



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.

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| 1. | Licence Number: | 309724 |
| 2. | Licence Holder: | IVFAustralia Pty Ltd |
| 3. | Licence Title: | Use of excess ART embryos for blastocyst-stage biopsy training |
| 4. | Date of Issue: | 21 April 2017 |
| 5. | Licence begins: | 21 April 2017 |
| 6. | Licence ends: | 21 April 2020 |
| 7. | Activity authorised by the licence: | <p>This licence authorises trainee embryologists to use excess ART embryos to attain proficiency in blastocyst-stage embryo biopsy.</p> <p>The embryos to be used under this licence are frozen embryos which have been declared to be excess to the reproductive needs of the responsible people concerned.</p> |
| 8. | Goals of the Activity: | <p>The goals of the licensed activity are to:</p> <ul style="list-style-type: none">allow embryologists to achieve competence in the technique of blastocyst-stage embryo biopsy through the use of limited numbers of excess ART embryos. |
| 9. | Standard Conditions: | All conditions that are specified in the <i>Standard Conditions of Licence</i> |
| 10. | Special Conditions: | All conditions that are specified in the <i>Special Conditions for Licence No. 309724</i> |

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 309724

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|-----------------|--|
| Licence Number: | 309724 |
| Licence Holder: | IVFAustralia Pty Ltd |
| Licence Title: | Use of excess ART embryos for blastocyst-stage biopsy training |

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 excess ART embryos

| <i>Condition Number</i> | <i>Condition</i> |
|-------------------------|---|
| 9101 | Except as allowed by Condition 9601, a maximum of 15 suitable excess ART embryos may be used to train each trainee authorised by condition 9303 to learn the technique of blastocyst-stage biopsy described on page 19 of the application submitted on 18 February 2017. |
| 9102 | A maximum of 24 excess ART embryos may be removed from cryostorage and thawed in order to obtain the 15 suitable blastocyst stage embryos for the purposes of training each trainee as permitted by condition 9101. Embryos must be thawed by a person named in Attachment A to this licence. |
| 9103 | When a trainee has used 15 suitable embryos or has reached proficiency as described in Condition 9402, the licence holder is not permitted to thaw any more excess ART embryos for that trainee. |
| 9104 | The training of a trainee may not commence unless the licence holder has obtained proper consent to use at least 12 excess ART embryos in respect of that trainee. |
| 9105 | An excess ART embryo is taken to be suitable for the purposes of condition 9101 if it was frozen at blastocyst stage and it re-expands in 1 to 3 hours following thawing. |
| 9106 | The excess ART embryos donated to this licence must not be used for any purpose except training in blastocyst-stage embryo biopsy. Any embryo which is not suitable for the purposes of Condition 9101 must be discarded when it is determined to be unsuitable. |

Specified Sites

| <i>Condition Number</i> | <i>Condition</i> |
|-------------------------|---|
| 9201 | <p>The licence holder must conduct the use of excess ART embryos authorised by the licence at the following sites:</p> <p>IVFAustralia – North Shore Level 2, 176 Pacific Highway Greenwich NSW 2065</p> <p>IVFAustralia – Eastern Suburbs Level 3, 15 Bowden Street Alexandria NSW 2015</p> <p>IVFAustralia – Western Suburbs Level 2, 20-22 Mons Road Westmead NSW 2145</p> <p>IVFAustralia (Canberra Fertility Centre) Suite 9, Level 2, Clinical Services Building John James Health Care Campus Strickland Crescent Deakin ACT 2600</p> <p>IVFAustralia (Hunter IVF) Suite 9, Cambridge Building Newcastle Private Hospital 14 Lookout Road New Lambton Heights NSW 2305</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>IVFAustralia – North Shore Level 2, 176 Pacific Highway Greenwich NSW 2065</p> <p>IVFAustralia – Eastern Suburbs Level 3, 15 Bowden Street Alexandria NSW 2015</p> <p>IVFAustralia – Western Suburbs Level 2, 20-22 Mons Road Westmead NSW 2145</p> <p>IVFAustralia (Canberra Fertility Centre) Suite 9, Level 2, Clinical Services Building John James Health Care Campus Strickland Crescent Deakin ACT 2600</p> <p>IVFAustralia (Hunter IVF) Suite 9, Cambridge Building Newcastle Private Hospital 14 Lookout Road New Lambton Heights NSW 2305</p> |

9203

Excess ART embryos used under this licence can only be obtained from the following sites:

IVFAustralia – North Shore
Level 2, 176 Pacific Highway
Greenwich NSW 2065

IVFAustralia – Eastern Suburbs
Level 3, 15 Bowden St
Alexandria NSW 2015

IVFAustralia – Western Suburbs
Level 2, 20-22 Mons Road
Westmead NSW 2145

IVFAustralia (Canberra Fertility Centre)
Suite 9, Level 2, Clinical Services Building
John James Health Care Campus
Strickland Crescent
Deakin ACT 2600

IVFAustralia (Hunter IVF)
Suite 9, Cambridge Building
Newcastle Private Hospital
14 Lookout Road
New Lambton Heights NSW 2305

IVFAustralia – Central Coast
Suite 2, 207 Albany St North
Gosford NSW 2250

9204

The licence holder must hold patient records associated with the licensed activity at the following sites:

IVFAustralia – North Shore
Level 2, 176 Pacific Highway
Greenwich NSW 2065

IVFAustralia – Eastern Suburbs
Level 3, 15 Bowden St
Alexandria NSW 2015

IVFAustralia – Western Suburbs
Level 2, 20-22 Mons Road
Westmead NSW 2145

IVFAustralia (Canberra Fertility Centre)
Suite 9, Level 2, Clinical Services Building
John James Health Care Campus
Strickland Crescent
Deakin ACT 2600

IVFAustralia (Hunter IVF)
Suite 9, Cambridge Building
Newcastle Private Hospital
14 Lookout Road
New Lambton Heights NSW 2305

IVFAustralia – Central Coast
Suite 2, 207 Albany St North
Gosford NSW 2250

IronMountain Australia
15 -23 Quarry Road
Erskine Park NSW 2759

IronMountain Australia
1 Johnston Rd
Campbelltown NSW 2560

9205

All records relating to the licensed activity must be accessible on-line from any of the sites listed in Condition 9201.

Persons authorised to conduct the licensed activity

| <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>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> |
| 9303 | <p>This licence authorises those people listed as trainees in Attachment A to be trained in the technique of blastocyst stage embryo biopsy.</p> <p>Other trainees may be permitted to undertake training in the future provided the requirements of Condition 9305 are satisfied in relation to each proposed trainee.</p> |
| 9304 | <p>Unless otherwise authorised by the Licensing Committee, the Principal Supervisor must ensure that, before any trainee uses an excess human ART embryo pursuant to this licence, that trainee has:</p> <ul style="list-style-type: none">(i) not previously performed blastocyst stage biopsies in a clinical setting(ii) not previously received training in blastocyst stage biopsy techniques using live human embryos; and(iii) demonstrated skill in blastocyst stage biopsy using animal embryos and dead human embryos before requesting training under this licence; and(iv) demonstrated skill in the micromanipulation of animal and human gametes and embryos before requesting training under this licence. |
| 9305 | <p>A trainee must not use an excess ART embryo for training in blastocyst-stage embryo biopsy as authorised by this licence, unless the licence holder has first:</p> <ul style="list-style-type: none">(i) submitted an application to the NHMRC Licensing Committee as specified at https://www.nhmrc.gov.au/research/embryo-research-licensing/information-applicants for that person to use excess ART embryos as authorised by this licence; and(ii) received approval in writing from the NHMRC Licensing Committee for the training of that person pursuant to this licence. |
| 9306 | <p>The Principal Supervisor (or an alternate Principal Supervisor, if any) must observe each blastocyst biopsy conducted under this licence.</p> |

Reporting

| <i>Condition Number</i> | <i>Condition</i> |
|-------------------------|--|
| 9401 | <p>When providing the reports required by condition 3001, the licence holder must provide the following information to the NHMRC Licensing Committee in addition to the requirements specified in condition 3001:</p> <ul style="list-style-type: none">(i) the name of each individual who has received training as authorised by this licence during the reporting period;(ii) how many suitable embryos have been used for or by each trainee; and(iii) the progress of the training. |
| 9402 | <p>The licence holder is required to report to the NHMRC Licensing Committee within 14 days of a trainee reaching proficiency in the method of blastocyst biopsy described in the application submitted on 18 February 2017.</p> <p>For the purposes of this condition the licence holder has defined proficiency as:</p> <ul style="list-style-type: none">(a) successful biopsy of 8 of the first 10 blastocysts; or(b) successful biopsy of 12 of the 15 suitable blastocysts allowed for that trainee. <p>In the foregoing, 'successful biopsy' means that the embryo survived, as shown by re-expansion 3 to 4 hours after the biopsy and survival of $\geq 50\%$ of the trophectoderm cells, and successful transfer of the biopsied cells was demonstrated, as shown by the presence of DNA in the sample tube.</p> |
| 9403 | <p>The licence holder is required to notify the NHMRC Licensing Committee in writing within 14 days if a trainee uses more than 15 suitable embryos as permitted by Condition 9601.</p> |

Conditions relating to proper consent

| <i>Condition Number</i> | <i>Condition</i> |
|-------------------------|--|
| 9501 | Only the consent process as described in the documents submitted on 18 February 2017 and subsequently approved by the NHMRC Licensing Committee may be used for obtaining proper consent to use excess ART embryos in the activities permitted by this licence. |
| 9502 | Only the <i>Plain Language Statement</i> provided on 18 February 2017 and <i>Consent for the use of excess embryos in a research project</i> Form provided on 18 February 2017 and approved by the NHMRC 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 2 weeks must be observed. |

Other conditions

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| 9601 | <p>Licence holders are required to manage the number of excess ART embryos thawed for use under the licence to limit the likelihood of obtaining greater than the allowable number of suitable embryos per trainee.</p> <p>In the event that a trainee has reached proficiency or has obtained 15 suitable embryos and suitable embryos remain in culture:</p> <ul style="list-style-type: none">(a) the excess suitable embryos may be transferred to another trainee who has not yet biopsied 15 suitable embryos or reached proficiency; or(b) where the excess suitable embryos cannot be used by another trainee, the trainee for whom the embryos were initially thawed may use the excess embryos for additional practice in the technique. In this case the total number of embryos used by the trainee must not exceed 20. |
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Table of Variations

| Date of Variation | Conditions Affected | Description of Changes |
|---------------------------------|----------------------------|---|
| 14 June 2018 (version 2) | 9302 | Removal of authorised person from list of authorised persons following completion of training |
| 14 June 2018 (version 2) | 9402 | Variation to reporting conditions relating to the definition of successful biopsy |
| 15 November 2018 (version 3) | 9201-9204 | Change of site of licensed activity, records storage and source of excess ART embryos |