



# The Australian Society for Medical Research

The ASMR Executive

16 July 2021

Committee Secretary  
Senate Standing Committees on Community Affairs  
PO Box 6100  
Parliament House  
Canberra ACT 2600

Phone: [+61 2 6277 3515](tel:+61262773515)  
Fax: +61 2 6277 5829  
[community.affairs.sen@aph.gov.au](mailto:community.affairs.sen@aph.gov.au)

Re: Submission on the **Mitochondrial Donation Law Reform (Maeve's Law) Bill 2021** from  
The Australian Society for Medical Research (ASMR)

Thank you for the opportunity to comment on this draft legislation.

Founded in 1961, the ASMR is the peak organisation representing the Australian health and medical research sector through its public, political and scientific advocacy. In addition to its core membership of health and medical researchers, the ASMR has affiliations with specialist societies, medical colleges, and patient foundations/groups that effectively expand ASMR's network to more than 100,000 stakeholders of Australian health and medical research.

The ASMR supports this well-crafted bill in principle, as it has the potential to positively impact families with a history of maternally-inherited mitochondrial DNA-based mitochondrial disease.

Mitochondrial disease encompasses a group of complex and debilitating conditions that impair the ability to produce energy. It is associated with recurrent miscarriages in affected women, severe suffering in children and young adults that often leads to premature death and chronic debilitating disease in those who reach adulthood.

Mitochondrial Donation is an assisted reproductive technique pioneered in the UK and legalised there in 2015. While not a cure, it provides a realistic chance of preventing or minimising severe disease from being passed on to a child. There are several forms of the technique, which involves transferring nuclear genetic material from an affected female patient and a male into a donor egg that has had the donor's nuclear DNA removed. If successful, the positive outcomes are not only evident in the next generation but also in future generations.

In our view, the requirement to obtain a licence to have the procedure performed, coupled with a staged process for the legal use of mitochondrial donation in research, training and clinical settings is extremely strong and will ensure best practice is ultimately used. After thorough preclinical research, a very limited number of families with a history of severe disease will be enrolled in a

small clinical trial to assess safety and efficacy in Australia. Only if this work demonstrates the safety and efficacy of the technology, will a broader implementation and licencing be considered.

All work, including the provision of a licence, will be administered and controlled by the National Health and Medical Research Council (NHMRC), one of the oldest and most trusted government authorities, with an impeccable track record of implementing and overseeing similar programs. The Bill outlines a reasonable framework for regulation, reporting and review of the technique under the stepwise licenced implementation.

Other countries have passed similar bills e.g., in 2015, mitochondrial donation was legalised in the UK House of Lords following a similarly extensive consultative and scientific review process as we have seen in Australia. With the Australian Bill largely modelled off the UK, this gives confidence that the proposed strict framework can be appropriately implemented.

While we acknowledge the ethical concerns raised during the initial consultation process, we strongly believe that the control mechanisms and governance that are incorporated in this draft legislation will ensure that research and clinical implementation will solely benefit the families at risk of having children with these devastating diseases and prevent any potential misuse of the technique.

Therefore, the ASMR strongly supports the Bill in its current form with the outlined license for research/training and clinical purposes and supports its passage into legislation.

Do not hesitate to contact the ASMR for further discussion (contact details below).

With best regards,



Professor Christoph Hagemeyer

Immediate past President and Executive Director  
Australian Society for Medical Research