

The key federal laws governing research and clinical practice in relation to embryology are the *Prohibition for Human Cloning for Reproduction Act 2002* and the *Research Involving Human Embryos Act 2002*.

These laws currently prohibit implantation of a human embryo that contains more than two people's genetic material. This is regardless of whether that material is simply transferred, as in mitochondrial donation, or where genetic modification is proposed.

WHAT NEEDS TO CHANGE

Changing the law is critical to allow affected individuals the opportunity to have genetically related children without the risk of them inheriting mitochondrial DNA defects which will drastically limit their life.

HOW MANY PEOPLE WOULD BENEFIT?

The New England Journal of Medicine, in an article entitled *Mitochondrial Donation – How Many Women Could Benefit*, estimates that “the average number of births per year among women at risk for transmitting mtDNA [mitochondrial DNA] disease is 152 in the United Kingdom and 778 in the United States.”

A simple extrapolation from the UK means that there are around 56 children each year in Australia who could potentially benefit from this technique, given the respective population sizes and assuming roughly equal age distribution and fertility.

Whilst this may seem a relatively low number, it represents a significant burden to our health system and a major burden and fear on behalf of families at risk. Conversely, eliminating this risk does not represent a significant cost or burden to the financial sustainability of the health system and would provide parents and families a choice regarding the health risks facing their child.

WHAT HAS HAPPENED TO DATE?

There have been multiple Australian inquiries and consultations about legalising mitochondrial donation over a number of years. These have included:

- An inquiry in 2018 by the Senate Community Affairs Committee into the *Science of mitochondrial disease and related matters*. The resulting report made a series of recommendations including that public consultation be undertaken about introducing mitochondrial donation and that ‘the Australian Government prepare a consultation paper, including options for legislative change that would be required’;
- A significant program of public consultation led by the NHMRC in 2019 with public forums, webinars, online submissions, a citizens’ panel and other activities to explore the Australian community’s views regarding the social and ethical issues regarding mitochondrial donation;
- An NHMRC Expert Committee that worked during 2019 and 2020 on scientific and other matters raised by the Senate inquiry. The final report and advice of this Committee and results of the public consultation can be found on the [NHMRC website](#);
- A public [consultation paper](#) issued by the Government in 2021 outlining a two-stage implementation process for the introduction of mitochondrial donation in Australia;
- A review by the Senate Standing Committee for the Scrutiny of Bills in June 2021; and
- An inquiry by the Senate Community Affairs Legislation Committee that reported in August 2021 summarising the submissions made and views expressed during the inquiry. As this is a conscience matter, the Committee made no recommendations.

NEXT STEPS

It is expected that the Bill introduced by Minister Hunt will be debated in Parliament in late 2021 or early 2022. Liberal, National and Labor MPs and Senators will be allowed a conscience vote on the Bill and we are asking for your support when the Bill comes before Parliament.