

PROXIMITY

Privacy Impact Assessment - Summary

Mitochondrial Donation Licensing Scheme

Establishment and Management of the Mitochondrial Donation Donor Register

Department of Health and Aged Care

17 January 2023

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Background

On 1 October 2022, the principal operative provisions of the *Mitochondrial Donation Law Reform (Maeve's Law) Act 2022* (Mitochondrial Donation Act) commenced. These provisions amended the existing framework of Commonwealth legislation to create a licensing regime that would regulate the use of mitochondrial donations for research, training, and human reproductive purposes in Australia. The principal enactments affected were the *Prohibition of Human Clones for Reproduction Act 2002* and the *Research Involving Human Embryos Act 2007* ('RIHE Act').

The implementation of a mitochondrial donation licensing scheme in Australia provides a means by which a woman with mitochondrial disease encoded on her mitochondrial DNA can avoid the risk of transmitting mitochondrial disease to her biological children. Mitochondrial donation involves the transfer of nuclear genetic material extracted from the prospective mother's egg and the placing of that material into a donor egg, which has had its own nuclear genetic material removed, but which retains its own intact mitochondria.

The amendments to the RIHE Act create a framework of 5 'cascading' licences (described collectively as mitochondrial donation licences) which collectively address research, training and eventual placement of an embryo created using a permitted mitochondrial donation technique in a woman. Responsibility for the regulation of this licensing scheme sits with the National Health and Medical Research Council (NHMRC) - more particularly with the NHMRC's Embryo Research Licensing Committee (NHMRC Licensing Committee).

The mitochondrial donation licensing scheme established by the Mitochondrial Donation Act is heavily circumscribed in privacy terms, with significant limits imposed on the amount of personal information about individuals that may be provided to the NHMRC as part of its licensing regulation role.

Mitochondrial Donation Donor Register

An important legislative feature of the mitochondrial donation licensing scheme is the establishment and ongoing management of the Mitochondrial Donation Donor Register (Register) by the Secretary of the Department of Health and Aged Care (Secretary).

Proximity Advisory has been commissioned to undertake a Privacy Impact Assessment (PIA) of the establishment and management of the Register.

Section 28R of the RIHE Act establishes a regime under which the holder of a clinical trial licence or a clinical practice licence (the two categories of licence under which a child may be born as a result of a licensed mitochondrial donation technique) must collect and keep records of certain categories of information about donors and use their best endeavors to collect and keep records of children born alive as a result of a mitochondrial donation technique.

The categories of information collected regarding a donor are set out in subsection 28R(1), the most significant categories of information being name and residential address. Subparagraph(1)(e) provides for other categories of information to be prescribed in the RIHE Regulations. At the moment, no additional categories of information have been prescribed.

The categories of information collected regarding a child born as a result of a mitochondrial donation technique are set out in subsection 28R(2). They include name, sex, date of birth and any other categories of information prescribed in the RIHE Regulations. At the moment, no additional categories of information have been prescribed.

Subsection 28R(5) provides that, where a child is born as a result of a licensed mitochondrial donation technique, the licence holder must, as soon as practicable:

- notify both the Secretary and the NHMRC Licensing Committee of the fact in a form approved by the Secretary - (paragraph (a)); and
- give the Secretary, in a form approved by the Secretary, specified information for the child and the donor as set out in subsections (1) and (3) - (paragraph (b)).

Reflecting the sensitivity of the information collected, subsection (6) provides that a notification under subsection 28R(5)(a) regarding a child must not include the name or other information that could be used to discover the identity of a trial participant, patient or child.

Subsection 29A(1) requires the Secretary to keep the above information received in accordance with subsection 28R(5)(b) - ie regarding donors and children born – on the Register.

Subsection 29A(2) provides that the Register may be kept by electronic means, a procedure which the Department has adopted. As the IT build for the Register may take up to six months, the Department has created an excel spreadsheet version of the Register as an interim stage, which has been created and stored in TRIM from 2 October 2022. The privacy issues identified and addressed in the PIA also cover this temporary version of the Register.

Access to the Register

There are significant legislative restrictions on access to the personal information held on the Register.

The Register must not be made publicly available (subsection 29A(3)).

However, subsection 29A(4) provides that a person born as a result of a mitochondrial donation technique who has reached the age of 18 years can apply to the Secretary to disclose information held in the Register to them about the donor 'in relation to the use of the technique'.

Additionally, subsection 29A(5) provides that a donor can apply to the Secretary for information held on the Register about them that is of a kind described in subsection 28R(1)

The Secretary must provide any information properly requested to a child or a donor (subsection 29A(6)).

In preparation for the commencement of the operative provisions of the Mitochondrial Donation Act, the Department developed a process overview document setting out the framework for the establishment and management of the Mitochondrial Donation Act Register. This document focussed heavily on meeting the Australian Privacy Principles (APPs) set out in Schedule 1 to the *Privacy Act 1988* and the access requirements imposed under the *Mitochondrial Donation Law Reform (Maeve's Law) Act 2022* (described above).

Undertaking a Privacy Impact Assessment (PIA)

Clause 12.1 of the Australian Government Agencies Privacy Code requires the Secretary to undertake a PIA for 'all high privacy risk' projects or initiatives that involve new or changed ways of handling personal information.

A PIA is a systematic assessment that identifies the impact a project instituted by a Commonwealth body bound by the Privacy Act might have or is having on the privacy of individuals.

In a practical sense, the process of assessing a project's potential privacy impact involves analysing the project or process and evaluating the flow of personal information (including collection, storage, use, and disclosure) against the 13 APPs set out in Schedule 1 to the *Privacy Act 1988* (noting that APPs 7 and 9 were not applicable in this case).

In undertaking the PIA, we had the benefit of considering the analysis and recommendations made in a preliminary PIA drafted by the Australian Government Solicitor (AGS) of the original Bill as it was introduced into Parliament. Having taken the AGS PIA into account and noting that the Department and NHMRC have already accepted all recommendations made in the AGS PIA, we focused on identifying whether there were any additional recommendations that may be worthy of consideration.

The PIA made a number of recommendations regarding the establishment and management of the Register. These recommendations and the Department's responses are set out below.

Recommendations Made in the PIA

1. That the Department's Privacy Policy be amended to refer to the existence of the Register and the kinds of personal information that may be held on it, which persons provide that information, and the fact that access to the information held on it is highly limited. Additionally, to satisfy APP 1.4(d) in the Privacy Policy itself, it should state how a relevant person (donor or child) can request access to applicable personal information (including the application form(s)) and, if necessary, seek its correction [APP 1].

Department response: The Department's Privacy Policy is reviewed regularly. The impacts of the existence of the Register will be considered as part of the Department's regular Privacy Policy review to ensure the Privacy Policy accurately reflects the collection, use, updating and disclosure of personal information associated with the Register

2. That the Department consider including in its Privacy Policy, under the heading 'Collection of personal information about children, young and vulnerable people' a reference to the collection of information regarding certain children for recording in the Register [APP 1].

Department response: As above, the Department's Privacy Policy is reviewed regularly. The impacts of the existence of the Register will be considered as part of the Department's regular Privacy Policy review to ensure the Privacy Policy accurately reflects the collection, use, updating and disclosure of personal information associated with the Register

3. As a possible alternative to making various amendments to its general Privacy Policy to accommodate the management of the Register, the Department consider establishing a separate privacy policy for the Register, in a manner similar to the Department's privacy policies for the COVIDSafe APP and the Australian Immunisation Register [APP 1].

Department response: The Department will consider developing a separate Privacy Policy to accommodate management of the Register as an alternative to making amendments to the general Departmental Privacy Policy.

4. Where an individual applies to the Department for information held on the Register, the Department would properly need to satisfy itself of the eligibility of the individual. This process would involve the individual providing personal information to the Department. We recommend that the form(s) developed by the Department for applicants under section 29A require the applicant to consent to the provision of their personal information as part of the application process, so that the Department can verify their eligibility.

Department response: The Department will consider including a consent requirement on the approved forms being developed for individuals seeking access to information about them that is held on the Register under section 29A.

5. To minimise the practical risk of unsolicited personal information being collected by the Department, that the form approved by the Secretary for the purposes of subsection 28R(5) not contain any space for 'free text' information. It will also be important for relevant Department staff to be trained to identify unsolicited personal information in order that it can be dealt with appropriately [APP 4].

Department response: The Department is in the process of developing an unsolicited information handling process. The Department is also developing bespoke training for staff working with the Register in relation to unsolicited information handling by officers working with the Register. The Department will refrain from the use of 'free text' fields in collection forms to minimise the risk of obtaining unsolicited personal information.

6. For the purposes of seamlessness and consistency, we recommend that the Department consult with the NHMRC in relation to the contents and structure of the form of notice to be approved by the Secretary for the purposes of subsection 28R(5)(a) and the need for both department and agency to have a common statement on their websites regarding the requirements surrounding the form. We also note there is a possibility that a licence holder may (inadvertently) notify one but not both the Department and the NHMRC, so we recommend that the two bodies also discuss the establishment of a protocol to advise each other each time a subsection 28R(5)(a) notification is received [APP 5].

Department response: Agreed. The Department will consult with the NHMRC regarding the content and structure of the form of notice and protocols for the handling of notifications.

7. That the Department consider the possibility of de-identified data held on the Register being potentially made available in the future for research or health policy development purposes and develop a protocol setting out the circumstances under which it may be willing to use/disclose any categories of (de-identified) information held on the Register for research or policy development purposes [APP 6].

Department response: Agreed. The Department will develop a protocol setting out the circumstances under which de-identified information held on the Register may be used or disclosed for research or policy development purposes.

8. That the Department consider various options in terms of engaging with NHMRC regarding the contents of their licence inspection programs and their licence conditions, or the regulation making power under subsection 29A(10), to assist in ensuring the Register is up to date [APP 10].

Department response: Agreed. The Department is committed to working closely with the NHMRC regarding the contents of their licence inspection programs and licence conditions, in the context of assisting to ensure the Register is up to date. Initial consultations on this matter have already commenced.

9. That the Department review the delegation framework for the Secretary's functions and powers in respect of the Register (under subsection 29A(8)), considering whether such a number of delegations is required in practice, with the aim of reducing the number of delegations [APP 6].

Department response: Agreed. The Department will review the delegation framework for the Secretary's function and powers in respect of the Register to ensure a limited but appropriate number of delegations are in place to support management of the Register.

10. That the Department engage with NHMRC regarding whether the agency would consider imposing a licence condition requiring licence holders to advise the agency when any of the personal information it provides to the Secretary for entering on the Register changes – and then providing the information to the Department [APP 10].

Department response: Agreed. The Department will consult with NHMRC with a view to imposing this licence condition.