



The Hon Mark Butler MP
Minister for Health and Ageing
Minister for Disability and the National Disability Insurance Scheme

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Dear Professor *Steve*

This Statement of Expectations (SOE) details my expectations of how the National Health and Medical Research Council (NHMRC) will achieve its regulatory objectives, carry out its regulatory functions, and exercise its regulatory powers.

The Australian Government recognises and respects the statutory independence exercised by the Embryo Research Licensing Committee (ERLC) of NHMRC when administering the human embryo research regulatory framework established by the *Research Involving Human Embryos Act 2002* (RIHE Act) and the *Prohibition of Human Cloning for Reproduction Act 2002* (PHCR Act).

The Government also recognises and respects the independence of your role as NHMRC's Chief Executive Officer and as the agency's Accountable Authority with responsibility under the *Public Governance, Performance and Accountability Act 2013* (PGPA Act) for ERLC's regulatory functions.

This SOE supports the delivery of these functions and contributes to the Australian Government's commitment to effective governance and performance of regulatory functions. It takes account of the whole-of-government objective for Commonwealth regulators to effectively balance risk mitigation with efficiency, growth and dynamism; maintaining a commitment to good corporate governance and reducing unnecessary burden on business and the community.

Overview

The regulatory framework established by the RIHE Act and the PHCR Act, prohibits certain practices, such as human cloning, and regulates the uses of excess human embryos created using assisted reproductive technology (ART) in research. It also results the creation and/or uses of other human embryos created through processes other than fertilisation, and the practice of permitted mitochondrial donation techniques in ART research in Australia.

The Australian Government recognises and respects the independence of ERLC in its delivery of regulatory functions under this framework. However, the Government is of the view that all regulators should have a risk-based approach to compliance obligations, engagement and enforcement that allows for proportionate responses appropriate to the nature and seriousness of identified risks.

This approach recognises that it is not possible to eliminate all risks, whilst enabling regulators to achieve their objectives effectively, including the prioritisation of opportunities for productivity improvements in the regulatory environment.

Regulatory reform

The regulatory reform agenda is a key component of the Government's plan to boost Australia's productivity and lower the cost of living by ensuring a fit for purpose regulatory environment. The Government is looking at ways to boost productivity through reducing unnecessary or duplicative regulatory costs. Cooperating with the states and territories and working with international partners identifies opportunities to improve the quality of regulation and lower the cost of living for Australians.

The Government is also improving regulator performance, capability and culture through regulatory stewardship. This supports the Government's commitment to Australian Public Service reform by building trust in government and its institutions and by putting the community and business at the centre of policy and services.

I expect NHMRC to contribute to the regulatory reform process by:

- embracing a proportionate risk-based approach to regulation to effectively balance risk mitigation with efficiency, growth and dynamism as a priority, and to consider the impact on productivity
- aligning regulatory activities with the 6 principles of the *Regulatory Policy, Practice and Performance Framework* in a way that is appropriately scaled to the role, regulatory posture, specific legislative objectives, functions, and environment that ERLC regulates
- seeking opportunities to reduce duplication and streamline processes in order to improve efficiency and lift productivity, including international harmonisation or alignment with international regulators, if appropriate
- acting in accordance with regulator best practice in its decision-making, policies, processes and communications practices, including reporting against key performance indicators and, as appropriate, service standards to maximise transparency and minimise compliance costs
- incorporating regulator performance reporting into NHMRC corporate reporting in line with the expectations of Resource Management Guide 128 (Regulator Performance) to support greater transparency and accountability to the Government for regulator performance
- giving consideration of cost recovery arrangements, if appropriate.

Best practice principles

In exercising its regulatory functions, I expect NHMRC to integrate the principles of regulatory best practice into its functions in an appropriate and proportional way:

1. **Targeted and risk based** – providing pragmatic solutions to minimise regulatory burden, while ensuring the regulatory intent is being met and essential safeguards remain in place
2. **Integrated in existing systems** – utilising a whole-of-system approach by integrating, leveraging, improving, and modernising existing regulatory systems, where appropriate
3. **User-centred** – applying good regulatory design that solves clear, well-defined problems and fosters changed behaviours, resulting in greater regulatory compliance
4. **Evidence-based and data-driven** – utilising evidence throughout the regulatory life cycle to predict and evaluate future need and potential challenges, and support the delivery of fit-for-purpose policy, practice, and performance outcomes
5. **Reflective of the digital era** – take advantage of digital and technology capabilities and practices, where appropriate, whilst ensuring equitable access to regulatory systems
6. **Continuously improved and outcomes-focused** – maintaining stewardship to evaluate and recommend improvement to regulation, ensuring regulatory systems are transparent and responsive to evolving regulatory environments and shifting expectations from government and community.

To support an efficient and effective regulatory environment that enables productivity gains, I expect NHMRC to monitor the environment in which ERLC operates to ensure regulatory approaches keep pace with changes in technology, industry practices, international regulation, and community expectations. I also expect NHMRC to regularly review and, where necessary, adjust policies, protocols and operational procedures, to ensure ERLC can respond to the changing social, technological and international regulatory environment and commercial context in which it operates.

Relationship with Minister and portfolio

As noted earlier, the Government and I appreciate and respect the independence of ERLC in its delivery of the agency's regulatory functions. I ask that you, as the Accountable Authority, provide me with accurate and timely advice on significant issues that may be impacting on delivery of ERLC's regulatory responsibilities.

Statement of Intent

I look forward to NHMRC's reply to this SOE with a Statement of Intent (SOI) outlining how you will implement these expectations. I request that this SOE and corresponding SOI be made available to the Australian community through NHMRC's website.

Yours sincerely



Mark Butler

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