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: | 309727 |
| 2. | Licence Holder: | Melbourne IVF Pty Ltd |
| 3: | Licence Title: | Comprehensive chromosomal analysis of human preimplantation embryos |
| 4. | Date of Issue: | 15 August 2022 |
| 5. | Licence begins: | 15 August 2022 |
| 6. | Licence ends: | 14 August 2025 |
| 7. | Activity authorised by the licence: | This licence authorises the culture and biopsy of excess ART embryos in order to assess the concordance between chromosomal analysis of the embryo and the media the embryo was cultured in. |
| 8. | Goal of the Activity: | The goal of the licensed activity is to better understand the human preimplantation embryo and its likelihood for implantation by analysing the chromosome status of the different parts of the embryo as well as the culture media the embryo was grown in. |
| 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 309727*. |

**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 309727

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|---|---|
| Licence Number: | 309727 |
| Licence Holder: | Melbourne IVF Pty Ltd |
| Licence Title: | Comprehensive chromosomal analysis of human preimplantation embryos |

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

| *Condition Number* | *Condition* |
|---|---|
| 9101 | A maximum of 100 excess ART embryos may be used for the activity authorised by the licence. |
| 9102 | A maximum of 200 excess ART embryos may be removed from cryostorage and thawed in order to obtain the 100 embryos for use in the activity authorised by the licence. |

## Specified Sites

| *Condition Number* | *Condition* |
|---|---|
| 9201 | The licence holder must conduct the activity authorised by the licence at the following site: Melbourne IVF, Level 1, 344 Victoria Parade, East Melbourne VIC 3002 |
| 9202 | The licence holder must hold records (other than patient records) associated with the activity authorised by the licence at the following site: Melbourne IVF, Ground Floor and Level 1, 344 Victoria Parade, East Melbourne VIC 3002 |
| 9203 | The licence holder must hold patient records associated with the activity authorised by the licence at the following site: Melbourne IVF, 344 Victoria Parade, East Melbourne VIC 3002 |

## Persons authorised to conduct the licensed activity

| *Condition Number* | *Condition* |
|---|---|
| 9301 | The Principal Supervisor is responsible for supervision of the activity authorised by the licence. |
| 9302 | The Alternative Principal Supervisor is responsible for supervision of the activity authorised by the licence wherever the absence of the Principal Supervisor is documented by the licence holder. |
| 9303 | Only Authorised Personnel may conduct the activity authorised by the licence. Authorised Personnel include the Principal Supervisor, Alternative Principal Supervisor and those other persons identified at **Attachment A** to this licence. |

## Reporting

| *Condition Number* | *Condition* |
|---|---|
| 9401 | The licence holder must provide the Licencing Committee with an interim report on outcomes from the activity authorised by the licence before exceeding the testing of 50 embryos under condition 9101. This report will detail:<br>– the number of embryos used under conditions 9101 and 9102<br>– the preliminary results of the activity authorised by the licence<br>– any planned amendment to the project design or adjustment to the project assumptions. |
| 9402 | The licence holder must provide any additional information requested by the Licencing Committee following consideration of the interim report. |

## Conditions relating to proper consent

| *Condition Number* | *Condition* |
|---|---|
| 9501 | To obtain proper consent to use excess ART embryos in the activities authorised by the licence the Licence Holder must use the consent process described in the documents provided to the Licencing Committee on 7 November 2019 and subsequently approved by the Licensing Committee on the Licence date of issue. |
| 9502 | For the avoidance of doubt, the requirements of Condition 9501 include use of the Plain Language Statement and Consent Form provided to the Licencing Committee on 7 November 2019 and approved by the Licensing Committee on the Licence date of issue. |
| 9503 | A ‘cooling off’ period of at least 14 days is required between obtaining proper consent and use of excess ART embryos in activities authorised under the licence. This is to be documented as part of the consent process. |

## Other conditions

| *Condition Number* | *Condition* |
|---|---|
| 9601 | The Licence Holder must lodge an application to vary the licence for any significant amendments to the activity authorised by the licence identified though Condition 9401, or at any other point in the life of the licence, including change to the experimental paradigm or goal. |

# Licence 309727: Table of Variations

| *Date of Variation* | *Conditions Affected* | *Description of Changes* |
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