

Guidelines for submitting an ethics application to the AH&MRC Human Research Ethics Committee

These guidelines are to assist applicants in their preparation of submissions to the AH&MRC HREC. The guidelines cover:

1. Who needs to submit an Application
2. Developing an application – Obtaining community support
3. Submitting an Application
4. Assessment of Applications
5. Approval of Applications

The guidelines are updated from time to time. Researchers should check the website each time they complete an application to ensure they are following the most current guidelines.

These guidelines and other relevant documents can be found on the website:

http://www.ahmrc.org.au/index.php?option=com_docman&task=cat_view&gid=22&Itemid=45

1. Who needs to 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.

Applications are received from the full range of people and organisations conducting research 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. There are a number of different projects that need to come to the AH&MRC Ethics Committee for approval which are outlined below.

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.

Research does not meet the above criteria may still need to come to the AH&MRC Ethics Committee for approval. Please see sections B and C for clarification. *It is emphasised that the following points provide guidelines only and that each specific case will need to be considered against the particular circumstances of that case.* If you are unsure, you should contact the Secretariat.

Research concerning the general population

Research that is not specifically directed at Aboriginal people or communities, such as for the total population or a sub-population (eg. rural NSW, people over 50 years old) can still potentially impact on Aboriginal people.

An application for research concerning the general population need only be made to the Committee if any one of the following applies:

- Any of the five factors listed above are present; or
- Aboriginal people are known, or are likely, to be significantly over-represented in the group being studied (eg. compared to the 2.1% of the total NSW population as shown in the 2006 Census); or
- The Aboriginal experience of the medical condition being studied is known, or is 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
- It is proposed to separately identify data relating to Aboriginal people in the results.

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. If you are unsure, you should contact the Secretariat.

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 (2003): 'When does quality assurance in health care require independent ethical review?'
- 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 program 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.

2. 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 will need to show evidence that they have the support of each local Aboriginal Community Controlled Health Service (ACCHS) where the research is being conducted.

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 (subject to the agreement of the Ethics Committee). The AH&MRC regional representative in the region may be able to provide assistance in identifying an appropriate alternative organisation.

An alternative organisation must be one that ensures the research is subject to Aboriginal community control, including people with experience and expertise in health. For example, an Aboriginal drug and alcohol agency or ADAN (Aboriginal Drug and Alcohol Network) may be appropriate for research on substance abuse.

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.

3. 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 two weeks before a Committee meeting if it is to be considered by that meeting.

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)
- Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Island Health Research (NH&MRC, 2003)
- Keeping Research on Track : A guide for Aboriginal and Torres Strait Islander peoples about health research ethics (NH&MRC, 2006)
- 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)

Content of an Application

An application must include the following documents:

1. Application Cover sheet

All applicants must complete an Application Cover Sheet. Please include the completed checklist (page 2 of cover sheet) with your application.

2. A statement (1-2 pages) addressing the AH&MRC's five criteria in relation to the project.

The criteria, and the key principles underpinning them, can be found in Sections 3 and 4 of the AH&MRC Guidelines for Research in Aboriginal Health – Key Principles.

To ensure the statement remains concise, it can include cross-references to more detailed papers such as the reference documents outlined above.

3. A copy of a completed ethics application form

This may be an application form that has been submitted to another Human Research Ethics Committees (HRECs) for the same project.

Where the AH&MRC is the only HREC to which an ethics application is being made, the Committee will accept an application completed on any standard form for an NH&MRC-approved HREC. You may use the National Ethics Application Form if you do not have access to any other form.

The application should include copies of the Participant Information Statement(s) and pro forma Consent Form(s) for Individual Participants. You may use the AH&MRC Ethics Committee's Model Consent Form for Individual Participants.

'The Aboriginal Health and Medical Research Council (AH&MRC) Ethics Committee' should be included on the Participant Information Form as a body to which participants can raise concerns or complaints about the research.

4. Signed Forms

Organisational Consent Forms or Letters of Support from Aboriginal Community Controlled Health Services (ACCHSs) or an appropriate alternative Aboriginal community body.

The form or letter must be signed by either the Board Chairman or CEO of the ACCHS. (The reason for this is to ensure that the most senior people in the ACCHS are aware of any commitments for the ACCHS arising from the research).

An application may be submitted without a signed form or letter, but the Committee will not give final approval for research to be conducted in any community until the signed form or letter from that community is received.

Where research is being conducted in a community where no ACCHS operates or the ACCHS is unable to participate in the research or provide a letter, the AH&MR Ethics Committee may accept a form or letter from an appropriate alternative organisation. The organisation must be one that ensures the research is subject to Aboriginal community control, including people with experience and expertise in health. (See Developing an Application – Obtaining Community Support.)

Please see our website to download the latest Model Consent Form.

5. A copy, or summary, of the study protocol for the research.

Where the protocol is reasonably concise (eg. less than 10 pages), the full version should be provided.

Where the protocol is lengthy, a summary that covers the major issues affecting ethics can be provided.

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 Area Health Service 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.

If you have submitted an application to another HREC, in addition to the other documents required by the AH&MRC Ethics Committee you should enclose 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.

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 Information and Ethics Committee
- (Northern Territory) Top End Human Research Ethics Committee
- (Northern Territory) Central Australian Human Research Ethics Committee.

Number of copies and format of application to be submitted

- Three (3) hard copies of the application, with the various parts stapled and presented in final form
- One (1) other hard copy, unstapled, in the same order as the stapled copies
- An electronic copy to be sent to ethics@ahmrc.org.au.
- All attachments should be numbered or lettered
- A summary list of attachments should be provided.

Attachments

- All attachments numbered or lettered
- A summary list of attachments has been provided

The preferred font for an application is Times New Roman 12 Point, although material previously prepared (eg. copy of an ethics application already submitted to another HREC) will be accepted.

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 has 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 two weeks before a Committee meeting if it is to be considered by that meeting. A calendar of the dates can be found on the website.

Receipt and Acknowledgement of Applications

An application is considered to have been submitted on the date when hard copies meeting all of the requirements set out in Submitting an Application and Content of an Application above have been received.

Applications will be acknowledged in writing within two week of the date of submission. The acknowledgement (and future formal communications) will be sent to the person designated as Chief Investigator on the Application Cover Sheet.

Checklist for Applications

Checklist for Applications	Yes/NA
Application Cover Sheet	
A brief statement addressing the AH&MRC's five criteria	
A completed ethics application form - this can be a copy of an application to another HREC	
A copy, or summary, of the research study protocol	
All necessary signatures have been obtained	
A copy of any requests from other HRECs for further information about your application, together with your response to the request.	
A copy of Approval letters from other HRECs (if received)	
Participant Information Statement(s)	
'Aboriginal Health and Medical Research Council Ethics Committee' included on the Participant Information Statement as a body to which participants can raise concerns or complaints	
Pro forma Consent Form(s) for Individual Participants	
Signed Organisational Consent Form or Letter of Support from all relevant ACCHSs	
Signed Organisational Consent Form or Letter of Support from all relevant AH&MRC (if appropriate, see section xx)	

4. 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;
- 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.

5. Approval of Applications

When the AH&MRC Ethics Committee grants approval for an ethics application, it sets eight [8] 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 approval is for a period of one year, with extension for an additional period subject to providing a report on the research prior to the end of year. (NB. Actual dates are given for each application).
[Annual Progress Report Form](#)
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 participant 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 at all times with:
 - the *AH&MRC Guidelines for Research in Aboriginal Health- Key Principles*
 - the *National Statement on Ethical Conduct in Research Involving Humans (April 2007)*; and
 - the *NSW Aboriginal Health Information Guidelines*.
7. The final draft report from the research, and any publication or presentation where 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.

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.

In addition to the standard requests, special conditions may apply.

The above conditions must be met to maintain ethical approval.