Research Involving Human Embryos Act 2002

LICENCE

Version 1, 5 December 2025

This licence is issued under s.21 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 309730*.

Licence Number:	309730
Licence Holder:	Number One Fertility Pty Ltd
Licence Title:	Investigating a new single step warming protocol for human embryos
Date of Issue:	5 December 2025
Licence begins:	5 December 2025
Licence ends:	4 December 2029
Activity authorised by the licence:	This study will assess the impact of a shortened, single rehydration step, during warming of vitrified embryos. Excess ART embryos will be warmed using either the new warming protocol or a standard IVF clinic warming protocol. Standard IVF laboratory measures such as embryo survival, resumption of embryo development and embryo re-expansion rate will be measured post-warm. Additionally, the embryo's subcellular structures such as the microtubule cytoskeleton, nucleus structure and cellular membranes will be imaged and assessed.
Goals of the Activity:	This study aims to determine whether a single step warming protocol for human embryos is safe and effective to implement into clinical practice in an IVF laboratory and to assess if subcellular structures can serve as novel biomarkers for human embryo quality.

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.

Research Involving Human Embryos Act 2002
Standard Conditions of Licence

Version 10, 1 August 2023

This document specifies the standard conditions that apply to licences that are issued by the Embryo Research Licensing Committee of the NHMRC (the NHMRC Licensing Committee) under the *Research Involving Human Embryos Act 2002* and corresponding State laws for the use of excess ART embryos, or human eggs (oocytes) or the creation or use of other embryos. The Standard Conditions apply to every licence unless the Special Conditions for a particular licence provide that a specific standard condition does not apply to that licence.

Current contact details

1 The licence holder must give written notice to the NHMRC Licensing Committee of 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 activity

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, 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 in the licence conditions.

4 The licence holder must give written notice to the NHMRC 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 If the licence holder is required to provide written notice under condition 4, all use of excess ART embryos or human eggs or creation and/or use of other embryos authorised by the licence must cease:

(a) from the date the Principal Supervisor ceases to be involved in the licensed activity until the NHMRC Licensing Committee has approved the licence holder's application for a person to be identified in the licence conditions as the new Principal Supervisor,

or

(b) from the date the licence holder notifies the NHMRC Licensing Committee that the Principal Supervisor is temporarily absent until the licence holder has advised the NHMRC Licensing Committee that the Principal Supervisor has returned to duty.

Conditions relating to proper consent

6 For the purposes of complying with s.24(1)(b) of the *Research Involving Human Embryos Act 2002*, the licence holder must report to the NHMRC Licensing Committee that 'proper consent' has been obtained from each responsible person in relation to the human egg or human embryo 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) in an alternative format which has previously been approved in writing by the Chair of the NHMRC Licensing Committee.

Notification must be provided prior to the authorised activity being conducted. 'Proper consent' for a general licence has the same meaning as in ss24(9) of the *Research Involving Human Embryos Act 2002*.

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

Reporting

8 During the currency of the licence, the licence holder must submit a written report to the Licensing Committee no later than 30 days after the end of each reporting period. The reporting periods run from 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 NHMRC Licensing Committee.

9 Prior to the expiry or surrender of the licence, the licence holder must also submit to the NHMRC 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: www.nhmrc.gov.au; or

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

10 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 NHMRC Licensing Committee of the breach or suspected breach; and

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

(c) within 7 days after providing a notification under standard condition 10(a), provide a written report to the NHMRC Licensing Committee that details a written report provided in accordance with this condition must include details on the following matters:

i. The activity or conduct that the licence holder believes 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 this 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 believes may constitute a non-compliance.

Where the licence holder is an individual, the licence holder is not required to give information that might tend to incriminate the individual or expose the individual to a penalty.

11 The licence holder must immediately, by notice in writing, inform the NHMRC 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

12 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.

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

14 The licence holder must provide reasonable assistance and cooperation to the NHMRC 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 excess ART embryos or human eggs, or creation or use of other embryos

15 The licence holder must maintain a tracking system that uniquely identifies each excess ART embryo or human egg used or other 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'; and

(b) record an outcome for each individual excess ART embryo or human egg used or other embryo created or used in the licensed activity, linking the outcome to the unique identifier for that embryo or egg.

16 Prior to the expiry or surrender of the licence, the licence holder must review the consent forms relating to any embryos or eggs still held in storage by the licence holder and must deal with those embryos or eggs 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 or eggs 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 or, if applicable, to consider donating the embryos for the purpose of achieving pregnancy in another woman; and

(c) deal with the embryos or eggs in accordance with the instructions obtained from the responsible persons.

HREC approval during the period of the licence

17 If the HREC that assessed the project ceases responsibility for ethical oversight of the project, the licence holder must notify the 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

18 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 Licensing Committee of the withdrawal or suspension of HREC approval as soon as practicable and within 2 working days. Licensed activities may not recommence until the Licensing Committee has granted approval for this to occur.

Storage of information

19 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.

20 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.

21 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.

22 If the licence holder is required to report a potential breach of data security that relates to the licensed activity, to the Office of the Australian Information Commissioner (OAIC), Australian Cyber Security Centre (ACSC) or the Australian Federal Police (AFP), the licence holder must advise the NHMRC Licensing Committee as soon as practicable and within 2 working days of notifying the potential breach to the relevant authority.

Research Involving Human Embryos Act 2002

Special Conditions for Licence 309730

Licence Number:	309730
Licence Holder:	Number One Fertility Pty Ltd
Licence Title:	Investigating a new single step warming protocol for human embryos.

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.24 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 use of embryos

23 A maximum of 400 excess ART embryos may be used for the activity authorised by the licence.

Specified Sites

24 The licence holder must conduct the activity authorised by the licence at the following site/s:
Number One Fertility Jolimont
Level 3, 120 Jolimont Rd
East Melbourne VIC 3002

Australian Regenerative Medicine Institute
Level 2, Rooms 264–267
15 Innovation Walk
Monash University
Clayton VIC 3800

Monash Micro Imaging
Ground Level
15 Innovation Walk
Monash University
Clayton VIC 3800

25 The licence holder must hold records (other than patient records) associated with the activity authorised by the licence at the following site/s:
Number One Fertility Jolimont
Level 3, 120 Jolimont Rd
East Melbourne VIC 3002

26 The licence holder must hold patient records associated with the activity authorised by the licence at the following site/s:
Number One Fertility Jolimont
Level 3, 120 Jolimont Rd
East Melbourne VIC 3002

Persons authorised to conduct the licensed activity

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

28 The Alternative Principal Supervisor is responsible for supervision of the activity authorised by the licence wherever the absence of the Principal Supervisor is documented by the licence holder.

29 Only Authorised Personnel may conduct the activity authorised by the licence. Authorised Personnel include the Principal Supervisor, Alternative Principal Supervisor and those other persons identified at **Attachment A** to this licence.

Conditions relating to proper consent

30 To obtain proper consent to use excess ART embryos in the activities authorised by the licence, the Licence Holder must use the consent process described in the documents provided on 16 September 2025.

31 For the avoidance of doubt, the requirements of Condition 31 include use of the Explanatory Statement and Consent Form provided to the NHMRC Licensing Committee on 16 September 2025.

32 A 'cooling off' period of at least 30 days (as specified in the application) is required between obtaining proper consent and use of excess ART embryos in activities authorised under the licence. This is to be documented as part of the consent process.

Other conditions

33 The Licence Holder must lodge an application to vary the licence for any significant amendments to the activity authorised by the licence at any point in the life of the licence, including change to the experimental paradigm or goal.

Table of Variations

Date of Variation	Conditions Affected	Description of Changes
9 November 2026 (version 1.1)	-	Amendment of minor administrative error.