Notification of Adverse Events Form for Clinical Trial Licences

A person who is or was the holder of a clinical trial licence must have in place, and comply with, protocols for:

- monitoring the pregnancy of trial participants who achieve pregnancy using a mitochondrial donation technique under the licence and any childbirths resulting from such pregnancies; and
- monitoring the ongoing health and development of children born as a result of such pregnancies; and
- notifying adverse events, for those participants or children, that the person becomes aware of as a result of monitoring.[1]

Where a person **becomes aware of** an adverse event for a trial participant or a child born as a result of a person's participation in a clinical trial, the person must notify the National Health and Medical Research Council's (NHMRC) Embryo Research Licensing Committee (**ERLC**) and the Secretary of the Department of Health (**Secretary**).

Notification of adverse events is essential for understanding and improving the safety and effectiveness of mitochondrial donation techniques. Information received from adverse event notifications will help to inform both development of the mitochondrial techniques and administration of the mitochondrial donation licensing scheme.

All notifications must be made using the attached form.

An **adverse event for a trial participant** is any of the following in connection with a pregnancy achieved in the trial participant as a result of using a mitochondrial donation technique:

(i) a failed embryo development (implantation failure)

(ii) a miscarriage

(iii) a premature birth of a child

(iv) the birth of a child with a birth defect, a genetic abnormality [2] or a diagnosis at birth of mitochondrial disease.[3]

An **adverse event for a child born of a trial participant**, as a result of using a mitochondrial donation technique, is a diagnosis at any time of mitochondrial disease.

The obligation to notify arises once a person who is or was the holder of a clinical trial licence becomes aware of the adverse event. In some cases, the ERLC recognises that it will not be possible to provide all information requested in the form as the circumstances surrounding the event may still be under investigation. In such cases, the ERLC expects licence holders to submit an incomplete form and provide further information as soon as it becomes available.

Contact Details

For further information or queries relating to this 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

Use one form to report adverse incidents in relation to a mother and child.

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

1 *Research Involving Human Embryos Act 2002* (Cth) section 28S.
2 This includes epigenetic modifications that may have resulted in adverse birth outcomes.
3 *Research Involving Human Embryos Regulations 2017* (Cth) regulation 7M.

Important Note

Information provided in this form must not include the name, or any other information that could be used to discover the identity of the trial participant or a child of the trial participant.

Section 1 – Licence details

1	**Licence number to which this notification relates:**

2	**Approval number to which this notification relates:**[4]

3	**Details of licence holder:**
	Organisation Name:
	Name:
	Address:
	Mobile:
	Email:
4	**Details of person making notification:**
	Name:
	Address:
	Mobile:
	Email:

4 This refers to the approval number allocated by ERLC in relation to the Section 28P application for *Approval to create an embryo for a woman using a mitochondrial donation technique or place an embryo created for a woman using a mitochondrial donation technique in the body of the woman.*

Section 2 – Person affected

Please tick and provide details:

☐ **TRIAL PARTICIPANT (DETAILS OF INCIDENT):**

☐ **Failed embryo development (cause(s) if known, number of previous failed embryo developments and any known recurrent implantation failure risk factors):**

☐ **Miscarriage (cause(s) if known, number of previous miscarriages and any known recurrent miscarriage risk factors):**

☐ **Premature birth of a child (including how many weeks gestation and any known risk factors):**

☐ **Birth of a child with a birth defect, a genetic abnormality[5] or a diagnosis at birth of mitochondrial disease. Outline the nature of the defect/abnormality/diagnosis and preliminary findings as to probable cause(s), pregnancy screening tests undertaken and findings of tests and any other maternal risk factors that may have contributed:**

5 This includes epigenetic modifications that may have resulted in adverse birth outcomes.

1	Is this the first adverse incident notification in relation to this affected person? If no, please list any earlier notification receipt number(s) issued by ERLC:

2	Outline the mitochondrial donation technique used:

3	Provide the number of embryos created for the affected person:

4	Provide the number of embryo placements that the affected person has undergone:

5	Outline the number of live births the affected person has achieved:

CHILD OF TRIAL PARTICIPANT

1. Outline the mitochondrial donation technique used:

2. Has an adverse incident notification in relation to the child's mother previously been made? If yes please list any earlier notification receipt number(s) issued by ERLC.

3. Details of the mitochondrial disease diagnosis:

4. Likely cause(s) of the disease:

Section 3 – Details of the adverse event

1	Date and time the adverse event occurred or became known:
2	Location of the event:
3	Summary of the adverse event:
4	Outline any action(s) taken in response to the adverse event and any proposed future action(s):
5	Outcome of the event (details of injury/illness to the affected person(s) and prognosis of child born):
6	Treating clinician details:

Name:

Address:

Mobile:

Email:

Section 4 – Declaration and signing

I have read and understood the *Mitochondrial Donation Licensing Scheme – Privacy and the protection of your personal information* (the *Privacy Notice*).

I have given a copy of the *Privacy Notice* to each person whose personal information is included in this form.

I have confirmed that no information is provided in this form that could be used to discover the identity of the trial participant or a child of the trial participant.

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

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

Signature

Date

Printed name