



Australian Government

National Health and
Medical Research Council

N H M R C

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:	309709
2. Licence holder:	Melbourne IVF Pty Ltd
3. Licence title:	A collaborative project between Melbourne IVF Pty Ltd and Stem Cell Sciences Pty Ltd to derive Human Embryonic Stem Cell Lines
4. Date of issue:	11 June 2004
5. Licence begins:	11 June 2004
6. Licence ends:	16 November 2009
7. Use of excess ART embryos authorised by the licence	Isolation of the inner cell mass from excess human ART embryos in order to establish ten embryonic stem cell lines under improved and defined culture conditions and to characterise those cell lines and study their growth and directed differentiation.
8. Standard conditions	All conditions that are specified in the document <i>Standard Conditions for Using Excess ART Embryos</i> as currently published on www.nhmrc.gov.au/embryo and as amended from time to time.
9. Special conditions:	All conditions that are specified in the <i>Special Conditions for Licence No. 309709</i> .

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

309709 – Licence and Special Conditions – version 9.0, 27 July 2009

WORKING TO BUILD A HEALTHY AUSTRALIA

www.nhmrc.gov.au

GPO Box 1421, Canberra ACT 2601

16 Marcus Clarke Street, Canberra City ACT 2600

T. 13 000 NHMRC (13 000 64672) or +61 2 6217 9000 F. +61 2 6217 9100 E. nhmrc@nhmrc.gov.au

ABN 88 601 010 284



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Research Involving Human Embryos Act 2002

Embryo Research Licensing Committee of the NHMRC

Special Conditions for Licence No. 309709

Licence number:	309709
Licence holder:	Melbourne IVF Pty Ltd
Licence title:	A collaborative project between Melbourne IVF Pty Ltd and Stem Cell Sciences Pty Ltd to derive Human Embryonic Stem Cell Lines

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

<i>Condition number</i>	<i>Condition</i>
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 the inner cell mass in order to establish ten embryonic stem cell lines under improved and defined culture conditions and to characterise those cell lines and study their growth and directed differentiation.

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9104	<p>No excess ART embryos may be removed from cryostorage and thawed after Stem Cell Sciences Pty Ltd has established ten embryonic stem cell lines according to the following criteria:</p> <ul style="list-style-type: none"> • the ES cell line must possess a normal human diploid karyotype, and express immunologically defined markers and genes specific for embryonic stem cells; • initial studies indicate that the cell line is immortal and pluripotent; and • these lines must have been passaged ten times in culture and have been successfully cryopreserved on two occasions and shown to be free of contamination by adventitious agents.
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9105	<p>The licence holder may not remove from cryostorage for the purpose of conducting the use authorised by the licence a greater number of excess ART embryos than the number specified in condition 9101.</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 site:</p> <p>Melbourne IVF 320 Victoria Parade EAST MELBOURNE VIC 3002</p>
9202	<p>The licence holder must hold all records, including patient records, associated with the use authorised by the licence at the following sites:</p> <p>Melbourne IVF 320 Victoria Parade EAST MELBOURNE VIC 3002</p>

Persons authorised to use excess ART embryos

<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>Stem Cell Sciences Pty Ltd is authorised to participate in the use of excess ART embryos under this licence.</p>
9303	<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>

Reporting

9401	<p>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.</p>
9402	<p>Stem Cell Sciences Pty Ltd must report to the licence holder in writing as soon as the ten embryonic stem cell lines have been established.</p>
9403	<p>The licence holder must report to the NHMRC Licensing Committee in writing as soon as the ten embryonic stem cell lines have been established – refer to conditions 9104 and 9402.</p>
9404	<p>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: http://www.nhmrc.gov.au/embryos/monitor/application/index.htm.</p>
9405	<p>In order to implement the revised reporting periods set out in Condition 3001 of the Standard Conditions of Licence (version 7), the reporting period which commenced on 1 April 2009 will end on 31 August 2009. The written report required by Condition 3001 must be submitted to the Licensing Committee no later than 30 September 2009.</p>

Other Conditions

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| 9501 | Mouse feeder cells may only be used in the initial culture conditions for two of the ten intended stem cell lines. |
| 9502 | Stem Cell Sciences Pty Ltd must not unreasonably refuse to permit Inspectors appointed by the NHMRC Licensing Committee to access its premises for the purposes of ensuring compliance with special conditions 9103, 9104, 9401, 9402 and 9403. |
| 9503 | The <i>Standard Conditions of Licence</i> , which apply to the licence holder, also apply to Stem Cell Sciences Pty Ltd, except for conditions 2301, 3001, 4101, and 5001. |
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SURRENDERED

Table of Variations

Date of Variation	Conditions Affected	Description of Changes
27 April 2005 (version 2)*	9102	Deletion of condition to reflect operation of sunset clause
27 April 2005 (version 2)	Expiry date	Extension of licence to 11 June 2006
27 April 2005 (version 2)	4201	Addition of new standard condition
19 December 2005	3001, 5001	Variation of standard conditions to improve clarity
31 May 2006 (version 3)	Expiry date	Extension of licence to 11 June 2007
29 June 2006 (version 3)	3001	Variation of standard condition to require final report on licensed activity
29 June 2006 (version 3)	9404	Addition of special condition requiring post-expiry report
8 February 2007 (version 4)	Item 7, 9103, 9104, 9403	Increase number of cell lines permitted to be established under the licence
30 March 2007	9303	Removal of authorised person from list of authorised persons
15 May 2007 (version 5)	Expiry date	Extension of licence to 11 June 2008
21 May 2008 (version 6)	Expiry date	Extension of licence to 11 June 2009
28 August 2008	2001, 2301, 3001, 3101, 3102, 3104, 3201, 3401, 3601, 4001, 4002, 4101, 4102, 4201, 5001	Standard conditions varied to reflect the <i>Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006</i>
20 March 2009 (version 7)	Delete 1001-1004, 2102, 3101-3104, 4001 Add 1101, 3105, 9105, Table of Variations Vary 3001, 4201, 5001, 9301, 9303	Standard Conditions and Special Conditions varied to simplify and clarify requirements
3 June 2009 (version 8)	Expiry date	Extension of licence to 11 June 2010
27 July 2009 (version 9)	3001, 9405	Standard Conditions and Special Conditions varied to implement revised reporting periods

* Where a variation resulted in a new version of the licence being issued, the version number is indicated.