Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Regulation 2015

Explanatory notes for SL 2015 No. 95

made under the

Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003

General Outline

Short title

Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Regulation 2015

Authorising law

Section 53 of the *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003*

Policy objectives and the reasons for them

The *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003* (the Queensland Act) regulates activities involving the use of human embryos and prohibits human cloning for reproduction and other unacceptable practices associated with reproductive technology**.**

Under part 7 of the *Statutory Instruments Act 1992*, the *Research Involving Human Embryos and Prohibition of Human Cloning Regulation 2003* (the 2003 Regulation) will expire on 31 August 2015. The *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Regulation 2015* (the Regulation) replaces the 2003 Regulation, prescribing certain matters to support the Queensland Act.

The Queensland Act is part of a national scheme and mirrors two Commonwealth Acts—the *Prohibition of Human Cloning for Reproduction Act 2002* (Cwlth) and the *Research Involving Human Embryos Act 2002* (Cwlth).

The 2003 Regulation prescribes the Reproductive Technology Accreditation Committee of the Fertility Society of Australia as an entity responsible for accrediting other entities as accredited assisted reproductive technology centres.

The National Health and Medical Research Council (NHMRC) is Australia's peak body responsible for regulating ethical standards about scientific developments in relation to human reproduction and the use of human embryos in research activities. The NHMRC Licensing Committee is the authorised entity responsible for issuing licences for research involving excess assisted reproductive technology embryos.

Under the Queensland Act, a person may apply to the NHMRC Licensing Committee for a licence authorising restricted activities, such as the use of excess assisted reproductive technology embryos. When considering an application for a licence, the NHMRC must, under section 29 of the Queensland Act, have regard to any relevant guidelines it has issued under the *National Health and Medical Research Council Act 1992* (Cwlth). These guidelines must be prescribed under regulation.

The 2003 Regulation prescribes two guidelines issued by the NHMRC as matters that must be taken into account by an NHMRC Licensing Committee when deciding whether to issue a licence. These guidelines are:

- the *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research*, issued by the NHMRC in 2004, and
- the *National Statement on Ethical Conduct in Human Research*, issued by the NHMRC in 1999.

Section 21 and the dictionary of the Queensland Act define respectively the terms *proper consent* and *unsuitable for implantation* by reference to guidelines issued by the NHMRC and prescribed by regulation. However, no guidelines are prescribed in the 2003 Regulation for the purpose of these definitions.

Achievement of policy objectives

The Regulation replaces the 2003 Regulation, prescribing matters necessary to support the Queensland Act. In particular, the Regulation:

- prescribes the Reproductive Technology Accreditation Committee of the Fertility Society of Australia as an authorised entity to accredit a person or body to carry out assisted reproductive technology
- prescribes guidelines issued by the NHMRC for the purposes of the definitions of *proper consent* and *unsuitable for implantation* and for the NHMRC Licensing Committee to consider when issuing licences for research involving excess assisted reproductive technology embryos, and
- ensures the short title of the Regulation is consistent with the short title of the Queensland Act.

The Regulation supports the Queensland Act by ensuring compliance with existing guidelines and ethical codes for activities associated with assisted reproductive technology in clinical practice and research. The Regulation ensures consistency with the national regulatory scheme established by the Council of Australian Governments to ban human cloning and

other unacceptable practices associated with reproductive technology and to regulate research involving human embryos.

Consistency with policy objectives of authorising law

The Regulation is consistent with the main objectives of the Queensland Act and the Commonwealth legislation.

Inconsistency with policy objectives of other legislation

No inconsistencies with the policy objectives of other legislation have been identified.

Alternative ways of achieving policy objectives

The Regulation is the only effective means of achieving the policy objectives.

Benefits and costs of implementation

The Regulation is consistent with the 2003 Regulation and accordingly imposes no additional costs on persons or organisations.

Consistency with fundamental legislative principles

The Regulation is consistent with fundamental legislative principles set out in section 4 of the *Legislative Standards Act 1992*.

Consultation

The Office of Best Practice Regulation was consulted on the Regulation and advised that a Regulatory Impact Statement was not required.

The Commonwealth Department of Health supports the Regulation. There was no other external consultation in relation to the Regulation as it is consistent with the 2003 Regulation.

Notes on provisions

Part 1 Preliminary

Short title

Clause 1 provides that the short title is the *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Regulation 2015*.

Prescribed accrediting entity

Clause 2 prescribes the Reproductive Technology Accreditation Committee of the Fertility Society of Australia as an entity authorised to accredit a person or body to carry out assisted reproductive technology, for the purpose of the definition of *authorised ART centre* in section 21 of the Queensland Act.

Prescribed guidelines

Clause 3 prescribes guidelines issued by NHMRC under the *National Health and Medical Research Council Act 1992* (Cwlth) for the purposes of:

- the definition of *proper consent* in section 21 of the Queensland Act
- the matters which must be considered by the NHMRC Licensing Committee under section 29(4)(c) of the Queensland Act when issuing licences for research involving excess assisted reproductive technology embryos, and
- the definition of *unsuitable for implantation* in the schedule of the Queensland Act.

The prescribed guidelines are:

- the *Ethical guidelines on the use of Assisted Reproductive Technology in clinical practice and research*, and
- the *National Statement on Ethical Conduct in Human Research*.

Repeal

Clause 4 provides that the *Research Involving Human Embryos and Prohibition of Human Cloning Regulation 2003*, SL No. 308 is repealed.