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:	309722
2.	Licence Holder:	Monash IVF Pty Ltd
3:	Licence Title:	Optimising embryo-endometrial interactions to improve pregnancy success during IVF
4.	Date of Issue:	11 December 2013
5.	Licence begins:	11 December 2013
6.	Licence ends:	11 December 2016
7.	Activity authorised by the licence:	The licence authorises removal of trophectoderm cells from excess ART embryos for use in studies of the interactions between trophectoderm and endometrial cells.
8.	Goals of the Activity:	The goals of the licensed activity are: • to determine which factors and pathways in trophectoderm-endometrium interactions are necessary for successful embryo implantation, and • to correlate these factors and pathways with embryo appearance *in vitro*.
9.	Standard Conditions:	All conditions that are specified in the *Standard Conditions of Licence*.
10.	Special Conditions:	All conditions that are specified in the *Special Conditions for Licence No. 309722*.

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 309722

Licence Number:	309722
Licence Holder:	Monash IVF Pty Ltd
Licence Title:	Optimising embryo-endometrial interactions to improve pregnancy success during IVF

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 embryos

Condition Number	*Condition*
9101	The licence holder is authorised to use up to 200 excess ART embryos to study the interactions between trophectoderm and human endometrial cells.
9102	The licence holder may not remove from cryostorage a greater number of excess ART embryos than the number specified in condition 9101 for the purpose of conducting the activity authorised by the licence.
9103	After the trophectoderm cells have been removed from each excess ART embryo, the inner cell mass must be allowed to succumb and must not be used in any experiments.
9104	The trophectoderm cells must be transferred to the Hudson Institute of Medical Research only for the purpose of conducting the studies proposed in the version of the application submitted on 22 November 2013 in accordance with s.20 of the *Research Involving Human Embryos Act 2002*.
9105	In the first stage of the licensed activity, the licence holder is authorised to thaw up to 60 excess ART embryos to allow the researchers at the Hudson Institute of Medical Research to conduct the pilot study proposed in the version of the application submitted on 22 November 2013 in accordance with s.20 of the *Research Involving Human Embryos Act 2002*. The licence holder may not thaw any more excess ART embryos until the requirements of condition 9401 have been met.
9106	In the second stage of the study the licence holder may only thaw the number of embryos determined by the Licensing Committee following its consideration of the report required by Condition 9401.

9107	Aneuploidy testing may be conducted on the excess ART embryos, as requested in the version of the application submitted on 16 May 2016.
9108	In the second stage of the study the licence holder may thaw up to 140 excess ART embryos.

Specified Sites

Condition Number	*Condition*
9201	The licence holder must conduct the use of excess ART embryos authorised by the licence at the following site: Monash IVF Pty Ltd Suite 1, 252-262 Clayton Road Clayton VIC 3168
9202	The licence holder must hold records (other than patient records) associated with the use authorised by the licence at the following sites: Monash IVF Pty Ltd Suite 1, 252-256 Clayton Road Clayton VIC 3168 Hudson Institute of Medical Research Level 4, Block E 246 Clayton Road Clayton VIC 3168
9203	The licence holder must hold patient records associated with the licensed activity at the following site: Monash IVF Pty Ltd Suite 1, 252-256 Clayton Road Clayton VIC 3168

Persons authorised to conduct the licensed activity

Condition Number	*Condition*
9301	The Principal Supervisors are the persons identified at **Attachment A** to this licence. The Principal Supervisors are responsible for supervision of the activity authorised by the licence.
9302	Only authorised personnel may conduct the activity authorised by this licence. The authorised personnel are the Principal Supervisors and those other persons identified at **Attachment A** to this licence.

Reporting

Condition Number	*Condition*
9401	Within 30 days of the completion of the pilot study, the licence holder must have requested and received a report on the outcomes of the pilot study and provided the report to the Embryo Research Licensing Committee. The report must state the numbers of excess ART embryos proposed to be used in the second stage of the study.
9402	When providing the 6-monthly reports required by Condition 3001, the licence holder is required to obtain and include information about the outcomes of use of the trophectoderm cells that have been transferred to Hudson Institute of Medical Research.

Conditions relating to proper consent

Condition Number	*Condition*
9501	Only the consent process as described in the documents provided on 22 November 2013 and subsequently approved by the Licensing Committee may be used for obtaining proper consent to use excess ART embryos in the activities permitted by this licence.
9502	From 11 December 2013 only the Plain Language Statement and Participant Information and Consent Forms provided on 22 November 2013 and approved by the 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 4 weeks must be observed.

Other conditions

Condition Number	*Condition*
9601	Hudson Institute of Medical Research 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 9104, 9105 and 9202.
9602	The *Standard Conditions of Licence*, which apply to the licence holder, also apply to Hudson Institute of Medical Research, except for conditions 3001, 4201, 5001 and 5002.

Table of Variations

Date of Variation	Conditions Affected	Description of Changes
27 August 2014 (version 2)	2301, 2302, 4301	Variation to Standard Conditions of Licence
27 August 2014 (version 2)	9104, 9105, 9202, 9402, 9601, 9602	Record new name of collaborating organisation
25 November 2015 (Version 3)	9301	Departure of Principal Supervisor Approval of new Principal Supervisor
25 November 2015 (Version 3)	9104, 9105, 9202, 9402, 9601, 9602	Record new name of collaborating organisation
24 June 2016 (version 4)	9107	Variation to the authorised activity
6 October 2016 (version 5)	9108	Variation to number of excess ART embryos authorised to be used
11 December 2016 (version 6)	Expiry	Licence expired