Pothida Youhorn
Committee Secretary
Committee Inquiry into the Mitochondrial Donation Law Reform

16th July 2021

Dear Pothida Youhorn,

RE: Inquiry into the Mitochondrial Donation Law Reform (Maeve's Law) Bill 2021

Thank you for the opportunity for Australian Genomics to provide a submission on issues relating to the proposed new legislation on mitochondrial donation in Australia (Maeve's Law). Australian Genomics is an Australian Government initiative supporting genomic research and its translation into clinical practice. Through broad engagement and a national collaborative approach, it achieves two key objectives: to improve efficiency, reach and timeliness of genomic research projects, and to support Commonwealth State and Territory health departments in the implementation of genomics research outcomes by refining and communicating evidence to inform policy development. Australian Genomics engages with current and emerging government policy and priorities to identify gaps and opportunities, to support policy and action for integrating genomic technologies into the health system. By interfacing with consumers, governments, industry and global genomics initiatives, Australian Genomics drives change and growth in the sector.

Australian Genomics supports the Mitochondrial Donation Law Reform (Maeve's Law) 2021, which will give families who previously had limited reproductive options an opportunity to restore their reproductive confidence, with the express aim of avoiding severe mitochondrial disease in their offspring.

Australian Genomics formally partners with the Mito Foundation, and our program's investigators include international experts in mitochondrial disease. These expertise encompass the mechanisms and clinical outcomes of mitochondrial disease, ethical considerations and family and societal impacts. Investigators include several members of the Mitochondrial Donation Expert Working Committee convened during consultations held in 2019 and 2020. **We fully support their views in relation to the Mitochondrial Donation Law Reform (Maeve's Law) Bill 2021**:

- The **legislation provides immediate and appropriate choice** to Australian families who wish to avoid the risk of passing mitochondrial disease onto their children.
- It does this in a **considered and sensible manner, including the various phases** provided for. The proposed 'clinical trial' model will enable those parents wanting to access mitochondrial

donation as soon as possible to do so, whilst also permitting the introduction of mitochondrial donation into clinical practice in the future. In addition, this approach will give state jurisdictions time to consider changes that might need to be made in their respective state legislation to align it with the federal legislation if they deem it appropriate.

- The **licensing requirements appear reasonable**. Licensing of one or more organisations with recognised capacity to develop and provide the expert clinical support and the necessary IVF expertise is very appropriate, but careful thought will need to be given as to the governance of the licensing body to minimise any perceptions or actual conflicts of interest.
- We also welcome the fact that **families will not require licenses** but acknowledge the need for individual approval to ensure that mitochondrial donation only occurs in appropriate circumstances. Providing individual approval must be done in a timely manner. This is particularly important given the experience in the UK where the approval or licensing process for each couple has sometimes caused considerable delays and potentially discrepant outcomes for women who have similar risk profiles.
- Careful consideration needs to be given as to the **appropriate criteria for identification of families** for who mitochondrial donation might be appropriate. The relevant committees and expert groups proposed to oversee mitochondrial donation are appropriate and proportionate. An **expert clinical panel** (including clinical subspecialists with expertise in the diagnosis and management of paediatric-onset or adult-onset mitochondrial disease, clinical geneticists, IVF experts and ethicists) should be convened. There will be many scenarios where it will be possible to reach very clear consensus that mitochondrial donation is an appropriate option without having to have an independent expert assessment every time such a scenario is presented for consideration. There will be other scenarios where the evidence is not clear cut, and where such an expert clinical panel could be convened to review referrals. Implementation of such processes will ensure timely access to and consistent application of the technology to the families who would benefit most from mitochondrial donation.

We would welcome participation in further discussion and collaboration to progress this important reform.

Kind regards,

Tiffany Boughtwood
Managing Director
Australian Genomics