STANDARD OPERATING PROCEDURES

ABORIGINAL HEALTH RESEARCH ETHICS COMMITTEE (AHREC)

1 MEETINGS

1.1 Operations

1.1.1 Meetings will be held a minimum of eight times per calendar year, excluding January.

1.1.2 Meeting dates and due dates for application submission are published on the AHCSA website.

1.1.3 Meetings are conducted virtually via videoconference (Microsoft Teams), unless booked otherwise.

1.1.4 Quorum:

- As per the *National Statement 5.2.3*, as far as is practicable, each meeting should be arranged to enable attendance of all members of the minimum membership categories. Where there is less than full attendance at a meeting, the Chair must be satisfied, before a decision is reached, that the view of those absent who belong to the minimum membership have been received and considered *(National Statement 5.2.5)*.
- If the quorum is lost during the meeting, decisions will be finalised out of session.

1.1.5 Attendance of people other than committee members may be permitted. External experts and invited observers are bound by the same confidentiality and disclosure of interest requirements as the AHREC members. At the discretion of the Chair/s, researchers may be invited to be present for discussion of, but not deliberations about, their proposed research.

1.2 Agenda

1.2.1 The AHREC Secretariat prepares an agenda for each meeting.

1.2.2 The meeting agenda and supporting documents are circulated to members electronically, ideally two weeks prior to the meeting date.

1.2.3 Research proposals received after submission due date are included on the agenda and/or tabled at the meeting at the discretion of the Chair/s and/or AHREC Secretariat.

1.2.4 In general, the agenda should include the following items:

- Acknowledgement of Country
- Attendance and apologies
- Conflict of interest declarations related to any of the agenda items
- Confirmation of the previous meeting minutes
- New research proposals seeking initial approval

- Approved research proposals seeking approval of modification/s, extension, and progress and final reports
- Researcher responses to requests for further information
- Any other business
- Date and time of next meeting

1.2.5 The following supporting documents may be provided with the agenda:

- Draft minutes of the previous meeting
- For new research proposals, a copy of the completed AHREC application form and attachments such as research protocol, participant information sheet and consent form, promotional material and data collection tools

1.2.6 The agenda and supporting documentation are confidential.

1.3 Conduct of meeting

1.3.1 The committee will conduct a robust and in-depth review of each application in line with the requirements of the *National Statement*, and with respect to the *Guidelines for ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities*.

1.3.2 The committee will endeavour to reach a decision concerning the ethical acceptability of a research proposal by general agreement. Any significant minority view (i.e., two or more members) will be noted in the meeting minutes.

1.3.3 The committee decision may include:

a) Approved
b) Approved, subject to additional conditions
c) Further information requested
    i. for out of session review by AHREC Secretariat or delegated member/s
    ii. for full committee review at a scheduled meeting
d) Not reviewed (outside committee scope)
e) Not approved (substantial revision to be reviewed by the full committee at a scheduled meeting)
f) Not approved (final decision)

1.3.4 All decisions will be recorded in the meeting minutes.

Declaration of conflict of interest

1.3.5 As a standing agenda item, members are required to declare any interest that may constitute a conflict of interest that is related to the research under review, including any:

- personal involvement or participation in the research
- financial or other interest in a research proposal or affiliation with a researcher
- involvement in competing research (e.g., research in the same field)

1.3.6 Declarations are to be made in writing to the Chair/s or AHREC Secretariat prior to the meeting, or prior to the matter being considered at the meeting. The committee determines whether the level of interest results in a substantial or non-substantial conflict of interest. A member may be asked to leave the meeting until deliberation of the agenda item has concluded, or they may not be scheduled to attend the meeting in its entirety.

1.3.7 The meeting minutes record all declarations of interest and the decisions of the committee on the procedure(s) to be followed.

Confidentiality

1.3.8 AHREC meetings are held in private, and members are encouraged to raise matters of concern. The meeting agenda and minutes, research proposals, supporting documentation and correspondence are all treated confidentially.

1.3.9 Attendance of visitors or observers at a meeting, as appropriate and approved by the Chair/s, is conditional on the attendee signing a confidentiality agreement.

1.3.10 AHREC correspondence is addressed to the Principal Researcher and sent to the Principal Researcher and the relevant contact person identified on the AHREC application form. Correspondence is not released to any other parties.

1.4 Preparation of minutes

1.4.1 Minutes are prepared by the AHREC Secretariat in consultation with the Chair/s and other members as necessary.

1.4.2 The minutes reflect each item listed for discussion on the agenda:

- Attendance and apologies
- Declarations of conflict of interest relating to agenda items
- Confirmation of minutes of the previous AHREC meeting
- Business arising since the previous meeting(s) that the committee indicated it wished to consider
- New research proposals seeking initial approval: committee deliberations and decisions, including summaries of the main issues considered
- Approved research proposals seeking approval of modification/s, extension, and progress and final reports: committee deliberations and decisions, including summaries of the main issues considered
- Researcher responses to requests for further information: committee deliberations and decisions
- Any other business: summary of each topic discussed
- Date and time of next meeting

1.4.3 The draft minutes are distributed via email to the members present at the meeting within two weeks of the meeting date. If a member declared a conflict of interest to an agenda

item/s, the member will be sent a version of the minutes without the relevant agenda item/s.

1.4.4 The minutes are submitted to the next meeting of the committee for ratification as a true record. Members are given the opportunity to seek amendments to the minutes prior to finalisation.

1.4.5 The minutes are confidential to the committee and are not disclosed to applicants.

2 APPLICATION PROCESS

2.1 Enquiries

Enquiries are frequently received from researchers as to whether a research proposal should be submitted to the AHREC and/or the format and content of applications. These enquiries are directed to the AHREC Secretariat.

2.1.1 Researchers should be asked to provide additional information about the proposal by email, if possible, such as a research synopsis or plan.

2.1.2 Guidance as to whether a research proposal should be submitted is available on the AHCSA website.

2.1.3 Additional information to assist in determining whether a project is a quality assurance or evaluation activity or a research proposal requiring ethical review can be found via the *Ethical considerations in quality assurance and evaluation activities*.

2.1.4 If further advice is required, the AHREC Secretariat should consult with the AHREC Chair/s.

2.1.5 Any correspondence generated through the enquiry (email advice to the researcher and/or from the Chair/s) should be retained in accordance with record keeping guidance outlined in section 3 below.

2.2 Administration

2.2.1 All research proposals are submitted according to the process set out on the AHCSA website.

2.2.2 New research proposals are reviewed by the full committee at a scheduled meeting and must include:

- completed AHREC application form
- study documents for approval (e.g., research protocol, participant information sheet and consent form, data collection instruments such as surveys, yarning/interview guides, and promotional/recruitment material)
- written confirmation of support (letter, email) for the research from relevant stakeholders, such as Aboriginal Community Controlled Health Organisations (ACCHOs) acting as study sites
- other ethics committee approval letters

- any other material that may assist the committee to conduct their review

2.2.3 The AHREC Secretariat conducts a preliminary assessment for all submitted applications to check for completeness and compliance with submission instructions, and to determine whether the application is within the AHREC scope for review.

2.2.4 For accepted applications, the AHREC Secretariat will respond to the researcher acknowledging receipt of the submission and confirming its inclusion on the agenda for the next scheduled meeting.

2.2.5 Applications that are incomplete, out of scope or vary significantly from the submission instructions may be returned to the researcher by the AHREC Secretariat, with a request for resubmission. This request will outline the revisions required and provide relevant guidance on how to address them. The revised application should be resubmitted for review by the full committee at a future scheduled meeting.

2.3 Review

2.3.1 New research proposals seeking initial approval will be listed on the meeting agenda.

2.3.2 Following the preliminary assessment by the AHREC Secretariat, two primary reviewers will be allocated to each new research proposal on the meeting agenda. Committee members may be assigned as a primary reviewer based on their area of expertise, membership category, connections to community or availability to review.

2.3.3 The primary reviewers will undertake a thorough review of the research proposal and associated documents and lead the committee's discussion and deliberation at the meeting.

2.3.4 The Chair/s will undertake a review of each application on the meeting agenda. Other members attending the meeting are also encouraged to review each application.

2.3.5 Reviews should be undertaken in a thorough and timely manner. In general, members should align their review to the characteristics of their allocated membership category. For example, community representatives may focus on engagement and participant recruitment, or the information and language used in participant-facing documents.

Criteria for assessment

2.3.6 In evaluating research proposals for ethical approval, committee members will ensure the applications meet the requirements of the *National Statement on Ethical Conduct in Human Research*.

2.3.7 Additional reference documents used by committee members to the determine ethical acceptability of research proposals include the *Guidelines for ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities* and the *South Australian Aboriginal Health Research Accord*.

2.3.8 All research submitted to AHREC must place the needs, priorities and wellbeing of the South Australian Aboriginal community before the needs of the study and present a

partnership approach at all phases with a feasible knowledge translation strategy involving relevant Aboriginal organisations.

2.3.9 All research submitted to AHREC must meet with good research practice and present rigorous methodology in terms of quantitative representativeness and qualitative data saturation. The methodology should be designed to adequately answer the research questions and achieve meaningful research outcomes for the South Australian Aboriginal community.

2.4 Decisions

2.4.1 Members present at the meeting are allowed reasonable opportunity to express relevant views on agenda items prior to any decision being made.

2.4.2 AHREC endeavours to reach its decisions by unanimous agreement (including on all matters concerning the ethical acceptability of a research proposal).

2.4.3 Where a unanimous decision cannot be reached, the matter is determined by a majority of members present at the meeting.

2.4.4 Discussions of significant issues and decisions are recorded in the meeting minutes. Committee members have the right to have their view recorded. For example, members can request their formal dissent from the decision of the committee be recorded in the meeting minutes.

2.4.5 To encourage free and open discussion and to emphasise the collegiate character of the committee, particular views are not attributed to individuals in the meeting minutes, except in circumstances where a member requests to have their opinions or objections recorded.

2.4.6 A committee member who is unable to attend a meeting may submit written comments regarding agenda items to the AHREC Secretariat prior to the meeting.

Decision making

2.4.7 The Chair/s will ensure one of the following decisions is made for each new application on the agenda:

a) Approved
b) Approved, subject to additional conditions
c) Further information requested
    i. responses to be reviewed out of session review by AHREC Secretariat or delegated member/s
    ii. responses to be reviewed by the full committee review at a scheduled meeting
d) Not reviewed (research proposal is outside committee scope)
e) Not approved (substantial revision for full committee review at a scheduled meeting)
f) Not approved (final decision)

2.4.8 All decisions are recorded in the meeting minutes.

2.4.9 Where the decision made is 'Further information requested - responses to be reviewed out of session by delegated member/s':

- the AHREC Secretariat will review the researcher responses for completeness and allocate to the delegated members,
- the Chair/s will provide final approval of the application,
- the outcome will be reported at the next scheduled meeting and recorded in the minutes.

The delegated member/s may choose to take the responses back to the full committee for consideration, either at a scheduled meeting or out of session.

Standard approval conditions

2.4.10 The following standard approval conditions will be applied and included in the outcome letter.

The Principal Researcher will:

1. immediately report anything that might warrant a review of the ethical approval of the project,
2. notify the AHREC of any event that requires a modification of the research protocol or other study documents and submit any required modifications in accordance with the process set out on the AHCSA website,
3. submit any necessary reports related to the safety of research participants in accordance with AHREC policy and procedures,
4. report to the AHREC annually using the AHREC Reporting Template and notify the committee when the research is completed at all study sites,
5. notify the AHREC if the research is discontinued at a participating study site before the expected completion date, with reasons provided,
6. notify the AHREC of any plan to extend the duration of the research project past the approval period and submit any associated required documentation,
7. notify the AHREC of their inability to continue as the Principal Researcher and provide the name and contact information for a replacement.

Additional conditions of ethical approval may be set for any application.

2.5 Notification of outcomes

2.5.1 The Principal Researcher is notified of the outcome of the committee review in a letter from the Chair/s. The letter will be prepared by the AHREC Secretariat using the corresponding letter template and sent via email.

2.5.2 The outcome letter will clearly communicate the committee decision and include an explicit statement that the research proposal meets or does not meet the requirements of the *National Statement*.

2.6 Modifications, extensions and annual reports

2.6.1 Requests for a modification to an approved research proposal, extension of ethical approval and annual progress reports are reviewed out of session by one or more delegated committee members and/or the Chair/s. Where possible, the delegated committee member/s should be the primary reviewers of the original proposal.

2.6.2 Annual progress reports and extension requests may be approved on behalf of the committee by the AHREC Secretariat or Chair/s.

2.6.3 The AHREC Secretariat will review the modification/extension request for completeness and allocate to the delegated members. The Chair/s will provide final approval of the request.

2.6.4 The AHREC Secretariat will notify the applicant of the outcome using the corresponding letter template.

2.6.5 The outcome of modifications and extension requests that are reviewed out of session will be reported at the next scheduled meeting and decisions recorded in the minutes.

2.6.6 Approval of modifications and extensions will not be granted unless an annual progress report has been submitted within the preceding 12 months (as per the conditions of approval). If an annual progress report is due or overdue, the researcher will be asked to complete the Annual Report form, which will be sent to the reviewers with the modification or extension request.

3 RECORD KEEPING

3.1 Maintenance of records

3.1.1 The AHREC Secretariat is responsible for ensuring:

- Files are kept securely and confidentially
- Files are up to date and complete
- AHREC maintains it electronic records only

3.1.2 Files are kept securely and confidentially for a minimum of 7 years. Records relating to research projects are kept for a minimum of 7 years after the completion date of the project.

3.1.3 Records may be retained after the minimum period or disposed of in a secure manner.

3.2 Access to records

3.2.1 The AHREC Secretariat has day-to-day access to the electronic files and records of the committee.

3.2.2 Requests for access to records by any other parties should be directed to the AHREC Secretariat or the Chair/s and will be considered on a case-by-case basis, considering the importance of maintaining security and confidentiality of information.

3.2.3 External parties accessing AHREC records may be required to sign a confidentiality agreement prior to access, including AHCSA staff who are not members of AHREC.

3.3 Records of meetings

3.3.1 Electronic records of all meetings are maintained (including agendas and minutes) as an electronic file. The minutes record discussions and decisions relating to general issues and consideration of research proposals.

3.4 Records of membership

3.4.1 The committee maintains a record, including resumes, biographies, contact details and conflicts of interest of AHREC members.

3.5 Records of applications

3.5.1 The committee maintains the following files:

a) Register of all applications received and reviewed in accordance with the *National Statement 5.2.19*, including but not limited to the:
- application identification number
- date application received
- application status
- research title
- name of the principal researcher(s)
- date application reviewed
- outcome of the review
- date of approval

b) Register of complaints

3.5.2 The committee retains a copy of all applications for ethics review, including approved project documentation and any relevant correspondence.

3.6 Other records

3.6.1 The committee maintains electronic records of any other business of the AHREC including:

- Reports to external bodies such as the AHCSA Board, NHMRC, Department for Health and Wellbeing, SA Health
- Member training
- Presentations
- Policies and procedures
- Research issues
- Involvement with other organisations, committees or initiatives
- Funding matters

4 MONITORING OF APPROVED RESEARCH

The primary responsibility for ensuring that research is reliably monitored lies with the institution under which the research is conducted (*National Statement 5.5)*.

4.1. AHREC monitors approved research applications to ensure compliance with the conditions of approval and to protect the rights, safety and welfare of participants and their communities.

4.2. AHREC requires, as a condition of approval, that the Principal Researcher provide the committee with:

a) annual progress reports for the duration of the approval,
b) adverse event reports and protocol deviations, at the time they occur, and
c) a final report at the conclusion of the research project.

4.3. Report templates are available on the AHCSA website.

4.4. The committee may request additional information to monitor individual projects depending on the complexity, design and risk perceived. This may include:

- discussion with the Principal Research and research team
- interview with research participants
- inspection of research sites, data or consent documentation (with permission sought through the appropriate channels, e.g., the CEO or Research Governance Officer where the research is undertaken)

4.5. Reminders will be sent to the Principal Researcher from the AHREC Secretariat to submit annual progress reports.

4.6. Reporting and handling of adverse events

4.6.1. It is a condition of project approval that any serious or adverse event is reported to the AHREC within 72 hours of the event taking place. The report should be submitted to the AHREC Secretariat using the 'AHREC-Reporting-Template-Revised-1.1'.

4.6.2. The AHREC Secretariat will notify the Chair/s upon receipt of the report, to consider the next steps for the committee in responding to the report. An appropriate response may include (but is not limited to):

- review by the full committee
- deliberation and decision delegated to the Chair/s
- suspension of AHREC approval for the research project
- withdrawal of AHREC approval
- recording of the event on the project file
- request for modification to the research protocol

4.6.3. Where the decision is made to suspend AHREC approval, the committee will advise the research institution where the research is undertaken, that the research should be instructed to stop.

4.6.4. Where the decision is made to withdraw AHREC approval, the research team, research institution and the research participants (where possible) will be informed of withdrawal. The researcher is required to halt the research activities, and continuation is subject to resubmission and reapproval by the AHREC.

4.7. Receiving and handling complaints

4.7.1. Complaints may be related to the conduct of the research or the research team, or the conduct or decision of the AHREC.

4.7.2. Complaints regarding the conduct of the research or the research team are reported to the AHREC Secretariat. The appropriate course of action will be determined in consultation with the Chair/s according to requirements of the:

- AHCSA *Complaints and Feedback Policy*
- AHCSA *Complaints and Feedback Procedure*
- NHMRC *Australian Code for the Responsible Conduct of Research*
- NHMRC *Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research*

4.7.3. Complaints regarding the conduct or decision of the AHREC should be made in writing to the Chair/s, detailing the grounds of the complaint, for their consideration.

4.7.4. If, after making an appeal in line with the steps outlined above, the appellant is dissatisfied with the outcome, they have the discretion to lodge an appeal with AHREC Secretariat or the Chair of the AHCSA Board or request the AHREC Chair/s to do so.

4.7.5. Documentation relating to a complaint is kept in the project file and is logged in the complaints register.

4.8. Suspension or withdrawal of ethics approval

4.8.1. Where AHREC has reason to believe that continuance of a research project will compromise participants' welfare or if the conditions of ethics approval (including reporting requirements) are not being adhered to, AHREC will immediately seek to establish whether ethics approval for the project should be suspended or withdrawn.

4.8.2. The Chair/s will send a notification letter to the Principal Researcher outlining the committee's concerns.

4.8.3. The Chair/s will determine the appropriate investigative action, which may include:

a) convening a subcommittee to investigate the matter,
b) seeking advice from other members of the committee or external persons,
c) seeking a response from the Principal Researcher, and/or
d) conducting interviews with relevant parties.

4.8.4. The investigation process should ensure that researchers and others involved in the project are treated fairly and with respect.

4.8.5. Where ethics approval for a research project is withdrawn by AHREC, the researcher, research institution and, where possible, the research participants should be informed of the withdrawal. Suspension of ethics approval can relate to some of or all the research activities.

4.8.6. If ethics approval is suspended or withdrawn, the research must be discontinued until further notice.

4.8.7. AHREC will not provide approval for the research to be resumed unless either:

a) the Principal Researcher establishes that continuance will not compromise participants' welfare, or
b) the research is modified to provide sufficient protection for participants, the modification is reviewed by AHREC, and the modification is approved by AHREC.