Research Involving Human Embryos Act 2002
LICENCE

Version 8, 4 June 2026

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 309729*.

Licence Number:	309729
Licence Holder:	Monash University
Licence Title:	The generation and study of a novel in-vitro model of human blastocysts ('iBlastoids').
Date of Issue:	19 October 2022
Licence begins:	19 October 2022
Licence ends:	18 October 2027
Activity authorised by the licence:	This licence authorises the creation and characterisation of iBlastoids, which are human embryos (and human embryo clones) that are generated by reprogramming adult skin cells *in vitro* into a three-dimensional cluster of cells that resembles a blastocyst and has the potential to develop up to the stage at which the primitive streak appears.
Goals of the Activity:	The goals of the licensed activity are to investigate iBlastoids and their role as an *in-vitro* model of early human development, by: • generating and characterising the molecular properties of iBlastoids • studying the molecular drivers for the establishment of iBlastoids • finding alternative methods for the generation of iBlastoids, and • deriving and studying different stem cell types from iBlastoids.

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 309729

Licence Number:	309729
Licence Holder:	Monash University
Licence Title:	The generation and study of a novel *in-vitro* model of human blastocysts ('iBlastoids').

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 creation and use of embryos

23 The licence holder is authorised to create embryos by reprogramming adult skin cells, using the method described in Liu et al., Nature 2021[1] and others as specified in the licence application. The licence holder is permitted minor deviations from the specific published protocols, in order to optimise the technique for this research activity (for example through altered incubation times or addition of different growth factors).

24 A maximum of 117,010 embryos (assessed as showing basic morphological features of an iBlastoid) may be used for the activity authorised by the licence. Any other structure that is created during this activity that does not show basic morphological features of an iBlastoid must be destroyed immediately. Any structure that is initially assessed as showing morphological features of an iBlastoid but is subsequently found not to be an iBlastoid, must be counted towards the number of embryos used.

25 Only fibroblast and keratinocyte cells obtained from Monash University staff and students who have given consent to this use of their cells, may be used as the source of cells for the iBlastoid embryos created under this licence.

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

27 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 first day for the period for development of an iBlastoid as the same day the cells commence aggregation;

(b) not allow an iBlastoid to develop for more than 14 days, including from the day of commencement provided for in (a), and

[1] Liu, X., Tan, J. P., Schröder, J., Aberkane, A., Ouyang, J. F., Mohenska, M., Lim, S. M., Sun, Y. B. Y., Chen, J., Sun, G., Zhou, Y., Poppe, D., Lister, R., Clark, A. T., Rackham, O. J. L., Zenker, J., & Polo, J. M. (2021). Modelling human blastocysts by reprogramming fibroblasts into iBlastoids. Nature, 591(7851), 627–632. https://doi.org/10.1038/s41586-021-03372-y

(c) monitor and record the development of each iBlastoid created, using morphological and/or molecular (gene expression) methods.

28 The licence holder must immediately cease development of an iBlastoid prior to 14 days if and when the following occur:

(a) an iBlastoid reaches a morphological or molecular stage equivalent to a fertilised human embryo at 14 days development; or

(b) an iBlastoid is developed in conditions that give rise to the development of the primitive streak, and/or evidence of gastrulation occurs.

29 For the avoidance of doubt, an iBlastoid created under this licence is a human embryo clone as defined in the *Prohibition of Human Cloning for Reproduction Act 2002*.

30 The licence holder is authorised to establish up to eighty (80) cloned human embryo derived stem cell lines from the embryos used according to Special Condition 24.

31 An embryonic stem cell line derived under this licence is considered to be established and will be counted as one of the cloned embryo derived stem cell lines authorised by Special Condition 30 when it meets, or has the potential to meet, the following criteria:

- the embryonic stem cell line must possess a stable human diploid karyotype, express immunologically defined markers and genes specific for embryonic stem cells; and
- results from initial studies indicate that the cell line is pluripotent and capable of self-renewal.

Specified Sites

32 The licence holder must conduct the activity authorised by the licence at the following site:
Department of Anatomy and Development Biology and The Australian Regenerative Medicine Institute
Level 3
15 Innovation Walk
Monash University
Clayton Victoria 3800

Monash Micro Imaging
Ground level, Building 75
15 Innovation Walk
Monash University
Clayton Victoria 3800

Biomedical Sciences
Level 3, Room 374 Building 76
19 Innovation Walk
Monash University
Clayton Victoria 3800

33 The licence holder must hold records (other than donor/patient records) associated with the use authorised by the licence at the following sites:
Department of Anatomy and Development Biology and The Australian Regenerative Medicine Institute, Level 3,
15 Innovation Walk
Monash University
Clayton Victoria 3800

Monash Micro Imaging
Ground level, Building 75
15 Innovation Walk
Monash University
Clayton Victoria 3800

Biomedical Sciences
Level 3, Room 374 Building 76
19 Innovation Walk
Monash University
Clayton Victoria 3800

Monash Research Office
Room 111 Chancellery Building D
26 Sports Walk
Wellington Road
Monash University
Clayton Victoria 3800

34 The licence holder must securely hold donor (patient) records associated with the skin biopsy component of the licensed activity in a secure facility at the following sites:
Department of Anatomy and Development Biology and The Australian Regenerative Medicine Institute
Level 3
15 Innovation Walk
Monash University
Clayton Victoria 3800

Monash University Health Services (Clayton Campus)
Ground Floor, Campus Centre, 21 Chancellors Walk
Monash University
Clayton Victoria 3800

35 The "use" (as defined in the *Research Involving Human Embryos Act 2002*) of iBlastoids created in accordance with this licence is only to occur at the site listed in Special Conditions 32. Live iBlastoids must not be transferred from this site to any other location.

36 The Licence Holder must be aware of, and act in compliance with, relevant legislation that regulates the transfer or export of stem cell lines derived from human embryo clones as it applies to iBlastoids created by activity authorised by this licence (see for example, the permit scheme under *Customs (Prohibited Export) Regulations 1958* (section 8A)).

Persons authorised to conduct the licensed activity

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

38 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.

39 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.

Reporting

40 The licence holder must submit a written report to the Licensing Committee no later than 30 days after the end of each reporting period, that described the activity conducted under the licence in the reporting period. The reporting periods run from 1 March to 31 August and 1 September to 28 February (or 29 February in leap years). For the purposes of monitoring Special Conditions 23 and 24, the report must include:

- information about the efficiency of generating iBlastoids
- tracking of actual numbers of iBlastoids used in experiment
- the number of cells, other structures and iBlastoids which are destroyed due to not being suitable or required for research.

For the purposes of monitoring Special Condition 27, the report must include:

- a description of the relevant research method for each iBlastoid
- a summary of the iBlastoid's development including observations and the results of any morphological and molecular (gene expression) testing carried out throughout its chronological development from aggregation, and
- any preliminary findings of the activity authorised by the licence.

This report is in addition to the requirements of Standard Condition 8.

41 The licence holder must within 7 days provide the Licensing Committee a written report on each occasion that the research inadvertently exceeds the morphological stage and/or demonstrates molecular gene expression consistent with exceeding this stage, as described in the application and Special Condition 28. A written report provided in accordance with this condition must include details on the following matters:

(a) a description of the relevant research method
(b) a summary of the iBlastoid's development including observations and any testing carried out throughout its chronological development from aggregation
(c) the likelihood of reoccurrence and whether any changes are proposed to the research methodology to prevent reoccurrence
(d) any preliminary findings on the extent to which the iBlastoid is a model for an early human blastocyst.

42 When recording an outcome for each skin sample that is donated to the project, as required by Special Condition 26, the licence holder is required to use the template specified in Standard Condition 8.

Conditions relating to proper consent

43 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 Licensing Committee on 26 September 2022 and subsequently approved by the Licensing Committee on 18 October 2022.

44 For the avoidance of doubt, the requirements of Special Condition 43 include use of the Participant Explanatory Statement and Consent Form provided to the Licensing Committee on 26 September 2022 and subsequently approved by the Licensing Committee on 18 October 2022.

45 A 'cooling off' period of at least 14 days is required between obtaining proper consent and reprogramming of fibroblast or keratinocyte cells in activities authorised under the licence. This is to be documented as part of the consent process.

46 As specified in the application, Monash University Human Research Ethics Committee will sight consent details for all skin cell samples that grow successfully and provide the notification of consent to the Licensing Committee.

Other conditions

47 If the licence holder or a report submitted to the Licensing Committee concludes that further creation of embryos within the project will not meet the goals of the activity, the licence holder must cease creation of embryos for the authorised activity.

48 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.

Table of Variations

Date of Variation	Conditions Affected	Description of Changes
30 June 2023 (version 2)	Attachment A (condition 9303)	Removed Other Authorised Person name
1 August 2023 (version 3)	various	Renumbering of all conditions to improve readability Reformatting for web accessibility Merging of Standard Conditions (v10) document into Special Conditions
22 April 2024 (version 4)	Attachment A (condition 39)	Added Other Authorised Person name Removed three Other Authorised Person names
28 October 2024 (version 5)	Attachment A (condition 39)	Added Other Authorised Person name
5 May 2025 (version 6)	Licence end date	Extension to period of licence
19 November 2025 (version 7)	Attachment A (condition 39)	Removed three Other Authorised Person names
4 June 2026 (version 8)	Attachment A (condition 39)	Added two Other Authorised Person names