**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 sunsetting 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*.

**ATTACHMENT**

**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 sunsetting 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.