

EXPLANATORY STATEMENT

Australian Institute of Health and Welfare Act 1987

Australian Institute of Health and Welfare (Ethics Committee) Regulations 2018

Section 32 of the *Australian Institute of Health and Welfare Act 1987* (the Act) provides the authority that the Governor-General may make regulations consistent with the Act prescribing matters required or permitted by the Act to be prescribed.

Subsection 16(1) of the Act requires the Institute to appoint a committee known as the Australian Institute of Health and Welfare Ethics Committee (the Ethics Committee).

Subsection 16(2) of the Act provides that the functions and composition of the Ethics Committee shall be as prescribed. The Act specifies no conditions need to be satisfied before the power to make the proposed Regulations may be exercised.

The purpose of the *Australian Institute of Health and Welfare (Ethics Committee) Regulations 2018* (the 2018 Regulations) is to repeal and remake, with modifications, the *Australian Institute of Health and Welfare Ethics Committee Regulations 1989* ('the 1989 Regulations'). This is necessary because, pursuant to Item 7 of Subsection 50(2) of the *Legislation Act 2003*, the 1989 Regulations are due to sunset on 1 April 2018.

The 2018 Regulations implement minor changes from the 1989 Regulations in order to be consistent with current guidance provided by the National Health and Medical Research Council (NHMRC) on the preferred composition of Human Research Ethics Committees. The 2018 Regulations will also align several important definitions with the relevant provisions and wording of the Act.

The functions of the Ethics Committee are set out in the 2018 Regulations in more detail than in the 1989 Regulations. This will not change the role of the Ethics Committee, but will provide a more helpful statement of the scope of its responsibilities. The definition of 'identifiable data' in section 6 is amended to 'persons' to align it with the meaning of this term as used in the Act, rather than the narrower definition of 'individuals' used in the 1989 Regulations. This change is necessary as 'individuals' relates only to living people, while the definition of 'persons' in the Act has a broader application, that is, living and deceased people, bodies and associations of persons, and bodies politic.

Unlike the 1989 Regulations, for the purposes of the composition of Ethics Committee, section 7 of the 2018 Regulations will provide for the position of Deputy Chair and for the appointment of more than one member in specified categories. This change will allow the Ethics Committee to better manage its workload and responsibilities, which have grown significantly since the 1989 Regulations were last amended in 2002. It will also allow the Committee to better comply with the

NHMRC recommendation that Human Research Ethics Committees have a pool of available members to attend meetings and provide expertise as required.

The 2018 Regulations will also correct an error in the 1989 Regulations, which may have allowed each State and Territory to appoint a registrar of births, deaths and marriages to the Ethics Committee, rather than just one to represent all of them, as originally intended.

As these changes are administrative in nature in terms of their application to the Ethics Committee, consultation occurred between the Institute and the Department of Health. No further consultation was necessary in the circumstances.

The Act specifies no prerequisites or conditions that need to be satisfied before the power to make the proposed Regulations may be exercised.

The 2018 Regulations will be a legislative instrument for the purposes of the *Legislation Act 2003*.

The 2018 Regulations will commence the day after registration on the Federal Register of Legislation.

Details of the proposed *Australian Institute of Health and Welfare (Ethics Committee) Regulations 2018*

Section 1 - Name of Regulations

This section provides that the title of the Regulations is the *Australian Institute of Health and Welfare (Ethics Committee) Regulations 2018*.

Section 2 - Commencement

This section provides for the Regulations to commence on the day after this instrument is registered.

Section 3 - Authority

This section provides that the *Australian Institute of Health and Welfare (Ethics Committee) Regulations 2018* is an instrument made under Section 32 of the *Australian Institute of Health and Welfare Act 1987*.

Section 4 - Schedule(s)

This section provides that each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Section 5 - Definitions

The section defines expressions for the purposes of this instrument.

Section 6 - Functions of Ethics Committee

The section will define the functions of the ethics committee for the purposes of subsection 16(2) of the Act. These functions will include considering and advising on ethical matters relating to Institute activities or Institute-assisted activities.

This section will also define how the Ethics Committee may advise on ethical matters relating to the collection and production of health-related and welfare-related information and statistics, and fulfils the function of the Ethics Committee under paragraph 29(2)(c) of the Act and the functions of a Human Research Ethics Committee under guidelines in force from time to time under sections 95 or 95A of the *Privacy Act 1988*. When fulfilling the functions mentioned in paragraphs (1)(a), (b) and (c) the Ethics Committee must have regard to any relevant ethical principles and standards formulated or adopted by the National Health and Medical Research Council, including the *National Statement on Ethical Conduct in Human Research* (as published and updated by the National Health and Medical Research Council from time-to-time). The Ethics Committee may also have regard to any other matters that the Ethics Committee considers relevant.

This section defines ‘Institute activities’ as being activities engaged in, or proposed to be engaged in, by the Institute, include releasing data (including identifiable data) or associating, or assisting, with Institute-assisted activities.

This section defines ‘Institute-assisted activities’ as being activities engaged in, or proposed to be engaged in, by bodies or persons (other than the Institute) in association with, or with the assistance of, the Institute.

This section defines ‘Identifiable data’ as being data from which a person (within the meaning of section 29 of the Act) can be identified.

Section 7 - Composition of Ethics Committee

This section will define the composition of the Ethics Committee. For the purposes of subsection 16(1) of the Act persons are appointed to the Ethics Committee by the Institute.

For the purposes of subsection 16(2) of the Act, the Ethics Committee will consist of the following members:

- (a) Chairperson;
- (b) a Deputy Chairperson;
- (b) the Director of the Institute (or a person nominated by the Director);
- (c) at least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people (this could include a medical practitioner, a clinical psychologist or a social worker);
- (d) at least one person with knowledge of, and current experience in, areas of research that are regularly considered by the Ethics Committee;
- (e) a person nominated by the persons responsible in the States and Territories for registering births, deaths and marriages;

- (f) at least one person who performs a pastoral care role in a community (this could include an Aboriginal elder or a minister of religion);
- (g) at least one lawyer; and
- (h) at least 2 people (including at least one man and at least one woman) who are able to represent general community attitudes, are not affiliated with the Institute and are not currently involved in medical, scientific or legal work.

Schedule 1

This schedule repeals the *Australian Institute of Health and Welfare Ethics Committee Regulations 1989*.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Australian Institute of Health and Welfare (Ethics Committee) Regulation 2018

Overview of the Disallowable Legislative Instrument

Section 32 of the *Australian Institute of Health and Welfare Act 1987* (the Act) provides that the Governor-General may make regulations consistent with the Act prescribing matters required or permitted by the Act to be prescribed. Subsection 16(1) of the Act requires the Institute to appoint a committee known as the Australian Institute of Health and Welfare Ethics Committee (Ethics Committee).

Subsection 16 (2) of the Act provides that the functions and composition of the Ethics Committee shall be as prescribed.

The Disallowable Legislative Instrument repeals and replaces the *Australian Institute of Health and Welfare Ethics Committee Regulations 1989*, and prescribes the new constitution and functions of the Ethics Committee.

Human rights implications

Human rights are defined in the *Human Rights (Parliamentary Scrutiny) Act 2011* as the rights and freedoms contained in the seven core international human rights treaties to which Australia is a party. These treaties are: the International Covenant on Civil and Political Rights (ICCPR); the International Covenant on Economic, Social and Cultural Rights (ICESCR); the International Convention on the Elimination of All Forms of Racial Discrimination (CERD); the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW); the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (CAT); the Convention on the Rights of the Child (CRC), and the Convention on the Rights of Persons with Disabilities (CRPD).

In order to meet Australia's obligations, as set out in these seven core international human rights treaties, the National Health and Medical Research Council ('The NHMRC') was established through the *National Health and Medical Research Council Act 1992*.

The NHMRC regularly issues a *National Statement on Ethical Conduct in Human Research (2007)*. This national statement was last updated in May 2015, and operates as a governance measure to emphasise institutions' responsibilities for the quality, safety and ethical acceptability of research that they sponsor or permit to be carried out under their auspices.

This Disallowable Legislative Instrument gives effect to the recommendations of the latest *National Statement on Ethical Conduct in Human Research 2007 (updated May 2015)* and does not contravene any of the applicable rights or freedoms contained in the international human rights treaties to which Australia is a party. The nature of the functions of the Ethics Committee is to ensure that the rights of persons are properly respected in the course of proposed human research, and that research proposed is appropriate and conducted to high standards of respect for human beings, privacy and research merit and integrity.

Conclusion

This Disallowable Legislative Instrument is completely compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.