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Research Governance Policy Directive

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Government of South Australia
SA Health

Contents

Research Governance Policy Directive

1. Policy Statement

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* (2018) (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. 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.

3. Policy Requirements

3.1 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.

3.2 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

3.2.1 Completing a SSA

There are two main SSA forms for research being undertaken across SA Health:

- Site Specific Assessment Form for Research reviewed by a HREC.
- Ethics and Governance Assessment Form for Low and Negligible Risk Research reviewed under an expedited review process.

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.

3.2.2 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.

3.2.3 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.

3.3 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.

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.

3.4 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 Coordinating Principal Investigator (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.

3.4.1 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.

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.

3.4.2 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 monitoring activities for approved studies, including:

- Approval of protocol amendments
- Reviewing adverse events
- For clinical trials, review of safety information in accordance with the NHMRC's (2016) *Safety monitoring and reporting in clinical trials involving therapeutic goods*.
- Review of progress and annual reports in accordance with the approved research protocol and any conditions of ethical approval

3.4.3 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 PI 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.

3.5 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.
- 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.

Researchers should have a TransCelerate accredited Good Clinical Practice (GCP) certificate dated within 3 years (mandatory for all investigators involved in CTN/CTX clinical trials at a SA Health organisation and highly recommended for all other researchers).

3.5.1 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 requirements of the TGAs Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) scheme, as applicable. Further details on these schemes may be found on the TGA website.

3.5.2 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.

3.5.3 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.

3.5.4 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.

3.5.5 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 should be reached with a suitable IBC to permit review of these proposals.

3.5.6 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.

3.6. PUBLICATION AND AUTHORSHIP

3.6.1 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 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.

3.6.2 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.

3.7 RESEARCH AGREEMENTS

All research projects involving an SA Health organisation and one or more external parties must be supported by an approved research agreement prior to commencing that clearly outlines the responsibilities of each party. Agreements should be in writing and may take various forms, including a legal contract, an exchange of letters, or a research management plan agreed by all parties or representatives of all parties.

If the SA Health organisation proposes to delegate or sub-contract specific responsibilities within the research project to a third party, this must also be formalised within an appropriate agreement that outlines the scope and responsibilities of the third party, and provides the SA Health organisation with appropriate assurances that the third party has the relevant expertise to undertake the research activities, as well as conforming with any standard SA Health requirements such as insurance and indemnity requirements.

3.7.1 Non-standard agreements

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

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.

3.7.2 Contracting party requirements

For research projects involving SA Health and an external party, the research agreement must include the name of the correct SA Health legal entity that is supporting the research study. For clarification, this must be one of the following:

- Minister for Health and Wellbeing
- Department for Health and Wellbeing
- Barossa Hills Fleurieu Local Health Network Incorporated
- Central Adelaide Local Health Network Incorporated
- Eyre and Far North Local Health Network Incorporated
- Flinders and Upper North Local Health Network Incorporated
- Limestone Coast Local Health Network Incorporated
- Northern Adelaide Local Health Network Incorporated
- Riverland Mallee Coorong Local Health Network Incorporated
- Southern Adelaide Local Health Network Incorporated
- Women's and Children's Health Network Incorporated
- Yorke and Northern Local Health Network Incorporated
- SA Ambulance Service Incorporated

3.7.3 Clinical trial research agreements

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 and Medical Technology Association of Australia for technologies and devices being undertaken across SA Health:

1) Clinical Trial Research Agreement – Medicines Australia Standard Form
2) Clinical Trial Research Agreement - Contract Research Organisation acting as the Local Sponsor
3) Clinical Trial Research Agreement - Collaborative or Cooperative Research Group (CRG) Studies
4) Clinical Trial Research Agreement - Phase 4 Clinical Trial (Medicines)
5) Clinical Trial Research Agreement – Phase 4 Clinical Trial (Medicines) Contract Research Organisation Acting as the Local Sponsor

The current versions of the Medicines Australia clinical trial research agreements approved for use by SA Health can be accessed from Medicines Australia .

The current versions of the MTAA Clinical Investigation Research Agreements can be accessed from the Medical Technology Association of Australia website.

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.

3.8 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 officer with oversight of the cost centre should confirm the appropriateness of the budget and availability/use of funding for the project prior to research governance authorisation occurring.

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.

Funding received from external entities (e.g. a commercial project sponsor) must be supported by a research agreement that stipulates all payments to be made to the SA Health organisation across the project life cycle. The project budget must be reviewed and approved by the delegated organisational SA Health finance officer before being finalised in the research agreement. For commercially sponsored clinical trials, it is a requirement that these trials are fully funded by the external sponsor.

All research project funding being received from an external entity must be paid directly to the SA Health organisation named in the project agreement and not to a third party on behalf of the SA Health organisation. It is the responsibility of the SA Health organisation to ensure there is appropriate oversight and accountability with respect to research project payments and systems must be implemented to ensure project invoicing is kept up-to-date.

3.9 INTELLECTUAL PROPERTY

It is a requirement for SA Health organisations participating in research projects to comply with the requirements of the SA Government *Intellectual Property Policy* (2018) and associated SA Health Finance Intellectual Property and Associated Monetary Reward Payments Procedure (2018).

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.

3.10 MANAGEMENT OF RESEARCH DATA

3.10.1 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 *Privacy Policy Directive*, 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.

3.10.2 Information privacy and confidentiality

As a principle and requirement of the SA Health *Privacy Policy Directive*, SA Health organisations must take reasonable steps to protect personal information they hold 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 access to this information.

Research ethics 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) and section 106(2)(f) of the *Mental Health Act* (2009), disclosure or use of personal information for medical or social research purposes can only occur if the research methodology 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) that states, where possible, consent should be sought from the individual to participate in the research. Consent provided by an individual to participate in a research study must at all times be voluntary and be based on a thorough understanding of what involvement in the proposed research entails, including any risks of participation. 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 is separate to the use of that information for medical or social research 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 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.

In certain circumstances where use of de-identified information is not appropriate for the research study, or it is impracticable to seek consent from individuals, identifiable personal information (or human bio specimens) may be disclosed and utilised for research purposes if a waiver of consent is approved by the HREC under the relevant provisions of the National Statement.

The approval from a research ethics committee is only approval for a researcher to receive personal information that SA Health holds. It is not approval for the researcher to have direct access to SA Health systems or databases containing personal information. Any proposed access to SA Health electronic systems or databases by individual researchers for research purposes requires separate research governance approval through the institutional research governance processes, requiring all legal, policy, information security and research governance requirements to be met.

Research governance considerations

As part of the SSA 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.

De-identification of Personal Information
Unless informed consent has been obtained from the individual or a legally authorised person, or the research ethics committee has expressly approved otherwise, personal information used or disclosed for research purposes must be de-identified.

Generally de-identification includes two steps:

- 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, e.g. contextual identifiers due to a rare characteristic of the individual or their condition, or a combination of unique characteristics.

It is expected that only employees of SA Health will perform the de-identification process prior to releasing the information for research purposes.

3.10.3 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 will not be permitted access to SA Health electronic systems for research purposes due to the sensitivity of the personal information held on such systems.

Sunrise EMR and PAS
Any proposed access to the Sunrise EMR and PAS by a non-SA Health employee / student for research purposes requires authorisation by the Executive Director of Medical Services of the respective Local Health Network and a request must first be submitted through the appropriate SA Health Research Governance Officer for consideration. A research ethics committee is not authorised to provide such approval.

Where such access is being requested, the following must be taken into consideration by the Executive Director of Medical Services (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 be permitted. A waiver of consent approved by a HREC is not sufficient and is not considered an appropriate justification 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 SA Health *Criminal and Relevant History Screening Policy Directive*, 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 is required to 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: a suitable arrangement must be proposed for the supervision of the researcher while using the system/s by a SA Health staff member.

If all of the above requirements are satisfied, the EDMS may consider granting approval for this request, subject to the individual researcher signing a confidentiality deed and fulfilling any other SA Health requirements as determined by the EDMS.

Access to SA Health systems by clinical trial sponsors
External clinical trial monitors may be granted approval to access SA Health systems to undertake source data verification where there is a signed Clinical Trial Research Agreement governing the conduct of the clinical trial at the site/Local Health Network. This must be authorised by the appropriate EDMS. All considerations outlined in the preceding section must be satisfied for such access to be granted.

3.11 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.

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.

3.12 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.

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

3.14 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.

4. Implementation & Monitoring

Each Local Health Network through the Chief Executive Officer is responsible for implementing the requirements of this Policy Directive.

The Department for Health and Wellbeing Office for Research is responsible for monitoring the implementation of this Policy Directive in conjunction with the Local Health Networks.

The Local Health Networks will report on key research outputs and performance measures linked to this Policy Directive through their annual research report provided to the Chief Executive, SA Health, as a component of the Service Level Agreements.

5. 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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6. 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.

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 and Wellbeing.

7. Associated Policy Directives / Policy Guidelines and Resources

- SA Health Privacy Policy Directive (2017)
- SA Health Research Ethics Policy Directive (2020)
- SA Health Special Purpose Fund Classification Policy Directive (2015)
- SA Health Interaction between SA Health and the Therapeutic Goods Industry Policy Directive (2015)

8. Document Ownership & History

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