

EXPLANATORY STATEMENT

Select Legislative Instrument No.

Issued by Authority of the Minister for Health

National Health and Medical Research Council Act 1992

National Health and Medical Research Council Regulation 2016

The *National Health and Medical Research Council Act 1992* (the Act) establishes a national body, the National Health and Medical Research Council (the NHMRC) to pursue activities designed to:

- raise the standard of individual and public health throughout Australia;
- foster the development of consistent health standards between the various States and Territories;
- foster medical research and training and public health research and training throughout Australia; and
- foster consideration of ethical issues relating to health.

Section 3 of the Act states that where practicable, the NHMRC should adopt a policy of public consultation in relation to individual and public health matters being considered by it from time to time.

The *National Health and Medical Research Council Regulations 2006* (the Principal Regulations) will sunset on 1 April 2017. The Principal Regulations, in relation to regulatory recommendations and guidelines, require the NHMRC to advertise forthcoming public consultation in a national daily newspaper.

The purpose of the *National Health and Medical Research Council Regulation 2016* is to:

- remake the Principal Regulations, prior to their sunset on 1 April 2017; and
- remove the requirement to advertise in a national daily newspaper when notifying the community regarding public consultation.

Notification in relation to public consultation will continue to occur on the NHMRC's website. NHMRC considers that paper based advertising is no longer the most comprehensive or effective way to reach stakeholders. Stakeholders' awareness of public consultations now occurs primarily via contact with NHMRC, through advice from professional or personal interest groups and through online social or broader media coverage.

Details of the proposed Regulation are set out in the [Attachment](#).

The Regulation commences on the day after registration on the Federal Register of Legislation Instruments.

The Office of Best Practice Regulation has advised that a Regulation Impact Statement is not required.

Consultation under section 17 of the *Legislation Act 2003* was undertaken with Professor Anne Kelso, NHMRC CEO, and the NHMRC Council.

The Regulation is a legislative instrument and is subject to the *Legislation Act 2003*.

Details of the proposed *National Health and Medical Research Council Regulation 2016*

Part 1- Preliminary

Section 1 - Name of Regulation

This section provides that the title of the Regulation is the *National Health and Medical Research Council Regulation 2016*.

Section 2 – Commencement

This section provides for the Regulation to commence on the day after this instrument receives registration.

Section 3 – Authority

This section provides that the *National Health and Research Council Regulation 2016* is made under the *National Health and Medical Research Council Act 1992*.

Section 4 – Schedules

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

This section provides definitions of the terms and expressions used in this instrument.

Part 2- Regulatory recommendations and guidelines

Section 6 – Consultation about regulatory recommendations – manner and form of notices

This section describes the process when conducting consultation regarding regulatory recommendations and the conditions that must be met.

Section 7 – Consultation about guidelines – manner and form of notice

This section details the consultation process required when conducting consultation on guidelines including that a notice must be published on the NHMRC website.

Section 8 – Interim regulatory recommendations and guidelines – manner and form of notices

This section describes the process when conducting consultation regarding interim regulatory recommendations and guidelines, and the conditions that must be met.

Section 9 – Proposal to dispense with consultation requirements – manner and form of notice

This section describes the process and requirements when releasing a guideline to the community when there is no consultation process. A notice must be published on the website 30 days after the Council or the Australian Health Ethics Committee decides to release a regulatory recommendation or guideline without a consultation process.

Part 3- Application, savings and transitional provisions

Section 10 – Savings – repeal of *National Health and Medical Research Council Regulations 2006*

This section provides that the repealed Principal Regulations continue to apply in relation to a notice published before commencement of this instrument as if the repeal had not happened.

SCHEDULE 1 – Repeals

Item [1] The whole of the Regulations

This item repeals the whole of the *National Health and Medical Research Council Regulations 2006*.

Statement of Compatibility with Human Rights

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

National Health and Medical Research Council Regulation 2016

This Regulation is 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*.

Overview of the Regulation

The National Health and Medical Research Council Regulations 2006 (the Principal Regulations) will sunset on 1 April 2017. The Principal Regulations, in relation to regulatory recommendations and guidelines, require the NHMRC to advertise forthcoming public consultation in a national daily newspaper.

The purpose of the *National Health and Medical Research Council Regulation 2016* is to:

- remake the Principal Regulations, prior to their sunset on 1 April 2017; and
- remove the requirement to advertise in a national daily newspaper when notifying the community regarding public consultation.

Human rights implications

This Regulation does not engage any of the applicable rights or freedoms.

Conclusion

This Regulation is compatible with human rights as it does not raise any human rights issues.