

# AH&MRC Ethical Guidelines: Key Principles (2020) V2.0

This document replaces the *AH&MRC Guidelines for Research into Aboriginal Health, 2016*

The AH&MRC Human Research Ethics Committee acknowledges the traditional Aboriginal custodians upon whose ancestral lands the AH&MRC stands.



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## Acronyms

ACCHS: Aboriginal Community Control Health Service

ACCH: Aboriginal Community Control Health

ACCHO: Aboriginal Community Control Health Organisation

AH&MRC: Aboriginal Health and Medical Research Council of NSW

AHC: Aboriginal Health College

HREC: Human Research Ethics Committee

HREA: Human Research Ethics Application

NSW: New South Wales

CEO: Chief Executive Officer

NACCHO: National Aboriginal Community Controlled Health Organisation

PM&C: Prime Minister & Cabinet

CAH: Centre for Aboriginal Health

DoH: Department of Health

AMSS: Aboriginal Medical Service

AHW: Aboriginal & Torres Strait Islander Health Worker

TOR: Terms of Reference

JH&FMHN: Justice Health and Forensic Mental Health Network

ARG: Aboriginal Reference Group

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# 1) Background, Purpose and Guiding Documents

## 1.1 Background

The AH&MRC Human Research Ethics Committee (Ethics Committee) was established in 1996 in response to the conduct of research on Aboriginal people which had largely been negative and without consultation with Aboriginal people and communities.

Our Committee's review is a necessary step to assist researchers to design meaningful, ethical, and culturally appropriate research projects to minimise harm and mitigate risks for Aboriginal Communities participating in research.

## 1.2 Purpose

The purpose of this document is to ensure that research that affects Aboriginal people and communities is done in a culturally appropriate way, involves and considers the people that it affects. This guideline may be useful for the following:

**1.2.1** Researchers that are planning to submit a research application for review by the AH&MRC Ethics Committee.

**1.2.2** AH&MRC Ethics Committee members who are reviewing ethics applications against all relevant guidelines.

## 1.3 Guiding Documents

All applications are assessed against the following documents, which may be found on the AH&MRC Ethics webpage.

**1.3.1 National Statement on Ethical Conduct in Human Research (2007, updated 2018):** The purpose of this document is to promote ethically good human research. [Click Here](#)

**1.3.2 Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (2018):** The purpose of this document is to ensure research is safe, respectful, responsible, high quality and of benefit to Aboriginal and Torres Strait Islander people and communities. [Click Here](#)

**1.3.3 Keeping research on track II (2018):** The purpose of this guideline is to act as a companion document to the abovementioned guideline (*refer to 1.3.2*). It is intended for use by Aboriginal and Torres Strait Islander research participants and communities but may also be useful for building researcher's knowledge about such research. [Click Here](#)

**1.3.4 Ethical Guidelines: Key Principles (2020):** The purpose of this document is to ensure that research that affects Aboriginal people and communities is done in a culturally appropriate way and has considered the people that it affects. This document should be used to guide the development of research proposals and ethics submissions for Aboriginal Health research.

**1.3.5 AH&MRC HREC Secretariat Standard Operating Procedures (SOPs):** The purpose of this document is to outline the AH&MRC HREC Terms of Reference and Operating Procedures. [Click Here](#)

## 2) Five Key Principles

All key principles must be imbedded throughout the application in the form of established processes and mechanisms, this will ensure that Aboriginal needs and perspectives have been meaningfully considered. The following are intended to provide guidance and should be considered when developing an application.

### 2.1 Net Benefits for Aboriginal people and communities

The benefits of the research may be for Aboriginal health in general or specifically for the health of Aboriginal people and communities participating in the project.

**2.1.1** Co-designing a research project with Aboriginal people and communities will help ensure that it is determined as a priority, a need and is of benefit to the Aboriginal people and communities affected.

**2.1.2** The research addresses and overcomes an identified issue.

**2.1.3** The risks have been identified, assessed, and mitigated.

**2.1.4** There will be a net benefit after considering known negatives and potential risks.

**(Links to the National Statement: 1.1, 1.3, 1.4, 1.6, 1.7, 1.8, 2.1.2, 2.2.2, 2.2.9, 4.7.7 - 4.7.9)**

### 2.2 Aboriginal Community Control of Research

Aboriginal Community Control must be a key focus of all projects affecting Aboriginal people. This means that at all stages of the research project, Aboriginal people and communities participating in or affected by the research will be fully informed about and agree with the purposes and conduct of the project.

**2.2.1** It is acknowledged that Aboriginal people have a right to make decisions about research affecting them.

**2.2.2** Aboriginal community involvement, support and consent has been sought.

**2.2.3** There is Aboriginal oversight and meaningful engagement at all stages of the project.

**2.2.4** Formal agreements have been developed with the people and communities affected.

**2.2.5** There is appropriate Aboriginal Governance of all stages of the project.

**2.2.6** Provide communities with all the relevant information and explanations on the intent, process and methodology, evaluation, and potential value of any research proposal.

**2.2.7** Comply with requests for further information from relevant community-controlled organisations associated with the research proposal.

**(Links to the National Statement: 1.3, 1.5, 1.11, 2.2.1, 2.2.2, 2.2.5, 2.2.9, 2.2.19, 2.2.20, 4.7.10 – 4.7.12)**

## 2.3 Cultural Sensitivity

Cultural protocols and community decision making processes will vary between Aboriginal communities, researchers should consider this when designing a project.

**2.3.1** Varying community protocols and processes have been considered and adhered to.

**2.3.2** Aboriginal community involvement, support and consent has been sought.

**2.3.3** Members of the community affected by the research have been properly consulted with and are informed of the purposes and conduct of the research.

**2.3.4** Outline your Aboriginal consultation and engagement to date.

**2.3.5** Questionnaires, surveys, and other documents must be determined culturally appropriate by the Aboriginal people and communities affected.

**2.3.6** History, colonisation and its ongoing impacts is addressed.

**(Links to the National Statement: 1.10, 1.1(d), 1.5, 1.11, 2.2.19, 2.2.20, 4.7.1 - 4.7.3)**

## 2.4 Reimbursement of costs

There must not be any imposition upon Aboriginal people and communities to be involved in the research project.

**2.4.1** Reimbursements may be financial or non-financial; but should be considerate of costs, time and travel incurred by Aboriginal people involved in the project. Knowledge and experience sharing must also be considered as a valuable resource.

**2.4.2** Must be appropriate to the scale of the research project but must not coerce participants to be involved.

**(Links to the National Statement: 2.2.9, 2.2.10, 2.2.11, 4.7.9, 4.7.11)**

## 2.5 Enhancing Aboriginal skills and knowledge

Build the capacity of Aboriginal people to participate in and lead research projects. Individuals may be from an Aboriginal Community Organisation, Aboriginal Reference Group, participants or researchers on the project team.

**2.5.1** Ensure that there is a process in place to disseminate information back to the Aboriginal people or communities affected by the research.

**2.5.2** Aboriginal people should be employed on research projects, wherever possible there should be training and development opportunities. There should be an emphasis on employing local Aboriginal people in line with cultural protocols.

**2.5.3** Aboriginal people should be listed investigators on research projects that affect Aboriginal communities. Aboriginal people in the project team should be offered authorship opportunities where possible.

**(Links to the National Statement: 1.1, 2.2.2, 2.2.19, 4.7.7, 4.7.11)**

### 3) Aboriginal Governance

There should be structures developed to ensure that appropriate Aboriginal Community engagement is undertaken throughout the entire project from design to final report, not just at the consultation stage. This may be achieved through the oversight of ACCHSs (or appropriate Aboriginal Community Controlled Organisation) or an Aboriginal Reference Group.

#### 3.1 Direct – ACCHS involvement

**3.1.1** The service has been given the opportunity to determine whether it would like to be a part of the research.

**3.1.2** The service plays an active role in the project and is meaningfully engaged with throughout the project.

**3.1.3** A mutually beneficial agreement has been drafted and consent has been sought from the services.

**3.1.4** Only written support will be considered as evidence. Written support may be in the form of a signed letter of support or a signed organisational consent form, whichever the service may determine appropriate.

**3.1.5** The services have been given all research tools and determine these culturally safe.

**3.1.6** The services have been given the opportunity to review publications prior to dissemination.

**3.1.7** There has been adequate timeframes for the ACCHS to respond appropriately.

**3.1.8** If the project is state-wide, engage with the AH&MRC for a letter of support.

**(Links to the National Statement: 1.1, 1.11, 2.2.19, 2.2.20, 4.7.2, 4.7.3, 4.7.8 – 4.7.10)**

#### 3.2 No ACCHS involvement – Aboriginal Reference Group

**3.2.1** Must be representative of the group being studied and have knowledge or experience of the research matter.

**3.2.2** Must be engaged throughout the life cycle of the project not just at the development or consultation stage.

**3.2.3** Develop terms of reference which should include:

- Purpose of the group
- Membership
- Which members identify as Aboriginal
- Frequency of meeting
- Who will chair the meeting
- Who will provide secretariat support
- How the group will be reported back to
- How will the group be reimbursed for their time

**(Links to the National Statement: 1.1, 1.11, 2.2.19, 2.2.20, 4.7.2, 4.7.3, 4.7.8 – 4.7.10)**

#### 3.3 Aboriginal Researchers:

**3.3.1** Ensure that the research team is adequately staffed with Aboriginal people to assist the cultural navigation of the project.

## 4 AH&MRC Review

This section will assist applicants and other HRECs to determine whether an application must be submitted.

Further information regarding this section may be found within the HREC Secretariat Standard Operating Procedures manual.

There are five criteria that are endorsed by the NSW Ministry of Health - Office of Health and Medical Research under policy directive (PD2010\_055) under which an application MUST be submitted to the AH&MRC HREC.

Approval from the AH&MRC HREC is required (PD2010\_055) where the research project involves research in, or concerning, NSW and any of the following applies:

<b>NSW Ministry of Health Policy Directive (PD2010_055):</b>	
1	The experience of Aboriginal people is an explicit focus of all or part of the research
2	Data collection is explicitly directed at Aboriginal peoples
3	Aboriginal peoples, as a group, are to be examined in the results
4	The information has an impact on one or more Aboriginal communities
5	Aboriginal health funds are a source of funding

### 4.1 The Submission Process

4.1.1 Thoroughly read all guiding documents listed in section 1.3.

4.1.2 Utilise all necessary templates on the AH&MRC Ethics webpage.

4.1.3 Prepare all necessary documents as outlined in the checklist in section 6.1.

4.1.4 Submit your application to the AH&MRC Ethics online platform, Submittable (see section 7.1).

4.1.5 The application will be delegated to reviewers on the closing date.

4.1.6 Initial reviews will be discussed at the HREC meeting.

4.1.7 Approvals and requests for further information will be sent from Submittable.

4.1.8 Once the HREC is satisfied with the quality of the application, it will be approved (subject to annual reporting).

### 4.2 Other HRECs

4.2.1 The AH&MRC HREC will review an application before, after or at the same time as another HREC.

4.2.2 National Projects may require review and approval from other Aboriginal Community Controlled HRECs

4.2.2.1 South Australian Aboriginal Health Research and Ethics Committee (AHREC SA)

4.2.2.2 Western Australian Aboriginal Health Ethics Committee (WAAHEC)

4.2.3 Other HRECs with an Aboriginal sub-committee

4.2.3.1 (Northern Territory) Top End Human Research Ethics Committee

4.2.3.2 (Northern Territory) Central Australian Human Research Ethics Committee

## 5 Checklist

### 5.1 Preparing an application

The AH&MRC HREC requires that applicants take the time to develop their application and ensure that it is consistent with all necessary guidelines. Ensuring that there is engagement with Aboriginal people from an early stage in the project design will assist with the cultural aspects of an application.

AH&MRC HREC Checklist:	
A copy of the Human Research Ethics Application	
A copy of the study protocol and/or plan	
A copy of the approval letters from other HRECs	
A copy of any requests from other HRECs for further information about your application, together with your response to the request.	
A copy of the Participant Information Statement(s) and make sure to include AH&MRC Ethics details in the complaints section:  <b>The Chairperson AH&amp;MRC Ethics Committee 35 Harvey Street Little Bay, NSW, 2012 Email: <a href="mailto:ethics@ahmrc.org.au">ethics@ahmrc.org.au</a></b>	
Obtained written consent from participating ACCHS	
If you have an Aboriginal reference group as a part of your community control, have you included Terms of Reference?	
Research Tools: Surveys, questionnaires, interview questions, focus groups and other data collection methods/ tools	
All submitted documents are named, numbered and have version control included in the footer	
A summary list of all attachments is included	
Have you embedded the AH&MRC Key Principles throughout your project?	
Has the participant information sheet and consent forms undergone a readability test?	
If your project is a national project, have you checked whether review is required by: <ul style="list-style-type: none"> <li>- South Australian Aboriginal Health Research and Ethics Committee</li> <li>- Western Australian Aboriginal Health Ethics Committee</li> <li>- (Northern Territory) Top End Human Research Ethics Committee</li> <li>- (Northern Territory) Central Australian Human Research Ethics Committee</li> </ul>	
All necessary signatures on the application forms and attachments have been obtained	
Submitted your application via the AH&MRC Ethics portal 'Submittable'	

## 6 Resources

The AH&MRC Secretariat has developed resources to assist with the application process, however, the Chief Investigator has overall responsibility to ensure that the application is of the highest standard at the time of submission.

Please ensure that you have taken the time to read all guiding documents and that you use all existing resources on the AH&MRC Ethics Webpage: <https://www.ahmrc.org.au/ethics/>

## 7 Further information

### 7.1 What is 'Community Control'?

The term 'Community 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.

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

**7.1.2** 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 or from an Aboriginal Reference Group.

**7.1.3** 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.

**7.1.4** The approval of Aboriginal people employed by government departments is not a substitute for consultation and negotiation with community agencies.

**(Links to the National Statement: 1.11, 3.1.18, 3.1.44, 3.1.57, 4.7.2, 4.7.10 – 4.7.12)**

## 7.2 AH&MRC Ethics and NSW Aboriginal Communities

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 role of the AH&MRC Ethics Committee is essentially advisory to Aboriginal communities. The existence of a statewide 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 health and medical research.

**7.2.1** The Ethics Committee may provide advice, but ultimately each Aboriginal community can itself decide if it wishes to participate in a research project.

**7.2.2** Where a project is state-wide and does not relate to any specific community (e.g. epidemiological research analysing state-wide data), the AH&MRC should be engaged for support.

## 7.3 Consent

**7.3.1** Formal written consent and agreement to a research project needs to be obtained from:

- Individuals who are participants in the project; and
- The ACCHSs and/or other Aboriginal community organisations responsible for exercising Aboriginal community control over the project.

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

**7.3.3** 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
- a requirement of future consent for use of information or biological materials for 'piggyback' or other research not explicitly covered by initial arrangements

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

- **Individual Participants Consent Form**
- **Aboriginal Community Organisation Consent Form**

(Links to the National Statement: 2.2.19, 2.2.20, 3.1.44, 3.1.55-3.1.57, 4.7.3 – 4.7.4, 4.7.10)

## 7.4 Aboriginal Ownership of Data and Publication findings

**7.4.1** The Aboriginal community, an ACCHS or appropriate alternative Aboriginal organisation are recognised as having:

- 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.

**7.4.2** In relation to these matters, researchers should develop and subsequently implement formal agreements which are in accordance 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 license for the use of data or results.

**7.4.3** 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.

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

**(Links to the National Statement: 3.1.55- 3.1.57, 4.7.1, 4.7.3, 4.7.11 – 4.7.12)**

## 7.5 Confidentiality and Privacy

A key principle contained within the Commonwealth Privacy Act (1988), the NSW Health Records Information Privacy Act (2002) and the National Statement on Ethical Conduct in Research Involving Humans (NHMRC, 2007 updated 2018) 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.

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.

## 8 References

- a) **National Statement on Ethical Conduct in Human Research, (2007, updated 2018)**  
<https://n8p4t5m5.stackpathcdn.com/wp-content/uploads/2019/07/national-statement-2018-updated.pdf>
- b) **Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for researchers and stakeholders, (2018)**  
<https://n8p4t5m5.stackpathcdn.com/wp-content/uploads/2019/07/Indigenous-ethical-guidelines.pdf>
- c) **NSW Aboriginal Health Information Guidelines (1998)**  
[https://www.ahmrc.org.au/wp-content/uploads/2019/07/ethics\\_nsw\\_aboriginal\\_health\\_information\\_guidelines.pdf](https://www.ahmrc.org.au/wp-content/uploads/2019/07/ethics_nsw_aboriginal_health_information_guidelines.pdf)
- d) **Guidelines for Ethical Research in Australian Indigenous Studies (2012)**  
<https://aiatsis.gov.au/sites/default/files/docs/research-and-guides/ethics/gerais.pdf>
- e) **Ten principles relevant to health research among Indigenous Australian populations, Lisa M Jamieson, Yin C Paradies, Sandra Eades, Alwin Chong, Louise Maple-Brown, Peter Morris, Ross Bailie, Alan Cass, Kaye Roberts-Thomson and Alex Brown Med J Aust 2012; 197 (1): 16-18.**  
<https://www.mja.com.au/journal/2012/197/1/ten-principles-relevant-health-research-among-indigenous-australian-populations>
- f) **The NSW Aboriginal Health Impact Statement and Guidelines (2017)**  
[https://www.medicalresearch.nsw.gov.au/wp-content/uploads/2019/05/NSW-Aboriginal-Health-Impactact-Statement\\_PD2017\\_034.pdf](https://www.medicalresearch.nsw.gov.au/wp-content/uploads/2019/05/NSW-Aboriginal-Health-Impactact-Statement_PD2017_034.pdf)
- g) **Keeping Research on Track II (2018):**  
<https://n8p4t5m5.stackpathcdn.com/wp-content/uploads/2019/09/Keeping-research-on-track.pdf>
- h) **The NHMRC Road Map 3: A Strategic Framework for Improving Aboriginal and Torres Strait Islander Health Through Research (2018)**  
<https://www.nhmrc.gov.au/sites/default/files/documents/attachments/road-map-3-strategic-framework.pdf>

i) **Why an Aboriginal Ethical Perspective is Necessary for Research into Aboriginal Health (AH&MRC Paper, written by Mundine, Edwards, & Williams, May 2001)**

k) **CRIAH Tools for Collaborative Research (December 2007)**

<http://esvc000239.bne001tu.server-web.com/Downloads/CRIAH%20Tools%20for%20Collaboration%20over1%20December2007/Tools%20for%20Collaboration%20Version%201%20December%202007.pdf>

l) **Guidelines for Ethical Research in Indigenous Studies (Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) 2011)**

<http://www.aiatsis.gov.au/research/docs/ethics.pdf>

m) **AH&MRC HREC Secretariat Standard Operating Procedures (SOPs):**

<https://n8p4t5m5.stackpathcdn.com/wp-content/uploads/2020/02/AHMRC-Ethics-Standard-Operating-Procedures-Manual-January2020.pdf>

AH&MRC Ethical Guidelines:	National Statement on Ethical Conduct in Human Research: Sections	Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and Communities: Values
2.1 Net Benefits for Aboriginal people and communities	1.1, 1.1, 1.3, 1.3, 1.3, 1.4, 1.6, 1.7, 1.8, 2.1.2, 2.2.2, 2.2.9, 4.7.7 - 4.7.9	SPIRIT AND INTEGRITY
2.2 Aboriginal Community Control of Research	1.3, 1.3, 1.5, 1.11, 2.2.1, 2.2.2, 2.2.5, 2.2.9, 2.2.19, 2.2.20, 4.7.10 – 4.7.12	
2.3 Cultural Sensitivity	1.10, 1.10, 1.10, 1.10, 1.1(d), 1.5, 1.11, 2.2.19, 2.2.20, 4.7.1 - 4.7.3	CULTURAL CONTINUITY
2.4 Reimbursement of costs	2.2.9, 2.2.10, 2.2.11, 4.7.9, 4.7.11	EQUITY
2.5 Enhancing Aboriginal skills and knowledge	1.1, 2.2.2, 2.2.19, 4.7.7, 4.7.11	
3.1 Direct – ACCHS involvement:	1.1, 1.11, 2.2.19, 2.2.20, 4.7.2, 4.7.3, 4.7.8 – 4.7.10	RECIPROCITY
3.2 No ACCHS involvement – Aboriginal Reference Group:	1.1, 1.11, 2.2.19, 2.2.20, 4.7.2, 4.7.3, 4.7.8 – 4.7.10	RESPECT
7.1 What is ‘Community Control’?	1.11, 3.1.18, 3.1.44, 3.1.57, 4.7.2, 4.7.10 – 4.7.12	
7.2 AH&MRC Ethics and NSW Aboriginal Communities	2.2.19, 2.2.20, 3.1.44, 3.1.55-3.1.57, 4.7.3 – 4.7.4, 4.7.10	
7.4 Aboriginal Ownership of Data and Publication findings	3.1.55- 3.1.57, 4.7.1, 4.7.3, 4.7.11 – 4.7.12	RESPONSIBILITY