

PROXIMITY

Privacy Impact Assessment

**Report on the Implementation and Ongoing Management of the
Mitochondrial Donation Licensing Scheme**

National Health and Medical Research Council (NHMRC)

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Part 1 Executive Summary and Recommendations

Preliminary

The implementation of a mitochondrial donation licensing scheme in Australia to provide a means through which a woman with mitochondrial disease encoded on her mitochondrial DNA can avoid transmitting mitochondrial disease to her biological children has raised significant privacy (and other) concerns within the Australian community. The passage of the supporting legislation (the *Mitochondrial Donation Law Reform (Maeve's Law) Act 2022*) was the subject of lengthy debate and the Bill itself was the subject of amendment during the legislative process.

The end result from a privacy perspective is that the mitochondrial donation licensing scheme is heavily circumscribed and many of the matters that might otherwise need to be addressed in a conventional Privacy Impact Assessment (PIA) have already been the subject of significant debate and legislative attention.

In particular, there are already significant statutory and regulatory restrictions relating to the protection of the privacy of individuals, requiring collection, holding and disclosure of personal information in only the most necessary circumstances, and frequent obligations relating to de-identification of information to minimise the risk of the identity of individuals being disclosed.

As a result, most of the privacy issues identified in this PIA relate to the licensing process itself (which is managed by the Embryo Research Licencing Committee (ERLC) as a principal committee of the National Health and Medical Research Council (NHMRC) and the conditions that ERLC imposes as part of the licensing process. The other main area that receives attention in this PIA relates to the security maintained by NHMRC over the very limited amounts of personal information that it will actually receive under the licensing scheme.

Recommendations

This PIA report makes the following recommendations:

1. Staff involved in the licence application process be provided with instructions on how to deal with unsolicited personal information contained in licence applications. [Australian Privacy Principle (APP) 4]
2. Impose compliance with the *Privacy Act 1988* as a licence condition in all mitochondrial donation licences. [APP5]
3. Make it a requirement in a mitochondrial donation licence application form that any individual who is required to provide personal information for the purposes of the licence application must be provided with a privacy collection notice in a form set by the NHMRC. [APP5]
4. Make it a condition of all issued licences that, even when the licence holder is collecting personal information from an individual that will not be required to be disclosed to NHMRC under the Scheme, the individual must still be provided with a form of privacy collection notice. [APP5]
5. That page 2 of the draft Privacy Collection Notice titled '*Mitochondrial Donation Licensing Scheme – Privacy and the protection of your personal information*', be amended by deleting the reference to the ERLC, and the reference to 'confidential information' be replaced with 'personal information'. [APP5]

6. Make it a requirement of the licence application process that the applicant must secure the consent of any embryologists and staff members nominated or noted in a licence application to the overseas disclosure of their personal information by NHMRC when it considers it necessary for verification purposes. [APP8]
7. The licence application form itself should also contain an item for each nominated person to formally confirm their consent. [APP8]
8. That the following changes be made to the NHMRC's Privacy Policy to reflect the application of the NHMRC's privacy regime to the mitochondrial donation licensing scheme:
 - a. That the section headed 'Collection of your personal information' be amended to refer to mitochondrial donation licence applications – viz 'NHMRC may also collect your personal information via a third party, such as when an institution...*applies for a mitochondrial donation licence*'. [APP 1.4(b)] [page. 6]
 - b. That the section headed 'Dealing with NHMRC anonymously or pseudonymously' be amended to include reference to mitochondrial donation licence applications, viz '*In the case of applications for research grants or mitochondrial donation licences, it is not practicable for NHMRC to deal with you on an anonymous or pseudonymous basis. NHMRC will not accept a grant or licence application or report that is anonymous or not in your real name.*' [APP1.4(f)], [page 7] [We note NHMRC has already advised that it proposes to include a statement in its privacy collection notices developed for this scheme to the effect that individuals will not be able to take advantage of anonymity or pseudonymity]
 - c. That the section headed 'Disclosure of Personal Information to Overseas Recipients' on page 10 be expanded to include a reference to potential disclosure of personal information contained in mitochondrial licence applications. [APP8]
9. As a matter of consistency, NHMRC amend its Privacy Policy to refer to the consent requirement for overseas disclosure of personal information in relation to mitochondrial licence applications similar to the disclosure statement used for grant application processes. [APP8]
10. NHMRC consider the imposing of a licence condition requiring licence holders to advise the agency when any of the personal information it provides in its licence application changes. [APP10]
11. That the NHMRC's licence inspection program includes review of the level of security over personal information held by a licence holder. [APP11]

Our Role

Proximity Advisory has been briefed to:

- Develop on behalf of the NHMRC a Privacy Impact Statement (PIA), considering the privacy impacts associated with the implementation of the Mitochondrial Donation Licensing Scheme introduced by the *Mitochondrial Donation Law Reform (Maeve's Law) Act 2022*
- Provide *ad hoc* legal advice (on request from NHMRC) on any privacy matters identified through the drafting of the PIA
- Review and advise the Department of Health and Aged Care on the establishment and management of the Mitochondrial Donation Donor Register.

In particular, we have been instructed to include a discussion around a practical understanding of any privacy impacts of the operation of the licensing scheme itself.

Review Methodology

In undertaking this PIA, we reviewed the Mitochondrial Donation Law Reform (Maeve's Law) Act 2022 (Mitochondrial Donation Act) and published explanatory material and consulted with NHMRC. Those consultations included reviewing internally prepared documents.

Material provided by staff

- Preliminary PIA prepared by Australian Government Solicitor (AGS) on the Mitochondrial Donation Law Reform (Maeve's Law) Bill 2021 as originally tabled in Parliament.
- NHMRC Privacy Policy, recently approved by NHMRC Executive
- Responses provided by NHMRC to discussions
- Draft licensing application material
- Draft Privacy Collection Notices

Legislation

- Research Involving Human Embryos Act 2002 (RIHE Act)
- Mitochondrial Donation Act

Publications

- Australian Government Agencies Privacy Code
- Office of the Australian Information Commissioner (OAIC) Privacy Guidelines

Report Structure

This project was effectively undertaken in two stages.

Stage 1 (this report) is a PIA of the implementation of the Mitochondrial Donation Licensing Scheme itself, which primarily revolved around the role of the NHMRC and the ERLC. This report was provided to the NHMRC.

Stage 2 is a privacy impact process reviewing the privacy framework that would be necessary for the establishment and management of the Mitochondrial Donation Donor Register by the Secretary. This stage involved consultation with officers of the Department.

In practice, of course, the undertaking of the two stages has overlapped to some extent.

Stakeholder Engagement

In undertaking this PIA, we consulted with:

- Dr Erica Crone, Assistant Director, Governance, Regulation & Secretariat Support, NHMRC
- Marita Sloan, Director, Governance, Regulation & Secretariat Support, NHMRC
- Bronwen Shelley, Principal Lawyer, NHMRC Legal Services Team.