Aboriginal Health and Medical Research Council of NSW

Human Research Ethics Committee

Secretariat Standard Operating Procedures (SOPS)

NHMRC Registration: EC00342

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Aboriginal Health & Medical Research Council of NSW

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Summary This Guideline contains the Standard Operating Procedures and Terms of Reference for the AH&MRC Human Research Ethics Committee, which operates in accordance with the *National Statement on Ethical Conduct in Human Research* (2007updated 2018).

Replaces Document: AH&MRC Ethics Committee Operations Manual, February 2014 **Status:** The Terms of Reference of the Ethics Committee (Section 3.) were submitted to theAH&MRC Board on 18 May 2018. The Ethics Secretariat was advised that the Board endorsed the Terms of Reference.

Review date: February 2022

Revisions: Any future amendments to this document (Terms of Reference or SOPs) shouldbe cross-checked with other sections within the document and with the Ethics Committee website to ensure consistency.

Table of Contents

1. CONTEXT

The Australian Health and Medical Research Council (AH&MRC) is the representative body of Aboriginal Community Controlled HealthServices (ACCHSs) in New South Wales. ACCHSs have been established to ensure that Aboriginal people and Aboriginal communities have control over their health services.

The AH&MRC Ethics Committee was first established in 1996. The
The AH&MRC Ethics Committee was established because for many years, much of the research about Aboriginal people was invasive, inappropriate, unnecessary and undertaken without Aboriginal community consultation or approval. The Constitution of the AH&MRC now requires it to operatean Ethics Committee.

The AH&MRC and its Ethics Committee are committed to supporting high quality projects in health and medical research that increase scientific knowledge, are of benefit to Aboriginal communities and are sensitive to Aboriginal culture. The AH&MRC and its Ethics Committee believes that it is integral that Aboriginal communities control of the research, and that the research builds the capacity of Aboriginal communities and the Aboriginal health workforce to conduct and assess research.

A major role of the AH&MRC Ethics Committee is to considering whether the applications of research is ethical in that it represents the views and interests of Aboriginal people across New South Wales.

The AH&MRC Ethics Committee is registered with the National Health and Medical Research Council and is part of the broader human research ethics framework within Australia and NSW, working cooperatively with Human Research Ethics Committees in universities, area health services and other organisations.

The role of the AH&MRC Ethics Committee is endorsed by the NSW Health Department and embodied within the Policy Directive *Ethical and scientific review of human researchin NSW Public Health Organisations* and the *NSW Aboriginal Health Information Guidelines* which guides all NSW government agencies responsible for the management of Aboriginal health and health-related information. These Guidelines operate in conjunction with the *NSW Aboriginal Health Partnership*, a formal agreement between the NSW Government and the AH&MRC.

References

- National Statement on Ethical Conduct in Human Research, 2007 updated 2018
- AH&MRC Guidelines for Research in Aboriginal Health ─ Key Principles, 2009
- Ethical Conduct of Research with Aboriginal and Torres Strait Islander Peoples andCommunities: Guidelines for researchers and stakeholders 2018
- NSW Aboriginal Health Information Guidelines**,** 1998
- NSW Aboriginal Health Partnership Agreement, 2008-2013
- Policy Directive PD2010_055 *Ethical and scientific review of human research in NSW PublicHealth Organisations,* 2010
- NSW Health Procedure *Operations Manual: Human Research Ethics Committees,* 2010
- NSW Health Procedure *Operations Manual: Human Research Ethics*

Committees ExecutiveOfficers, 2010

2. PURPOSE

This Operating Manual contains the terms of reference and standard operating procedures for the Aboriginal Health and Medical Research Council (AH&MRC) Human Research Ethics Committee (HREC).

These guidelines help ensure the AH&MRC Ethics Committee is constituted and operates in accordance with the *National Statement on Ethical Conduct in Human Research* (2007 updated 2018) by the National Health and Medical Research Council, Australian Research Council and Australian Vice-Chancellors' Committee. The Operations Manual provides guidance to the AH&MRC Ethics Committee Members and Secretariat in particular.

The structures and practices described are consistent with the NSW Department of Health Guideline *Operations Manual: Human Research Ethics Committees.*

3. Aboriginal Health & Medical Research Council (NSW) Human Research Ethics Committee (HREC) Terms of Reference

1. OBJECTIVES

1.1 The objectives of the AH&MRC Ethics Committee are to:

a) Protect the mental and physical welfare, rights, dignity, and safety of participants (and their communities) in research and subsequent outcomes of research into Aboriginal health in NSW.
b) Promote ethical principles in Aboriginal health-related research.
c) Review Aboriginal health-related research in NSW in accordance with:
   - the *National Statement on Ethical Conduct in Human Research* (2007) updated 2018.
   - the *AH&MRC Guidelines for Research in Aboriginal Health - Key Principles (2018)*; and
   - *the Ethical conduct in research Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders 2018.*
   - *Keeping research on track II 2018*
d) Facilitate ethical research through efficient and effective processes to review the conduct and outcomes of research.

2. FUNCTIONS

2.1 The Ethics Committee's functions, on behalf of the AH&MRC, are to:

a) Provide independent Aboriginal oversight of health-related research projects relevant to Aboriginal people, as per the below definition of Aboriginal Health:
"Aboriginal health means not just physical health well-being of an individual but refers to the social, emotional and cultural well-being of the whole Community in which each individual is able to achieve their full potential as a human being thereby bringing about the total well-being of their community"
b) Provide thorough, timely review and monitoring of Aboriginal health-related research projects in respect to their ethical and scientific acceptability for as long as projects are active;
c) Determine the compliance of an Aboriginal health-related research project with the National Statement and the AH&MRC Guidelines for Research in Aboriginal Health - Key Principles, and grant, withhold or withdraw ethical approval; and
d) Provide advice to the AH&MRC on strategies to promote awareness of the ethical conduct of Aboriginal health-related research.
e) Represent the views and interests of Aboriginal people across New South Wales, in relation to research into Aboriginal health.

2.2 The Committee works cooperatively with other Ethics Committees to ensure the objective and functions noted above in 1.1 and 2.1 are met.

3. ACCOUNTABILITY

3.1. The AH&MRC Ethics Committee is directly accountable to the Board of Directors of the AH&MRC, under which it is constituted. An Ethics Committee report is provided for consideration at each meeting of the Board of Directors. The report to the Board of Directors will include details of any changes to the staffing of the secretariat or membership of the committee, the number of research proposals reviewed, the average review time, benefits of approved research to the Aboriginal communities in New South Wales and any upcoming initiative of the committee.

3.2. At the end of each financial year, the AH&MRC Ethics Committee provides a report forinclusion in the AH&MRC annual report.

3.3 The AH&MRC Ethics Committee will bring issues of significant ethical concern relating to researchto the attention of the AH&MRC Board of Directors.

3.4 The AH&MRC Ethics Committee provides the following reports on behalf of the AH&MRC:

- Australian Health Ethics Committee (AHEC) report in accordance with the requirements of the National Health and Medical Research Council (NHMRC);
- NSW Privacy Commissioner Report in accordance with the requirements of the *Health Records and Information Privacy Act 2002* (NSW).
- New South Wales Ministry of Health report on Key Performance Indicators.

4. SCOPE OF RESPONSIBILITY

4.1 Ethical Review of Research

4.1.1. The AH&MRC Ethics Committee is responsible for reviewing health-related research projects conducted in, or concerning NSW and anyone of the following:

- The experience of Aboriginal people is an explicit focus of all or part of the research.
- Data collection is explicitly directed at Aboriginal people.
- Aboriginal peoples, as a group, are to be examined in the results.
- The information has an impact on one or more Aboriginal communities; or
- Aboriginal health funds are a source of funding.

4.1.2 It is a requirement of the AH&MRC Ethics Committee that projects meeting the above criteria will be submitted to the AH&MRC Ethics Committee irrespective of whether they have been submitted to other HRECs or not.

4.1.3 Approval of the AH&MRC Ethics Committee is a requirement for Aboriginal health-related research undertaken in NSW Public Health Organisations. (Reference: NSW Health Procedure *Research - Ethical & Scientific Review ofHuman Research in NSW Public Health Organisations, 2010, Section 5.2.)*

4.1.4 Approval of the AH&MRC Ethics Committee is a requirement by some universities in NSW for Aboriginal health-related research

4.2 Other Activities

The AH&MRC Ethics Committee may also be involved in a range of other activities designed to promote the objectives of the AH&MRC Ethics Committee. This may include trainingworkshops for researchers and participation state and national initiatives in relation to research ethics.

4.3 The Co-Chairs

4.3.1 The Co-Chairs are responsible for:

- the effectiveness and overall functioning of the AH&MRC Ethics Committee.
- the conduct of HREC business; and
- ensuring that the HREC reaches decisions on all applications.

4.3.2 Where the other Co-Chair is unavailable, the meeting will be chaired by the other assigned Co-Chair if available. If both Co-Chairs are unavailable, the members present will appoint a Chair for the meeting.

5. ORGANISATION CONTEXT

5.1 The Research Ethics Coordinator is accountable to the Co-Chairs of the HREC on all research issues. The Research Ethics Coordinator reports dayto the Research Ethics Director on matters relating to the operation of HREC. The Research Ethics Coordinator is responsible for ensuring the provision of hghlevel secretariat services.

6. MEMBERSHIP

6.1 Composition

6.1.1 The composition of the AH&MRCs Ethics Committee is consistent with the *NationalStatement,* which requires it to have:

a) A Chairperson with suitable experience whose other responsibilities willnot impair the HREC capacity to carry out its obligations under the National Statement.
b) At least two members who are lay people, one man and one woman, withno affiliation with the institution or organisation and not currently involved in medical, scientific, legal or academic work.
c) At least one member with knowledge of, and current experience in, theprofessional care, counselling or treatment of people.
d) At least one member who performs a pastoral care role in the community,for example, an Aboriginal elder or a minister of religion.
e) At least one member who is a lawyer, where possible one who is notengaged to advise the institution for which the HREC is reviewing research; and
f) At least two members with knowledge of and current research experiencethat is relevant to the applications to be considered at the meetings they attend

6.1.2 Membership of the AH&MRC Ethics Committee comprises up to seventeen members. Where possible, members are Aboriginal and as far as possible, men andwomen are represented in equal numbers. Membership comprises representatives from the following categories*:

a) A representative of the AH&MRC Board of Directors who is selected asthe Co-Chairs of the AH&MRC Ethics Committee.
b) Two members who are members of an Aboriginal Community ControlledHealth Service (ACCHS).
c) Two Aboriginal elders, preferably one female and one male.
d) Two members who are lay people with no affiliation with the institution ororganisation and not currently involved in medical, scientific, legal or academic work;
e) At least one member with knowledge of, and current experience in, theprofessional care, counselling or treatment of people;
f) At least one member with knowledge of and current research experiencethat is relevant to the applications to be considered at the meetings they attend;
g) At least one member who is a lawyer, where possible one who is notengaged to advise the institution for which the AH&MRC Ethics Committee is reviewing research.
h) One member who is a youth representative, aged between 18-25 years.

6.2 Appointment of members

6.2.1 AH&MRC Ethics Committee members are appointed using open and transparent processes. Members may be recruited by direct approach, nomination or by advertisement. In determining appointments and renewals of appointments, consideration is given to continuity, development of expertise within the AH&MRC EthicsCommittee, and regular input of fresh ideas and approaches.

6.2.2 Prospective members may be invited to observe a meeting of the AH&MRC EthicsCommittee.

6.2.3 Members are appointed as individuals for their knowledge, qualities and experience and not as representatives of any organisation, group or opinion.

6.2.4 Membership of the AH&MRC Ethics Committee is made publicly available on theAH&MRC website.

6.2.5 All members including the Co-Chairs Chairperson are appointed by the AH&MRC Board, following the recommendation of the Research Ethics Coordinator and their AH&MRC supervisor. Each member will receive a letter of appointment which includes the date of appointment, length of tenure, indemnity and termination.

6.2.6 Members are appointed for a period of up to 3 years and may serve a maximumof 6 years. The Co-Chairs of the AH&MRC Board or delegate, in consultation with the AH&MRC Ethics Committee Co-Chairs, may implement a probationary period for members of the AH&MRC Ethics Committee.

6.3 Responsibilities of members

6.3.1 Upon appointment, members are provided with an orientation package andasked to sign a statement undertaking:

a) that all matters of which he/she becomes aware of duringhis/her work on the AH&MRC Ethics Committee will be kept confidential.
b) that any conflicts of interest, which exist or arise during his/her tenure on the AH&MRC Ethics Committee will be declared; and
c) that he/she has not been, and continues to not be subject to any legal or disciplinary action, which may prejudice his/her standing as an AH&MRC Ethics Committee member.
d) that members act with integrity at all times and seek to provide reviews of ethics applications in a timely and professional manner.

Participation

6.3.2 Members are required to regularly attend meetings. Membership to AH&MRCs Ethics Committee ceases if amember fails to attend:

a) Three consecutive meetings without reasonable excuse/apology in advance or exceptional circumstances; and
b) At least two thirds of all scheduled AH&MRC Ethics Committee meetings in eachyear, barring exceptional circumstances.

6.3.3 Members will contribute to the ongoing functioning of the Committee through undertaking timely reviews of ethics applications in line with the National Statement of Ethical Conduct in Research and Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines

for researchers and stakeholders. Membership to AH&MRCs Ethics Committee will cease if members areunable to carry out their duties of reviewing applications.

6.3.4 The Co-Chairs of the AH&MRC will notify the member of a cessation of membership in writing. Steps will then be taken to fill the vacancy.

6.3.5 Members seeking to resign or take a leave of absence for an extended period from the AH&MRC Ethics Committee are asked to give written notice to the Co-Chairs of the AH&MRC HREC. Steps will then be taken to fill the vacancy either permanently or temporarily.

6.3.6 The appointment of any member of the AH&MRC Ethics Committee may be terminated ifthe AH&MRC Board is of the opinion that:

a) It is necessary for the proper and effective functioning of the AH&MRC EthicsCommittee.
b) The person is not a fit and proper person to serve on an Ethics Committee; or
c) The person has failed to carry out their duties as an AH&MRC Ethics Committee member.

6.3.7 Members may be required to participate in relevant specialised working groupsor subcommittees.

Confidentiality

6.3.7 Ethics Committee meetings are to be held in private and all members are encouraged toraise matters of concern. The agenda and minutes of meetings, applications, supporting documentation and correspondences are all treated confidentially.

6.3.8 Members are required to sign a confidentiality agreement upon being appointed to AH&MRCs Ethics Committee.

Declaration of conflict of interest

6.3.9 A conflict of interest may compromise the review process for an application, or may take into consideration other matters, that may lead to decisions being based on factors outside the requirements of an ethical review.

6.3.10 A conflict of interest exists where:

- A person's individual interests or responsibilities have the potential to influence the carrying out of his or her role or professional obligations; or
- An institution's interests or responsibilities have the potential to influence the carrying out of its obligations.

6.3.11 Conflict of interest includes financial interests, personal, professional or institutional benefits or advantages that depend significantly on the research outcomes.

6.3.12 An AH&MRC Ethics Committee member must declare to the AH&MRC Ethics Committee anyconflicts of interest she/he has in relation to an application for ethical and scientific review or any other matter for consideration by the Committee.

6.3.13 Declarations are to be made in writing to the Co-Chairperson or Secretariat prior to the matter being considered. The AH&MRC Ethics Committee will then determine whether the level of interest results in:

a) A substantial conflict of interest: a member is excluded from the meeting where there is a substantial conflict of interest until the AH&MRC Ethics Committee has concluded consideration of the matter. Being an investigator on a research project is considered to represent a substantial conflict of interest;or

b) A non-substantial conflict of interest: the Committee has discretion to ask a member to leave during the discussion of the matter.

6.3.14 The minutes record a declaration of interest and the decision of the AH&MRC Ethics Committee on the procedures to be followed. A register of conflicts of interest ismaintained on the AH&MRC server.

6.4 Orientation and training of members

6.4.1 New members to AH&MRCs Ethics Committee are provided with orientation/training asrecommended by the Executive Officer.

6.4.2 Orientation may involve some of, or all of the following:
a) Introduction to other Ethics Committee members prior to the Ethics Committee meeting.
b) Provision of an orientation package.
c) Informal meeting with the Co-Chairpersons and the Executive Officer to explain their responsibilities as a member of AH&MRC's Ethics Committee, the Ethics Committee processes and procedures; and
d) Partnering with another Ethics Committee member in the same category.

6.4.3 Each member is:
a) Expected to become familiar with the National Statement, the AH&MRC Guidelines for Research in Aboriginal Health - Key Principles, the NHMRC's Ethical conduct for research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders and other guidelines relevant to the review of specific research applications; and
b) Encouraged to attend continuing education or professional developmentactivities in research ethics once in each period of appointment.

6.5 Liability Coverage

6.5.1 The AH&MRC provides indemnity for members of the AH&MRC Ethics Committee for liabilities that arise as a result of the member exercising their duties in goodfaith.

6.6 External Reference Panel

6.6.1 The Ethics Committee has established an Ethics External Reference Panel who can provide expert advice in relation to research applications if required, provided there is no conflict of interest, and an undertaking of confidentiality according to the Terms of Reference is given.Persons consulted should have expertise in Aboriginal health. Such person(s) are not entitled to vote on any matter.

6.6.2 The Ethics Secretariat staff will hold inductions for Ethics External Reference Panel members once yearly to familiarise panel members with the assessment requirements of the AH&MRC Ethics Committee.

7. CONDUCT OF BUSINESS

7.1 Meeting Procedures

7.1.1. The AH&MRC's Ethics Committee conducts its business in accordance with the Terms ofReference and Standard Operating Procedures.

7.2 Meetings

7.2.1 The AH&MRC's Ethics Committee meets on a regular basis. It holds at least 8 scheduledmeetings in each year for the purposes of:

- Reviewing new applications.
- considering requests for amendments, extensions and review of reports, etc;
- determining policy.
- Updates/discussions on developments affecting the Ethics Committee.

7.2.2 Meeting dates and application closing dates are made publicly available.

7.2.3 The schedule of AH&MRC Ethics Committee meetings for the calendar year commencing 1 January is ratified by the Ethics Committee before or at the last meeting of theprevious year. The schedule sets out the dates, times and venues of meetings, and the closing date for submission of applications.

7.3 Quorum requirements

7.3.1 A quorum is required at each meeting for the AH&MRC Ethics Committee to reach a final decision on any agenda item. The quorum for meetings is at least one memberfrom each of the core categories and the Co-Chairs as specified in the *National Statement* (see 6.1.1 above) attending in person or viatelephone or videoconference.

7.3.2 A quorum can be reached where there is:

(i) less than a full attendance of the minimum membership at a meeting, but the Co-Chairs are satisfied that the views of those absent who belong to the minimum membership have been received and considered, for instance through prior submission of written comments.

7.4 Decision making

7.4.1 Members present are to be allowed reasonable opportunity to express relevant views on matters on the agenda.

7.4.2 The AH&MRC Ethics Committee endeavors to reach a decision concerning the ethicaland scientific acceptability of a research project by unanimous agreement.

7.4.3 Where a unanimous decisions cannot be reached, the matter is determined by a two-thirds majority of members present at the meeting, provided that the majority includes at least one lay person.

7.4.4 Any significant minority view (i.e., 2 or more members) is noted in the minutes.

7.4.5 A Committee Member has the right to have his/her view recorded.

7.4.6 If the AH&MRC Ethics Committee wishes to request further information, the Ethics Committee is required to reference the appropriate section of the National Statement, Values& Ethics Guidelines or AH&MRC Key Criteria under which the information is being requested.

7.5 Approval process for applications

7.5.1 Applications for research must meet the requirements of the *National Statement on Ethical Conduct in Human Research (2007) updated 2018* for ethical approval to be granted, and satisfactorily address the *AH&MRC Guidelines for Research in Aboriginal Health - Key Principles (2016)*.

7.5.2 All applications go before the full Committee at least once before approval is granted. Approval may then be granted out of session, and the decision ratified at the next meeting.

7.5.3 The full Committee may make a decision about the application, or delegate it to a sub-group of two or more members to undertake the detailed review and approval. Delegated members may choose to take the application back to the full Committee for further consideration/approval if required.

7.5.4 One or more external reviewer(s) may be asked to provide comments. This is most likely when:

- technical/scientific advice is required; and/or
- the AH&MRC Ethics Committee is the only ethics committee to which the application is submitted.

7.5.6 Approval is made on the basis that the following standard conditions will be applied:

- In the instance of research being conducted in partnership or under the lead ofan Aboriginal Medical Service, that service has signed a research agreement, and this has been provided in the application,

OR

- In the instance of research being conducted without the involvement of an Aboriginal Medical Service, the researchers have demonstrated adequate Aboriginal Governance; Community Control and Aboriginal Capacity Buildingaspects of the research have been satisfactorily addressed.

1. Approval is for the period of time noted on the initial application, subject to the receipt and review of an approved annual report from the researchers. Initial approval can only be granted for a maximum period of 5 years.
2. All research participants are to be provided with a relevant Participant Information Statement and Consent Form in the format provided with the application.
3. Copies of all signed consent forms must be retained and made available to the AH&MRC Ethics Committee on request. A request will only be made if there is a dispute or complaint in relation to a participant.
4. Any changes to the staffing, methodology, timeframe, or any other aspect of the research relevant to continued ethical acceptability of the project must have the prior written approval of the AH&MRC Ethics Committee.
5. The AH&MRC Ethics Committee must be immediately notified in writing of any serious or unexpected adverse effects on participants.
6. The research must comply with:
   - the *AH&MRC Guidelines for Research in Aboriginal Health – Key Principles*.
   - the *National Statement on Ethical Conduct in Research Involving Humans* (2007) updated 2018.
   - the *NSW Aboriginal Health Information Guidelines.*
7. The final draft report from the research, and any publication or presentation prior to that report where new data or findings are presented, must be provided to the AH&MRC Ethics Committee to be reviewed for compliance with ethical and cultural criteria prior to:
   - any submission for publication; and/or
   - any dissemination of the report.
8. A copy of the final published version of any publication is to be provided to the AH&MRC Ethics Committee.
9.

Additional conditions of ethical approval may be set for specific projects.

7.5.7 The Chief Investigator is notified of the Committee's decision in a letter from theChair.

7.6 Records

7.6.1 Electronic records (including agendas and minutes) of all meetings of the AH&MRC EthicsCommittee are maintained. The minutes also record decisions made out of session.

7.6.2 Electronic records are maintained of all application and associated documentsincluding any correspondence in relation to the application.

7.6.3 The AH&MRC Ethics Committee maintains a register of all the applications received andreviewed in accordance with the National Statement.

7.6.4 Electronic records are maintained of all other businesses of the AH&MRC Ethics Committee.

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

7.6.6 Records may be retained after the minimum period or disposed of in a securemanner.

7.7 Monitoring approved research projects

7.7.1 The AH&MRC Ethics Committee monitors approved research projects to ensure compliance with the conditions of approval to protect the rights, safety andwelfare of participants and their communities. This includes review of annual progress reports and final reports, safety reports and reports of protocol violations.

7.7.2 The AH&MRC Ethics Committee may request additional information to monitor individualprojects depending on the complexity, design and risk perceived. This may include:

- Discussing relevant aspects of the project with investigators, at any time
- Conducting interviews with research participants or gaining other forms of feedback from them
- Requesting and reviewing reports from relevant bodies regarding theproject
- Inspection of research sites, data, or consent documentation (permissionshould be sought through appropriate channels, e.g., from the CEO or Research Ethics Director where the research is undertaken).

7.8 Ethics Committee reporting requirements

7.8.1 An Ethics Committee report is provided for consideration at each meeting of theAH&MRC Board and at the end of each financial year for inclusion in the AH&MRC annual report, which includes:

a) Membership/membership changes
b) Number of meetings
c) Number of research projects reviewed and the outcome of the reviews
d) The Ethics Committee metrics including average review time of anapplication.
e) Issues identified by the AH&MRC Ethics Committee in undertaking its monitoring role
f) Description of any appeals and complaints received and their outcome
g) Description of any research where Ethics Committee approval has beensuspended or withdrawn and the reasons for this action
h) Other issues relating to the operation of the Committee, outcomes of policydiscussions, and promotion of ethical conduct of Aboriginal health-related research
i) Resources to assist the Ethics Committee in fulfilling its role.

7.8.2 The AH&MRC Ethics Committee completes and submits reports on behalf of theAH&MRC to the:

a) Australian Health Ethics Committee (AHEC) in accordance with therequirements of the NHMRC; and
b) NSW Privacy Commissioner in accordance with the requirements of theHealth Records and Information Privacy Act 2002 (NSW).

7.9 Information made publicly available

7.9.1 The AH&MRC makes information publicly available about the EthicsCommittee, including:

a) Contact details for the Ethics Committee secretariat
b) Submission closing dates for Ethics Committee meetings
c) Ethics Committee meeting dates
d) Information on completing, submitting, review and approval of applications
e) The Committee's Terms of Reference
f) Complaint's handling procedures.

8.APPEALS AND COMPLAINTS

8.1 Appeals regarding Ethics Committee rejection

Where the AH&MRC Ethics Committee has rejected an application, the investigator hasthe discretion to:

a) Submit a new application, taking due account of the Ethics Committee'sconcerns; or
b) Lodge an appeal with the AH&MRC Ethics Committee Co-Chairs specifying thegrounds of the appeal in writing.

8.2 Appeals regarding Ethics Committee approval

Where the AH&MRC Ethics Committee has given a favourable decision on an applicationand an ethical or scientific issue is subsequently identified by any party; or, it has become apparent that the decision was based on inconsistent application of policy and guidelines, or if information provided to the Ethics Committee is found tohave been incorrect or incomplete, an electronically written appeal may be lodged with the Co-Chairs in the first instance.

8.3 Appeals to the Co-Chairs of the AH&MRC Board

If, after an appeal is made, the aplicant considers that the AH&MRC Ethics Committee has failed to follow due process and remains unsatisfied with the outcome, he or she has the discretion to lodge an appeal with the Research Ethics Coordinator or the Chairperson of the AH&MRC Board or request that the Ethics Committee Co-Chairs do so.

8.4 Complaints about the conduct of Ethics Committee members

If there is a complaint about the conduct of a AH&MRC Ethics Committee member, itshould be directed to the Chair of the AH&MRC Board.

8.5 Complaints about the conduct of an approved research project.

Complaints about the conduct of an authorised research project, including allegations of research misconduct, should be directed to the Ethics Committeesecretariat or the Co-Chairs of the Ethics Committee. They are managed in accordance with the Ethics Committee's procedures outlined in *SOP 2.5: Complaint's handling.*

4. STANDARD OPERATING PROCEDURES

Applications – External Information

1.1 Guidelines for submitting an application.

Processing of Applications - Internal

2.1 Enquiries regarding the need to submit an application.

2.2 Administration of applications – with timeline

2.3 Review of applications

2.4 ACCHS (or alternative) involvement in research

2.5 Complaints

2.6 Monitoring research projects

Committee Meetings

3.1 Preparation of agendas

3.2 Conduct of meetings

3.3 Preparation of minutes

Records

4.1 Record keeping

SOP 1.1 Guidelines for submitting an application.

These guidelines to assist applicants in the preparation of their submission. They are available on the AH&MRC Ethics webpage on under the section titled 'Ethics Application Process'.

The guidelines are updated as required. The date of the most recent update is recorded at the top of this page.

The following is an extract from *Application process section* of the Ethics Committee web page (as at 13 January 2020).

Stages of an Application

This section covers:

a) Developing an Application;
b) Submitting an Application;
c) Contents of an Application;
d) Checklist for Applications;
e) Assessment of Applications.

(A) Developing an Application

Obtaining Community Support

One of the Committee's major criteria in assessing an application is to ensure that there is Aboriginal community involvement in, and control over the research. Researchers should in the inception stages of their research; attempt to engage with the Aboriginal Medical Service in the local area that the research will be conducted in.

Researchers should work with Aboriginal Medical Services to design research projects that fit the needs of Aboriginal people and communities. Where the local Aboriginal Medical Service determines that it is unable to participate in the research, researchers should address Aboriginal involvement in the project in other ways. This may include ensuring that there are Aboriginal researchers listed on the project, Aboriginal Reference Groups are engaged, opportunities for Aboriginal people to further build their research skills. Researchers should send notification of the project to the local Aboriginal Medical Service for their information.

Researchers should work with the relevant ACCHSs or an appropriate alternative body from the earliest stages in the development of their application. This will help to ensure that their research agenda is consistent with the needs of Aboriginal people and that their methodology is both acceptable to Aboriginal people and able to produce the most accurate and useful results. It will also help to ensure that the application meets the Committee's requirements.

b) Submitting an Application

Researchers should work with ACCHSs and other relevant Aboriginal community groups from the earliest stages in the development of their application. This will help to ensure the application meets the Committee's requirements.

Note that an application must be received by the closing date which is three weeks before a Committee meeting if it is to be considered by that meeting. The online portal will close after each closing date and all applications received after this date will be accepted into the next round.

Who should submit an application?

The Committee considers applications relating to research that may affect the health and well-being of Aboriginal people and communities.

The project should involve research in, or concerning, New South Wales. Where projects also involve research outside New South Wales, an ethics application must also be made to the relevant Aboriginal HREC(s) in the other states and territories.

An application should be made for research for which any one of the following applies:

- The experience of Aboriginal people is an explicit focus of all or part of the research; or
- Data collection is explicitly directed at Aboriginal peoples; or
- Aboriginal peoples, as a group, are to be examined in the results; or
- The information has an impact on one or more Aboriginal communities; or
- Aboriginal health funds are a source of funding.

The Committee advises an application should be made if your project meets any of the below criteria:

- Any of the five factors listed above are present; or
- The Aboriginal experience of the medical condition being studied is known, oris likely, to be different from the overall population; or
- There are Aboriginal people who use the services being studied in distinctive ways, or who have distinctive barriers that limit their access to the services; or
- Aboriginal people are known, or likely, to be significantly over-represented inthe group being studied (compared to the 3.4% of total NSW population)

and/or it is proposed to separately identify data relating to Aboriginal people at any stage in the project.

Applications are received from the full range of people and organisations conducting research that meet the above criteria, including staff from universities, research institutes, Aboriginal Community Controlled Health Services (ACCHSs), the NSW Department of Health, and community agencies; undergraduate and post-graduate students; and independent researchers.

Seeking advice

If you are unsure whether an application should be submitted, you can contact the AH&MRC Ethics Committee Secretariat for advice (Ph.02 9212 4777, or email ethics@ahmrc.org.au).
There are a number of different types of research where researchers have sought advice in the past. The following provides some examples as guidance for researchers.

It is emphasised that the following points are guidelines only and that each specific case will need to be considered against the particular circumstances of that project. If you are unsure, you should contact the Secretariat.

ii) Research where health is not a major focus

Some research may have some reference to health issues, but be essentially about other matters, such as education, social welfare, justice, etc, and thus an application to this committee may not be necessary. However, terms such as 'resilience' and 'well-being' in the description and design of the project may indicate that it has important health implications.

iii) Program planning, monitoring, and quality improvement activities

Organisations undertake a range of research-type activities aimed at planning, monitoring, or ensuring the quality of their policy, programs, and operation.
There are two government documents that provide guidance on how to determine if a project is predominantly 'quality improvement ' rather than research:

- NHMRC (2014): Ethical Considerations in Quality Assurance and Evaluation Activities
- NSW Health (2007): Quality Improvement and Ethical Review

In general, even where such activities involve a study of client records and/or interviews with clients, **an application to the Committee is *not* necessary if *all* of the following apply**:

- Any questions to participants or discussions with them relate only to (i) their experience of a specific programs or material, or their use of a program and/or their perception of factors affecting their use of and benefits from that program, or (ii) their views about specific aspects of proposed programs (eg. new information material, changed hours of operation, etc); and

- The information to be obtained will be for internal use only and will not be published in any form externally; and
- Aboriginal people with expertise and experience in the subject matter of the research will be actively involved in the design and conduct of any such activities significantly affecting Aboriginal people; and
- Ethics approval for the activity or for similar activities has not been sought from another ethics committee.

iv) Applications to Other Human Research Ethics Committees

If your research project meets the above conditions you should submit an application to the AH&MRC Ethics Committee even if you have obtained approval from the HREC in your institution or organisation.

Most research projects for which the AH&MRC Ethics Committee receives applications are also submitted to at least one other Human Research Ethics Committee (eg. a University HREC, or a NSW Department of Health Area Health Service HREC). For some projects, University and Local Health District HRECS have required researchers to obtain AH&MRC approval before they will grant ethics approval.

The AH&MRC Ethics Committee is prepared to accept an application at any stage of its progress with another HREC. Each individual researcher can decide whether he/she will seek AH&MRC approval before submitting to other HRECs, or after approval by other HRECs, or simultaneously.

Your application to the AH&MRC Ethics Committee should include copies of:
- Your application to one other HREC;
- Approval letters from other HRECs;
- Requests to you from other HRECs for additional information about your application, together with your responses to the requests.

v) Aboriginal HRECs in other States and Territories

Where projects also involve research outside New South Wales, an ethics application must also be made to the relevant Aboriginal HREC(s) in the other states and territories.
The following Aboriginal HRECs operate outside New South Wales:
- South Australian Aboriginal Health Research and Ethics Committee;
- Western Australian Aboriginal Health Ethics Committee;
- (Northern Territory) Top End Human Research Ethics Committee;
- (Northern Territory) Central Australian Human Research Ethics Committee.

c) Developing an Application

Applications for AH&MRC HREC review are accepted through the AH&MRC Submittable portal.

You may apply for AH&MRC HREC review here:
https://ahmrc.submittable.com/submit

Applicants should follow the below steps:

1) Log on to the AH&MRC HREC Submittable portal
2) When applicants log on to the AH&MRC HREC Submittable home page the portal to the next AH&MRC HREC meeting will be available with a button to the left that says “Apply now”.
3) Applicants will be redirected to an online form requesting the project details. This online form becomes the covering letter of the application.
4) Within the online form, applicants are asked to address the AH&MRC HREC 5 Key Principles. Each principle is described to the right of the text box. For further information, researcher are encouraged to access the “AH&MRC Guidelines for Research into Aboriginal Health – Key Principles”. This document provides in depth guidance regarding the purpose and expectations underpinning each principle.
5) At the bottom of the online form, applicants are asked to complete a checklist. The checklist is mandatory and contains the minimum documents required to make an application.
6) At the bottom of the page, applicants are asked to upload the relevant documents. Applicants must submit all relevant information as one document. This may mean applicants need to merge a number of files into one document to apply. All applications to the AH&MRC HREC must include at least:
    - The completed online cover form
    - A completed Human Research Ethics Application form, prfereably the HREA which was developed by the National Health and Medical Research Council.
    - A research protocol
    - Participant Information Sheet and Consent Form, or statement of justification for a Waiver of Consent
    - Letters of Support signed by either the Research Ethics Director or Chair of the Board of Directors of the relevant ACCHSs involved in the project.
    - A Terms of Reference for any advisory, reference or steering group
7) Finally, applicants are asked to “Apply Now” or “Save Draft”. Applicants are able to save the information as a draft and log in later to continue the application.

Reference Documents

There are a number of other documents that applicants could consult to ensure that their applications are consistent with the ethical standards required for Aboriginal health and medical research. These include:

- NSW Aboriginal Health Information Guidelines (1998)
- Why an Aboriginal Ethical Perspective is Necessary for Research into Aboriginal Health (AH&MRC Paper, written by Mundine, Edwards, & Williams, May 2001)
- Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (NH&MRC, 2018)
- Keeping Research on Track II : A guide for Aboriginal and Torres Strait Islander peoples about health research ethics (NH&MRC, 2018)
- NHMRC Road Map II: A Strategic Framework for Improving the Health of Aboriginal and Torres Strait Islander People through Research (2010)
- Guidelines for Ethical Research in Indigenous Studies (Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) (2011)

Some Points to Note

To ensure a timely assessment of applications, researchers should ensure that the following matters are addressed in their application:

- All necessary signatures on the application forms and attachments have been obtained
- The AH&MRC Ethics Committee contact details have been included on the Participant Information Form as a body to which participants can raise concerns or complaints about the research.

Deadlines

An application must be received four weeks before a Committee meeting if it is to be considered by that meeting.

Receipt and Acknowledgement of Applications

Applications will be acknowledged in writing within the submittable portal and applicants are encouraged to confirm that this has been received.

e) Assessment of applications

Preliminary Assessment

In order to assist the timely processing of applications, the Committee Secretariat will generally seek to review an application before it goes to the Committee and give applicants the opportunity to provide supplementary material to address any gaps or likely issues before the Committee formally considers the application. It is thus desirable to submit an application as early as possible before the next meeting to enable a preliminary assessment.

Consideration by the Committee

The application will be reviewed on the basis of the criteria and guidelines for assessment that have been established by the Committee.

The Committee may draw on the advice of the External Reference Panel and any supplementary material provided by the researcher(s) in considering any application.
Comments on Broader Research Methodology

The AH&MRC and the Ethics Committee have a broad objective to improve the quality of research in Aboriginal Health and consider the quality and validity of research to be an essential condition of its ethical acceptability.

As a means of contributing to improving the quality of research, the Ethics Committee and its External Reference Panel may comment on aspects of the research design that are not directly ethical requirements of the Committee, but are aimed to assist researchers to enhance the quality of the research and its benefit to Aboriginal people and communities. Where this occurs, the specific ethics requirements of the Committee will be clearly distinguished from any broader advice.

External Reference Panel

In line with the recommendations of the Reid Review, the Ethics Committee has established an External Reference Panel to assist it in assessing applications. The Panel does not meet as a group, but rather is comprised of experts with scientific and technical expertise in their field who can be asked for advice as required on specific applications for ethics approval or on broader issues affecting their field.

Criteria and Guidelines for Assessment

In evaluating applications for ethical approval of proposed research and data collection projects, the Committee ensures the projects meet the requirements of three main documents.

1) AH&MRC Guidelines for Research in Aboriginal Health – Key Principles

The AH&MRC document Guidelines for Research in Aboriginal Health - Key Principles, is the core document used by the Committee in assessing applications.

As noted in that document, in order to obtain approval from the AH&MRC Ethics Committee, **research projects must meet all of the following five (5) criteria:**

- The research will advance scientific knowledge and result in demonstrated net benefit for the health of Aboriginal people and communities;

- There is Aboriginal community control over all aspects of the proposed research, including research design, ownership of data, data interpretation, and publication of research findings;

- The research will be conducted in a manner sensitive to the cultural principles of Aboriginal society and will recognise the historical aspects and impact of colonisation on Aboriginal people

- Aboriginal communities and organisations will be reimbursed for all costs arising from their participation in the research process; and

- The project will utilise available opportunities to enhance the skills and knowledge of Aboriginal people, communities and organisations that are participating in the project.

Guidelines for Research in Aboriginal Health - Key Principles also sets out (Section 4) the key principles underpinning these criteria.

2) National Statement on Ethical Conduct in Human Research (2007)

3) NSW Aboriginal Health Information Guidelines

Researchers should work with ACCHSs and other relevant Aboriginal community groups from the earliest stages in the development of their application. This will help to ensure the application meets the above requirements.

Approval of Applications

When the AH&MRC Ethics Committee grants approval for an ethics application, it sets eight [6] standard conditions for all projects subject to applicability (eg. Condition [2] below may not be relevant for an epidemiological project). The Committee may also set additional special conditions for a particular project. The eight standard conditions are:

Standard Conditions of Approval (where applicable to the project)

1. The Coordinating Principal Investigator will immediately report anything that might warrant a review of the ethical approval of the project.
2. The Coordinating Principal Investigator will notify the AH&MRC Ethics Committee of any event that requires a modification to the protocol or other project documents and submit any required amendments in accordance with the instructions provided by the HREC. These instructions can be found at www.ahmrc.org.au/ethics.
3. The Coordinating Principal Investigator will submit any necessary reports related to the safety of research participants in accordance with the AH&MRC Ethics Committee policy and procedures. These instructions can be found at www.ahmrc.org.au/ethics.
4. The Coordinating Principal Investigator will report to the AH&MRC Ethics Committee annually in the specified format and notify the HREC when the project is completed at all sites.
5. The Coordinating Principal Investigator will notify the AH&MRC Ethics Committee if the project is discontinued at a participating site before the expected completion date, with reasons provided.

6. The Coordinating Principal Investigator will notify the AH&MRC Ethics Committee of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation. Instructions for obtaining an extension of approval can be found at www.ahmrc.org.au/ethics.
7. The Coordinating Principal Investigator will notify the AH&MRC Ethics Committee of his or her inability to continue as Coordinating Principal Investigator including the name of and contact information for a replacement.
8. The Coordinating Principal Investigator will submit the final draft report from the research, and any publication or presentation where data or findings are presented, to the AH&MRC Ethics Committee to be reviewed for compliance with ethical and cultural criteria prior to:
   • Any submission for publication; and/or
   · Any dissemination of the report

The Committee may also set special conditions for a particular project.

It is the responsibility of the applicant to ensure that all conditions can be met. For example, where the applicant has been commissioned to undertake the research by another organisation (eg. a government department), the applicant should ensure that the commissioning body agrees to Condition [7] in writing. An application may be submitted while this agreement is being sought.

Draft publications sent for review under Condition [7] must be provided with adequate time for the Committee to consider it before any publishing /presentation deadlines. In general, at least two weeks should be allowed before any deadlines.

The approval letter from the Committee also contains a request that the researcher(s) agree that the AH&MRC may, on request, obtain access to data from the research in order to assist the future development of policy and programs in Aboriginal health. This is not a condition of approval.

SOP 2.1: Enquiries regarding the need to submit an application

Enquiries are frequently made by researchers as to whether they need to submit an application to the AH&MRC Ethics Committee and/or the format and content of applications. Usually these enquiries come to a member of the Secretariat.

Procedure

1. Researchers should be asked to provide by email some additional information about the project, if possible, such as a project synopsis or research plan. Ethics staff **will not** provide determination as to whether an application should be submitted to the AH&MRC Ethics Committee by phone, this advice will only be provided in writing.

2. Guidance is provided on the Ethics Committee website in the section *Who should submit an application?* and the Ethics staff response should refer to the criteria listed there.

3. The following documents have additional information to assist in determining whether a project is quality assurance or research requiring ethical review:
   - NSW Health (2007): *Quality Improvement and Ethical Review* *http://www.health.nsw.gov.au/policies/gl/2007/pdf/GL2007_020.pdf*
   - NHMRC (2014): *Ethical Considerations in Quality Assurance and Evaluation Activities* https://www.nhmrc.gov.au/sites/default/files/documents/attachments/ethical-considerations-in-quality-assurance-and-evaluation-activites.pdf

4. If an Ethics staff member is unable to provide advice after taking the above steps, advice should be sought from the Research Ethics Coordinator and/or a member of the Ethics Committee.

5. The advice and reasoning behind the advice should be reported to the researcher and documented in the Enquiries folder.

SOP 2.2: Procedure for administration of applications

1. Application is received in Submittable	
2. Check that all required documents are provided . - AH&MRC Submittable Online Form is complete - A full Ethics Application Form - Consent Form(s) and Participant Information Form(s) - Letter of support or Consent Form from ACCHS(s)	*Ethics Administration Officer*
3. Request applicants to fill any gaps in application.	*Research Ethics Coordinator*
4. a. Confirm that the project has received an acknowledgement via Submittable b. Identify for the HREC papers key details of project, namely: • Chief Investigator • Institution • Title of project	Research Ethics Coordinator
. *5.* Conduct Preliminary Review	*Research Ethics Coordinator*
6. Allocate the application to two HREC members **Note:** if the research is gender-specific, the application should be reviewed by at least one Committee Member of the same gender.	*Research Ethics Coordinator*
7. Identify and contact additional assessor if necessary • Expert Panel • AH&MRC Staff (eg. Medical Officer) • Other The Ethics Manager or Senior HREC Officer should seek assurance (preferably in writing) from any external reviewers that they: • are able to complete the review within the required time to ensure a timely decision by the Committee; do not have a conflict of interest in reviewing the	*Research Ethics Coordinator*

8. (For new Expert Panel members), send package • PRO FORMA – Letter to Expert Panel member PRO FORMA – Confidentiality Agreement	*Ethics Administration Officer*
9. Send copy of application to Expert Panel member and an assessment form for the reviewer to complete • PRO FORMA – Assessment of Ethics Applications	*Ethics Administration Officer*
10. Provide declaration of previous involvement and/or potential conflict of interest	*Ethics Administration Officer*
11. Obtain advice from Committee member(s) □ With follow-up discussion as necessary	*Research Ethics Coordinator*
12. Obtain advice from Expert Panel member(s) □ With follow-up discussion as necessary	*Research Ethics Coordinator*
13. Obtain response of applicant □ With follow-up discussion as necessary May involve some iterations	*Research Ethics Coordinator*

10 Days - 1 Week before EC meeting

14. Determine documents to be provided to the Committee • Current application • Any addendums provided by applicant • Previous and associated papers • Any written advice from Expert Adviser(s)	*Research Ethics Coordinator*
15. Prepare Overview Advice to the Committee Where steps [10]-[12] have not been completed, the Overview Advice may need to be a progress report.	*Research Ethics Coordinator*
16. Collate and copy papers to be provided to the Committee • Application • Comments and applicant responses	*Research Ethics Coordinator*

Week after EC Meeting

17.	Finalise notes on Meeting Outcomes for each application	*Research Ethics Coordinator*
18.	Finalise Meeting Minutes for each application	*Research Ethics Coordinator*
19.	Review meeting minutes for each application	*Research Ethics Coordinator*
20.	Contact applicant for uncompleted applications	*Ethics staff*

For completed applications

21.	Through Submittable, finalise letters to applicant for completed applications	*Research Ethics Coordinator*

The following steps relate to applications seeking Amendment/ Extensions/ Reports and Information etc.

Turnaround timeframe – within 3 weeks if possible, where no major concerns are identified.

1.	When documents are not an initial application but an application seeking approval for an amendment/ extension/ report etc, identify whether this is a protocol amendment or administrative amendment	*Ethics Administration Officer*
2.	Provide a copy of the amendment request to one of the previous reviewers of the file, If the amendment is administrative such as the addition of a research assistant to the project team, this can be approved by the Ethics Manager.	*Ethics Administration Officer*
3.	Put a copy of the documentation (including subsequent correspondence and advice) in the amendments/ extensions/reports folder for the next meeting.	*Ethics Administration Officer*
5.	Note the progression of this application and the members	reviewing on the

Amendments table. *Ethics staff*

7. Inform the researcher of the outcome:
   - Approval letters are sent for amendments, extensions etc.
   - PRO FORMA – Approval Extension/Amendment letter

Ethics AdministrationOfficer

SOP 2.3: Procedure for review of applications

(Refer also to SOP1.1: *Guidelines for submitting an application* and SOP2.2 *Procedure for administration of applications*).

1. Review of projects seeking initial approval

1.1 The Research Ethics Coordinator ensures each application received is complete.

1.2 The Research Ethics Director Identifies a minimum of two Committee members to undertake a detailed review of the application. (For gender-specific research, atleast one of the reviewers should be of that gender.)

External Review

1.3 If required, additional advice about an application may be sought from an external person who may or may not be a member of the External Reference Panel.

1.3.1 External advice may be sought, especially if:
- technical/scientific advice is needed; and/or
- AH&MRC Ethics Committee is the only Ethics Committee to which the application is submitted.

1.3.2 External advice may be requested by:
- a Committee member; or
- the Senior Ethics staff at the time of allocating applications for detailed review.

1.3.3 External reviewers may be identified through:
- recommendation of an Ethics Committee member;
- advice from senior AH&MRC staff;
- Aboriginal medical and health associations;
- other professional medical and health associations;
- other suitable means.

1.3.4 Initial contact and ongoing liaison with members of the External Reference Panel and any other external reviewers is, in most cases, undertaken by the Research Ethics Director.

1.4 Reviews should be undertaken in a thorough and timely manner.

1.5 External reviewers must complete the AH&MRC Ethics assessment sheet

1.6 All applications must go before the full Committee at least once before approval is granted. Approval may then be granted out of session, and the decision ratified at the next meeting.

1.7 The full Committee may make a decision about the application, or delegate it to a sub-group of two or more members to undertake the detailed review and approval. Delegated members may choose to take the application back to the full Committee for further consideration/approval if required.

Criteria for Assessment

1.8 In evaluating applications for ethical approval of proposed research and data collection projects, the reviewers ensure the projects meet the requirements of three main documents.

1) AH&MRC Guidelines for Research in Aboriginal Health – Key Principles

This is the core document used by the Committee in assessing applications.

As noted in that document, in order to obtain approval from the AH&MRC Ethics Committee, research projects must meet all of the following five (5) criteria:

- The research will advance scientific knowledge and result in demonstrated net benefit for the health of Aboriginal people and communities;
- There is Aboriginal community control over all aspects of the proposed research, including research design, ownership of data, data interpretation, and publication of research findings;
- The research will be conducted in a manner sensitive to the cultural principles of Aboriginal society and will recognise the historical aspects and impact of colonisation on Aboriginal people.
- Aboriginal communities and organisations will be reimbursed for all costs arising from their participation in the research process; and
- The project will utilise available opportunities to enhance the skills and knowledge of Aboriginal people, communities and organisations that are participating in the project.

2) National Statement on Ethical Conduct in Human Research (2007 updated 2018)

3) NSW Aboriginal Health Information Guidelines

1.8. Committee members (and external experts) delegated to undertake a detailed review of application, should complete the Assessment of Applications within Submittable for further action, based on the reviewers' recommendation that:

- further information be sought from the applicant, or
- the application:
  - be approved
  - be approved subject to additional conditions
  - be approved subject to advice of external reviewers, or
  - not be approved.

1.9. The following standard conditions will be applied:

1. The Coordinating Principal Investigator will immediately report anything that might warrant a review of the ethical approval of the project.

2. The Coordinating Principal Investigator will notify the AH&MRC Ethics Committee of any event that requires a modification to the protocol or other project documents and submit any required amendments in accordance with the instructions provided by the HREC. These instructions can be found at www.ahmrc.org.au/ethics.

3. The Coordinating Principal Investigator will submit any necessary reports related to the safety of research participants in accordance with the AH&MRC Ethics Committee policy and procedures. These instructions can be found at www.ahmrc.org.au/ethics.

4. The Coordinating Principal Investigator will report to the AH&MRC Ethics Committee annually in the specified format and notify the HREC when the project is completed at all sites.

5. The Coordinating Principal Investigator will notify the AH&MRC Ethics Committee if the project is discontinued at a participating site before the expected completion date, with reasons provided.

6. The Coordinating Principal Investigator will notify the AH&MRC Ethics Committee of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation. Instructions for obtaining an extension of approval can be found at www.ahmrc.org.au/ethics.

7. The Coordinating Principal Investigator will notify the AH&MRC Ethics Committee of his or her inability to continue as Coordinating Principal Investigator including the name of and contact information for a replacement.

8. The Coordinating Principal Investigator will submit the final draft report from the research, and any publication or presentation where data or findings are presented, to the AH&MRC Ethics Committee to be reviewed for compliance with ethical and cultural criteria prior to:
• Any submission for publication; and/or
• Any dissemination of the report

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

1.10. The Chief Investigator is notified promptly of the Committee's decision in a letter from the Chair.

2. Review of applications for Clinical Trials

2.1 Where the AH&MRC Ethics Committee receives an application for a clinical trial involving a new therapeutic good or new uses of a therapeutic good, the Committee may decide to come to an agreement with another HREC regarding ethical oversight of the project. In such cases there will need to be a written agreement outlining respective roles and responsibilities of the two HRECs with regard to the project.

For example, both the AH&MRC HREC and the other HREC may retain oversight of matters such as recruitment, consent processes and dissemination of results. However, it may be agreed that the other HREC will be solely responsible for certain aspects relating to oversight of medical and technical dimensions of the project (eg. safety reporting, administration of medications).

3. Review of projects seeking amendment or extension of approval

3.1 Requests for an approval of an amendment to the project or extension of ethical approval are delegated to one or more Committee members for approval. Where possible, a member who reviewed the original application should review the request.

3.2 The Ethics Committee Co-Chairs can approve annual reports and extension requests on behalf of the Committee, as an alternative to sending the requests to the reviewers of the original application. The Research Ethics Director can approve annual reports with no notable changes if the researchers have met all conditions of approval. To assist Committee members reviewing these requests, the Secretariat should provide summary information of the project with a proposed recommendation for the reviewer's consideration.

3.3 Approvals of Amendments and Extension 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 researchers will be asked to complete the Annual Report form, which once completed will be sent to the reviewers with the amendment/extension request.

3.4 The Ethics staff should also obtain written confirmation from the relevant ACCHS, that the ACCHS supports the continuation of the project.

3.5 Where there are concerns about a project, the request for an extension or amendment will be referred to the full Committee.

3.6 Once a decision has been made by the full Committee or by the individual reviewer, the Ethics staff will promptly undertake any follow up action required. This may be to:

a) prepare the approval of the amendment/extension to the Chief Investigator, for the Co-Chairs to sign; or
b) request further information from the researcher; or
c) where an extension or amendment is not approved, prepare a letter in consultation with the Committee and Research Ethics Coordinator advising the Chief Investigator of the outcome.

4. Duration of approval

4.1 Initial approval applies for the period of time noted in the initial application, subject to the receipt of an annual report at each 12 month interval.

4.2 Approval for an extension will generally apply for the duration of the project or five years (whichever is the least), except where action is taken to suspend or terminate the decision. The Committee may decide in specific cases for the extension to be for a shorter period. Extension of approval is granted upon submission of a satisfactory progress report and there being no ethical concerns about the project.

4.3 Approval for a further extension may apply as per 4.2.

5. Review of reports, publications and presentations arising from approved projects

5.1 As noted in the conditions of approval (see 1.8 above) researchers are required to submit draft reports, publications and presentation to be reviewed for compliance with ethical and cultural criteria prior to publication.

5.2 These are delegated to at least one Committee member to review. Where possible this should be a member who reviewed the original application. They may also be referred to a member of the External Reference Panel.

5.3 Where there are concerns about a publication or presentation, which cannot be resolved with the author, the matter may be referred to the full Committee.

5.4 Where necessary, the reviewer should make recommendations to amend a publication so that it is more culturally sensitive/appropriate.

5.5 As a general principle, the Ethics Committee does not ‘approve’, ‘reject’ or ‘veto’ a publication. Rather, it is hoped that the author will seek to accommodate any concerns by revision of the paper.

SOP 2.4: ACCHS (or alternative organisation) involvement in research

A. Procedures for Ensuring ACCHS Involvement in Research

1. Involvement of the ACCHSs in the local areas affected by a research project is a key principle to ensure Aboriginal community control of that research.

2. Even if a research project does not involve the direct participation of an ACCHS in the collection of data, the Committee expects that researchers will seek the involvement of relevant ACCHSs and keep them informed about the progress of the research.

3. Where an ACCHS is involved in a research project, it is a requirement of the Committee that the researcher obtain a letter or a consent form signed by the Chairman or CEO of the ACCHS.

4. (Model organisational consent forms are on the *Ethics & Research* page on the AH&MRC website).

5. If the Ethics Committee Secretariat is approached by researchers who plan to do research but they have not yet made contact with the local ACCHS the Secretariat member should direct the researcher back to the relevant ACCHS.

6. The researcher and ACCHS should discuss and come to an agreement about:

   - Action to be undertaken regarding consultation with Aboriginal people and communities, especially Aboriginal health personnel.

   - The researcher's availability to discuss the research proposal and the mechanisms by which it is proposed that the ACCHS will be involved in the research and by which Aboriginal community control will be achieved.

   - The researcher's commitment to ensuring ongoing consultation and provision of information to the ACCHS as the research progresses.

7. Due to resource and other constraints, it is not always possible for ACCHSs to be closely involved in every research project affecting them. In such cases, the Committee follows the approach (endorsed by the Board in 2007) of ensuring that the researcher:

   a) agrees to keep the ACCHS informed about the research; and
   b) Identifies an appropriate group or organisation that can ensure genuine Aboriginal community control of the research. (See Section B below)

8. Each ACCHS will be requested to nominate a Board member or senior member of staff to be the contact person in relation to research (ie. to be known as the Research Contact Person).

9. When an application relevant to a local ACCHS is received by the AH&MRC, the Ethics Committee Secretariat will inform the Research Contact Person in any ACCHS that is affected.

10. Similarly, if the ACCHS becomes aware of any other research in which it has an interest, the ACCHS Research Contact Person should inform the Ethics Committee Secretariat about this research.

11. The AH&MRC Ethics Committee will make an assessment of each application, taking into account the arrangements made under paragraph [5] above. Approval will only be given where there are satisfactory arrangements to ensure Aboriginal involvement at all stages of the research.

12. The Committee may, in consultation with relevant ACCHSs, set conditions for the initial consent and ongoing involvement of the ACCHS with the research.

13. The Ethics Committee will formally advise the ACCHS of its decision re approval of the application and ensure the ACCHS is kept up to date with any developments in the research.

14. Approval of an application by the AH&MRC Ethics Committee, does not place a requirement upon the ACCHS to participate. The decision to be involved in a research project lies with the individual ACCHS.

Opposition by an ACCHS to a research project

1. Should a researcher be informed that an ACCHS does **not** support a proposed research project, the researcher may seek advice from the Ethics Committee about how he/she might progress the situation. However, it is the responsibility of the researcher to gain support for a project (and not the responsibility of the Ethics Committee to advocate or negotiate on behalf of the researcher to achieve a positive outcome).

2. The researcher may seek further advice from the AH&MRC (as the peak body) on how to resolve the situation.

3. The Committee may, in exceptional circumstances, approve an alternative organisation giving consent to the project, with agreement from the AH&MRC.

B. Procedures for involving Aboriginal community bodies other than an ACCHS

1. As a first step, researchers should seek the active involvement and support of local Aboriginal Community Controlled Health Services (ACCHSs), as the Aboriginal community-based body with expertise and experience in health.

2. Where research is being conducted in a community where no ACCHS operates or the ACCHS is unable to participate in the research, the required support may be obtained from an alternative appropriate Aboriginal organisation.

3. The Committee Secretariat will inform the AH&MRC CEO of any case where an alternative arrangement is necessary, and as necessary consult with the CEO to identify an appropriate Aboriginal community body.

4. A list of AH&MRC regional representatives is available at the AH&MRC website: https://www.ahmrc.org.au/about/members/ An alternative organisation must be one that ensures the research is subject to Aboriginal community control from a body that has experience and expertise in health and/or the subject being studied. For example, AbSec, the Aboriginal Child, Family & Community Care State Secretariat, may be appropriate for research on child protection. A *community* perspective is essential. The approval of Aboriginal people employed by government departments is not a substitute for consultation and negotiation with community agencies.

5. The involvement of an organisation as an alternative to the local ACCHS(s) will require the agreement of the Ethics Committee in order to obtain ethical approval.

6. Where a project is state-wide and does not relate to any specific community (eg. epidemiological research analysing state-wide data), the AH&MRC and/or the Ethics Committee, as the representatives of ACCHSs, will have the responsibility of providing Aboriginal community control.

Note

Information for researchers about engaging with ACCHSs (or identifying a suitable alternative) is available on the website in the *AH&MRC Guidelines for Research into Aboriginal Health - Key principles Section 4.2 Aboriginal Community Control of Research.*

SOP 2.5: Complaints

A. Complaints about the AH&MRC Ethics Committee

1. a. Appeals regarding Ethics Committee rejection

(NB: Outright rejection of an application to the Ethics Committee is a rare occurrence and the *National Statement* is silent on mechanisms to deal with this circumstance.)

Where the Ethics Committee has rejected an application, the investigator may:

a) Submit a new application, taking due account of the Ethics Committee's concerns; or
b) Lodge an appeal with the Ethics Committee Co-Chairs specifying the grounds of the appeal in writing.

b. Appeals regarding Ethics Committee approval

Where the Ethics Committee has given a favourable decision on an application and an ethical or scientific issue is subsequently identified by any party, or it has become apparent that either (i) the application contained inaccurate content or (ii) the decision was based on inconsistent application of policy and guidelines, the concerned party may lodge a written appeal with the Ethics Committee Co-Chairs in the first instance.

2. Appeals to the Chair of AH&MRC Board

If, after making an appeal in line with steps outlined above, the appellant is dissatisfied with the outcome, he or she has the discretion to lodge an appeal with the Research Ethics Coordinator or the Chair of the AH&MRC Board or request that the Ethics Committee Co-Chairs do so.

3. Complaints about the conduct of Ethics Committee members

Any complaint about the conduct of an Ethics Committee member should be made in writing to the Co-Chairs of the Ethics Committee, who will raise the matter with the Chair of the AH&MRC Board or Research Ethics Director decide uponan appropriate course of action. The complainant will be informed of the outcome.

B. Complaints about the conduct of an approved research project

4. Complaints information to be provided to participants

1.1 It is a requirement for all applications to the Aboriginal Health and Medical Research Council (AH&MRC) Human Research Ethics Committee ('the Committee') that the full name of the Committee be included on the Participant Information Statement as a body to which participants may raise concerns or complaints. The following paragraph has been suggested for use:

If at any stage you have complaints or concerns about this research, you may contact: The Chairperson
AH&MRC Ethics Committee
Aboriginal Health & Medical Research
Council of NSWPO Box 1565
STRAWBERRY HILLS NSW 2012
Phone 02-9212 4777 or email: ethics@ahmrc.org.au

For research conducted at Aboriginal medical services, the following wording may be preferable:

If at any stage you have complaints or concerns about this research, you may contact the CEO of (insert name of Aboriginal medical service). Alternatively, or if your concerns are not able to be resolved at the local level, you may contact:
The Chairperson
AH&MRC Ethics Committee
Aboriginal Health & Medical Research
Council of NSWPO Box 1565
STRAWBERRY HILLS NSW 2012
Phone 02-9212 4777 or email: ethics@ahmrc.org.au

4.2 Initial steps on receipt of a concern/complaint:

4.2.1 On receipt of the complaint, the Senior HREC Officer of the Committee will ascertain whether it might be possible to resolve the concerns raised without initiating a formal investigation procedure (eg. if the concerns are based on a factual error).

4.2.2 If action under 4.2.1 does not resolve the matter, the grounds for the complaint should, ideally, be provided in writing before the procedures set out in this document can begin. The Committee may choose to accept a verbal complaint where the complainant is reluctant to provide a written statement.

4.2.3 A letter of acknowledgement is to be sent once the complaint has been received in writing. A further letter may be sent once the Committee decides

to accept the complaint and initiate action as below.

4.2.4 The complaint is to be initially referred to the legal member of the Committee for advice as to whether the facts present *prima facea* grounds for further action to take place.

4.3 The Co-Chairs will then determine the appropriate investigative action. This may include the Co-Chairs or her/his nominee:

- convening a sub-committee to investigate the matter;
- seeking advice from other members of Committee or from external persons;
- seeking a response from the Chief Investigator of the project which is the subject of the complaint; and/or
- interviewing any relevant party.

4.4 If an investigation is conducted, the Co-Chairs will send a letter of notification to the Chief Investigator of the project, outlining the complaint and the mechanism for investigating the complaint.

4.5 The CEO of the AH&MRC is to be informed that the complaint has been made if it involves a member organisation of the AH&MRC or staff of the AH&MRC.

4.6 If the complaint is substantiated, action may include:

- a requirement to amend the project (eg. the research protocol) which may include increased monitoring by the Committee; and/or
- temporary suspension of the project pending resolution of the concern/complaint; and/or
- termination of the project; and/or
- other action to resolve the complaint.

4.7 The complainant shall be informed of the outcome of the Committee's investigation.

4.8 Where ethical approval for a research project is withdrawn by the Ethics Committee, the researcher, the institution(s) and, where possible, theparticipants should be informed of the withdrawal.
(Refer also to SOP2.6 *Monitoring research projects,* Section 4. Suspension orcessation of research.)

4.9 If the complainant or Chief Investigator is not satisfied with the outcome of the Committee's investigation, and wishes further action to be undertaken, the Co-Chairs may refer the complaint to the Chair of the AH&MRC Board,together with a copy of all relevant information and documents. The Chair of theAH&MRC Board will determine whether there is to be a further investigation by the AH&MRC of the complaint.

4.10 Where no further investigation is to be undertaken, the Chair of the AH&MRC Board or delegate will inform the complainant and Ethics CommitteeCo-Chairs.

4.11 Where the Chair of the AH&MRC Board determines a further investigation is necessary, she/he will establish a panel to consider the complaint. The panel will include, at least, the following members:

- The CEO or her nominee as convenor of the panel;
- Two nominees of the CEO (not members of the Committee);
- The Research Ethics Director of the Committee.

4.11.1 The panel will have access to all documents relating to the project. The panel may interview or seek submissions from, the Committee Chairperson, the complainant, the Chief Investigator of the project, or any other relevant party. The panel may also seek internal and external expert advice.

4.11.2 The Chair of the AH&MRC Board will notify the complainant and the Co-Chairs of the outcome of the panel's investigation.

4.12 Documentation in relation to a complaint is kept in the relevant project file. The complaint is also logged in the complaints register and a copy of documentation placed in the complaints folder.

SOP 2.6: Monitoring research projects

Note: The National Statement on Ethical Conduct in Research, Chapter 5.5, states that responsibility for ensuring the research is reliably monitored lies within the institution under which the research is conducted. However, the Statement also requires that HRECs establish, implement and document procedures for monitoring approved research.

1.1 The AH&MRC Ethics Committee monitors approved research projects to ensure compliance with the conditions of approval and to protect the rights, safety and welfare of participants and their communities.

1.2 Applicants are required to provide the Committee with
a) an annual progress report (see 2 below); and
b) final drafts for review by the Committee of any report, publication or presentation containing new data arising from the research (see 3 below).

1.3 The Ethics Committee requires, as a condition of approval, that investigators immediately report anything which might warrant review of the ethical approval of the protocol, including:
- any changes to the staffing, methodology, timeframe
- any serious or unexpected adverse effects on participants
- any other aspect of the research relevant to continued ethical acceptability of the project.

1.4 The Ethics Committee may request additional information to monitor individual projects depending on the complexity, design and risk perceived. This may include:
- Discussing relevant aspects of the project with investigators, at any time
- Interview with research participants or other forms of feedback from them
- Requesting and reviewing reports from relevant bodies regarding the project
- Inspection of research sites, data, or consent documentation (permission should be sought through appropriate channels, eg, from the CEO or Research Governance Officer where the research is undertaken).

1.5 Reminders are sent to Chief Investigators from the Ethics Secretariat to submit annual progress reports. (Refer to SOP 2.2)

2. Format of annual progress reports

2.1 The Ethics Committee provides an annual progress report pro forma for use by researchers.
- PRO FORMA – Annual Progress Report (available on the website).

3. Review of reports, publications and presentations arising from approved projects

3.1 As stated in the conditions of approval, researchers are required to submit draft reports, publications and presentation to be reviewed for compliance with ethical and cultural criteria prior to publication.

3.2 These are delegated to at least one Committee member to review. Where possible this should be a member who reviewed the original application. They may also be referred to a member of the External Reference Panel.

3.3 Where there are concerns about a publication or presentation, the matter may be referred to the full committee.

3.4 The reviewer may make recommendations to improve a publication so that it is more culturally sensitive/appropriate.

3.5 As a general principle, the Ethics Committee does not 'approve' or disapprove' a publication, or 'veto' a publication. Rather, it is hoped that the author will seek to accommodate any concerns by revision of the paper.

4. Suspension or cessation of research

4.1 The Ethics Committee will immediately seek to establish if ethical approval for a project should be withdrawn, if:

- The Committee finds reason to believe that a project is not, or cannot be, conducted in accordance with the conditions of approval or that the rights, safety, or welfare of participants may be compromised. (from NSW Health); or
- After repeated requests, information such as an annual progress report, to establish the compliance of the project to the conditions of approval, has not been provided. (from UNSW HREC).

4.2 The Co-Chairs will send a letter of notification to the Chief Investigator of the project, outlining the Committee's concerns.

4.3 The Co-Chairs will determine the appropriate investigative action. This may include the Co-Chairs or her/his nominee:

- convening a sub-committee to investigate the matter;
- seeking advice from other members of Committee or from external persons;
- seeking a response from the Chief Investigator of the project; and/or
- interviewing any relevant party.

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

4.5 Where ethical approval for a research project is withdrawn by the Ethics Committee, the researcher, the institution(s) and, where possible, the participants should be informed of the withdrawal. Suspension can relate to some or all project activities.

4.6 If approval is suspended or withdrawn, the research must be discontinued until further notification.

4.7 The Ethics Committee will not permit the research to be resumed unless either:

a) the researcher subsequently establishes that continuance will not compromise the participants' welfare; or
b) the research is modified to provide sufficient protection for participants, the modification is ethically reviewed, and the modified research is approved.

SOP 3.1: Agenda

1.1. The Research Ethics Director and Research Ethics Coordinator prepare an agenda for each Ethics Committee meeting.

1.2. The meeting agenda and associated documents are circulated to Ethics Committee members at least 7 days prior to the next meeting electronically

1.3. Applications and documentation received after the closing date are included on the agenda and/or tabled at the meeting at the discretion of the Co-Chairs and/or Research Ethics Coordinator

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

a) Acknowledgement to Country
b) Attendance and apologies;
c) Declarations of conflicts of interest relating to agenda items;
d) Confirmation of minutes of the previous Ethics Committee meeting;
e) Business arising since the previous meeting(s) that the Ethics Committee indicated it wished to reconsider;
f) Individual applications – Seeking initial approval;
g) Individual applications – Requests for extension; amendments, progress and final reports, publications and presentations; complaints;
h) Reports of serious adverse events and suspected unexpected serious adverse reactions;
i) Correspondence;
j) AH&MRC Ethics Committee reports (eg. to AH&MRC Board, NH&MRC, Privacy NSW);
Research Issues;
k) NHMRC Issues;
l) Committee – Operations and Resources;
m) Application processes;
n) General business; and
o) Notification of the date, time and venue of the next scheduled meeting.

4.4 The agenda and all documentation are confidential.

2. Supporting documentation

2.1 The following supporting documentation will be provided, as a minimum:

a) Draft minutes of the previous Ethics Committee meeting
b) For applications seeking initial approval:
- list of new, in progress, and completed applications
- overview of all applications yet to receive initial approval
- copy of individual applications and other relevant documents, including advice from delegated reviewers and External Reference Panel member(s).

c) For approved projects seeking extension, amendments, or submitting progress and final reports, publications and presentations for review:

- List of new, in progress and completed requests for approval/review of extensions, amendments reports etc
- Documentation in relation to requests for extension, amendments, progress and final reports, publications and presentations.

d) Complaints – documentation if a complaint is received
e) Reports of serious adverse events and suspected unexpected serious adverse reactions – if a report is made
f) Correspondence including summary lists of correspondence in and out
g) Reports by AH&MRC Ethics Committee (eg. to AH&MRC Board, NH&MRC, Privacy NSW, other)
h) Documentation for any other issues as they arise.

SOP 3.2: Conduct of meetings

1. Schedule of meetings

1.1 The Ethics Committee meets on a regular basis. It holds at least 8 scheduled meetings in each year for the purposes of:

- reviewing new applications;
- considering requests for amendments, extensions and review of reports, etc;
- determining policy;
- updates/discussions on developments affecting the Ethics Committee.

1.2 Meeting dates and application closing dates are made publicly available.

1.3 The schedule of Ethics Committee meetings for the calendar year commencing 1 January is determined by the Ethics Committee before or at the last meeting of the previous year. The schedule sets out the dates, times and venues of meetings, and the closing date for submission of applications.

2. Quorum requirements

2.1 A quorum is required at each meeting for the Ethics Committee to reach a final decision on any agenda item. The quorum for meetings is at least one member from each of the core categories and the Chairperson/Deputy Chairperson as specified in the National Statement attending in person or via telephone or videoconference.

2.2 A quorum can be reached where there is:

- less than a full attendance of the minimum membership at a meeting if the Co-Chairs are satisfied 'that the views of those absent who belong to the minimum membership have been received and considered'; and
- a minimum of five (5) members present.

2.3 Where a quorum is not reached, provided that the Co-Chairs) and at least one other member is present, the Ethics Committeehas the discretion to discuss matters and propose action which will later be put to all members for decision.

2.4 Where the Ethics Manager is concerned that a forthcoming meeting will not be attended by a quorum of members the Ethics Manager notifies the Co-Chairs and the following options are considered:

- Postponing and re-scheduling the meeting; or
- Cancelling the meeting.

3. Declaration of conflict of interest

3.1 An Ethics Committee member declares to the Ethics Committee any conflicts of interest they have in relation to an application for ethical and scientific review or any other matter for consideration at that meeting. Conflict of interest includes financial interests, personal, professional or institutional benefits or advantages that depend significantly on the research outcomes.

3.2 Declarations are made in writing on the Conflict of Interest Pro forma at the meeting prior to the matter being considered or in writing to the Chairperson prior to the meeting. The Ethics Committee determines whether the level of interest results in:

a) A substantial conflict of interest: a member is excluded from the meeting where there is a substantial conflict of interest until the Ethics Committee has concluded consideration of the matter. Being an investigator on a research project is considered to represent a substantial conflict of interest.
b) A non-substantial conflict of interest: the member has the discretion to leave during the discussion of the matter.

3.3 The minutes record all declarations of interest and the decision of the Ethics Committee on the procedures to be followed.

4. Confidentiality

4.1 The confidentiality of Ethics Committee proceedings is essential as:

- members do not sit on the Ethics Committee in a representative capacity
- applications need to be discussed freely
- there may be sensitivities in relation to the Aboriginal individuals and communities
- applications may have commercial implications.

4.2 Ethics Committee meetings are held in private and members are encouraged to raise matters of concern. The agenda and minutes of meetings, applications, supporting documentation and correspondences are all treated confidentially.

4.3 Attendance of visitors or observers at a meeting, as appropriate and approved by the Co-Chairs, is conditional on the attendee signing a confidentiality agreement.

4.4 Ethics Committee correspondence is addressed to the Chief Investigator and sent to the Chief Investigator or the relevant contact person identified on the application form. Correspondence is not released to any other parties.

4.5 Chief Investigators forward information about matters raised in the ethical review to other parties where necessary.

5. Decision making

5.1 Members present are allowed sufficient opportunity to express relevant views on matters on the agenda prior to any decision.

5.2 The Ethics Committee endeavours to reach its decisions by unanimous agreement (including on all matters concerning the ethical and scientific acceptability of a research project).

5.3 Where a unanimous decision is not reached, the matter is determined by a majority of members present at the meeting.

5.4 Discussions of significant issues and decisions are recorded in the minutes. A Committee member has the right to have her/his view recorded. For example, where members wish, a record of their formal dissent from the decision of the Ethics Committee is recorded.

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

5.6 An Ethics Committee member unable to attend a meeting may submit comments in writing on agenda items to the Research Ethics Coordinator or Co-Chair prior to the meeting.

5.7 All applications must go before the full Committee at least once before approval is granted. Approval may then be granted out of session, and the decision ratified at the next meeting.

<u>Decisions available to the Ethics Committee in relation to applications</u>

5.8 The full Committee may:
a) make a decision about the application; or, in cases where there appear to be no major concerns with the proposal
b) delegate it to a sub-group of two or more members to undertake a detailed review and approval.

5.9 Where a matter has been delegated, members may choose to take the application back to the full Committee for further consideration/approval if required.

5.9 The full Committee, or delegated members, make one of the following decisions on any application:
a) approve the application as being ethically and scientifically acceptable;
b) approve the application, subject to additional conditions, as being ethically and scientifically acceptable;
c) request modification or further information/clarification;

d) seek further advice from external reviewer(s); or
e) reject the application.

5.9 The Co-Chairs ensures that one of the above decisions is made on every application considered at an HREC meeting.

5.10 Decisions are recorded in the minutes. Where the decision has been made out of session, the decision is reported at the following meeting and recorded in the minutes.

(Refer also to the SOP *Review of Applications*)

SOP 3.3: Preparation of Minutes

1. The Research Ethics Coordinator prepares the minutes of the Ethics Committee meeting in consultation with the Chairperson and other members as necessary.

2. The minutes are reviewed by the Research Ethics Director and Co-Chairs.

3. The minutes reflect each item listed for discussion on the agenda:
   a) Attendance and apologies;
   b) Declarations of conflicts of interest relating to agenda items;
   c) Confirmation of minutes of the previous HREC meeting;
   d) Business arising since the previous meeting(s) that the HREC indicated it wished to reconsider;
   e) Individual applications – Seeking initial approval. HREC deliberations and decisions on new applications, including summaries of the main issues considered;
   f) Individual applications –requests for extension; amendments, progress and final reports, publications and presentations; complaints. HREC deliberations and decisions, including summaries of the main issues considered;
   g) Reports of serious adverse events and suspected unexpected serious adverse reactions;
   h) Correspondence;
   i) AH&MRC Ethics Committee reports – to AH&MRC Board, NH&MRC, Privacy NSW, other;
   j) Committee operations and resources;
   k) Application processes;
   l) General business; and
   m) Notification of the date, time and venue of the next scheduled meeting.

4. The draft minutes are distributed electronically to members within two weeks of the meeting.

5. The minutes are submitted to the next meeting of the Ethics Committee for ratification as a true record. Members are given the opportunity to seek amendments to the minutes prior to their finalisation.

6. The minutes are confidential to the Committee and are not disclosed to investigators.

SOP 4.1: Record Keeping

1. Maintenance of records

1.1 The Research Ethics Director is responsible for ensuring:
- Files are kept securely and confidentially.
- Files are up to date and complete.
- The Ethics Committee maintains its electronic records only.

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.

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

2. Access to records

2.1 The Ethics Committee Secretariat has day-to-day access to the electronic files and records of the Ethics Committee.

2.2 Requests for access to records by any other parties should be directed to the Chair of the Ethics Committee or the Research Ethics Director and will be considered ona case-by-case basis, taking into account the importance of maintaining security and confidentiality of information.

2.3 External parties accessing Ethics Committee records may be required to sign a confidentiality agreement prior to access. (This includes AH&MRC staff who are not members of the Ethics Committee or Ethics Committee secretariat.)

3. Records of Meetings

3.1 Electronic records of all meetings of the Ethics Committee are maintained (including agendas and minutes) as an electronic file. The minutes records discussions and decisions relating to (i) general issues and (ii) consideration of applications.

4. Records of Membership

4.1 The Ethics Committee maintains a record, which includes resumes, biography, contact details and conflicts of interest of
- Members of the Ethics Committee
- Members of the External Reference Panel

5. Records of Applications

5.1 The Ethics Committee maintains the following files:
- A register of all applications received and reviewed in accordance with the National Statement. The register includes details of:

a) Project identification number
b) Chief Investigator
c) Organisation
d) Address
e) Title of project
f) Date received
g) Date approved

- A register of enquiries
- .A register of complaints.

6. Other records

6.1 The Ethics Committee maintains electronic copies of any other business of the Ethics Committee, including:

a) Reports to external bodies such as AH&MRC Board, NHMRC and Privacy NSW
b) Training
c) Presentations
d) Policies and procedures
e) Research issues
f) Involvement with other organisations/committees/initiatives
g) Funding matters.

APPENDIX – FORMS AND TEMPLATES

For Use by Applicants

1. PRO FORMA – Application Cover Sheet and Key Principles
2. PRO FORMA – Individual Participant Consent Form
3. PRO FORMA – Aboriginal Community Organisation Consent Form
4. PRO FORMA – Annual Progress Report

For Use by Secretariat

5. PRO FORMA – Acknowledgement Letter
6. PRO FORMA – Approval Letter
7. PRO FORMA – Email to ACCHS CEO re notification of approval
8. PRO FORMA – Approval of Extension
9. PRO FORMA – Approval of Amendment
10. PRO FORMA – Email reminder to research re Extension/Annual Report
11. PRO FORMA – Email to researcher re publication for review
12. PRO FORMA – Letter to Expert Panel Member
13. PRO FORMA – Confidentiality Agreement

For Use by Committee

14. PRO FORMA – Assessment of Ethics Applications