and beverages, accommodation, entertainment, remuneration, educational event attendance (including registration fees)

Conflicts of interest must also be disclosed to research participants in the Participant Information and Consent Form.

The CALHN Research Office will maintain a record of how each disclosed conflict is managed.
SA Health's Conflict of Interest – Declaration and Management Policy Directive

Any uncertainty or enquiries regarding conflicts of interest in research should be directed to the CALHN Research Office.

12. Collaborative Research Across Institutions

Collaborative Research is recognised as supporting high quality and innovative research and occurs within institutions, between institutions and internationally.

As research practices differ between countries, researchers supported by Australian public funding should make every effort to comply with the *Australian Code for the Responsible Conduct of Research,* even when conducting research outside of Australia.

Collaborative research projects must have a collaboration agreement in place before a project can commence. The agreement should follow the general principles of the *Australian Code for the Responsible Conduct of Research*

Collaboration Agreements are entered into where investigators wish to collaborate on a proposed research project.

The collaborative research agreement must be in writing and address the following:

- Intellectual property
- Confidentiality
- Consultancies/secondments
- Ethics approval
- Ownership of equipment
- Copyright
- Financial management
- Commercial returns, and

> Reporting to appropriate agencies

The agreement should also address the protocols to be followed by the research partners when disseminating the research outcomes, and the management of research data and primary research materials.

The collaborating parties in any joint agreement should each identify a person to be involved in the management of research data, primary materials and other items to be retained at the end of the project.

A process for resolving any disputes should be established in the research agreement. Disputes arising from collaborative research should be dealt with in an appropriate and timely manner.

13. Research Agreements

The CALHN Research Office is responsible for managing all research related agreements for CALHN – including the Royal Adelaide Hospital, The Queen Elizabeth Hospital, SA Pathology and Statewide Clinical Support Services under the governance of CALHN. The scope of work includes, but is not limited to, grants, consultancy, research and services agreements, including contract and collaborative research projects with other research organisations or commercial companies. Additionally, the CALHN Research Office manages the Intellectual Property (IP) ownership associated with any agreements.

Contract research may arise from a request from an external agency (industry, government, or semi-government body) or a jointly initiated collaborative project between CALHN and the external agency for a specified research project to be undertaken with identified aims, objectives and milestones. Contract research projects generally relate to applied research and often have commercial outcomes.

In many cases contract research and commercialisation of research outcomes require formation of partnerships with companies and, to maximise the potential value, may also require additional research and development (R&D) work. Funding for this type of R&D work is generally not supported by competitive grant funding bodies, venture funds or other industry or government sources, but is necessary to attract ongoing interest from industry, and contributes to overall CALHN research (e.g. publications) and research training.

The CALHN Research Office provides assistance with all aspects of negotiating contract research. All research contracts are assessed by the CALHN Research Office, which reviews the research project and assesses any possible risks to CALHN, and makes a recommendation as to whether the contract should be signed.

It is important to involve the CALHN Research Office at the earliest possible stage of negotiating the terms of a research contract. This will ensure that the final agreement can be processed and recommended for signing as soon as possible.

It is at the sole discretion of CALHN to determine whether a contract under review must proceed to Legal Governance and Insurance Services for a formal legal review.

Research projects associated with the agreements must not commence until governance / site specific assessment has been conducted and the project is authorised to commence.

All CALHN research agreements must be submitted to and reviewed by the CALHN Research Office.

Note: Staff are not authorised to sign agreements with external organisations.

External organisations must contract with the Central Adelaide Local Health Network Inc. (ABN 96 269 526 412). Agreements must be approved and signed by the CALHN Executive Director Medical Services or delegate.

The CALHN Research Office will:
> Review all research agreements
> Liaise with the involved organisation(s)
> Arrange for execution of the agreement
> Notify the Researcher when complete

Agreements reviewed and managed by the Research Office include:

13.1 Confidentiality Agreements (CDAs)

A Confidentiality Agreement (or Non Disclosure Agreement) is used when a Researcher wishes to discuss the details of a proposed project with a third party.

This is particularly important for protecting background IP, project design and any confidential information which a party does not want publicly disclosed, or used other than for the purpose of the proposed research or service.

13.2 Material Transfer Agreements (MTA)

An MTA governs the receipt or supply of materials from one organisation to another (e.g. cells, animals, viruses, plasmids, etc).

CALHN as the Supplier Institution
If a Researcher receives a request for the supply of CALHN material from another organisation, they must forward the request to the CALHN Research Office. Evidence of approval from the Department Head that this material may be transferred must also be provided. The CALHN Research Office will then negotiate a MTA with the requesting organisation.

CALHN as the Recipient Institution
If a Researcher wishes to receive material from an external organisation, they must forward the draft, Microsoft Word version MTA from the supplying organisation to the Research Office for review and negotiation. Where costs will be incurred in obtaining the material the Researcher must receive authorisation from the relevant finance delegate stipulating that the Researcher has sufficient funds in the appropriate cost centre The CALHN Research Office will review the agreement and liaise with the supplying institution.

Note: If a Researcher leaves CALHN they cannot take materials that have been obtained under an MTA with them. The Researcher's new employer must negotiate a MTA for the material.

13.3 Grant Agreements

Grant funded research differs from contract research in that IP arising from the research project is generally owned by CALHN, and/or only supports direct research project costs.
All grant agreements must be forwarded to the Research Office for review.

All grant funded research must also have governance review. Research projects cannot commence at a CALHN site without governance authorisation.

13.4 Collaborative Research Agreements (CRAs)

CRAs are entered into between organisations where investigators wish to collaborate on a proposed research project.

Collaborative research projects must have all arrangements agreed upon before a project begins and must be in writing. The collaboration must cover:

- Ethics and safety approvals
- Financial management
- Authorship and publication
- Confidentiality and copyright issues
- Ownership of equipment and data
- Intellectual property
- Commercial returns; and
- Reporting to appropriate agencies.

The agreement may take various forms, including a legal contract signed by CALHN's CEO or their delegate, an exchange of letters, a research management plan signed by all parties, or management plans signed by appropriate representatives from all parties.

A collaboration involving transfer of Funds and / or Materials and IP must be in the form of a legal contract and must be reviewed by the Research Office.

Each organisation must ensure that its researchers are aware of, and understand, the policy and agreements governing the research collaboration.

CALHN Research Office may seek legal advice in the negotiation of these agreements at their sole discretion. Any legal questions a Principal Investigator may have must be directed to CALHN Research Office.

Disputes arising from collaborative research should be dealt with in an appropriate and timely manner, and a process for resolving any disputes must be established in the research contract.

13.5 Research Services Agreements

Contract research and services agreements generally are the result of a request from an industry, government, or semi-government body for a specific project or service to be undertaken with identified aims and objectives. It can also be classified as non-investigator initiated research.

They may also include for example: a Speaking Appointment for a Professor, or a contract for the hiring of Research Nurse in an ongoing study.

In many cases contract research and the commercialisation of research outcomes require partnerships with companies, and may also require additional research and development work. Funding for this type of work is generally not supported by competitive grant funding bodies.

13.6 Clinical Trial and Clinical Research Agreements

Clinical research agreements include both sponsored studies and investigator initiated studies. Examples include but are not limited to:

- Clinical trials (e.g. studies involving human subjects designed to answer specific Questions about the safety and/or effectiveness of drugs)
- clinical investigations (e.g. studies involving human subjects designed to answer specific questions about the safety and/or effectiveness of devices, treatments, or nutritional and behavioural strategies)
- Observational studies (those that do not test interventions)

Where a clinical trial is funded by a pharmaceutical or medical device company, or other research institution a Clinical Trial Research Agreement must be negotiated between CALHN and the company.

It is recommended that Medicines Australia Clinical Trial Research Agreement templates are used. See Medicines Australia website

All clinical research must also have governance review. Research projects cannot commence at a CALHN site without governance authorisation.

14. Grants

CALHN staff are encouraged to source external funds for their research.

The CALHN Research Office will review the application and provide feedback and guidance where necessary and will assist with any liaison required with University Research Administration Offices.
If awarded, the Researcher takes all responsibility for conducting the project within the available budget.

All Grants must be registered with the CALHN Research Office, who will guide the researcher in obtaining relevant signatures and submitting the application.

CALHN research staff (Clinical and Affiliate Title Holders) affiliated with a University and non-affiliated staff must co-ordinate applications through CALHN Research Office. Contact: Health.CALHNResearchGrants@sa.gov.au

CALHN Research Office will review applications and liaise with the Researcher regarding any changes or key conditions of note.

Where a funding body requires evidence of institutional support from CALHN (eg signatures or letters of in principle support), the Executive Director Medical Services or their delegate, are the only individuals who have authority to provide this evidence. Researchers, Medical and Administration staff are not authorised to sign on behalf of CALHN.

Research funded by a Grant must not commence until the project has been approved by the Executive Director Medical Services, or their delegate.

Research projects involving financial contributions by, or to, CALHN institutions must have a project budget authorised by an appropriate finance authority (e.g. Manager of Business Operations).

14.1 Post Award Administration

The CALHN Research Office will liaise with the researcher, financial advisor/resource accountant, University Research Administration Offices, collaborating institutions and funding bodies regarding the Grant and any final reports, project variations and general queries in relation to Grant funds.

Advice from the CALHN Research Office can be accessed for information on the appropriate mechanism for financial management of the grant, directing the completed paperwork to the relevant financial advisor/resource accountant and the legitimate expenditure of funds in accordance with the specific funding agreement.

Researchers must ensure they are aware of, and comply with, all reporting requirements of the grant funding body. These may include milestone or annual reports, and final reports upon completion of the funding period (irrespective of whether the project is complete).

Where financial reports (ie acquittals) are required, the Researcher must liaise with the CALHN Research Office including the Financial Advisor to ensure accurate and complete information is provided.

The Financial Advisor will arrange for:

- A Cost Centre Terms of Reference document that is specific to the Grant
- A Cost Centre (separate cost centre is usually required for each project)

If required, submitting invoices to the funding body, a University, or other organisation for incoming funds per the funding agreement

Note: Funds may not be transferred to outside parties without the necessary Collaborating Institution Agreements / Service Agreements / Material Transfer Agreements in place. The Financial Advisor may consult with the CALHN Research Office in this regard.

14.2 Collaborating Institutions

Whenever there is collaboration with another institution (whether or not there is a transfer of funds) a Multi-Institution Agreement (MIA) is required.

The MIA holds all parties to the original terms of the funding body, and indicates the agreed funding distribution and intellectual property processes. The MIA should be initiated by the lead Researcher's administering institution and signed by all relevant parties.

The CALHN Research Office will review the MIA and liaise with the Researcher and the UniRAO or other institution's grant officers where required. Once finalised, the CALHN Research Office will arrange for all documentation to the the Executive Director of Medical Services or their delegate, for approval/execution.

15. Financial Management

Budgets are an essential component of any research project and must be included with the original research governance applications to the CALHN Research Office.

Where there are costs involved in a study beyond in kind support, an approved budget is required before the project can be authorised to commence.

Budgets for grant funded studies

All studies funded by research grants must have a budget detailing how funds will be expended.

Where CALHN is the administering institution, or will receive grant funds from another organisation acting as the administering institution, the CALHN Research Office will prepare a detailed budget for review and approval by CALHN Research Financial Advisor (RFA).

Contact the CALHN Research Office for budget preparation, review and queries regarding grant funded studies: Health.CALHNResearchGrants@sa.gov.au

Budgets for Clinical Trials
All Clinical Trials funded by pharmaceutical or medical device companies, or research institutions must have a budget detailing how funds will be expended. This budget or a summary thereof must be included in any clinical trial agreements.

Clinical trial coordinators must prepare the budget and negotiate with the funding party to ensure that all site costs are covered. The CALHN Research Office can assist with this negotiation process.

Information regarding the budget process for Clinical Trials can be found under Project Resourcing at: https://www.rahresearchfund.com.au/rah-research-institute/for-researchers/clinical-trials/ or contact Health.CALHNResearchGovernance@sa.gov.au

15.1 Budget Submission and Review

When submitting a budget for review, the following documentation is required:

- Clinical Trial Research Agreements (CTRA), the funding agreement or letter of offer, or details of how resources that will be used to conduct the project will be funded. (A completed draft version of the relevant agreement is sufficient for preliminary budget review however, a finalised version will be required for final approval.)
- Project protocol or proposal – This document describes the objectives, design, methodology, statistics, and organisation of the project
- Site Specific Assessment (SSA) – An SSA must be completed and signed by each of the relevant CALHN department heads whose resources are involved in the completion of the project, including services, staffing/ recruitment or infrastructure.
- Estimated labour time – Details of the estimated time that all CALHN staff members will contribute to the conduct of the study using the Estimated Labour Time Template
- Special Purpose Funds (SPF) – the CALHN SPF cost centre number from which the project will operate. The Oracle SPF application form can be found at: http://in.health.sa.gov.au/OracleAssist/OracleTemplatesandForms.aspx under Project Forms and ADI Templates.
- Other project expenses – for example, archiving costs, capital equipment, ethics fees, meal allowances, postage, printing & stationery, statistical analysis, software, travel allowances etc.
- Participants – details of the anticipated number of people to be recruited at each site and the anticipated period of recruitment.

15.2 Budget Approval and Notification

Once the budget has been approved, the budget approval documentation will be e-mailed to the researcher as either:

- A budget document endorsed by BOM or RFA,
- A confirmation by the RFA that the project budget has been review

> Final confirmation or signed SSA by the BOM or delegate

Budget approval notification will be at least three weeks from the date of the meeting with the BOM/RFA. This approval must then be submitted to CALHN Research Office as part of the submissions for project governance authorisation.

15.3 Opening a Cost Centre

Where funds are being paid to CALHN into a Research Special Purpose Fund (SPF), the RFA will arrange for a Cost Centre to be opened. A separate cost centre is usually required for each project.

15.4 Post Grant Award Administration

The CALHN Research Office will liaise with the researcher, financial advisor/resource accountant, University Research Administration Offices, collaborating institutions and funding bodies regarding the Grant and any final reports, project variations and general queries in relation to Grant funds.

The CALHN Research Office is available for advice on the appropriate mechanism for financial management of the grant, directing the completed paperwork to the relevant financial advisor/resource accountant and the legitimate expenditure of funds in accordance with the specific funding agreement.

15.1 Invoicing

All funding agreements to which CALHN is a party must include the standard invoicing and payment clauses in information about Payments. This includes the CALHN myIP reference number allocated by the CALHN Research Office.

Note: Funds may not be transferred to outside parties without the necessary Collaborating Institution Agreements / Service Agreements / Material Transfer Agreements in place. The Financial Advisor may consult with the CALHN Research Office in this regard. For further or contact Health.CALHNResearchGovernance@sa.gov.au, or 7117 2231.

16. Intellectual Property

Researchers should be aware that Intellectual Property is an important component of Research. Research, pathology, medical and clinical innovations all have the potential to generate novel intellectual property (IP) that could one day be of benefit to the wider community.

All CALHN staff engaged in research should be aware of the SA Health Intellectual Property Policy and SA Health Research Governance Policy.

CALHN researchers must notify the CALHN Research Office of any invention that they believe should be protected. The CALHN Research Office will provide an initial assessment of the opportunity and work with AusHealth Pty Ltd (Aushealth), CALHN's commercialisation company, to determine the best commercialisation pathway.

If the IP has been generated as part of a collaboration, all collaborative partners will also need to contact their research or commercialisation offices to notify them. The CALHN Research Office will liaise with the co-owning organisation for the IP protection and commercialisation.

If the IP is developed by *Specified Personnel* of the Centre for Cancer Biology (CCB), the project IP must be discussed with the CCB Joint Directors and be disclosed to UniSA Ventures, the technology commercialisation arm of the University of South Australia.

CCB researchers employed by CALHN must notify the CALHN Research Office prior the commercialising new CCB IP and liaise with the CALHN Research Office throughout the process of commercialisation.

Contact the CALHN Research Office for queries relating to IP:
Health.CALHNResearchGovernance@sa.gov.au, 7117 2231

16.1 Protecting the Invention

If the CALHN Research Office believes the IP should be protected and has commercial potential, the IP may be referred to AusHealth. AusHealth is the commercialisation agent for CALHN, and can provide a range of support and advice including:

- Evaluation of innovations
- Best development path
- Development of commercialisation strategies
- Evaluation of market potential
- Protection of Intellectual Property
- Patents
- Trademarks
- Marketing IP and identifying strategic commercial development partners
- Negotiating Licenses and Commercial Agreements
- Limited financial support to assist IP development

Please note that AusHealth must not be contacted directly. IP must be referred to AusHealth via the CALHN Research Office.

In order to protect novel IP, please contact the CALHN Research Office Health.CALHNResearchGovernance@sa.gov.au. 7117 2231 to discuss and arrange a meeting.

This CALHN Invention Disclosure Form (IDF) form must be completed as soon as possible and sent to the CALHN Research Office. The IDF assists in gaining a broad understanding of the invention, identifying any third parties which may have a claim to the IP, and in assessing the commercial potential of the invention.

All inventors must be identified and listed in the IDF. It is important to identify all inventors prior to submitting a patent application. Some countries (e.g. USA) require the inventors to be listed as the applicants.

16.2 Confidentiality Agreements

If an inventor intends to speak to any individuals not employed by CALHN or any external organisations (eg. Pharmaceutical companies, academic institutions etc) about the novel IP, the investor **must** ensure that any disclosure is protected by a Confidentiality Agreement. The CALHN Research Office will prepare and negotiate any Confidentiality Agreement(s) required.

16.3 Public Disclosures

If the intention is to obtain patent protection of the invention, then it is essential that no public disclosures of the invention are made until a patent application has been filed. For this reason, all proposed public disclosures (abstracts, manuscripts, posters, presentations, media interviews, etc.) should be reviewed by the CALHN Research Office **prior to submission/presentation.**

Often modifications can be made that enable publications to be submitted or presentations to proceed without compromising the ability to obtain patent protection. However if suitable modifications cannot be made, the CALHN Research Office will recommend that the disclosure be delayed until a patent application has been filed

17. Indemnity

All research projects hosted by SA Health institutions involving SA Health or external staff must have appropriate insurance and indemnity prior to the project commencing. Page 5 of 7 CALHN Low/Negligible Risk Ethics and Governance Application Guidelines Version 2.2 December 2015 Indemnity for projects undertaken by SA Health researchers within the capacity of their employment is automatically provided through SA Health's corporate insurance arrangements. No further documentation is required. If an SA Health employee has dual employment with a University or SAHMRI or another organisation, or is also a university student, and is conducting a research project outside of their SA Health employment capacity, indemnity must be provided by the University or other institution. For wholly private or commercially sponsored studies, indemnity must be provided by the researcher's institution or sponsor. In both these circumstances a copy of a certificate of currency for the indemnity must be provided with the LNR EGA form. Further information is available from Legal Governance and Insurance Services.

18. Research Misconduct

These guidelines set out the procedures to follow for allegations of research misconduct at Central Adelaide Local Health Network (CALHN) institutions.

The guidelines govern all researchers and others conducting research at CALHN. https://www.nhmrc.gov.au/about-us/resources/nhmrc-research-integrity-and-misconduct-policy.

CALHN adopts the *Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research* 2018

The Investigation Guide provides a framework to manage, investigate and resolve complaints about potential breaches of the Code.

CALHN investigation roles and responsibilities are:

- Responsible Executive Officer (REO) – Executive Director, Medical Services
- Designated Officer (DO) – Manager, CALHN Research Office
- Assessment Officer (AO) – Research Ethics and Governance Officer
- Research Integrity Advisor (RIA) – CALHN Research Director
- Research Integrity Office (RIO) – CALHN Research Office
- Review Officer – an appropriate nominee of CALHN

Any allegation of a breach of the Code and /or research misconduct should be made to the Designated Officer (DO) who will obtain the information required to undertake a preliminary

assessment. The preliminary assessment will be undertaken by the Designated Officer, Assessment Officer (AO) and CALHN HREC Chair within the CALHN Research Office.

The DO and AO undertake a preliminary assessment and determine:
- the need for further investigation;
- if the issue can be resolved without need for investigation;
- if the issue can be referred to other institutional processes; or
- if it is to be dismissed.

The outcome of the assessment will then be discussed with the Research Integrity Advisor (RIA) and the appropriate next steps determined based on whether the allegation can or cannot be dismissed.

The RIA can provide confidential advice to staff, students/trainees or other persons about:
- actions that might constitute a breach of the Code and/or misconduct;
- the rights and responsibilities of the complainant; and
- the procedures that will apply in the handling of allegations of breaches of the Code and/or misconduct at CALHN

If research misconduct is established the DO and RIA will discuss with Responsible Executive Officer (REO) who will advise the person against whom the allegation was made and inform what disciplinary actions are to be taken or decides that the matter is referred for further investigation.

The REO may refer the matter to an independent external panel. The external panel makes a decision taking into account results of internal finding and the original submission.
Direction for corrective or other outcomes is recorded and actioned. All parties are notified of the outcomes and decisions recorded.

All records of complaints and/or allegations of a breach of the Code and /or research misconduct and any related correspondence (internal and external) will be securely located within the CALHN Research Office. Privacy in all matters will be upheld in accordance with the Guidelines Approved under Section 95A of the Privacy Act 1988 (2001) and the Guidelines Issued under Section 95 of the Privacy Act 1988 (2000).

19. References

SA Health Research Governance Policy 2013 (D0264)

SA Health Research Ethics Operational Policy 2013 (D0262)

The Australian Code for the Responsible Conduct of Research (2007 / 2018)

The National Statement on Ethical Conduct in Human Research 2007 (Updated May 2015)

20. Document Control

Version	Date	Summary	Approved By
1.0	May 2019	New	Don Mackie, Executive Director, Medical Services
1.1	August 2019	Reference updates	Bernadette Swart, Manager CALHN Research Services