



AIHW Ethics Committee (the Committee) Terms of Reference

Establishment

The AIHW Ethics Committee (the Committee) is established under section 16(1) of the *AIHW Act 1989* (the AIHW Act) and is a registered Human Research Ethics Committee with the National Health and Medical Research Council (NHMRC).

Functions

The functions of the Committee are prescribed in the *Australian Institute of Health and Welfare (Ethics Committee) Regulations 2018*:

- (a) to consider ethical matters relating to Institute activities or Institute-assisted activities, including:
 - (i) advising the Institute on such matters; or
 - (ii) imposing conditions, on ethical grounds, on the Institute engaging in Institute activities;
- (b) to advise any body or person on ethical matters relating to the collection and production of:
 - (i) health-related information and statistics; or
 - (ii) welfare-related information and statistics;
- (c) the function of the Ethics Committee under paragraph 29(2)(c) of the Act, ie. specifying person(s) to whom 'information concerning a person' may be released, providing this is consistent with written terms and conditions of the relevant data supplier(s).
- (d) the functions of a Human Research Ethics Committee under guidelines in force from time to time under section 95 or 95A of the *Privacy Act 1988* (Privacy Act);
- (e) to provide written annual reports of the Ethics Committee's operations to the Institute;
- (f) any other functions of the Ethics Committee under the Act or any other law.

The Regulations provide that in performing its functions, the Committee must have regard to any relevant ethical principles and standards formulated or adopted by the NHMRC.

In relation to paragraph 1(b), the AIHW Board has endorsed an approach whereby approval is required from the AIHW Chief Executive Officer for the Ethics Committee to provide advisory opinions in circumstances where there is no direct AIHW involvement. These generally involve activities of other Commonwealth agencies.

Ethics approval of Institute activities

Consistent with its functions and responsibilities described above, the Ethics Committee determined that the full Committee, or a subset of the Committee, must consider and provide ethics approval for all AIHW work involving any of the following:

- creation of new data collections and/or the acquisition of data collections from data suppliers
- changing the nature or expanding the scope of existing data collections
- projects requiring the use of identifiable data (including 'personal information' under the Privacy Act and/or 'information concerning a person' under the AIHW Act)
- project proposals requiring a waiver under s.95 or s.95A of the Privacy Act
- project proposals relating to specific categories of participants, as specified in the NHMRC National Statement on Ethical Conduct in Human Research (National Statement), including Aboriginal and Torres Strait Islander people
- proposals associated with My Health Record data
- proposals involving any new or changed ways of handling personal information that are likely to have a significant impact on the privacy of individuals, and therefore require a formal Privacy Impact Assessment under the Australian Government Agencies Privacy Code
- proposals referred to it by the AIHW Chief Executive Officer for consideration.

Sub-Committee

The AIHW Ethics Committee has a Sub-Committee comprising of at least the Committee Chairperson or Deputy Chairperson or the Committee Secretary (Head, Ethics and Privacy Unit). The Sub-Committee is delegated to undertake expedited review and approval of business that does not require full Committee review, as determined from time to time by the Committee, including but limited to:

- amendment requests to approved projects seeking changes to research staff or extensions of time
- 'lower risk research' in which the only foreseeable risk is one of discomfort.

Relationship to other processes of research review

In accordance with the National Statement, the AIHW may establish non-HREC levels of ethical review for quality assurance and evaluation activities and human research that falls into the Lower Risk categories:

- Minimal: No risk of harm or discomfort; potential for minor burden or inconvenience
- Low: No risk of harm; risk of discomfort (+/- foreseeable burden)

AIHW may choose to exempt from ethical review research that (a) is lower risk research; and (b) involves the use of existing collections of data or records that contain only non-identifiable data about human beings.

All research will be assessed by the AIHW for its level of risk, in accordance with the guidance on risk provided in Chapter 2.1 of the National Statement and the establishment of a non-HREC pathway for review of research will be done in accordance with sections 5.1.10 to 5.1.18 of the National Statement.

Accountability

The Ethics Committee is not subject to direction by the AIHW Board, however the Board oversees the activities of the Ethics Committee as part of its overall responsibility for the good governance of

the AIHW, through an annual written report on its operations and invitation to inform the Board on areas of concern as they arise.

The Committee also provides a yearly report of its operations to the NHMRC.

The minutes of each Committee meeting are published on the AIHW intranet following endorsement.

The Terms of Reference for the Committee will be reviewed biennially.

Membership

Membership of the AIHW Ethics Committee is established in accordance with the Regulations and with regard to the National Statement. It must comprise:

- a chairperson with suitable experience, including previous membership of an HREC, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National Statement
- a deputy chairperson
- the AIHW CEO or a person nominated by the CEO
- at least one man and one woman who bring a broader community or consumer perspective and who have no paid affiliation with the institution
- at least one person with knowledge of, and current experience in, the professional care or treatment of people; for example, a nurse, counsellor or allied health professional
- at least one person who performs a pastoral care role in a community including, but not limited to, an Aboriginal and/or Torres Strait Islander Elder or community leader, a chaplain or a minister of religion or other religious leader
- at least one qualified lawyer, who may or may not be currently practicing and, where possible, is not engaged to advise the institution on research-related or any other matters
- at least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend, including a person who is Aboriginal and/or Torres Strait Islander with specialist knowledge and expertise in Aboriginal and Torres Strait Islander health and welfare research
- a person nominated by the persons responsible in the States and Territories for registering births, deaths and marriages.

Membership appointment and terms

Members of the Committee are appointed by the Board except for the member categories: *the CEO or a person nominated by the CEO and a person nominated by the persons responsible in the States and Territories for registering births, deaths and marriages.*

The *National Statement on Ethical Conduct in Human Research 2023* requires that members should be appointed 'using open and transparent processes' and that 'Institutions should consider reviewing appointments to the HREC at least every 3 years' (s. 5.1.40). The Board agreed that these processes include:

- advertising or seeking expressions of interest (unless it is a consecutive appointment)
- a standing Selection Committee would advise the Board on Ethics Committee appointments, being comprised of: the Chair of the Board or their nominee (being a member of the Board); the Chair of the Committee; and the AIHW CEO
- members will be appointed for an initial 3-year term
- appointments will be reviewed every 3 years and serving Committee members may be provided with the opportunity for an additional 3-year re-appointment

- serving Committee members may be offered re-appointment for a one or 2-year term if they are unable to commit to the (default) 3-year term
- members may be re-appointed for additional 3-year terms, generally up to a maximum of 3 terms, i.e. 9 years in total.

Secretariat

Secretariat services for the Committee will be provided by the Ethics and Privacy Unit.

Meetings

The AIHW Ethics Committee meets approximately 9 times per year.

Agenda and papers

The Secretariat compiles the agenda based on new and amended applications, reports and papers requiring ethical review, action items from previous meetings and other items.

The agenda and papers are cleared by the Chair of the Committee and the Group Head of the Data Governance and Integration Group.

All meeting papers will be issued to members by the secretariat approximately 10 days prior to scheduled meeting.

Records of meetings

A record of AIHW Ethics Committee meetings will be prepared by the Secretariat and distributed to members at the next full meeting for endorsement. The endorsed minutes are published on the AIHW intranet.

Remuneration of members

External members are offered sessional fees for meetings determined by the [Remuneration Tribunal \(Remuneration and Allowances for Holders of Part-time Public Office\) Determination](#).

Where members attend meetings in person, the Institute will pay official travel and accommodation costs subject to delegate approval. Payment of travel allowances are determined by the [Remuneration Tribunal \(Official Travel\) Determination](#).

Fees for ethics review

Fees for ethics applications and amendment requests submitted for consideration by the AIHW Ethics Committee are based on the complexity and risk of the project as determined by [AIHW Ethics Committee application fee schedule](#).