Policy

Policy Directive: compliance is mandatory

Research Ethics Operational Policy Directive

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Government of South Australia
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04/01/16	V.3	Portfolio Executive	NMA and general updates, removal of obsolete material
01/07/13	V.2	Portfolio Executive	Inclusion of NMA requirements
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1. Objective

SA Health is committed to supporting the conduct of high quality health and medical research across the South Australian public health system.

It is important that research involving human participants is conducted in a manner that respects and protects all involved, including the researcher, the research participants and the Institution. Obtaining research ethics approval helps to ensure that the research is carried out professionally and takes into account relevant legal, ethical, organisational and cultural standards.

SA Health has an obligation to ensure that research being conducted within the South Australian public health system by staff or external researchers is of a high standard and observes all ethical requirements in accordance with applicable guidelines and standards, including the NHMRC's *National Statement on the Ethical Conduct of Human Research* (hereafter referred to as the "National Statement").

This Policy Directive outlines the operational requirements for Human Research Ethics Committees (HRECs) under the jurisdiction of SA Health, and outlines requirements for researchers wishing to conduct research within the South Australian public health system.

2. Scope

This Policy Directive applies to all human research being conducted within the South Australian public health system. This includes:

- Clinical trials.
- Clinical research.
- Health services research.
- Population health research.
- Epidemiological research.
- Tissues banking.
- Data linkage research.
- Qualitative health research.

The Policy Directive applies equally to SA Health employees and non-SA Health employees who are undertaking approved research across SA Health.

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 ensuring sufficient protection for patients, research participants and public health organisations.
- The efficient and effective administration of research ethics applications will be ensured through the use of standard procedures across SA Health HRECs.

4. Detail

4.1 STREAMLINED ETHICAL REVIEW

SA Health promotes efficiency in the ethical and scientific review of research projects being undertaken across SA Health by ensuring that reviews are sufficiently rigorous, undertaken in accordance with the risk level of the project, and are conducted with reference to the National Statement and other relevant guidelines.

SA Health supports two approaches for streamlined review based upon the mutual recognition of ethical review by properly constituted HRECs. These approaches are complementary, and provide two pathways for researchers conducting research within the South Australian public health system to efficiently gain ethical approval:

- The SA Health Single Ethical Review Model – for research taking place within the South Australian public health system only.
- National Mutual Acceptance – for multi-centre human research projects taking place across participating Australian jurisdictions (public health organisations only).

4.2 SA HEALTH SINGLE ETHICAL REVIEW MODEL

1. Every research project which is to be conducted at a site under the jurisdiction of SA Health will be ethically and scientifically reviewed once only by a SA Health HREC (single review). The reviewing committee is designated the lead HREC.
2. All sites under the jurisdiction of SA Health that are participating in the proposed research will accept the review of the lead HREC without further ethical or scientific consideration.
3. The research ethics applicant (the Coordinating Principal Investigator or CPI) will select a lead HREC to undertake single review from a register of HRECs on the SA Health ethics website. Generally, this lead committee will be located at the institution of the CPI. The applicant will assume responsibility for submitting all required documentation in accordance with SA Health and local HREC requirements.
4. Lead HRECs must be appropriately constituted in accordance with the requirements of the NHMRC, and fulfil the requirements of the National Statement (section 5.2). Additionally they must have access to the required expertise to undertake a full scientific and ethical review of the type of research which is submitted.
5. Every research application must undergo a separate research governance review at each site where the research is to be conducted to permit consideration and approval of the research governance requirements at that site (a site specific assessment). This is distinct from the scientific and ethical review by the lead HREC.
6. The lead HREC will be responsible for the full scientific and ethical review of the research application. Once completed, the lead HREC will be responsible for notifying the CPI of the outcome of the review. It is the CPIs responsibility to notify the outcome of this review to each of the other sites where the project is proposed to take place, via the Research Governance Officer associated with the site/s.
7. Under this model, HRECs will have the right to refuse to consider a multi-site application only under the following circumstances:
   i. The HREC Chairperson determines there is insufficient expertise on or available to the HREC to permit an adequate scientific and ethical review of the proposal; or
   ii. The HREC is not able to review the proposal in a timely manner (e.g. the meeting agenda for the next HREC meeting has reached capacity).

8. In these circumstances (7 [i] and [ii]), the HREC should notify the applicant as soon as practicable in order that they can then submit to another suitable SA Health HREC.
9. The South Australian Aboriginal Health Research Ethics Committee (AHREC) reviews all research applications where the focus is on a topic or disease/health burden identified as being of specific concern to Aboriginal and Torres Strait Islander people (based on 4.7.6 of the National Statement, 2007). In addition to a research application having been submitted to and reviewed by SA Health HREC, proposals are required to be submitted to the AHREC if:
    - The experience of Aboriginal and Torres Strait Islander people is an explicit focus of all or part of the research; or
    - Data collection is explicitly directed at Aboriginal and Torres Strait Islander people; or
    - Where it is proposed to separately identify Aboriginal and Torres Strait Islander people in the results; or
    - The information has an impact on one or more Aboriginal and Torres Strait Islander communities; or
    - The geographic location of the research is such that a significant number of the population are likely to be of Aboriginal and Torres Strait Islander origin (based on 4.7.6 of the National Statement, 2007); or
    - Where terms such as 'resilience'; 'well-being'; 'cultural safely'; 'cultural health'; and 'language and culture' are used in the description and design of the project indicating that the project has important health implications; or
    - Aboriginal and Torres Strait Islander health funds are a source of funding.

10. The CPI should provide the AHREC with a copy of the research application and the lead HRECs ethical determination on the project for consideration as soon as practicable. The AHREC will then provide their evaluation of the project to the lead HREC for consideration prior to providing feedback to the applicant. The AHREC will expedite their review where possible.

11. Ethics applications predominantly involving access to a database or data registry held by a SA Health organisations should be submitted to the SA Health HREC affiliated with the organisation. If there are multiple sites involved, the applicant should only apply to one HREC.

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

13. Any multi-site project where the primary data being used for the project is held by the Department for Health and Ageing (e.g. ISAAC, SAMSS or Cancer Registry Data) may be submitted to the Department for Health and Ageing HREC for review as the lead HREC.

14. Projects that have been reviewed by a HREC outside the jurisdiction of SA Health may be reviewed again at the discretion of a SA Health HREC. However, if the research is being undertaken at multiple SA Health sites, these projects should only be reviewed once by an additional SA Health HREC to minimise further duplication of review.

15. If a research site is added to an existing project with lead HREC approval, SA Health requires that the CPI completes a Site Specific Assessment (SSA) form and submits this to the Research Governance Officer (RGO) responsible for that site along with a copy of the lead HREC's approval letter.

16. For quality assurance purposes, HRECs that have jurisdiction over the sites where the research is being undertaken (but who have not performed the lead ethical review) may choose to conduct a full ethical and scientific review of up to two submissions which have been previously reviewed by a lead SA Health HREC. These reviews will be provided to the lead HREC. This quality assurance review may happen concurrently with the initial review or subsequently. When it happens subsequent to the initial review, the original review outcome will still apply.

4.3 NATIONAL MUTUAL ACCEPTANCE

National Mutual Acceptance (NMA) supports the single scientific and ethical review of multi-centre human research projects across participating Australian jurisdictions (public health organisations). SA Health currently participates in NMA, along with Victoria, New South Wales and Queensland. Other jurisdictions may participate in the future. The Standard Principles for Operation for NMA, available on the SA Health website provide the overarching framework for NMA and should be referred to by SA Health HRECs, researchers and others who may be involved in seeking approval to undertake research using the NMA system.

NMA permits the review of any form of human research, as defined in the National Statement on Ethical Conduct in Human Research (2007) or any replacement of that document published by the National Health and Medical Research Council (NHMRC), for which an application must be made to an HREC for the purpose of research being conducted at a public health organisation. This includes low and negligible risk research review by a full HREC using a national ethics form (National Ethics Application Form).

In accordance with the Standard Principles for Operation, SA Health organisations are required to accept the approval of a NHMRC Certified HREC for a project submitted under NMA without requiring further ethical and scientific review. There are two categories of research that are exempt from being considered under NMA, being Phase 0 (first time in human) and Phase 1 Clinical Trials, and Aboriginal and Torres Strait Islander Projects. For further details on the two exemption areas, refer to section 8 of this Policy Directive.
A list of Certified HRECs can be found here.

4.3.1 SA Health HREC Certification

The following SA Health HRECs have been certified by the NHMRC to undertake review in the categories of research outlined.

Women's and Children's Health Network Human Research Ethics Committee (EC00197)

Certification categories:

- Clinical trials phase I, II, III, IV.
- Clinical trials drugs and devices.
- Clinical trials surgery.
- Clinical trials other.
- Clinical interventional research other than clinical trials.
- Population health and/or public health.
- Qualitative research.
- Mental health.
- Paediatric research.
- Other health and medical research:
    - Women's health.
    - Genetic studies.
    - Oncology.
    - Tissue banking.

Southern Adelaide Clinical Human Research Ethics Committee (EC00188)

Certification categories:

- Clinical trials phase II, III, IV.
- Qualitative research.
- Mental health.
- Paediatric research.
- Other health and medical research:
    - Palliative care.
    - Oncology.
    - Intensive care.

Royal Adelaide Hospital Human Research Ethics Committee (EC00192)

Certification categories:

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

Human Research Ethics Committee (TQEH/LMH/MH) (EC00190)

Certification categories:

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

SA Department for Health and Ageing Human Research Ethics Committee (EC00304)

Certification categories:

- Population health and/or public health.
- Qualitative research.
- Mental health.
- Other health and medical research:
    - Data linkage research.

4.3.2 Procedures for SA Health HRECs acting as the 'lead' HREC for NMA

1. South Australian researchers who wish to undertake a new research project eligible for review under NMA should identify an appropriate Certified SA Health HREC (the 'lead' HREC).
2. The CPI should submit their ethics protocol to the HREC affiliated with their employing public health organisation, where possible.
3. The CPI must complete the ethics application using the National Ethics Application Form (or its replacement) hosted on Online Forms.
4. The lead HREC should review the ethics protocol in accordance with their standard operating procedures, and usual committee processes.

5. A timeframe of 60 days (the 60 day clock) will apply to the ethical and scientific review of proposals.
6. Once the review of the protocol is complete, the lead HREC will notify the CPI of the outcome of the ethical and scientific review.
7. The CPI will be responsible for communicating the outcomes of the ethical and scientific review to all participating research sites through their Principal Investigators.
8. Where a protocol is not approved, the CPI may resubmit the protocol to the lead HREC, providing the grounds for non-approval are remedied.
9. The lead HREC will be responsible for reviewing any amendments to the protocol that are submitted during the life of the research project. In all cases, the CPI is responsible for notifying other participating sites of the outcomes of the review rather than the HREC.
10. The lead HREC will be responsible for reviewing all adverse events that may occur during the life of the research project.

4.4 ETHICS FORM REQUIREMENTS

The National Ethics Application Form (NEAF) has been developed by the NHMRC as a standardised human research ethics application form that may be accepted by Australian research ethics committees. A licensed version of the NEAF is available on Online Forms.

SA Health supports the use of the NEAF (and in the future, its replacement) and the following guidelines should be observed.

4.4.1 SA Health only research

For multi-centre research proposals being conducted across SA Health, SA Health HRECs are encouraged to accept the NEAF. Ethics applicants may discuss alternative application forms with the reviewing HREC. For single-site research only, the HREC may choose to accept proposals using a locally developed ethics application form or the NEAF.

4.4.2 National Mutual Acceptance

The NEAF (and in the future, its replacement) is a requirement for all research ethics proposals submitted under NMA.

4.5 ETHICS APPLICATION SUBMISSION

SA Health HRECs are responsible for ensuring human research ethics submission requirements are published appropriately and readily available to applicants.

While the electronic submission of HREC applications is preferable, each SA Health HREC is responsible for developing submission guidelines that meet their individual needs.

The ethics applicant is responsible for submitting all required documents to the HREC in accordance with the submission requirements.

4.5.1 Low and Negligible Risk Research

The National Statement enables HRECs to adopt processes for expediting the review of low risk projects. Low risk projects are those where the 'only foreseeable risk is one of discomfort', while negligible risk projects include those which may only involve 'inconvenience' to research participants. Projects that are of negligible risk only may be exempt from ethical review.

SA Health HRECs should have clear and documented processes for expediting the review of low risk project applications included in their SOPs. These processes should be consistent with the requirements of NMA in relation to low and negligible risk research (refer to section 4.3 of this Policy Directive).

To facilitate the efficient review of research applications deemed to be low/negligible risk within South Australia **only**, SA Health has developed a Low and Negligible Risk (LNR) Ethics Application Form that should be supported by SA Health HRECs. This form is available for researchers on Online Forms.

The determination as to whether a project qualifies as low or negligible risk must be made by the reviewing HREC in consultation with the National Statement. Interventional studies including clinical trials generally should not be considered for expedited review as they are not typically 'low risk', and nor should projects involving research on sensitive personal or cultural issues or involving 'at risk' individuals or groups.

Researchers should contact their local HREC office to discuss the proposed research and identify whether the project may be considered for expedited review.

4.6 BENCHMARKS FOR REVIEW: THE 60 DAY CLOCK

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

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

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

4.7 STANDARD OPERATING PROCEDURES

SA public health system HRECs are required to develop and publish their own standard operating procedures (SOPs) that describe how their HREC operates. The SOPs must be made available to all HREC members and research ethics applicants, and should be maintained and updated appropriately.

4.8 HREC COMPLAINTS AND APPEALS PROCESS

Section 5.1(4) of the National Statement requires institutions to establish processes to handle complaints concerning research. Where a SA public health system HREC rejects a research proposal outright on ethical grounds, makes an unfavourable decision about a component of the research proposal, or fails to reach a decision about the ethics of a research proposal, the investigator has the following rights:

a) Where a proposal has been rejected, the investigator may submit a new application to the HREC, taking due account of the HREC's concerns. The revised application will be processed and reviewed in accordance with the HREC's usual processes; or
b) Where (a) does not apply, the investigator may lodge a written appeal with the HREC Chairperson specifying the grounds of the appeal. The Chairperson will investigate the appeal, and recommend to the HREC the appropriate course of action within 4 weeks from the date of the appeal being lodged. The HREC will notify the appellant of the course of action and determination in a timely manner.

4.8.1 Appeals Mechanism

Following an appeal being lodged to the HREC Chairperson, if the appellant considers that the HREC has not followed due process or remains unsatisfied with the outcome, they may choose to lodge an appeal with the Chief Executive Officer / delegate responsible for the HREC.

The following process will be followed:

a) The Chairperson will provide the Chief Executive Officer / delegate with all relevant material, including:
    a. Details of the appeal;
    b. Material reviewed by the HREC; and
    c. The outcome/decision of the ethical review process.

b) The Chief Executive Officer / delegate will determine if further investigation of the appeal is necessary. If so, a panel will be established to consider the appeal. The panel will include the following members:
    a. The Chief Executive Officer / delegate;
    b. Two nominees of the Chief Executive Officer / delegate (not members of the HREC);
    c. At least one nominee with relevant expertise in human research ethics; and
    d. Expert(s) in a discipline of research related to the project under consideration.

c) The panel will allow the HREC and the appellant the opportunity to make submissions.

d) The Chief Executive Officer / delegate will notify the HREC and the appellant of the outcome of the investigation. The possible outcomes include:
    a. The appeal is dismissed; or
    b. The appeal is upheld and the panel makes recommendation to resolve the issues based on the findings of the panel. The panel does not have the authority to approve an ethics application, but may choose to refer an ethics application to an independent ethics committee for re-review.

If the panel or Chief Executive Officer / delegate requests that a second ethical review is required as a recommendation of the investigation, an alternative SA public health system HREC (where possible) with suitable expertise and no prior involvement in the matter will be invited to undertake this review.

The panel or Chief Executive Officer / delegate cannot reverse the final determination of any HREC.

4.9 USE OF APPROVED AND UNAPPROVED MEDICINES AND MEDICAL DEVICES

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

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

4.10 CLINICAL RESEARCH TRIALS CONDUCTED UNDER THE CTN OR CTX SCHEMES

The TGA permits the use of unregistered or unapproved medicines or medical devices to assess their safety and efficacy within the context of a monitored clinical research trial

under Sections 18 and 19 of the *Therapeutic Goods Act* (1989). This is done through either the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) schemes.

For the CTN scheme, the reviewing HREC has sole responsibility for reviewing all the data relating to the trial, such as safety data pertaining to the investigative medicine or device. It also has responsibility for making a determination about the scientific and ethical merit of the trial.

For the CTX scheme, the TGA has responsibility for reviewing relevant data including preclinical data pertaining to the investigative medicine or device. The TGA's review of this data is taken into account by the reviewing HREC, who will then make a determination about the scientific and ethical merit of the trial as a whole.

Under both schemes, the reviewing HREC has the authority to approve (or reject) the trial based on the scientific and ethical merit of the trial.

4.11 REGULATION OF GENE TECHNOLOGIES AND RELATED THERAPIES

Health and medical researchers in South Australia are legally required to comply with the *Gene Technology Act* (2001) and the *Gene Technology Regulations* (2002) for research involving Genetically Modified Organisms.

SA Health facilities in which researchers are using gene technology must be accredited and maintain, or have an established link with, a properly constituted Institutional Biosafety Committee (IBC) within a collaborating organisation.

Any formal review provided by an IBC should be given to the lead HREC by the applicant upon submission of a new application for review.

All research protocols involving gene therapy and related gene technologies including xenotransplantation must be submitted to a HREC for review.

Research involving embryos must comply with the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryos Research Amendment Act* (2006), and the *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* (NHMRC, 2007).

4.12 IONISING RADIATION

All research involving any form of radiation must comply with relevant National and State legislation, organisational policies and procedures, and codes and standards of practice provided by the NHMRC and the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).

SA Health HRECs assessing research proposals involving exposure of participants to ionising radiation must be provided with a written report from an accredited medical physicist.

In South Australia, the Environment Protection Authority (EPA) has responsibility for administering the *Environmental Protection Act* (1993) and *Radiation Protection and Control Act* (1982). The Radiation Protection Branch of the EPA must be notified of all research involving exposure of research participants to ionising radiation. This form should be used for notification purposes.

4.13 RESEARCH INVOLVING SA HEALTH DATA

For research ethics applications that require access to data or confidential information held by SA Health, it is a requirement that access be granted on the basis of ethical

approval from an appropriate Certified HREC and project authorisation by the appropriate Institution/s, following submission of a complete and satisfactory SSA.

For projects being undertaken in South Australia only, the CPI should contact the HREC affiliated with their Institution to determine whether it is able to review the ethics application.

Any SA based project where the primary data being used for the project is held by the Department for Health and Ageing (e.g. ISAAC or Cancer Registry Data) may be submitted to the Department for Health and Ageing HREC for ethical review.

The data custodian has ultimate responsibility to approve or refuse the release of data for a specific research project, independent of the ethical determination made by the reviewing HREC.

4.14 ADVERSE EVENTS REPORTING

Upon ethical approval of a research application, the lead HREC shall require notification of anything which might warrant review of the ethical approval of the project, including serious and unexpected adverse events (SAEs). If the adverse event applies to participants at a specific site, the HREC associated with this site should be notified. If it applies to all sites equally, then reports should be provided to each of the associated HRECs. The Coordinating Principal Investigator is responsible for reporting adverse events.

For multi-centre clinical trials, the reporting of serious adverse events or serious adverse reactions should follow the requirements of the NHMRC AHEC Position Statement. The Statement sets out the monitoring and reporting requirements, including reporting of adverse events, for clinical trials. A HREC may impose additional reporting requirements reflecting the degree of risk of the research to participants.

The HREC SOP's should outline the specific adverse event reporting requirements of the local HREC.

4.15 COMPLAINTS PROCESS

Each SA Health HREC is responsible for maintaining an appropriate complaints process for health and medical research projects that undergo ethics review and/or ethics approval that should consider:

- Complaints made by research participants and/or research (or other) staff concerning the conduct of approved research being undertaken at an Institution;
- Complaints made by ethics applicants regarding the ethical review process and/or outcome.

The process for dealing with such complaints should be documented in the HREC SOPs, and be published on the local HREC website.

SA Health organisations must also have policies and/or procedures for managing complaints related to health and medical research projects in the event the complaint cannot be resolved by the HREC, or falls outside the scope of the HREC responsibilities.

4.16 SUSPENSION OR WITHDRAWAL OF RESEARCH ETHICS APPROVAL

SA Health HRECs reserve the right to suspend activity on an approved research project should the CPI fail to observe the HRECs conditions of approval or any other reasonable requirement of the HREC. Grounds for suspending the activity on a project may include:

- Failure to provide regular (at least annual) reports of progress;

- The reporting of a serious adverse event that poses a risk to other participants involved in the research at the local Institution;
- A complaint issued by a research participant and/or staff member that has ethical or scientific implications for the ongoing conduct of the project.

It is recommended that each SA Health HREC has documented processes that outline how breaches of ethical approval will be managed. These processes should be included in the HREC SOPs, and provide a consistent and transparent approach to these issues.

All matters concerning possible breaches of research ethics approval should be dealt with in a timely manner, and any decision to either suspend or withdraw ethics approval should be communicated clearly to all key parties involved with the conduct of the project.

4.17 DATA STORAGE, RETENTION AND DISPOSAL REQUIREMENTS

4.17.1 SA Health records management requirements

SA Health organisations are required to comply with the specific organisational requirements that apply to the retention, storage and disposal of HREC related materials, and research material and data specifically outlined in the *General Disposal Schedule No. 28: Clinical and Client-Related Records of Public Health Units in South Australia (Section 6: Research and Ethics)*.

4.17.2 General requirements for researchers

Researchers are responsible for ensuring appropriate arrangements with respect to the collection, storage and disposal of research materials including data, in compliance with all applicable requirements. Access to data and information collected during the conduct of research should be limited to those who are directly involved in the conduct of the project, and mechanisms such as use of locked filing cabinets or password protected computers may be warranted. Arrangements should be established for the ongoing handling of research materials in the event the investigator leaves the organisation.

The Australian Code (section 2) outlines general requirements for the retention of research data, which should be observed by researchers undertaking approved research across SA Health:

- In general, the minimum recommended period for retention of research data is 5 years from the date of publication. However, in any particular case, the period for which data should be retained should be determined by the specific type of research. For example:
    - For short term research projects, that are for assessment purposes only (e.g. research projects completed by students), retention of research data for 12 months after completion of the project may be sufficient.
    - For clinical trials, data should be retained for a minimum of 15 years for adult studies or 25 years for paediatric studies after formal notification is received that all study procedures are completed and the study is closed.
    - For areas such as gene therapy, research data must be retained permanently (e.g. patient records).
    - If the work has community or heritage value, research data should be kept permanently, preferably within a national collection.

4.18 RESEARCH MONITORING

Under the National Statement (chapter 5.5), it is a responsibility of the Institution hosting the research to monitor the conduct of approved research.

Across the SA public health system, this function should be undertaken by the HREC and/or RGO that has provided the ethical and/or research governance approval for the

project. Institutions must establish processes whereby approved research is effectively monitored.

Research monitoring may include:

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

The level of monitoring that is undertaken should correspond to the risk profile of the project. The CPI has a significant responsibility to monitor the research over the course of the project, and advise the Institution, via the HREC or RGO, of matters which may impact the ethical and scientific acceptability of the project, or site (research governance) acceptance of the project.

NMA applicants, HRECs and RGOs should refer to the NMA *Monitoring and Reporting Framework* available on the SA Health website for further guidance.

4.19 MANAGEMENT OF HREC APPLICATIONS

SA Health requires HRECs to use the approved research management system for all research ethics submissions. HRECs are required to maintain complete records of human research ethics applications, including correspondence and decisions relating to the review of HREC submissions, in accordance with the requirements of Section 5 of the *National Statement*. SA Health HRECs are also required to record review times for HREC submissions using the approved research management system to enable appropriate monitoring and reporting as required.

5. Roles and Responsibilities

Local Health Network Chief Executive Officers are responsible for:

- Ensuring staff are aware of the requirements outlined in this Policy Directive;
- Providing appropriate resources and support for Human Research Ethics Committees under their jurisdiction; and
- Supporting a culture of responsible research practice across their Local Health Network.

SA Health HRECs are responsible for the ethical review of research projects being undertaken across SA Health, and ongoing monitoring of approved projects, in accordance with their Standard Operating Procedures, the requirements of the *National Statement of Ethical Conduct in Human Research*, and other legislative, policy and operational requirements.

Researchers are responsible for undertaking research across SA Health in a safe and ethical manner, in compliance with this Policy Directive and all relevant policies, guidelines and procedures.

6. Reporting

Not applicable.

7. EPAS

Not applicable.

8. Exemption

NMA exemptions – South Australia
The following categories of research are exempt from being considered under NMA:

1) Phase 0 (first time in human) and Phase 1 clinical trials: where a Certified HREC from another jurisdiction has provided prior approval for a Phase 0 or Phase 1 clinical trial application, these applications will be re-reviewed ethically by the appropriate HREC in South Australia.

2) Aboriginal and Torres Strait Islander projects
Approval from the Aboriginal Health Research Ethics Committee (AHREC), South Australia, will be required where:
   - The experience of South Australian Aboriginal and Torres Strait Islander people is an explicit focus of all or part of the research; or
   - Data collection is explicitly directed at South Australian Aboriginal and Torres Strait Islander people; or
   - Where it is proposed to separately identify South Australian Aboriginal and Torres Strait Islander people in the results; or
   - The information has an impact on one or more South Australian Aboriginal and Torres Strait Islander communities; or
   - The geographic location of the research is such that a significant number of the population are likely to be of Aboriginal and Torres Strait Islander origin (based on 4.7.6 of the National Statement, 2007); or
   - Where terms such as 'resilience'; 'well-being'; 'cultural safely'; 'cultural health'; and 'language and culture' are used in the description and design of the project indicating that the project has important health implications; or
   - South Australian Aboriginal and Torres Strait Islander health funds are a source of funding.

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 the consideration and approval of research ethics applications across SA Health. LHNs and SA Health HRECs 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 ethics.

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 ethics initiatives.

12. Definitions

In the context of this document:

AHREC means Aboriginal Health Research Ethics Committee.

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 means a research study designed to test the safety and/or efficacy of a medical treatment or intervention, often involving a treatment and control arm.

CTN means the Clinical Trial Notification scheme developed by the Therapeutic Goods Administration (TGA) to permit unregistered medicines and medical devices to be used in the context of a clinical research trial. For CTN trials, the local HREC is solely responsible for reviewing and determining the safety and appropriateness of the medicine/device in the context of the trial.

CTX means the Clinical Trial Exemption scheme developed by the Therapeutic Goods Administration (TGA) to permit unregistered medicines and medical devices to be used in the context of a clinical research trial. For CTX trials, the TGA is also involved in assessing the safety and appropriateness of the medicine/device in the context of the 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.

HREC means Human Research Ethics Committee.

IBC means Institutional Biosafety Committee.

ISAAC means the Integrated South Australian Activity Collection (ISAAC), an admitted patient morbidity data collection maintained by SA Health.

Lead HREC means the human research ethics committee responsible for the single ethical and scientific review of a research ethics application.

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

National Statement means The NHMRC's *National Statement on Ethical Conduct in Human Research* (2007).

NEAF means the National Ethics Application Form.

NHMRC means National Health and Medical Research Council.

NHMRC Certified HREC means an institution/HREC that has been certified by the NHMRC to undertake the single scientific and ethical review of human research projects.

OACIS means an electronic clinical patient information system owned by SA Health.

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

RGO means Research Governance Officer.

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

SAE means: Serious Adverse Event.

SOP means: Standard Operating Procedure.

SSA means: Site Specific Assessment.

TGA means: Therapeutic Goods Administration.

13. Associated Policy Directives / Policy Guidelines

SA Health Research Governance Policy Directive (2015)
SA Health Code of Fair Information Practice (2006)
General Disposal Schedule No. 28: Clinical and Client-Related Records of Public Health Units in South Australia (2014).

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)
- Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (NHMRC) (2007)
- International Conference on Harmonisation / Good Clinical Practice Guidelines (ICHGCP Guidelines)
- National Statement on Ethical Conduct in Human Research (NHMRC) (2007)
- NHMRC Position Statement: Monitoring and Reporting of Safety for Clinical Trials (2009)
- Prohibition of Human Cloning for Reproduction and Regulation of Human Embryos Research Amendment Act (2006)
- Standard Principles for Operation (National Mutual Acceptance) (2015)
- Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Research (NHMRC) (2003)