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National Health and Medical Research Council
NHMRC

INVESTING IN AUSTRALIA'S HEALTH
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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:	309708
2.	Licence holder:	IVF Australia Pty Ltd
3.	Licence title:	A collaborative project between IVF Australia and the Diabetes Transplant Unit, Prince of Wales Hospital to derive Human Embryonic Stem Cell Lines for the treatment of Diabetes
4.	Date of issue:	5 November 2004
5.	Licence begins:	5 November 2004
6.	Licence ends:	5 November 2008
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 six embryonic stem cell lines.
8.	Standard conditions	All conditions that are specified in the document *Standard Conditions for Using Excess ART Embryos* 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 *Special Conditions for Licence No. 309708.*

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*.

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Special Conditions for Licence No. 309708

1.	Licence number:	309708
2.	Licence holder:	IVF Australia Pty Ltd
3.	Licence title:	A collaborative project between IVF Australia and the Diabetes Transplant Unit, Prince of Wales Hospital to derive Human Embryonic Stem Cell Lines for the treatment of Diabetes

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	The licence holder may remove from cryostorage and thaw up to 100 excess ART embryos subject to the conditions contained in this licence.
9103	The excess ART embryos must only be used to isolate their inner cell masses.
9104	The licence holder is authorised to isolate inner cell masses and these must be transferred to the Diabetes Transplant Unit, Prince of Wales Hospital ("the Diabetes Transplant Unit") only for the purpose of establishing six (6) embryonic stem cell lines and undertaking the activities and achieving the goals proposed in Attachment 1 to the application dated 1 October 2003 and lodged in accordance with s.20 of the *Research Involving Human Embryos Act 2002* ("the licence application").

9105

(1) The licence holder is authorised to use the excess ART embryos mentioned in Condition 9101 to produce 6 established stem cell lines in accordance with Condition 9104.

(2) In the first stage of the licensed use, the licence holder is authorised to thaw up to 30 of the excess ART embryos to isolate inner cell masses. Should any inner cell masses be isolated, they shall be transferred to the Diabetes Transplant Unit. Should no inner cell masses result from the initial 30 embryos, a further 10 excess ART embryos may be thawed and any inner cell masses isolated from that further 10 shall be transferred to the Diabetes Transplant Unit. If no inner cell masses result from the initial 30 embryos and the further 10 embryos, then the licence holder must report promptly in writing to the Licensing Committee and no further embryos may be thawed without the written approval of the Licensing Committee.

(3) Following transfer of any inner cell masses isolated in the first stage, the licence holder shall request a report from the Diabetes Transplant Unit that describes the outcome for each inner cell mass supplied.

(4) The licence holder may not thaw any more excess ART embryos until the licence holder has received the report from the Diabetes Transplant Unit described in (3) above.

(5) If the report from the Diabetes Transplant Unit states that fewer than 6 embryonic stem cell lines have been established according to the criteria in Condition 9106 below, the licence holder may use up to 10 more excess ART embryos to isolate inner cell masses. Any additional inner cell masses that result must be transferred to the Diabetes Transplant Unit.

(6) Following the transfer in (5), the licence holder is again required to request a report from the Diabetes Transplant Unit that describes the outcome for each inner cell mass transferred and no further excess ART embryos may be thawed until that report has been received.

(7) If the report referred to in (6) states that fewer than 6 embryonic stem cell lines have been established according to the criteria in Condition 9106 below, the licence holder may again thaw up to 10 more excess ART embryos to derive additional inner cell masses and transfer these to the Diabetes Transplant Unit.

(8) This process of thawing batches of embryos and transferring inner cell masses in response to a report from the Diabetes Transplant Unit can continue as often as necessary, but subject to condition 9101 above, until 6 embryonic stem cell lines have been established according to the criteria in Condition 9106 below.

9106	No excess ART embryos may be removed from cryostorage and thawed after the Diabetes Transplant Unit has reported to the licence holder that it has established 6 embryonic stem cell lines according to the following criteria: • the embryonic stem cell line must possess a normal human diploid karyotype, and express antigens and genes specific for embryonic stem cells; • initial studies indicate that the cell line is pluripotent and capable of self-renewal; 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.
9107	When 6 embryonic stem cell lines are established in accordance with condition 9106, any remaining cell lines under evaluation by the Diabetes Transplant Unit may, subject to condition 9402, continue to be used to meet the goals of the project proposed in Attachment 1 to the application dated 1 October 2003 and lodged in accordance with s.20 of the *Research Involving Human Embryos Act 2002*.

Specified sites

Condition number	*Condition*
9201	The use of excess ART embryos authorised by the licence may only be conducted at the following sites: IVF Australia North Hunters Hill Hospital 9 Mount St HUNTERS HILL NSW 2110 IVF Australia Western Sydney City West Day Surgery 30 Mons Rd WESTMEAD NSW 2145 IVF Australia Eastern Suburbs Level 1 Maroubra Day Surgery 225 Maroubra Rd MAROUBRA NSW 2035

9202 The licence holder may only hold records (other than patient records) associated with the use authorised by the licence at the following sites:

IVF Australia North
Hunters Hill Hospital
9 Mount St
HUNTERS HILL NSW 2110

IVF Australia Western Sydney
City West Day Surgery
30 Mons Rd
WESTMEAD NSW 2145

IVF Australia Eastern Suburbs
Level 1
Maroubra Day Surgery
225 Maroubra Rd
MAROUBRA NSW 2035

9203 The licence holder may only hold patient records associated with the excess ART embryos used in accordance with this licence at the following sites:

IVF Australia North
Level 1
24 Thomas St
CHATSWOOD NSW 2067

IVF Australia Central Coast
Suite 24, Level 2
207 North Albany Street
Gosford, NSW, 2250

IVF Australia Western Sydney
12 Caroline St
WESTMEAD NSW 2145

IVF Australia Eastern Suburbs
Level 1
Maroubra Day Surgery
225 Maroubra Rd
MAROUBRA NSW 2035

IVF Australia Southern Sydney
Level 3
St George Private Hospital
South St
KOGARAH NSW 2217

Persons authorised to use excess ART embryos

Condition number	*Condition*
9301	The Principal Supervisor is authorised by the licence to participate in the use of excess ART embryos. The Principal Supervisor is that person identified in Section A Part 2 of the application dated 1 October 2003 (2003/59734, f. 18) and lodged in accordance with s.20 of the *Research Involving Human Embryos Act 2002*, or as subsequently notified to and authorised by the Licensing Committee. The Principal Supervisor is 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 in the attachments received on 16 December 2003 (2003/59734, f. 77) and 25 May 2004 (2004/30104, f. 15) to the application dated 1 October 2003, and lodged in accordance with s.20 of the *Research Involving Human Embryos Act 2002*, 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 40 of the 100 excess ART embryos authorised in condition 9101 have been used.
9402	The licence holder must report immediately in writing to the Licensing Committee when each or either of the following situations arises: (a) the combined total of: (i) the number of established embryonic stem cell lines, being fewer than 6; and (ii) the number of potential embryonic stem cell lines under investigation exceeds 6; and (b) the number of established embryonic stem cell lines equals or exceeds 6.
9403	In the event that any potential lines under evaluation referred to in condition 9402 above, result in the establishment of one or more embryonic stem cell lines so that the total number of embryonic stem cell lines exceeds the authorised limit of 6 as provided in condition 9104, then the licence holder must immediately report that fact in writing to the Licensing Committee.
9404	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.

Variation – effective 26 February 2008

The variation affects the following conditions:

Specified sites

Condition No.	
9201	Vary the condition to add a new address: IVF Australia North 176 Pacific Highway Greenwich NSW 2065 Other addresses remain unchanged.
9202	Vary the condition to add a new address: IVF Australia North 176 Pacific Highway Greenwich NSW 2065 Other addresses remain unchanged.
9203	Vary the condition to add a new address: IVF Australia North 176 Pacific Highway Greenwich NSW 2065 Other addresses remain unchanged.

Variation – effective 24 April 2008

The variation affects the following conditions:

Specified sites

Condition No.	
9201	Vary the condition to remove the following address: IVF Australia North Hunters Hill Hospital 9 Mount St HUNTERS HILL NSW 2110 Other addresses remain unchanged.
9202	Vary the condition to remove the following address: IVF Australia North Hunters Hill Hospital 9 Mount St HUNTERS HILL NSW 2110 Other addresses remain unchanged.
9203	Vary the condition to remove the following address: IVF Australia North Level 1, 24 Thomas St CHATSWOOD NSW 2067 Other addresses remain unchanged.