Australian Government

Department of Health

Mr Jason Lange
Executive Director
Office of Best Practice Regulation
Department of the Prime Minister and Cabinet
1 National Circuit
BARTON ACT 2600

Email: helpdesk-OBPR@pmc.gov.au

Dear Mr Lange

Regulation Impact Statement – Legislation of mitochondrial donation in Australia – Second Pass Final Assessment

I am writing in relation to the attached Regulation Impact Statement (RIS) prepared for the introduction of legislation permitting the introduction of mitochondrial donation in Australia.

I am satisfied that the RIS addresses the concerns raised in your letter of 4 March 2021. Specifically, your letter suggested the RIS needs to:

1. further draw together the various threads of argument to more fully explain how Option 2A offers the highest net benefit relative to the other options, and Option 2B in particular;

2. outline the results of the latest consultation on the staged approach to legalisation; and

3. provide additional precision in its explanation and presentation of the regulatory costs.

The specific items raised in Attachment A to your letter are addressed throughout the body of the RIS. You will note that with regard to the first principal issue you ask to be addressed, the RIS sets out more clearly and in more detail on pages 15-16 why Option 2A, a staged approach to legalising mitochondrial donation as a pathway to clinical use, is the preferred option. This includes discussion of why it is preferred over Option 2B. This discussion is supported by additional analysis on pages 11—13 assessing the superior net social benefit of Option 2A, which includes discussion of how Option 2A is preferable to Option 2B in terms of managing potential risks or unintended consequences.

A staged approach to introducing the legalisation also received support with regard to the second issue you asked to be addressed, that is the outcomes of the latest consultation on the Government's proposed approach. This is outlined on pages 14-15.

The analysis and presentation of the regulatory costs has also been expanded and refocused in accordance with your request.

These regulatory costs are nil for Options 1 and 3; $0.19 million per year for Option 2A (preferred) and $0.14 million per year for Option 2B.

The RIS does not identify specific offsets for Option 2A as Stage 1 of this option will only allow licensed organisations to do research and training, and then a small scale clinical trial with limited numbers of participants. Any offsets, in terms of reduced health expenditure from fewer babies being born with severe mitochondrial disease, will be negligible during the ten year period associated with Stage 1. The Department of Health was unable to identify an appropriate reduction in regulatory burden to offset the increased burden in this proposal. The Department notes the increase and will investigate offset opportunities across the Department as we work on other proposals.

Accordingly, I am satisfied that the RIS is now consistent with the six principles for Australian Government policy makers as specified in the *Australian Government Guide to Regulatory Impact Analysis*.

I submit the RIS to the Office of Best Practice Regulation for formal final assessment.

The contact person in the Department is Ms Angela Wallbank, Assistant Secretary, Strategic Policy Branch. She is available on (02) 6289 9629 or via email at: Angela.Wallbank@health.gov.au.

Yours sincerely

Caroline Edwards
Associate Secretary
Department of Health
12 March 2021