Australian Government

National Health and Medical Research Council

Research Involving Human Embryos Act 2002

Embryo Research Licensing Committee of the NHMRC

LICENCE

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 items 9 and 10 below.

1.	Licence Number:	309723
2.	Licence Holder:	Melbourne IVF Pty Ltd
3:	Licence Title:	Use of excess ART embryos for blastocyst-stage biopsy training
4.	Date of Issue:	19 December 2014
5.	Licence begins:	19 December 2014
6.	Licence ends:	19 December 2020
7.	Activity authorised by the licence:	This licence authorises trainee embryologists to use excess ART embryos to attain proficiency in blastocyst-stage embryo biopsy. 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.
8.	Goals of the Activity:	The goals of the licensed activity are to: • allow trainee embryologists to achieve competence in the technique of blastocyst-stage embryo biopsy through the use of limited numbers of excess ART embryos.
9.	Standard Conditions:	All conditions that are specified in the *Standard Conditions of Licence*.
10.	Special Conditions:	All conditions that are specified in the *Special Conditions for Licence No. 309723*.

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.

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Special Conditions for Licence 309723

Licence Number:	309723
Licence Holder:	Melbourne IVF Pty Ltd
Licence Title:	Use of excess ART embryos for blastocyst-stage biopsy training

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 excess ART embryos

Condition Number	*Condition*
9101	Except as allowed by Condition 9601, a maximum of 15 suitable excess ART embryos may be used to train each trainee authorised by condition 9303 in the technique of blastocyst stage biopsy.
9102	An excess ART embryo is taken to be suitable for the purposes of condition 9101 if greater than 50% of its blastomeres are intact immediately following thawing and it reaches the expanded blastocyst stage of development within 4 days following thawing.
9103	A maximum of 50 excess ART embryos may be removed from cryostorage and thawed in order to obtain the 15 suitable blastocyst stage embryos for the purposes of training each trainee.
9104	When a trainee has used 15 suitable blastocyst stage embryos or has reached proficiency as described in Condition 9402, the licence holder is not permitted to thaw any more excess ART embryos for that trainee.
9105	The training of a trainee may not commence unless the licence holder has obtained proper consent to use at least 25 excess ART embryos in respect of that trainee.
9106	The excess ART embryos donated to this licence must not be used for any purpose except training in blastocyst stage embryo biopsy. Any embryo which is not suitable for the purposes of Condition 9101 must be discarded when it is determined to be unsuitable.
9107	An excess ART embryo is deemed to have survived blastocyst biopsy if it has re-expanded 4 hours after biopsy and has not degenerated 24 hours after biopsy. Except as allowed by Condition 9108, embryos must be discarded as soon as survival has been confirmed.

9108	Those excess ART embryos which have survived blastocyst biopsy may be biopsied a second time to obtain additional cells and thus allow trainees to fulfil the criteria specified in Condition 9402 for successful transfer of biopsied cells into a sample tube without requiring the use of additional excess ART embryos. The embryos must be discarded immediately following the second biopsy procedure.

Specified Sites

Condition Number	*Condition*
9201	The licence holder must conduct the use of excess ART embryos authorised by the licence at the following site: Melbourne IVF Level 1, 344 Victoria Parade East Melbourne VIC 3002
9202	The licence holder must hold records (other than patient records) associated with the use authorised by the licence at the following site: Melbourne IVF Level 1, 344 Victoria Parade East Melbourne VIC 3002
9203	The licence holder must hold patient records associated with the licensed activity at the following site: Melbourne IVF Level 1, 344 Victoria Parade East Melbourne VIC 3002

Persons authorised to conduct the licensed activity

Condition Number	*Condition*
9301	The Principal Supervisor is responsible for supervision of the activity authorised by the licence. The Principal Supervisor is that person identified at **Attachment A** to this licence.
9302	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** to this licence.
9303	This licence authorises those people listed as trainees in **Attachment A** to be trained in the technique of blastocyst stage embryo biopsy. Other trainees may be permitted to undertake training in the future provided the requirements of Condition 9305 are satisfied in relation to each proposed trainee.
9304	Unless otherwise authorised by the Licensing Committee, the Principal Supervisor must ensure that, before any trainee uses an excess human ART embryo pursuant to this licence, that trainee has: (i) not previously received training in blastocyst stage biopsy techniques using live human embryos; and (ii) demonstrated skill in blastocyst stage biopsy using animal embryos and dead human embryos before requesting training under this licence; and (iii) demonstrated skill in the micromanipulation of animal and human gametes before requesting training under this licence.
9305	A trainee must not use an excess ART embryo for training as authorised by this licence, unless the licence holder has first: (i) submitted an application to the NHMRC Licensing Committee as specified at http://www.nhmrc.gov.au/research/information-licence-holders for that trainee to use excess ART embryos as authorised by this licence; and (ii) received approval in writing from the NHMRC Licensing Committee for the training of that trainee pursuant to this licence.
9306	The Principal Supervisor (or an alternate Principal Supervisor, if any) must oversee all blastocyst biopsies conducted under this licence.

Reporting

Condition Number	*Condition*
9401	When providing the reports required by condition 3001, the licence holder must provide the following information to the NHMRC Licensing Committee in addition to the requirements specified in condition 3001: (i) the name of each individual who has received training as authorised by this licence during the reporting period; (ii) how many suitable embryos have been used for or by each trainee; (iii) the progress of the training: and (iv) whether an embryo has been biopsied twice as allowed by condition 9108.
9402	The licence holder is required to report to the NHMRC Licensing Committee within 14 days of a trainee reaching proficiency in blastocyst biopsy. For the purposes of this condition the licence holder has defined proficiency as: (a) successful biopsy of at least 10 but not more than 15 blastocysts, with the number used being determined by the Principal Supervisor or Alternate Principal Supervisor; and (b) successful transfer of cells to sample tubes in 18 or more of 20 attempts. In the foregoing, 'successful biopsy' means that the embryo survived and transfer of biopsied cells to the sample tube was confirmed.
9403	The licence holder is required to notify the NHMRC Licensing Committee in writing within 14 days if a trainee uses more than 15 suitable embryos as permitted by Condition 9601.

Conditions relating to proper consent

Condition Number	*Condition*
9501	Only the consent process as described in the documents provided on 12 December 2014 and subsequently approved by the NHMRC Licensing Committee may be used for obtaining proper consent to use excess ART embryos in the activities permitted by this licence.
9502	Only the Plain Language Statement provided on 12 July 2016 and Consent Form for provided on 12 December 2014 and approved by the NHMRC Licensing Committee may be used for obtaining proper consent to use excess ART embryos in the activities permitted by this licence.
9503	When cryostored excess ART embryos are used under the licence a “cooling-off” period of at least 2 weeks must be observed.

Other conditions

9601	Licence holders are required to manage the number of excess ART embryos thawed for use under the licence to limit the likelihood of obtaining greater than the allowable number of suitable embryos per trainee. In the event that a trainee has reached proficiency or has obtained 15 suitable embryos and suitable embryos remain in culture: (a) the excess suitable embryos may be transferred to another trainee who has not yet biopsied 15 suitable embryos or reached proficiency; or (b) where the excess suitable embryos cannot be used by another trainee, the trainee for whom the embryos were initially thawed may use the excess embryos. In this case the total number of embryos used by the trainee must not exceed 20.

Table of Variations

Date of Variation	Conditions Affected	Description of Changes
12 June 2015 (version 2)	9302	Removal of authorised person from list of authorised persons
25 November 2015 (version 3)	9302	Removal of authorised people from list of authorised persons
25 November 2015 (version 3)	9301	Addition of Alternate Principal Supervisor
25 November 2015 (version 3)	9302	Addition of authorised people to list of authorised persons
14 June 2016 (version 4)	9301	Departure of Principal Supervisor
14 June 2016 (version 4)	9302	Departure of Authorised Person
14 June 2016 (version 4)	Attachment A	Notification of completion of preliminary training required by Condition 9304
14 June 2016 (version 4)	9402	Clarification of licence condition
14 June 2016 (version 4)	3001, 5001	Approval of modified 'Authorised use spreadsheet' and 'Consent notification spreadsheet'
30 September 2016 (version 5)	9301	Approval of new Principal Supervisor and Alternate Principal Supervisor
30 September 2016 (version 5)	9302	Addition of authorised person to list of authorised persons
30 September 2016 (version 5)	9302	Removal of authorised person from list of authorised persons following completion of training
6 October 2016 (version 6)	9502	Approval of amended Plain Language Statement
6 October 2016 (version 6)	9302	Removal of authorised person from list of authorised persons following completion of training
6 October 2016 (version 6)	9302	Removal of authorised person from list of authorised persons following completion of training
24 October 2016 (version 7)	9302	Addition of authorised person to list of authorised persons
9 March 2017 (version 8)	3001, 5001	Approval of modified 'Authorised use spreadsheet' and 'Consent notification spreadsheet'
9 March 2017 (version 8)	9402	Variation to reporting conditions relating to the completion of training
9 March 2017 (version 8)	9107, 9108	Clarification of conditions relating to use of excess ART embryos

31 March 2017 (version 9)	9302	Removal of authorised person from list of authorised persons following completion of training
28 November 2017 (version 10)	9402	Variation to reporting conditions relating to the definition of successful biopsy
28 November 2017 (version 10)	Expiry date	Extension of licence to 19 December 2020
14 June 2018 (version 11)	9302	Removal of authorised person from list of authorised persons following completion of training