



The Hon Mark Butler MP
Minister for Health and Aged Care

Ref No: MC24-001405

Professor Steve Wesselingh
Chief Executive Officer
National Health and Medical Research Council
GPO Box 1421
CANBERRA ACT 2601

Dear Professor

Steve

I write to outline 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.

Whilst the Government recognises the statutory independence of the Embryo Research Licensing Committee (ERLC) of NHMRC, it notes that you, as NHMRC Chief Executive Officer (CEO) are the Accountable Authority for NHMRC under the *Public Governance, Performance and Accountability Act 2013* (PGPA Act) for these regulatory functions.

This Statement of Expectations (SOE) will assist with the Australian Government's commitment to effective governance and performance of regulatory functions, guided by the PGPA Act. It forms part of the Government's commitment to good corporate governance of regulatory bodies and reducing unnecessary burden on business and the community.

Overview

As the responsible Commonwealth Minister, this SOE sets out my expectations of the regulatory function undertaken by the ERLC. That being, to administer the human embryo research regulatory framework established by the *Research Involving Human Embryos Act 2002* and the *Prohibition of Human Cloning for Reproduction Act 2002*.

These Acts establish a framework to prohibit certain practices, such as human cloning, and regulate the uses of excess assisted reproductive technology embryos, the creation or uses of other human embryos created through processes other than fertilisation and the practice of permitted mitochondrial donation techniques in Australia.

The Government recognises and respects the independence of the NHMRC CEO as the Accountable Authority. The Government also recognises and respects the independence of ERLC in its delivery of the agency's regulatory functions. However, the Government is of the view that 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 allows regulators to achieve objectives more effectively while recognising that it is not possible to eliminate all risks.

The Government's policy priorities and objectives

Regulatory reform agenda

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 business and community at the centre of policy and services.

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

- 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, in order to maximise transparency and minimise compliance costs
- applying the Resource Management Guide 128 Regulator Performance to its regulatory functions to assess its performance and engagement with stakeholders
- incorporating regulator performance reporting into the entity's reporting processes, as required by Resource Management Guide 128 Regulator Performance under the *Public Governance, Performance and Accountability Act 2013*, Public Governance and Performance and Accountability Rule 2014 to support greater transparency and accountability of regulator performance
- giving consideration of cost recovery arrangements, if appropriate.

Principles of regulator best practice

In exercising its functions and powers in accordance with these principles, I expect NHMRC to display the following principles of regulator best practice:

1. Continuous improvement and building trust:

- use qualitative and quantitative analysis as important tools for assessing and reporting on performance, and to support continuous improvement
- promote a work culture that builds public confidence in NHMRC's work and promotes trust in Government decision-making.

2. Risk-based and data-driven:

- actively understand, engage with and effectively mitigate strategic risks in order to successfully manage its regulatory functions without unnecessarily impeding the operations of regulated entities
- use data sources that meet relevant data assurance standards for assessing and reporting on the quality of statistical information.

3. Collaboration and engagement:

- Open, transparent and consistent engagement with stakeholders including industry, government and the broader community is crucial to maintaining competent and innovative regulatory practices. Consequently, I expect NHMRC to:
 - seek opportunities to engage and consult genuinely with stakeholders
 - be receptive to feedback and diverse stakeholder views
 - seek to increase transparency in decision-making processes
 - provide up-to-date, clear and accessible guidance and information to assist regulated entities with compliance, including the sharing of information/intelligence as appropriate and in adherence to any secrecy or privacy obligations.

Innovation and regulatory change

I expect NHMRC to continually 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 impacting on ERLC's delivery of these functions so that the Government can respond promptly to any policy challenges.

Statement of Intent

I look forward to NHMRC's reply to this SOE with a Statement of Intent outlining how you will implement the above-mentioned expectations.

I request that this SOE and corresponding Statement of Intent be made available to the Australian community through NHMRC's Corporate Plan or Annual Report.

Yours sincerely



Mark Butler

19 / 11 / 2024