Australian Government

National Health and Medical Research Council

Research Involving Human Embryos Act 2002

Embryo Research Licensing Committee of the NHMRC

Standard Conditions of Licence

This document specifies the standard conditions that apply to licences that are issued by the Embryo Research Licensing Committee of the NHMRC (the NHMRC Licensing Committee) under the *Research Involving Human Embryos Act 2002* and corresponding State laws for the use of excess ART embryos, or human eggs or the creation or use of other embryos. The *Standard Conditions* apply to *every* licence unless the *Special Conditions* for a particular licence provide that a specific standard condition does not apply to that licence.

Current contact details

Condition number	*Condition*
1101	The licence holder must give written notice to the NHMRC Licensing Committee of a proposed change in their organisation's or their primary contact person's telephone number, email address or postal address.

Persons authorised to participate in the licensed activity

Condition number	*Condition*
2001	The licence holder must ensure that each person who is authorised to participate in the licensed activity is at all times fully informed of the requirements of the licence, the *Research Involving Human Embryos Act 2002*, the *Prohibition of Human Cloning for Reproduction Act 2002* and any corresponding State law.
2101	The licence holder must not permit a person to participate in the licensed activity unless the person is authorised to do so in the licence conditions.
2301	The licence holder must give written notice to the NHMRC Licensing Committee no later than 7 days after a person who is identified in the licence conditions as the Principal Supervisor: (a) ceases to be involved in the licensed activity; or (b) is, for any reason, temporarily unable to perform the duties of the Principal Supervisor.
2302	Condition 4301 does not apply if the NHMRC Licensing Committee has previously approved more than one Principal Supervisor from the licence holder organisation.

Reporting

Condition number	*Condition*
3001	During the currency of the licence, the licence holder must submit a written report to the Licensing Committee no later than 30 days after the end of each reporting period. The reporting periods run from 1 March to 31 August and 1 September to 28 February (or 29 February in leap years). Each report must be submitted in the format specified in the document "Six monthly report on licensed activities" and the cumulative details of authorised use in the spreadsheet "Authorised use spreadsheet" as published and amended from time to time on the NHMRC website: http://www.nhmrc.gov.au *or* in an alternative format which has previously been approved in writing by the Chair of the NHMRC Licensing Committee. Prior to the expiry or surrender of the licence, the licence holder must also submit to the NHMRC Licensing Committee a written report in the format specified in the document "Final report on licensed activities" and the cumulative details of authorised use in the spreadsheet "Authorised use spreadsheet" as published and amended from time to time on the NHMRC website: http://www.nhmrc.gov.au *or* in an alternative format which has previously been approved in writing by the Chair of the NHMRC Licensing Committee.
3105	If the licence holder becomes aware of a non-compliance with a licence condition, the *Research Involving Human Embryos Act 2002*, the *Prohibition of Human Cloning for Reproduction Act 2002*, or any corresponding State law, the licence holder must within 7 days provide a written report to the NHMRC Licensing Committee. A written report provided in accordance with this condition must include details on the following matters: (a) The activity or conduct that the licence holder believes may constitute a non-compliance; (b) The names of the persons who participated in the activity or conduct and their role in the organisation; (c) The period during which this activity or conduct took place; (d) The site at which this activity or conduct took place; and (e) The circumstances that led to the activity or conduct that the licence holder believes may constitute a non-compliance. Where the licence holder is an individual, the licence holder is not required to give information that might tend to incriminate the individual or expose the individual to a penalty.
3201	The licence holder must immediately, by notice in writing, inform the NHMRC Licensing Committee of any investigation or prosecution by a Commonwealth, State or Territory agency that involves any matters that might reasonably be considered to affect the suitability of the licence holder to undertake the activity authorised by the licence.

Monitoring

3401	The licence holder must implement and maintain processes that ensure that adequate records are made and stored to allow the conduct of the licensed activity to be monitored for compliance with the requirements of the licence, the *Research Involving Human Embryos Act 2002*, the *Prohibition of Human Cloning for Reproduction Act 2002* and any corresponding State law.
3501	The licence holder must not unreasonably refuse to provide any additional information requested by the NHMRC Licensing Committee. The information must be in the form, if any, specified in the request.
3601	The licence holder must provide reasonable assistance and cooperation to the NHMRC Licensing Committee and its Inspectors in carrying out their powers, functions and duties under the *Research Involving Human Embryos Act 2002*, the *Prohibition of Human Cloning for Reproduction Act 2002*, and any corresponding State law.

Use of excess ART embryos or human eggs, or creation or use of other embryos

Condition number	*Condition*
4101	The licence holder must maintain a tracking system that uniquely identifies each excess ART embryo or human egg used or other embryo created or used in connection with the licence. The tracking system must link the unique identifier for each individual embryo or egg to a specific licence and each 'responsible person'; 'responsible person' has the same meaning as in s.8 of the *Research Involving Human Embryos Act 2002*.
4102	The licence holder must record an outcome for each individual excess ART embryo or human egg used or other embryo created or used in the licensed activity, linking the outcome to the unique identifier for that embryo or egg.
4201	Prior to the expiry or surrender of the licence, the licence holder must review the consent forms relating to any embryos or eggs still held in storage by the licence holder and must deal with those embryos or eggs in accordance with the instructions, if any, given by the responsible persons when proper consent was obtained. If the consent forms do not contain the relevant instructions, the licence holder must: (a) take all reasonable steps to inform the responsible persons who provided the proper consent that their embryos or eggs have not been used under the licence; and (b) inform the responsible persons that the options in respect of those embryos or eggs are to allow them to succumb or, if applicable, to consider giving consent to donating them to another project or, if applicable, to consider donating the embryos for the purpose of achieving pregnancy in another woman; and (c) deal with the embryos or eggs in accordance with the instructions obtained from the responsible persons.

4301	If the licence holder is required to provide written notice according to Condition 2301, all use of excess ART embryos or human eggs or creation and/or use of other embryos authorised by the licence must cease: (a) from the date the Principal Supervisor ceases to be involved in the licensed activity until the NHMRC Licensing Committee has approved the licence holder's application for a person to be identified in the licence conditions as the new Principal Supervisor, or (b) from the date the licence holder notifies the NHMRC Licensing Committee that the Principal Supervisor is temporarily absent until the licence holder has advised the NHMRC Licensing Committee that the Principal Supervisor has returned to duty.

Conditions relating to proper consent

Condition number	*Condition*
5001	For the purposes of complying with s.24(1)(b) of the *Research Involving Human Embryos Act 2002*, the licence holder must report to the NHMRC Licensing Committee that 'proper consent' has been obtained using the "consent notification spreadsheet" as published and amended from time to time on the NHMRC website: http://www.nhmrc.gov.au *or* in an alternative format which has previously been approved in writing by the Chair of the NHMRC Licensing Committee. Notification must be provided prior to the authorised activity being conducted. 'Proper consent' has the same meaning as in s.8 of the *Research Involving Human Embryos Act 2002*.
5002	The licence holder must ensure that only the consent protocols (including the participant information and consent forms), as assessed by the HREC, and as approved by the Licensing Committee at issue of the licence (or as subsequently varied and approved by the Licensing Committee) are used for obtaining proper consent under this licence.

HREC approval during the period of the licence

Condition number	*Condition*
6001	If the HREC that assessed the project ceases responsibility for ethical oversight of the project, the licence holder must notify the Licensing Committee within five (5) working days. The licence holder must provide information on the reasons for the change in HREC and written confirmation from the Chair of the new HREC that they will be responsible for the ethical oversight of the project.
6002	If the HREC that has ethical oversight of the project withdraws or suspends approval for the project, the licence holder must immediately suspend all licensed activities. The licence holder must inform the Licensing Committee of the withdrawal or suspension of HREC approval within two (2) working days. Licensed activities may not recommence until the Licensing Committee has granted approval for this to occur.