Mitochondrial Donation Supplementary Section to the ART Guidelines

Invitation to provide feedback on the 'Mitochondrial Donation Supplementary Section to the *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research*' by Monday 19 December 2022 at 5:00 pm (AEDT).

The Australian Health Ethics Committee (AHEC) is conducting a limited review of the *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* (the ART Guidelines) in response to the introduction of legislation to permit mitochondrial donation in Australia.

The *Mitochondrial Donation Law Reform (Maeve's Law) Act 2022* came into effect on 2 October 2022 and amended the *Research Involving Human Embryos Act 2002* (RIHE Act) and the *Prohibition of Human Cloning for Reproduction Act 2002* (PHCR Act) to facilitate the staged introduction of mitochondrial donation into Australian clinical IVF practice. To support the ethical implementation of this technology, AHEC has developed the 'Mitochondrial Donation Supplementary Section to the Ethical guidelines on the use of Assisted Reproductive Technology in clinical practice and research' (the Supplementary Section).

This survey is designed to capture feedback on the proposed Supplementary Section in a way that assists NHMRC to analyse the submissions. Please read the Supplementary Section, or have it available, as you complete the survey questions. Please note that the scope of this consultation is limited to the Supplementary Section only and feedback that is out of scope will not be considered.

As submissions cannot be saved, it may be helpful to draft your response using the offline MS Word template and then complete your submission online (PDF or word submissions will not be accepted). This will allow you to retain a copy of your submission for your records.

We thank you for your participation and look forward to receiving your comments on the Supplementary Section.

Consultation documents

The Supplementary Section and offline template are available at Ethical guidelines for Assisted Reproductive Technology.

Consultation dates

9 November 2022 to 5:00 pm AEDT Monday 19 December 2022.

Extensions

Late submissions will only be considered under exceptional circumstances. Requests for extensions must be submitted to mito.consultation@nhmrc.gov.au before the closing date.

Privacy collection notice

To ensure your answers are anonymous, you are encouraged to exclude information from your survey responses that may identify you or others. Any personal information collected via this form will be stored in Australia and used in accordance with NHMRC's obligations under the *Privacy Act 1988*, and in accordance with the NHMRC Privacy Policy.

Contact for further information

Email: mito.consultation@nhmrc.gov.au

Contact details

Providing this information assists us to get in contact with you if we need further information to understand your submission. It also helps us to understand the perspective of organisations and individuals providing each submission. Any personal information collected via this form will be stored in Australia and used in accordance with NHMRC's obligations under the Privacy Act 1988*, and in accordance with the NHMRC Privacy Policy (www.nhmrc.gov.au/privacy).*

1. Full name*	
2. Email*	
3. Contact number	
4. State*	☐ Victoria ☐ New South Wales ☐ Queensland ☐ South Australia ☐ Western Australia ☐ Tasmania ☐ Australian Capital Territory ☐ Northern Territory ☐ International
5. Does this submission reflect the views of an organisation?*	☐ Yes ☐ No
6. If yes, please provide the organisation name.	
7. Does this submission reflect the views of an individual?*	☐ Yes ☐ No
8. Please select the category that best describes the individual making this submission.*	☐ Researcher/Academic ☐ Personal experience ☐ Medical professional ☐ Human Research Ethics Committee ☐ Government/Regulator ☐ Prefer not to say
9. Would you like to receive notification when the Supplementary Section is finalised? (if yes, ensure you have provided an email address at question 2).*	☐ Yes ☐ No

* This question must be answered.

Introduction, abbreviations and key terms

The Introduction provides information about mitochondrial donation and the regulatory system to allow the technique in Australia to prevent transmission of severe mitochondrial disease. The Key Terms should be read in conjunction with the key terms in the main ART Guidelines.

10. Is the information in the introduction, abbreviations and key terms clear and accurate?*

- ☐ Yes, it is clear and accurate
- ☐ It is mostly clear and accurate (please provide comments below)
- ☐ No, the information is unclear and/or inaccurate (please provide suggestions for improvement below)
- ☐ No comment

11. Specific comments on the introduction, abbreviations or key terms (250 words or less)

Guiding Principles

The guiding principles of the ART Guidelines inform this Supplementary Section and aim to support the clinical practice of mitochondrial donation.

12. Are the guiding principles in the Supplementary Section (S4) clear and easy to understand?

- ☐ Yes, they are clear and accurate
- ☐ They are mostly clear and accurate (please provide comments below)
- ☐ No, the information is unclear (please provide suggestions for improvement below)
- ☐ No comment

13. Specific comments on the guiding principles (S4) in the Supplementary Section (250 words or less)

Information giving and counselling

Part S5 of the Supplementary Section describes the requirements for the provision of relevant information and effective counselling.

14. Is the guidance on information giving and counselling (S5) clear and easy to understand?

- ☐ Yes, it is clear
- ☐ It is mostly clear (please provide suggestions for improvement below)
- ☐ No, the information is unclear (please provide comments below)
- ☐ No comment

15. Specific comments on information giving and counselling (S5) in the Supplementary Section (250 words or less)

Consent

Part S6 of the Supplementary Section describes the processes for obtaining consent from all relevant parties.

16. Is the guidance on information consent (S6) clear and easy to understand?

- ☐ Yes, it is clear
- ☐ It is mostly clear (please provide suggestions for improvement below)
- ☐ No, the information is unclear (please provide comments below)
- ☐ No comment

17. **Specific comments on consent (S6) in the Supplementary Section (250 words or less)**

Use of donated gametes and responsibility for stored material

Part S7 of the Supplementary Section describes the considerations relating to the use of donated eggs in mitochondrial donation. Part S8 designates responsibility for the storage of stored gametes or embryos.

18. **Is the guidance on the use of donated gametes (S7) and responsibility for stored gametes and embryos (S8) clear and easy to understand?**

- ☐ Yes, it is clear
- ☐ It is mostly clear (please provide suggestions for improvement below)
- ☐ No, the information is unclear (please provide comments below)
- ☐ No comment

19. **Specific comments on the use of donated gametes (S7) and responsibility for stored gametes and embryos (S8) in the Supplementary Section (250 words or less)**

Record keeping and data reporting

Part S9 of the Supplementary Section describes the requirements for record keeping and data reporting, while protecting the privacy and confidentiality of those participating in mitochondrial donation.

20. **Is the guidance on record keeping and data recording (S9) clear and easy to understand?**

- ☐ Yes, it is clear
- ☐ It is mostly clear (please provide suggestions for improvement below)
- ☐ No, the information is unclear (please provide comments below)
- ☐ No comment

21. **Specific comments on record keeping and data recording (S9) in the Supplementary Section (250 words or less)**

Sex selection in mitochondrial donation

Part S10 of the Supplementary Section outlines the requirements of the mitochondrial donation legislation in relation to sex selection. The legislation includes a condition of licence that "a human embryo created for a woman using a licensed mitochondrial donation technique is not to be selected for implantation in that woman on the basis of the sex of the embryo" (s28Q(d) RIHE Act).

Note: *Comments on sex selection outside the context of mitochondrial donation techniques, is not within the scope of this consultation and will not be considered.*

22. **Is the guidance on sex selection in mitochondrial donation (S10) clear and easy to understand?**

- ☐ Yes, it is clear
- ☐ It is mostly clear (please provide suggestions for improvement below)
- ☐ No, the information is unclear (please provide comments below)
- ☐ No comment

23. **Specific comments on sex selection in mitochondrial donation (S10) in the Supplementary Section (250 words or less)**

Other comments and finalisation

24. **Do you have any other comments in relation to the Supplementary Section? (500 words or less)**

Consent and finalisation

NHMRC may decide to publish submissions received on the Supplementary Section. We encourage you not to include information in your survey responses that may identify you or others.

25. **Do you consent to de-identified components of your submission being made publicly available?**

- ☐ Yes
- ☐ No

26. Do you consent to the publication of your submission?

- ☐ Yes / Include name
- ☐ Yes / Anonymously
- ☐ No

You have completed the survey, thank you for your participation.

Please submit responses to NHMRC via the online survey.