

**Aboriginal Health & Medical Research Council
of New South Wales (AH&MRC)**

AH&MRC Ethics Committee

**AH&MRC Guidelines for Research
into Aboriginal Health**

Key principles

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1. BACKGROUND

In 1996 the forerunner to the AH&MRC (the NSW Aboriginal Health Resources Cooperative) established an Ethics Committee in response to the fact that for many years much health and medical research about Aboriginal people had been invasive, inappropriate, unnecessary, and undertaken without consultation with or approval by Aboriginal people and communities.

In 1999, the AH&MRC Ethics Committee produced a document, *Guidelines for Research into Aboriginal Health* that has since provided the basis for the Committee's consideration of, and decisions about, applications for ethical approval of individual research projects.

That document is currently under review by the AH&MRC and the Ethics Committee to ensure that it reflects contemporary needs and circumstances.

In the interim while the review is underway, this document has been prepared to inform researchers about the key principles contained in the 1999 *Guidelines*. This should be read in conjunction with the information about the Committee's procedures that are contained on the Ethics page of the AH&MRC website.

Note that a number of the procedures set out in the 1999 *Guidelines document* have been amended, and researchers should now follow the procedures currently contained on the Ethics webpage. However, the core principles regarding Aboriginal community control of research and the criteria by which the Ethics Committee assesses applications remain unchanged from the *Guidelines document*

2. THE DEVELOPMENT OF ETHICAL STANDARDS FOR RESEARCH IN ABORIGINAL HEALTH

2.1. Historical Context

The 1999 *Guidelines* document sets out the history of the development of ethical standards for research in Aboriginal health. It provides background on the following events and papers:

- National Conference on Research Priorities into Aboriginal Health, Alice Springs, December 1986.
- National Workshop on Ethics in Aboriginal Health, Camden, 1987.
- National Workshop on Ethics of Research in Aboriginal Health (NAIHO Report), 1987.
- National Aboriginal Health Strategy, 1989.
- NH&MRC Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Research, 1991.
- Recommendations of the Royal Commission into Aboriginal Deaths in Custody, 1991.
- Aboriginal and Torres Strait Islander Health, Goals and Targets (ATSIC, Department of Health, Housing and Community Services, Department of Employment, Education, and Training, with input from Aboriginal community organisations), March 1992.
- OATSIHS/NACCHO National Aboriginal & Torres Strait Islander Health Data Protocols for the Routine Collection of Standardised Data on Aboriginal and Torres Strait Islander Health, October 1997.

2.2. Current Key Documents

There are a number of documents that can assist researchers in understanding the ethical standards now required for Aboriginal health and medical research. The major ones are:

- *National Statement on Ethical Conduct in Research Involving Humans* (NH&MRC, 2007)
http://www.nhmrc.gov.au/guidelines/ethics/human_research/index.htm
- *NSW Aboriginal Health Information Guidelines (1998)*
(A4 – to come)
- *Why an Aboriginal Ethical Perspective is Necessary for Research into Aboriginal Health* (AH&MRC Paper, written by Mundine, Edwards, & Williams, May 2001)
(K2 – to come)
- *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Island Health Research* (NH&MRC, 2003)
<http://www.nhmrc.gov.au/publications/synopses/e52syn.htm>
- *Keeping Research on Track : A guide for Aboriginal and Torres Strait Islander peoples about health research ethics* (NH&MRC, 2005)
<http://www.nhmrc.gov.au/publications/synopses/e65syn.htm>
- *The NHMRC Road Map: A Strategic Framework for Improving Aboriginal and Torres Strait Islander Health Through Research (2002)*
<http://www.nhmrc.gov.au/publications/synopses/r28syn.htm>
[Note that the NH&MRC is currently undertaking a review of this document].

- *CRIAH Tools for Collaborative Research (December 2007).*
<http://www.ahmrc.org.au/CRIAH%20Tools%20for%20Collaboration.htm>
- *Guidelines for Ethical Research in Indigenous Studies (Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) 2000)*
http://www.aiatsis.gov.au/_data/assets/pdf_file/2290/ethics_guidelines.pdf

3. EVALUATION PROCEDURE

The AH&MRC Ethics Committee assesses applications against the following criteria

- a) Consistency with the *National Statement on Ethical Conduct in Research Involving Humans* (NH&MRC, 2007)
- b) The Committee will only approve a project where:
 - (i) The research will advance scientific knowledge and result in a demonstrated net benefit for the health of Aboriginal people and communities.
 - (ii) 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
 - (iii) The research will be conducted in a manner sensitive to the cultural principles of Aboriginal society.
 - (iv) Aboriginal communities and organisations will be reimbursed for all costs arising from their participation in the research process.
 - (v) The project will utilise available opportunities to enhance the skills and knowledge of Aboriginal people, communities and organisations that are participating in the project.

4. KEY PRINCIPLES TO BE ADDRESSED IN ETHICS APPLICATIONS TO THE AHMRC

It is NOT sufficient to simply assert that the above criteria will be met. Applicants must indicate the specific processes and mechanisms that will be established to ensure that the criteria will be met.

The following is intended to provide some guidance as to the meaning of each of the criterion.

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 AH&MRC Ethics Committee Secretariat for advice (Ph. 02-92124777, or email ethics@ahmrc.org.au).

4.1. Net Benefits for Aboriginal people and communities

Applications must indicate:

- the particular problem that the research is addressing and explain specifically how the research can contribute to overcoming the problem;
- that all risks have been identified and assessed; and
- there will be a *net* benefit after taking into account known negatives and potential risks.

The benefits for the research may be for Aboriginal health in general or simply for the health of those Aboriginal people and communities that are participating in the project.

In working with Aboriginal people in communities and organisations in the development of a research proposal, researchers should provide information and advice about the usefulness of the research to the community.

4.2. Aboriginal Community Control of Research

There must be *Aboriginal community control* over all aspects of proposed research including the design and conduct of the research, ownership of data, interpretation of data, and the reporting and publication of findings from research affecting the health of Aboriginal people.

When is Aboriginal Community Consent for Research Necessary?

Aboriginal community consent is considered necessary for the collection and use of health and health-related community information if any one of the following factors apply:

- 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 Meaning of 'Control'

The term 'control' essentially means that at all stages of the research, Aboriginal people and communities participating in, or directly affected by the research will be fully informed about,

and agree with, the purposes and conduct of the project. It goes beyond either involvement or consultation, and requires an acknowledgment that Aboriginal people have the right to make decisions about research affecting them. However, the way in which ‘control’ will be implemented will vary between projects.

The specific processes and mechanisms by which control is achieved will vary with each project following negotiation and formal agreement by the local communities.

In ensuring Aboriginal community control, researchers and bodies requesting data must:

- provide communities with all the relevant information and explanations on the intent, process and methodology, evaluation, and potential value of any research proposal;
- comply with requests for further information from relevant community controlled agencies associated with the research proposal;
- seek the formal consent of each participating Aboriginal community;
- respect the Aboriginal community’s process of decision making when they seek the consent of communities to research, recognizing that each community will have different decision-making processes reflecting their particular social and cultural values; and
- ensure that appropriate cultural protocols and procedures are in place at each stage in the development, conduct, and reporting of the research.

Community

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.

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. The AH&MRC regional representative [click here for a list of all our Member Organisations by Region](#) 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 from a body that has experience and expertise in health and/or the subject being studied. For example, an Aboriginal drug and alcohol agency or ADAN (Aboriginal Drug and Alcohol Network) may be appropriate for research on substance abuse.

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.

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.

Similarly, the role of the AH&MRC Ethics Committee is essentially advisory to Aboriginal communities. The existence of a state wide ethical body reflects the fact that ACCHSs and local communities need assistance with assessing research projects given the workload involved and the complex and specialist nature of much health and medical research. However, the work of the Ethics Committee is carried out in conjunction with Aboriginal

communities and is not a substitute for the Aboriginal community decision making process. The Ethics Committee may provide advice, but ultimately each Aboriginal community can itself decide if it wishes to participate in a research project.

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.

Formal Consent

Formal consent and agreement to a research project needs to be obtained from both:

- individual people who are participants in the project; and
- the ACCHS(s) and/or other Aboriginal community organisations responsible for exercising Aboriginal community control over the project.

Model consent forms are available on the Ethics webpage for *individual participants* (H2 – [Click to Doc H](#)) XX and *organisations* (J2 – [Click to Doc J](#))

The consent obtained from individuals and organisations must be free, informed, and in writing.

A consent agreement with an ACCHS or other Aboriginal community organisation should include:

- a statement as to the objectives of the research
- an explanation of why the information is being collected and how it will be used;
- provisions for additional consent for any future changes to the agreed use of the information or the agreed research design;
- identification of who will, or is likely to, have access to the information;
- provision for withdrawal of consent; and
- a requirement of future consent for use of information or biological materials for ‘piggy back’ or other research not explicitly covered by initial arrangements.

The consent agreement may also include the right of a community to seek independent advice on the research proposal.

Aboriginal Ownership of Data and the Publication of Findings

The Aboriginal community (or an ACCHS or appropriate alternative Aboriginal organisation as described above) should have:

- ownership of the data provided to researchers;
- ownership of the data resulting from the research (eg. arising from the collation and analysis of original data);
- rights over the reporting and publication of the results and findings from the research; and
- an on-going role in monitoring the implementation of research.

In relation to these matters, researchers should develop and subsequently implement formal agreements which accord with Aboriginal cultural principles. For any project, there needs to be a formal mechanism or process both for:

- vesting these rights in the community; and
- the community to transfer the rights or grant a licence for the use of data or results.

Researchers should ensure that there is a clear and formal agreement prior to the start of research about the rights that communities have in relation to data and publication. This should cover matters such as:

- storage and archiving of data
- access to data and security
- publication procedures and protocol
- changes in the proposed use of the data.
- Community ownership of blood or tissues samples gathered during the project;
- negotiation over the disposal or storage of raw data;
- publication and appropriate acknowledgement;
- the terms on which a community may exercise a right to veto or edit the publication of sensitive information.

Acknowledgement of the contributors to the research should include recognition of the participation and assistance of Aboriginal individuals, communities and organisations.

Confidentiality and Privacy

A key principle contained within the *Commonwealth Privacy Act* (1988), the *NSW Health Records Information Privacy Act* and the *National Statement on Ethical Conduct in Research Involving Humans* (NH&MRC, 2007) is that personal information which has been collected by researchers or within a health data system cannot be used for any purpose other than that for which explicit informed consent has been obtained from the person to whom the information refers. While there are public interest provisions that enable some exemptions from this requirement, it is expected that the requirement will generally apply to research in Aboriginal health.

Hence, in order to obtain ethics approval from the AH&MRC Ethics Committee, it is essential that researchers and bodies responsible for obtaining, collating, researching, analysing and reporting data on Aboriginal health information clearly state their specific purpose and identify appropriate personnel who are responsible for ensuring that consent agreements are complied with.

In addition to concerns about the use of personal information about *individuals* provided for research and data systems there is also the need for provisions to protect Aboriginal *communities* where anonymity is considered necessary and to ensure correct use of cultural information provided to researchers or data repository bodies.

4.3. Cultural Sensitivity

Cultural requirements will vary between Aboriginal communities. The documents listed in Section 2.2 above will assist researchers to identify the matters that need to be considered in each case.

Researchers should ensure that they have considered the following matters in terms of the *process* of the research:

- the decision-making processes in each community;
- ensuring that all members of the community affected by the research have been properly consulted and informed (eg. family groups, gender issues, etc);
- adequate time frames for consultation and conduct of the research; and
- that questionnaires and survey forms are culturally appropriate.

4.4. Reimbursement of costs

In seeking the co-operation of Aboriginal communities and local community controlled agencies, researchers should reimburse participants for any cost incurred which relates, directly or indirectly, to the research project. Such costs could include telephones, transport, freight, gas and water, accommodation, supervision costs and wages of assistants and interpreters.

There should be no imposition upon the Aboriginal community controlled health sector to be involved in processes that are not adequately funded or resourced.

4.5. Enhancing Aboriginal skills and knowledge

Where possible, Aboriginal people (and especially local community members) should be employed in research projects, including as co-investigators. This will improve the quality of communication and the researcher's understanding of the community.

Wherever possible, there should be arrangements for the training and development of indigenous research workers.

Where Aboriginal people are locally employed in health research projects, recruitment, selection and employment should be undertaken in association with ACCHSs (or an alternative Aboriginal community organisation as described above.
