

Research Involving Human Embryos Regulations 2003 2003 No. 22

EXPLANATORY STATEMENT

STATUTORY RULES 2003 No. 22

Issued by the authority of the Minister for Ageing

Research Involving Human Embryos Act 2002

Research Involving Human Embryos Regulations 2003

Subsection 48(1) of the *Research Involving Human Embryos Act 2002* (the Act) provides that the Governor-General may make regulations prescribing, among other things, matters required or permitted by the Act and matters necessary or convenient for carrying out or giving effect to the Act.

Subsection 48(2) of the Act provides before the Governor-General makes regulations under the Act, the Minister must be satisfied that the States have been consulted in relation to the proposed regulations and the proposed regulations have been prepared having regard to views expressed by the States in those consultations.

The object of the Act is to address concerns, including ethical concerns, about scientific developments in relation to human reproduction and the utilisation of human embryos by regulating activities that involve the use of certain human embryos created by assisted reproductive technology (ART). To this end, the legislation establishes the Embryo Research Licensing Committee of the National Health and Medical Research Council (the NHMRC Licensing Committee) to licence certain activities involving the use of excess human embryos created through ART.

The purpose of the Regulations is to set the parameters for appointment of members to the NHMRC Embryo Research Licensing Committee; to establish guidelines for licensing certain activities using human embryos; and to describe the form of identity cards to be issued to inspectors appointed by the Chairperson of the NHMRC Licensing Committee.

Details of the Regulations are set out in the attachment.

The Regulations commence on gazettal.

ATTACHMENT

DETAILS OF THE RESEARCH INVOLVING HUMAN EMBRYOS REGULATIONS 2003

PART 1 PRELIMINARY

Regulation 1.1

Regulation 1.1 provides that the Regulations may be cited as the Research Involving Human Embryos Regulations 2003.

Regulation 1.2

Regulation 1.2 provides that the Regulations commence on gazettal.

Regulation 1.3

Regulation 1.3 clarifies that in the Regulations references to "Act" mean the *Research Involving Human Embryos Act 2002*.

PART 2 REGULATION OF CERTAIN USES INVOLVING EXCESS ART EMBRYOS

Regulation 2.1

Regulation 2.1 provides that the bodies from which the Minister must seek nominations before appointing a member to the NHMRC Licensing Committee (under section 16 of the Act) are prescribed in Schedule 1 of the Regulations. Sub-section 16(2) of the Act provides that the Minister must appoint the members of the NHMRC Licensing Committee. Subsection 16(3) provides that before appointing the members the Minister must, among other things, seek nominations from such bodies as are prescribed by the regulations for the purpose.

Regulation 2.2

Regulation 2.2 provides that, in considering whether to issue a licence, the NHMRC Licensing Committee must have regard to two sets of Guidelines issued by the NHMRC:

- (a) the Ethical Guidelines on Assisted Reproductive Technology, issued by the NHMRC in 1996; and
- (b) the National Statement on Ethical Conduct in Research Involving Humans, issued by the NHMRC in 1999.

PART 3 MISCELLANEOUS

Regulation 3.1

Regulation 3.1 prescribes information that must be included on identity cards carried by inspectors. Section 33 of the Act enables the Chairperson of the NHMRC Licensing Committee to appoint inspectors to exercise certain powers and functions detailed in the legislation. In accordance with sub-section 34(1), the Chairperson of the NHMRC Licensing Committee must issue all such inspectors with an identity card. The identity card must, as required by subparagraph 34(2)(a) be in a form prescribed by the regulations. The information on the card (date of issue, period of validity and recent photograph of the inspector's face) enables the cardholder's identity and authority to act as an Inspector to be readily ascertained and verified by someone to whom it is shown.

SCHEDULE 1 COMMITTEE - PRESCRIBED BODIES FROM WHICH NOMINATIONS MUST BE SOUGHT

The Schedule details each of the bodies from which nominations to the NHMRC Licensing Committee must be sought.