Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Regulation 2025

Explanatory notes for SL 2025 No. 91

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 2025

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* (Act) aims to address concerns, including ethical concerns, about scientific developments in relation to human reproduction and the use of human embryos.

The Act achieves this objective by:

- prohibiting human cloning and certain other practices associated with assisted reproductive technology (ART); and
- regulating activities that involve the use of certain human embryos created by ART or by other means.

The Act was made as part of an inter-governmental agreement in 2002 between the Commonwealth, State and Territory governments to introduce nationally consistent legislation to prohibit human cloning and other unacceptable practices, and to regulate research involving excess ART embryos. Following the Commonwealth enacting the *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) and *Research Involving Human Embryos Act 2002*

(Cth), all State and Territory governments except the Northern Territory have enacted corresponding legislation that facilitates the national regulatory scheme.

The *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Regulation 2015* (2015 Regulation) supports the Act by prescribing:

- the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia and New Zealand as the body responsible for accrediting entities to carry out ART; and
- guidelines to support key definitions and the licensing system in the Act authorising activities involving the use of human embryos.

Prescribed accrediting entity

Section 21 of the Act provides that an *accredited ART centre* is an entity that has been accredited to carry out ART by an entity prescribed under a regulation. Under the Act, particular activities such as the use of an excess ART embryo are prohibited unless they are carried out in an accredited ART centre. The accreditation process supports the objects of the Act by ensuring appropriate oversight and regulation, requiring that entities carrying out activities that involve the use of certain human embryos created by ART are accredited to do so by a prescribed accrediting body.

Section 2 of the 2015 Regulation prescribes RTAC as the prescribed entity for the purposes of accrediting ART centres to carry out ART. RTAC is a professional group of the Board of the Fertility Society of Australia and New Zealand. RTAC is responsible for setting standards for the performance of ART through an audited Code of Practice and the granting of licences to practice ART in Australia.

Prescribed guidelines

Section 3 of the 2015 Regulation prescribes the *Ethical guidelines on the use of Assisted Reproductive Technology in clinical practice and research* (Ethical guidelines) and *National Statement on Ethical Conduct in Human Research* (National Statement) as guidelines for the Act. These guidelines are issued by the National Health and Medical Research Council (NHMRC) and prescribed to support the licensing framework and key definitions in the Act.

<u>Determination of a licence application</u>

To support the regulation of activities involving the use of certain human embryos, section 28 of the Act requires a person to apply to the NHMRC Licensing Committee for authorisation to undertake particular activities. Section 28(1) of the Act lists the different activities that a person may apply to the NHMRC Licensing Committee for. In deciding whether to issue a licence, section 29 of the Act provides that the Licensing Committee must have regard to several matters, including any relevant guidelines, or relevant parts of guidelines, issued by the NHMRC which are prescribed under a regulation.

Accordingly, the 2015 Regulation prescribes the Ethical guidelines and the National Statement. Part C of the Ethical guidelines set out ethical principles in ART research and requirements for

research involving gametes (eggs and sperm) and embryos, including guidance on obtaining a licence, and matters the Licensing Committee must have regard to in making decisions. The National Statement provides a framework for ethical conduct in human research and notes that there are specific considerations for research involving human embryos, requiring application to the Licensing Committee.

Requiring the Licensing Committee to have regard to these documents in deciding whether to issue a licence under section 28 support the activities listed under section 28 being conducted ethically and in accordance with the required standards.

Proper consent

Section 21 of the Act includes a definition of *proper consent* in relation to the use of an excess ART embryo or a human egg, or the creation or use of any other embryo. Proper consent is consent obtained in accordance with guidelines issued by the CEO of the NHMRC under the *National Health and Medical Research Council Act 1992* (Cth) and prescribed under a regulation for the purposes of the definition.

As outlined above, the Act establishes a licensing system that requires a person to apply to the NHMRC Licensing Committee for a licence to conduct particular activities. Before issuing a licence, the Licensing Committee must be satisfied, in accordance with section 29(3)(a), that appropriate protocols are in place to obtain proper consent. Section 32 provides that a licence is subject to conditions, including that each responsible person must have given proper consent; that the licence holder must report the consent and any restrictions to which the consent is subject in writing to the Licensing Committee; and that any activities must be carried out in accordance with any restrictions to which the proper consent is subject.

The Ethical guidelines and National Statement support the definition in the Act by providing detailed guidance on obtaining proper consent as part of undertaking research.

Unsuitable for implantation

As outlined above, the Act sets out a licensing framework to regulate particular activities. For excess ART embryos that are unsuitable for implantation, section 32(8) provides that the Ethical guidelines apply in a modified form. This means that ordinary consent considerations in the Ethical guidelines, like the cooling-off period to withdraw consent, may be altered for the use of excess ART embryos that are unsuitable for implantation. To support this, the Act includes a definition of *unsuitable for implantation*. A human embryo is unsuitable for implantation if it is:

- diagnosed as unsuitable for implantation by preimplantation genetic diagnosis, in accordance with the Ethical guidelines; or
- determined to be unsuitable for implantation in the body of a woman, in accordance with objective criteria specified in guidelines issued by the NHMRC and prescribed under a regulation.

The objective criteria referred to in the second limb of the definition is described in Part C of the Ethical guidelines. Prescribing the Ethical guidelines in the 2015 Regulation for the purposes of the second limb of the definition of *unsuitable for implantation* supports the definition, and the regulation of the use of such embryos.

Expiry of 2015 Regulation

Section 54 of the *Statutory Instruments Act 1992* provides that subordinate legislation expires 10 years after its making. The 2015 Regulation is due to expire on 1 September 2025. The *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Regulation 2025* (Regulation) has been prepared to replace the 2015 Regulation.

Achievement of policy objectives

The Regulation replaces the 2015 Regulation to ensure the continued effective operation of the Act. The Regulation is largely consistent with the 2015 Regulation, with minor and technical changes to ensure the Regulation remains current and reflects modern drafting practices.

The Regulation commences on 1 September 2025.

Consistency with policy objectives of authorising law

The Regulation is consistent with the policy objectives of the Act.

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.

Maintaining the status quo would result in the expiry of the 2015 Regulation and the Act operating without supporting subordinate legislation. This would lead to gaps in the regulatory framework and prevent the objectives of the Act from being achieved.

Benefits and costs of implementation

The Regulation is consistent with the 2015 Regulation other than minor and technical changes to reflect contemporary drafting practices and accordingly imposes no additional costs on persons or organisations.

Consistency with fundamental legislative principles

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

Institution of Parliament: Does the subordinate legislation allow for the subdelegation to appropriate persons and in appropriate cases?

Clauses 4 and 5 of the Regulation reference the Ethical guidelines and National Statement and clause 6 references the Ethical guidelines. Relying on external documents that are not subject to parliamentary scrutiny may be seen to breach section 4(5)(e) of the *Legislative Standards Act 1992*, which provides that the subdelegation of a power delegated by an Act should only occur in appropriate cases and to appropriate persons, and if authorised by an Act.

The external documents prescribed in the Regulation may be amended from time to time and as such, the Department has considered whether the exercise of delegated power is sufficiently subjected to parliamentary scrutiny.

The Ethical guidelines and National Statement are both issued by NHMRC. Part C of the Ethical guidelines set out ethical principles in ART research and requirements for research involving gametes and embryos. The National Statement provides a framework for ethical conduct in human research and notes that there are specific considerations for research involving human embryos. The Ethical guidelines and National Statement are publicly available and free of charge. The documents do not provide for the delegation of any administrative powers (or sub-delegation of these powers).

This potential breach of the fundamental legislative principle is considered justified as it supports consistency and compliance with the national regulatory framework and the ethical use of certain human embryos by:

- ensuring the NHMRC Licensing Committee gives consideration to relevant documents in deciding whether to issue a licence to undertake particular activities, supporting these activities being conducted ethically and in accordance with the required standards;
- providing detailed guidance on how proper consent should be obtained in undertaking research; and
- providing objective criteria for determining when an embryo is unsuitable for implantation in a person's body, supporting the regulation of the use of such embryos.

Reference to external documents is considered justified noting the detailed, technical and clinical nature of the matters contained in the documents, and the flexibility this provides the scheme to remain up to date with current practices and requirements. If the matters referenced in external documents were contained in the Regulation, they would regularly be out of date and not reflect changing practices and activities.

Consultation

In June 2025, a consultation paper was published on the Queensland Health website and disseminated to relevant stakeholders, including the Fertility Society of Australia and New Zealand, RTAC, the Australian Medical Association Queensland, Queensland Law Society and Queensland ART providers (fertility clinics). Relevant Queensland Health stakeholders, including research units within Hospital and Health Services, were also consulted.

Feedback was received from the IVF Medical Directors Group (a subcommittee of the Fertility Society of Australia and New Zealand) and Metro South Research (Metro South Hospital and Health Service) in support of the Regulation.

The Office of Best Practice Regulation assessed the Regulation in accordance with *The Queensland Government Guide to Better Regulation* and was satisfied that Queensland Health met the requirements for the sunset review.