Policy

Policy Directive: compliance is mandatory

Research Governance Policy Directive

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Research Governance Policy Directive

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1. Objective

The purpose of this Policy Directive is to outline the research governance requirements applicable to research being undertaken across the South Australian public health system. This Policy Directive aims to promote high quality, accountable and responsible research compliant with all local and national policies, standards and guidelines.

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 that participate in health and medical research to adopt policies and procedures to support effective governance of research.

Research governance is concerned with the principles, requirements and standards of research. It addresses protection of research participants, the safety and quality of research, privacy and confidentiality, financial probity, legal and regulatory matters, risk management and monitoring arrangements and promotes good research culture and practice.

2. Scope

This Policy Directive applies to all parties involved in the conduct of health and medical research (including animal research) at South Australian public health organisations, or which involves clients/patients, resources or facilities of South Australian public health organisations including Local Health Networks, hospitals, community health services, public health clinics and associated programs established under the *Health Care Act (2008).*

This Policy Directive is applicable to all employees of SA Health including visiting medical officers, visiting health professionals, contractors and consultants, and external researchers including clinical and non-clinical university academics, who are undertaking approved research at South Australian public health organisations.

3. Principles

The following principles support this Policy Directive:

- SA Health is committed to supporting and participating in high quality health and medical research relevant to SA Health priorities.
- The safe and responsible conduct of research undertaken across SA Health, including compliance with all ethical, scientific, regulatory and professional standards, is of key importance to ensure sufficient protection for patients, research participants and public health organisations.
- The efficient and effective administration of research governance applications will be ensured through the use of standardised procedures across SA Health.

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4. Detail

4.1 RESEARCH GOVERNANCE OFFICERS It is a requirement that each Local Health Network (LHN) appoints a Research Governance Officer (RGO), and supporting staff where required, to manage research governance applications, procedures and processes. It is the responsibility of each LHN to determine the resources and staffing arrangements required to support this function.

RGOs and others assigned responsibility for managing research governance will have oversight of the following as well as any other responsibilities determined by the LHN:

- Review of research governance applications (site specific assessments).
- Provision of advice on research governance matters to a range of parties reflecting policies, guidelines and other reference material adopted by the jurisdiction.
- Provision of advice to researchers, ethics officers, research sponsors and other parties involved in the conduct and management of research.
- Monitoring of research conducted at relevant sites within their jurisdiction.
- Development of processes, systems and methods for the effective governance of research.
- Undertaking risk management assessments and procedures to promote responsible research conduct.
- Review of contracts and agreements applicable to research, where required.

The contact details of RGOs should be published on local websites and communicated to researchers and others involved in research conduct.

4.2 SITE SPECIFIC ASSESSMENT

SA Health organisations must ensure research projects undertaken at the organisation involving staff, patients, resources or facilities 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.

To permit SA Health organisations participating in research projects to undertake an appropriate assessment of research governance issues relevant to the research, this Policy Directive requires a Site Specific Assessment (SSA) form to be completed and submitted by the Principal Investigator (PI) to the appropriate SA Health RGO for each organisation at which it is proposed a research project will be undertaken. A SSA is to be submitted for every research project, except where otherwise advised by the RGO. This requirement is separate and additional to ethical review (HREC) requirements.

The SSA considers a range of areas, including:

- The capacity for the site to support the project.
- Research participants at the site.
- Financial arrangements for the project.
- Insurance arrangements.
- Credentialing and training of project staff.
- Data access.
- Local approvals relevant to the conduct of the project.

4.2.1 Completing a SSA

There are two SSA forms that are available on Online Forms for research being undertaken across SA Health:

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- Standard Site Specific Assessment Form for Research.
- Site Specific Assessment Form for Low and Negligible Risk Research.

The RGO is required to advise researchers on the use of these forms for research projects where research governance approval is required. Where possible, the SSA application should be submitted concurrently with the HREC application to permit efficient consideration of the SSA.

Once the SSA form has been completed by the PI of the research project (or delegate) with all relevant materials attached, it should be submitted to the appropriate RGO or delegate for review.

4.2.2 Assessment of the SSA

The organisation, through the nominated RGO, will have responsibility for assessing and endorsing the completed SSA form in accordance with relevant SOPs. Once a decision to support an SSA has been made, the application and recommendation should be provided to the organisational delegate for authorisation.

4.2.3 Project Authorisation

Authorisation of a research project is the final approval granted by the organisation before the research project can commence. Authorisation should only occur after the research protocol has been approved by an appropriate HREC, and once the RGO has endorsed the SSA. The responsibility for authorising the project to commence lies with the Chief Executive Officer / Executive Director / General Manager (or nominated delegate) of the site.

To enable a decision to be made concerning authorisation, the responsible RGO should supply copies of the HREC approval letter, endorsed SSA form, and any other relevant documentation to the authorised delegate.

4.3 SSA COMPLAINTS AND APPEALS PROCESS

The following process will be applied where a 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.

1. The site PI may appeal the final decision of the SSA, where a decision has been made to not authorise a SSA, if he/she considers the decision has been made improperly or without due consideration of all relevant information.

2. The PI may also lodge a formal complaint about the SSA review process, where the PI considers the process has been unsatisfactory.

3. In both instances, the PI should outline their concerns in writing to the appropriate RGO, or delegate.

4. The PI may resubmit or amend their SSA application to meet any requirements outlined by the RGO. This application will be assessed according to the usual processes of the RGO and within a reasonable timeframe.

5. Where a complaint has been lodged, the RGO will notify the responsible CEO, or delegate, of any such complaints in a timely manner.

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6. Following consideration and further investigation by the RGO and CEO/delegate (as required), the PI will be notified in writing of the outcomes of the investigation including any further action to be taken to resolve the complaint.

7. If the PI remains dissatisfied with the outcomes of any further action by the RGO and/or CEO/delegate, this should be communicated in writing to the CEO/delegate. In these instances, the following process will be followed:

   - The CEO will determine if further investigation is necessary. If so, the CEO will establish a panel to consider the matter.
   - The panel will include the following members:
     - The CEO/delegate;
     - Two nominees of the CEO/delegate, including at least one independent nominee with expertise in research governance matters, including the requirements of the SA Health Research Governance Policy, the Australian Code for the Responsible Conduct of Research, and other applicable policy documents and guidelines.
   - The panel will allow the RGO and the PI the opportunity to make submissions.
   - The CEO/delegate will notify the RGO and the PI of the outcomes of the investigation.
   - Any recommendation or decision of the panel will be final.

4.4 RESEARCH MONITORING

To ensure research projects continue to meet the ethical and governance requirements of the organisation, it is essential that parties involved in the conduct of research including investigators, institutions and research sponsors have arrangements in place to effectively monitor approved research.

The CPI, PIs, and research personnel are best placed to directly monitor the conduct of the research and appropriately follow up matters that impact research participants, or which may affect the safety and ethical acceptability of the project.

The level of monitoring of approved research projects undertaken by the HREC and organisation through the RGO should be aligned with the risk profile of the project and specific ethical, research governance, legislative and regulatory requirements that underpin the research.

Appropriate mechanisms for monitoring approved research are outlined in the National Statement, and can include activities such as:

- Review of progress reports for approved research.
- Review of reports from independent agencies concerning the research (such as data and safety monitoring boards).
- Review of adverse event reports.
- Inspections of research sites, data or consent documentation.
- Interviews with research participants.

RGOs are responsible for providing guidance to researchers on reporting and monitoring requirements for approved research projects in accordance with organisational requirements, SOPs and relevant guidelines and policies.

4.4.1 Monitoring of NMA Research Projects

Under National Mutual Acceptance (NMA), there are specific monitoring considerations that should be taken into account by the Certified HREC responsible for providing the single ethical and scientific review of the research project, and organisations that accept the single scientific and ethical review of a Certified HREC.

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The NHMRC has developed a Monitoring Framework applicable to single ethical and scientific review, which should be considered by SA public health organisations, HRECs and RGOs when developing their own policies and practices for monitoring approved research projects.

A key principle of this framework is that, only the Certified HREC can take on those elements of monitoring a research project that are attributable to HRECs.

The broad allocation of monitoring responsibilities for research projects approved under NMA falls across a number of key parties, as follows:

- The Certified HREC.
- Participating organisations, through their RGO or delegated personnel.
- Coordinating and Principal Investigators.
- Project Sponsors.
- For clinical trials, data and safety monitoring boards.

The responsibilities for the first two of these parties are explored further in the following sections.

4.4.2 Monitoring responsibilities of the Certified HREC

The lead HREC that undertakes the single ethical and scientific review of the human research project will have responsibility for a range of post-approval and monitoring activities across approved sites, including:

- Approval of protocol amendments.
- Reviewing adverse events.
- For clinical trials, review of safety information, including serious adverse event (SAE) reports, unexpected adverse reaction (SUSAR) reports and protocol violations.
- Review of progress and annual reports in accordance with the approved research protocol and any conditions of ethical approval.

4.4.3 Monitoring responsibilities of the Organisation

The participating organisation, through their RGO or delegate, has responsibility for monitoring the conduct of a human research project that has received site approval through a range of mechanisms, including:

- Review of progress and annual reports to ensure the project is being conducted in accordance with conditions of governance approval and other relevant frameworks, policies and requirements.
- Review of SSA amendments that may be submitted where changes are proposed to the project that may impact the institution.
- Review and consideration of advice provided by the lead HREC or Principal Investigator that may impact the ethical and scientific acceptability of the project.
- Undertaking additional specific monitoring activities that may be determined by the institution, for example auditing, or interviews with participants.

As a minimum requirement all Serious Adverse Events (SAEs) and Adverse Events (AEs) should be reported and monitored according to the requirements outlined in the *Monitoring and Reporting Tables* document available online.

4.5 SAFETY AND QUALITY OF RESEARCH

It is a requirement that all SA Health organisations 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.

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- Ongoing monitoring of research projects to ensure compliance with conditions of ethical approval, and ethical standards and guidelines.
- Undertaking appropriate risk management measures, for example 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.

4.5.1 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), it is a requirement that the Sponsor, 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.

4.5.2 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.

4.5.3 Safety Reporting for Clinical Drug and Device Trials

The AHEC *Position Statement: Monitoring and Reporting of Safety for Clinical Trials involving Therapeutic Products (2009)* outlines the responsibilities of all parties, including institutions, HRECs and clinical trial investigators and sponsors, in relation to reporting and monitoring adverse events that occur during a clinical trial. The requirements outlined in this Statement are supported by SA Health.

4.5.4 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.

4.5.5 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 Directive*.

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.

4.6. PUBLICATION AND AUTHORSHIP

4.6.1 Publications

As a general principle, the findings of research funded with public funding should be made available to the wider community to facilitate knowledge and understanding.

Publication of research results irrespective of whether they are favourable or unfavourable is considered good ethical practice, promoting transparency and knowledge, and is

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supported by SA Health. For these purposes, a 'publication' can be a hard copy, electronic copy or online (internet) publication. Project findings should also be appropriately communicated to research participants.

Publication of research findings and outcomes may be dependent on project funding arrangements and contractual obligations with project sponsors; agreed publication processes of participating organisations; and intellectual property considerations that may apply to the research.

It is the responsibility of the CPI to ensure any contractual requirements concerning publication of findings arranged with the project sponsor or funding body are honoured.

Where SA Health has a significant interest in a project, and / or where the findings of the project or nature of the project may be sensitive and reflect upon a policy, decision or practice of a SA Health organisation, SA Health through the nominated contact should be given the opportunity to review and comment on draft manuscripts before publication occurs.

SA Health should also be appropriately acknowledged in publications for projects for which it has contributed funding, resources or in-kind contributions, including publications authored by SA health employees.

4.6.2 Authorship

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 in publications. 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. As described in Section 5 of the *Australian Code*, 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.

4.7 RESEARCH AGREEMENTS

4.7.1 Non-standard agreements

Investigator-led collaborative projects and other multi-party research projects often require unique agreements to be developed that reflect the specific scope, purpose and arrangements of the research project across a number of areas.

SA Health requires a formal written agreement be developed for each multi-party research project that clearly specifies the responsibilities of each party involved in the project. The agreement should consider matters such as intellectual property; project funding; confidentiality and copyright; data management; responsibility for ethics and research governance approval; handling of disputes and dispute resolution; and reporting obligations.

It is recommended that SA Health organisations be provided with draft copies of research agreements early in the negotiation of the research project, to enable appropriate legal review of the agreement prior to finalisation. The RGO responsible for the organisation should be contacted to advise on these matters.

4.7.2 Clinical trial research agreements

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SA Health endorses the use of the current versions of each of the following standard clinical trial research agreements developed by Medicines Australia for new clinical trials being undertaken across SA Health:

1) Standard Clinical Trial Research Agreement for Commercially Sponsored Clinical Trials
2) Standard Clinical Trial Research Agreement for Contract Research Organisations
3) Standard Clinical Trial Research Agreement for Collaborative Research Group (CRG) Studies
4) Standard Clinical Trial Research Agreement for Phase IV Clinical Trials

Proposed variations to the standard clauses in the CTRAs must receive prior approval by the SA Health organisation before being accepted. The appropriate RGO should be contacted where variations to the standard clauses are proposed to determine the acceptability of the clauses before the CTRA is presented to the organisation for execution.

4.8 FINANCIAL MANAGEMENT

It is a requirement that funding provided for research undertaken across SA Health by SA Health employees is managed responsibly, in accordance with all applicable SA Health financial management requirements including (but not limited to) the *Special Purpose Fund Classification Policy Directive*.

Where projects involve funding contributed or managed by SA Health organisations, an appropriate finance authority (e.g. Finance Director or Head of Department/Division) with oversight of the cost centre should confirm the appropriateness of the budget and availability/use of funding for the project by endorsing the SSA specific to the research project.

Research that involves collaboration between multiple parties, including third parties such as universities or research institutes, and a SA public health organisation, should be governed by a research agreement that clearly outlines funding contributions and use of funding for the research project.

4.9 INTELLECTUAL PROPERTY

It is a requirement for SA Health to comply with the requirements of the SA Government *Intellectual Property Policy* (2006) and *Monetary Rewards Framework*.

The *Intellectual Property Policy* provides a framework for South Australian Government agencies to manage intellectual property. A key principle of this policy is that the Government should seek to retain ownership of Intellectual Property it has developed or substantially contributed to.

Intellectual property arrangements should always be considered prior to the commencement of a research project and formalised in a written agreement between the parties involved in the project.

In the event that intellectual property generated by research projects undertaken by SA Health employees is commercialised, 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.

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4.10 MANAGEMENT OF RESEARCH DATA

4.10.1 Retention and storage of data

Research data collected for approved research projects undertaken across SA Health should be handled, stored and disposed of in accordance with the requirements of the SA Health *Code of Fair Information Practice*, the *National Statement on Ethical Conduct in Human Research*, the *Australian Code* and any other applicable guidelines and policies.

Researchers should give appropriate consideration to the storage of data in such a way as to prevent inappropriate access (e.g. use of locked storage facilities or password protected computers), and must adhere to any conditions of HREC approval and/or research governance authorisation regarding data use, retention and storage.

4.10.2 Information privacy and confidentiality

For research that involves access to and use of personal information held by SA Health, the *Code of Fair Information Practice* outlines the requirements pertaining to the appropriate use of personal information. These requirements must be observed by SA Health organisations and researchers who may require access to personal information held by SA Health for the purposes of undertaking approved research.

As a principle and requirement of the *Code of Fair Information Practice*, SA Health organisations must take reasonable steps to protect personal information it holds from misuse and loss and from unauthorised access, modification or disclosure.

Where there is a requirement for a researcher to access personal information held in a registry, database or electronic system managed by SA Health, the SA Health data custodian is responsible for implementing procedures and processes to ensure appropriate anonymisation of personal information where required, and mechanisms to prevent the unauthorised disclosure of this information. Researchers are ultimately responsible for the appropriate management and use of personal information being utilised for research to ensure relevant confidentiality and privacy requirements are met.

4.11 INSURANCE AND INDEMNITY

All research projects hosted by SA Health involving SA Health or external staff must have appropriate insurance and indemnity prior to the project commencing.

For SA Health-investigator initiated research projects undertaken in accordance with employment arrangements, insurance cover is provided through SA Health's corporate insurance arrangements. The CPI must contact their RGO to ascertain whether their project is covered prior to submitting their SSA.

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 the RGO for review and endorsement prior to site authorisation.

A guide is available for RGOs to assist them in assessing each project's indemnity and is available on the SA Health Insurance Services intranet. SA Health's Legal Governance and Insurance Services (LGIS) unit is also available to assist RGOs where necessary in complex cases.

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The RGO or delegate should maintain current copies of insurance certificates and related documentation for research projects which have received site approval.

The RGO or delegate must provide a list of approved research projects and clinical trials to LGIS on a quarterly basis. LGIS will provide RGOs with a template for this purpose. Completed templates can be submitted to LGIS via the following e-mail: Health.LGISResearchTrials@sa.gov.au.

4.12 RESEARCH MISCONDUCT

It is a requirement that all organisations under the jurisdiction of SA Health that conduct 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.

4.13 CONFLICTS OF INTEREST

A conflict of interest may exist where there is a divergence between the individual interests of a person and their professional responsibilities such that an independent observer might reasonably conclude that the professional actions of that person are unduly influenced by their own interests. Conflicts of interest may be actual or perceived, and include professional, personal and financial conflicts of interest.

SA Health organisations are required to develop policies for managing conflicts of interest that apply to research conduct. Policies should address relevant conflicts that may arise in the context of research, and specify appropriate procedures and processes for managing conflicts of interest at an organisational level. Such policies should be published and made available to researchers and other staff.
Researchers are responsible for disclosing conflicts of interest in any applicable research ethics and research governance (SSA) applications, and must maintain appropriate records of activities that may lead to conflicts of interest. These records should be made available to the organisation if and where required. SA Health staff must also comply with

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the *Interaction between SA Health and the Therapeutic Goods Industry Policy Directive* (2015).

4.14 MANAGING SSA SUBMISSIONS

SA Health requires LHNs to manage SSA submissions use the recommended SA Health research management system. RGOs are required to maintain records of SSA applications, including correspondence and decisions relating to the review of SSAs, and record review times for SSAs to enable appropriate monitoring and reporting as required.

5. Roles and Responsibilities

Chief Executive, SA Health is responsible for ensuring the overall effective and responsible governance of research across the South Australian public health system.

Local Health Network Chief Executive Officers are responsible for:

- Ensuring staff are aware of the requirements outlined in this Policy Directive;
- Appointing a Research Governance Officer and support staff where required to fulfil the requirements of this Policy Directive; and
- Supporting a culture of responsible research practice across their Local Health Network.

Public Health Organisations
The Chief Executives / Executive Directors / General Managers (or equivalent) of public health organisations are responsible for ensuring all research undertaken at their site complies with the requirements of this Policy Directive.

Researchers who undertake research across SA Health either as employees of SA Health or external organisations are required to carry out their research in a professional, safe, ethical and competent manner in accordance with the requirements of this Policy Directive.

Research Governance Officers are responsible for ensuring the overall efficient and effective coordination of research governance applications, procedures and processes.

6. Reporting

Not applicable.

7. EPAS

Not applicable.

8. Exemption

There are no exemptions to the provisions of this Policy Directive.

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9. National Safety and Quality Health Service Standards

National Standard 1 Governance for Safety and Quality in Health Care	National Standard 2 Partnering with Consumers	National Standard 3 Preventing & Controlling Healthcare associated infections	National Standard 4 Medication Safety	National Standard 5 Patient Identification & Procedure Matching	National Standard 6 Clinical Handover	National Standard 7 Blood and Blood Products	National Standard 8 Preventing & Managing Pressure Injuries	National Standard 9 Recognising & Responding to Clinical Deterioration	National Standard 10 Preventing Falls & Harm from Falls
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10. Risk Management

A risk management approach underpins research governance across SA Health. LHNs and hospitals are responsible for establishing local guidelines, procedures and processes consistent with this Policy Directive to ensure the identification, mitigation and management of risks related to research governance.

11. Evaluation

This Policy Directive will be evaluated and reviewed five years from the date of initial approval in line with Department for Health and Ageing requirements. Updates to the Policy Directive may occur more frequently if required to ensure alignment with national and local research governance initiatives.

12. Definitions

In the context of this Policy Directive the following definitions apply:

Certified HREC means a Human Research Ethics Committee that has received certification by the NHMRC to undertake the single scientific and ethical review of a multi-centre research project.

Clinical trial research agreement (CTRA) means an agreement between a clinical trial sponsor and the organisation legally responsible for undertaking the clinical trial.

Coordinating Principal Investigator (CPI) means 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 means 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 means a hospital incorporated under the *Health Care Act* (2008).

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

National Mutual Acceptance (NMA) means the system for the single scientific and ethical review of human research projects across participating jurisdictions.

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Public health organisation means a publicly funded health care facility.

Principal Investigator (PI) means the lead investigator responsible for the conduct and management of a research project at a Site.

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

Research Governance Officer (RGO) means A person assigned to the management and oversight of research governance at the public health organisation.

Site means the public health organisation where the research project is being conducted.

Site Specific Assessment (SSA) means a research governance form that enables the public health organisation to determine whether the proposed research meets the standards and research governance requirements of the organisation.

SA Health means the health portfolio of services and agencies responsible to the Minister for Health, the Minister for Mental Health and Substance Abuse and the Minister for Ageing.

13. Associated Policy Directives / Policy Guidelines

- Code of Fair Information Practice (2006)
- SA Health Research Ethics Operational Policy Directive (2015)
- SA Health Special Purpose Fund Classification Policy Directive (2015)
- Interaction between SA Health and the Therapeutic Goods Industry Policy Directive (2015)

14. References, Resources and Related Documents

- Access to Unapproved Therapeutic Goods - Clinical Trials in Australia (TGA)
- Australian Code for the Responsible Conduct of Research (2007)
- Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (NHMRC)
- Framework for Monitoring: Guidance for the National Approach to single ethical review of multi-centre research (NHMRC, 2012)
- Guidelines to promote the Wellbeing of Animals Used for Scientific Purposes: The Assessment and Alleviation of Pain and Distress in Research Animals (NHMRC, 2008)
- International Conference on Harmonisation / Good Clinical Practice Guidelines (ICHGCP Guidelines)
- National Statement on Ethical Conduct in Human Research (NHMRC) (2007)
- NHMRC AHEC Position Statement, Monitoring and Reporting of Safety for Clinical Trials involving therapeutic products (2009)
- Research Governance Handbook: Guidance for the national approach to single ethical review (NHMRC, 2011)
- Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Research (NHMRC, 2003)

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