

14 July 2021

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

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

Thank you for the invitation to make a submission to the Inquiry into the Mitochondrial Donation Law Reform (Maeve's Law) Bill 2021.

## Research Australia supports the two stage implementation approach proposed in the Bill.

Research Australia is the national peak body for Australian health and medical research, representing the entire health and medical research pipeline, from the laboratory to patient and the marketplace. Research Australia works to position Australian health and medical research as a significant driver of a healthy population and a healthy economy.

Australia's health and medical research sector has been key in bringing mitochondrial donation therapies to the stage they are at now. We note that both the Senate Community Affairs References Committee and the National Health and Medical Research Council have looked at the science and ethics of mitochondrial donation and undertaken significant consultation with the community in recent years. The Department of Health also undertook public consultation as part of the development of the Bill. All of this work has informed the Bill that is currently before the Parliament.

After ten years of scientific and ethical review, the UK Parliament approved regulations to allow mitochondrial donation in 2015. Although the benefits of this legalisation have not been fully captured yet, Australia's proposed approach reflects a similar stringent framework to license the provision of mitochondrial donation for research and clinical practice.

The approach of initially allowing mitochondrial donation as part of a clinical trial is an appropriate recognition of the stage of development of this technology. It ensures that mitochondrial donation will only occur with the informed consent of participants and in a highly regulated environment.



Further availability of mitochondrial donation in clinical practice will be dependent on the outcome of the clinical trials.

The proposed licensing and regulatory requirements are onerous, but appropriately so, and the Embryo Research Licensing Committee (ERLC) of the NHMRC is the appropriate body to provide oversight.

Requiring individuals to obtain approval from the ERLC is also appropriate. It is essential the ERLC is appropriately resourced (clinical expertise and otherwise) to be able to undertake these oversight and approval activities in a timely manner, and while this this is beyond the scope of the Bill, we urge the Committee to make such a recommendation to the Minister for Health and Aged Care.

In conclusion, Research Australia believes the approach to mitochondrial donation outlined in the Bill will provide Australian couples with appropriate access to this emerging health technologies whilst providing a strictly controlled and regulated framework for the continued research and development of mitochondrial donation practices.

Yours sincerely

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