Research Involving Human Embryos Act 2002
Standard licence conditions for mitochondrial donation licences

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Introduction

The *Research Involving Human Embryos Act 2002* (RIHE Act) sets out a number of conditions to which all mitochondrial donation licences are subject to. If the National Health and Medical Research Council's (NHMRC) Embryo Research Licensing Committee (ERLC) decides to issue a licence, the licence holder will be provided with the licence instrument which includes all the conditions that licence is subject to. A copy of the licence instrument will also be provided to the relevant Human Research Ethics Committee (HREC) and relevant State body.[1]

Licence conditions relate to:

Section 28N – Conditions applying to mitochondrial donation licences generally:

- before any of the activities that are authorised by the licence are carried out each responsible person in relation to the genetic material used under the licence has given proper consent to its use and the licence holder has reported such consent and any restrictions it may be subject to, in a de-identified way, to the Embryo Research Licensing Committee; and
- the carrying out of any activities authorised by the licence must be in accordance with any restrictions to which the proper consent to use genetic material is subject to.

Section 28P – Clinical trial licences are subject to the condition that the licence holder must obtain approval from ERLC before the creation and placement of an embryo using the mitochondrial donation technique to which the licence relates.

Section 28Q – Further specific conditions clinical trial licences are subject to:

- that the technique specified in the licence only be used under the licence by the embryologist(s) nominated in the licence;
- that embryologist(s) use of the technique is in accordance with the protocols the licence holder has in place for using the technique safely and effectively in a clinical trial for the purpose of minimising the risk of women's offspring inheriting mitochondria that would predispose them to mitochondrial disease;
- that the embryologist(s) remain technically competent to use the technique; and
- that a human embryo created for a woman using the technique is not selected for implantation in that woman on the basis of the sex of the embryo.

[1] *Research Involving Human Embryos Act 2002* section 28K

In addition to the conditions set out in the RIHE Act, ERLC may impose such other conditions on mitochondrial donation licences as ERLC considers appropriate. Such conditions may include, but are not limited to, conditions relating to the following matters:

- embryologists and other persons authorised by the licence to carry out activities that are authorised by the licence;
- the number of human eggs authorised to be used under the licence, or the number of embryos or zygotes authorised to be created or used under the licence;
- reporting;
- monitoring;
- information to be given by the licence holder to embryologists and other persons authorised by the licence to carry out activities that are authorised by the licence; and
- disposing of material produced by using the relevant mitochondrial donation technique as authorised by the licence.

Standard Licence Conditions

ERLC has determined that the following standard conditions will be applied to all mitochondrial donation licences unless individual circumstances require otherwise.

Licence holder contact details

1 The licence holder must give written notice to the Embryo Research Licensing Committee no later than 7 days before a proposed change in their organisation's or their primary contact person's telephone number, email address or postal address.

Persons authorised to participate in the licensed activities

2 The licence holder must ensure that each person who is authorised to participate in the licensed activity is at all times fully informed of the requirements of the licence (including the conditions it is subject to), the *Research Involving Human Embryos Act 2002*, the *Prohibition of Human Cloning for Reproduction Act 2002* and any corresponding State law.

3 The licence holder must not permit a person to participate in the licensed activity unless the person is authorised to do so under the licence.

4 The licence holder must give written notice to the Embryo Research Licensing Committee no later than 7 days after a person who is identified in the licence conditions as the Principal Supervisor:

(a) ceases to be involved in the licensed activity; or

(b) is, for any reason, temporarily unable to perform the duties of the Principal Supervisor.

5 The licence holder must give written notice to the Embryo Research Licensing Committee no later than 7 days after a person who is identified in the licence conditions as the Principal Investigator:

(a) ceases to be involved in the licensed activity; or

(b) is, for any reason, temporarily unable to perform the duties of the Principal Investigator.

6 The licence holder must give written notice to the Embryo Research Licensing Committee no later than 7 days after the person whois identified in the licence as a Nominated Embryologist:

(a) ceases to be involved in the licensed activity; or

(b) is, for any reason, temporarily unable to perform the duties of the Nominated Embryologist.

7 If the licence holder is required to provide written notice under conditions 4, 5 or 6, all licensed activities must cease from the date the Principal Supervisor, Principal Investigator or Nominated Embryologist ceases to be involved in the licensed activity until either:

(a) the Embryo Research Licensing Committee has approved the licence holder's application for a person to be identified in the licence conditions as the new Principal Supervisor, Principal Investigator or Nominated Embryologist; or

(b) if there is more than one nominated embryologist that has been approved by the licence and the licence holder does not propose to nominate a new embryologist the Embryo Research Licensing Committee has approved the continuation of the licensed activities without a further embryologist being approved.

Specified sites

8 If the licence holder proposes to change the location of sites specified in the licence where the licensed activities are authorised to be carried out the licence holder must apply to the Embryo Research Licensing Committee for approval not less than 28 days before the date that the licence holder proposes to change the location of the licensed activities.

9 The licence holder must give written notice to the Embryo Research Licensing Committee as soon as practicable, and in any event not longer than 72 hours after a change in the accreditation status of sites specified in the licence, [2] where such change may impact on the suitability of the sites, where the licensed activities are authorised to be carried out.

[2] Change in accreditation status refers to any restrictions, conditions, variations imposed by an accreditation body or revocation of accreditation that adversely affects the suitability of facilities, equipment or processes for using the licensed technique at a specified premises.

Proper Consent

10 For the purposes of complying with section 28N(1) of the *Research Involving Human Embryos Act 2002*, the licence holder must report to the Embryo Research Licensing Committee that 'proper consent' has been obtained from each responsible person in relation to the human egg or human sperm to be used under the licence using:

(a) the 'Consent notification spreadsheet' as published and amended from time to time on the NHMRC website: www.nhmrc.gov.au; or

(b) an alternative format which has previously been approved in writing by the Chair of the Embryo Research Licensing Committee.[3]

Notification must be provided prior to the authorised activity being conducted. [4]
'Proper consent' in relation to the use of a human egg or sperm under a mitochondrial donation licence refers to the requirements set out in Part D of the NHMRC *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research*.

11 The licence holder must ensure that only the consent protocols (including the participant information and consent forms), as approved by the Embryo Research Licensing Committee are used for obtaining proper consent under the licence.

12 The licence holder must ensure that the use of a human egg or a human sperm is in accordance with any restrictions to which proper consent has been obtained in accordance with condition 10.[5]

13 In addition to the requirements for obtaining proper consent the licence holder must ensure that any legal requirements required by relevant State and Territory Assisted Reproductive Treatment laws for consent, counselling and donation of gametes are complied with.

Reporting

14 Any report to the Embryo Research Licensing Committee, required by these conditions, must not include identifiable information about a responsible person.[6]

15 During the currency of the licence, the licence holder must submit a written report to the Embryo Research Licensing Committee no later than 30 days after the end of each reporting period. The reporting periods are 1 March to 31 August and 1 September to 28 February (or 29 February in leap years).
Each report must be submitted:

(a) in the format specified in the document 'Six monthly report on licensed activities' and the cumulative details of authorised use in the spreadsheet 'Authorised use spreadsheet' as published and amended from time to time on the NHMRC website: www.nhmrc.gov.au; or

[3] A report to Embryo Research Licensing Committee notifying of proper consent must not include the name, or any other information that could be used to discover the identity, of a responsible person.

[4] This is a mandatory condition: see section 28N(1).

[5] This is a mandatory condition: see section 28N(3).

[6] This is a mandatory condition: see section 28N(2).

(b) in an alternative format which has previously been approved in writing by the Chair of the Embryo Research Licensing Committee.

16 Prior to the expiry or surrender of the licence, the licence holder must also submit to the Embryo Research Licensing Committee a written report in:

(a) the format specified in the document 'Final report on licensed activities' and the cumulative details of authorised use in the spreadsheet 'Authorised use spreadsheet' as published and amended from time to time on the NHMRC website: http://www. nhmrc.gov.au; or

(b) in an alternative format which has previously been approved in writing by the Chair of the Embryo Research Licensing Committee.

17 If the licence holder becomes aware of, or suspects that there may have been a non compliance with a licence condition, the *Research Involving Human Embryos Act 2002*, the *Prohibition of Human Cloning for Reproduction Act 2002*, or any corresponding State law, the licence holder must:

(a) immediately and by notice in writing, notify the Embryo Research Licensing Committee of the breach or suspected breach; and

(b) as soon as reasonably practicable provide any documents or information requested by the Embryo Research Licensing Committee; and

(c) within 7 days after providing a notification under condition 17(a) the licence holder must provide a written report to the Embryo Research Licensing Committee that details:

i. the activity or conduct that the licence holder knows or suspects may constitute a non-compliance;

ii. the names of the persons who participated in or who may be able to provide information about the activity or conduct and their role in the organisation;

iii. the period during which this activity or conduct took place;

iv. the site at which the activity or conduct took place or is suspected to have taken place; and

v. the circumstances that led to the activity or conduct that the licence holder knows or suspects may constitute a non-compliance.

18 The licence holder must immediately, by notice in writing, inform the Embryo Research Licensing Committee of any investigation or prosecution by a Commonwealth, State or Territory agency that involves any matters that might reasonably be considered to affect the suitability of the licence holder to undertake the activity authorised by the licence.

Monitoring

19 The licence holder must implement and maintain processes that ensure that adequate records are made and stored to allow the conduct of the licensed activity to be monitored for compliance with the requirements of the licence, the *Research Involving Human Embryos Act 2002*, *the Prohibition of Human Cloning for Reproduction Act 2002* and any corresponding State law.

20 The licence holder must not unreasonably refuse to provide any information relating to the conduct or the licensed activity or the suitability of the licence holder to conduct the licensed activity requested by the Embryo Research Licensing Committee. The information must be in the form, if any, specified in the request.

21 The licence holder must provide reasonable assistance and cooperation to the Embryo Research Licensing Committee and its Inspectors in carrying out their powers, functions and duties under the *Research Involving Human Embryos Act 2002*, the *Prohibition of Human Cloning for Reproduction Act 2002*, and any corresponding State law.

Use of materials created, developed or produced under a mitochondrial donation licence

22 The licence holder must maintain a tracking system that uniquely identifies each human egg used or embryo created or used in connection with the licence. The tracking system must:

(a) link the unique identifier for each individual embryo or egg to a specific licence and each 'responsible person';
(b) record an outcome for each individual human egg or human sperm used or embryo created or used in the licensed activity, linking the outcome to the unique identifier for that embryo or egg.

23 Prior to the expiry or surrender of the licence, the licence holder must review the consent forms relating to any embryos, eggs or sperm still held in storage by the licence holder and must deal with those embryos, eggs or sperm in accordance with the instructions, if any, given by the responsible persons when proper consent was obtained. If the consent forms do not contain the relevant instructions, the licence holder must:

(a) take all reasonable steps to inform the responsible persons who provided the proper consent that their embryos, eggs or sperm have not been used under the licence; and
(b) inform the responsible persons that the options in respect of those embryos or eggs are to allow them to succumb or, if applicable, to consider giving consent to donating them to another project; and
(c) deal with the embryos, eggs or sperm in accordance with the instructions obtained from the responsible persons.

24 Subject to any limit(s) imposed in the licence the licence holder must not create or use any more embryos, zygotes or eggs than is necessary to achieve the goals or the project proposed in the licence application.

25 The licence holder must ensure that where appropriate material created under the licence is disposed of in accordance with the terms of the proper consent provided by the responsible person.

Human Research Ethics Committee (HREC) approval during the period of the licence

26 If the HREC that assessed the project ceases responsibility for ethical oversight of the project, the licence holder must notify the Embryo Research Licensing Committee within 5 working days. The licence holder must provide information on the reasons for the change in HREC and written confirmation from the Chair of the new HREC that they will be responsible for the ethical oversight of the project.

27 If the HREC that has ethical oversight of the project withdraws or suspends approval for the project, the licence holder must immediately suspend all licensed activities. The licence holder must inform the Embryo Research Licensing Committee of the withdrawal or suspension of HREC approval as soon as practicable and within not more than 2 working days. Licensed activities may not recommence until the Embryo Research Licensing Committee has granted approval for this to occur.

Storage of information

28 The licence holder represents and warrants that it will ensure that there are security policy and procedures in place to:

(a) prevent unauthorised access to all locations at which any part of the licensed activity is conducted;

(b) protect all information technology hardware and software associated with licensed activities, including but not limited to:

i. Encryption of data at rest and in transit
ii. Access Controls that prevent unauthorised access by both internal and external actors
iii. Authentication (preferably multi-factor authentication) is conducted for all attempts to access the data
iv. All accounts that access the data are approved by an appropriate authority within the organisation, the approval is recorded and reviewed at least annually
v. Security patching of the system holding the data is maintained to prevent the exploitation of system vulnerabilities
vi. System hardening of the platform is in accordance with industry best practice
vii. Conduct regular backups to ensure recovery from disaster; and

(c) prevent unauthorised access to documents and data (including patient/consent information, research information and experiment details) pertaining to licensed activities.

29 Where cloud storage is used by the licence holder to receive, create, access or hold information in connection with any activities authorised by this licence, the licence holder:

(a) must ensure that all information is able to be accessed from the licensed premises for the purposes of monitoring compliance; and
(b) should use an Australian based, Infosec Registered Assessors Program (IRAP) assessed cloud service provider where possible. If an Australian based cloud provider is not practical, the cloud service provider must meet an accredited international IT security standard such as American National Institute of Standards and Technology's "Cybersecurity Framework" (NIST CSF) or ISO 27001.

30 In relation to any personal information the licence holder receives, creates, accesses or holds in connection with any activities authorised by this licence, the licence holder must take all reasonable steps to protect the security of that personal information by:

(a) dealing with it in accordance with the requirements of the *Privacy Act 1988* (Cth);
(b) regularly assessing the risk of misuse, interference, loss, and unauthorised access, modification or disclosure of that information and documenting the assessment and any actions taken as a result of the assessment;
(c) taking appropriate measures to address those risks;
(d) conducting regular reviews to assess whether it has adequately complied with or implemented these measures; and
(e) immediately notifying the person to whom that personal information relates if the licence holder becomes aware of an actual or possible breach of this condition.

Special conditions for clinical trial licences

31 The licence holder must apply for and be granted approval by the Embryo Research Licensing Committee before the creation of, and placement of an embryo, using the mitochondrial donation technique to which the licence relates, in a particular woman for reproductive purposes.[7]
An application may be made by the licence holder using the form available at www.nhmrc.gov.au

32 An approval referred to in condition 29 in relation to a particular woman must be current at the time of the creation and the placement of an embryo into that woman.

33 The licence holder must provide the nominated embryologist(s) with a copy of any Embryo Research Licensing Committee current approval for the creation and/or placement of an embryo created under a mitochondrial donation clinical trial licence in a particular woman.

34 A nominated embryologist must not create an embryo for a particular woman under the licence unless they have been given a copy of a current approval for the women concerned.

[7] This is a mandatory condition under 28P(1).

35 A person must not place an embryo created under the licence in the body of a woman unless they have been given a copy of a current approval for the woman concerned.

36 The licence holder and embryologist(s) specified in the licence must ensure that embryos are not selected for implantation on the basis of the sex of the embryo.

37 The licence holder must ensure that:[8]

(a) the mitochondrial donation technique permitted by the licence is only undertaken by a nominated embryologist that is specified in the licence;

(b) the embryologist's use of the technique is in accordance with the protocols established for the licence to ensure the use of the technique safely and effectively in a clinical trial for the purposes of minimising the risk of the women's offspring inheriting mitochondria that would predispose them to mitochondrial disease; and

(c) all nominated embryologists specified in the licence remain technically competent to use the technique for the duration of the licence.

38 The nominated embryologist(s) specified in the licence who is authorised to use the mitochondrial donation technique to which the licence relates must:

(a) Ensure their use of the technique is in accordance with the protocols established for the licence; and

(b) They remain technically competent to use the technique for the duration of the licence.[9]

39 In addition to conditions 10-12 the proper consent obtained from participants under a clinical trial licence must address consent for the licence holder to collect the following information about a child born as part of the licensed activities:

(a) the child's full name;

(b) the child's sex;

(c) the child's date of birth.

Participant/patient counselling

40 A licence holder must ensure that pre- treatment counselling is provided by counsellors with full ANZICA membership in order to ensure Assisted Reproductive Technology procedures using mitochondrial donation techniques are conducted in a way that is respectful of all involved.

41 Where approval for creation or placement of an embryo is being sought by the licence holder it is a condition of the licence that in making an application the licence holder include a report setting out the required pre-treatment counselling provided to trial participants and responsible persons.

[8] This is a mandatory condition: see section 28Q(1)(a)-(c).

[9] This is a mandatory condition: see section 28Q(1)(b) and (d).

Selection of embryos

42 A licence holder must ensure that embryos selected for implantation in a woman following the use of a mitochondrial donation technique are not selected on the basis of the sex of the embryo.

Record Keeping

43 The licence holder must ensure that it is complying with the requirements of section 28R of the *Research Involving Human Embryos Act 2002* and in addition to the requirement in conditions 14-15 the licence holder must include in the periodic reports to NHMRC an attestation that:

(a) the licence holder has satisfied its record keeping obligations arising under either:

i. the *Research Involving Human Embryos Act 2002*

ii. the *Research Involving Human Embryos Regulations 2017*; and

iii. any conditions to the licence.

(b) The protocols in place for ensuring that the relevant records have been kept are being complied with or details of any changes to protocols since the last reporting period.

44 The licence holder must have a data collection, retention and disposal schedule to ensure that the information required by s28R[10] is collected and retained for a period of 25 years from the date of creation of such records.

45 If the licence holder ceases to be a viable entity during the 25 year record retention period or becomes aware that it will soon cease to become a viable entity, or for any other reason is unable to retain the information required by s28R, the licence holder must inform the relevant HREC and the Embryo Research Licensing Committee; and ensure all relevant records that fall within the retention period are transferred to another suitable entity. This may only occur with the agreement of both the relevant HREC and the Embryo Research Licensing Committee.

46 In addition to the requirement in conditions 14-15 the licence holder must include in the periodic reports to the NHMRC ERLC the following information:

(a) Number of:

i. trial participants who achieve pregnancy using the licensed technique;

ii. live births resulting from such pregnancies;

iii. adverse events for trial participants or children reported to NHMRC;

arising in the preceding period.

(b) any analysis of trends/issues arising from the above data regarding efficacy of the licensed technique

[10] Section 28R requires a clinical trial licence holder and clinical practice licence holders to collect and use their best endeavours to collect certain information about donors, and children born as a result of the use of mitochondrial donation techniques.