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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:	309707
2. Licence holder:	Monash University
3. Licence title:	Derivation of embryonic stem cell lines from the human embryo
4. Date of issue:	21 December 2004
5. Licence begins:	21 December 2004
6. Licence ends:	21 December 2007 (expired)
7. Use of excess ART embryos authorised by the licence	Derivation of twenty embryonic stem cell lines from human embryos with improved properties relative to existing cell lines.
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. 309707</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 309707 – version 3.0, 21 December 2007



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## Research Involving Human Embryos Act 2002

### Embryo Research Licensing Committee of the NHMRC

# Special Conditions for Licence No. 309707

1. Licence number:	309707
2. Licence holder:	Monash University
3. Licence title:	Derivation of embryonic stem cell lines from the human embryo

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 200 excess ART embryos may be removed from cryostorage and thawed in connection with this licence.
9103	The excess ART embryos must only be used to isolate pluripotential cells in order to establish twenty embryonic stem cell lines and to undertake the activities and to achieve the goals proposed in Attachment 1 to the application dated 1 September 2003 and in the statements provided in the letters dated 10 December 2003 and 4 May 2004 and lodged in accordance with section 20 of the <i>Research Involving Human Embryos Act 2002</i> ("the licence application").

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9104	<p>No excess ART embryos may be removed from cryostorage and thawed in connection with this licence after the licence holder has established twenty embryonic stem cell lines according to the following criteria:</p> <ul style="list-style-type: none"><li>• the embryonic stem cell line must possess a normal human diploid karyotype, and express immunologically defined markers and genes specific for embryonic stem cells;</li><li>• initial studies indicate that the cell line is pluripotent and capable of self-renewal; and</li><li>• these lines must have been passaged ten times in culture, been successfully cryopreserved on two occasions and been shown to be free of contamination by microbial agents.</li></ul>
9105	<p>When twenty embryonic stem cell lines have been established in accordance with condition 9104, any remaining cell lines under evaluation may, subject to condition 9402, be used to meet the goals of the project as described in the documents referenced in condition 9103.</p>
9106	<p>The licence holder must not receive or accept any excess ART embryos unless the licence holder has first done both of the following:</p> <ul style="list-style-type: none"><li>(a) received from Monash IVF a valid consent in writing, for the purposes of section 35(2)(a) of the <i>Research Involving Human Embryos Act 2002</i> (the Act), for an inspector to enter its premises to inspect records which would reveal whether or not “proper consent”, as defined in the Act, has been given; and</li><li>(b) provided to the NHMRC Licensing Committee a copy of that written consent from the occupier to enter the premises.</li></ul>
9107	<p>The licence holder must implement practices and procedures and develop such protocols, as are practicable in all the circumstances, to ensure that the particular licence condition imposed by paragraph 24(1)(b) of the <i>Research Involving Human Embryos Act 2002</i> is fully complied with, specifically that no use can be made of an excess ART embryo unless the licence holder has satisfied itself that the NHMRC Licensing Committee has received a written report stating that proper consent exists in relation to the excess ART embryo intended to be used.</p>

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## 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 Institute of Reproduction and Development Level 3 27-31 Wright St Clayton VIC 3168</p> <p>Department of Physiology Monash University Ground Floor, Building 13f, Room FG29A Wellington Rd Clayton VIC 3168</p> <p>Monash Immunology and Stem Cell Laboratories Science, Technology, Research and Innovation Precinct Level 3 Wellington Rd Clayton VIC 3168</p>
9202	<p>The licence holder must hold records (other than patient records) associated with the use authorised by the licence at the following sites:</p> <p>Monash Institute of Reproduction and Development Level 3 27-31 Wright St Clayton VIC 3168</p> <p>Department of Physiology Monash University Ground Floor, Building 13f, Room FG29A Wellington Rd Clayton VIC 3168</p> <p>Science, Technology, Research and Innovation Precinct Level 3 Wellington Rd Clayton VIC 3168</p>

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9203      The licence holder must obtain excess ART embryos to be used in accordance with this licence only from the following sites:

Monash IVF, Epworth Hospital  
Level 4, 89 Bridge Rd  
Richmond Vic 3121

Monash IVF, Monash Surgical Private Hospital  
252-256 Clayton Rd  
Clayton VIC 3168

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9204      The patient records associated with those excess ART embryos referred to in condition 9203 must be held only at the following sites:

Monash IVF, Epworth Hospital  
Level 4, 89 Bridge Rd  
Richmond Vic 3121

Monash IVF, Monash Surgical Private Hospital  
252-256 Clayton Rd  
Clayton VIC 3168

AusDoc Information Management Pty Ltd  
Store 1, 477 Plummer St  
Port Melbourne VIC 3207

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## Persons authorised to use excess ART embryos

<i>Condition number</i>	<i>Condition</i>
9301	The Principal Supervisors are authorised by the licence to participate in the use of excess ART embryos. The Principal Supervisors are those persons identified in the application received on 17 September 2003 and lodged in accordance with section 20 of the <i>Research Involving Human Embryos Act 2002</i> , or as subsequently notified to and authorised by the Licensing Committee. The Principal Supervisors are responsible for supervision of the use of excess ART embryos as authorised by the licence.
9302	Other personnel authorised by the licence to participate in the use of excess ART embryos are those identified by the applicant on 26 July 2004 (2004/11879, folio 159), in the attachment to the application 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 Licensing Committee.

## Reporting

9401	The licence holder must report progress on establishing embryonic stem cell lines in writing to the NHMRC Licensing Committee when the first 50 of the 200 excess ART embryos authorised in condition 9101 have been used.
9402	<p>The licence holder must report immediately in writing to the Licensing Committee when each or either of the following situations arises:</p> <ul style="list-style-type: none"><li>(a) the combined total of:<ul style="list-style-type: none"><li>(i) the number of established embryonic stem cell lines, being fewer than twenty; and</li><li>(ii) the number of potential embryonic stem cell lines under investigation;</li></ul>exceeds twenty; or</li><li>(b) the number of established embryonic stem cell lines equals or exceeds twenty.</li></ul>
9403	In addition to the reports required by Standard Condition 3001, the licence holder is required to provide a further written report no later than 6 months following the expiry, revocation or surrender of the licence. This report must use the format specified in the document "Post-expiry report on embryonic stem cell lines established in accordance with a licence issued by the NHMRC Embryo Research Licensing Committee" as published and amended from time to time at the following website: <a href="http://www.nhmrc.gov.au/embryos/monitor/application/index.htm">http://www.nhmrc.gov.au/embryos/monitor/application/index.htm</a> .

## Other Conditions

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9501 The licence holder is required to report to the Licensing Committee within 14 days of the commencement of licensed work in the Science, Technology, Research and Innovation Precinct.

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Expired