Mitochondrial Donation Application Form

Approval to create an embryo for a woman using a mitochondrial donation technique and/or place an embryo created for a woman using a mitochondrial donation technique in the body of the woman

Background

It is a condition of all clinical trial licences that an approval must be obtained from the National Health and Medical Research Council's (NHMRC) Embryo Research Licensing Committee (ERLC) before an:

- embryo can be created for a woman using a mitochondrial donation technique, and
- embryo created for a woman using a mitochondrial donation technique can be implanted in the woman.

Before making an application a licence holder must have obtained written consent to the making of the application from the woman for whom the embryo will be created and whose body it will be implanted in. [1]

For ERLC to grant an approval it must be satisfied that:

(a) there is a particular risk of the woman's offspring inheriting mitochondria from the woman that would predispose the offspring to mitochondrial disease and

(b) there is a significant risk that the mitochondrial disease that would develop in those offspring would result in a serious illness or other serious medical condition and

(c) other available techniques that could potentially be used to minimise the risks referred to in paragraphs (a) and (b) would be inappropriate or unlikely to succeed and

(d) the woman and her spouse (if any) have attended counselling and been fully informed of:

  (i) the risks involved in using mitochondrial donation techniques; and

  (ii) alternatives to using mitochondrial donation techniques; and

(e) the woman has given written consent to the making of the application. [2]

In making that decision ERLC must have regard to the following:

(a) the clinical basis of the risk of the woman's offspring inheriting mitochondria from the woman that would predispose the offspring to mitochondrial disease

(b) the inheritance pattern in the woman's family

(c) the likely clinical manifestations of disease for the woman's offspring. [3]

Approvals granted by the ERLC come into effect on the date they are granted and will expire at the earliest of the following:

- 5 years from the date the approval is granted or
- the time a child is born alive as a result of a pregnancy achieved in the woman by the placement of an embryo under the approval. [4]

A clinical trial licence holder may apply for a further approval after the expiry of an approval.

Note that embryos created under a mitochondrial donation licence are specifically created for a trial participant. In the event that an embryo created for a woman under a mitochondrial donation licence becomes excess to the woman's reproductive needs, it may be used under a mitochondrial donation licence for research and training, however, it cannot be donated to another woman for use in reproductive treatment.

1 *Research Involving Human Embryos Act 2002* section 28P(4)(e).
2 *Research Involving Human Embryos Act 2002* section 28P(4).
3 *Research Involving Human Embryos Act 2002* section 28P(5).
4 *Research Involving Human Embryos Act 2002* section 28P(8).

Contact Details

For further information or queries relating to this Licence Application Form contact Embryo Research Licensing:

Email: **embryo.research@nhmrc.gov.au**

GPO Box 1421,
CANBERRA ACT 2601

Tel: 1300 064 672 in Australia
+61 2 6217 9000 for international callers.

Important Note

- You are advised to familiarise yourself with the requirements of the *Research Involving Human Embryos Act 2002* and the *Prohibition of Human Cloning for Reproduction Act 2002*.
- You are also advised to consider any relevant State or Territory legislation and, if necessary, seek independent legal advice.
- If additional information is provided as part of the application please include the names of any files that are provided as attachments to the application form.
- When completed and signed by all relevant parties the form should be saved as a PDF file and submitted by email to Embryo Research Licensing at **embryo.research@nhmrc.gov.au**

Annexure 1
Application form

BUILDING
A HEALTHY
AUSTRALIA

Clinical trial licence holder application for approval to create an embryo for a woman using a mitochondrial donation technique and/or to place an embryo created for a woman using a mitochondrial donation technique in the body of the woman.

ALL SECTIONS OF THIS FORM MUST BE COMPLETED

Section 1 – Licence details

1	**Licence number to which this application relates:**
2	**Licence Holder Organisation:**
3	**Licence Holder Contact Person:**
4	**Name and contact details of person making this application:**
	Contact Name:
	Postal Address:
	Contact number(s):
	Email address:
5	**I have been given a copy of the *Mitochondrial Donation Licensing Scheme – Privacy and the protection of your personal* information notice.**
	Yes ☐ No ☐

Section 2 – Type of approval

6	**Type of approval**
	Tick the approval type(s) being applied for.
☐	(a) creation of an embryo for a woman using a mitochondrial donation technique
☐	(b) placement of an embryo created for a woman using a mitochondrial donation technique in the body of the woman the embryo was created for
☐	(c) both (a) and (b).

Section 3 – Trial participant information

This application must <u>not</u> include the name of a trial participant or any information that could be used to discover the identity of the trial participant.[5]

RISKS TO OFFSPRING:
Provide details of the following:

7. The clinical basis of the risk of the woman's offspring inheriting mitochondria from the woman that would predispose the offspring to mitochondrial disease.

Please attach reports from appropriate specialists supporting the claims for the offspring for the woman. Please ensure all personal details of the woman have been redacted from any reports that are provided.

8. The inheritance pattern of mitochondrial disease in the woman's family (including any relevant genomic sequencing that has been undertaken).

9. The likely clinical manifestations of mitochondrial disease for the woman's offspring. [6]

5 *Research Involving Human Embryos Act 2002* section 28P(7).
6 Note that this should address information and evidence to demonstrate that there is a significant risk that the mitochondrial disease that would develop in the woman's offspring would result in a serious illness or other serious medical condition (s28P(4)(b))

ALTERNATIVE RISK MITIGATION OPTIONS

10. **Provide details of other available techniques that have been considered and/or used to mitigate risks of the woman's offspring being predisposed to mitochondrial disease and why any available techniques that have not been used would be inappropriate or unlikely to succeed.**

PRE- TREATMENT COUNSELLING

11. **Provide a report [7] of the pre-treatment counselling undertaken by the trial participant that confirms she (and her spouse if any) has attended counselling and is fully informed of the risks involved in using the licensed mitochondrial donation technique and the alternatives to using the licensed mitochondrial donation technique.**

Provide attachments if necessary and note the attachment numbers in this box.

12. **The woman and her spouse (if any) have been informed that embryos cannot be selected for implantation on the basis of sex. [8]**

NUMBER OF EMBRYOS TO BE CREATED

13. **Proposed number of embryos to be created for the woman and an explanation of why the number proposed is necessary.[9]**

7 A mitochondrial donation licence holder should ensure that pre-treatment counselling is provided by counsellors with full ANZICA membership in order to ensure ART procedures using MDT are conducted in a way that is respectful of all involved. Clinical decisions must respect, primarily, the interests and welfare of the persons who may be born, as well as the long term health and psychological welfare of all participants including gamete donors'. Note that pre-treatment counselling and the preparation of this report may require input from a multi-disciplinary team with expertise in genetics, gamete donation in ART, and disease specialists.

8 *Research Involving Human Embryos Act 2002* section 28Q(1)(d).

9 Please note that ERLC had regard to restricting the number of excess ART embryos, other embryos, or human eggs or zygotes that were likely to be necessary to achieve the goals of the activity proposed in the licence application. If the number of eggs proposed to be used create the embryos to which this approval relates exceeds the number of eggs detailed in the licence please contact NHMRC for advice **embryo.research@nhmrc.gov.au**

Section 4 – Certification and signing

14	**I certify that the trial participant/patient to whom this application relates has given consent to the licence holder to make this application.**

Yes ☐ No ☐

15	**I am authorised to make this application on behalf of the woman to whom it relates for the licence holder.**

Yes ☐ No ☐

16	**I certify that relevant protocols[10] required for the approval of the clinical trial licence have been applied to the woman to whom this application relates.**

Yes ☐ No ☐

I declare that to the best of my knowledge, having made reasonable inquiries, the information provided in this application is true and correct and not misleading.

I understand that providing misleading information to the NHMRC is an offence under Commonwealth Law.

Signature

Printed Name

Date

10 This includes informing the woman (and her partner, if any) about the risks of mitochondrial donation (28J(5)(g)(ii)), obtaining donor consent and ensuring the woman understands the operation of the register (28J(5)(f)).