SA Health

Policy

Research Ethics and Governance

Version 4.0

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PDS Reference No: D0264

Government of South Australia
SA Health

1. Name of Policy

Research Ethics and Governance

2. Policy statement

This policy provides the mandatory requirements in relation to the approval, administration, coordination, and management of all research across SA Health (referred to as health and medical research).

3. Applicability

This policy applies to:

- All employees and contracted staff of SA Health; that is all employees and contracted staff of the Department for Health and Wellbeing (DHW), Local Health Networks (LHNs) including state-wide services aligned with those Networks, SA Ambulance Service (SAAS), and non-SA Health study team members, and
- Any research undertaken within an SA Health facility, or involving SA Health resources, staff, patients or clients.

4. Policy principles

SA Health's approach to research ethics and governance is underpinned by the following principles:

- We ensure appropriate governance structures and processes are in place for health and medical research.
- We promote and support high quality research practices including those that can be translated into health policy, clinical practice, and patient/population health outcomes.
- We will ensure effective, efficient, appropriate administration and ethical review of health and medical research.
- We support high quality health and medical research that meets relevant scholarly and scientific standards.
- We will collaborate with all stakeholders to support safe, effective health and medical research.

5. Policy requirements

Ethical Review

- DHW and LHNs must ensure Human Research Ethics Committees (HREC) review health and medical research (HMR) in accordance with the National Health and Medical Research Council (HMRC) *National Statement on Ethical Conduct in Human Research (2023)*.

Support and Oversight of Health and Medical Research

- DHW and LHNs must establish local procedures that align with the use of the State's research management system for HMR occurring within their organisations including:
    - Prioritisation of HMR as routine business
    - Appointment of a Research Governance Officer (RGO) to coordinate and assess applications, and
    - Resource support for HREC (if applicable), and management of HMR applications and approvals.

Ethical and Scientific Approval of Research

- Research with human participants must be ethically and scientifically reviewed by one of the following (in line with Appendix 1: Human Research Ethics Review Mandatory Instruction):
    - a SA Health HREC
    - another certified South Australian HREC, or
    - another certified HREC recognised under the National Mutual Acceptance arrangements.
- Animal research projects must:
    - be approved by an Animal Ethics Committee (AEC) prior to commencement
    - comply with the *Australian code for the care and use of animals for scientific purpose 2013*, and
    - reach an agreement with a suitable AEC to permit review of these proposals where the Institution hosting the animal research does not have an associated AEC in place to review proposals.
- Projects involving the use of animals for scientific purposes must be approved by an appropriately constituted AEC prior to commencement.

Resource Governance Review and Authorisation

- A site-specific research governance review (Site Specific Assessment (SSA), or low risk equivalent) must be undertaken by the nominated SA Health RGO for all research projects that involve SA Health sites.
- Appropriate local Head of Department approval must be included in the site-specific assessment review.
- Delegates must be nominated to authorise HMR following the site research governance review.
- All authorisation delegates must be approved by the Chief Executive or Chief Executive Officer of the SA Health agency (as applicable).

Research Monitoring and Integrity

- DHW and LHNs must ensure researchers are responsible for submitting post-approval monitoring applications including progress reporting, safety reporting, amendments, and final reports.
- Review of post-approval monitoring applications and site monitoring for all approved HMR must occur and be coordinated by the HREC or RGO.
- Monitoring arrangements must be commensurate with the risk, size and complexity of the study and agreed frameworks and standards. Refer to the supporting information of this policy for a summary of frameworks and standards.
- Local procedures must be implemented to ensure compliance with the *Australian Code for the Responsible Conduct of Research 2018*, including the management of breaches of the code and misconduct in a fair and transparent way.

Research Administration

- All applications for higher risk (greater than low risk) HMR must be submitted via the SA Health Research Management System (Research GEMS).
- Research GEMS must be used to administer HMR greater than low risk projects, including the acceptance, processing, approval, and post-approval monitoring of applications.
- Lower risk studies must be managed outside of the Research GEMS platform in accordance with each LHNs local procedure.

Screening Requirements

- Prior to commencing a research project, confirmation must be provided that the researchers:
    - Are credentialled to work at the study site
    - Have complied with all requirements of the Criminal and Relevant History Screening Policy
    - Have declared all conflicts of interest before commencing their projects in accordance with the Declaration and Management of Interests Policy
    - Have training and qualifications relevant to the project
    - Have been provided access to responsible research conduct training, and
    - If conducting Clinical Trials, have completed Good Clinical Practice (GCP) training with a TransCelerate certificate (or equivalent) dated within three years.
- DHW and LHNs must ensure a copy of this policy is provided to the non-SA Health Study Team members.

Legislative Compliance

- DHW and LHNs must comply with all relevant legislation that applies to the conduct of HMR across SA Health agencies. Refer Appendix 4: Summary of Legislation Mandatory Instruction.
- DHW and LHNs must implement processes to ensure staff are aware of, and comply with, their obligations under applicable legislation.

Research Safety

DHW and LHNs must:

- Develop safety and quality systems and processes in accordance with the *National Clinical Trials Governance Framework*.
- Ensure researchers:
    - have all required safety and regulatory approvals prior to commencing their HMR, and
    - handle hazardous materials including biological materials safely and appropriately, including adherence to relevant guidelines, standards, and procedures.
- Ensure any HMR involving administration of radiation abide by associated codes and standards of practice provided by the NHMRC, and the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).

Data Management and Intellectual Property

DHW and LHNs must:

- Implement processes for the safe and secure handling of data arising from research projects to prevent unauthorised access, use and disclosure.
- Apply the requirements of the *General Disposal Schedule (GDS) No. 28: Clinical and Client-Related Records of Public Health Units in South Australia* (Section 6: Research and Ethics).
- Ensure all SA Health agencies, employees and others involved in the conduct of HMR adhere to the Intellectual Property Policy.This extends to maintaining a register of Intellectual Property assets with significant commercial or operational value.
- Refer to Appendix 2: Access to Personal Information for Research Purposes Mandatory Instruction.

Research Performance, Outputs and Deliverables

- All nationally agreed key research performance indicators and performance reporting requirements must be captured through Research GEMS.
- DHW must publish appropriate data of system wide key performance indicators.

Insurance and Indemnity

DHW and LHNs must:

- Implement processes to ensure compliance with the indemnity insurance requirements, and
- Ensure all researchers submit the required documentation to satisfy the indemnity insurance requirements.

Privacy and Consent

- DHW and LHNs must ensure persons undertaking HMR across SA Health that apply to the access and use of Personal Information for research, including information held on SA Health patient and clinical systems, are aware of, and abide by the relevant requirements of the:
    - *Health Care Act (2008)*
    - *Mental Health Act (2009)*
    - Department of the Premier and Cabinet (DPC) Circular 12 (PC012) Information Privacy Principles Instructions, and the
    - Privacy Policy.
- Individual consent must be sought for Personal Information, including patient/client information held on electronic and clinical systems, to be utilised for research purposes, except for where a waiver of consent is approved by a recognised HREC.
- Refer Appendix 2: Access to Personal Information for Research Purposes Mandatory Instruction.

Agreements

- Collaborative research projects between DHW and/or LHNs with an external party must be governed by an approved agreement outlining responsibilities.
- Approval must be by an authorised officer on behalf of the DHW or LHN, within the delegation of their role.
- Refer Clinical Research Agreement Guideline.

Standard Operating Procedures

- DHW and LHNs must develop and publish standard operating procedures (SOPs) that are maintained and updated appropriately, to describe how they (and where relevant, their HREC) operate.
- The SOPs must align with the use of the State's research management system and be made available to all relevant employees, HREC members, and (where appropriate) researchers.

Complaints and Appeals Process

- In accordance with the *National Statement on Ethical Conduct in Human Research (2023)*, processes must be implemented for receiving, handling and resolution of complaints about researchers, or the conduct of their research, or about the conduct of an HREC or other review body.
- All complaints must be handled promptly and sensitively.
- Refer Appendix 3: Research Compliance Mandatory Instruction.

6. Mandatory related documents

The following documents must be complied with under this Policy, to the extent that they are relevant:

- Criminal and Relevant History Screening Policy
- *Consent to Medical Treatment and Palliative Care Act 1995* (SA)
- Declaration and Management of Interests Policy
- DPC Circular: PC 012, Information Privacy Principles (IPPS) Instruction
- General Disposal Schedule (GDS) No. 28: Clinical and Client-Related Records of Public Health Units in South Australia (esp. Section 6)
- *Health Care Act 2008* (SA) (esp. Section 93)
- Interaction between SA Health and the Therapeutic Goods Industry Policy
- *Mental Health Care Act 2009* (SA) (esp. Section 106)
- Monetary Rewards Framework Policy (SA Health Intranet only)
- Privacy Policy
- *SA Government Intellectual Property Policy*
- Special Purpose Funds Classification Policy (SA Health Intranet Only) (esp. Section 3.2.3)

7. Supporting information

- Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS)
- *Code of Ethics for Aboriginal and Torres Strait Islander Research*
- *International Council for Harmonisation (ICH) Guideline for Good Clinical Practice* (with TGA comments)
- National Mutual Acceptance Scheme *Monitoring and Reporting Tables*
- NHMRC, *Australian code for the care and use of animals for scientific purposes*
- NHMRC, Australian Universities, *Australian Code for the Responsible Conduct of Research*
- NHMRC, *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders*
- NHMRC, *Framework for Monitoring: Guidance for the national approach to single ethical review of multi-centre research*
- NHMRC, *National Statement on Ethical Conduct in Human Research*
- NHMRC, *Safety monitoring and reporting in Clinical Trials involving therapeutic goods*

8. Definitions

- **Clinical trial** means any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.
- **Good clinical practice** means the international ethical, scientific, and practical standard to which all clinical research is conducted.
- **Health and Medical Research (HMR)** means all research across the spectrum of basic research, clinical research, population health research and health services research, directed at the improvement of human health and wellbeing.

- **National Mutual Acceptance (NMA)** means the Australian scheme that supports the single ethical and scientific review of all human health and medical research projects.
- **Organisational Feedback Mechanism** means the mechanism applied where a Principal Investigator (PI) is not satisfied with the result of their appeal, or other interested parties choose to register a complaint or other feedback regarding HMR.
- **Personal Information** means information or an opinion, whether true or not, relating to a person or the affairs of a person whose identity is apparent, or can reasonably be ascertained, from the information or opinion.
- **Research authorisation** means the final research governance approval assigned to a research project by an authorised officer on behalf of the SA Health agency.
- **Researcher** means a person who carries out health and medical, academic, or scientific research.
- **Statewide Services** means Statewide Clinical Support Services, Prison Health, SA Dental Service, BreastScreen SA and any other state-wide services that fall under the governance of the Local Health Networks.

9. Compliance

This policy is binding on those to whom it applies or relates. Implementation at a local level may be subject to audit/assessment. The Domain Custodian must work towards the establishment of systems which demonstrate compliance with this policy, in accordance with the requirements of the Integrated Compliance Policy.

Any instance of non-compliance with this policy must be reported to the Domain Custodian for the Research Domain and the Domain Custodian for the Risk, Compliance and Audit Policy Domain.

10. Document ownership

Policy owner: Domain Custodian for the Research Domain

Title: Research Ethics and Governance Policy

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11. Document history

Version	Date approved	Approved by	Amendment notes
1.0	01/04/2012	Portfolio Executive	
2.0	01/07/2013	Portfolio Executive	Inclusion of NMA requirements
3.0	04/01/2016	Portfolio Executive	NMA, Insurance and COI updates, removal of obsolete material
3.1	13/11/2017	Portfolio Executive	General revisions
3.2	30/07/2020	Deputy Chief Executive, Systems Leadership & Design	Updated privacy, finance and contracting requirements
4.0	01/12/2023	Deputy Chief Executive, Clinical System Support & Improvement	Updated to align with Policy Framework. Amalgamated the Research Ethics Policy Directive.

12. Appendices

1. Human Research Ethics Review Mandatory Instruction
2. Access to Personal Information for Research Purposes Mandatory Instruction
3. Research Compliance Mandatory Instruction
4. Summary of Legislation Mandatory Instruction

Appendix 1: Human Research Ethics Review Mandatory Instruction

The following Instruction must be complied with to meet the requirements of this Policy.

1. SA Health Single Review Model

1.1 The following processes must apply to the human ethical and scientific review of research projects occurring across one or multiple SA Health organisations only.

- Every HMR project which is to be conducted at a site under the jurisdiction of SA Health must be ethically and scientifically reviewed once only by a SA Health HREC or another South Australian based NHMRC certified HREC. The reviewing committee is designated the lead HREC.
- All sites under the jurisdiction of SA Health that are participating in the proposed research must accept the review of the lead HREC without further ethical or scientific consideration unless an exception has been granted by the LHN Board or Chief Executive (as applicable).
- The research ethics applicant (the Coordinating Principal Investigator (CPI) or delegate) must select a lead SA Health HREC or other SA based NHMRC certified HREC to undertake the ethical and scientific review. The applicant is responsible for submitting all required documentation in accordance with HREC submission requirements.
- Lead HRECs must be appropriately constituted in accordance with the requirements of the National Statement and fulfil all requirements that concern the operation and functioning of a HREC outlined in the National Statement.
- The lead HREC must be responsible for the full scientific and ethical review of the research application, and once approved, must have oversight and monitor the project until completed, closed or terminated.
- When the application is approved, the lead HREC must notify the CPI of the outcome of the review in writing. The lead HREC must specify the SA Health site/s at which the project is approved in the letter of approval.
- HRECs must have the right to refuse to review a multi-site (SA Health) application under the following circumstances:
    - The HREC Chairperson determines the Committee has insufficient expertise available to permit an adequate scientific and ethical review of the proposal; or
    - The HREC is not able to review the proposal in a timely manner.
- In the above two circumstances, the HREC must notify the applicant as soon as practicable to facilitate submission to another suitable SA Health HREC.
- The South Australian Aboriginal Health Research Ethics Committee (AHREC) must review all research applications where the focus is on a topic or disease/health burden identified as being of specific concern to Aboriginal and Torres Strait Islander people (based on chapter 4.7 of the National Statement, 2023). Review by the AHREC is required in addition to a SA certified HREC approval, for applicable projects.
- Research proposals must be submitted to the AHREC if:
    - The primary research goals and questions of study are directly related to health research and well-being and the experience of Aboriginal and/or Torres Strait Islander people (hereafter referred to as Aboriginal) is an explicit focus of all or part of the research
    - Data collection is explicitly directed at Aboriginal people
    - It is proposed to conduct sub-group analyses and separately analyse Aboriginal people in the results
    - The information, potential over-representation in the dataset or geographic location has an impact on one or more Aboriginal communities, or

- Governmental Aboriginal health funds are a source of funding, eg if it is a review of governmental services that may impact on the Aboriginal Community or organisations and there is an intention to disseminate key findings or recommendations in a public report.

> The AHREC must be provided with a copy of the lead HRECs ethical determination on the project for consideration as soon as practicable, should a SA Health or other SA certified HREC review the proposal first. Where the AHREC reviews and approves the proposal first, the CPI/delegate must provide a copy of the AHREC approval letter with the submission to the SA certified HREC.

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

> Any multi-site (SA-based) project where the primary data being used for the project is held by DHW must be submitted to the DHW HREC for review as the lead HREC.

> If a research site is added to an existing HMR project that has HREC approval, an amendment must be submitted to the lead HREC to approve the new site, with the approval communicated in writing to the CPI/delegate.

1.2 Benchmarks For Review: The 60 Day Clock

> SA Health adopts a benchmark of 60 calendar days (60 day clock) for full scientific and ethical review of HMR proposals. This clock must commence upon receipt of a valid (complete) research ethics application.

> Should the ethics application be incomplete or if the HREC requires further information, the CPI must be requested to resubmit the application and supply any additional information required by the HREC. The clock must be stopped if the HREC requests further information in order to make a decision about the application.

> It should be noted that the 60 day clock is a measure of performance only. Should the review period exceed 60 days, the CPI must not be entitled to any remedies, such as the return of any ethics review fees that may be charged by the HREC.

2. National Mutual Acceptance Scheme

2.1 SA Health is a participating jurisdiction in the National Mutual Acceptance (NMA) scheme with other jurisdictions to support single ethical and scientific review of multi-centre/cross-jurisdictional research proposals. The following processes must apply to the ethical and scientific review of NMA research projects.

> A HMR proposal must be submitted for approval by a NMA certified HREC through the NMA pathway where there is one or more SA Health site/s participating in the project, and one or more other public health organisations in participating NMA jurisdictions outside South Australia participating in the project.

> The NMA Standard Principles for Operation, available on the SA Health website, provide the overarching operational framework for NMA and must be referred to by SA Health HRECs and research ethics applicants seeking ethical approval for research using the NMA scheme.

> Researchers applying for ethical approval through the NMA scheme within South Australia are responsible for identifying an appropriate certified SA Health HREC that has expertise in the field of research (the 'lead' HREC). Where possible and appropriate, the SA Health HREC affiliated with their employing organisation must be selected as the lead HREC.

> The lead HREC is responsible for the ethical and scientific oversight of the approved NMA project across the life of the research project until such time as the project is completed, closed or terminated. This oversight extends to the review of project amendments, adverse events, progress reports and other matters requiring HREC review.

- The Coordinating Principal Investigator/delegate must prepare their ethics submission using the Human Research Ethics Application (HREA) form (or its replacement) hosted on the approved SA Health Research Management system, Research GEMS. All other submission requirements of the lead HREC must be followed. The applicant must list all the sites and investigators involved in the project in the HREA form.
- The lead HREC must review the ethics submission and protocol in accordance with their standard operating procedures, and usual committee processes.
- For proposals involving other jurisdictional departments of health, additional documents required by the relevant state HREC (such as a state-specific module) must form part of the NMA submission and the CPI/delegate must provide the jurisdictional module/s to the HREC for review as part of the overall submission.
- Once the review of the protocol is complete, the lead HREC must notify the CPI of the outcome of the ethical and scientific review in writing in accordance with standard processes.
- Where approved, the HREC must specify each NMA-affiliated public health organisation/site at which the project is approved in its letter of approval, making reference to the participating organisations/sites specified in the HREA.
- The CPI must communicate the outcomes of the ethical and scientific review to all participating research sites through their Principal Investigators.
- Where a submission is not approved, the CPI must only resubmit the protocol and any other requested amended documents to the lead HREC in accordance with the usual HREC processes and requirements, providing the grounds for non-approval are remedied.
- In all instances where a SA Health HREC is involved in assessing a NMA research application, the application must be submitted, processed and outcomes recorded on Research GEMS, including project amendments and post-approval correspondence.
- Where a research proposal is approved by an interstate NMA H REC, a site-specific research governance review (Site Specific Assessment) must be submitted for assessment by a SA Hea lth Research Governance Officer for all research projects that involve SA Health. Applications that are greater than low risk must be submitted in Research GEMS.

3. Exemptions to the NMA Scheme

3.1 The following categories of research must not be considered under the NMA scheme by SA Health organisations:

- Phase 0 (first time in human) and Phase 1 Clinical Trials
- Projects that require review by the Women's and Children's Health Network HREC review (section 1.1.k).
- Projects with relevance to Aboriginal and Torres Strait Islanders
- Low and negligible risk research applications other than where a full HREC has reviewed the application using the appropriate national ethics form.
- In each instance, a local (SA Health) HREC review must occur, and for (c), the South Australian Aboriginal Health Council Research Ethics Committee must be consulted to determine ethical review requirements.

Appendix 2: Access to Personal Information for Research Purposes Mandatory Instruction

The following Instruction must be complied with to meet the requirements of this Policy.

1. Information privacy and confidentiality

- SA Health agencies must take reasonable steps to protect Personal Health Information they hold from misuse and loss and from unauthorised access, modification or disclosure. This aligns with the requirements of the DPC *Circular 12 (PC012) Information Privacy Principles Instructions*.
- Where there is an approved requirement for a researcher to access personal information held in a registry, database or electronic system managed by SA Health, the nominated SA Health data custodian must ensure appropriate access and use of the information contained within through implementing local procedures.

2. Human Research Ethics Committee considerations

- In order for personal information to be used for medical or social purposes, the use of this information must first be approved by a HREC.
- In accordance with section 93(3)(f) of the Health Care Act 2008 (SA) and section 106(2)(f) of the Mental Health Act 2009 (SA), disclosure or use of Personal Information for HMR purposes must only occur if the research has been approved by a SA Health Human Research Ethics Committee (HREC) or a NHMRC certified HREC under a recognised mutual recognition framework.
- All HRECs must act in accordance with the NHMRC's National Statement on Ethical Conduct in Human Research (National Statement, 2023) that states, where possible, consent must be sought from the individual to participate in the HMR. Consent provided by an individual to participate in a HMR project must at all times be voluntary and be based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it Where an individual lacks the capacity to consent, a person exercising lawful authority for the individual can decide whether the individual will participate in the proposed research.
- For clarification, consent provided by a patient or legally authorised person for Personal Information to be disclosed and used for medical treatment and care must be separate to the use of that information for HMR purposes.
- As part of the review and approval process, the research ethics committee must take account of all relevant provisions of the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research (National Statement), as well as applicable legislation, policies and frameworks that impact the proposed research. It is required that any proposed access to paper and/or electronic medical records for the purpose of identifying prospective research participants (participant screening), including details and credentials of the person accessing such information, is fully disclosed to the research ethics committee to permit a full consideration of the appropriateness of the methodology. Where Personal Information is intended to be accessed prior to a formal consent process, a waiver of consent must first be approved by a research ethics committee.
- A waiver of consent must be approved by the HREC under the relevant provisions of the National Statement in circumstances where use of de-identified information is not appropriate for the research study, or it is impracticable to seek consent from individuals, for identifiable Personal Information (or human bio specimens) to be disclosed and utilised for research purposes.
    a) In this context, the approval provided by a HREC is only ethical approval for a researcher to receive Personal Information that is held by SA Health. It is not approval for the researcher to have direct access to SA Health systems or databases containing Personal Information. This approval must be sought separately.
    b) Any proposed access to SA Health electronic systems or databases by individual researchers for research purposes must include separate research governance approval through the institutional research governance processes, requiring all legal, policy, information security and research governance requirements to be met.

3. Research governance considerations

> As part of the SSA submission and project authorisation processes, and low risk application processes, access to and use of SA Health information for the research must be approved by the data custodian(s) of the information or data.

4. De-identification of Personal Information

> Unless informed consent has been obtained from the individual or a legally authorised person, or the HREC has expressly approved otherwise, Personal Information used or disclosed for research purposes must be de-identified before release.

a) De-identification must include:

- removing personal identifiers, such as name, address, date of birth, hospital record number, or other identifying information.
- removing or altering other information that may allow an individual to be identified, eg contextual identifiers due to a rare characteristic of the individual or their condition, or a combination of unique characteristics.

b) Only employees of SA Health must perform the de-identification process prior to releasing the information for research purposes.

c) For further information consult the *Office of the Australian Information Commissioner*.

5. Access to SA Health electronic systems for research purposes

> Under ordinary circumstances, unless through an arrangement approved by the relevant Chief Executive Officer in consultation with the nominated data custodian/s, non-SA Health employees and students must not be permitted access to SA Health electronic systems for research purposes due to the sensitivity of the Personal Information held on such systems.

5.1 Electronic Medical Records (EMR), including Sunrise EMR and PAS

> Any proposed access to an EMR by a non-SA Health employee, or employee acting in the capacity of a non-SA Health agency for research purposes requires authorisation by the Executive Director of Medical Services (EDMS) of the respective SA Health Organisation and an Honorary Research Affiliate and a request must first be submitted through the appropriate SA Health Research Governance Officer for consideration. A HREC can only provide ethical approval and is not authorised to provide access approval.

> Where such access is being requested, the following must be taken into consideration by a LHN Chief Executive Officer or their appropriate delegate, the EDMS, before approval is considered for the researcher:

- Individual consent: if consent is not being sought from the individual patient for their personal medical record/Personal Information to be accessed for the research project, access must not normally be permitted. A waiver of consent approved by the appropriate HREC may be sufficient justification if the EDMS or appropriate delegate agree to accept the waiver for a non-SA Health researcher to access electronic systems of SA Health for research purposes.
- Genuine need: access to SA Health electronic systems by external researchers to retrieve Personal Information for research must not be granted on the basis of convenience. Where there is another method for extracting the data from the system/s, including by an SA Health employee, this must be considered first. If other methods are considered and deemed to be not appropriate, this information must be supplied with the request.
- Suitability of the individual: the researcher must comply with the requirements of the Criminal and Relevant History Screening Policy, and evidence of relevant training and qualifications must be submitted in support of an individual application.

- System security: the EDMS must be assured that a decision to approve access to a SA Health system would not compromise the security or integrity of the system.
- Information privacy and security: the EDMS must consider whether granting an external researcher with access to patient information held on SA Health electronic systems will expose patients not involved in the research to any potential breaches of privacy. If so, access must not be permitted. The nominated data custodian/s must be consulted as part of this process and endorse the request for access prior to consideration by the EDMS.
- Monitoring and oversight: Supervision of the researcher while using the system/s through quarterly Digital Health SA Clinical Trial Electronic Medical Record (EMR) Access Audit Requests by a SA Health staff member must be implemented.
- The EDMS must only consider granting approval for this request if all of the above requirements are satisfied, subject to the individual researcher signing a confidentiality deed and fulfilling any other SA Health requirements as determined by the EDMS.

5.2 Access to SA Health systems by clinical trial sponsors

> External Clinical Trial monitors must only be granted temporary approval to access SA Health systems to undertake source data verification where there is a signed Clinical Trial/Investigation Research Agreement governing the conduct of the Clinical Trial at the SA Health agency, and this approval must be granted by the appropriate EDMS.

> All considerations outlined in the preceding section must be satisfied for such access to be granted.

Appendix 3: Research Compliance Mandatory Instruction

The following Instruction must be complied with to meet the requirements of this policy.

1. Feedback management

> SA Health agencies must take reasonable steps to be able to receive, record and respond to feedback relating to the conduct of HMR.

2. Complaints and appeals

> The National Statement (Section 5) requires institutional HRECs to establish processes to handle, record, and report complaints concerning research. These processes must also be available to all aspects of HMR, including (but not limited to) research governance applications, researcher conduct, and patient, public and community feedback.

3. HREC complaints and appeals process

> Where a proposal has been rejected, the Principal Investigator (PI) must submit a new application to the HREC, taking due account of the HRECs concerns. The revised application must be processed and reviewed in accordance with the HRECs usual processes.

> The CPI may lodge a written appeal with the HREC Chairperson specifying the grounds of the appeal. The HREC Chairperson must investigate the appeal and recommend to the HREC the appropriate course of action within four weeks from the date of the appeal being lodged. The HREC must notify the applicant of the course of action and determination in a timely manner.

Following an appeal being lodged to the HREC Chairperson, if the CPI considers that the HREC has not followed due process or remains unsatisfied with the outcome, they may choose to lodge an appeal with the Chief Executive Officer / delegate responsible for the HREC, utilising the Organisational Appeals Mechanism. In this instance the CPI must utilise the Organisational Feedback Mechanism.

4. Research Governance / Site Specific Assessment (SSA) complaints and appeals process

> Where a proposal has been rejected, the CPI may submit a new application to the Research Governance Officer (RGO), taking due account of the previous concerns. The revised application must be processed and reviewed in accordance with the usual processes.

If the CPI considers that the RGO has not followed due process or remains unsatisfied with the outcome, they may choose to lodge an appeal with the Chief Executive Officer / delegate responsible for research governance, utilising the Organisational Appeals Mechanism. In this instance the CPI must utilise the Organisational Feedback Mechanism.

5. Feedback Mechanism

5.1 HREC Appeals

> Following an appeal being lodged to the HREC Chairperson, if the CPI considers that the HREC has not followed due process or remains unsatisfied with the outcome, they may choose to lodge an appeal.

> An appeal may be lodged by the CPI with the Manager of the Research Office responsible for the administration of the research governance.

> In the event that the CPI is not satisfied with the response of the manager of the Research Office they may consider escalating the appeal with the Chief Executive Officer / delegate responsible for the HREC.

> The following process must be followed for HREC appeals:

- The HREC Chairperson or Research Office Manager must provide the Chief Executive Officer / delegate with all relevant material, including:
  - Details of the appeal
  - Material reviewed by the HREC, and
  - The outcome/decision of the ethical review process.

  The Chief Executive Officer / delegate must determine if further investigation of the appeal is necessary. If so, a panel will be established to consider the appeal. The panel must include the following members:
  - Chief Executive Officer / delegate
  - Two nominees of the Chief Executive Officer / delegate (not members of the HREC)
  - At least one nominee with relevant expertise in human research ethics, and
  - Expert(s) in a discipline of research related to the project under consideration.
- The panel must allow the HREC/RGO and the CPI the opportunity to make submissions.
- The Chief Executive Officer / delegate must notify the HREC and the CPI of the outcome of the investigation. The possible outcomes include:
  - The appeal is dismissed, or
  - The appeal is upheld, and the panel makes recommendation to resolve the issues based on the findings of the panel. The panel does not have the authority to approve an ethics application but may choose to refer an ethics application to an independent ethics committee for re-review.
- If the panel or Chief Executive Officer / delegate requests that a second ethical review is required as a recommendation of the investigation, an alternative SA public health system HREC (where possible) with suitable expertise and no prior involvement in the matter must be invited to undertake this review. The panel or Chief Executive Officer / delegate cannot reverse the final determination of any HREC.

5.2 Research Governance Complaints and Appeals Process

- The site Principal Investigator (PI) may appeal the final decision of the SSA, where a decision has been made to not authorise a research governance application, if the PI considers the decision has been made improperly or without due consideration of all relevant information.
- The PI may resubmit or amend their research governance application to meet any requirements outlined by the RGO. This application must be assessed according to the usual processes of the RGO and within a reasonable timeframe.
- The PI may also lodge a formal complaint about the research governance review process, where the PI considers the process has been unsatisfactory.
- In both instances, the PI must outline their concerns in writing to the appropriate RGO, or delegate.
- The following process must be applied where a site PI wishes to appeal the decision of the SSA assessment process, or make a complaint about the review of a SSA submitted to a SA Health RGO:
  - Where a complaint has been lodged, the RGO must notify the responsible CEO, or delegate, of any such complaints in a timely manner.
  - Following consideration and further investigation by the RGO and CEO/delegate (as required), the PI must be notified in writing of the outcomes of the investigation including any further action to be taken to resolve the complaint.
- If the PI remains dissatisfied with the outcomes of any further action by the RGO and/or CEO/delegate, this must be communicated in writing to the CEO/delegate. In these instances, the following process must be followed:
  - The CEO must determine if further investigation is necessary. If so, the CEO must establish a panel to consider the matter. The panel must include the following members:

- CEO/delegate
- Two nominees of the CEO/delegate, including at least one independent nominee with expertise in research governance matters

- The panel must allow the RGO and the PI the opportunity to make submissions.
- The CEO/delegate must notify the RGO and the PI of the outcomes of the investigation.
- Any recommendation or decision of the panel must be final.

> Other interested parties wishing to provide feedback must also do so via the Research Office Manager.

Appendix 4: Summary of Legislation Mandatory Instruction

The following Instruction must be complied with to meet the requirements of this policy.

1. Safety And Quality of Research

SA Health agencies must promote high quality, ethical and safe research, by maintaining a culture of good research practice and must take account of the following legislative and administrative issues:

- Timely and high-quality ethical review of proposed HMR projects.
- Ongoing monitoring of research projects to ensure compliance with conditions of ethical approval, and ethical standards and guidelines.
- Undertaking appropriate risk management measures, including maintaining current copies of insurance and indemnity certificates for approved research projects; following up on research complaints in a timely manner.
- Appropriate training and supervision of research staff.
- Sound records management procedures and practices.
- Appropriate publication and dissemination of research findings.

2. Use Of Approved and Unapproved Medicines and Medical Devices

- Research that involves the use of approved or unapproved medicines, medical devices, blood, tissues and chemicals must be compliant with the legislation, regulations and guidelines of the Therapeutic Goods Administration (TGA).

Use of medicines or medical devices within the context of an approved research project must not be considered a guarantee of their use beyond the scope of the research project.

3. Clinical Research Trials Conducted Under the CTN or CTA Schemes

- The TGA permits the use of unregistered or unapproved medicines or medical devices to assess their safety and efficacy within the context of a monitored clinical research trial under Sections 18 and 19 of the Therapeutic Goods Act (1989). This must be done through either the Clinical Trial Notification (CTN) or Clinical Trial Approval (CTA) schemes.
- For the CTN scheme, the reviewing HREC must have sole responsibility for reviewing all the data relating to the trial, such as safety data pertaining to the investigative medicine or device. It must also have responsibility for making a determination about the scientific and ethical merit of the trial.
- For the CTA scheme, the TGA has responsibility for reviewing relevant data including preclinical data pertaining to the investigative medicine or device.
    - The TGA's review of this data must be taken into account by the reviewing HREC who must make a determination about the scientific and ethical merit of the trial as a whole.
- Under both schemes, the reviewing HREC must have the authority to approve (or reject) the trial based on the scientific and ethical merit of the trial.

4. Regulation Of Gene Technologies and Related Therapies

Health and medical researchers in South Australia must comply with the legal requirements of the Gene Technology Act (2001) and the Gene Technology Regulations (2002) for research involving Genetically Modified Organisms.

- SA Health facilities in which researchers are using gene technology must be accredited and maintain, or have an established link with, a properly constituted Institutional Biosafety Committee (IBC) within a collaborating organisation.
- Any formal review provided by an IBC must be given to the lead HREC by the applicant upon submission of a new application for review.

- All research protocols involving gene therapy and related gene technologies including xenotransplantation must be submitted to a HREC for review.
- Research involving embryos must comply with the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryos Research Amendment Act (2006),* and the Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (NHMRC, 2007).

5. Ionising Radiation

- SA Health HRECs assessing research proposals involving exposure of participants to ionising radiation must be provided with a written report from an accredited medical physicist.
- In South Australia, the Environment Protection Authority (EPA) has responsibility for administering the *Environmental Protection Act (1993*) and *Radiation Protection and Control Act (2021)*. The Radiation Protection Branch of the EPA must be notified of all research involving exposure of research participants to ionising radiation.

6. Clinical Research Trials Involving an Unregistered Product

- For Clinical Trials involving an unregistered therapeutic agent, that is, one that has not been approved by the Therapeutic Goods Administration (TGA), the Sponsor, Coordinating Principal Investigator and Institution must comply with the requirements of the TGAs Clinical Trial Notification (CTN) or Clinical Trial Approval (CTA) scheme, as applicable. Further details on these schemes may be found on the TGA website.

7. Clinical Trial Registration

- All researchers undertaking Clinical Trials involving SA Health sites/institutions and facilities must register the trial with an appropriate Clinical Trial registry, such as the Australian New Zealand Clinical Trial Registry (ANZCTR) prior to participant recruitment.

8. Safety Reporting for Clinical Drug and Device Trials

- SA Health endorses the requirements set out in the NHMRC's (2016) Safety monitoring and reporting in Clinical Trials involving therapeutic goods. This document outlines the reporting responsibilities of all parties involved in the conduct of Clinical Trials, including Clinical Trial sponsors, investigators, reviewing HRECs and RGOs/institutions. These requirements must be complied with.

9. Projects involving Genetically Modified Organisms (GMOs)

- All projects involving the use of GMOs for scientific purposes must be approved by an appropriately constituted Institutional Biosafety Committee (IBC) prior to commencement. Typically, the Institution hosting the GMO research will have an associated IBC in place to review proposals. If this is not the case, an agreement must be reached with a suitable IBC to permit review of these proposals.

10. Specific Safety Issues

- Evidence of specific notification for research involving gene technology and related therapies, drugs and/or ionising radiation must be attached to the research governance submission to permit the RGO to assess whether the appropriate processes and documents have been completed by the applicant.

11. Legislation

The following is a summary of State and Commonwealth legislation that must apply to the conduct of health and medical research projects across SA Health, or by SA Health employed researchers.

This is provided as a general guide only and more specific advice must be sought where applicable. Local institutional requirements and policies must be reviewed in conjunction with the applicable legislative requirements.

12. South Australian Legislation

Name	Comments
Assisted Reproductive Treatment Act (1988)	Refer s18
Gene Technology Act (2001); Gene Technology Regulations (2017)	
Prohibition of Human Cloning for Reproduction Act (2003) Research Involving Human Embryos Act (2003) Research Involving Human Embryos Regulations (2003)	
Transplantation and Anatomy Act (1983)	Refer s39
Coroner's Act (2003)	Refer s38
Radiation Protection and Control (Ionising Radiation) Regulations (2015)	Refer Part 3, Division 2
Controlled Substances Act (1984)	Refer Division 2 and 3; section 56
Mental Health Act (2009)	Refer s106 (2)
Health Care Act (2008)	Refer s93 (3)
Consent to Medical Treatment and Palliative Care Act (1995) SA	

Please refer to the South Australian register of legislation to review the above

13. Commonwealth Legislation

Name	Comments
Therapeutic Goods Act (1989); Therapeutic Goods (Medical Devices) Regulations (2002); Therapeutic Goods Regulations (1990)	
Australian Research Council Act (2001)	
Gene Technology (Licence Charges) Act (2000)	
Privacy Act (1988); Guidelines under Section 95 of the Privacy Act; Guidelines under Section 95A of the Privacy Act.	
Prohibition of Human Cloning for Reproduction Act (2002)	
Epidemiological Studies (Confidentiality) Act (1981); Epidemiological Studies (Confidentiality) Regulations (2018)	

Mitochondrial Donation Law Reform (Maeve's Law) Act (2022)	

Please refer to the Federal Register of Legislation to review the above.