Research Involving Human Embryos Act 2002
Mitochondrial Donation
Pre-clinical research and training licence

Version 2, 20 November 2026

This licence is issued under s.28J of the *Research Involving Human Embryos Act 2002*. This licence authorises the activity specified below, subject to the conditions specified in the *Standard Conditions of licence* and *Special Conditions for Licence MD001*.

Licence Number:	MD001
Licence Holder:	Monash University
Licence Title:	Pre-Clinical Research and Training Licence: mitoHOPE: Improving mitochondrial donation technologies (MST)
Date of Issue:	17 October 2025
Licence begins:	17 October 2025
Licence ends:	31 May 2029
Activity authorised by the licence:	This licence authorises the creation of human embryos through the use of the permitted mitochondrial donation technique, maternal spindle transfer (MST), and the characterisation of those embryos. This licence authorises the licence holder to undertake the following activities, as described in this licence instrument, the licence application and Study Protocol version 16 (as approved by the relevant Human Research Ethics Committee on 3 September 2026 and submitted to ERLC on 4 November): 1. creation of human embryos that contain genetic material provided by more than 2 persons, using MST: a. by fertilisation of a human egg by a human sperm outside the body of a woman or b. other than by the fertilisation of a human egg by a human sperm

and use[1] of embryos created

2. creation of human embryos by a process of the fertilisation of a human egg by a human sperm outside the body of a woman using the MST technique and use of the embryos
3. research and training involving the fertilisation of a human egg by a human sperm up to, including and after the first mitotic division, outside the body of a woman for the purposes of research or training in the use of the MST technique
4. use of 'any material'[2] (other than an excess ART embryo) created, developed or produced under a mitochondrial donation licence.

Goals of the Activity:	The goals of the licensed activity are to develop expertise in mitochondrial donation using maternal spindle transfer (MST), including to: · Develop clinical embryology expertise in optimised MST procedures in readiness for assessment of proficiency under a potential future Clinical Trial Research and Training licence. · Develop modifications to the enucleation and fusion procedures to increase the yield of viable embryos created using MST. · Investigate genetic drivers of mitochondrial genome reversion to inform clinical policies on matching egg donors with women undergoing MST treatment.

[1] For the purpose of this licence, "use" in relation to donated gametes, embryos, zygotes or any material includes, but is not limited to:

- collection of gametes specifically for this activity including related fertility treatments; or
- performing *in vitro* maturation of gametes; or
- removal of any material from storage; or
- transport of any material; or
- observation of any material (including taking a photograph or taking a recording from which a visual image can be produced); or
- destroying or discarding any material; or
- any other activity that results in development of any material.

[2] For the purposes of this licence 'any material' (RIHE Act 28C (2)(e)) includes, but may not be limited to, the following:

- ES cell lines
- zygotes
- enucleated gametes
- cytoplasts
- karyoplasts
- blastocysts
- genetic (or other -omic) samples generated from donated gametes, embryos, ES cell lines or other cellular components.

Note: The activity authorised under this licence is subject to the provisions of *the Research Involving Human Embryos Act 2002* and the *Prohibition of Human Cloning for Reproduction Act 2002*. Terms used in this licence which are defined in those Acts carry the same meanings as they do in those Acts.

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.[3]

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.

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.

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

Standard Licence Conditions – Pre-clinical research and training licences

Version 3, 29 April 2025

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 who is 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[4], where such change may impact on the suitability of the sites, where the licensed activities are authorised to be carried out.

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.[5]

    Notification must be provided prior to the authorised activity being conducted. [6]

[4] 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.

[5] 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.

[6] This is a mandatory condition: see section 28N(1). '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.[7]

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.[8]

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

    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:

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

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

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 17a 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, or sperm straw used or embryo created or used in connection with the licence. The tracking system must:

a. link the unique identifier for each human egg, sperm straw or embryo to a specific licence and each 'responsible person';

b. record an outcome for each human egg or human sperm straw used or embryo created or used in the licensed activity, linking the outcome to the unique identifier for that egg or sperm straw or embryo.

23. Prior to the expiry or surrender of the licence, the licence holder must review the consent forms relating to any eggs, sperm straws or embryos still held in storage under the licence and must deal with those embryos, eggs or sperm in accordance with the instructions given by the responsible persons when proper consent was obtained.

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.

Research Involving Human Embryos Act 2002
Special Conditions for Licence MD001

Licence Number:	MD001
Licence Holder:	Monash University
Licence Title:	Pre-Clinical Research and Training Licence: mitoHOPE: Improving mitochondrial donation technologies (MST).

The conditions that are specified below are the special conditions that apply to this licence. The *Special Conditions* operate **in addition to** conditions set out in s.28N of the *Research Involving Human Embryos Act 2002* (the statutory conditions) and all conditions identified in the *Standard Conditions of Licence*. The *Special Conditions* prevail where there is an inconsistency between a special condition and a standard condition.

Conditions relating to Specified Sites

31. The licence holder must only conduct the activity authorised by the licence at the following sites:

- **a. Monash University**
  - i. Monash Biomedicine Discovery Institute (Ground Floor, Building 16, 11 Chancellors Walk, Monash University, Clayton VIC 3800). Use of donated material and 'any material' authorised by the licence may occur at this location.
- **b. Monash IVF**
  - i. Monash Surgical Private Hospital (252/256 Clayton Rd, Clayton VIC 3168). Participant recruitment activities may be undertaken here but no records must be stored at this location.
  - ii. Cremorne (Level 1/510 Church Street, Cremorne VIC 3121). Any activity authorised by the licence can undertaken at this location.
    1. Gametes donated specifically for the research to be conducted under this licence must only be collected at this site. This site must remain accredited by the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia for the duration of the licence (see Standard Licence Condition 9).
  - iii. Monash IVF Genetics (180 Fullarton Road, Dulwich SA 5065). Genetic analysis of material authorised by this licence and storge of genetic samples for analysis is allowed here.
- **c. Murdoch Children's Research Institute and the Victorian Clinical Genetics Service**
  - i. MCRI and VCGS at the Royal Children's Hospital (50 Flemington Rd, Parkville VIC 3052). Genetic analysis of material authorised by this licence and storge of genetic samples for analysis is allowed here.

32. The licence holder must hold records (other than donor/patient records) associated with the activity authorised by the licence at the following sites:

- **a. Monash University**
  - i. A restricted access secure database may be used to store research information.

The databases must be stored on the Monash University servers. Access must be restricted to research team members authorised by the Principal Supervisor. The REDCap database may also be used to store and analyse genetic data generated at Murdoch Children's Research Institute and the Monash IVF Genetics service.

1. A REDCap database (the 'mitoHOPE Research and Training Database').

ii. Non-identifying hardcopy laboratory sheets can be written, used and stored within the limited access laboratory at:

1. Monash Biomedicine Discovery Institute, Ground Floor, Building 16
11 Chancellors Walk Monash University
Clayton VIC 3800

b. Murdoch Children's Research Institute and the Victorian Clinical Genetics Service

i. Electronic records of non-identifying genome sequencing data can be stored on restricted electronic Drives secured by MCRI or VCGS Servers.

c. Monash IVF Group

i. A secure, restricted access secure databases maybe used to store information relevant to the research.

1. The Monash IVF Genetics Secured Server may be used to store genome sequencing data files generated by Monash IVF Genetics (Dulwich, South Australia).

If virtual laboratory notebooks are used by team members at any of the above locations they must been stored on the relevant server and must not be saved to unique computer hard drives.

33. The licence holder must hold donor (patient) records associated with the donation of gametes in a secure facility at the following sites:

d. Monash University

i. A secure database to store participant Expressions of Interest. Database access limited to the Donor Coordinator and the Research Compliance Officer (if needed for compliance matters).

e. Monash IVF Group

ii. The Monash IVF Patient Management System (RIMS) may be used to store electronic records of gamete donors.

iii. Hardcopy participant information and consent forms may only be stored in a locked box accessed by the Donor Coordinator at:
Level 1/510 Church Street
Cremorne VIC 3121.

34. The licence holder must ensure that people authorised to access research data do not download research data to personal computers, other networks or external storage devices.

35. The use of embryos created in accordance with this licence, and 'any material' created, developed or produced, is only to occur at the site(s) listed in Special Condition 31. Embryos or 'any material' must not be transferred from this site(s) to any other location.

36. When transferring any material created, developed or produced under the licence the

Licence Holder must be aware of, and act in compliance with, any relevant legislation that regulates the transfer or export of such material.

37. If a Research Governance Team with responsibility for a site specific assessment (SSA) approves a SSA the licence holder must inform the Embryo Research Licensing Committee of the approval in writing before any activities authorised under the licence can occur at the location.

38. If a Research Governance Team with responsibility for a SSA suspends or withdraws a SSA the licence holder must inform the Embryo Research Licensing Committee of the suspension or withdrawal as soon as practicable and within not more than 2 working days. Licensed activities may not recommence at that Specified Site until the Embryo Research Licensing Committee has granted approval for this to occur.

Persons authorised to conduct the licensed activity

39. The Principal Supervisor is responsible for supervision of the activity authorised by the licence.

40. Only Authorised Persons may conduct the activity authorised by the licence. Authorised Persons include the Principal Supervisor, Principal Investigators, Nominated Embryologists and those other persons identified at Attachment A to this licence.

Other authorised persons

41. For the purposes of complying with section 28N(7c) of the *Research Involving Human Embryos Act 2002*, the licence holder must report to the Embryo Research Licensing Committee that each Other Authorised Person who carries out a use or an activity authorised by this licence is aware that they are undertaking a use or activity authorised by the licence. This requirement applies to any Other Authorised Person not listed at Attachment A of this licence instrument who, from time to time, carries out a use or an activity authorised by this licence. The notification must be made using:

    a. the 'Notification of Other Authorised Person' 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.

42. Notification must be provided prior to the Other Authorised Person undertaking a use or activity authorised by this licence.

43. Standard Conditions 2 and 3 apply to all Other Authorised Persons.

44. The use of 'any material' created or developed under this licence is allowed by staff of the VCGS for the sole purpose of undertaking genetic analysis as detailed in the Study Protocol (referred to at "**Activity authorised by the licence"**). Special Licence Conditions 41 and 42 apply.

Conditions relating to proper consent

45. In accordance with the *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research 2017 (updated 2023)* the licence holder must make sure that the donation of gametes or cells is voluntary and free from exploitation or coercion. Recruitment of donors must exclude potential participants who are in a dependent or unequal relationship with the Principal Supervisor(s), Alternative Principal Supervisor(s), Principal Investigator(s), Alternative Principal Investigator(s), Nominated Embryologist(s) or other Authorised Persons.

46. To obtain proper consent for the activities authorised by the licence, the Licence Holder must use the consent process documented in the application form and supporting attachments, as provided to the Embryo Research Licensing Committee on 17 September 2025 (including the updated Study Protocol referred to at "**Activity authorised by the licence"**).

47. Proper consent must be obtained on each occasion that gametes are donated to the licensed activity as follows:

    a. For Category 1 donors, consent must be provided prior to the commencement of each egg collection cycle.

    b. For Category 2 donors, consent must be provided on each occasion stored eggs are transferred from clinical storage to research.

    c. For Category 3 donors, consent must be provided prior to the commencement of each egg collection cycle.

    d. For Category 4 donors, consent must be provided on each occasion stored sperm are transferred from clinical storage to research.

    e. For Category 5 donors, consent must be provided prior to collection of each sperm sample.

48. A potential donor must be given at least 5 working days to consider the relevant PICF and associated information provided by the licence holder before the licence holder approaches the potential donor to confirm their choice to participate of not. The potential donor must be made aware that counselling is accessible during this time. As part of the proper consent process, the licence holder must document the date the potential donor was provided the PIC, the date the potential donor was contacted in relation to participation and the date the potential donor advised of their decision.

49. The licence holder must ensure that all gamete donors (including potential donors) are aware that counselling specific to the research project is available free of charge and can be accessed by a donor, or a potential donor. This condition applies to all donor categories (as defined in the application approved by the relevant HREC, see "**Activity authorised by the licence"**).

50. The licence holder is not permitted to allow an individual person to provide consent to participate in more than 2 (two) egg retrieval cycles specifically for a for mitochondrial donation research licensed by ERLC.

Conditions relating to the creation and use of embryos

51. The licence holder is authorised to create embryos using the permitted technique, Maternal Spindle Transfer (MST), using the method as specified in the licence application (Dated 17 September 2025).

52. A maximum of 254 embryos may be created for the activity authorised by the licence. Any other biological structure that is created during this activity that does not show basic morphological features of an MST embryo must be destroyed immediately.

53. The licence holder is authorised to use the number of eggs and sperm straws from each Donor Category as detailed in Attachment B Donor Numbers and Rationale (submitted to ERLC on 17 September 2025).

54. The licence holder is permitted to recruit the number of Participants from each Donor Category as detailed in Attachment B Donor Numbers and Rationale (submitted to ERLC on 17 September 2025).

55. Only egg and sperm cells donated specifically to this project by donors who have given proper consent to this use of their cells, may be used as the source of gametes for the embryos created under this licence.

56. An outcome must be recorded for every gamete (or sperm straw) donated to the research project, irrespective of whether the donated material is used in the research project.

57. The licence holder will use *in vitro* matured eggs where practical for all activities authorised by this licence. If the use of *in vitro* matured eggs is impractical the licence holder must undertake the following steps before using *in vivo* matured eggs:
    a. Investigate the possibility of improving egg quality by adjusting the *in vitro* maturation conditions.
    b. Increase the allocation of *in vitro* matured eggs to obtain sufficient useable eggs.
    c. Use *in vivo* matured eggs and, if necessary, extend the timescales for attaining the research goals accordingly.

58. The licence holder must not exceed the total number of eggs allowed to be used under Special Licence Condition 53.

59. For the purposes of monitoring the licence holder's compliance with section 14 of the *Prohibition of Human Cloning for Reproduction Act 2002* the licence holder must:

    a. record the day each embryo is created;

    b. record the date by which each embryo created must be discarded or otherwise destroyed;

    c. record the day each embryo is discarded, used in a destructive experiment, or otherwise destroyed;

    d. not allow an embryo to develop for more than 14 days from, and including the day the embryo is created, refer to (a);

        i. if an embryos development is paused (i.e. vitrified) the date the developed is paused and the developmental day must be recorded;

        ii. the date the embryo is thawed and the developmental day of the embryo must

also be recorded; and

e. monitor and record the development of each embryo created, at least once every 7 days.

Conditions relating to the creation and use of embryonic stem cell lines

60. The licence holder is authorised to establish up to 10 human embryo derived stem cell lines from the embryos created and used according to Special Condition 52.

61. An embryonic stem cell line derived under this licence is considered to be established and will be counted as one of the embryo derived stem cell lines authorised by Special Condition 60 when it meets, or has the potential to meet, the following criteria:

    a. the embryonic stem cell line must possess a stable human diploid karyotype, express immunologically defined markers and genes specific for embryonic stem cells; and

    b. results from initial studies indicate that the cell line is pluripotent and capable of self-renewal.

62. In addition to Standard Licence Conditions 22 to 24 the licence holder must maintain a tracking system that:

    a. links any human embryonic stem cell line created to the human embryo, human egg and human sperm straw developed or used in the creation of the stem cell line;

    b. links the unique identifier for 'any material' created, developed or used to a specific licence and each 'responsible person'

    c. records the location of each individual embryo, egg, sperm straw or 'any material' is stored or used, and

    d. if an individual embryo, egg, sperm straw or 'any material' is moved between Specified Sites records the name of the Authorised Person undertaking the activity, the Specified Sites and the date of the activity.

Reporting

63. In addition to Standard Licence Conditions 14 and 15 the licence holder must include information on the following:

    a. the number of embryonic stem cell lines established in the reporting period

    b. details of 'any material' created, developed or used from gametes donated to licensed activities

    c. the percentage of mitochondrial carry over measured in embryos created during the reporting period (when carry over is measured by the licence holder)

    d. the percentage of reversion detected in embryonic stem cell lines (when the reversion is measured in the reporting period).

64. The licence holder must provide the report required under Standard Licence Condition 16

to the Embryo Research Licensing Committee at least 30 days prior to the surrender or expiry of the licence.

Other conditions

65. The licence holder may publish genetic data on international controlled access repositories as detailed in the PICFs. In line with Special Licence Condition 32, Specified Sites, the licence holder must not share data with international partner institutions.

66. The licence holder must submit an application to vary the licence if, for any reason, including interim analysis or new research, it requires amendments to the activity authorised by the licence, including change to the experimental paradigm or goals.

Transport of materials between specified sites

67. For the purpose of this licence, "use" of donated gametes, embryos, zygotes or any material authorised under this licence includes transport of these materials (refer to footnotes 1 and 2).

68. The transport of gametes, embryos, zygotes or 'any material' donated to, created or developed under this licence is allowed by staff of the courier company(ies) listed in Attachment A for the sole purpose of transporting materials directly from one Specified Site to another Specified Site (Special Condition 31) as detailed in the Study Protocol.

69. For the purposes of complying with s.28N(7)(c) of the *Research Involving Human Embryos Act 2002*, the licence holder must retain detailed records of the transport of licensed materials between Specified Sites, including the times, locations, name of the company and each individual person that undertakes transport activities as authorised by the licence.

70. The licence holder is responsible for ensuring that a courier company listed in Attachment A is aware that they are undertaking a use or activity authorised by the licence.

71. Standard Conditions 2 and 3 apply to the courier company(ies) listed in Attachment A. The licence holder is responsible for ensuring the company understands and complies with all requirements of the legislation, licence, approved processes and protocols relevant to the transport of materials under this licence.

72. The licence holder must advise ERLC if a courier company listed in Attachment A is no longer involved in the transport of material.

Table of Variations

Date of Variation	Conditions Affected	Description of Changes
20 November 2026 (Version 2)	Activity authorised by the licence Special Conditions 67–72 Attachment A	Updated authorised Study Protocol Added special conditions for Transport of Materials between Sites Added new Authorised Persons (Attachment A)

Attachment B - Donor Numbers and Rationale

Projected numbers by Category

Donor Categories	Projected total number of oocytes/ eggs	Projected number of sperm straws	Projected number of embryos	Rationale
Category I	200	-	75	The projection of 200 immature oocytes to yield 134 Met II eggs (67% maturation); The estimated number of embryos is based on: 80% survival after MST and 70% fertilisation
Category II	200	-	106	The projected number of Category II eggs is based on 95% survival after vitrification and warming to yield 190 useable eggs. The projected number of embryos is based on: • 80% survival after MST and 70% fertilisation • the minimum number required to detect an effect on blastocyst formation (alpha 0.05; power of 80%)
Category III	130	-	73	The projected number of Category III eggs is based on ~78% of eggs being at metaphase II at the time of egg retrieval to a yield a total of 130 usable *in vivo* matured eggs. The projected number of embryos is based on: • 80% survival after MST and 70% fertilisation • 20% good quality blastocysts (suitable for ES cell derivation)
Category IV	-	119		The projected number of straws of frozen sperm to be used is based on using a single straw per experiment. It is anticipated that each experiment will involve ~2-6 eggs. A sperm straw has been allocated for every two embryos to be used under the licence. Based on the numbers of Cat II-donated straws currently available at Monash IVF, it is not anticipated that Cat V donors will be used under this licence. If required a licence variation to use Category V-donated sperm will be sort.
Category V	-	0		
Total	**530**	**119**	**254**	

Projected Participant Numbers

Category	Total projected number of oocytes/eggs	Projected number of oocytes/eggs per participant	Projected number of egg donor participants	Projected number of sperm straws	Projected number of sperm donor participants
Category I	200	1-2	133	-	-
Category II	200	10	20	-	-
Category III	130	10	13	-	-
Category IV	-	-	-	119	6*
Category V	-	-	-	0	0
Total	**530**		**166**	**119**	**6***

*Prediction based on Monash IVF clinical data.