

The AH&MRC Ethics Committee

ACCHS control of ACCHS data

Ethical issues

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- Ethical principles around data collation, management and sharing
 - for research in general
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- Mechanisms to ensure Aboriginal community control

HISTORY

The current Committee began in 1996 within the NSW Aboriginal Health Resources Cooperative (later renamed the AH&MRC)

- Established 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.
- Also to assist ACCHSs that were being approached by researchers, but lacked the resources or expertise to assess whether they should become involved.

HISTORY cont.

NSW Aboriginal Health Information Guidelines 1998 (Developed by ACCHSs, AHRC, NSW Health)

- To ensure consistency and good practice in the management of health and health-related information about Aboriginal peoples in NSW.
- Applies to the collection, ownership, storage, security, access, release, usage, reporting and interpretation of information, as well as issues of confidentiality and privacy.

HISTORY cont.

AH&MRC Guidelines for Research into Aboriginal Health - 5 key principles:

- Demonstrated net benefit for the health of Aboriginal people and communities
- Aboriginal community control over all aspects of the proposed research
- Sensitive to cultural principles of Aboriginal society
- Reimbursement of cost for participants
- Enhance skills and knowledge of Aboriginal people,

Ethical principles

AH&MRC Ethics Committee is concerned with the rights, mental & physical welfare, dignity and safety of participants and their communities.

In the context of research into Aboriginal Health

Research proposals considered by ethics committees always involve collection, collation and analysis of data.

ACCHS data relate to two groups:

- Patients – may include personal and confidential information
- ACCHSs – (service provision, financial info etc) may include confidential information

Ethical Concerns in Human Research

When considering ethical principles in relation to how data are collated, managed and shared, key concerns include:

- **Risk vs benefit**

- do the potential benefits outweigh the potential risks?
- need to minimise risk

- **Requirements for consent**

- Free and informed consent
- Does patient know how info is being used?
- Are they free to decline to participate?
- Waiver of consent?

Ethical Concerns in Human Research

When considering ethical principles in relation to how data are collated, managed and shared, key concerns include (cont.):

- **Right to privacy**

- Not disclose personal information
- Need to maintain confidentiality; risk when using/sharing data
- Are data de-identified?
- Who is extracting the data?
- How are data transported? Could they be accessed by 3rd party?

Privacy

Health information collected by a doctor or health service while caring for a patients imposes a duty of confidentiality.

Obligation not to use or disclose information for purposes other than those for which it was provided. Any other use is a breach of confidentiality.

Data stored in an identifiable form cannot be used in research that is exempt from ethical review. *

Use and disclosure of personal information (identifiable) for research is not lawful unless approved by a HREC.

*National Statement on Ethical Conduct in Human Research, Section 3.2.20

**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)*

Ethical Concerns cont

For research into Aboriginal health, a key ethical requirement in relation to data is :

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.

What mechanisms can help ensure control in relation to data?

AH&MRC Guidelines for Research into Aboriginal Health require:

“The Aboriginal community (or an ACCHS or appropriate alternative Aboriginal organisation) 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. ”**

What mechanisms can help ensure control in relation to data? Cont.

Need 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. eg. **Data Management Agreement**

Formal agreement to 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
- negotiation over the disposal or storage of raw data
- appropriate acknowledgement on publications
- the terms on which a community may exercise a right to veto or edit the publication of sensitive information.

Minimising Risk

- Only release data that has been de-identified and is non-identifiable to external parties (names, addresses and other identifying info removed)
- Only release data items that are essential for the project
- Limit the personnel that can access data
- Specify the use of data – not to be used for other purposes unless prior approval is given



What projects should come to the AH&MRC HREC?

Health research in NSW where any of the following 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.



What about quality improvement studies?

Although an activity using data may not be 'research' per se, the activity may need ethical review, because there are potential ethical risks involved such as those described above.

The use of ACCHS data for auditing, quality improvement activities or for service evaluations, may need to be reviewed by the AH&MRC Ethics Committee.

Research or Quality Improvement?

An application is not required if all these 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.

CONCLUSIONS

- Ethical principles applied by ethics committees in relation for research are relevant when considering use of ACCHS data for various purposes.
- Mechanisms used to ensure research has appropriate Aboriginal governance are applicable for data sharing between ACCHSs and with external parties.

Applying ethical principles and review processes

- ACCHS data reported to government as condition of funding;
- ACCHS data used by ACCHS for CQI purpose and planning;
- ACCHS data collated at state level used to :
 - support ACCHS
 - inform policy and planning.

RESOURCES



Full details on Ethics webpage on the AH&MRC website <http://www.ahmrc.org.au/ethics2.php>

Documents on Ethical Research that guide researchers, HRECs, and institutions

Contact Ethics Secretariat

e: ethics@ahmrc.org.au

t: 9212 4777

- EXTRA SLIDES

If required

Guidelines

Applications for ethical approval of research should :

- Demomstrate that the research is consistent with the National Statement on Ethical Conduct in Human Research
- address the AH&MRC Guidelines for Research into Aboriginal Health – Key Principles

Waiver of Consent

Privacy legislation says that personal information cannot be used for research without the person's consent unless it is approved by an HREC in accordance with the relevant guidelines.

When can a waiver of consent be considered?

- In the public interest in the research substantially outweighs the public interest in the protection of privacy;
- Disclosure is necessary for the purpose
- The purpose cannot be served by de-identified data;
- Reasonable steps have been undertaken to de-identify it;
- It is impracticable to obtain consent (or reasonable to proceed without consent);
- It is necessary to use identified or potentially identifiable data.