1. Overview

SAHMRI’s vision is to transform research into better health outcomes. In order to achieve this vision, our researchers are committed to undertaking high-quality and innovative health and medical research that can be transformed into practical benefits for patients and the community.

SAHMRI is committed to the conduct of methodologically and ethically sound research that complies with the Australian Code for the Responsible Conduct of Research (“the Code”), and other national guidelines in relation to values and community engagement.

Our research will be conducted with:

- Honesty and integrity;
- Respect for human participants, animals and the environment;
- Responsible use of public resources to conduct research;
- Appropriate acknowledgement of the role of others in research; and
- Responsible communication of research results.

The procedures outlined below are intended to provide a framework for ensuring monitoring and compliance by SAHMRI and its researchers. The procedures are based on the understanding that researchers associated with SAHMRI are committed to excellence and high standards of professional conduct, and that their work enhances the good name of SAHMRI and the profession to which they belong.

2. Responsibilities of SAHMRI researchers

SAHMRI researchers are required to comply with the following:

- **Australian Code for the Responsible Conduct of Research** (the Code);
- SAHMRI Procedures for Research Practice and any other relevant SAHMRI policies, procedures and guidelines as well as any applicable national guidelines including those covering ethical requirements for human and animal studies, requirements for confidentiality, occupational health and safety matters, and requirements for use of potentially hazardous agents; and
- NHMRC approved standards and guidelines on the NHMRC website which include, but are not limited to:
  - National Statement on Ethical Conduct in Human Research;
  - Guidelines Approved under Section 95A of the Privacy Act 1988;
  - Guidelines Issued under Section 95 of the Privacy Act 1988;
  - National Principles of Intellectual Property Management for Publicly Funded Research;
• Guidelines for Genetic Registers and Associated Genetic Material;
• Australian Code of Practice for the Care and Use of Animals for Scientific Purposes;
• Guidelines to Promote the Wellbeing of Animals Used for Scientific Purposes - the assessment and alleviation of pain and distress in research animals.

All researchers associated with SAHMRI research activities, as outlined in the NHMRC Researchers’ Main Responsibilities, the Code and the SAHMRI Procedures for Research Practice, are expected to:

- Maintain high standards of responsible research;
- Report research responsibly;
- Respect research participants;
- Respect animals used in research;
- Respect the environment; and
- Report research misconduct.

2.1 Aboriginal and Torres Strait Islander peoples
Researchers associated with SAHMRI acknowledge and value Aboriginal and Torres Strait Islander peoples and communities:

Researchers are expected to read the Code in conjunction with Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (NHMRC 2003) and the Guidelines for Ethical Research in Indigenous Studies (Australian Institute of Aboriginal and Torres Strait Islander Studies 2012).

SAHMRI Researchers are also required to conduct research in accordance with the South Australian Aboriginal Health Research Accord, developed by Wardliparingga. The Accord has been developed through a series of consultations with Aboriginal Elders, organisations and community members. The South Australian Aboriginal Health Research Accord sets out nine principles by which Aboriginal health research in South Australia should be conducted. The principles within the Accord apply beyond Aboriginal Health research and the relevance of them relates to all research and activities within SAHMRI and encourages a ‘culture of excellence’ in health and medical research.

PRIORITIES: Research should be conducted on priorities arising from and endorsed by the Aboriginal community to enhance acceptability, relevance and accountability.

INVOLVEMENT: The involvement of Aboriginal people and organisations is essential in developing, implementing and translating research.

PARTNERSHIP: Research should be based on the establishment of mutual trust, and equivalent partnerships, and the ability to work competently across cultures.
RESPECT: Researchers must demonstrate respect for Aboriginal knowledge, Aboriginal knowledge systems and custodianship of that knowledge.

COMMUNICATION: Communication must be culturally and community relevant and involve a willingness to listen and learn.

RECIPROCITY: Research should deliver tangible benefits to Aboriginal communities. These benefits should be determined by Aboriginal people themselves and consider outcomes and processes during, and as a result of, the research.

OWNERSHIP: Researchers should acknowledge, respect, and protect Aboriginal intellectual property rights and ensure transparent negotiation of intellectual property use and benefit sharing.

CONTROL: Researchers must ensure the respectful and culturally appropriate management of all biological and non-biological research materials.

KNOWLEDGE TRANSLATION AND EXCHANGE: Sharing and translation of knowledge generated through research must be integrated into all elements of the research process to maximise impact on policy and practice.

2.2 Diversity and equity in health and medical research
SAHMRI supports diversity and equality within the Institution and is committed to ensuring that staff, researchers and students/trainees work in an environment free from discrimination, victimisation, harassment and bullying. For more information, please refer to the SAHMRI Equality in Employment Policy.

Additionally, SAHMRI acknowledges and is committed to the NHMRC gender equity principles, including the progression and retention of women in health and medical research. To support this, SAHMRI has implemented an Institution-wide Gender Equity Strategy. For more information, please, contact SAHMRI's Gender Equity Project Officer, Ms Sandra Elias.

2.3 Consumer and community engagement
SAHMRI researchers are encouraged to engage and facilitate consumer and community participation in their research with a commitment to transforming research into better health outcomes. This is a priority area for SAHMRI, evidenced by the establishment of the SAHMRI Consumer Engagement Committee. SAHMRI, in collaboration with Health Consumers Alliance SA, has prepared a Consumer Engagement Framework which all staff should be familiar with.

In addition, researchers are expected to be familiar with the Statement on Consumer and Community Participation in Health and Medical Research (NHMRC and Consumers’ Health Forum of Australia Inc. 2002).
2.4 Research conduct
Research activity within SAHMRI must only be undertaken following appropriate human and/or animal research ethics committee approval (see section 3.12). If required, approvals for the use of genetically modified organisms, carcinogenic/toxic chemicals and human/animal stem cells must also be obtained prior to commencement of research. Research conducted within SAHMRI also requires Research Governance notification by submitting the relevant approval documentation to the SAHMRI Research Office. In accordance with the Code, misconduct in research will be taken very seriously by SAHMRI (see section 3.13).

3. Guidelines regarding specific areas of responsible research conduct

3.1. Management of research materials, data and records
Researchers involved in any SAHMRI research activity must act in accordance with the Code to ensure that all research material, data (including electronic data), laboratory books and/or records are maintained, retained and stored in a durable, compliant and appropriately referenced form. SAHMRI researchers are responsible for ensuring appropriate security for all confidential material and research data, including electronic data.

All researchers associated with SAHMRI research activities, as outlined in the Code are expected to:
- Record their research methods (including experimental plan, design, data, results and outcomes) in an approved laboratory book. The laboratory book should be reviewed on a regular basis by the laboratory leader;
- Record the location of the laboratory book/s, research data and primary materials (hard and electronic copies);
- Maintain and retain the laboratory book/s, research data and primary materials;
- Manage the storage of research data, data sources including any approvals granted, and primary materials; and
- Maintain confidentiality of research data and primary materials, if required.

Whenever possible, original materials and data must be retained within the SAHMRI Theme or Group in which they were generated. Data should be held for sufficient time to allow reference. Researchers should refer to the Code, section 2.1.1 for specific suggested periods of material/data retention dependent on the type of research. The process for the secure and safe disposal of research data and primary materials when the specified period of retention has finished should be decided in-conjunction with the relevant Research Manager.

When data are obtained from limited access databases, or via a contractual arrangement, written indication of the location of the original data, or key information regarding the database from which it was collected, must be retained by the researcher.
and the responsible SAHMRI Theme or Group. Clinical trial data accessed at SAHMRI must be in accordance with the SA Health Data Retention Policy and the SAHMRI Information Security Management System Policy.

Where confidentiality provisions apply (for example, where the researchers or Institution have given undertakings to third parties, such as the subjects of the research), data must be kept in a way that reference to them by third parties can occur without breaching such confidentiality.

3.2 Hospital sites
When research is being undertaken at external sites to SAHMRI, including but not limited to hospital sites, supervisors must ensure that all researchers are aware of, and comply with, the appropriate confidentiality procedures and local codes of conduct, this is particularly important for students/trainees and early career researchers.

3.3 Reporting to research funding bodies
The lead researcher or chief investigator receiving funding for a research activity or equipment item is the person responsible for reporting to the funding body, and as otherwise required. SAHMRI researchers receiving research grant funding from the NHMRC or any other funding body (government or private sponsor) must comply with reporting processes as specified by the funding body.

3.4 Supervision of research students and/or trainees
Supervisors must ensure appropriate induction and ongoing advice is provided to students/trainees on the Code, SAHMRI’s principles for research practice, the management of research materials/data, records, applicable guidelines including those covering ethical approvals for research studies, requirements for confidentiality, work health and safety matters, and requirements for the use of potentially hazardous agents.

3.5 Applying for funding
Grant applications where SAHMRI is the Administering Institution are to be submitted to the funding body by the Research Office unless alternative arrangements have been made through prior consultation.

It is the responsibility of the applicant to contact the Research Office at least two weeks prior to the due date of any intended grant application to allow for adequate administration. For NHMRC funding applications, a signed Grant Application Cover Sheet must be provided to the Research Office before a review of the application can be undertaken.

Letters of support, signatures, referee reports and any other additional documentation required as part of a grant application are the responsibility of the applicant to arrange and ensure that they are included in the final version of the application to be submitted to the funding body.
The applicant is responsible for obtaining consent from other researchers (chief investigators and associate investigators) to be named on a grant application, if this is required. For NHMRC funding schemes, copies of the consents are to be provided to the Research Office before an application can be submitted.

All ethical approvals and/or safety clearances that are required for the research to be undertaken are the responsibility of the applicant to arrange. The relevant documentation must be provided to the Research Office.

For NHMRC funded research, the chief investigator is required to complete ethics data at award in the Research Grants Management System (RGMS) before payments can commence. This information is required to be certified by the Research Office in RGMS.

3.6 Intellectual property
Please refer to the SAHMRI Intellectual Property Policy (Policy Number 025).

3.7 Publication and dissemination of research findings
SAHMRI encourages its researchers to publish and disseminate their research in the most effective manner to allow access by other researchers and the wider community and at the earliest opportunity. SAHMRI adopts the principles of the Code for publication and dissemination of research findings. Publication and dissemination includes but is not limited to journal articles, correspondences, public announcements, conference and/or seminar presentations, advertising materials, research reports or other materials.

All reasonable steps must be taken to ensure that research findings, statistics, cited references and public statements about research activities are complete, accurate and unambiguous.

In order that SAHMRI’s achievements and investment in research receive appropriate acknowledgement and contribute to relevant measures of performance, SAHMRI is to be attributed as the affiliated Institution by all SAHMRI staff and students/trainees. This should be the case when the work was conducted at SAHMRI or elsewhere, even if the author has subsequently left the Institution. Joint publications of collaborative research projects must acknowledge all relevant institutions/organisations.

For publication and dissemination of research activities funded by the NHMRC, the acknowledgement requirements are outlined in the NHMRC Funding Agreement, Clause 20.Clause 20.2 indicates:

Any material published in respect of a Research Activity must:

a. include the Grant Identification Number for the Research Activity; and
b. specify that the contents of the published material are solely the responsibility of the Administering Institution, a Participating Institution or individual authors and do not reflect the views of NHMRC.

Clauses 20.3 and 20.4 indicate that the NHMRC logo must not be used without NHMRC’s prior written consent to that specific use of the logo, which the NHMRC may give, refuse or revoke in its absolute discretion. This includes its font, colour, size and placement.

Published journal articles and other research reports must be deposited into SAHMRI’s open access institutional repository as soon as possible following the date of publication.

3.8 Authorship
SAHMRI adopts the principles of the Code for attribution of authorship in the publication of research findings.

Authorship is significant partaking, requiring the:
- conception and design, or analysis and interpretation of data;
- drafting the article or revising it critically for important intellectual content; and
- final approval of the publication version.

When there is more than one author of a research output, one author should be nominated as executive author for the whole research output, and should take responsibility for record keeping regarding the research output.

Any part of an article critical to its main conclusion should be the responsibility of at least one author. An author’s role in a research output should be sufficient for that person to take public responsibility for at least that part of the output in the person’s area of expertise.

Authors should ensure that others who have contributed to the work are recognised in the research output and that the work of research students and/or trainees, research assistants and technical officers is properly acknowledged. Individuals and/or organisations that provided facilities that contributed to the research activity should also be acknowledged.

Disputes over authorship may arise (for example, regarding conflict of interest or authorship order). Where researchers are unable to reach mutual agreement on an issue of authorship, the following procedures may apply:

1. Any person involved in the dispute may seek advice from the Designated Person (Dr Leanne Sutherland) or Post-Graduate Student Coordinator (if involving Higher Degree Research students). A record of the dispute will be made in the Authorship Dispute Register, maintained by the SAHMRI Research Office.
2. Continuing disputes over authorship may be referred to the SAHMRI Theme Leader of the corresponding author for attempted resolution. Disputes involving co-authors from other institutions are to be handled by the institution of the corresponding author.

3. If the dispute remains unresolved after 30 days of acknowledgement, it may be referred to the SAHMRI Executive Director for determination. The Executive Director may engage an external arbitrator or mediator to assist in this process, although the final decision remains with the Executive Director.

4. Any determination made as part of a dispute resolution will be recorded in the Authorship Dispute Register but will not be considered as grounds for findings of research misconduct. However, proceeding to publication without agreement or formal determination of authorship following an acknowledged dispute may be considered a breach of the Code or a case of research misconduct.

3.9 Peer review
SAHMRI recognises the importance of peer review and encourages its researchers to participate in the peer review process, this includes but is not limited to the preparation of research publications, grant applications, rebuttals, interviews, conference and seminar presentations. Peer review should be undertaken and contributed to in a fair and timely manner. Participants have a responsibility to declare any conflicts of interest.

3.10 Conflict of interest
Researchers have an obligation to disclose to their Manager and the Chief Operating Officer any conflict of interest which has the potential to influence research activities and/or outputs, this includes but is not limited to publications (for example, in authorship), public announcements, grant applications and applications for appointment and promotion. These may be a personal, financial or other interest which may represent an actual, potential or perceived conflict of interest. For more information on conflict of interest, please refer to the SAHMRI Code of Conduct Policy.

Disputes involving conflict of interests (for example, authorship) should be reported to the SAHMRI Designated Person (Dr Leanne Sutherland) or Post-Graduate Student Coordinator (if involving Higher Degree Research students) for advice and assistance in timely resolution. A record of the dispute and outcome will be made in the Conflict of Interest Register, maintained by the SAHMRI Research Office.

3.11 Confidentiality
If data of a confidential nature are obtained, for example from individual patient records or from certain questionnaires, confidentiality must be observed and researchers must not use such information for their own personal advantage or that of a third party. Confidentiality may also be necessary for a limited period in the case of contracted research or of non-contractual research, which is under consideration for patent protection.
Confidentiality agreements may be required between SAHMRI, other Institutions, a researcher and/or a funder of the research.

**3.12 Ethical review of research applications**

SAHMRI researchers have an obligation to achieve and maintain the highest standards of ethical honesty in the conduct of their research.

SAHMRI staff undertaking research involving animal experimentation, human participants (including surveys for research purposes), genetically modified organisms, carcinogenic/toxic chemicals or human or animal stem cells must have their research approved and monitored by a relevant authorised regulatory body. The research activity is unable to commence until the researchers involved have undertaken any required training.

In accordance with the provisions and processes identified by the relevant authorised regulatory body, all SAHMRI researchers are expected to:

- obtain relevant consents and approvals, including variations to research protocols, and maintain evidence of such approvals;
- comply with any relevant legislation, guidelines, policies and directives;
- comply with the requirement for monitoring and reporting on their research activities;
- provide relevant information about their research and research data, including progress reports, as requested; and
- notify the relevant authorised body immediately of any adverse events or experiences in their research that may be of concern in respect of ethical or safety matters.

Where the research has been funded, SAHMRI will notify the funding body and/or any other body immediately of any instances of non-compliance.

Research conducted within SAHMRI will also require Research Governance notification by submitting copies of all relevant approval documentation to the SAHMRI Research Office.

Research must be approved and monitored by a relevant authorised body, as outlined below:

- proposals involving experimentation with animals are to be submitted to the SAHMRI Animal Ethics Committee;
- proposals involving the participation of human subjects, or the use of human tissue or blood, or those that involve participation of or may impact on Indigenous peoples, are to be submitted to a relevant authorised regulatory Human Research Ethics Committee;
- proposals involving the use of clinical drugs in research trials must be submitted to a relevant authorised regulatory Clinical Drug Trials Committee;
proposals involving biosafety matters including experimentation involving genetic modification or work with a genetically modified organisms; carcinogens; toxic substances; and infectious substances; must be submitted to the SAHMRI Biosafety Committee;

- proposals involving radiation, where appropriate, must be submitted to the SAHMRI Radiation Safety Officer;

- where a proposal may involve research with significant hazards advice should be sought from the SAHMRI Director of Research Support Services and, where appropriate, a relevant authorised regulatory body.

3.13 Research integrity
SAHMRI is committed to the conduct of methodologically and ethically sound research that complies with the core principles of research conduct as outlined by the Code:

- Honesty and Integrity;
- Respect for human participants, animals and the environment;
- Responsible use of public resources to conduct research;
- Appropriate acknowledgement of the role of others in research; and
- Responsible communication of research results.

Concerns or allegations regarding breaches of the Code, research misconduct or fraud in research will be taken very seriously by SAHMRI. These may include, but are not limited to, the following:

- fabrication of data: claiming results where none has been obtained;
- falsification of data, including changing records;
- plagiarism, including the direct copying of textual material, the use from other people without adequate attribution;
- inclusion of inaccurate or misleading information relating to a research activity;
- misleading ascription of authorship, including the listing of authors without their permission, attributing work to others who have not in fact contributed to the research, and the lack of appropriate acknowledgment of the work of a student/trainee or associate;
- other practices that seriously deviate from those commonly accepted within the research community for proposing, conducting or reporting research;
- an infringement of SAHMRI’s research policies and procedures on research conduct or other research related policies that is either intentional or caused by negligence;
- negligence, or failure to uphold commonly accepted standards in the conduct of research within the relevant field of research.

Misconduct does not generally include honest errors, or honest differences in interpretation or judgement about data.

Staff are encouraged to contact the Designated Person in the first instance to discuss any concerns, please see the flowchart below for further detail. A complaint alleging
research misconduct may be made in writing or orally to the Designated Person, confidentiality will be maintained throughout this process. Conflicts of interest must also be reported and will be managed.

Designated Person
SAHMRI has appointed a senior staff member from the Research Office as the Designated Person. Any allegation of research misconduct should be made to the Designated Person who will obtain the information required to undertake an initial assessment. The documentation will then be discussed in detail with the Research Integrity Advisor. Following assessment of whether the allegation can or cannot be dismissed, the matter will then be directed to the Executive Director as appropriate. Dr Leanne Sutherland is the Research Misconduct Designated Person.

Advisor in Research Integrity
The Research Integrity Advisory can provide confidential advice to staff, students or other persons about:

- Actions that might constitute misconduct;
- The rights and responsibilities of the complainant; and
- The procedures that will apply in the handling of allegations of research misconduct at SAHMRI.

Professor Maria Makrides is SAHMRI's Advisor in Research Integrity.

In the case of research funded by grant funding bodies, the mechanism to handle complaints and allegations of research misconduct will be compliant with the grant funding bodies policy/s in relation to research misconduct (for example, the NHMRC, as per Part B of the Code).

All records of complaints and/or allegations of research misconduct and any related correspondence (internal and external) will be securely located within the SAHMRI Research Office. Privacy in all matters will be upheld in accordance with the Guidelines Approved under Section 95A of the Privacy Act 1988 (2001) and the Guidelines Issued under Section 95 of the Privacy Act 1988 (2000).
Once a complaint or allegation has been received by the Designated Person

Designated Person informs the Research Integrity Advisor and provides any information that the complainant has presented about the matter

Designated Officer undertakes preliminary investigation and recommends whether a case for a formal inquiry exists and what form it should take

If an investigation is to be undertaken

Designated Officer and Research Integrity Advisor convenes an internal investigation panel and makes the appropriate notifications

If research misconduct is established

Designated Officer will discuss with Executive Director who will advise the person against whom the allegation was made and inform what disciplinary actions are to be taken

If that person contests the finding of the internal investigation panel

Designated Officer will refer the matter to an independent external research misconduct panel and will ensure that procedural fairness is afforded to the person against whom the allegation has been made

External panel makes a decision taking into account results of internal finding plus submissions put by person against whom finding is made

Decision communicated to the Executive Director, person who made allegation, person against whom allegation made, any funding body, SAHMRI Board

If research misconduct is established

External panel will make a recommendation as to the appropriate course of action