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Australian Government
National Health and Medical Research Council

NHMRC

Ref: MS25-001314

The Hon Mark Butler MP
Minister for Health and Aged Care
Parliament House
CANBERRA ACT 2600

Dear Minister

This Statement of Intent (SOI) responds to the Statement of Expectations (SOE) dated 18 December 2025. It sets out my intentions regarding how the National Health and Medical Research Council (NHMRC) will support the Embryo Research Licensing Committee (ERLC) to carry out its regulatory functions and exercise its regulatory powers.

The Australian Government has identified better regulation as a key driver in boosting Australia's productivity, improving economic resilience, and reducing undue burdens on businesses and consumers. This SOI outlines NHMRC's approach to regulatory stewardship, integrating the principles of regulator best practice and stakeholder relationship management; delivering on the Government's policy priorities as set out in the Commonwealth's *Regulatory Policy, Practice and Performance Framework* (the Regulatory Framework).

Overview

NHMRC is proud to be Australia's leading expert body in health and medical research. For nearly a century, we've been driving innovation, integrity and impact – funding exceptional research, setting national health standards and providing trusted, evidence-based health advice to improve the health and lives of all Australians. Through clinical, public health and environmental health guidelines, NHMRC supports the translation of research into health practice and policy. By providing guidance on responsible research practices and ethical issues, NHMRC fosters the highest standards of integrity in the conduct of research and the delivery of health care.

Our responsibilities extend to the regulation of the use of human embryos in research through administration of the *Research Involving Human Embryos Act 2002* (RIHE Act) and the *Prohibition of Human Cloning for Reproduction Act 2002* (PHCR Act). These Acts address community concerns about scientific developments in human reproduction and the use of human embryos in research activities.

The legislation establishes a framework to prohibit certain practices, such as human cloning, and regulates the use of excess embryos created through assisted reproductive technology, along with the creation and uses of embryos created through processes other than fertilisation. Since 2022, these Acts have also regulated the use of certain mitochondrial donation techniques to create human embryos using assisted reproductive technology. The RIHE Act establishes ERLC, a principal committee of NHMRC, as the national regulator of activities defined in the Acts.

Regulatory stewardship

The careful and responsible regulation of human embryo research in Australia by ERLC reflects community expectations of this legislation. Strong stewardship helps to ensure that the regulation of this research is efficient and effective in meeting its dual objectives of protecting the health and safety of the community, whilst enabling innovative and novel research to occur in Australia.

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NHMRC will continue to support ERLC to align its regulatory activities with the 6 principles of the Regulatory Framework in a way that is appropriately scaled to the role, regulatory posture, specific legislative objectives, functions, and environment that ERLC regulates, and to implement their legislated functions in a manner that is consistent with the guidance provided in *Resource Management Guide 128 (Regulator Performance)* (RMG 128).

Regulatory reform and best practice

Consistent with your expectations, NHMRC recognises the importance of applying the principles of regulator best practice in our activities. Ensuring compliance with national standards and maintaining constructive stakeholder relationships in the regulatory environment. The agency continues to integrate regulatory best practice principles in activities that support delivery of ERLC's functions.

Targeted and risk based

We embrace a proportionate, risk-based approach; actively seeking to understand, engage with, and effectively mitigate strategic risks to deliver ERLC's regulatory functions. This includes the identification and implementation of pragmatic solutions to minimise regulatory burden on the research sector wherever possible, whilst acting within the essential community safeguards established by the RIHE and PHCR Acts.

Integrated

We ensure that the policies, protocols and procedures that support the human embryo research framework are reviewed regularly and are proactive in our approach to monitoring and evaluating the framework to ensure remains fit-for-purpose. NHMRC also continues to engage with other Commonwealth regulators, particularly within the Health Portfolio, to learn from their expertise and where appropriate, to help drive improved regulator performance at a whole-of-system level.

User-centered

We ensure that the regulation of human embryo research in Australia reflects contemporary regulatory practice, with a focus on being open, transparent and consistent when engaging with stakeholders. We engage and consult on significant changes to the framework, are receptive to feedback, and provide clear and accessible guidance and information to assist regulated entities to meet their compliance obligations.

Evidence-based and data-driven

We support and monitor license holder compliance with the regulatory framework and manage risk proportionately, and in line with the legislated expectations. We identify opportunities to reduce duplication and streamline processes to improve efficiency and lift productivity.

Reflective of the digital era

We maintain essential safeguards, using data and digital technology, wherever possible and appropriate, to manage risks and minimise regulatory burden on applicants. We support those we regulate to comply with, and enhance their understanding of, the requirements of the legislation.

Continuously improved and outcomes-focused

We use quantitative and qualitative analysis to assess regulator and license holder performance, reporting against performance measures in NHMRC corporate documents. We also regularly review and, where necessary, adjust protocols and operating procedures to ensure that ERLC remains agile and responsive to sector needs and promotes a culture that builds public confidence in NHMRC's activities and trust in government decision-making.

Relationship with Minister and portfolio

I acknowledge your request that I provide you with advice on significant issues that may be impacting on delivery of ERLC's regulatory responsibilities. ERLC, supported by NHMRC, will continue to monitor the regulatory environment to ensure that, in as far as the legislation will

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facilitate, the regulatory approach keeps pace with changes in technology, research innovation and community expectations.

In line with RIHE Act requirements, ERLC will also continue to report twice a year to the Parliament of Australia to maintain consistent, timely and transparent engagement with parliamentarians on the performance of its functions and the activities of the licence holders it regulates.

I will make the 2025 SOE and this SOI available on the NHMRC website and ensure that the associated performance measures and reporting are integrated into NHMRC's corporate reporting processes.

Yours sincerely

Professor Steve Wesselingh
Chief Executive Officer

19 December 2025

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