Research Involving Human Embryos Act 2002
LICENCE 309718

Version 29, 1 November 2023

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 309718*.

Licence Number:	309718
Licence Holder:	Genea Limited
Licence Title:	Use of excess ART embryos and clinically unusable eggs for validation of an IVF device
Date of Issue:	8 December 2011
Licence begins:	8 December 2011
Licence ends:	7 December 2024
Activity authorised by the licence:	The activity authorised by this licence is: • Use of excess ART embryos and clinically unusable human eggs (oocytes) to validate an IVF device. The human eggs to be used under this licence are those excluded from clinical use because they have fertilised abnormally. Such eggs are therefore considered unsuitable for transfer to a woman during assisted reproductive technology (ART) treatment. The embryos to be used under this licence are frozen embryos which have been declared to be excess to the reproductive needs of the responsible people concerned.
Goals of the Activity:	The goals of the licensed activity are: • to validate a device for freezing embryos which aims to reduce handling variability and improve embryo traceability and viability, thus reducing human errors and stress on the embryos, by using groups of 60 eggs (that is, 30 test and 30 control eggs) or 60 embryos (that is, 30 test and 30 control embryos) to test each set of parameters for confirmation or validation of the device.

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.

Reporting

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 309718

Licence Number:	309718
Licence Holder:	Genea Limited
Licence Title:	Use of excess ART embryos and clinically unusable eggs for validation of an IVF device

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 eggs and use of embryos

23 The licence holder is authorised to use up to 1000 eggs which have been determined to be clinically unusable due to the presence of 1 pronucleus or 3 pronuclei when examined not less than 14 hours after insemination, and which have been determined to be suitable (as judged by one of the licence holder's scientists) for the activity authorised by this licence.
For the purposes of this licence, abnormally fertilised eggs must be frozen following the determination that they are clinically unusable and use of each egg is deemed to commence when it is thawed following the period in frozen storage.

24 An outcome must be recorded for every egg donated to the research project, irrespective of whether the egg is used in the research project.

25 The licence holder is authorised to use up to 345 excess ART embryos.

26 The licence holder may not remove from cryostorage for the purpose of conducting the activity authorised by the licence a greater number of excess ART embryos than the number specified in Special Condition 25.

27 When testing each set of parameters, the licence holder is required to make an interim assessment of the results. If after the first 10 test and 10 control eggs or the first 10 test and 10 control embryos have been used, the results show poor recovery and/or poor survival of the test eggs or embryos compared to the controls and the controls are comparable to current clinical results then no more eggs or embryos may be used to test that set of parameters.
In this context poor recovery or poor survival of embryos means less than 80% recovery or less than 80% survival. Poor recovery or poor survival of eggs means less than 50% recovery or less than 50% survival.

28 In the absence of a notification provided in accordance with Special Condition 38, no more excess ART embryos may be used under this licence.

29 In the absence of a notification provided in accordance with Special Condition 38, no more clinically unusable eggs may be used under this licence

Specified Sites

30 The licence holder must conduct the use of excess ART embryos and clinically unusable eggs authorised by the licence at the following sites:
Genea Limited
321 Kent St
Sydney NSW 2000

31 The licence holder must hold records (other than patient records) associated with the use authorised by the licence at the following sites:
Genea Limited
321 Kent St
Sydney NSW 2000

32 The licence holder must hold patient records associated with the licensed activity at the following sites:
Genea Limited
321 Kent St
Sydney NSW 2000

Filesaver Pty Ltd
2151 Castlereagh Road
Penrith NSW 2750

Persons authorised to conduct the licensed activity

33 The Principal Supervisor is responsible for supervision of the activity authorised by the licence. The Principal Supervisor is the person identified at **Attachment A** to this licence.

34 Only authorised personnel may conduct the activity authorised by this licence. The authorised personnel are the Principal Supervisor and those other persons identified at **Attachment A** and **Attachment B** to this licence.

35 A person identified in **Attachment B** to this licence may receive training under the licence as authorised by Special Condition 46. The person is an authorised person under the licence but must be supervised when using any technique listed against the person's name in **Attachment B**.

Reporting

36 When recording an outcome for each egg as required by Special Condition 24, the licence holder is required to use the template specified in Standard Condition 8.

37 The licence holder must report to the Licensing Committee within 14 days of determining that the situation described in Special Condition 27 has occurred. The report must include an analysis of and reasons for the observed results and a plan for resolving the problem. Use of eggs or embryos to test the proposed plan for resolving the problem may only commence after the Licensing Committee has approved the report.

38 If,

(a) the process for obtaining regulatory approval in any jurisdiction, or

(b) proposed modifications to the device or freeze protocols, or

(c) approval of modifications to the device or protocols,

requires additional testing then the licence holder is required to notify the Licensing Committee before commencing the testing.
The notification must inform the Licensing Committee as to whether the testing requires the use of excess ART embryos or clinically unusable human eggs or both.

39 If a notification has been made in accordance with Special Condition 38, the licence holder is required to report to Licensing Committee within 14 days of the completion of the additional testing. Following this reporting, Special Conditions 28 and 29 apply until such time as a further notification is made in accordance with Special Condition 38.

40 When providing the reports required by Standard Condition 8, the licence holder must identify any excess ART embryos and clinically unusable eggs, that, in addition to their use in the activity authorised by this licence, have been used for training activities as allowed by Special Condition 46.

Conditions relating to proper consent

41 When cryostored excess ART embryos and clinically unusable eggs are used under the licence a 'cooling-off' period of at least 2 weeks must have been observed.

42 Amendments to the consent process are permitted, provided the licence holder ensures that the consent process remains consistent with the *Consent checklist for licensed activities using excess ART embryos* available from www.nhmrc.gov.au. This replaces the requirements of Standard Condition 7.

43 Amendments to the *Participant Information and Consent Form for clinically unsuitable eggs*, the *Participant Information and Consent Form* for excess ART embryos and the *Declaration of excess clinically unsuitable eggs* are permitted provided the licence holder ensures that the documents remain consistent with the *Consent checklist for licensed activities using excess ART embryos* available from www.nhmrc.gov.au. This replaces the requirements of Standard Condition 7.

44 When requested, the licence holder is required to provide copies of the documents currently in use to NHMRC inspectors for assessment of compliance with the licence conditions, applicable guidelines and consent checklist.

45 An excess ART embryo or clinically unusable egg may only be used for the training activities allowed by Condition 46 if the people responsible for the embryo or egg have given consent for its use in the training activities in addition to consent for the activities authorised by this licence.

Training activities included in licensed activity

46 When excess ART embryos or clinically unsuitable eggs are used in the activity authorised by this licence and the activity involves the use of a technique for which a person identified in **Attachment B** requires training, the use of that technique may be used as a training activity.

47 When receiving training in accordance with Special Condition 46, the person identified in **Attachment B** must be supervised at all times by an authorised person identified in **Attachment A**.

Table of Variations

Date of Variation	Conditions Affected	Description of Changes
21 March 2012 (version 2)	9402	Reworded to clarify reporting requirements
21 March 2012 (version 2)	9302	Addition of new authorised person
15 August 2013 (version 3)	9302	Removal of authorised person from list of authorised persons
15 August 2013 (version 3)	various	Update licence to reflect Sydney IVF's name change to Genea Limited
15 August 2013 (version 3)	9101, 9501, 9504, 9505	Variation to process for obtaining proper consent
15 August 2013 (version 3)	9502, 9503	Variation to documents used to obtain proper consent
28 February 2014 (version 4)	9302	Removal of authorised person from list of authorised persons
26 June 2014 (version 5)	9302	Addition of new authorised persons
26 June 2014 (version 5)	Attachment A	Removal of condition relating to an authorised person's use of excess ART embryos
27 August 2014 (version 6)	2301, 2302, 4301	Variation to Standard Conditions of Licence
1 October 2014 (version 7)	Expiry date	Extension of licence to 8 December 2016
1 October 2014 (version 7)	9103	Increase in number of excess ART embryos authorised for use
1 October 2014 (version 7)	9301	Add Alternate Principal Supervisor
16 October 2014 (version 8)	9302	Addition of new authorised person
14 November 2014 (version 9)	9106, 9107, 9403 – 9407	Variation to reporting requirements
26 March 2015 (version 10)	9302	Addition of new authorised person; removal of authorised person from list of authorised persons.
14 April 2015 (version 11)	9302	Addition of new authorised persons
23 June 2015 (version 12)	9302	Addition of new authorised person
25 November 2015 (version 13)	9301	New Principal Supervisor and Alternate Principal Supervisor

Date of Variation	Conditions Affected	Description of Changes
25 November 2015 (version 13)	9302	Removal of authorised person from list of authorised persons
25 November 2015 (version 13)	9501-9503, 9506-9508	Variation to process for obtaining proper consent
7 March 2016 (Version 14)	9302, 9303 9408 9509 9701, 9702	Addition of authorised persons Changes to reporting conditions Requirement to obtain consent Approval of training activities within licensed activity
6 April 2016 (Version 15)	9201-9203	Addition of new site for licensed activity and records storage
6 June 2016 (Version 16)	9302	Removal of authorised person from list of authorised persons
6 June 2016 (Version 16)	9302, 9303	Removal of authorised person from list of authorised persons
6 October 2016 (Version 17)	Expiry date	Extension of licence to 8 December 2018
8 March 2017 (Version 18)	9201-9203	Removal of site for licensed activity and records storage
8 March 2017 (Version 18)	9301	Departure of Principal Supervisor Approval of new Principal Supervisor
8 March 2017 (Version 18)	9302	Removal of authorised person from list of authorised persons
8 March 2017 (Version 18)	Attachment A	Removal of condition relating to an authorised person's use of excess ART embryos
7 June 2017 (Version 19)	9302	Removal of authorised person from list of authorised persons
6 November 2017 (Version 20)	9106-9107 9403-9407	Variation to reporting requirements
28 February 2018 (Version 21)	9302	Removal of authorised person from list of authorised persons
7 December 2018 (Version 22)	9302	Removal of authorised person from list of authorised persons
7 December 2018 (Version 22)	9302	Addition of authorised person
7 December 2018 (Version 22)	Expiry date	Extension of licence to 8 December 2021

Date of Variation	Conditions Affected	Description of Changes
10 January 2020 (Version 23)	9302	Removal of authorised person from list of authorised persons
10 August 2020 (Version 24)	9301	Departure of Principal Supervisor Approval of new Principal Supervisor
30 June 2021 (Version 25)	9302	Removal of authorised person from list of authorised persons
30 November 2021 (Version 26)	Expiry date	Extension of licence to 7 December 2024
20 December 2022 (Version 27)	9301	Departure of Principal Supervisor Approval of new Principal Supervisor
20 December 2022 (Version 27)	9302	Departure of 3 authorised persons Approval of minor editorial change
1 August 2023 (Version 28)	various	Renumbering of all conditions to improve readability Reformatting for web accessibility Merging Standard Condition (v10) document into Special Conditions
1 November 2023 (version 29)	33	Departure of Principal Supervisor Approval of new Principal Supervisor