



Australian Government

Department of the Prime Minister and Cabinet  
Office of Best Practice Regulation

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Ms Caroline Edwards  
Associate Secretary  
Department of Health

Dear Ms Edwards

## **Regulation Impact Statement – Second-Pass Final Assessment – Legalisation of mitochondrial donation in Australia**

Thank you for your letter received 15 March 2021 submitting a Regulation Impact Statement (RIS) on Legalisation of mitochondrial donation in Australia for formal Second-Pass Final Assessment.

The Office of Best Practice Regulation's (OBPR's) assessment is that the quality of the regulatory impact analysis in the RIS is adequate to meet the Australian Government's RIS requirements. While the analysis in the RIS is sufficient to inform a final decision, to be consistent with good practice the RIS would have required further analysis to articulate both the costs and benefits of each option, including the status quo, for businesses, individuals and the community.

The RIS may now be provided to the decision-maker to inform their decision.

We would appreciate you advising us when a final decision has been announced and forwarding a copy of the RIS in a form meeting the Government's accessibility requirements. The OBPR will publish the RIS, along with your certification and this assessment, on the OBPR's website <https://ris.pmc.gov.au>.

If you have any further queries, please do not hesitate to contact me.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Jason Lange', written in a cursive style.

Jason Lange  
Executive Director  
16 March 2021