Impact Analysis Statement template

Summary IAS

Details

Lead department	Queensland Health
Name of the proposal	Sunset review and remake of the *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction 2015*
Submission type (*Summary IAS / Consultation IAS / Decision IAS)*	Summary IAS
Title of related legislative or regulatory instrument	Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Regulation 2025
Date of issue	August 2025

For all other proposals

What is the nature, size and scope of the problem? What are the objectives of government action?

Sunset Review

The *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Regulation 2015* (2015 Regulation) is due to expire on 1 September 2025 pursuant to section 54 of the *Statutory Instruments Act 1992.* A sunset review was conducted to ensure that the 2015 Regulation remains effective.

Background

The 2015 Regulation supports the effective operation of the *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003* (Act). The object of the Act is to address concerns, including ethical concerns, regarding scientific developments in human reproduction and the use of human embryos. This object is mainly achieved by:

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

The Act was made as part of an inter-governmental agreement in 2002 between the Commonwealth, State and Territory governments to introduce a nationally consistent legislation to prohibit human cloning and other practices, and to regulate research involving excess ART embryos. Accordingly, the *Prohibition of Human Cloning for Reproduction Act 2002 (Cth)* and *Research Involving Human Embryos Act 2002 (Cth)* was enacted. All State and Territory governments, except the Northern Territory, have enacted corresponding legislation that facilitates the national regulatory scheme.

The 2015 Regulation was made to support the Act by prescribing matters essential to its effective operation.

Scope

Section 53 of the Act provides broad regulation-making powers. The Act also includes specific regulation-making powers, including to prescribe an entity for accrediting ART centres, and guidelines for determining a licence application for the use of human embryos and defining the terms *proper consent* and *unsuitable for implantation.*

Currently, the 2015 Regulation prescribes:

- the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia as the entity responsible for accrediting other entities as accredited ART centres for the purposes of section 21 of the Act; and
- 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) for the purposes of determining a licence application for the use of human embryos and defining *proper consent* and *unsuitable for implantation*, which are key terms in the Act. These guidelines are issued by the National Health and Medical Research Council (NHMRC).

Remake

The Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Regulation 2025 (Regulation) has been prepared to replace the expiring 2015 Regulation. The Regulation will commence on 1 September 2025. The Regulation is largely consistent with the 2015 Regulation, with technical changes made to improve clarity and reflect modern drafting standards.

The matters contained in the 2015 Regulation are necessary for the effective operation of the Act and must be replaced to ensure the legislative scheme can continue in effect.

What options were considered?

Option 1 – Allow the 2015 Regulation to expire

The 2015 Regulation will expire on 1 September 2025. Allowing the 2015 Regulation to expire without a replacement Regulation is not a suitable policy option. If the 2015 Regulation is allowed to expire, it would create a regulatory gap in the legislative framework. It would also limit the operation of the Act in facilitating the national regulatory scheme.

Option 2 – Remake the 2015 Regulation (preferred)

Remaking the 2015 Regulation with technical changes to reflect current drafting standards is the only viable option to ensure that the prescribed matters continue to support the objects of the Act. It will also ensure that Queensland continues to recognise the national regulatory scheme and maintains alignment with other Australian jurisdictions.

What are the impacts?

Need for Regulatory Action

The Regulation is required to recognise matters prescribed by the Act. Specifically, to ensure that RTAC continues to be recognised as the prescribed entity for accrediting ART centres as accredited ART centres for carrying out ART, and to ensure that the Ethical guidelines and National Statement continue to be the prescribed guidelines for determining licence applications and defining key terms in the Act. To ensure that the legislative scheme in the Act can continue in effect, regulatory action is required to remake the 2015 Regulation.

If the 2015 Regulation is allowed to expire, it would limit the effective operation of the Act. The Act would incorrectly state that a regulation prescribes an entity to accredited other entities as accredited ART centres and prescribes guidelines for determining licence applications and defining key terms. Under the national regulatory scheme, all other Australian jurisdictions, except the Northern Territory, recognise RTAC as the prescribed entity and recognise the Ethical guidelines and National Statement as prescribed guidelines. Without a replacement Regulation, Queensland will be out of step with other Australian jurisdictions. This

would also create a gap in the regulatory framework. Allowing the 2015 Regulation to expire would potentially undermine the objects of the Act.

Remaking the 2015 Regulation supports the Queensland Act to operate effectively, and to remain consistent with the national regulatory scheme. Prescribing RTAC as the prescribed entity ensures that ART centres in Queensland continue to be accredited in accordance with RTAC's Code of Practice, which promotes continuous quality of care for people accessing ART treatment. Further, remaking the 2015 Regulation ensures that licensing decisions made by the NHMRC Licensing Committee under the Act are guided by the standards established in the Ethical guidelines and the National Statement. The prescribed guidelines provide a framework for ART activities to be conducted in a manner that shows respect, minimises potential harms and supports the ongoing wellbeing of parties, including persons born as a result of ART.

Effectiveness of regulatory objectives

The regulation was first made in 2003 as the *Research Involving Human Embryos and Prohibition of Human Cloning Regulation 2003.* Since then, the only policy change, which was made as part of the 2015 remake, was to broaden the scope of the prescribed guidelines to include definitions for *proper consent* and *unsuitable for implantation.* This was in line with the changes to the Commonwealth Acts in 2006.

Who was consulted?

Public consultation is proposed to be undertaken about the remake, with a consultation paper to be circulated via the Queensland Health stakeholder consultation website, explaining the changes between the 2015 Regulation and the Regulation.

What is the recommended option and why?

Option 2 – Remake the 2015 Regulation. This will ensure the continuation of the prescribed matters and accommodate minor and technical changes to ensure currency. Making the Regulation is the only viable option to ensure the matters prescribed by the Act continue in effect to support the regulatory framework in the Act and consistency with the national scheme.

Impact assessment

	First full year	First 10 years**
Direct costs – *Compliance costs**	$0	$0
Direct costs – *Government costs*	$0	$0

* The *direct costs calculator tool* (available at www.treasury.qld.gov.au/betterregulation) should be used to calculate direct costs of regulatory burden. If the proposal has no costs, report as zero. **Agency to note where a longer or different timeframe may be more appropriate.

Signed

Director-General, Queensland Health
Date: 14/07/2025

Minister for Health and Ambulance Services
Date: 23/7/25