

National Health and Medical Research Council Regulation 2016

I, General the Honourable Sir Peter Cosgrove AK MC (Ret’d), Governor‑General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulation.

Dated 05 May 2016

Peter Cosgrove

Governor‑General

By His Excellency’s Command

Sussan Ley

Minister for Health

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Part 1—Preliminary

1 Name

This is the *National Health and Medical Research Council Regulation 2016*.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

| Commencement information | | |
| --- | --- | --- |
| Column 1 | Column 2 | Column 3 |
| Provisions | Commencement | Date/Details |
| 1. The whole of this instrument | The day after this instrument is registered. | 7 May 2016 |

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under the *National Health and Medical Research Council Act 1992*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

5 Definitions

In this instrument:

***Act*** means the *National Health and Medical Research Council Act 1992*.

***NHMRC website*** means the website established and maintained by the NHMRC.

Part 2—Regulatory recommendations and guidelines

6 Consultation about regulatory recommendations—manner and form of notices

(1) A notice under subsection 12(2) or paragraph 12(3)(a) or (b) of the Act must be published on the NHMRC website.

(2) A notice under subsection 12(2) of the Act must include the following:

(a) the subject matter of the proposed regulatory recommendation to which the notice relates;

(b) a summary of the proposed recommendation;

(c) the last day on which the Council will accept submissions relating to the proposed recommendation, which must be a day that is at least 30 days after the notice is published under subsection (1) of this section.

Note: A notice under subsection 12(2) of the Act must also include the information mentioned in that subsection.

(3) A notice under paragraph 12(3)(a) of the Act must include the following:

(a) the subject matter of the draft recommendation;

(b) the last day on which the Council will accept submissions relating to the draft recommendation, which must be a day that is at least 30 days after the notice is published under subsection (1) of this section.

Note: A notice under paragraph 12(3)(a) of the Act must also include the information mentioned in that paragraph.

(4) A notice under paragraph 12(3)(b) of the Act must include the following:

(a) the subject matter of the recommendation;

(b) the reasons why the Council no longer proposes to provide the recommendation to the CEO.

Note: A notice under paragraph 12(3)(b) of the Act must also include the information mentioned in that paragraph.

7 Consultation about guidelines—manner and form of notice

(1) A notice under paragraph 13(d) of the Act must be published on the NHMRC website.

(2) A notice under paragraph 13(d) of the Act must include the following:

(a) the subject matter of the draft guidelines to which the notice relates;

(b) the last day on which the Council or the Australian Health Ethics Committee will accept submissions relating to the draft guidelines, which must be a day that is at least 30 days after the notice is published under subsection (1) of this section.

Note: A notice under paragraph 13(d) of the Act must also include the information mentioned in that paragraph.

8 Interim regulatory recommendations and guidelines—manner and form of notices

(1) A notice under subsection 14(2), (4) or (6) of the Act must be published on the NHMRC website.

(2) A notice under subsection 14(2), (4) or (6) of the Act must include the following:

(a) the subject matter of the interim regulatory recommendation, or the interim guidelines, to which the notice relates;

(b) a statement about where copies of the interim regulatory recommendation or interim guidelines can be obtained;

(c) the last day on which the Council or the Australian Health Ethics Committee will accept submissions relating to the interim regulatory recommendation or interim guidelines, which must be a day that is at least 30 days after the notice is published under subsection (1) of this section.

Note: A notice under subsection 14(2), (4) or (6) of the Act must also include the information mentioned in subsection 14(2), (4) or (6) of the Act, as the case requires.

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

(1) A notice under subsection 14B(2) of the Act must be published on the NHMRC website within 30 days after the day the Council, or the Australian Health Ethics Committee, decides to propose to dispense with the requirements (the ***consultation requirements***) set out in section 12 or 13, or subsection 14A(2), of the Act.

(2) A notice under subsection 14B(2) of the Act must include the following:

(a) the subject matter of the proposed regulatory recommendation or the proposed guidelines in relation to which the Council or the Australian Health Ethics Committee proposes to dispense with the consultation requirements;

(b) a summary of the proposed regulatory recommendation or the proposed guidelines.

Note: A notice under subsection 14B(2) of the Act must also include the information mentioned in that subsection.

Part 3—Application, savings and transitional provisions

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

Despite the repeal of the *National Health and Medical Research Council Regulations 2006* by Schedule 1 to this instrument, those Regulations as in force immediately before they were repealed continue to apply, in relation to a notice published before the commencement of this instrument, as if the repeal had not happened.

Schedule 1—Repeals

National Health and Medical Research Council Regulations 2006

1 The whole of the Regulations

Repeal the Regulations.