



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:	309725
2.	Licence Holder:	TasIVF Pty Ltd
3.	Licence Title:	Use of excess ART embryos for blastocyst-stage embryo biopsy training
4.	Date of Issue:	1 September 2017
5.	Licence begins:	1 September 2017
6.	Licence ends:	1 September 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: <ul style="list-style-type: none">allow 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 <i>Standard Conditions of Licence</i> .
10.	Special Conditions:	All conditions that are specified in the <i>Special Conditions for Licence No. 309725</i> .

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 309725

Licence Number:	309725
Licence Holder:	TasIVF Pty Ltd
Licence Title:	Use of excess ART embryos for blastocyst-stage embryo 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

<i>Condition Number</i>	<i>Condition</i>
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, which was frozen at cleavage stage, 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. An excess ART embryo, which was frozen at blastocyst stage, 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 re-expands within 2 hours.
9103	A maximum of 52 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.
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Specified Sites

<i>Condition Number</i>	<i>Condition</i>
9201	The licence holder must conduct the use of excess ART embryos authorised by the licence at the following site: Tas IVF 2 Melville Street Hobart TAS 7000
9202	The licence holder must hold records (other than patient records) associated with the use authorised by the licence at the following site: Tas IVF 2 Melville Street Hobart TAS 7000
9203	Excess ART embryos used under this licence can only be obtained from the following sites: Tas IVF 2 Melville Street Hobart TAS 7000 Tas IVF Queen Victoria Tower Level 4, 11 High Street East Launceston TAS 7250
9204	The licence holder must hold patient records associated with the licensed activity at the following sites: Tas IVF 2 Melville Street Hobart TAS 7000 Tas IVF Queen Victoria Tower Level 4, 11 High Street East Launceston TAS 7250

Persons authorised to conduct the licensed activity

<i>Condition Number</i>	<i>Condition</i>
9301	<p>The Principal Supervisor is responsible for supervision of the activity authorised by the licence.</p> <p>The Principal Supervisor is that person identified at Attachment A to this licence.</p>
9302	<p>Only authorised personnel may conduct the activity authorised by this licence.</p> <p>The authorised personnel are the Principal Supervisor and those other persons identified at Attachment A to this licence.</p>
9303	<p>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.</p>
9304	<p>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:</p> <ul style="list-style-type: none"> (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	<p>A trainee must not use an excess ART embryo for training as authorised by this licence, unless the licence holder has first:</p> <ul style="list-style-type: none"> (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	<p>The Principal Supervisor (or an alternate Principal Supervisor, if any) must oversee all blastocyst biopsies conducted under this licence.</p>

Reporting

<i>Condition Number</i>	<i>Condition</i>
9401	<p>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:</p> <ul style="list-style-type: none">(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; and(iii) the progress of the training.
9402	<p>The licence holder is required to report to the NHMRC Licensing Committee within 14 days of a trainee reaching proficiency in blastocyst-stage biopsy. For the purposes of this condition the licence holder has defined proficiency as:</p> <ul style="list-style-type: none">(a) successful biopsy of the first 8 blastocysts or(b) successful biopsy of 11 out of the 15 suitable blastocysts allowed for that trainee. <p>In the foregoing, 'successful biopsy' means that the embryo survived, and transfer of biopsied cells to the sample tube was confirmed.</p>
9403	<p>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.</p>

Conditions relating to proper consent

<i>Condition Number</i>	<i>Condition</i>
9501	Only the consent process as described in the documents provided on 29 May 2017 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 26 October 2018 and Consent Form provided on 9 May 2017 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 1 month must be observed.

Other conditions

9601	<p>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.</p> <p>In the event that a trainee has reached proficiency or has obtained 15 suitable embryos and suitable embryos remain in culture:</p> <ul style="list-style-type: none">(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 for additional practice in the technique. In this case the total number of embryos used by the trainee must not exceed 20.
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Table of Variations

Date of Variation	Conditions Affected	Description of Changes
14 June 2018 (version 2)	9302	Removal of authorised person from list of authorised persons following completion of training
15 November 2018 (version 3)	9201-9204	Change of site of licensed activity, records storage and source of excess ART embryos
15 November 2018 (version 3)	9502	Amendments to Plain Language Statement following site change