Australian Government
National Health and Medical Research Council

NHMRC

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*	Matilda Haas
2. Email*	Matilda.Haas@mcri.edu.au
3. Contact number	(03) 99366453
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.	Australian Genomics
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)

As stated in the introduction, the new section (28P(4)) stipulates that ERLC may only grant a licence when it is satisfied that (a) there is **particular** risk of inheritance of mitochondria that would predispose the offspring of developing mitochondrial disease; and (b) there is **significant** risk that ensuring mitochondrial disease would be **serious**.
The qualitative nature of the terms "particular", "significant", "serious" would make it very challenging for ERLC to make decisions unambiguously, impartially, and consistently on whether a licence approval should be granted. Thus, we suggest consideration of developing more quantitative measures of risk and 'seriousness' or severity of illness, and/or development of a deliberative framework to guide the ERLC decision-making process. Alternatively, removal of these words would be preferential and would align better with the legislation. Use of the term "severe" should also be revised.

The abbreviations are accurate. In the key terms section, we query the inclusion of the definition of responsible person: "Responsible person: Each person whose reproductive material, genetic material or cell was used, or is proposed to be used, in the creation, development, production or use of the material produced as authorised by a mitochondrial donation licence". Our query relates to whether the roles and responsibilities of others who are required to obtained licenses as part of the mitochondrial donation process (e.g. the trialists) should also be included in key terms, or reference to the guidelines they must adhere to in carrying out their roles.

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)

Guiding principle 7 states: Processes and policies for determining an individual's or a couple's eligibility to access ART services must be just, **equitable, transparent** and respectful of human dignity and the natural human rights of all persons, including the right to not be unlawfully or unreasonably discriminated against.

As noted in response to question 11, to satisfy transparency and equity, more quantitative, clear and/or or structured processes to inform consideration by ERLC as to clinical risk and 'seriousness' of the licence application under consideration.

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)

The Mito Foundation has provided the feedback to this consultation that information provision and counselling should be consistent and non-alarmist. Australian Genomics supports all points raised by Mito Foundation in relation to this section of the supplement.

In addition, draft section S5.1.2 states that "detailed **written information** with respect to the risks to both themselves and any offspring, including those specific to mitochondrial disease". It is increasingly acknowledged that written material alone does not fulfil the information needs of all people. This should be expanded to included opportunities for multi-media (e.g. videos, infographics, interactive tools) alongside written information.

The statement in S5.1.2 "an appreciation of the risk of mortality, permanent disability or other serious morbidities that may result from ART procedures, and from medical complications in any resulting pregnancy, including those specific to mitochondrial disease" is alarmist and should be revised. Mito Foundation also highlighted the concerns with this statement and advised the wording should be adjusted so that it aligns with that of the ART guidelines.

The use of the term “Spouse” in S5.2.2 should be revised, potentially to “reproductive partner”. Section S5.2.5 uses “spouse or partner”, which is a better alternative.

Also, in section S5.2.2, “the impact of haplotype matching” - is “impact” the right word in this context? One might be more likely to refer to the potential impact of **not** haplotype matching. Perhaps consider using “potential implications” instead.

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)

Inclusion of the definition of proper consent in the key terms section is advised, since this term is important but may not be as familiar as informed or valid consent, and it also required some effort to find / refer to in the existing ART guidelines.

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)

S.7.3.1 uses the term **valid** consent rather than proper consent. Since it is alluded that these terms mean slightly different things there should be an effort to achieve consistency across the guidelines.

S7.3.1 "There should be voluntary exchange of information between persons born from mitochondrial donation techniques, donors and trial participants or patients, with the valid consent of all parties." Should it be noted that not providing consent to this exchange of information will not exclude persons from accessing the technique?

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)

S9.3.2 "Licence holders should make non-identified data available to appropriate bodies, to enable subsequent collation of national statistical information". Should there be an addition to this statement about the availability (or non-availability) of data on the Donor Register or trial registries for research purposes?

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)

S10. "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)."
This wording could have been clearer. Grammatically it would have been better if it read "…not to be selected on the basis of sex of the embryo for implantation in that woman…".

Other comments and finalisation

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

Australian Genomics has no further comments except to attest support to the feedback submitted by the Mito Foundation.
Australian Genomics commends Australian Government for legislating Maeve's Law and is willing to participate in any further consultations required to support the introduction of mitochondrial donation in Australia.

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.