



Australian Government
National Health and Medical Research Council



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 19 November 2024. It sets out my intentions regarding how NHMRC will support the Embryo Research Licensing Committee (ERLC) to achieve its regulatory objectives, carry out its regulatory functions, and exercise its regulatory powers. This SOI outlines NHMRC's approach to regulatory stewardship, integrating the principles of regulator best practice and stakeholder relationship management, the Government's policy priorities, and innovation and regulatory change.

Overview

As the Government's lead agency for funding health and medical research, NHMRC has a unique role in the Australian health system. It invests in the creation of new knowledge about the origins, prevention and treatment of disease and the promotion of health and wellbeing. 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 ethics and integrity in the conduct of research and the delivery of health care.

NHMRC additionally administers the *Research Involving Human Embryos Act 2002* (RIHE Act) and the *Prohibition of Human Cloning for Reproduction Act 2002*. These Acts were developed to address community concerns about scientific developments in relation to 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 regulate the uses of excess assisted reproductive technology (ART) embryos, the creation or uses of human embryos created through processes other than fertilisation and the practice of permitted mitochondrial donation techniques in Australia. The RIHE Act establishes ERLC, a principal committee of NHMRC, as the national regulator of activities defined in the Acts.

Regulatory stewardship

Stewardship covers the range of functions that ERLC delivers. It helps ensure that the regulation of human embryo research is efficient and effective in meeting its objective to protect the health and safety of the community whilst enabling innovative research. My agency will seek to embed the principles set out in Resource Management Guide 128 – Regulator Performance (RMG 128) under the *Public Governance, Performance and Accountability Act 2013*, and will:

- ensure that the policies, protocols and procedures that support the human embryo research framework is subject to are regular review to maintain their currency
- take a whole-of-system, life-cycle view of regulation that balances legislative intent and community expectations to support innovative health and medical research
- adopt a proactive, collaborative approach to the monitoring and evaluation of the regulatory framework to ensure it remains fit-for-purpose.

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To achieve this, NHMRC will engage with other Commonwealth regulators, particularly in the Health portfolio, and learn from their regulatory expertise and where appropriate, to help drive improved regulator performance at a whole-of-system level.

Principles of regulator best practice

Consistent with your expectations, NHMRC will continue to support ERLC to implement their functions in ways that realise the three main principles of RMG 128.

Continuous improvement and building trust

ERLC will continue to identify opportunities for continual improvement and ensure practices are fit-for-purpose. This will include:

- adopting a whole-of-system perspective, continuously improving performance, capability and culture, to build trust and confidence in Australia's regulatory settings
- using quantitative and qualitative analysis as important tools for assessing and reporting on performance. Delivery against performance measures will be reported in NHMRC corporate documents, thereby supporting continuous improvement
- promoting a culture that builds public confidence in NHMRC's work and promotes trust in government decision-making.

Risk-based and data-driven

ERLC will continue to maintain and review compliance and enforcement of the embryo research regulatory framework and manage risk appropriately and in line with the legislation. This will include:

- seeking opportunities to remove any duplication and streamline processes to improve efficiency and lift productivity
- maintain essential safeguards, using data and digital technology to manage risks proportionately to minimise regulatory burden on applicants and to support those it regulates to comply with and enhance their understanding of the requirements of the legislation
- actively understand, engage with and effectively mitigate strategic risks to successfully manage its regulatory functions
- use data sources that meet relevant data assurance standards for assessing and reporting on the quality of statistical information, wherever possible.

Collaboration and engagement

ERLC will continue to ensure that the regulation of embryo research in Australia is transparent and responsive. That regulation is implemented in a modern way, with a focus on being open, transparent and consistent when engaging with stakeholders. This will include:

- seeking opportunities to engage and consult genuinely with stakeholders on any significant changes to how the regulatory framework is implemented
- being receptive to feedback and diverse stakeholder views
- being transparent and consistent in decision-making processes
- providing up-to-date, clear and accessible guidance and information to assist regulated entities with compliance.

NHMRC acknowledges the importance of the principles of regulator best practice in ensuring compliance with national standards and maintaining constructive stakeholder relationships in the regulatory environment. The agency will continue to embed the principles of regulator best practice and strengthen reporting to evaluate performance.

Innovation and regulatory change

ERLC, supported by NHMRC, will continue to monitor the regulatory environment to ensure that, in as far as the legislation will facilitate, the regulatory approach keeps pace with changes in technology, research innovation and community expectations. The agency will also regularly review and, where necessary, adjust protocols and operating procedures to ensure that ERLC remains agile and responsive.

Relationship with Minister and portfolio

As required under the RIHE Act, ERLC will continue to report twice a year to the Parliament of Australia through your office to maintain consistent, timely and transparent engagement with parliamentarians on the performance of its functions and the activities of the licence holders it regulates.

As requested, I will make the SOE and this SOI available to the Australian community— initially via the NHMRC website, ensuring that they, along with the associated performance measures and reporting, are subsequently integrated into NHMRC’s corporate reporting processes.

Yours sincerely



Professor Steve Wesselingh
Chief Executive Officer

6 December 2024