

Aboriginal Health and Medical Research Council of NSW

Human Research Ethics Committee Terms of Reference

(Reviewed 2019)



**Aboriginal
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of NSW**

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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:

- e) 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 the physical 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.
- f) Provide thorough, timely review and monitoring of Aboriginal health-related research projects in respect of their ethical and scientific acceptability for as long as projects are active;
- g) 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
- h) Provide advice to the AH&MRC on strategies to promote awareness of the ethical conduct of Aboriginal health-related research.
- i) 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 Ethics Committee provides a report for inclusion in the AH&MRC annual report.
- 3.3 The Ethics Committee brings issues of significant concern relating to research ethics matters to the attention of the AH&MRC Board of Directors.
- 3.4 The 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 where they involve research in, or concerning, NSW, and any one of the following applies:
- 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.
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- 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 of Human Research in NSW Public Health Organisations, 2010](#), Section 5.2.)
- 4.1.4 Approval of the AH&MRC Ethics Committee is a requirement of some universities for Aboriginal health-related research undertaken in NSW by researchers at that university.

4.2 Other Activities

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

4.3 The Chairperson

- 4.3.1 The Chairperson is responsible for:
- the effectiveness and overall functioning of the Ethics Committee;
 - the conduct of HREC business; and
 - ensuring that the HREC reaches decisions on all applications.
- 4.3.2 Where the Chairperson is unavailable the meeting will be chaired by the Deputy Chairperson if available. If both are unavailable, the members present will appoint a Chair for the meeting.

5. ORGANISATION CONTEXT

- 5.1 The Executive Officer of Research Ethics is accountable to the Chair of the HREC on all research issues. The Executive Officer of Research Ethics reports directly to the Chief Executive Officer on matters of operation of the HREC. The Executive Officer of Research Ethics is responsible for ensuring the provision of high level secretariat services.

6. MEMBERSHIP

6.1 Composition

- 6.1.1 The composition of the Ethics Committee is consistent with the *National Statement*, which requires it to have:
- a) A Chairperson with suitable experience whose other responsibilities will not 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, with no 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, the professional 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 not engaged to advise the institution for which the HREC is reviewing research; and
- f) At least two members with knowledge of and current research experience that 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 twenty members. Where possible, members are Aboriginal and as far as possible, men and women 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 as the Chairperson of the Ethics Committee.
- c) Four members who are members of an Aboriginal Community Controlled Health Service (ACCHS);
- d) Two Aboriginal elders, preferably one female and one male;
- e) Two members who are lay people with no affiliation with the institution or organisation and not currently involved in medical, scientific, legal or academic work;
- f) At least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people;
- g) At least two members with knowledge of and current research experience that is relevant to the applications to be considered at the meetings they attend;
- h) At least one member who is a lawyer, where possible one who is not engaged to advise the institution for which the Ethics Committee is reviewing research.
- l) One member who is a youth representative, aged between 18-25 years.

6.2 Appointment of members

6.2.1 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 Ethics Committee, and regular input of fresh ideas and approaches.

- 6.2.2 Prospective members may be invited to observe a meeting of the Ethics Committee.
- 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 Ethics Committee is made publicly available on the AH&MRC website.
- 6.2.5 All members including the Chairperson and Deputy Chairperson are appointed by the AH&MRC Board, following the recommendation of the Executive Officer of Research Ethics 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 maximum of 6 years. The Chair of the AH&MRC Board or delegate, in consultation with the Ethics Committee Chairperson, may implement a probationary period.

6.3 Responsibilities of members

- 6.3.1 Upon appointment, members are provided with an orientation package and asked to sign a statement undertaking:
- a) that all matters of which he/she becomes aware during the course of his/her work on the Ethics Committee will be kept confidential;
 - b) that any conflicts of interest, which exist or may arise during his/her tenure on the Ethics Committee will be declared; and
 - c) that he/she has not been subject to any legal or disciplinary action, which may prejudice his/her standing as an Ethics Committee member.
 - d) that members will 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 ceases if a member 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 Ethics Committee meetings in each year, 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 will cease if members are unable to carry out their duties of reviewing applications.

- 6.3.4 The Chair of the AH&MRC Board notifies the member of a cessation of membership in writing. Steps are taken to fill the vacancy.
- 6.3.5 Members seeking to resign or take a leave of absence for an extended period from the Ethics Committee are asked to give written notice to the Chair of the AH&MRC HREC. Steps are taken to fill the vacancy or temporary vacancy.
- 6.3.6 The appointment of any member of the Ethics Committee may be terminated if the AH&MRC Board is of the opinion that:
- a) It is necessary for the proper and effective functioning of the Ethics Committee;
 - 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 Ethics Committee member.
- 6.3.7 Members may be required to participate in relevant specialised working groups or subcommittees.

Confidentiality

- 6.3.7 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.
- 6.3.8 Members are required to sign a confidentiality agreement upon being appointed to the Ethics Committee.

Declaration of conflict of interest

- 6.3.9 A conflict of interest may compromise the process of review of applications or consideration of other matters, and may lead to decisions being based on factors outside the requirements of 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 Ethics Committee member must declare to the Ethics Committee any conflicts 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 made in writing to the Chairperson or Secretariat prior to the matter being considered. 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; 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 declaration of interest and the decision of the Ethics Committee on the procedures to be followed. A register of conflicts of interest is maintained on the AH&MRC server.

6.4 Orientation and training of members

- 6.4.1 New Ethics Committee members are provided with orientation/training as recommended by the Executive Officer.
- 6.4.2 Orientation involves some 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 Chairperson and Executive Officer to explain their responsibilities as an Ethics Committee member, 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 in 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 development activities 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 Ethics Committee for liabilities that arise as a result of the member exercising their duties in good faith.

6.6 External Reference Panel

- 6.6.1 The Ethics Committee has established an External Reference Panel of experts who can provide advice in relation to research applications if required, provided that there is no conflict of interest and an undertaking of confidentiality 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 Ethics Committee conducts its business in accordance with the Terms of Reference and Standard Operating Procedures.

7.2 Meetings

- 7.2.1 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.
- 7.2.2 Meeting dates and application closing dates are made publicly available.
- 7.2.3 The schedule of Ethics Committee meetings for the calendar year commencing 1 January is ratified 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.

7.3 Quorum requirements

- 7.3.1 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* (see 6.1.1 above) attending in person or via telephone 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 if the Chairperson is 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 Ethics Committee endeavours to reach a decision concerning the ethical and scientific acceptability of a research project by unanimous agreement.
- 7.4.3 Where a unanimous decision is not reached, the matter is determined by a majority of two-thirds of members present at the meeting, provided that the majority includes at least one layperson.
- 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 Committee wishes to request further information, the 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 reviewers 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 of an Aboriginal Medical Service, that service has signed a research agreement and this has been provided in the application.

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 Building aspects of the research have been satisfactorily addressed.

AND

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 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 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.

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 the Chair.

7.6 Records

- 7.6.1 Electronic records (including agendas and minutes) of all meetings of the Ethics Committee are maintained. The minutes also record decisions made out of session.
- 7.6.2 Electronic records are maintained of all application and associated documents including any correspondence in relation to the application.
- 7.6.3 The Ethics Committee maintains a register of all the applications received and reviewed in accordance with the National Statement.
- 7.6.4 Electronic records are maintained of all other business of the Ethics Committee.
- 7.6.5 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.
- 7.6.6 Records may be retained after the minimum period or disposed of in a secure manner.

7.7 Monitoring approved research projects

- 7.7.1 The 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. This includes review of annual progress reports and final reports, safety reports and reports of protocol violations.
- 7.7.2 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).

7.8 Ethics Committee reporting requirements

- 7.8.1 An Ethics Committee report is provided for consideration at each meeting of the AH&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
- d) The Ethics Committee metrics including average review time of an application.
- e) Issues identified by the 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 been suspended or withdrawn and the reasons for this action
- h) Other issues relating to the operation of the Committee, outcomes of policy discussions, 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 Ethics Committee completes and submits reports on behalf of the AH&MRC to the:

- a) Australian Health Ethics Committee (AHEC) in accordance with the requirements of the NHMRC; and
- b) NSW Privacy Commissioner in accordance with the requirements of the Health 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 Ethics Committee, 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) Complaints handling procedures.

8. APPEALS AND COMPLAINTS

8.1 Appeals regarding Ethics Committee rejection

Where the Ethics Committee has rejected an application, the investigator has the discretion to:

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

8.2 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 the decision was based on inconsistent application of policy and guidelines, or if information provided to the Committee is found to have been incorrect or incomplete, an electronically written appeal may be lodged with the Chairperson in the first instance.

8.3 Appeals to the Chair of the AH&MRC Board

If, after an appeal is made, the appellant considers that the 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 Chief Executive Officer or the Chair of the AH&MRC Board or request that the Ethics Committee Chairperson do so.

8.4 Complaints about the conduct of Ethics Committee members

If there is a complaint about the conduct of an Ethics Committee member, it should 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 Committee secretariat or the Chair of the Ethics Committee. They are managed in accordance with the Ethics Committee's procedures outlined in *SOP 2.5: Complaints handling*.



