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## 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 use of excess ART embryos specified below, subject to the conditions specified in items 8 and 9 below.

1. Licence number:	309700
2. Licence holder:	Monash IVF Pty Ltd
3. Licence title:	Use of Excess ART Embryos for Training in Embryo Biopsy
4. Date of issue:	11 March 2005
5. Licence begins:	11 March 2005
6. Licence ends:	11 March 2008 (surrendered 21 December 2007)
7. Use of excess ART embryos authorised by the licence	Training in the techniques of embryo biopsy to enable the embryologists so trained to remove a cell or cells from an embryo and leave it in a suitable condition for subsequent implantation.
8. Standard conditions	All conditions that are specified in the document <i>Standard Conditions for Using Excess ART Embryos</i> as currently published on <a href="http://www.nhmrc.gov.au/embryo">www.nhmrc.gov.au/embryo</a> and as amended from time to time.
9. Special conditions:	All conditions that are specified in the <i>Special Conditions for Licence No. 309700</i> .

The licence holder is reminded of the statutory provisions of the *Research Involving Human Embryos Act 2002* and the *Prohibition of Human Cloning Act 2002*.

Licence 309700 – version 2.0, 21 December 2007



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# Special Conditions for Licence No. 309700

1. Licence number:	309700
2. Licence holder:	Monash IVF Pty Ltd
3. Licence title:	Use of Excess ART Embryos for Training in Embryo Biopsy

The conditions that are specified below are the special conditions that apply to this licence. The *Special Conditions* operate **in addition to** all conditions identified in the *Standard Conditions for Using Excess ART Embryos*. The *Special Conditions* prevail where there is an inconsistency between a special condition and a standard condition.

### Number of embryos

Condition number	Condition
9101	A maximum of 175 excess ART embryos may be removed from cryostorage and thawed for the purposes of training a maximum of 7 trainees in embryo biopsy procedures and techniques.
9103	A maximum of 15 suitable excess ART embryos may be used to train each trainee described in condition 9303 in the technique of embryo biopsy.
9104	An excess ART embryo is taken to be suitable for the purposes of condition 9103 if it is an excess ART embryo which has greater than 50% of its blastomeres intact immediately following thawing.
9105	No excess ART embryo may be used to commence the training of any person unless the licence holder has first obtained proper consent to use at least 25 excess ART embryos in respect of that person.

## Specified sites

<i>Condition number</i>	<i>Condition</i>
9201	<p>The use authorised by the licence must be conducted at the following sites:</p> <p>Monash IVF, Epworth Hospital Level 4, 89 Bridge Rd Richmond Vic 3121</p> <p>Monash IVF, Monash Surgical Private Hospital 252-256 Clayton Rd Clayton VIC 3168</p> <p>Monash IVF Queensland Suite 12, McCullough Centre Sunnybank QLD 4109</p> <p>Monash IVF Gold Coast Suite 1, 25 Spindelove St Southport QLD 4215</p>
9202	<p>The licence holder must hold, or cause to be held, all records, including patient records, associated with the use authorised by the licence only at the following sites:</p> <p>Monash IVF, Epworth Hospital Level 4, 89 Bridge Rd Richmond Vic 3121</p> <p>Monash IVF, Monash Surgical Private Hospital 252-256 Clayton Rd Clayton VIC 3168</p> <p>Monash IVF Queensland Suite 12, McCullough Centre Sunnybank QLD 4109</p> <p>Monash IVF Gold Coast Suite 1, 25 Spindelove St Southport QLD 4215</p> <p>AusDoc Information Management Pty Ltd Store 1, 477 Plummer St Port Melbourne VIC 3207</p>

## Persons authorised to use excess ART embryos

Condition number	Condition
9301	The Principal Supervisor is that person identified in the application dated 16 April 2003 and lodged in accordance with s.20 of the <i>Research Involving Human Embryos Act 2002</i> , or as subsequently notified to and authorised by the NHMRC Licensing Committee. The Principal Supervisor is responsible for supervision of the use of excess ART embryos as authorised by the licence.
9302	Personnel authorised by the licence to conduct or supervise the authorised use of excess ART embryos are those identified in the attachments to the letter dated 11 September 2003 (2003/54643, f. 24), and lodged in accordance with s.20 of the <i>Research Involving Human Embryos Act 2002</i> , or as subsequently notified to and authorised by the NHMRC Licensing Committee.
9303	During the period of the licence the licence holder may train no more than 7 people in the technique of embryo biopsy. These people may be employees of the licence holder or employees of other organisations who are being trained at the sites operated by the licence holder as listed in condition 9201. These people are authorised to use excess ART embryos according to condition 9103. Before training commences the requirements of condition 9305 must be satisfied.
9304	The Principal Supervisor must ensure that, before any trainee uses an excess human ART embryo pursuant to this licence, that trainee has: <ul style="list-style-type: none"><li>(i) not previously received training in embryo biopsy techniques using live human embryos; and</li><li>(ii) been trained in embryo biopsy using animal embryos and dead human embryos before requesting training under this licence; and</li><li>(iii) demonstrated skill in the micromanipulation of animal and human gametes before requesting training under this licence.</li></ul>
9305	A trainee must not use an excess ART embryo pursuant to this licence, unless the licence holder has first: <ul style="list-style-type: none"><li>(i) submitted an application to the NHMRC Licensing Committee for that trainee to use excess ART embryos as authorised by this licence, the application format for which is that specified in the document 'Application to permit Trainee to use Excess ART Embryos' currently published at <a href="http://www.nhmrc.gov.au/embryo">www.nhmrc.gov.au/embryo</a>, and as amended from time to time; and</li><li>(ii) received approval in writing from the NHMRC Licensing Committee for the training of that trainee pursuant to this licence.</li></ul>

## Reporting

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- 9401 When reporting pursuant to 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 and employer of each individual who has received training as authorised by this licence;
  - (ii) the site/s where each trainee has been trained;
  - (iii) how many suitable embryos have been used for or by each trainee; and
  - (iv) the outcomes of the training.
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## Other Conditions

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- 9501 Excess ART embryos that have been used, pursuant to this licence, for training in embryo biopsy may subsequently be used to train trainees approved in accordance with condition 9305 in the technique of cell fixation before they are discarded. Use of excess ART embryos solely for training in cell fixation is not permitted.
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