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NHMRC Embryo Research Licensing Committee: Information Kit

WORKING TO BUILD A HEALTHY AUSTRALIA

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Explanation of Key Terms

Accredited ART centre	A person or body accredited to carry out assisted reproductive technology by: (a) The Reproductive Technology Accreditation Committee of the Fertility Society of Australia (a) If the regulations prescribe another body or other bodies in addition to, or instead of, the body mentioned in paragraph (a) – that other body or any of those other bodies, as the case requires. [RIHE s8]
AFP	Australian Federal Police
Amendment Act	*Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (an Act to amend the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002* based on the Lockhart Report recommendations, and for related purposes)
ART	Assisted Reproductive Technology
ART Guidelines	*Ethical Guidelines on the use of Assisted Reproductive Technology in Clinical Practice and Research, 2017*
CEO	Chief Executive Officer
CDPP	Commonwealth Director of Public Prosecutions
COAG	The Council of Australian Governments
Embryo Research Licensing	NHMRC staff providing support to the NHMRC Licensing Committee
Excess ART embryo	A human embryo that: (a) was created, by assisted reproductive technology, for use in the assisted reproductive technology treatment of a woman; and (b) is excess to the needs of: (i) the woman for whom it was created; and (ii) her spouse (if any) at the time the embryo was created. For the purposes of paragraph (b) of the definition of an excess ART embryo, a human embryo is excess to the needs of the persons mentioned in that paragraph at a particular time if: (a) each such person has given written authority for use of the embryo for a purpose other than a purpose relating to the assisted reproductive technology treatment of the woman concerned, and the authority is in force at that time; or (b) each such person has determined in writing that the embryo is excess to their needs, and the determination is in force at that time. [RIHE Act s9]
Heerey Report	*Report of the Independent Review of the* Prohibition of Human Cloning for Reproduction Act 2002 *and* Research Involving Human Embryos Act 2002 *(2011)*
HREC	Human Research Ethics Committee
Human embryo clone	A genetic copy of another living or dead human, but does not include a human embryo created by the fertilisation of a human egg by a human sperm. [PHCR Act s8(1)]

Human embryo	A discrete entity that has arisen from either: (a) the first mitotic division when fertilisation of a human oocyte by a human sperm is complete; or (b) any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears; and has not yet reached 8 weeks of development since the first mitotic division. [RIHE Act s7(1)]
Living embryo	An embryo is considered to be a living embryo unless: • when maintained in suitable culture conditions, the embryo has not undergone cell division between successive observations not less than 24 hours apart; or • the embryo has been allowed to succumb by standing at room temperature for a period of not less than 24 hours. Once an embryo has more than 12 cells it is not possible to determine whether any individual cell has divided within a 24-hour period. Therefore, such embryos can be considered to have succumbed only after a 24-hour period at room temperature. *Disclaimer:* This information is for guidance only. It is not intended to be taken as legal advice. If you are in any doubt about provisions of, or consequences arising from the operation of, the legislation or the issuing of licences, you should seek your own independent legal advice.
IVF	*In vitro* fertilisation
Licence	A licence issued under section 21 of the RIHE Act. [PHCR Act s8(1)]
Lockhart Report	*Legislation Review:* Prohibition of Human Cloning Act 2002 *and the* Research Involving Human Embryos Act 2002*, Reports* (2005)
National Statement	*National Statement on Ethical Conduct in Human Research, 2007*– Updated May 2015
NHMRC	The National Health and Medical Research Council
NHMRC Act	*National Health and Medical Research Council Act 1992*
NHMRC Licensing Committee	Embryo Research Licensing Committee of the NHMRC
Objective Criteria	The *Objective criteria for embryos that are unsuitable for implantation* (Objective Criteria) and accompanying contextual information issued as guidelines by the CEO of the NHMRC on 6 December 2007 as required by the definition of 'unsuitable for implantation' in section 7 of the RIHE Act.
'Other embryos'	(a) human embryos created by a process other than the fertilisation of a human egg by a human sperm; or (b) human embryos created by a process other than the fertilisation of a human egg by a human sperm that contain genetic material provided by more than 2 persons; or (c) human embryos created using precursor cells taken from a human embryo or a human fetus; or (d) hybrid embryos. [RIHE Act s10A]
PGD	Preimplantation Genetic Diagnosis
PHC Act	*Prohibition of Human Cloning Act 2002*
PHCR Act	*Prohibition of Human Cloning for Reproduction Act 2002*

Proper consent	In relation to the use of an excess ART embryo or a human egg, or the creation or use of any other embryo, proper consent means consent obtained in accordance with guidelines issued by the CEO of NHMRC under the *National Health and Medical Research Council Act 1992* and prescribed by the regulations for the purposes of this definition.
Responsible persons	a) In relation to an excess ART embryo: (i) each person who provided the egg or sperm from which the embryo was created; and (ii) the woman for whom the embryo was created, for the purpose of achieving her pregnancy; and (iii) any person who was the spouse of a person mentioned in subparagraph (i) at the time the egg or sperm mentioned in that subparagraph was provided[a]; and (iv) any person who was the spouse of the woman mentioned in subparagraph (ii) at the time the embryo was created; or (b) in relation to an embryo other than an excess ART embryo — each person whose reproductive material, genetic material or cell was used, or is proposed to be used, in the creation or use of the embryo; or (c) In relation to a human egg — the woman who was the biological donor of the egg. *See also* 'spouse' [RIHE Act s8]
RIHE Act	*Research Involving Human Embryos Act 2002*
SCNT	Somatic Cell Nuclear Transfer
Spouse	In relation to a person, includes a de facto partner of the person as defined by the *Acts Interpretation Act 1901*.
Unsuitable for implantation	(a) is diagnosed by preimplantation genetic diagnosis as unsuitable for implantation, in accordance with the *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (2004)*, issued by the CEO of the NHMRC; or (b) is determined to be unsuitable for implantation in the body of a woman, in accordance with objective criteria specified in guidelines issued by the CEO of the NHMRC under the *National Health and Medical Research Council Act 1992* [RIHE Act s7 (1)] and prescribed by the regulations for the purposes of this paragraph.
Unsuitable for transfer	The criteria for determining that an embryo is unsuitable for transfer are based on whether there is a low likelihood of implantation according to the clinic's established policies and procedures for grading embryos. These embryos may or may not be classified as excess ART embryos under section 9 of the RIHE Act. Further information on 'unsuitable for transfer' embryos is available on the NHMRC website. Note: This term is used to denote the clinical context and should not be confused with the term 'unsuitable for implantation' as used in the RIHE Act.

a Note: This differs from the 2017 ART guidelines which do not require consent from the donor's partner for use in treatment. However, consent from a gamete donor's partner is required if the use is under licence.

Introduction

This information kit has been prepared on behalf of the Embryo Research Licensing Committee of the National Health and Medical Research Council (NHMRC Licensing Committee). It provides an overview of the regulatory framework and is intended primarily for individuals and organisations who may be considering applying for a licence or who currently hold a licence under the *Research Involving Human Embryos Act 2002* (RIHE Act) and their Human Research Ethics Committees (HRECs). The kit has five chapters:

- *Chapter 1: Overview of the Regulatory Framework* provides general information about the operation of the RIHE Act and the *Prohibition of Human Cloning for Reproduction Act 2002* (PHCR Act), including prohibited practices and licensable activities.
- *Chapter 2: Applying for a Licence* provides information for people and organisations applying for licences to use excess assisted reproductive technology (ART) embryos or human eggs, or to create embryos for research purposes.
- *Chapter 3: Information for Licence Holders* outlines the responsibilities and obligations of licence holders.
- *Chapter 4: Information for Human Research Ethics Committees* provides advice for members of HRECs. It is intended to assist with the consideration of research proposals which fall under the scope of the RIHE Act.
- *Chapter 5: Monitoring Compliance with the Legislation* provides advice for licence holders on NHMRC's inspection procedures for monitoring compliance with the RIHE Act and the PHCR Act, as well as information for the general public about reporting suspected breaches.

Further Information

The NHMRC website is at www.nhmrc.gov.au. This website, particularly the pages linked from https://www.nhmrc.gov.au/research/embryo-research-licensing contains more information about embryo research, and is referred to frequently in this information kit. Relevant information, including copies of the RIHE and PHCR Acts, application forms and detailed instructions, checklists and other explanatory material can be accessed from the Embryo Research Licensing pages of the website.

Contact Information

If you have any queries about the legislation, the monitoring and compliance requirements contained in the legislation, or how the legislation may affect you or your organisation, please contact:

NHMRC Embryo Research Licensing
GPO Box 1421
Canberra ACT 2601

Tel: 02 6217 9468
02 6217 9000

Email: embryo.research@nhmrc.gov.au

Disclaimer

This information kit is intended primarily to provide information for persons who may be considering applying for a licence, and for HRECs reviewing applications for research which fall under the scope of the RIHE Act. It contains summaries and explanations designed to assist in interpreting the provisions of the Acts and associated legal requirements.

It should not be relied on as either a comprehensive or authoritative statement of the law and, in particular, should not be taken as a substitute for reading the Acts.

You are advised to seek your own independent legal advice before making any decisions or undertaking any course of activity, or if you are in any doubt about particular provisions. The Australian Government will not be responsible for any consequences that may arise as a result of any person acting on the basis of the contents of this information kit.

1. OVERVIEW OF THE REGULATORY FRAMEWORK

1.1. Background and History

In response to community concerns, including ethical concerns about scientific developments related to the creation of, or use of human embryos for research, the Australian Parliament passed two Acts in December 2002 — the *Prohibition of Human Cloning Act 2002* (PHC Act) and the *Research Involving Human Embryos Act 2002* (RIHE Act). The combined effect of these two Acts was to prohibit human cloning for any purpose and to restrict human embryo research to only those embryos created through assisted reproductive technology (ART) that are no longer required by the people for whom the embryos were created for that purpose.

The Acts each included a statutory requirement for an independent review after three years. Accordingly, in June 2005, the six-member Legislation Review Committee was appointed, chaired by the Hon. John Lockhart QC. The terms of reference for the review were provided by the then Minister for Ageing and the Chief Executive Officer (CEO) of NHMRC based on the requirements of the legislation. A major focus of the review was on the creation of embryos for research, particularly embryos created by techniques other than by the fertilisation of a human egg by a human sperm.

The Legislation Review Committee's report (Lockhart Report) was tabled in the Australian Parliament in December 2005. In response to the recommendations of the Lockhart Report, the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (Amendment Act) was passed by the Australian Parliament in December 2006. The Amendment Act changed the title of the PHC Act to the *Prohibition of Human Cloning for Reproduction Act 2002* (PHCR Act) and implemented many of the recommendations of the Lockhart Report. The amendments permit the licensing of some practices previously prohibited, such as the use of embryos created specifically for research through somatic cell nuclear transfer (SCNT).

The Amendment Act also included a requirement for a further independent review to be conducted and specified the terms of reference for the review. The five-member Legislation Review Committee, chaired by the Hon. Peter Heerey AO QC, was appointed in December 2010. The Committee's report (Heerey Report) was tabled in the Australian Parliament in July 2011.

Table 1.1 summarises the key milestones in the regulation of embryo research and the prohibition of human cloning in Australia since December 1998.

TABLE 1.1 STEPS TOWARDS NATIONAL REGULATION AND THE DEVELOPMENT OF THE ACTS

Date	Event
December 1998	The NHMRC Australian Health Ethics Committee, in response to a request from the Minister for Health and Aged Care, produced the report *Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings*[b].
August 1999	The Minister referred the Australian Health Ethics Committee report to the House of Representatives Standing Committee on Legal and Constitutional Affairs (Andrews Committee).
August 2001	The Andrews Committee released the report, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (Andrews Report)[c].
April 2002	The Council of Australian Governments (COAG) agreed to establish a national approach to the prohibition of human cloning and other 'unacceptable' practices and the regulation of research involving excess ART embryos.
June 2002	The Prohibition of Human Cloning and Research Involving Embryos Bill 2002 was introduced into the Australian Parliament. This was subsequently split into two Bills by the House of Representatives.
December 2002	After further debate in both houses and review by the Senate Community Affairs Committee, the *Prohibition of Human Cloning Act 2002* (PHC Act) and the *Research Involving Human Embryos Act 2002* (RIHE Act) were passed by the Australian Parliament.
January 2003	The PHC Act and the RIHE Act came into effect.
June 2005	The Minister for Ageing appointed the six-member Legislation Review Committee to independently review the operations of the PHC Act and the RIHE Act.
December 2005	The Legislation Review Committee released its report (Lockhart Report)[d], which was tabled in the Australian Parliament on 19 December 2005.
September 2006	A private members' bill, Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006, was debated in the Australian Parliament and was passed in December 2006.
June 2007	The *Prohibition of Human Cloning for Reproduction Act* (PHCR Act) and the amended RIHE Act came into effect.
December 2010	The Minister for Mental Health and Ageing appointed the five-member Legislation Review Committee to independently review the operations of the PHCR Act and the RIHE Act.
July 2011	The Legislation Review Committee's report (Heerey Report)[e], was tabled in the Australian Parliament on 7 July 2011.

b https://www.nhmrc.gov.au/guidelines-publications/e45

c http://www.aph.gov.au/parliamentary_business/committees/house_of_representatives_committees?url=/laca/humancloning/contents.htm.

d https://www.nhmrc.gov.au/research/embryo-research-licensing/commonwealth-and-state-legislation

e https://www.nhmrc.gov.au/guidelines-publications/hc38/?

1.2. Overview of the Legislation

The purposes of the PHCR Act and the RIHE Act are to ban human reproductive cloning and other unacceptable practices associated with reproductive technology, and to regulate research involving human embryos. The Acts also address the need for a nationally consistent approach to regulate research involving human embryos. The PHCR Act and the RIHE Act have provided the statutory framework for States and Territories to introduce nationally consistent legislation for research involving human embryos, as agreed by COAG in 2002. Most States and Territories have implemented corresponding legislation.

1.2.1. PHCR Act

The PHCR Act prohibits human cloning for reproduction, as well as some other practices, including:

- creating an embryo from a human egg and a human sperm for purposes other than achieving pregnancy in a woman
- developing a human embryo outside the body of a woman for more than 14 days
- commercial trading in human embryos and gametes (see Part 2 of the PHCR Act).

The PHCR Act also prohibits the creation and/or use of embryos by techniques other than by the fertilisation of a human egg by a human sperm, which includes SCNT and some other associated activities, except under licence.

1.2.2. RIHE Act

The amended RIHE Act sets out a regulatory framework for research on human embryos in Australia and encompasses:

- the use of excess ART embryos, that is embryos created through ART to assist people to have children, but that have been determined by the people for whom the embryos were created, to be no longer required for that purpose (see Box 1.1 for definitions)
- the creation or use of certain other types of human embryos created by methods other than the fertilisation of a human egg by a human sperm (see Explanation of Key Terms)
- the creation of hybrid embryos by the fertilisation of an animal egg with a human sperm, and the use of such embryos up to, but not including, the first mitotic division for testing sperm quality in an accredited ART centre
- the fertilisation of a human egg by a human sperm up to, but not including, the first mitotic division, outside the body of a woman for ART research or training purposes.

Under the RIHE Act, the following may be donated for use, under licence:

- embryos that are no longer required after ART (excess ART embryos) which may include embryos that have been determined to be unsuitable for implantation
- human eggs, human sperm and other human cells or genetic material for the creation of other embryos.

The activities specified under the RIHE Act are tightly regulated by a licensing system overseen by the NHMRC Embryo Research Licensing Committee (NHMRC Licensing Committee). The members of this committee, which is a Principal Committee of NHMRC, are appointed in accordance with the RIHE Act. Inspectors appointed under the RIHE Act are responsible for monitoring compliance with both Acts. The RIHE Act sets out the conditions that need to be met before a licence can be granted and the regulatory arrangements for managing the licensing process.

BOX 1.1 KEY DEFINITIONS COVERED BY THE LEGISLATION

A human embryo means a discrete entity that has arisen from either:

(a) the first mitotic division when fertilisation of a human oocyte by a human sperm is complete; or

(b) any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears;

and has not yet reached 8 weeks of development since the first mitotic division.

Under the Act, references to an embryo, including a human embryo, refer to a live embryo. References to a human embryo do not include hybrid embryos or human embryonic stem cell lines.

An 'excess ART embryo' means a human embryo that:

(a) was created, by assisted reproductive technology, for use in the assisted reproductive technology treatment of a woman; and

(b) is excess to the needs of:

(i) the woman for whom it was created; and
(ii) her spouse (if any) at the time the embryo was created.

For the purposes of paragraph (b) of the definition of an excess ART embryo, a human embryo is excess to the needs of the persons mentioned in that paragraph at a particular time if:

(a) each such person has given written authority for use of the embryo for a purpose other than a purpose relating to the assisted reproductive technology treatment of the woman concerned, and the authority is in force at that time; or

(b) each such person has determined in writing that the embryo is excess to their needs, and the determination is in force at that time.

An embryo that is 'unsuitable for implantation' means a human embryo that:

(a) is diagnosed by preimplantation genetic diagnosis as unsuitable for implantation, in accordance with the *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (2004),* issued by the CEO of the NHMRC; or

(b) is determined to be unsuitable for implantation in the body of a woman, in accordance with objective criteria specified in guidelines issued by the CEO of the NHMRC under the *National Health and Medical Research Council Act 1992* and prescribed by the regulations for the purposes of this paragraph.

Sources: *Research Involving Human Embryos Act 2002* section 7 and section 9; and *Prohibition of Human Cloning for Reproduction Act 2002* section 8.

For the definition of 'Other embryos' and human embryo clone, see the Explanation of Key Terms.

1.2.3. RIHE Regulations

The RIHE Act has associated Regulations, which were first made in 2003 and were remade in 2017. The Research Involving Human Embryos Regulations 2017 prescribe the NHMRC guidelines that the NHMRC Licensing Committee must have regard to when issuing and overseeing a licence. These are:

- The *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* (ART Guidelines)
- The *National Statement on Ethical Conduct in Research Involving Humans* (National Statement)
- The *Objective Criteria for Embryos Unsuitable for Implantation* guidelines (Objective Criteria, see 'Information for Applicants' page on NHMRC website).

The Regulations must be consulted to determine which versions of the ART Guidelines and National Statement are prescribed at any given time[f]. The Regulations also prescribe a list of organisations from which the Minister must seek nominations before appointing members to the NHMRC Licensing Committee.

There are currently no regulations associated with the PHCR Act.

1.3. NHMRC Licensing Committee

The RIHE Act sets out a regulatory framework which the NHMRC Licensing Committee administers as a Principal Committee of NHMRC. The committee members are appointed by the Australian Government Minister with portfolio responsibility for human cloning and embryo research, in consultation with the States and Territories. Committee members have expertise in research ethics, ART, law, consumer issues and other relevant expertise as specified in the RIHE Act. The current members of the NHMRC Licensing Committee and their declared interests are listed on the NHMRC website. The role of the NHMRC Licensing Committee includes:

- considering applications for a licence to use excess ART embryos or human eggs, or to create or use other embryos
- refusing or granting licences subject to conditions
- establishing and maintaining a public database on the NHMRC website containing information about licences issued by the committee for the use of excess ART embryos or human eggs, or the creation or use of other embryos
- ensuring that compliance with the legislation is monitored through a framework that encourages cooperative compliance
- ensuring that non-compliance is investigated as required
- reporting to the Australian Parliament on the operation of the RIHE Act and licences issued under the Act (previous reports are available on the NHMRC website at www.nhmrc.gov.au).

Individuals and organisations wishing to undertake research using excess ART embryos or human eggs, or to create or use other embryos, must apply to the NHMRC Licensing Committee for a licence. The NHMRC Licensing Committee undertakes a comprehensive assessment of each application against the criteria set out in the RIHE Act and grants or refuses licences accordingly. Chapter 2 outlines licence application requirements.

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f As the ART Guidelines and National Statement are now subject to rolling review, the version prescribed in the RIHE Regulations may not be the most recent version of either document. If you require advice as to which version is required for compliance, please contact Embryo Research Licensing.

1.4. Overview of Licensed Uses

1.4.1. Activities which are permitted by the legislation

Excess ART embryos

Any use of an excess ART embryo which is not an 'exempt' use (see below) may only be conducted if it is done in accordance with a licence issued by the NHMRC Licensing Committee.

Licensable uses of excess ART embryos (including those that are unsuitable for implantation or unsuitable for transfer) fall into three broad categories:

- research
- training[g], and
- quality assurance.

An embryo must exist before it can be declared to be an excess ART embryo and the declaration or consent for another use must be made in writing (see Box 1.1). If these conditions are not met, the embryo is not an excess ART embryo. For example, an embryo that has been determined to be unsuitable for transfer (see Explanation of Key Terms) may not be an excess ART embryo. It will depend on when decisions were made about the eventual fate of the embryos and when the relevant consent forms were signed. In addition, the criteria for deciding that an embryo is unsuitable for transfer may differ from the Objective Criteria[h].

Other embryos

Licensed uses of other embryos – that is, those created by means other than the fertilisation of a human egg by a human sperm – cover the development and use of such embryos for research (e.g. to develop disease treatments), training (e.g. for improving ART practices), and for testing sperm quality (PHCR Act sections 22–23B).

The prohibition on developing these embryos beyond 14 days, and the prohibition on placing them in the body of a woman, prevents them from being used for reproductive purposes (PHCR Act sections 9, 13, 14 and 20). Creation of embryos by fertilisation of a human egg by a human sperm for a purpose other than reproduction is also prohibited (PHCR Act section 12).

Human eggs

Under the RIHE Act, licensed use of human eggs covers research or training in ART involving fertilisation of a human egg by a human sperm outside the body of a woman, up to, but not including, the first mitotic division (RIHE Act section 10B). Uses of human eggs that are solely directed towards achieving a pregnancy in a woman do not require a licence.

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g The NHMRC Licensing Committee has published additional information to assist ART providers to assess whether their training and/or quality assurance activities require a licence (see https://www.nhmrc.gov.au/research/embryo-research-licensing/training-and-quality-assurance-activities-when-licence-required).

h See Objective Criteria on the Information for Applicants page of the NHMRC website. These criteria must be used for determining which embryos can be used under licence in circumstances where subsection 24(8) of the RIHE Act applies. The Objective Criteria do not apply to clinical decisions.

The use of human eggs in the creation of other embryos is also permitted under licence by the RIHE Act (RIHE Act subsection 20 (1)) and some activities using eggs which have fertilised abnormally may require a licence[i].

1.4.2. Live embryos

The RIHE Act only applies to the use of living embryos. Therefore, determining whether an embryo is living is critical to deciding whether an activity requires a licence. The NHMRC Licensing Committee has provided a description of a living embryo to help guide licence applicants (see Explanation of Key Terms). In brief, an embryo is considered living unless:

- when maintained in suitable culture conditions, the embryo has not undergone cell division between successive observations not less than 24 hours apart; or
- the embryo has been allowed to succumb by standing at room temperature for a period of not less than 24 hours.

Once an embryo has more than 12 cells it is not possible to determine whether any individual cell has divided within a 24-hour period. Therefore, such embryos can be considered to have succumbed only after a 24-hour period at room temperature.

1.4.3. Embryonic stem cell lines

A licence is not required if researchers wish to conduct research using existing human embryonic stem cell lines. However, a licence is required if researchers wish to use excess ART embryos or human eggs, or to create or use other embryos, to establish new human embryonic stem cell lines. For example, under licence, embryonic stem cells can be obtained from:

- excess ART embryos
- other embryos:
  - embryos created by processes other than the fertilisation of a human egg by a human sperm; for example, those produced by SCNT (human embryo clones) or by parthenogenesis
  - human embryos produced from the genetic material of more than two persons (provided this does not involve the fertilisation of a human egg by a human sperm)
  - human embryos created from precursor cells from another human embryo or from a human fetus.

The PHCR Act (sections 9, 13, 14 and 20) prohibits such embryos from being implanted in the body of a woman, or being allowed to develop beyond 14 days.

Where the derivation of a new embryonic stem cell line is authorised by a licence, the licence conditions cease to apply when the embryo has been destroyed by the process of deriving the embryonic stem cell line, and it is therefore no longer a living embryo.

1.4.4. Induced pluripotent stem cells

Research involving induced pluripotent stem cells does not require a licence from the NHMRC Licensing Committee. The process of derivation does not require a licence because it does not involve an entity which is covered by the definition of human embryo. As noted above, research involving existing cell lines is not covered by the legislation. However, if research using human stem cell lines will be directed towards the creation and testing of *in vitro* derived gametes, it is recommended that researchers consult Embryo Research Licensing about whether the research requires a licence.

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i Contact Embryo Research Licensing for more information.

1.4.5. Routine ART clinical practice

Routine ART clinical practice (i.e. the creation and use of embryos for the purpose of achieving a pregnancy in a woman) is not subject to licensing by the NHMRC Licensing Committee but is subject to the requirements of the Reproductive Technology Accreditation Committee of the Fertility Society of Australia[j], as well as applicable State or Territory legislation. However, some training and quality assurance activities may require a licence. Information can be found on the Training and Quality Assurance page of the NHMRC website[k].

1.5. Exempt Uses of Excess ART Embryos

Some uses of excess ART embryos are 'exempt' uses and do not require a licence from the NHMRC Licensing Committee.

According to subsection 10(2) of the RIHE Act, the use of an excess ART embryo is exempt if:

- the use consists only of:
  - storage of the excess ART embryo; or
  - removal of the excess ART embryo from storage; or
  - transport of the excess ART embryo; or
  - observation of the excess ART embryo; or
  - allowing the excess ART embryo to succumb; or
- the use is carried out by an accredited ART centre, and:
  - the excess ART embryo is not suitable to be placed in the body of the woman for whom it was created, where the suitability of the embryo is determined only on the basis of its biological fitness for implantation; and
  - the use forms part of diagnostic investigations conducted in connection with the ART treatment of the woman for whom the embryo was created; or
- the use is carried out by an accredited ART centre, and:
  - is for the purposes of achieving pregnancy in a woman other than the woman for whom the excess ART embryo was created.

Uses of excess ART embryos other than those specified in subsection 10(2) are not exempt and require a licence. For example:

- A researcher may culture excess ART embryos to increase the number of cells available and then allow the embryos to succumb before using them in a research project. Although the embryos are dead when the research results are obtained, the NHMRC Licensing Committee considers that the culturing is an integral part of the experimental design and the project requires a licence.
- A researcher wishes to test whether particular storage or transport conditions affect the viability of stored embryos. Excess ART embryos are transferred from standard conditions to the experimental conditions for a period before being thawed and assessed for viability. The embryos are then allowed to succumb. The NHMRC Licensing Committee considers

j See the Reproductive Technology Accreditation Committee *Code of Practice for Assisted Reproductive Technology Units* (2015) at http://www.fertilitysociety.com.au/rtac/australian-nz-cop/.

k See https://www.nhmrc.gov.au/research/embryo-research-licensing/training-and-quality-assurance-activities-when-licence-required.

that although the embryos were removed from storage and allowed to succumb, the period in altered storage conditions and the related assessment of viability following thawing requires a licence.

Organisations or individuals who have queries about whether their current or proposed work is exempt are advised to contact Embryo Research Licensing at NHMRC (see Introduction for contact details).

1.6. Import, Export and Trade of Embryos, Gametes and Stem Cells

- Under the PHCR Act (sections 10 and 20) it is prohibited to import or export a human embryo clone or prohibited embryos (e.g. embryos created by SCNT, hybrids or chimeras).
- Commercial trading in human embryos, sperm and eggs is prohibited in Australia under the PHCR Act (section 21).
- Import or export of a stem cell line derived from a human embryo clone requires a permit issued through NHMRC by the Minister with responsibility for the PHCR Act (section 23C).

1.7. Monitoring Compliance with the Acts

The RIHE Act extends the monitoring powers of the NHMRC Licensing Committee to the PHCR Act. This ensures that prohibited practices are not undertaken in Australia, and the responsibilities of the NHMRC Licensing Committee include overseeing compliance with both Acts.

Under the RIHE Act, the Chairperson of the NHMRC Licensing Committee appoints inspectors to monitor compliance with the RIHE Act, the PHCR Act and licence conditions. Monitoring compliance with the legislation is discussed in greater detail in Chapter 5.

2. APPLYING FOR A LICENCE

2.1. Deciding Whether a Licence is Required

Information about particular categories of embryos (e.g. excess ART embryos or other embryos), human eggs, live embryos and embryonic stem cell lines is provided in Chapter 1. This information will assist potential applicants to determine whether a licence is required.

2.1.1. Research Licences

Research which involves the use of excess ART embryos or human eggs, or the creation or use of other embryos, can only be carried out if authorised by a licence issued by the NHMRC Licensing Committee. Examples of licensable activities include deriving an embryonic stem cell line from an excess ART embryo and combining a skin cell with an enucleated egg to create an embryo by SCNT. A licence is not required if the only proposed uses of an excess ART embryo are classified as exempt activities as defined in RIHE Act subsection 10(2) (see also Chapter 1).

2.1.2. Training and Quality Assurance Licences

Under the RIHE Act, the NHMRC Licensing Committee can issue licences for training or quality assurance in ART. For example, a licence is required for training embryologists in blastocyst biopsy using excess ART embryos. This is a complex area and it can be difficult to determine whether a particular training activity or the use of a particular embryo in a training activity requires a licence. The NHMRC Licensing Committee has published information on the NHMRC website to assist ART providers to understand their responsibilities under the legislation[1]. If additional advice is required, prospective applicants are requested to contact Embryo Research Licensing.

2.2. Overview of the Licence Assessment Process

The NHMRC Licensing Committee assesses applications for licences and issues licences in accordance with the RIHE Act.

When a licence application is received by NHMRC, an acknowledgement will be sent and the application will be checked to ensure it includes all information required. If there are any omissions in the application, the applicant will be contacted before any further action is taken.

The NHMRC Licensing Committee reviews the application and supporting documents and considers the following issues:

- Do the proposals fall into one of the categories of licensable activities listed in subsection 20(1) of the RIHE Act? If so, which one(s)?
- Is the proposed activity likely to lead to a significant advance in knowledge or improvement in technologies for treatment?
- Could this advance in knowledge or improvement in technologies for treatment reasonably be achieved by other means?

1 https://www.nhmrc.gov.au/research/embryo-research-licensing/training-and-quality-assurance-activities-when-licence-required

- Has the work proposed been carried out before? If so, is there justification for repeating the experiments?
- Have experiments on animal models and/or other types of human cells reached a point at which the use of human embryos is justified?
- Are the objectives clearly defined and the methods proposed likely to yield relevant and clear results? If not, what are the problems?
- Has the requested number of excess assisted reproductive technology (ART) embryos, other embryos or eggs been restricted to that necessary to achieve the goals of the proposed research or activity?
- Is the proposed duration appropriate?
- Do the proposed authorised persons have the necessary qualifications and ability to carry out the proposed work?
- Do the proposed consent processes for donation or use of material meet the all the criteria as specified in the relevant legislation and guidelines, including the ART guidelines? Has the relevant consent checklist been completed and attached to the application?

A subgroup of the NHMRC Licensing Committee (the Working Group) assisted by Embryo Research Licensing conducts the detailed assessment of the application against the requirements of the RIHE Act. The Working Group may request additional information or seek clarification from the applicant. This may involve a teleconference to resolve identified issues. Other members of the NHMRC Licensing Committee may also raise additional issues that could result in further information being requested from the applicant.

Where necessary, the NHMRC Licensing Committee may ask external experts to provide additional advice in relation to the application. However, confidential information contained in applications will be protected[m]. In accordance with the requirements of procedural fairness, advice from an external expert will be provided to the applicant, in a de-identified form, and the applicant will be given an opportunity to comment on the advice.

Once the Working Group is satisfied that all issues have been resolved, the Working Group will make a recommendation to the full NHMRC Licensing Committee. Before granting a licence the NHMRC Licensing Committee must be satisfied that the application meets the criteria in subsection 21(3) and must have had regard to the criteria in subsection 21(4) of the RIHE Act (see section 2.4).

If the NHMRC Licensing Committee decides to grant a licence, the committee will determine the Special Conditions that will be specific for this licence. The Special Conditions operate in addition to the Standard Conditions that apply to all licences

m Before assessment of an application commences, NHMRC Licensing Committee members are asked whether they have any interests that would preclude their participation in assessment of the application. Members with such an interest do not receive any information about the application. Furthermore, an application would not be sent to an external expert who had a conflict of interest with the applicant or the subject matter of the application.

2.3. Preparing A Licence Application

Table 2.1 summarises the main steps in applying for a licence, and the relevant considerations that apply to each step of the application process. Applicants should refer to the legislation when preparing the application. Embryo Research Licensing can also be contacted for discussion and guidance (see Introduction for contact details).

2.3.1. Preparing the Application

Research Licences

The NHMRC Licence Application Form and detailed instructions for completing the application form have been developed by the NHMRC Licensing Committee and are available for download from the NHMRC website[n].

Training Licences

A shorter licence application form has been developed for the situation where embryologists will receive training in embryo biopsy using excess ART embryos. The form and associated instructions can be downloaded from the NHMRC website. Prospective applicants are requested to consult Embryo Research Licensing for advice before adapting the application form to other training situations. Licence applications for quality assurance activities should be made using the standard application form.

Each person who will be trained under a training licence must be approved by the NHMRC Licensing Committee before training commences. This can either be done as part of the initial licence application or as a separate process once the licence has been issued.

n https://www.nhmrc.gov.au/research/embryo-research-licensing/information-applicants

TABLE 2.1 STEPS IN PREPARING A LICENCE APPLICATION

Step	Goal	Consideration
1	Develop a detailed proposal and gain approval from your HREC	The NHMRC Licensing Committee cannot issue a licence if the proposal does not have HREC approval. The HREC must be constituted in accordance with the NHMRC *National Statement on Ethical Conduct in Human Research* (2007) (National Statement). The proposal should include a detailed description of the process for obtaining proper consent and describe the categories of responsible persons who will be required to give consent. This process will depend on the type of project. Work must not begin on the basis of HREC approval only. See Chapter 4 and the National Statement for further information about HREC approval.
2	Complete the relevant NHMRC licence application forms	Application forms can be obtained from the NHMRC website. Advice on how to complete the form is provided in this chapter and in the instructions for completing the forms. Complete the applicable consent checklist while developing the consent process and documents and include it with the application.
3	Attach HREC evaluation	Attach the written evaluation prepared by the HREC at the time the proposal was approved.
4	Obtain signature of HREC chairperson	Ensure that the chairperson of the HREC that considered the original proposal signs the application.
5	Obtain all other signatures	Obtain signatures required in Section 8 of the application form.
6	Submit application to Embryo Research Licensing.	Include all attachments and reference the attachments on the application form. Electronic copies are preferred but a hard copy of the signature page may also be submitted.
7	Note application number	Embryo Research Licensing will acknowledge receipt of the application and assign an application number. This number should be used in further correspondence about the application.

2.3.2. Obtaining Human Research Ethics Committee approval

HRECs are established by institutions to review research proposals involving humans. Under the RIHE Act, the NHMRC Licensing Committee cannot issue a licence unless it is satisfied that the proposed activity or project has been assessed and approved by an HREC.

The HREC must evaluate the research proposal according to the National Statement, the ART Guidelines, and advice from the NHMRC Licensing Committee. The HREC may approve or reject the proposal, or request amendments.

Once a proposal has been approved by the HREC, the researcher or organisation may submit a licence application to the NHMRC Licensing Committee. The research described in the proposal may only begin once a licence has been issued by the NHMRC Licensing Committee. The HREC approval alone is not permission to commence the use of excess ART embryos or human eggs or creation or use of other embryos.

If the HREC decides that the proposal should not proceed, the applicant may not apply for a licence from the NHMRC Licensing Committee.

The process of HREC consideration of research proposals is described in more detail in Chapter 4.

2.3.3. Protection of confidential information

Information contained in a licence application may be confidential for a number of reasons. For example, it may be personal information or it may have commercial value that could be diminished if it were disclosed. Under the *Privacy Act 1988* and the RIHE Act, both types of information are protected from public disclosure by NHMRC.

If information contained in a licence application is confidential commercial information, applicants should clearly identify that information and justify why it should be protected from public disclosure or release under the *Freedom of Information Act 1982*.

2.3.4. Submitting the application

Applications can only be considered by the NHMRC Licensing Committee if signed by a person with authority to sign on behalf of the applicant organisation, the principal supervisor and the HREC chairperson.

If the proposed use of embryos involves collaboration between two or more organisations, the application must include information about the organisations and their roles in the proposed activity. The NHMRC Licensing Committee may decide which organisation will be the licence holder. In the situation where a licence is issued to joint licence holders the NHMRC Licensing Committee may also specify which licence holder has responsibility for complying with particular licence conditions.

Applications and all attachments should be submitted to embryo.research@nhmrc.gov.au. All attachments should be referenced on the application form. The signature page may be submitted as a scanned version or as the original hard copy. When the application is received, Embryo Research Licensing will issue an application number, which should be used on subsequent correspondence.

2.4. Obtaining Proper Consent

The NHMRC Licensing Committee must not issue a licence until it is satisfied that processes are in place for obtaining proper consent from all responsible persons. The RIHE Act (section 8) provides a definition of 'proper consent', which must be obtained from all responsible persons for the use of human embryos, human eggs, or the creation and use of other embryos that are permitted by licence under the Act. The consent must be provided in writing.

See the Explanation of Key Terms for the definitions of proper consent and responsible persons given in the RIHE Act. It is critical to identify all the people required to consent for the use of each embryo under licence, particularly if donated gametes have been used to create the embryo. Advice on the ethical requirements regarding consent processes is outlined in the ART Guidelines and the National Statement.

BOX 2.1 DEFINITION OF RESPONSIBLE PERSON

Responsible Person means*:*

(a) In relation to an excess ART embryo:

(i) each person who provided the egg or sperm from which the embryo was created; and

(ii) the woman for whom the embryo was created, for the purpose of achieving her pregnancy; and

(iii) any person who was the spouse of a person mentioned in subparagraph (i) at the time the egg or sperm mentioned in that subparagraph was provided; and

(iv) any person who was the spouse of the woman mentioned in subparagraph (ii) at the time the embryo was created; or

(b) in relation to an embryo other than an excess ART embryo — each person whose reproductive material, genetic material or cell was used, or is proposed to be used, in the creation or use of the embryo; or

(c) In relation to a human egg — the woman who was the biological donor of the egg.

Source: RIHE Act section 8

NHMRC has developed checklists (*Consent checklist for licensed activities using excess ART embryos* and *Consent checklist for other licensed research*) to help researchers and organisations applying for a licence ensure that they have completed all the necessary steps for obtaining proper consent. The checklists and additional advice (*Additional information on obtaining consent*) can be downloaded from the Information for Applicants page of the NHMRC website. The applicable checklist should be completed and included in the application. Guidance about the consent issues that HRECs evaluating research proposals must consider is provided in Chapter 4.

2.5. Criteria the NHMRC Licensing Committee Must Consider

Section 21 of the RIHE Act specifies the criteria the NHMRC Licensing Committee must consider before making a determination to issue a licence. When considering licence applications, the NHMRC Licensing Committee must be satisfied that:

- appropriate protocols are in place so that proper consent is obtained before an excess ART embryo or human egg is used, or other embryo is created or used, and that any restrictions the responsible persons have placed on the use will be observed, and
- the proposed project has been considered and approved by a HREC that is constituted in accordance with, and is acting in compliance with the National Statement.

The NHMRC Licensing Committee must also have regard to the following:

- restricting the number of excess ART embryos, other embryos or human eggs to that likely to be necessary to achieve the goals of the proposed research or activity
- the likelihood of significant advance in knowledge or improvement in technologies for treatment as a result of the proposed use, which could not reasonably be achieved by other means
- any relevant guidelines, or parts of guidelines, issued by NHMRC (currently, the National Statement, the ART Guidelines and the Objective Criteria), and
- the HREC assessment of the application.

2.6. Issuing Licences

2.6.1. Successful licence applications

When the NHMRC Licensing Committee makes a decision to issue a licence, the committee forwards a draft of the proposed licence and its conditions to the applicant for their consideration.

A complete copy of the application including any revisions made during the assessment process will be required at this time and will be referenced in the licence. The HREC is required to review and approve the revised application before the licence can be issued.

The applicant should determine whether the details included in the licence are correct, and decide whether the conditions are acceptable. Any concerns or queries about the proposed licence should be forwarded to Embryo Research Licensing within two weeks of the notification about the proposed licence. The NHMRC Licensing Committee will consider the issues raised and work with the applicant to resolve the issues. Once all issues have been resolved, the licence will be issued.

2.6.2. Unsuccessful licence applications

If, following assessment of a licence application, the NHMRC Licensing Committee declines an application for a licence, a statement of reasons will be provided to the applicant. Any concerns about the decision may be forwarded to Embryo Research Licensing for consideration by the NHMRC Licensing Committee.

2.6.3. Appeals

Applicants may appeal to the Administrative Appeals Tribunal for review of certain decisions taken by the NHMRC Licensing Committee (see Appendix 2.1).

2.6.4. Notifying relevant parties of the outcomes of licence applications

The RIHE Act requires the NHMRC Licensing Committee to notify the HREC that assessed and approved a proposed activity, and the relevant State or Territory body of the outcome of an application.

2.6.5. Public database

The RIHE Act requires the NHMRC Licensing Committee to maintain a public database containing the following information in relation to each licence:

- the name of the person or organisation to whom the licence was issued
- the nature of the activities that are authorised by the licence
- any conditions to which the licence is subject
- the number of excess ART embryos or human eggs authorised to be used under the licence, and the number of other embryos authorised to be created or used under the licence
- the date the licence was issued
- the period for which the licence is to remain in force.

This information is made available on the NHMRC website as soon as the licence is issued and is updated whenever a licence is varied.

Appendix 2.1: Review of decisions of the NHMRC Licensing Committee by the Administrative Appeals Tribunal

Which decisions are reviewable?

Decisions of the NHMRC Licensing Committee that are reviewable by the Administrative Appeals Tribunal (AAT) include:

- a decision under section 21 of the *Research Involving Human Embryos Act 2002* (the RIHE Act) not to issue a licence
- a decision in respect of the period throughout which the licence is to be in force under section 23 of the RIHE Act
- a decision to specify a licence condition under subsection 24(4) of the RIHE Act
- a decision to modify guidelines under subsection 24(8) of the RIHE Act in respect of a licence
- a decision to vary or refuse to vary a licence under section 25 of the RIHE Act
- a decision to suspend or revoke a licence under section 26 of the RIHE Act.

Who can apply?

An application for review of a decision of the NHMRC Licensing Committee may be made by the:

- applicant for the licence in relation to a decision under section 21 of the RIHE Act not to issue a licence
- licence holder in relation to a decision in respect of the period throughout which the licence is to be in force under section 23 of the RIHE Act
- licence holder in relation to a decision to specify a licence condition under subsection 24(4) of the RIHE Act
- licence holder in relation to a decision to modify guidelines under subsection 24(8) of the RIHE Act in respect of a licence
- licence holder in relation to a decision to vary or refuse to vary a licence under section 25 of the RIHE Act
- person who was the licence holder immediately before the suspension or revocation in relation to a decision to suspend or revoke a licence under section 26 of the RIHE Act.

What are the time limits?

There are time limits on lodging applications with the AAT. Applications to the AAT for review of reviewable decisions of the NHMRC Licensing Committee should be made within 28 days of the date the decision is received.

What are the fees?

In most cases, an application fee must accompany an application for review. The application fee may be waived by the AAT or refunded in certain circumstances.

Further information

Contact details for the AAT can be found in your local telephone directory. The address for all correspondence is:

Deputy Registrar
Administrative Appeals Tribunal
GPO Box 9955
[your State or Territory capital city]

3. INFORMATION FOR LICENCE HOLDERS

3.1. Licences

Licences comprise a coversheet, a set of standard conditions and a set of special conditions. All licences are subject to the provisions of the RIHE Act and the PHCR Act but these provisions are not repeated in the licence conditions.

3.1.1. Standard licence conditions

Standard conditions are those conditions imposed by the NHMRC Licensing Committee that apply to all licences. Standard conditions include requirements relating to:

- the licence holder's current contact details
- authorised persons
- reporting
- monitoring
- use of excess ART embryos or human eggs, or creation or use of other embryos
- notification that proper consent has been obtained
- ongoing oversight by an HREC.

The NHMRC Licensing Committee may vary the Standard Conditions if it considers it necessary to do so. All licence holders are informed of any changes and given an opportunity to comment before the varied conditions are implemented. The current version of the Standard Conditions is available on the licence database page of the NHMRC website.

3.1.2. Special licence conditions

Special conditions are those conditions imposed by the NHMRC Licensing Committee that apply to a particular licence, and may include conditions relating to, but not limited to:

- the number of excess ART embryos or eggs authorised for use
- the number of other embryos authorised to be created and/or used
- the people authorised to create and/or use them
- the authorised sites
- the processes for obtaining consent.

3.2. Licence Holder Responsibilities

3.2.1. Compliance with licence conditions

The licence holder is responsible for ensuring that they comply with all licence conditions. The licence holder must ensure that each person who is identified in the licence conditions as a person who is authorised to participate in the licensed activity is at all times fully informed of the requirements of the Commonwealth legislation, any corresponding State or Territory law, and the licence and its conditions.

As a minimum, licence holders must:

- comply with all mandatory conditions imposed by the legislation and all licence conditions
- undertake the licensed activity only during the period of the licence
- provide a written report to the NHMRC Licensing Committee every six months, as specified in the licence, and provide a final report before the licence expires or is surrendered
- maintain a tracking system that uniquely identifies each egg or embryo created or used in connection with the licence
- record an outcome for each individual egg or embryo
- ensure that adequate records are maintained to facilitate monitoring of the licensed activity
- seek approval from the NHMRC Licensing Committee to vary any condition of the licence and await formal notification that the licence has been varied before implementing the requested change.

3.2.2. Notifying that consent has been obtained

A licence includes a date when the research project may start. However, the use of an egg or an excess ART embryo, or the creation or use of any other embryo must not begin until:

- proper consent has been given by each responsible person (see Explanation of Key Terms) in relation to the use of each embryo, egg, reproductive material, genetic material or cell (see paragraph 24(1)(a) of the RIHE Act, and the Information for Applicants page of the NHMRC website)
- the licence holder has reported in writing to the NHMRC Licensing Committee that such consent has been obtained, and notified any restrictions to which the consent is subject (see paragraph 24(1)(b) of the RIHE Act). The licence holder must notify consent for each embryo, egg, reproductive material, genetic material or cell before each entity can be used in the project.

Information about the processes for notifying the NHMRC Licensing Committee can be found on the Information for Licence Holders page of the NHMRC website. Failure to notify the committee that consent has been obtained constitutes a breach of licence conditions and may be an offence under section 12 of the RIHE Act.

Licence holders should be particularly careful to identify *all* the responsible people in situations where donated gametes were used to create an embryo that has been declared excess and donated to the licensed activity. In some cases, up to six people may be required to give their consent to the use of the embryo. If any one of those people has not given consent the embryo must not be used[o].

o For example, if a gamete donor had a partner at the time the gametes were donated, that partner is a responsible person under the legislation and must be asked to give consent to the use of the excess ART embryo in the licensed activity.

3.2.3. Reporting

Standard Condition 3001 requires licence holders to submit a report to the NHMRC Licensing Committee within 30 days of the end of each six-month reporting period (1 September to 28 February, and 1 March to 31 August). The report includes a record of the use of excess ART embryos or human eggs or creation and/or use of embryos under licence. Licence holders are also required to submit a final report before a licence expires or is surrendered. Report templates can be found on the Information for Licence Holders page of the NHMRC website. The special conditions of a licence may specify additional reporting requirements.

3.3. Licence Variations

Section 25 of the RIHE Act allows for a licence to be varied, either by the initiative of the NHMRC Licensing Committee or following application by the licence holder to the NHMRC Licensing Committee.

3.3.1. Variation initiated by licence holder

If circumstances change, the licence holder must request a variation to the existing licence and wait for written notification that the NHMRC Licensing Committee has varied the licence.

For convenience, the NHMRC Licensing Committee categorises applications to vary licences as either "administrative" or "significant".

Administrative variations

Administrative variations include changes such as:

- the addition of new authorised persons
- changes to the addresses of records storage sites.

For administrative variations, a letter stating the details that need to be varied and the reason for the variation will usually be sufficient. The committee generally considers applications for administrative variations by an out-of-session process.

Significant variations

Significant variations include:

- changes to the licensed activity (and related changes to the consent process and documents if required)
- a change to the principal supervisor.

For significant variations, the relevant sections of the approved licence application should be edited and the document resubmitted to the NHMRC Licensing Committee, with the new or altered information highlighted in the submission.

Requests to vary a licence should be submitted to the NHMRC Licensing Committee through Embryo Research Licensing. The committee assesses all variation applications in accordance with the requirements of the RIHE Act in the same way it assesses initial applications for licences.

Evidence of HREC approval of the variation is required before the NHMRC Licensing Committee can approve variations to the licensed activity. However, the HREC and NHMRC Licensing Committee may consider the variation concurrently.

Significant variations are referred to a Working Group for initial assessment and then considered by the committee at a scheduled meeting. The committee may request further information from a licence holder in relation to a variation application.

More detail about the information required for different types of variations is provided on the Information for Licence Holders page of the NHMRC website. For additional information or to discuss a proposed variation application, please contact Embryo Research Licensing.

3.3.2. Variation initiated by NHMRC Licensing Committee

The NHMRC Licensing Committee may also initiate a variation to a licence. Such variations will be discussed with the licence holder before being implemented.

3.3.3. Appeals

The licence holder may appeal to the Administrative Appeals Tribunal for a review of a decision by the NHMRC Licensing Committee to vary or not to vary a licence (see Appendix 2.1).

3.4. Suspension, Revocation or Surrender of a Licence

3.4.1. Licence suspension or revocation

The NHMRC Licensing Committee can suspend or revoke a licence at any time if it believes, on reasonable grounds, that a licence condition has been breached. If the NHMRC Licensing Committee suspects that non-compliance has occurred, it will work through its Inspectors to investigate the situation. Subsequent actions will be determined on a case-by-case basis (see Chapter 5).

If a licence holder is convicted of an offence under the RIHE Act or the PHCR Act, the NHMRC Licensing Committee must revoke each licence held by the licence holder.

3.4.2. Appeals

If the NHMRC Licensing Committee suspends or revokes a licence, the licence holder has the right to appeal to the Administrative Appeals Tribunal for a review of the decision (see Appendix 2.1).

3.4.3. Licence surrender

A licence holder may surrender a licence at any time by writing to the NHMRC Licensing Committee. However, it is recommended that the licence holder consult with the NHMRC Licensing Committee regarding the date of surrender, as this will facilitate preparation of the Final Report and the timing of the Final Inspection (see Chapter 5).

4. INFORMATION FOR HUMAN RESEARCH ETHICS COMMITTEES

4.1. Evaluating Research Proposals

The purpose of this chapter is to provide advice for members of HRECs to assist them with the consideration of research proposals which fall under the scope of the RIHE Act.

4.1.1. Guidance for Human Research Ethics Committees

HRECs should be guided in their consideration of research proposals involving the use of excess ART embryos or human eggs, or the creation or use of other embryos by the National Statement and the ART Guidelines[p].

The purpose of the National Statement is to promote ethical human research by clarifying the responsibilities of researchers, HRECs, institutions and review bodies in the design, conduct, dissemination and review of human research. The National Statement was developed in accordance with the *National Health and Medical Research Council Act 1992*.

The ART Guidelines were developed to provide ethical guidelines for clinical practice and research involving assisted reproductive technology. They are intended for practitioners, researchers, ART clinic administrators, HRECs, and State and national government officials.

The ART Guidelines also take into account the legal requirements of the RIHE Act and PHCR Act in relation to prohibited and licensable activities. Both guidance documents are available on the NHMRC website (www.nhmrc.gov.au). HRECs can also contact Embryo Research Licensing for guidance on evaluating research proposals that require a licence to permit the use of excess ART embryos or human eggs, or the creation or use of other embryos.

In addition, paragraph 5.2.19 of the National Statement authorises HRECs to seek advice and assistance from experts. HRECs should satisfy themselves that such experts have no conflicts of interest in relation to the research proposal under consideration.

4.1.2. Obtaining proper consent

HRECs must be satisfied that the activity or project has been designed so that proper consent is obtained from all responsible persons in relation to the use of excess ART embryos, eggs, sperm, genetic material or cells. Proper consent means consent obtained in accordance with the ART Guidelines and the National Statement (see Explanation of Key Terms). In summary, consent should be:

- *Informed* — all responsible persons should be provided with information, at their level of comprehension, about the purpose, methods and possible outcomes of research, including the likelihood and form of publication of research results. This information should be given orally and supported by timely provision of written information.

p For the purposes of the RIHE Act, these guidelines are the prescribed guidelines under the RIHE Act section 8 (obtaining proper consent) and subsection 21(4)(c) (matters to be considered by the NHMRC Licensing Committee when deciding whether to issue a licence). The RIHE Regulations specify which versions of the guidelines are prescribed at any given time and HRECs should ensure that they refer to the correct version. Copies of the applicable versions can be obtained from Embryo Research Licensing if required.

- *Given by a person competent to do so* — in the context of the RIHE Act, only the responsible person or persons defined in the Act may give consent and all responsible persons must give their consent before donated material can be used under the licence (see Explanation of Key Terms). Therefore, the material must not be used if any responsible person is unwilling or unable to give consent.

  In addition, each person who gives consent must be cognitively competent at the time consent is given. For example, the consent process must be designed so that consent is not requested or obtained at times when a woman may be affected by medication used during egg retrieval.
- *Voluntary* — consent must not be subject to any coercion, inducement or influence, such as financial or other rewards.
- *Specific* — the consent form must specify the purpose for which the relevant material may be used.
- *Timely* — there should be adequate time for consideration of the information and adequate opportunities for personal preparation.
- *In writing* — section 9 of the RIHE Act refers to "written authority" or "written determination" in relation to obtaining consent.

Definitions of responsible persons can be found in section 8 of the RIHE Act (see Explanation of Key Terms) and up to six people may be required to give consent to the use of an excess ART embryo. These people are:

- the woman for whom the embryo was created and her spouse[q] if any at the time the embryo was created;
- If the people who provided the egg and sperm used to create the embryo are different from the people for whom the embryo was created then the egg and/or sperm donor must give consent;
- In addition if either the egg and/or sperm donor had a spouse at the time the egg or sperm was donated then these people also must give their consent.

The processes for obtaining proper consent for the use of excess ART embryos, human gametes and human genetic material (for creation of other embryos) are described in more detail in the *Consent checklist for licensed activities using excess ART embryos*, *Consent checklist for other licensed research* and *Additional information on obtaining consent* documents available from the Information for Applicants page of the NHMRC website. These documents will assist HRECs and applicants to ensure consent protocols meet the NHMRC Licensing Committee's requirements. The applicant is required to include the completed checklist in the application.

Signed consent forms that include personal information about donors must not be sent to the NHMRC Licensing Committee or Embryo Research Licensing. These consent forms must be retained by the licence holder. Inspectors appointed by the Chair of the NHMRC Licensing Committee will inspect these records when they undertake monitoring visits (see Chapter 5 for more information on monitoring visits).

q In relation to a person, 'spouse' includes a de facto partner of the person as defined by the *Acts Interpretation Act 1901*.

4.2. Approving a Research Proposal

Under the RIHE Act, the NHMRC Licensing Committee cannot issue a licence unless it is satisfied that the proposed activity or project has been assessed and approved by a HREC (RIHE Act subsection 21(3)). When considering licence proposals, a HREC must be constituted and conduct its activities in accordance with the National Statement.

After the HREC has evaluated the research proposal in the light of the National Statement and the ART Guidelines, the HREC may approve the proposal, request amendments or reject the proposal.

If the HREC decides that the proposal should not proceed, the applicant may not apply for a licence from the NHMRC Licensing Committee.

If the HREC approves the proposal (including after any requested amendments have been made), the applicant can submit an application to the NHMRC Licensing Committee.

A copy of the HREC's assessment and approval of the licence proposal should be provided to the NHMRC Licensing Committee and should contain the following:

- a statement that the HREC was constituted in accordance with the National Statement (see paragraph 5.1.30 of the National Statement)
- a statement that members fulfilling the required roles were present or otherwise had an opportunity to comment on the application
- a statement of how the application meets the requirements of the RIHE Act and relevant guidelines (e.g. ART Guidelines)
- a statement of how the consent process and documents will allow for proper consent to be obtained, in accordance with the ART Guidelines and the National Statement.

HREC approval does not provide the licence applicant with permission to commence the project. The research described in the proposal may only begin once a licence has been issued by the NHMRC Licensing Committee, and all necessary conditions have been met.

If the NHMRC Licensing Committee requires the applicant to amend the application during the assessment process, the HREC will be asked to approve the amended version before a licence is issued.

4.3. Approving Variations to an Existing Licence

The HREC overseeing the licensed activity is required to approve significant variations before the variations can be approved by the NHMRC Licensing Committee (see section 3.3.1 for more detail).

4.4. Monitoring Research Outcomes

The National Statement provides detailed information about the responsibilities of organisations and their HRECs for ensuring that the conduct of research approved by the HREC is monitored using procedures or existing mechanisms within the organisation (see the National Statement, Chapter 5.5 — 'Monitoring approved research'). The RIHE Act and the PHCR Act do not impose an additional monitoring role on HRECs. Inspectors appointed by the Chair of the NHMRC Licensing Committee monitor licence holders' compliance with the requirements of the legislation.

5. MONITORING COMPLIANCE WITH THE LEGISLATION

5.1. Role Of NHMRC in Monitoring Compliance with the Legislation

Under the RIHE and PHCR Acts, NHMRC has responsibility for monitoring compliance with the legislation. To achieve this, the Chair of the NHMRC Licensing Committee appoints inspectors under section 33 of the RIHE Act to monitor compliance with the legislation and report their findings to the NHMRC Licensing Committee. Under section 26 of the RIHE Act, the NHMRC Licensing Committee is also responsible for revoking or suspending licences, if it believes on reasonable grounds that a licence condition has been breached. The NHMRC Licensing Committee must revoke licences if the licence holder is convicted of an offence under either the RIHE Act or the PHCR Act.

Information on the offences under the RIHE Act and prohibited practices under the PHCR Act is provided in Chapter 1. Information on the exempt uses of excess ART embryos, which do not require a licence, is also provided in Chapter 1 (see also the RIHE Act subsection 10(2)).

5.2. Licence Holder Monitoring and Compliance Strategy

All licences[r] issued by the NHMRC Licensing Committee are subject to licence conditions against which inspectors are able to assess compliance. At minimum, licence conditions include those relating to:

- reporting requirements
- people who are authorised to carry out the licensed activities
- sites where the authorised activity can be conducted
- tracking of embryos or eggs used in licensed activities
- record keeping
- special conditions as required by the nature of the work being carried out under licence.

To monitor licence holder compliance with the legislative requirements and licence conditions, inspectors have developed a monitoring and compliance strategy in accordance with relevant government standards. As well as assessing compliance against licence conditions, inspectors may also focus on other elements of the research activity, for example:

- qualifications and training of the research scientists in all aspects of the authorised activity, for example knowledge of standard operating procedures, training in the techniques that may be regularly used in that particular research activity such as micromanipulation or freezing
- processes relating to the use of the eggs, embryos or other genetic material such as storage and disposal
- criteria used for the selection of eggs, embryos or other genetic material considered suitable to be entered into the research protocols.

r The Embryo Research Licensing pages of the NHMRC website at http://www.nhmrc.gov.au contain a publicly available licence database which provides the licences that have been issued and their conditions.

5.3. Monitoring and Compliance Activities

The legal framework for monitoring compliance with the Acts is established in Part 3 of the RIHE Act.

5.3.1. Co-operative compliance approach

The NHMRC Licensing Committee considers that providing opportunities for communication with stakeholders will minimise the likelihood of a breach of legislation or licence conditions. Consequently, licence holders, organisations and people subject to the legislation are encouraged to contact Embryo Research Licensing for information on issues relating to the legislation or any other matters, such as the conditions issued as part of a licence.

5.3.2. Inspections of licensed premises

Part 3 of the RIHE Act sets out the monitoring powers of inspectors. In particular, under section 35, inspectors may enter premises (at a reasonable time) where activities authorised by a licence are carried out to exercise the monitoring powers specified in section 36. Using this provision, inspectors use a variety of methods to monitor licence holders' compliance with licence conditions as follows:

- inspections or audits of records, documentation systems and processes relating to tracking of embryos or eggs used in licensed activities, and of the processes and documentation demonstrating that proper consent has been obtained (records audit inspection)
- announced inspections such as monitoring and final inspections, that are arranged in consultation with the licence holder
- unannounced or short notice inspections that may be used in response to suspected breaches of the legislation
- investigations in response to reports of an alleged breach of the legislation.

These different types of inspections are explained in more detail below.

5.3.3. Records audit inspection

Records audit inspections are conducted to provide assurance to the NHMRC Licensing Committee that licence holders have implemented robust systems to enable their compliance with the legislation and licence conditions.

The records audit is the foundation on which future inspections will be built. At the records audit inspection, inspectors assess whether the record keeping and documentation systems relating to the use of excess ART embryos, human eggs and other material used in licensed research meet the requirements of licence conditions and the legislation. The records audit inspection of the licence holder is carried out at a mutually agreed date and time before the licence is issued.

5.3.4. Monitoring inspections

Monitoring inspections are announced inspections which may be carried out annually for the duration of the licence. The purpose of a monitoring inspection is to ensure compliance with licence conditions and legislation. Monitoring inspections may be carried out more frequently if compliance issues become apparent. Licence holders will be contacted before the monitoring inspection to advise them of the intention to conduct an inspection and to arrange a mutually acceptable date and time.

The aims of monitoring inspections are to:

- review the licensed activity
- assess the level of compliance with the legislative requirements
- assess the level of compliance with the licence conditions.

During monitoring inspections, inspectors may:

- examine records and documents relating to the use of eggs and/or excess ART embryos to ensure proper consent was obtained in accordance with licence requirements and the legislation
- track selected embryos or eggs from consent to the outcomes of their use in the authorised activity to ensure that the embryos or eggs were used only for the purposes authorised by the licence
- assess the licence holders' procedures for complying with licence conditions, including but not limited to:
  - procedures for informing potential participants about the research project
  - notification to NHMRC that proper consent has been obtained
  - ensuring all reporting requirements are met.

In conjunction with monitoring inspections, inspectors may request that copies of signed consent forms and other documents relating to a licensed activity are sent to the inspectors for review. This process is intended to reduce the time required for the on-site inspection. These documents will be handled in confidence as outlined below. Monitoring inspections may also be used as a means of transferring information between the NHMRC Licensing Committee and licence holders, for example changes in licence conditions or legislative requirements. Information obtained during licence inspections will be passed on to the NHMRC Licensing Committee for consideration. Licence holders are encouraged to use the inspection process as an opportunity to raise issues with the NHMRC Licensing Committee.

5.3.5. Inspections of unlicensed premises

Inspections of unlicensed premises are carried out in cases where the unlicensed organisation and a licence holder are collaborating on a research project. When a licence authorises a research project where a licence holder and unlicensed organisation are in collaboration, a special condition may specify that inspectors are allowed to enter the unlicensed premises for the purpose of monitoring activities related to the licensed activity.

In addition, for the purpose of determining whether the RIHE Act and the regulations are being complied with, inspectors are permitted to enter unlicensed premises if:

- the occupier of the premises has given their consent, or
- inspectors have obtained a warrant from a magistrate to gain entry into the premises.

On admission to the premises, inspectors may exercise the monitoring powers described in section 36 of the RIHE Act.

5.3.6. Unannounced and short notice inspections

Under the provisions of section 35 of the RIHE Act, inspectors do not have to give advance notice of an inspection of premises occupied by licence holders. Inspectors may use such unannounced inspections as a way to determine whether there has been a breach of licence conditions. Such inspections must be held at a reasonable time.

Inspectors may choose to conduct short notice inspections instead of unannounced inspections in response to information that suggests that there has been a breach of licence conditions. For example, they may take this approach to avoid disrupting clinical activities at an ART clinic. Licence holders are usually given forty eight hours notice of the intention to conduct a short-notice inspection.

5.3.7. Final inspections

Final inspections are carried out on or immediately before the licence expiry date. The objectives of final inspections include, but are not limited to:

- ensuring the licensed activity will cease when the licence ends
- ensuring licence holders have fulfilled all legislative requirements
- ensuring licence holders have fulfilled all licence conditions
- ensuring licence holders have made adequate arrangements to deal with any unused materials obtained under the licence.

5.3.8. Reporting of inspections

After each inspection, inspectors will inform the licence holder of their initial observations resulting from the inspection. Inspectors report the outcomes of inspections to the Chair of the NHMRC Licensing Committee. The licence holders are sent a formal notice of the inspection outcomes. Information regarding inspections is included in the NHMRC Embryo Research Licensing Committee Biannual Reports to the Parliament of Australia.

5.3.9. Privacy and confidentiality

One of the monitoring powers available to Inspectors under section 36 of the RIHE Act is to inspect any book, record or document on the premises during an inspection. As such, inspectors will have access to a licence holder's confidential records. However, inspectors must comply with the provisions of the *Privacy Act 1988* to protect the privacy of individuals and recognise the sensitivities surrounding patient records. In addition, section 30 of the RIHE Act prohibits inspectors from making unauthorised disclosures of confidential commercial information.

5.4. Reporting Suspected Non-Compliance and Alleged Breaches of Legislation

If members of the public or individuals involved in activities regulated under the legislation become aware of non-compliant activity, they are encouraged to report their concerns to NHMRC. Reporting non-compliance is also a condition of all licences issued by the NHMRC Licensing Committee. The gravity of each alleged breach of licence conditions or legislation will be taken into account, with outcomes of such considerations tailored to the particular event. Further information on how the NHMRC Licensing Committee responds to noncompliance with the regulatory requirements governing embryo research is given in section 5.5.

As much detail as possible should be provided in the report; however, it is not necessary to gather evidence or to prove that non-compliance has occurred. Individuals should not conduct their own private investigations, as they may break a range of Australian laws by doing so. In addition, their actions may damage the integrity of any future NHMRC investigation and as such the evidence may be inadmissible in a court of law.

NHMRC ensures that all information received, as well as its source, is treated in confidence. However, in some cases, it is not possible to pursue a matter or refer it to other agencies, including the police, without identifying the person who reported the issue. For this reason, people reporting issues to NHMRC will be asked to indicate whether they consent to their identity being disclosed to other agencies including the police. Reported information may not necessarily result in an investigation.

5.5. Responding to Non-Compliance

Under the *Commonwealth Fraud Control Framework*[f] Australian Government agencies are required to investigate offences against agency programs, irrespective of whether the investigation results in an administrative response or referral for prosecution. The legislation gives inspectors broad powers to investigate any allegations of a breach of the legislation (see Box 5.1 for circumstances in which an investigation may be initiated). Based on the outcome of this initial investigation and the relevant provisions of the legislation, NHMRC will determine the appropriate level if any, of further investigation and response.

BOX 5.1 REASONS FOR INVESTIGATING NON-COMPLIANCE

An investigation may be initiated as a result of:

- An inspection conducted by inspectors;
- an allegation by a third party (e.g. member of the general public, non-government organisation);
- a report by a licence holder; and/or
- a referral by another Australian Government agency or by a State or Territory government agency.

5.5.1. NHMRC responses to non-compliance

Breaches of the legislation and licence conditions carry high penalties. As such, the gravity of each breach will be assessed before an appropriate response is applied.

On becoming aware of a suspected breach of the legislation, NHMRC will conduct an investigation to ascertain if there has indeed been an incidence of non-compliance. Details of ongoing and incomplete investigations will not be released to the public since the information may:

- jeopardise current or future investigations
- be protected by legislation such as the *Privacy Act 1998*
- unfairly damage the reputation of a company or individual under investigation if the allegation is proven to be unfounded
- unfairly damage the reputation of third parties who have not themselves breached legislation requirements.

Depending on the severity of the breach, NHMRC may refer the investigation to a panel of investigators, or to another organisation or agency such as the Australian Federal Police (AFP). The role of the AFP and other agencies is discussed in section 5.5.2.

5.5.2. The role of the Australian Federal Police, State and Territory Police or other qualified investigators

NHMRC investigates breaches of the legislation to the point where enough evidence is available to determine both the seriousness of the matter and whether referral to the AFP or another investigation agency is appropriate. The AFP may subsequently refer the matter to the Commonwealth Director of Public Prosecutions (CDPP) for a decision on whether to proceed with prosecution. Where an offence falls under a corresponding State or Territory law, the matter is referred to the police in that State or Territory. A brief of evidence may be prepared for the State or Territory Director of Public Prosecutions for a decision on whether to proceed with prosecution under the State or Territory law.

5.5.3. Sanctions in response to non-compliance with a licence

Offences may be categorised into those related to practices that are prohibited unless authorised by a licence and practices that are completely prohibited uses of human reproductive material. Both these categories are described in further detail in sections 9-23B of the PHCR Act and also in sections10-12A of the RIHE Act. Penalties of between five and 15 years' imprisonment are applicable to breaches of the RIHE and PHCR Acts. Investigations of breaches of legislation by the AFP (or other investigation agency) and subsequent referral to the CDPP may result in the application of a criminal sanction such as the imprisonment of those responsible for the breach.

In the case of non-compliance with licence conditions or the legislation, the NHMRC Licensing Committee can impose one of the following measures:

- Vary the special or standard licence conditions — the NHMRC Licensing Committee may introduce new, or vary existing, licence conditions to ensure that the non-compliance is not repeated[s]
- Endorse increased compliance activities including, but not limited to more frequent inspections, and/or increased reporting requirements
- Suspend a licence — the NHMRC Licensing Committee may suspend a licence if the committee believes on reasonable grounds that a licence condition has been breached
- Revoke a licence — the NHMRC Licensing Committee may revoke a licence if they believe, on reasonable grounds, that a licence condition has been breached. If a licence holder is convicted of an offence under the PHCR Act or RIHE Act the committee must revoke all licences issued to the licence holder.
- Affected persons may apply to the Administrative Appeals Tribunal for a review of these decisions of the NHMRC Licensing Committee (see Appendix 2.1).
- Information about completed investigations and findings of the investigations are included in the NHMRC Licensing Committee's Biannual Report to the Parliament of Australia.

s This administrative response to non-compliance may be used in, but is not limited to, situations where the CDPP or the Director of Public Prosecutions of the relevant jurisdiction has made a decision not to prosecute.