Policy

Directive: compliance is mandatory

SA Health Research Governance Policy

Objective file number: 2009-01833
Policy developed by: Health Reform Division, Office of Research Development
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Summary The objective of this policy is to establish a standardised set of processes to facilitate the governance of research across sites and institutions under the jurisdiction of SA Health.

Keywords Research governance, human research, ethics administration, Human Research Ethics Committee

Policy history Is this a new policy? **Y**
Does this policy amend or update an existing policy? **N**
Does this policy replace an existing policy? **N**

Applies to All SA Health Portfolio

Staff impact All Staff, Management, Admin, Students; Volunteers

PDS reference OCE use only

Version control and change history

Version	Date from	Date to	Amendment
1.0	21/03/2012	Current	Original version

Government of South Australia
SA Health

1. PURPOSE

The purpose of this Policy is to outline the research governance requirements applicable to researchers and institutions involved in the conduct and administration of health and medical research across the South Australian public health system.

This Policy aims to promote high quality, accountable and responsible research conduct compliant with all local and national standards and guidelines.

2. GLOSSARY

Coordinating Principal Investigator: the lead investigator on a research study taking overall responsibility for the conduct of the study at all of the study sites.

Health and medical research: basic, applied, clinical, population health and health systems/services research directed at understanding and improving health and wellbeing and its treatment across the population.

Local Health Network: one of five South Australian bodies established to administer health services in accordance with the *Health Care Act* (2008) under the national health reform process.

Human Research Ethics Committee (HREC): a committee formally constituted under the NHMRC for the purposes of reviewing research ethics applications.

Institution or Site: a health care facility that supports health and medical research (e.g. hospital or health service).

National Approach to Single Ethical Review of Multi-Centre Research: a national initiative developed by the NHMRC to permit single ethical review of multi-centre research.

Principal Investigator: the lead investigator responsible for the conduct and management of a research project at a local Institution or Site.

Project Sponsor: a commercial (or other) entity providing financial or other resources to support the conduct of a research project.

Research Governance: those matters concerning the 'quality, safety, privacy, risk management, financial management and ethical acceptability' of research[1].

Research Governance Officer (RGO): A person assigned to the management and oversight of research governance.

[1] Australian Code, Section 1, 1.3.

South Australian public health system: Those institutions under the jurisdiction of SA Health.

Single Review Model: an SA Health only system of mutual recognition of ethics review, whereby research ethics applicants can apply for ethics approval from one SA Health HREC, and it will be accepted by all other SA Health HRECs associated with sites where the research will be conducted.

Site Specific Assessment (SSA): a separate form and review process used to determine whether a project has satisfied the research governance requirements of the site.

3. SCOPE

This Policy applies to all parties involved in the conduct of health and medical research (including animal research) at South Australian public health institutions, or involving clients of South Australian public health institutions, including regional health services; hospitals; community health services; public health clinics and associated programs, and who fall under the delegated responsibility of SA Health in the *SA Health Care Act (2008)*. It applies equally to employees of SA Health and external researchers who are undertaking approved research activity at South Australian public health system institutions.

It does not apply to human research undertaken at institutions external to those outlined above, or research involving SA Health staff wholly at institutions external to those outlined above, where local institutional policies will apply.

4. KEY DOCUMENTS

The key policy, guidelines and documents that have applicability to this policy include:

- Australian Code for the Responsible Conduct of Research (2007)
- National Statement on Ethical Conduct in Human Research (NHMRC) (2007)
- Access to Unapproved Therapeutic Goods - Clinical Trials in Australia (TGA)
- Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (NHMRC)
- Guidelines to promote the Wellbeing of Animals Used for Scientific Purposes: The Assessment and Alleviation of Pain and Distress in Research Animals (NHMRC) (2008)
- Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Research (NHMRC) (2003)
- International Conference on Harmonisation / Good Clinical Practice Guidelines (ICHGCP Guidelines)
- SA Health Code of Fair Information Practice (2006)

- SA Whole of Government Intellectual Property Policy (SA Health Monetary Rewards Framework)
- SA Health Risk Management Policy
- SA Health Financial Management Manual
- SA Health Research Ethics Operational Policy (2012)

5. RESPONSIBILITIES

1) Chief Executive, SA Health

The Chief Executive, SA Health, is responsible for ensuring the overall effective and responsible governance of research across SA Health sites and institutions.

2) Local Health Network Chief Executive Officers

The Local Health Network Chief Executive Officers are responsible for:

- ensuring awareness and compliance with this policy by researchers and staff based at health services within their jurisdiction involved in the conduct of research;
- ensuring appropriate support and resources are provided to sites and institutions to meet the requirements of this policy; and
- supporting a culture of responsible research practice across their Local Health Network.

3) Institutions

The Chief Executives / Executive Directors / General Managers (or equivalent) of Institutions are responsible for:

- ensuring all research undertaken at their site complies with the requirements of this policy; and
- ensuring there are adequate processes and resources in place to support the effective governance and management of research within their institution.

4) Researchers

Researchers who undertake research across the South Australian public health system, either as employees of SA Health or external agencies, are required to carry out their research in a professional, safe, ethical and competent manner, by fulfilling the requirements stipulated by this policy, and by adhering to all relevant State and Commonwealth legislation, policy and guidelines relevant to their research.

5) **Research Governance Officers**

Research Governance Officers are responsible for:

- Ensuring the overall efficient and effective coordination of research governance matters within their local jurisdiction.

6. INTRODUCTION

Under the *Australian Code for the Responsible Conduct of Research (2007)* (hereafter referred to as 'The Australian Code'), jointly issued by the National Health and Medical Research Council (NHMRC), Australian Research Council (ARC) and Universities Australia, it is mandatory for all Australian institutions who participate in health and medical research to have policies and processes in place to fulfil a range of research management and governance requirements.

The responsibility for fulfilling these requirements falls principally to the Institution that hosts the research and the researchers who conduct health and medical research.

This Policy outlines the requirements for the management and governance of health and medical research activities within SA Health institutions, and is written as a supporting document to the SA Health Research Ethics Operational Policy.

7. THE RESEARCH GOVERNANCE OFFICER

It is a requirement that each Local Health Network of SA Health nominates a person/s to fulfil the role of Research Governance Officer (RGO) to effectively manage research governance matters for sites and institutions within their jurisdiction. It is the responsibility of each Local Health Network to determine the resources and staffing arrangements required to support this function in consultation with the institutions and sites within their jurisdiction.

The RGO should perform the following functions as part of his or her role:

- Provision of advice on research governance matters to a range of parties reflecting policies, guidelines and other reference material adopted by the jurisdiction
- Review of Site Specific Assessment forms
- Liaison with researchers, ethics officers, research sponsors and other key staff and bodies involved in the conduct and management of research
- Monitoring of research conducted at the site/s for which the RGO has responsibility
- Development of processes, systems and methods for the effective governance of research at the site/s for which the RGO has responsibility
- Undertaking risk management assessments and procedures to promote responsible research conduct
- Review of contracts and agreements applicable to sponsored research ethics applications, where possible.

The contact details for this person/s should be made available on relevant local websites (e.g. research ethics sites) that are accessed and utilised by researchers and others involved in the administration and management of research.

8. ETHICS REVIEW AND SITE SPECIFIC ASSESSMENT

It is the responsibility of each institution to ensure all research projects being undertaken at the institution have undergone a process of ethical review and approval by an appropriately constituted Human Research Ethics Committee (HREC) and/or Animal Ethics Committee (AEC) prior to commencement.

Ethics committees under the jurisdiction of SA Health should minimise duplication of ethical review where possible. For research conducted at multiple sites across the South Australian public health system, SA Health endorses a system of single ethical review (the Single Review Model) for multi-site health and medical research (please refer to Section 5 of the *SA Health Research Ethics Operational Policy*).

To complement the Single Review Model, and to meet the future requirements of the national ethics streamlining approach being implemented nationally in 2012 (the National Approach to Single Ethical Review of Multi-Centre Research), a Site Specific Assessment (SSA) form has been introduced to permit an assessment of the feasibility and suitability of research projects at individual sites/institutions. The SSA is designed to permit a review of research governance considerations relevant to research projects being undertaken across the South Australian public health system.

The SSA considers areas relevant to the research including:

- The availability of local resources to support the conduct of the project at the institution;
- Whether relevant approvals have been sought and obtained, to enable the project to occur (e.g. Departments and/or Facilities where the project is to be conducted);
- Whether the project meets site specific administrative, financial and governance requirements.

The Coordinating Principal Investigator (CPI) will be required to complete and submit the SSA form following submission of the ethics application. The SSA will be required for both single and multi-site research projects.

The RGO will have responsibility for assessing and endorsing the completed SSA forms prior to the research project being authorised by the delegated Institutional authority.

9. AU RED

To enable the effective management of research ethics and governance applications across the South Australian public health system, SA Health has purchased the Infonetica's AU RED (Australian Research Ethics Database) system to process, administer and manage all applications. Each of the public health sector HRECs will have access to this system, along with associated RGO's. Use of this system is mandatory.

10. RESEARCH MONITORING

As an important component of research governance and ensuring the ongoing ethical compliance of approved research projects, Institutions must maintain appropriate mechanisms to monitor all research being undertaken. This role should be negotiated between the associated HREC and RGO, and consideration must be given to the capacity and expertise of the person/s undertaking a monitoring role on behalf of the site or institution (see Section 23, *SA Health Research Ethics Operational Policy*).

11. SAFETY AND QUALITY OF RESEARCH

It is a requirement that all South Australian public health system Institutions promote high quality, ethical and safe research, by maintaining a culture of good research practice, taking account of the following issues:

- Timely and high quality ethical review of proposed research projects;
- Ongoing monitoring of research projects to ensure compliance with conditions of ethical approval, and ethical standards and guidelines;
- Undertaking appropriate risk management measures, e.g. 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.

Clinical Research Trials

Clinical research trials typically involve the testing of a medical intervention (e.g. drug or device), and may be investigator initiated or sponsored by a commercial entity.

For trials involving an unregistered therapeutic agent, that is, one that has not been approved by the Therapeutic Goods Administration (TGA), it is a requirement that the Coordinating Principal Investigator and Institution comply with the relevant Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) scheme. Further details on these schemes may be found on the TGA website.

The Research Governance Officer will assess whether the correct TGA processes and document requirements have been fulfilled by the Coordinating Principal Investigator on provision of a completed SSA form. The relevant CTN and CTX forms should be signed by the Institution once the project has been authorised by the head of the Institution (or delegate).

Clinical Trial Registration

It is an expectation that all researchers undertaking clinical trials involving SA Health sites/institutions and facilities ensure their trial is registered with an appropriate clinical trial registry, such as the Australian New Zealand Clinical Trial Registry (ANZCTR). A trial should be registered prior to participant recruitment. Please refer to the ANZCTR website for further information.

Projects involving Animals

All projects involving the use of animals for scientific purposes must be approved by an appropriately constituted Animal Ethics Committee (AEC) prior to commencement. Typically the Institution hosting the animal research will have an associated AEC in place to review proposals. If this is not the case, an agreement should be reached with a suitable AEC to permit review of these proposals.

Specific Safety Issues

Research involving gene technology and related therapies, drugs and/or ionising radiation may require specific notification, registration or licence requirements. Please refer to the SA Health Research Ethics Operational Policy.

Evidence of these requirements should be attached to the SSA to permit the RGO to assess whether the appropriate processes and documents have been completed by the applicant.

12. PUBLICATION AND AUTHORSHIP

As a general principle, the findings of research funded by the public should be in the public domain for the benefit of all. Publication of research results irrespective of whether they show 'positive' or 'negative' findings is considered good ethical practice and supported by SA Health. For these purposes, 'publication' may be defined as hard copy, electronic copy or internet publication.

Capacity to freely publish and disseminate research findings will depend on project funding arrangements and any relevant restrictions or conditions provided by the project sponsor, whether the project is collaborative and involves project staff from multiple organisations, and any explicit intellectual property arrangements that have been negotiated.

It is the responsibility of the CPI to ensure any contractual requirements concerning publication of findings arranged with the project sponsor or funding body (where applicable) are understood and satisfied.

As a general principle, SA Health should be provided with the opportunity to review draft manuscripts for research projects it has supported through funding, resources or in-kind contributions. SA Health should also receive acknowledgement in such publications.

Authorship should be decided early in the planning process of a research project, to determine who will be credited as authors, contributors and who will be acknowledged. Ideally this will be documented and maintained as part of the project records. It is the responsibility of the Institution to ensure that disputes regarding authorship are addressed in a timely manner prior to, or during, the conduct of the project.

13. RESEARCH COLLABORATION

Research collaboration can bring many benefits to researchers and the Institution. Exchange of ideas and expertise across disciplinary areas can strengthen the quality of research and enhance research uptake. Collaboration may occur across institutions and organisations intra- or inter-State, and will have a range of implications for those involved.

SA Health recommends that a formal written agreement exist for all collaborative research that clearly specifies the responsibilities of each party involved in the project. This should consider matters such as intellectual property; confidentiality and copyright; data management; responsibility for ethics approval; and reporting obligations.

Legal advice may be sought if required in the negotiation of these agreements. Please read the Legal and Governance Unit's Guideline on Accessing Legal Services for the Health Portfolio available online. This document provides guidance on the required format and process for requesting legal advice.

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

14. FINANCIAL MANAGEMENT

Appropriate and accountable financial management practices are a requirement for all research projects conducted at SA Health institutions. These practices should be consistent with current best practice, and be compliant with the requirements of the SA Health *Financial Management Manual*.

For projects involving financial contributions by SA Health institutions, the project budget should be authorised by an appropriate finance authority (e.g. Finance Director or Head of Department/Division). Any funding agreement or contract between an SA Health institution and an external agency should be clear and transparent.

15. INTELLECTUAL PROPERTY

SA Health requires that all considerations and negotiations made by SA Health researchers and incorporated institutions in relation to intellectual property take account of the Whole of Government Intellectual Property policy (South Australia), and the SA Health *Monetary Rewards Framework*.

The Whole of Government Intellectual Property policy provides a framework for the South Australian Government to manage intellectual property. A key principle of this policy is that the Government should seek to retain ownership of Intellectual Property for which it has played a significant role in developing. For SA Health, examples of this may include where SA Health researchers have made a significant contribution to a project that generates new

intellectual property, or where SA Health is the primary funding body for a project that generates new intellectual property.

In the event that intellectual property generated by such projects has commercial potential, the SA Health Monetary Rewards Framework specifies that the net returns are equally split between the Institution, the inventors (employees) and the Health and Medical Research Fund, which has been established to support health and medical research in South Australia.

Variances to such arrangements may exist, for example, where multiple parties are involved in funding and/or resourcing a research project, and where intellectual property rights are by negotiation shared across a number or organisations, or where a commercial sponsor is involved in funding a research project.

Matters concerning intellectual property should be considered prior to project commencement and clearly outlined in the research or funding contract/agreement. The Intellectual Property Manager, SA Health, may be consulted to advise on the suitability of intellectual property arrangements if required, through the Director, Office for Research Development, SA Health.

16. CONFIDENTIALITY AND PRIVACY

Health and medical research often entails collecting personal information and data concerning clients, staff or services. Some of this information and data may be obtained directly from research participants through a process of informed consent; while at other times it will be sourced from databases or registries that may involve additional authorisation and approval from the data custodian/s.

SA Health maintains a *Code of Fair Information Practice* that contains standards pertaining to the collection, use, quality and security of information and data. This framework draws on the National Privacy Principles and has applicability to all staff and services across SA Health. SA Health institutions are responsible for ensuring researchers are aware of the principles established in this document, and maintaining good information management practices.

Storage of Data and Information

It is imperative that all data and information collected and used for research purposes is stored in accordance with the principles outlined in SA Health's *Code of Fair Information Practice* and the *National Statement on Ethical Conduct in Human Research (2007)* and *The Australian Code for the Responsible Conduct of Research (2007)*. Research data should be stored securely at all times (e.g. in locked storage facilities and password protected computers), and safeguarded against inappropriate access.

17. INSURANCE AND INDEMNITY

All research projects hosted by SA Health institutions involving SA Health or external staff must have appropriate insurance and indemnity (approved by Insurance Services, SA Health) prior to the project commencing. Insurance Services may be contacted at ISUHealth@health.sa.gov.au.

For investigator initiated research projects undertaken by SA Health researchers, insurance cover is provided through SA Health's corporate insurance arrangements. Note that this cover is neither automatic nor guaranteed and the CPI must contact Insurance Services to ascertain whether their project is covered prior to commencement.

For private/commercially sponsored studies, the sponsor is responsible for arranging appropriate insurance and indemnity documentation that meets the requirements of SA Health. For these studies, a copy of all insurance/indemnity documentation must be provided by the CPI to Insurance Services, SA Health, for review and endorsement prior to project commencement.

The RGO associated with the SA Health institution where the research is being conducted should maintain current copies of insurance certificates and related documentation for research projects for which they have oversight.

18. RESEARCH MISCONDUCT

It is a requirement of SA Health that all institutions under their jurisdiction that host or participate in research have a written policy concerning complaints or allegations of research misconduct.

This policy should be separate to any existing institutional policy regarding employee misconduct, even though in practice they may intersect. The following considerations should be taken account of by institutions in developing a written policy for research misconduct:

- Research misconduct includes fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting the results of research, and failure to declare or manage a serious conflict of interest.
- Misconduct includes avoidable failure to follow an approved research protocol, particularly where this failure may result in unreasonable risk or harm to humans, animals or the environment. It also includes the wilful concealment or facilitation of research misconduct by others.
- Research misconduct does not include honest differences in judgement in the management of the research project, and may not include honest errors that are minor or unintentional.
- Any complaint or allegation of research misconduct must be investigated appropriately with due sensitivity and consideration. Should the complaint or allegation be substantiated by compelling evidence, appropriate disciplinary action should be pursued by the

Institution. Any disciplinary action should be determined by the Institution and be consistent with the nature of the misconduct.

- Institutions are encouraged to examine the framework for complaints and allegations presented in The Australian Code. It is the responsibility of the Institution to devise an appropriate documented process for complaints investigation consistent with the requirements of The Australian Code.