Research Involving Human Embryos Act 2002

No. 145, 2002

Compilation No. 7

Compilation date:	1 October 2022
Includes amendments up to:	Act No. 26, 2022
Registered:	6 October 2022

Prepared by the Office of Parliamentary Counsel, Canberra

About this compilation

This compilation

This is a compilation of the *Research Involving Human Embryos Act 2002* that shows the text of the law as amended and in force on 1 October 2022 (the ***compilation date***).

The notes at the end of this compilation (the ***endnotes***) include information about amending laws and the amendment history of provisions of the compiled law.

Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Legislation Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the series page on the Legislation Register for the compiled law.

Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

Editorial changes

For more information about any editorial changes made in this compilation, see the endnotes.

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the series page on the Legislation Register for the compiled law.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

Contents

An Act to regulate certain activities involving the use of human embryos, and for related purposes

Part 1—Preliminary

1 Short title

This Act may be cited as the *Research Involving Human Embryos Act 2002*.

2 Commencement

(1) Each provision of this Act specified in column 1 of the table commences, or is taken to have commenced, on the day or at the time specified in column 2 of the table.

Commencement information

Column 1	Column 2	Column 3
Provision(s)	**Commencement**	**Date/Details**
1. Sections 1 and 2 and anything in this Act not elsewhere covered by this table	The day on which this Act receives the Royal Assent	19 December 2002
2. Sections 3 to 9	The 28th day after the day on which this Act receives the Royal Assent	16 January 2003
3. Sections 10 to 12	At the end of the period of 6 months beginning on the day on which this Act receives the Royal Assent	19 June 2003
4. Sections 13 to 48	The 28th day after the day on which this Act receives the Royal Assent	16 January 2003

Note: This table relates only to the provisions of this Act as originally passed by the Parliament and assented to. It will not be expanded to deal with provisions inserted in this Act after assent.

(2) Column 3 of the table is for additional information that is not part of this Act. This information may be included in any published version of this Act.

3 Object of Act

The object of this Act is to address concerns, including ethical concerns, about scientific developments in relation to human reproduction and the utilisation of human embryos by regulating activities that involve the use of certain human embryos created by assisted reproductive technology or by other means.

4 Operation of Act

(1) This Act applies as follows:

(a) to things done, or omitted to be done, by constitutional corporations;

(b) to things done, or omitted to be done, in the course of constitutional trade or commerce;

(c) to matters within the legislative power of the Commonwealth under paragraph 51(xxix) of the Constitution;

(d) to the Commonwealth and Commonwealth authorities;

(e) for purposes relating to the collection, compilation, analysis and dissemination of statistics;

(f) to matters within the legislative power of the Commonwealth under paragraph 51(xxxix) of the Constitution, so far as it relates to the matters mentioned in paragraphs (a) to (e) of this subsection.

Note: See also section 28B in relation to mitochondrial donation licences.

(2) In this section:

constitutional trade or commerce means trade or commerce:

(a) between Australia and places outside Australia; or

(b) among the States; or

(c) by way of the supply of services to the Commonwealth or to a Commonwealth authority.

Note: For ***constitutional corporation***, see subsection 7(1).

5 Act to bind the Crown

(1) This Act binds the Crown in each of its capacities.

(2) Nothing in this Act renders the Crown liable to be prosecuted for an offence.

6 External Territories

This Act extends to every external Territory.

7 Definitions

(1) In this Act:

Commonwealth authority means the following:

(a) a body corporate established for a public purpose by or under an Act;

(b) a company in which a controlling interest is held by any one of the following persons, or by 2 or more of the following persons together:

(i) the Commonwealth;

(ii) a body covered by paragraph (a);

(iii) a body covered by either of the above subparagraphs.

constitutional corporation means a trading, foreign or financial corporation within the meaning of paragraph 51(xx) of the Constitution.

corresponding State law, in relation to a State, means a law of that State declared by the Minister, by notice in the *Gazette*, to be a corresponding State law for the purposes of this Act.

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.

hybrid embryo means:

(a) an embryo created by the fertilisation of a human egg by animal sperm; or

(b) an embryo created by the fertilisation of an animal egg by human sperm; or

(c) a human egg into which the nucleus of an animal cell has been introduced; or

(d) an animal egg into which the nucleus of a human cell has been introduced; or

(e) a thing declared by the regulations to be a hybrid embryo.

inspector means a person appointed as an inspector under subsection 33(1).

NHMRC Licensing Committee means the Committee established by section 13.

Secretary means the Secretary of the Department.

spouse, in relation to a person, includes a de facto partner of the person within the meaning of the *Acts Interpretation Act 1901*.

State includes the Australian Capital Territory and the Northern Territory.

the NHMRC means the National Health and Medical Research Council established by the *National Health and Medical Research Council Act 1992*.

unsuitable for implantation, in relation to a human embryo, 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*, issued by the CEO of the NHMRC under the *National Health and Medical Research Council Act 1992*, as existing from time to time; 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.

use includes develop, or development, as the case requires.

woman means a female human.

(2) For the purposes of the definition of ***human embryo*** in subsection (1), in working out the length of the period of development of a human embryo, any period when the development of the embryo is suspended is to be disregarded.

(3) A reference in this Act to an embryo (including a human embryo) is a reference to a living embryo.

(4) A reference in this Act to a human egg is a reference to a human oocyte.

(5) A reference in this Act to a human embryo does not include a reference to:

(a) a hybrid embryo; or

(b) a human embryonic stem cell line.

Part 2—Regulation of the use of excess ART embryos and other material

Division 1—Interpretation

8 Definitions

In this Part:

accredited ART centre means a person or body accredited to carry out assisted reproductive technology by:

(a) the Reproductive Technology Accreditation Committee of the Fertility Society of Australia; or

(b) 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.

AHEC means the Australian Health Ethics Committee established by the *National Health and Medical Research Council Act 1992*.

clinical practice licence means a licence referred to in section 28G.

clinical practice research and training licence means a licence referred to in section 28F.

clinical trial licence means a licence referred to in section 28E.

clinical trial research and training licence means a licence referred to in section 28D.

confidential commercial information means information that has a commercial or other value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed.

disclose, in relation to information, means give or communicate in any way.

donor, in relation to a particular use of a mitochondrial donation technique, has the meaning given by subsection 28R(2).

engage in conduct means:

(a) do an act; or

(b) omit to perform an act.

excess ART embryo has the meaning given by section 9.

general licence means a licence issued under section 21.

HREC means a Human Research Ethics Committee.

mitochondrial donation licence means:

(a) a pre-clinical research and training licence; or

(b) a clinical trial research and training licence; or

(c) a clinical trial licence; or

(d) a clinical practice research and training licence; or

(e) a clinical practice licence.

mitochondrial donation technique means a technique, prescribed by the regulations for the purposes of this definition, that:

(a) can be used to minimise the risk of a woman's offspring inheriting mitochondria from that woman that would predispose the offspring to mitochondrial disease; and

(b) involves using assisted reproductive technology to create a zygote that:

(i) has nuclear DNA from the woman and a man; and

(ii) contains mitochondria from a human egg of a different woman; and

(c) does not involve:

(i) intentionally modifying nuclear DNA or mitochondrial DNA; or

(ii) using any cell, or any component part of a cell, of an animal; or

(iii) creating a chimeric embryo (within the meaning of the *Prohibition of Human Cloning for Reproduction Act 2002*) or a hybrid embryo.

National Statement means the *National Statement on Ethical Conduct in Human Research*, issued by the CEO of the NHMRC under the *National Health and Medical Research Council Act 1992*, as existing from time to time.

Note: The National Statement could in 2021 be viewed on the website of the NHMRC (https://www.nhmrc.gov.au).

patient means a woman whose pregnancy is sought to be achieved using a mitochondrial donation technique under a clinical practice licence.

Note: For a human embryo to be created for, or placed in the body of, a woman under a clinical practice licence, the NHMRC Licensing Committee must be satisfied that there is a particular risk of the woman's offspring inheriting mitochondria from the woman that would predispose the offspring to mitochondrial disease: see paragraph 28P(4)(a).

permitted technique for a mitochondrial donation licence of a particular kind means a mitochondrial donation technique that is declared by the regulations to be a permitted technique for a mitochondrial donation licence of that kind.

pre-clinical research and training licence means a licence referred to in section 28C.

proper consent:

(a) for the purposes of Division 4 (general licences) of Part 2—has the meaning given by subsection 24(9); and

(b) for the purposes of Division 4A (mitochondrial donation licences) of Part 2—has the meaning given by subsection 28N(8).

relevant State body means a person or body notified by a State to the Chairperson of the NHMRC Licensing Committee for the purposes of this Part.

responsible person:

(a) for the purposes of Division 4 (general licences) of Part 2—has the meaning given by subsection 24(9); and

(b) for the purposes of Division 4A (mitochondrial donation licences) of Part 2—has the meaning given by subsection 28N(8).

trial participant means a woman whose pregnancy is sought to be achieved using a mitochondrial donation technique under a clinical trial licence.

Note: For a human embryo to be created for, or placed in the body of, a woman under a clinical trial licence, the NHMRC Licensing Committee must be satisfied that there is a particular risk of the woman's offspring inheriting mitochondria from the woman that would predispose the offspring to mitochondrial disease: see paragraph 28P(4)(a).

9 Meaning of *excess ART embryo*

(1) In this Part:

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.

(2) For the purposes of paragraph (b) of the definition of ***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.

Division 2—Offences

10 Offence—use of excess ART embryo

(1) A person commits an offence if the person intentionally uses an excess ART embryo, unless:

(a) the excess ART embryo is created other than by using a mitochondrial donation technique and the use of the embryo by the person is authorised by a general licence; or

(aa) the excess ART embryo is created using a mitochondrial donation technique and the use of the embryo by the person is permitted under section 28B (carrying out activities authorised by mitochondrial donation licences); or

(b) the use by the person is an exempt use within the meaning of subsection (2).

Penalty: Imprisonment for 5 years.

(2) A use of an excess ART embryo by a person is an ***exempt use*** for the purposes of subsection (1) if:

(a) the use consists only of:

(i) storage of the excess ART embryo; or

(ii) removal of the excess ART embryo from storage; or

(iii) transport of the excess ART embryo; or

(b) the use consists only of observation of the excess ART embryo; or

(c) the use consists only of allowing the excess ART embryo to succumb; or

(d) the use is carried out by an accredited ART centre, and:

(i) 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

(ii) the use forms part of diagnostic investigations conducted in connection with the assisted reproductive

technology treatment of the woman for whom the excess ART embryo was created; or

(e) the use is carried out by an accredited ART centre, and:

(i) the use is for the purposes of achieving pregnancy in a woman other than the woman for whom the excess ART embryo was created; and

(ii) the excess ART embryo was not created using a mitochondrial donation technique as permitted under section 28B (carrying out activities authorised by mitochondrial donation licences); or

(f) the use is of a kind prescribed by the regulations for the purposes of this paragraph.

(3) Despite subsection 13.3(3) of the *Criminal Code*, a defendant does not bear an evidential burden in relation to any matter in subsection (1) or (2) of this section.

(4) In subsection (2):

diagnostic investigation, in relation to an excess ART embryo, means any procedure undertaken on embryos for the sole purpose of diagnostic investigations for the direct benefit of the woman for whom it was created.

observation, in relation to an excess ART embryo, includes taking a photograph of the embryo, or taking a recording of the embryo from which a visual image can be produced.

10A Offence—use of other embryos

A person commits an offence if:

(a) the person intentionally uses an embryo; and

(b) the embryo is:

(i) a human embryo created by a process other than the fertilisation of a human egg by a human sperm; or

(ii) a human embryo created by a process other than the fertilisation of a human egg by a human sperm that

contains genetic material provided by more than 2 persons; or

(iii) a human embryo created using precursor cells taken from a human embryo or a human fetus; or

(iv) a hybrid embryo; and

(c) the use by the person is not authorised by a general licence or, if subparagraph (b)(i) or (ii) applies, permitted under section 28B (carrying out activities authorised by mitochondrial donation licences).

Penalty: Imprisonment for 5 years.

Note: The creation or development of embryos mentioned in this section is prohibited under Part 2 of the *Prohibition of Human Cloning for Reproduction Act 2002*, unless authorised by a general licence under this Act, or if subparagraph (b)(i) or (ii) applies, permitted under section 28B of this Act.

10B Offence—certain activities involving use of human eggs

A person commits an offence if:

(a) the person undertakes research or training involving 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 the purposes of research or training in assisted reproductive technology; and

(b) neither of the following apply:

(i) the person is authorised to undertake the research or training by a general licence;

(ii) the person is permitted under section 28B to undertake the research or training because of a pre-clinical research and training licence, a clinical trial research and training licence or a clinical practice research and training licence.

Penalty: Imprisonment for 5 years.

11 Offence—use of embryo that is not an excess ART embryo

A person commits an offence if:

(a) the person intentionally uses, outside the body of a woman, a human embryo:

(i) that was created by fertilisation of a human egg by a human sperm; and

(ii) that is not an excess ART embryo; and

(b) the use is not for a purpose relating to the assisted reproductive technology treatment of a woman carried out by an accredited ART centre, and the person knows or is reckless as to that fact; and

(c) the use by the person is not permitted under section 28B (carrying out activities authorised by mitochondrial donation licences).

Penalty: Imprisonment for 5 years.

11A Offence—use of material created under mitochondrial donation licence

A person commits an offence if:

(a) the person intentionally uses any material (other than an excess ART embryo) created, developed or produced under a mitochondrial donation licence; and

(b) the use of the material by the person is not permitted under section 28B (carrying out activities authorised by mitochondrial donation licences).

Penalty: Imprisonment for 5 years.

12 Offence—breaching a general licence or mitochondrial donation licence condition

A person commits an offence if the person intentionally engages in conduct, knowing that the conduct contravenes a condition of a general licence or mitochondrial donation licence that applies to

the person, or reckless as to whether the conduct contravenes a condition of such a licence.

Penalty: Imprisonment for 5 years.

12A Person not liable for conduct purportedly authorised

(1) To avoid doubt, a person is not criminally responsible for a licence offence in respect of particular conduct if:

(a) the conduct by the person is purportedly authorised by a provision of a general licence or mitochondrial donation licence; and

(b) the licence or the provision is invalid, whether because of a technical defect or irregularity or for any other reason; and

(c) the person did not know, and could not reasonably be expected to have known, of the invalidity of the licence or the provision.

(2) In this section:

general licence includes a purported general licence.

licence offence means:

(a) for a general licence—an offence against section 10, 10A, 10B or 12; or

(b) for a mitochondrial donation licence—an offence against:

(i) section 10; or

(ii) section 10A, in so far as it applies because of subparagraph (b)(i) or (ii) of that section; or

(iii) section 10B in so far as it applies to a pre-clinical research and training licence, a clinical trial research and training licence or a clinical practice research and training licence; or

(iv) section 11, 11A or 12.

mitochondrial donation licence includes a purported mitochondrial donation licence.

Division 3—Embryo Research Licensing Committee of the NHMRC

13 Establishment of Committee

(1) The Embryo Research Licensing Committee of the NHMRC (the ***NHMRC Licensing Committee***) is established by this section.

(2) The NHMRC Licensing Committee is taken to be a Principal Committee within the meaning of the *National Health and Medical Research Council Act 1992*, other than for the purposes of the following provisions of that Act:
  (a) sections 5D and 5E;
  (b) section 35;
  (c) section 41;
  (d) section 80;
  (e) subsections 82(1C) and (2).

(3) This section has effect despite the definition of ***Principal Committee*** in section 4 of the *National Health and Medical Research Council Act 1992*.

(4) The regulations may make provision for and in relation to the disclosure of members' interests in matters being considered by the NHMRC Licensing Committee.

(5) The following provisions do not have effect in relation to the NHMRC Licensing Committee at any time when regulations under subsection (4) are in force:
  (a) section 42A of the *National Health and Medical Research Council Act 1992*;
  (b) section 29 of the *Public Governance, Performance and Accountability Act 2013* (which deals with the duty to disclose interests) and any rules made for the purposes of that section.

14 Functions of Committee

The functions of the NHMRC Licensing Committee are:

(a) to perform functions in relation to general licences under Division 4; and

(aa) to perform functions in relation to mitochondrial donation licences under Division 4A; and

(b) to perform functions in relation to databases under section 29; and

(c) to perform such other functions as are conferred on it by this Act or any other law.

15 Powers of Committee

The NHMRC Licensing Committee has power to do all things necessary or convenient to be done for or in connection with the performance of its functions.

16 Membership of Committee

(1) The NHMRC Licensing Committee consists of the following members:

(a) a member of AHEC;

(b) a person with expertise in research ethics;

(c) a person with expertise in a relevant area of research;

(d) a person with expertise in assisted reproductive technology;

(e) a person with expertise in a relevant area of law;

(f) a person with expertise in consumer health issues relating to disability and disease;

(g) a person with expertise in consumer issues relating to assisted reproductive technology;

(h) a person with expertise in the regulation of assisted reproductive technology;

(i) a person with expertise in embryology.

(2) The Minister must appoint the members of the NHMRC Licensing Committee.

(3) Before appointing a member, the Minister must:
   (a) seek nominations from the States and from such bodies as are prescribed by the regulations for the purpose;
   (b) consult, and have regard to the views expressed by, the States on the proposed appointment; and
   (c) be satisfied upon receipt of a written declaration by the member proposed to be appointed that the member proposed does not have a direct or indirect pecuniary interest in a body that undertakes uses of excess ART embryos or human eggs, or creation or uses of other embryos, being an interest of a kind that could conflict with the proper performance of the member's functions.

(4) The Minister must appoint one of the members, other than the member mentioned in paragraph (1)(a), as the Chairperson of the NHMRC Licensing Committee.

(5) The Minister must not appoint a person:
   (a) as the Chairperson under subsection (4); or
   (b) as the member mentioned in paragraph (1)(h);
unless a majority of the States agree with that appointment.

(6) In appointing the members of the NHMRC Licensing Committee, the Minister must have regard to the desirability of ensuring that the Committee as a whole comprises members from different States.

(7) It is the intention of the Parliament that any vacancy on the NHMRC Licensing Committee be filled as soon as possible.

(8) If there is a vacancy in the membership of the NHMRC Licensing Committee for a period of 3 months the Minister must, within 3 sitting days of the expiration of that 3 months, table in each House of the Parliament a written statement of reasons for the failure to fill the vacancy.

17 Terms of appointment

(1) A member of the NHMRC Licensing Committee holds office on a part-time basis.

(2) A member holds office for a period not exceeding 3 years that is specified in the instrument of appointment, but is eligible for reappointment.

18 Annual report

(1) The annual report prepared by the CEO of the NHMRC under section 46 of the *Public Governance, Performance and Accountability Act 2013* must, in addition to the matters set out in section 83 of the *National Health and Medical Research Council Act 1992*, include details relating to the operations of the NHMRC Licensing Committee.

(2) The NHMRC Licensing Committee must give written details relating to its operations to the CEO of the NHMRC for the purposes of subsection (1).

19 Reports to Parliament

(1) The NHMRC Licensing Committee may at any time cause a report about matters relating to the Committee's functions to be tabled in either House of the Parliament.

(2) The NHMRC Licensing Committee must give a copy of the report to the Minister and to each State.

(3) The NHMRC Licensing Committee must cause a report to be tabled in either House of Parliament on or before:

(a) 30 June of each year; and

(b) 31 December of each year; and

(c) any other time required by either House of Parliament;

that must include information about:

(d) the operation of this Act; and

(e) the general licences and mitochondrial donation licences issued under this Act.

(4) A report under this section must not include information about any of the following matters unless the NHMRC Licensing Committee considers that the information does not identify, and is not reasonably capable of being used to identify, any person:

(a) approvals under subsection 28P(3) (including applications for such approvals and the outcomes of those applications);

(b) births of children as a result of pregnancies achieved using a mitochondrial donation technique under a clinical trial licence or a clinical practice licence;

(c) adverse events notified to the NHMRC Licensing Committee under paragraph 28S(3)(a).

Division 4—General licences

20 Applying for a general licence

(1) A person may apply to the NHMRC Licensing Committee for a licence (a ***general licence***) authorising one or more of the following:

(a) use of excess ART embryos;

(b) creation of human embryos other than by fertilisation of a human egg by a human sperm, and use of such embryos;

(c) creation of human embryos other than by fertilisation of a human egg by a human sperm that contain genetic material provided by more than 2 persons, and use of such embryos;

(d) creation of human embryos using precursor cells from a human embryo or a human fetus, and use of such embryos;

(e) research and training involving 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 the purposes of research or training in assisted reproductive technology;

(f) creation of hybrid embryos by the fertilisation of an animal egg by a human sperm, and use of such embryos up to, but not including, the first mitotic division, if:

(i) the creation or use is for the purposes of testing sperm quality; and

(ii) the creation or use will occur in an accredited ART centre.

(1A) To avoid doubt, paragraphs (1)(a), (b), (c) and (d) do not permit the NHMRC Licensing Committee to authorise any use of an excess ART embryo or other embryo that would result in the development of the embryo for a period of more than 14 days, excluding any period when development is suspended.

(1B) Subsection (1) does not permit the NHMRC Licensing Committee to authorise:

(a) any activity that involves the use of a mitochondrial donation technique; or

(b) the use of any material created, developed or produced under a mitochondrial donation licence.

(2) An application under subsection (1):

(a) must be made in accordance with the requirements (if any) specified in writing by the NHMRC Licensing Committee; and

(b) must be accompanied by the fee (if any) prescribed by the regulations.

21 Determination of application by Committee

(1) This section applies if a person has made an application under section 20 for a general licence.

(2) The NHMRC Licensing Committee must decide, in accordance with this section, whether or not to issue the licence.

(3) The NHMRC Licensing Committee must not issue the licence unless it is satisfied of the following:

(a) that appropriate protocols are in place:

(i) to enable proper consent to be obtained before an excess ART embryo or human egg is used, or other embryo is created or used under the licence (see paragraph 24(1)(a)); and

(ii) to enable compliance with any restrictions on such consent;

(c) that the activity or project proposed in the application has been assessed and approved by a HREC that is constituted in accordance with, and acting in compliance with, the National Statement.

(4) In deciding whether to issue the licence, the NHMRC Licensing Committee must have regard to the following:

(a) restricting the number of excess ART embryos, other embryos or human eggs, to that likely to be necessary to

achieve the goals of the activity or project proposed in the application;

(b) the likelihood of significant advance in knowledge or improvement in technologies for treatment as a result of the use of excess ART embryos or human eggs, or the creation or use of other embryos, proposed in the application, which could not reasonably be achieved by other means;

(c) any relevant guidelines, or relevant parts of 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;

(d) the HREC assessment of the application mentioned in paragraph (3)(c);

(e) such additional matters (if any) as are prescribed by the regulations.

22 Notification of decision

(1) The NHMRC Licensing Committee must notify its decision on an application for a general licence under section 20 to the following:

(a) the applicant;

(b) the HREC that assessed and approved the activity or project proposed in the application as mentioned in paragraph 21(3)(c);

(c) the relevant State body in relation to the State in which the use is to occur.

(2) If the NHMRC Licensing Committee decides to issue the licence, it must, in addition to issuing the licence to the applicant, give a copy of the licence to the bodies mentioned in paragraphs (1)(b) and (c).

23 Period of a general licence

(1) A general licence:

(a) comes into force on the day specified in the licence, or if no day is specified, on the day on which it is issued; and

(b) remains in force until the day specified in the licence, unless it is suspended, revoked or surrendered before that day.

(2) A general licence is not in force throughout any period of suspension.

24 Conditions of general licences

(1) A general licence is subject to the condition that before an excess ART embryo or human egg is used, or any other embryo is created or used, as authorised by the licence:

(a) each responsible person in relation to the excess ART embryo, human egg or other embryo must have given proper consent to that creation or use; and

(b) the licence holder must have reported in writing to the NHMRC Licensing Committee that such consent has been obtained, and any restrictions to which the consent is subject.

(2) A general licence is subject to the condition that the use of an excess ART embryo or human egg, or the creation or use of any other embryo, must be in accordance with any restrictions to which the proper consent under subsection (1) is subject.

(4) A general licence is subject to such other conditions as are specified in the licence.

(5) The conditions specified in the licence may include, but are not limited to, conditions relating to the following:

(a) the persons authorised by the licence to use excess ART embryos or human eggs, or create or use other embryos;

(b) the number of excess ART embryos or human eggs authorised to be used under the licence, or the number of other embryos authorised to be created or used under the licence;

(c) reporting;

(d) monitoring;

(e) information to be given by the licence holder to persons authorised by the licence to use excess ART embryos or human eggs, or to create or use other embryos.

(6) The licence conditions set out in subsections (1) and (2) apply to all persons who are authorised by the licence to use excess ART embryos or human eggs, or to create or use other embryos.

(7) Licence conditions specified in the licence apply to:
(a) the licence holder; and
(b) such other persons authorised by the licence to use excess ART embryos or human eggs, or to create or use other embryos as are specified in the licence.

(8) For the purposes of applying the condition referred to in paragraph (1)(a):
(a) a general licence may provide that the guidelines referred to in the definition of ***proper consent*** in subsection (9) apply in a modified form in relation to the use, under the licence, of excess ART embryos that are unsuitable for implantation; and
(b) if a general licence so provides, the guidelines as modified by the licence have effect in relation to the giving of consent for such creation or use.

Note: For example, the guidelines could apply to a particular licence in a modified form, to alter the cooling-off period required in relation to the use of excess ART embryos that are unsuitable for implantation.

(9) In this Division:

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, means consent obtained in accordance with 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 definition.

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.

25 Variation of a general licence

(1) The NHMRC Licensing Committee may, by notice in writing given to the licence holder, vary a general licence if the Committee believes on reasonable grounds that it is necessary or desirable to do so.

(2) The NHMRC Licensing Committee may vary a general licence under subsection (1) on its own initiative or on application by the licence holder.

(3) Without limiting subsection (1), the NHMRC Licensing Committee may vary the licence by specifying additional conditions or varying existing conditions.

(4) The NHMRC Licensing Committee must not vary a general licence in such a way that, had a person applied under section 20 for the licence as varied, the Committee would not have been permitted by this Division to issue the licence.

26 Suspension or revocation of a general licence

(1) The NHMRC Licensing Committee may, by notice in writing given to the licence holder, suspend or revoke a general licence if the Committee believes on reasonable grounds that a condition of the licence has been breached.

(2) If a licence holder is convicted of an offence under this Act or the *Prohibition of Human Cloning Act 2002*, the NHMRC Licensing Committee must, by notice in writing given to the licence holder, revoke each general licence held by the licence holder.

27 Surrender of a general licence

A licence holder may surrender a general licence by written notice given to the NHMRC Licensing Committee.

28 Notification of variation, suspension or revocation of a general licence

(1) If the NHMRC Licensing Committee varies, suspends or revokes a general licence, the Committee must notify:

(a) the licence holder; and

(b) the HREC and the relevant State body to which the NHMRC Licensing Committee notified its decision on the application for the licence under section 22.

(2) The NHMRC Licensing Committee must also notify the bodies mentioned in paragraph (1)(b) if a general licence is surrendered.

Division 4A—Mitochondrial donation licences

Subdivision A—Kinds of mitochondrial donation licences and what they authorise

28A Kinds of mitochondrial donation licences

There are 5 kinds of mitochondrial donation licences, which are as follows:

(a) pre-clinical research and training licences referred to in section 28C;

(b) clinical trial research and training licences referred to in section 28D;

(c) clinical trial licences referred to in section 28E;

(d) clinical practice research and training licences referred to in section 28F;

(e) clinical practice licences referred to in section 28G.

28B Carrying out activities authorised by mitochondrial donation licences

(1) A person may carry out an activity as authorised by a pre-clinical research and training licence, a clinical trial research and training licence or a clinical trial licence (see section 28C, 28D or 28E) if:

(a) the licence is in force; and

(b) the licence holder is a constitutional corporation.

(2) Subsection (1) applies despite a law of a State.

(3) A person may carry out an activity as authorised by a clinical practice research and training licence or a clinical practice licence (see section 28F or 28G) in a particular State if:

(a) the licence is in force; and

(b) carrying out the activity is authorised by a law of that State.

28C What a pre-clinical research and training licence authorises

(1) A ***pre-clinical research and training licence*** authorises carrying out any of the activities mentioned in subsection (2) that are specified in the licence in undertaking research and training for the purpose of doing all of the following:

(a) developing the permitted technique specified in the licence for potential future use in a clinical setting as a way to minimise the risk of women's offspring inheriting mitochondria that would predispose them to mitochondrial disease, but without the immediate aim of:

(i) conducting a clinical trial; or

(ii) using the technique in a clinical practice setting;

(b) better understanding the technique, including its safety and efficacy in minimising the risk of women's offspring inheriting mitochondria that would predispose them to mitochondrial disease;

(c) building expertise in the technique and how to use it.

(2) The activities are as follows:

(a) creation of human embryos other than by fertilisation of a human egg by a human sperm, using the permitted technique specified in the licence, and use of such embryos;

(b) creation of human embryos that contain genetic material provided by more than 2 persons, using the permitted technique specified in the licence:

(i) by fertilisation of a human egg by a human sperm outside the body of a woman; or

(ii) other than by the fertilisation of a human egg by a human sperm;

and use of such embryos;

(c) creation of human embryos by a process of the fertilisation of a human egg by a human sperm outside the body of a woman, using the permitted technique specified in the licence, and use of such embryos;

(d) research and training involving the fertilisation of a human egg by a human sperm up to, including and after the first

mitotic division, outside the body of a woman for the purposes of research or training in the use of the permitted technique specified in the licence;

(e) use of any material (other than an excess ART embryo) created, developed or produced under a mitochondrial donation licence.

(3) A pre-clinical research and training licence does not authorise any use of a human embryo that would:

(a) result in the development of a human embryo for a period of more than 14 days, excluding any period when development is suspended; or

(b) involve placing a human embryo into the body of a woman for the purposes of achieving pregnancy in that woman.

28D What a clinical trial research and training licence authorises

(1) A ***clinical trial research and training licence*** authorises carrying out any of the activities mentioned in subsection (2) that are specified in the licence, at an accredited ART centre, in undertaking research and training for the purpose of doing all of the following in preparation for using the permitted technique specified in the licence in a particular clinical trial:

(a) developing protocols for using the technique safely and effectively, in a clinical trial setting, for the purpose of minimising the risk of women's offspring inheriting mitochondria that would predispose them to mitochondrial disease;

(b) ensuring that each embryologist nominated under subsection 28H(5) has technical competence in the use of the technique in accordance with those protocols;

(c) ensuring that the holder's facilities, equipment, processes and protocols for using the technique are suitable for using the technique in a clinical trial setting.

(2) The activities are as follows:

(a) creation of human embryos other than by fertilisation of a human egg by a human sperm, using the permitted technique specified in the licence, and use of such embryos;

(b) creation of human embryos that contain genetic material provided by more than 2 persons, using the permitted technique specified in the licence:

(i) by fertilisation of a human egg by a human sperm outside the body of a woman; or

(ii) other than by the fertilisation of a human egg by a human sperm;

and use of such embryos;

(c) creation of human embryos by a process of the fertilisation of a human egg by a human sperm outside the body of a woman, using the permitted technique specified in the licence, and use of such embryos;

(d) research and training involving the fertilisation of a human egg by a human sperm up to, including and after the first mitotic division, outside the body of a woman for the purposes of research or training in the use of the permitted technique specified in the licence;

(e) use of any material (other than an excess ART embryo) created, developed or produced under a mitochondrial donation licence.

(3) A clinical trial research and training licence does not authorise any use of a human embryo that would:

(a) result in the development of a human embryo for a period of more than 14 days, excluding any period when development is suspended; or

(b) involve placing a human embryo into the body of a woman for the purposes of achieving pregnancy in that woman.

28E What a clinical trial licence authorises

(1) A ***clinical trial licence*** authorises carrying out any of the activities mentioned in subsection (2) that are specified in the licence, at an accredited ART centre, for the purpose of doing both of the

following in conducting a clinical trial to determine whether the permitted technique specified in the licence is sufficiently safe and effective to use in a clinical practice setting:

(a) creating a human embryo for a trial participant, using the permitted technique specified in the licence, with the intention of minimising the risk of the embryo inheriting mitochondria that would predispose any resulting child to mitochondrial disease;

(b) placing the embryo in the body of the trial participant for the purposes of achieving her pregnancy.

(2) The activities are as follows:

(a) creation of human embryos other than by fertilisation of a human egg by a human sperm, using the permitted technique specified in the licence, and use of such embryos;

(b) creation of human embryos that contain genetic material provided by more than 2 persons, using the permitted technique specified in the licence:

(i) by fertilisation of a human egg by a human sperm outside the body of a woman; or

(ii) other than by the fertilisation of a human egg by a human sperm;

and use of such embryos;

(c) alteration of the genome of a human cell (within the meaning of section 15 of the *Prohibition of Human Cloning for Reproduction Act 2002*) using the permitted technique specified in the licence, in such a way that the alteration is heritable by descendants of the human whose cell was altered;

(d) placement in the body of a woman of any of the following kinds of human embryo created using the permitted technique specified in the licence:

(i) a human embryo created by a process other than the fertilisation of a human egg by human sperm;

(ii) a human embryo that contains genetic material provided by more than 2 persons;

(iii) a human embryo that contains a human cell (within the meaning of section 15 of the *Prohibition of Human Cloning for Reproduction Act 2002*) whose genome has been altered in such a way that the alteration is heritable by descendants of the human whose cell was altered;

(e) use of any material (other than an excess ART embryo) created, developed or produced under a mitochondrial donation licence.

(3) A clinical trial licence does not authorise any use of a human embryo that would result in the development of the embryo outside the body of a woman for a period of more than 14 days, excluding any period when development is suspended.

28F What a clinical practice research and training licence authorises

(1) A ***clinical practice research and training licence*** authorises carrying out any of the activities mentioned in subsection (2) that are specified in the licence, at an accredited ART centre, in undertaking research and training for the purpose of doing all of the following in preparation for using the permitted technique specified in the licence in a clinical practice setting:

(a) developing protocols for using the technique safely and effectively, in a clinical practice setting, for the purpose of minimising the risk of women's offspring inheriting mitochondria that would predispose them to mitochondrial disease;

(b) ensuring that each embryologist nominated under subsection 28H(5) has technical competence in the use of the technique in accordance with those protocols;

(c) ensuring that the holder's facilities, equipment, processes and protocols for using the technique are suitable for using the technique in a clinical practice setting.

(2) The activities are as follows:

(a) creation of human embryos other than by fertilisation of a human egg by a human sperm, using the permitted technique specified in the licence, and use of such embryos;

(b) creation of human embryos that contain genetic material provided by more than 2 persons, using the permitted technique specified in the licence:

(i) by fertilisation of a human egg by a human sperm outside the body of a woman; or

(ii) other than by the fertilisation of a human egg by a human sperm;

and use of such embryos;

(c) creation of human embryos by a process of the fertilisation of a human egg by a human sperm outside the body of a woman, using the permitted technique specified in the licence, and use of such embryos;

(d) research and training involving the fertilisation of a human egg by a human sperm up to, including and after the first mitotic division, outside the body of a woman for the purposes of research or training in the use of the permitted technique specified in the licence;

(e) use of any material (other than an excess ART embryo) created, developed or produced under a mitochondrial donation licence.

(3) A clinical practice research and training licence does not authorise any use of a human embryo that would:

(a) result in the development of a human embryo for a period of more than 14 days, excluding any period when development is suspended; or

(b) involve placing a human embryo into the body of a woman for the purposes of achieving pregnancy in that woman.

28G What a clinical practice licence authorises

(1) A ***clinical practice licence*** authorises carrying out any of the activities mentioned in subsection (2) that are specified in the licence, at an accredited ART centre, for the purpose of doing both of the following in a clinical practice setting:

(a) creating a human embryo for a patient, using the permitted technique specified in the licence, with the intention of

minimising the risk of the embryo inheriting mitochondria that would predispose any resulting child to mitochondrial disease;

(b) placing the embryo in the body of the patient for the purposes of achieving her pregnancy.

(2) The activities are as follows:

(a) creation of human embryos other than by fertilisation of a human egg by a human sperm, using the permitted technique specified in the licence, and use of such embryos;

(b) creation of human embryos that contain genetic material provided by more than 2 persons, using the permitted technique specified in the licence:

(i) by fertilisation of a human egg by a human sperm outside the body of a woman; or

(ii) other than by the fertilisation of a human egg by a human sperm;

and use of such embryos;

(c) alteration of the genome of a human cell (within the meaning of section 15 of the *Prohibition of Human Cloning for Reproduction Act 2002*) using the permitted technique specified in the licence, in such a way that the alteration is heritable by descendants of the human whose cell was altered;

(d) placement in the body of a woman of any of the following kinds of human embryo created using the permitted technique specified in the licence:

(i) a human embryo created by a process other than the fertilisation of a human egg by human sperm;

(ii) a human embryo that contains genetic material provided by more than 2 persons;

(iii) a human embryo that contains a human cell (within the meaning of section 15 of the *Prohibition of Human Cloning for Reproduction Act 2002*) whose genome has been altered in such a way that the alteration is heritable by descendants of the human whose cell was altered;

(e) use of any material (other than an excess ART embryo) created, developed or produced under a mitochondrial donation licence.

(2) A clinical practice licence does not authorise any use of a human embryo that would result in the development of the embryo outside the body of a woman for a period of more than 14 days, excluding any period when development is suspended.

Subdivision B—Applying for a mitochondrial donation licence

28H Applying for a mitochondrial donation licence

(1) A person may, subject to subsections (2) to (7), apply to the NHMRC Licensing Committee for:

(a) a pre-clinical research and training licence, relating to a permitted technique for such a licence, that authorises one or more of the activities referred to in subsection 28C(2); or

(b) a clinical trial research and training licence, relating to a permitted technique for such a licence, that authorises one or more of the activities referred to in subsection 28D(2); or

(c) a clinical trial licence, relating to a permitted technique for such a licence, that authorises one or more of the activities referred to in subsection 28E(2); or

(d) a clinical practice research and training licence, relating to a permitted technique for such a licence, that authorises one or more of the activities referred to in subsection 28F(2); or

(e) a clinical practice licence, relating to a permitted technique for such a licence, that authorises one or more of the activities referred to in subsection 28G(2).

(2) A person cannot apply for any of the following licences unless the person is a constitutional corporation:

(a) a pre-clinical research and training licence;

(b) a clinical trial research and training licence;

(c) a clinical trial licence.

(3) A person cannot apply for a clinical trial licence relating to a particular mitochondrial donation technique unless the person has held a clinical trial research and training licence relating to that technique.

(4) A person cannot apply for a clinical practice licence relating to a particular mitochondrial donation technique unless the person has held a clinical practice research and training licence relating to that technique.

(5) An application for a mitochondrial donation licence relating to a particular mitochondrial donation technique must nominate one or more embryologists who will be authorised to use the technique under the licence.

(6) A single application cannot relate to:
  (a) more than one kind of mitochondrial donation licence; or
  (b) more than one permitted technique for a mitochondrial donation licence.

(7) An application for a mitochondrial donation licence must:
  (a) be in the form approved by the NHMRC Licensing Committee; and
  (b) specify the following:
    (i) the kind of mitochondrial donation licence;
    (ii) the permitted technique to which the licence will relate; and
  (c) be made in accordance with:
    (i) the requirements specified in the regulations for the purposes of this subparagraph (if any); and
    (ii) such other requirements (if any) as are specified in writing by the NHMRC Licensing Committee and are not inconsistent with requirements specified under subparagraph (i); and
  (d) be accompanied by the fee (if any) prescribed by the regulations.

(8) A form approved for the purposes of paragraph (7)(a) may require:

(a) an application to contain, or be accompanied by, such information as is required by the form; and
(b) any such information to be verified by statutory declaration.

Subdivision C—Determining applications for mitochondrial donation licences

28J Determination of application by Committee

(1) If a person applies under subsection 28H(1) for a mitochondrial donation licence relating to a mitochondrial donation technique that is a permitted technique for the licence, the NHMRC Licensing Committee must decide, in accordance with this section, whether or not to issue the licence.

(2) The NHMRC Licensing Committee must not issue the licence unless it is satisfied of the following:
(a) that appropriate protocols are in place to enable proper consent to be obtained before any of the following activities are carried out under the licence (see paragraph 28N(1A)(a)):
(i) an excess ART embryo, a human egg or a human sperm is used;
(ii) a human zygote or a human embryo (other than an excess ART embryo) is created or used;
(iii) any material not covered by subparagraph (i) or (ii) of this paragraph is created, developed, produced or used;
(aa) that appropriate protocols are in place to enable compliance with any restrictions on such consent;
(b) that the activity or project proposed in the application has been assessed and approved by a HREC that is constituted in accordance with, and acting in compliance with, the National Statement.

(3) In deciding whether to issue the licence, the NHMRC Licensing Committee must have regard to the following:
(a) restricting the number of excess ART embryos, other embryos, or human eggs or zygotes, to that likely to be

necessary to achieve the goals of the activity or project proposed in the application;

(b) any relevant guidelines, or relevant parts of 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;

(c) the HREC assessment of the application mentioned in paragraph (2)(b);

(d) whether the applicant has complied with the conditions of any other mitochondrial donation licence.

(4) Without limiting section 15, the NHMRC Licensing Committee may also request, and have regard to, advice from any person having appropriate expertise.

(5) The NHMRC Licensing Committee must not issue a clinical trial licence, or a clinical practice licence, relating to a particular mitochondrial donation technique unless it is satisfied that:

(a) the applicant has in place protocols for using the technique safely and effectively in a clinical trial or in clinical practice (as the case requires) for the purpose of minimising the risk of women's offspring inheriting mitochondria that would predispose them to mitochondrial disease; and

(b) each embryologist nominated under subsection 28H(5) has:

(i) consented in writing to being so nominated; and

(ii) demonstrated technical competence in the use of the technique in accordance with the protocols referred to in paragraph (a) of this subsection; and

(iii) understands the embryologist's obligations under this Act; and

(c) the applicant's facilities, equipment and processes for using the technique under the licence are suitable for that purpose; and

(d) the staff, other than embryologists, who will carry out activities directly connected with the clinical trial or clinical practice (as the case requires) are appropriately qualified, trained and competent to do so; and

(e) the applicant is likely to be able to comply with its obligations under section 28R (information about donors and children); and

(f) the applicant has protocols in place to ensure that each donor in relation to a use of the technique is aware that any children born as a result of a pregnancy achieved by using the technique will be able to obtain information about the donor in accordance with subsections 29A(4) and (6) (disclosure of information on the Mitochondrial Donation Donor Register); and

(g) the applicant has protocols in place to ensure that trial participants or patients (as the case requires) have been fully informed about:

(i) the risks involved in using mitochondrial donation techniques; and

(ii) alternatives to using mitochondrial donation techniques.

(6) The regulations may specify:

(a) matters that the NHMRC Licensing Committee may, must or must not have regard to when deciding whether to issue a mitochondrial donation licence; and

(b) matters that the NHMRC Licensing Committee must be satisfied of before issuing a mitochondrial donation licence; and

(c) procedural and other requirements that the NHMRC Licensing Committee must follow in deciding whether to issue a mitochondrial donation licence; and

(d) requirements for demonstrating the technical competence of an embryologist in the use of a particular mitochondrial donation technique for the purposes of subparagraph (5)(b)(ii).

28K Notification of decision

(1) The NHMRC Licensing Committee must notify its decision on an application for a licence under section 28H to the following:

(a) the applicant;

(b) the HREC that assessed and approved the activity or project proposed in the application as mentioned in paragraph 28J(2)(b);
(c) the relevant State body in relation to the State in which the use is to occur.

(2) If the NHMRC Licensing Committee decides to issue the licence, it must, in addition to issuing the licence to the applicant, give a copy of the licence to the bodies mentioned in paragraphs (1)(b) and (c).

28L Matters to be specified in a mitochondrial donation licence

If the NHMRC Licensing Committee decides to issue a mitochondrial donation licence, the licence must specify the following matters:

(a) the mitochondrial donation technique to which the licence relates;
(b) the activity or activities referred to in subsection 28C(2), 28D(2), 28E(2), 28F(2) or 28G(2) (as the case requires) that are authorised by the licence;
(c) the name of each embryologist nominated under subsection 28H(5).

28M Period of a mitochondrial donation licence

(1) A mitochondrial donation licence:
(a) comes into force on the day specified in the licence, or if no day is specified, on the day on which it is issued; and
(b) remains in force until the day specified in the licence, unless it is suspended, revoked or surrendered before that day.

(2) A mitochondrial donation licence is not in force throughout any period of suspension.

Subdivision D—Conditions of mitochondrial donation licences

28N Conditions of mitochondrial donation licences generally

(1) A mitochondrial donation licence is subject to the condition that the requirements of subsection (1A) are met before any of the following activities are carried out as authorised by the licence:

(a) an excess ART embryo, a human egg or a human sperm is used;

(b) a zygote or a human embryo (other than an excess ART embryo) is created or used;

(c) any material not covered by paragraph (a) or (b) of this subsection is created, developed, produced or used.

(1A) The requirements are as follows:

(a) each responsible person in relation to the material referred to in paragraph (1)(a), (b) or (c) must have given proper consent to the carrying out of the activity;

(b) the licence holder must have reported in writing to the NHMRC Licensing Committee that such consent has been obtained, and any restrictions to which the consent is subject.

(2) A mitochondrial donation licence is subject to the condition that a report to the NHMRC Licensing Committee for the purposes of paragraph (1A)(b) must not include the name, or any other information that could be used to discover the identity, of a responsible person.

(3) A mitochondrial donation licence is subject to the condition that the carrying out of an activity referred to in paragraph (1)(a), (b) or (c) must be in accordance with any restrictions to which the proper consent under paragraph (1A)(a) is subject.

(4) A mitochondrial donation licence is subject to such other conditions as are specified in the licence.

(5) The conditions specified in the licence may include, but are not limited to, conditions relating to the following:

(a) embryologists and other persons authorised by the licence to carry out activities that are authorised by the licence;
(b) the number of human eggs authorised to be used under the licence, or the number of embryos or zygotes authorised to be created or used under the licence;
(c) reporting;
(d) monitoring;
(e) information to be given by the licence holder to the following:
(i) embryologists and other persons authorised by the licence to carry out activities that are authorised by the licence;
(ii) other persons;
(f) disposing of material produced by using the relevant mitochondrial donation technique as authorised by the licence.

(6) The licence conditions set out in subsections (1), (2) and (3) apply to:
(a) each embryologist specified in the licence who is authorised to use the mitochondrial donation technique to which the licence relates; and
(b) each other person who carries out activities that are authorised by the licence.

(7) Licence conditions specified in the licence apply to:
(a) the licence holder; and
(b) each embryologist specified in the licence who is authorised to use the mitochondrial donation technique to which the licence relates; and
(c) each other person who carries out activities that are authorised by the licence.

(8) In this Division:

proper consent in relation to the carrying out of an activity referred to in paragraph (1)(a), (b) or (c) means consent:

(a) that is obtained in accordance with 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; and

(b) in relation to which such other requirements (if any) as are prescribed by the regulations for the purposes of this paragraph are satisfied.

responsible person, in relation to material mentioned in an item of the following table, means a person mentioned in column 2 of the item.

Responsible persons for material

Item	Column 1 Material	Column 2 Responsible persons
1	a human egg	the person who was the biological donor of the egg
2	a human sperm	the person who was the biological donor of the sperm
3	a zygote	each person whose reproductive material, genetic material or cell was used, or is proposed to be used, in the creation or use of the zygote
4	an excess ART embryo	each of the following: (a) each person whose reproductive material, genetic material or cell was used in the creation of the embryo; (b) the spouse of each person mentioned in paragraph (a), at the time the reproductive material, genetic material or cell was provided; (c) the woman for whom the embryo was created, for the purpose of achieving her pregnancy; (d) the spouse of the woman referred

Responsible persons for material		
Item	**Column 1** **Material**	**Column 2** **Responsible persons**
		to in paragraph (c) at the time the embryo was created
5	a human 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
6	any material not covered by any of table items 1 to 5 that is created, developed or produced as authorised by a mitochondrial donation licence	each person whose reproductive material, genetic material or cell was used, or is proposed to be used, in the creation, development, production or use of the material

(9) Without limiting paragraph (b) of the definition of ***proper consent*** in subsection (8), regulations made for the purposes of that paragraph may:

(a) provide in relation to the withdrawal of consent; and

(b) without limiting paragraph (a) of this subsection, provide that consent cannot be withdrawn in specified circumstances.

28P Additional condition of clinical trial licences and clinical practice licences—Committee approval before creation or placement of embryo

(1) A clinical trial licence or clinical practice licence is subject to the condition that an approval granted under subsection (3) is in force at the time either of the following activities are carried out in relation to a woman who is a trial participant or patient (as the case requires) for the licence:

(a) creating a human embryo for the woman using the mitochondrial donation technique to which the licence relates;

(b) placing a human embryo created for the woman using the mitochondrial donation technique to which the licence relates in the body of the woman for the purposes of achieving her pregnancy.

(2) The licence holder for a clinical trial licence or a clinical practice licence may apply to the NHMRC Licensing Committee, in the form approved by the Committee and in accordance with such other requirements (if any) as are specified in writing by the Committee, for approval to carry out an activity referred to in paragraph (1)(a) or (b) in relation to a woman who is a trial participant or patient (as the case requires) for the licence.

(3) If the NHMRC Licensing Committee receives an application under subsection (2), the Committee must decide whether or not to grant the approval.

(4) The NHMRC Licensing Committee must not grant the approval unless it is satisfied:

(a) that there is a particular risk of the woman's offspring inheriting mitochondria from the woman that would predispose the offspring to mitochondrial disease; and

(b) that there is a significant risk that the mitochondrial disease that would develop in those offspring would result in a serious illness or other serious medical condition; and

(c) that other available techniques that could potentially be used to minimise the risks referred to in paragraphs (a) and (b) would be inappropriate or unlikely to succeed; and

(d) that the woman and her spouse (if any) have attended counselling and been fully informed of:

(i) the risks involved in using mitochondrial donation techniques; and

(ii) alternatives to using mitochondrial donation techniques; and

(e) that the woman has given written consent to the making of the application; and

(f) of such other matters as are specified in the regulations for the purposes of this paragraph.

(5) In deciding whether to grant the approval, the NHMRC Licensing Committee must have regard to the following:
  (a) the clinical basis of the risk of the woman's offspring inheriting mitochondria from the woman that would predispose the offspring to mitochondrial disease;
  (b) the inheritance pattern in the woman's family;
  (c) the likely clinical manifestations of disease for the woman's offspring.

(5A) Without limiting section 15, the NHMRC Licensing Committee may also request, and have regard to, advice from any person having appropriate expertise.

(6) The NHMRC Licensing Committee must notify its decision on an application under subsection (2) to the licence holder.

(7) A form approved by the NHMRC Licensing Committee for the purposes of subsection (2):
  (a) may require an application to contain, or be accompanied by, such information as is required by the form and require the information to be verified by statutory declaration; but
  (b) must not require an application to contain, or be accompanied by, any of the following information:
    (i) the name of a trial participant or patient;
    (ii) any other information that could be used to discover the identity of a trial participant or patient, other than information that is directly necessary for the purpose of determining an application.

(8) An approval granted by the NHMRC Licensing Committee in relation to a woman for the purposes of subsection (1) comes into force when it is granted and ceases to be in force at the earlier of the following times:
  (a) 5 years after the approval is granted;
  (b) the time a child is born alive as a result of a pregnancy achieved in the woman by the placement of a human embryo under the approval as described in paragraph (1)(b).

(9) The licence condition set out in subsection (1) applies to:
  (a) the licence holder; and
  (b) each embryologist specified in the licence who is authorised to use the mitochondrial donation technique to which the licence relates.

28Q Other conditions of clinical trial licences and clinical practice licences

(1) A clinical trial licence or a clinical practice licence is subject to the following conditions:
  (a) that the technique specified in the licence only be used under the licence by an embryologist specified in the licence;
  (b) that the embryologist's use of the technique is in accordance with the protocols mentioned in paragraph 28J(5)(a);
  (c) that the embryologist remains technically competent to use the technique;
  (d) that a human embryo created for a woman using the technique is not selected for implantation in that woman on the basis of the sex of the embryo.

(2) The licence conditions set out in this section apply to:
  (a) the licence holder; and
  (b) for a condition set out in paragraph (1)(b) or (d)—each embryologist specified in the licence who is authorised to use the mitochondrial donation technique to which the licence relates.

Subdivision E—Ongoing requirements for holders of mitochondrial donation licences

28R Clinical trial licences and clinical practice licences—information about donors and children

(1) The holder of a clinical trial licence or a clinical practice licence must collect the following information for the donor in relation to each use of a mitochondrial donation technique under the licence:

(a) the donor's full name;
(b) the donor's residential address at the time the donor gave the proper consent required by paragraph 28N(1A)(a) to the use of the donor's egg;
(c) the donor's date and place of birth;
(d) any other information the donor gives the licence holder, for the purposes of inclusion on the Mitochondrial Donation Donor Register under section 29A, at the time referred to in paragraph (b) of this subsection;
(e) any other information about the donor prescribed by the regulations for the purposes of this paragraph.

(2) If a particular use of a mitochondrial donation technique results in the creation of a zygote that:
(a) has nuclear DNA from a woman and a man; and
(b) contains mitochondria from a human egg of a different woman;

the woman mentioned in paragraph (b) is the ***donor*** in relation to that use of the technique.

(3) A person who is or was the holder of a clinical trial licence or a clinical practice licence must use the person's best endeavours to collect the following information for each child born alive as a result of a pregnancy achieved using a mitochondrial donation technique under the licence:
(a) the child's full name;
(b) the child's sex;
(c) the child's date of birth;
(d) any other information about the child prescribed by the regulations for the purposes of this paragraph.

(4) A person who is or was the holder of a clinical trial licence or a clinical practice licence must keep records of information the person collects as required by subsection (1) or (3) for the period prescribed by the regulations for the purposes of this subsection.

(5) If a person who is or was the holder of a clinical trial licence or a clinical practice licence becomes aware that a child has been born alive as a result of a pregnancy achieved using a mitochondrial donation technique under the licence, the person must:
  (a) as soon as practicable after the birth of the child, notify the Secretary and the NHMRC Licensing Committee of that fact, in the form (if any) approved by the Secretary; and
  (b) give the Secretary, in the form (if any) approved by the Secretary:
    (i) the information collected as required by subsection (1) for the donor in relation to the particular use of the technique that achieved the pregnancy, as soon as practicable after the birth of the child; and
    (ii) the information collected as required by subsection (3) for the child, as soon as practicable after the person collects the information.

(6) A person who is or was the holder of a clinical trial licence or a clinical practice licence must not include in a notification for the purposes of paragraph (5)(a) the name, or any other information that could be used to discover the identity, of:
  (a) a trial participant or patient; or
  (b) a child of a trial participant or patient.

(6A) A person who is or was the holder of a clinical trial licence or a clinical practice licence must take reasonable steps to ensure that information the person collects as required by subsection (1) or (3) is not disclosed to another person except for the purpose of complying with this Act.

(6B) A person who is or was any of the following must not disclose information collected as required by subsection (1) or (3) to another person except for the purpose of complying with this Act:
  (a) the holder of a clinical trial licence or a clinical practice licence;
  (b) an embryologist specified in such a licence;

(c) a person authorised by such a licence to carry out an activity authorised by the licence.

(6C) Subsections (6A) and (6B) apply despite a law of a State. However, those subsections do not prevent a person from disclosing information to a Registrar of births, deaths and marriages (however described) of a State in accordance with a law of that State relating to the notification or registration of births.

Note: A defendant bears an evidential burden in relation to the matter in this subsection (see subsection 13.3(3) of the *Criminal Code*).

(7) Despite subsections (1), (3), (4), (5), (6), (6A) and (6B), in the case of a clinical trial licence a person is not subject to a requirement under any of those subsections unless the person who is or was the holder of the licence is a constitutional corporation.

(8) A person commits an offence if the person intentionally engages in conduct knowing that, or reckless as to whether, the conduct breaches a requirement under subsection (1), (3), (4), (5), (6), (6A) or (6B) to which the person is subject.

Penalty for a contravention of this subsection: Imprisonment for 2 years.

28S Clinical trial licences and clinical practice licences—requirement for ongoing monitoring protocols and to notify adverse events

(1) A person who is or was the holder of a clinical trial licence must have in place, and comply with, protocols for:

(a) monitoring the pregnancy of trial participants who achieve pregnancy using a mitochondrial donation technique under the licence and any childbirths resulting from such pregnancies; and

(b) monitoring the ongoing health and development of children born as a result of such pregnancies; and

(c) seeking the ongoing engagement of trial participants referred to in paragraph (a), and children referred to in paragraph (b), in relation to such monitoring; and

(d) notifying in accordance with subsection (3) adverse events, for those participants or children, that the person becomes aware of as a result of monitoring referred to in paragraph (a) or (b) of this subsection.

(2) A person who is or was the holder of a clinical practice licence must have in place, and comply with, protocols for:

(a) monitoring the pregnancy of patients who achieve pregnancy using a mitochondrial donation technique under the licence and any childbirths resulting from such pregnancies; and

(b) notifying in accordance with subsection (3) adverse events, for those patients, that the person becomes aware of as a result of monitoring referred to in paragraph (a) of this subsection.

(3) If a person who is or was the holder of a clinical trial licence or a clinical practice licence becomes aware of an adverse event for a trial participant referred to in paragraph (1)(a), a child referred to in paragraph (1)(b) or a patient referred to in paragraph (2)(a), the person must notify the adverse event to:

(a) the NHMRC Licensing Committee; and

(b) the Secretary; and

(c) such other persons as are prescribed by the regulations for the purposes of this paragraph;

within the period, in a form and manner, and in accordance with any other requirements, specified in the regulations.

(4) Without limiting subsection (3), the regulations may require a notification to be in the form approved by the CEO of the NHMRC and to contain any information required by the form.

(5) A person who is or was the holder of a clinical trial licence or a clinical practice licence must not include in a notification for the purposes of subsection (3) the name, or any other information that could be used to discover the identity, of:

(a) a trial participant or patient; or

(b) a child of a trial participant or patient.

(6) Despite subsections (1), (3) and (5), in the case of a clinical trial licence a person is not subject to a requirement under any of those subsections unless the person is a constitutional corporation.

(7) A person commits an offence if the person intentionally engages in conduct knowing that, or reckless as to whether, the conduct breaches a requirement under subsection (1), (2), (3) or (5) to which the person is subject.

Penalty: Imprisonment for 2 years.

(8) In this section:

adverse event, for a trial participant or patient, or a child of a trial participant, has the meaning given by the regulations.

28T Record-keeping obligations for all holders of mitochondrial donation licences

(1) The regulations may prescribe record-keeping obligations that apply in relation to the use of mitochondrial donation techniques under mitochondrial donation licences.

(2) Regulations for the purposes of subsection (1) may impose such obligations only on a person who:

(a) is or was the holder of a mitochondrial donation licence; and

(b) for a mitochondrial donation licence other than a clinical practice research and training licence or a clinical practice licence—is a constitutional corporation.

(3) Regulations for the purposes of subsection (1) may prescribe penalties, not exceeding 50 penalty units, for offences against such regulations.

Subdivision F—Variation, suspension, revocation and surrender

28U Variation of a mitochondrial donation licence

(1) The NHMRC Licensing Committee may, by notice in writing given to the licence holder, vary a mitochondrial donation licence if the Committee believes on reasonable grounds that it is necessary or desirable to do so.

(2) The NHMRC Licensing Committee may vary a mitochondrial donation licence under subsection (1) on its own initiative or on application by the licence holder.

(3) Without limiting subsection (1), the NHMRC Licensing Committee may vary the licence by specifying additional conditions or varying existing conditions.

(4) The NHMRC Licensing Committee must not vary a mitochondrial donation licence in such a way that, had a person applied under section 28H for the licence as varied, the Committee would not have been permitted by this Division to issue the licence.

28V Suspension or revocation of a mitochondrial donation licence

(1) The NHMRC Licensing Committee may, by notice in writing given to the licence holder, suspend or revoke a mitochondrial donation licence if the Committee believes on reasonable grounds that a condition of the licence has been breached.

(2) If the holder of a mitochondrial donation licence is convicted of an offence under this Act or the regulations, or the *Prohibition of Human Cloning for Reproduction Act 2002*, the NHMRC Licensing Committee must, by notice in writing given to the licence holder, revoke each mitochondrial donation licence held by the licence holder.

(3) If the holder of a pre-clinical research and training licence, a clinical trial research and training licence or a clinical trial licence

stops being a constitutional corporation at a particular time, the NHMRC Licensing Committee is taken to have revoked the licence at that time.

28W Surrender of a mitochondrial donation licence

The holder of a mitochondrial donation licence may surrender the licence by written notice given to the NHMRC Licensing Committee.

28X Notification of variation, suspension or revocation of a mitochondrial donation licence

(1) If the NHMRC Licensing Committee varies, suspends or revokes a mitochondrial donation licence, the Committee must notify:
  (a) the licence holder; and
  (b) the HREC and the relevant State body to which the NHMRC Licensing Committee notified its decision on the application for the licence under section 28K.

(2) The NHMRC Licensing Committee must also notify the bodies mentioned in paragraph (1)(b) if a mitochondrial donation licence is surrendered.

Division 5—Protection and disclosure of information

29 NHMRC Licensing Committee to make certain information publicly available

(1) The NHMRC Licensing Committee must maintain a database containing the following information in relation to each general licence and each mitochondrial donation licence (including a licence as varied):

(a) the name of the person to whom the licence was issued;

(b) for a general licence—a short statement about the nature of the uses of excess ART embryos or human eggs, and creations or uses of other embryos, that are authorised by the licence;

(ba) for a mitochondrial donation licence—a short statement about the nature of the uses of excess ART embryos or human eggs, and creations or uses of other embryos or zygotes, that are authorised by the licence;

(d) for a general licence—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;

(e) for a mitochondrial donation licence—the number of excess ART embryos or human eggs authorised to be used under the licence, and the number of other embryos or zygotes authorised to be created or used under the licence;

(f) in any case:

(i) any conditions to which the licence is subject; and

(ii) the date on which the licence was issued; and

(iii) the period throughout which the licence is to remain in force.

(2) The database is to be made publicly available.

(3) The database may be kept and made publicly available in electronic form.

(4) Information mentioned in subsection (1) must not be such as to disclose confidential commercial information.

29A Mitochondrial Donation Donor Register

(1) The Secretary must keep a register, to be known as the Mitochondrial Donation Donor Register, in which the Secretary includes information given to the Secretary in accordance with paragraph 28R(5)(b).

(2) The Secretary may keep the register by electronic means.

(3) The register must not be made publicly available.

(4) A person who:
   (a) was born as a result of the use of a mitochondrial donation technique under a mitochondrial donation licence; and
   (b) is 18 or over;

may apply, in the form approved by the Secretary, for the Secretary to disclose to the person information in the register about the donor in relation to the use of the technique.

(5) The donor in relation to the use of a mitochondrial donation technique may apply, in the form approved by the Secretary, for the Secretary to disclose to the donor information in the register about the donor that is of a kind described in subsection 28R(1).

(6) The Secretary must, on application under subsection (4) or (5), disclose the information to the applicant.

(7) A person commits an offence if:
   (a) the person discloses information; and
   (b) the person knows the information is on the register; and
   (c) the person has the information only because of performing duties or functions under this section or paragraph 28R(5)(b); and
   (d) the disclosure is not:
      (i) in accordance with subsection (6) of this section; or

(ii) by order of a court.

Penalty: Imprisonment for 2 years.

(8) The Secretary may, in writing, delegate any or all of the Secretary's powers or functions under this section or paragraph 28R(5)(b) to an SES employee or acting SES employee in the Department.

Note: The expressions ***SES employee*** and ***acting SES employee*** are defined in section 2B of the *Acts Interpretation Act 1901*.

(9) In exercising powers or functions delegated under subsection (8), the delegate must comply with any directions of the Secretary.

(10) The regulations may provide for and in relation to the following:
(a) information that must be included in the register in addition to the information mentioned in subsection (1);
(b) correcting or updating information on the register;
(c) the keeping and maintenance of the register;
(d) the verification of information included in an application to the Secretary under subsection (4) or (5) for the disclosure of information on the register, including by statutory declaration.

30 Confidential commercial information may only be disclosed in certain circumstances

(1) A person commits an offence if:
(a) the person discloses confidential commercial information that the person has only because of performing duties or functions under this Act or under a corresponding State law; and
(b) the person knows that the information is confidential commercial information; and
(c) the disclosure is not:
(i) to the Commonwealth, a Commonwealth authority or a State agency in the course of carrying out duties or functions under this Act or under a corresponding State law; or

(ii) by order of a court; or
(iii) with the consent of each person to whom the information has a commercial or other value.

Penalty: Imprisonment for 2 years.

(2) A person commits an offence if:
(a) the person discloses confidential commercial information that the person has only because of a disclosure permitted under subsection (1) or this subsection; and
(b) the person knows that the information is confidential commercial information; and
(c) the disclosure is not:
(i) to the Commonwealth, a Commonwealth authority or a State agency in the course of carrying out duties or functions under this Act or under a corresponding State law; or
(ii) by order of a court; or
(iii) with the consent of each person to whom the information has a commercial or other value.

Penalty: Imprisonment for 2 years.

(3) In this section:

court includes a tribunal, authority or person having power to require the production of documents or the answering of questions.

State agency means the following:
(a) the Crown in right of a State;
(b) a Minister of a State;
(c) a State Government department;
(d) an instrumentality of a State, including a body corporate established for a public purpose by or under a law of a State;
(e) a company in which a controlling interest is held by any one of the following persons, or by 2 or more of the following persons together:
(i) the Crown in right of a State;

(ii) a person or body covered by paragraph (b) or (d);
(iii) a person or body covered by either of the above subparagraphs.

Note: For the definition of ***confidential commercial information***, see section 8.

Division 6—Review provisions

31 Meaning of terms

In this Division:

decision has the same meaning as in the *Administrative Appeals Tribunal Act 1975*.

eligible person, in relation to a decision of the NHMRC Licensing Committee, means:

(a) in relation to a decision under section 21 or 28J not to issue a licence—the applicant for the licence; or

(b) in relation to a decision in respect of the period throughout which the licence is to be in force under section 23 or 28M—the licence holder; or

(c) in relation to a decision to specify a licence condition under subsection 24(4) or 28N(4)—the licence holder; or

(ca) in relation to a decision to modify guidelines under subsection 24(8) in respect of a licence—the licence holder; or

(d) in relation to a decision to vary or refuse to vary a licence under section 25 or 28U—the licence holder; or

(e) in relation to a decision to suspend or revoke a licence under section 26 or subsection 28V(1) or (2)—the person who was the licence holder immediately before the suspension or revocation; or

(f) in relation to a decision under subsection 28P(3) not to grant an approval to carry out an activity referred to in paragraph 28P(1)(a) or (b) in relation to a trial participant or a patient:

(i) the licence holder who applied for the approval; and

(ii) the trial participant or patient.

32 Review of decisions

(1) An eligible person may apply to the Administrative Appeals Tribunal for review of the following decisions of the NHMRC Licensing Committee:

(a) a decision under section 21 or 28J not to issue a licence;

(b) a decision in respect of the period throughout which the licence is to be in force under section 23 or 28M;

(c) a decision to specify a licence condition under subsection 24(4) or 28N(4);

(ca) a decision to modify guidelines under subsection 24(8) in respect of a licence;

(d) a decision to vary or refuse to vary a licence under section 25 or 28U;

(e) a decision to suspend or revoke a licence under section 26 or subsection 28V(1) or (2);

(f) a decision under subsection 28P(3) not to grant an approval to carry out an activity referred to in paragraph 28P(1)(a) or (b) in relation to a trial participant or patient.

(2) This section has effect subject to the *Administrative Appeals Tribunal Act 1975*.

Part 3—Monitoring powers

33 Appointment of inspectors

(1) The Chairperson of the NHMRC Licensing Committee may, by instrument in writing, appoint any of the following persons as inspectors:

(a) a person who is appointed or employed by the Commonwealth;

(b) a person who is appointed or employed by a State.

(2) In exercising powers or performing functions as an inspector, an inspector must comply with any directions of the Chairperson of the NHMRC Licensing Committee.

(3) The Chairperson of the NHMRC Licensing Committee must not appoint a person as an inspector under subsection (1) unless he or she is satisfied that the person has appropriate skills and experience.

34 Identity card

(1) The Chairperson of the NHMRC Licensing Committee must issue an identity card to an inspector.

(2) The identity card:

(a) must be in the form prescribed by the regulations; and

(b) must contain a recent photograph of the inspector.

(3) If a person to whom an identity card has been issued ceases to be an inspector, the person must return the identity card to the Chairperson of the NHMRC Licensing Committee as soon as practicable.

Penalty: 1 penalty unit.

(4) An inspector must carry his or her identity card at all times when exercising powers or performing functions as an inspector.

35 Powers available to inspectors for monitoring compliance

(1) For the purpose of finding out whether this Act or the regulations have been complied with, an inspector may:
  (a) enter any premises; and
  (b) exercise the monitoring powers set out in section 36.

(2) An inspector is not authorised to enter premises under subsection (1) unless:
  (a) the occupier of the premises has consented to the entry; or
  (b) the premises are premises at which the occupier of the premises is carrying out activities authorised by a licence issued under section 21 or 28J, and the entry is at a reasonable time; or
  (c) the entry is made under a warrant under section 37A.

36 Monitoring powers

(1) The monitoring powers that an inspector may exercise under paragraph 35(1)(b) are as follows:
  (a) to search the premises and any thing on the premises;
  (b) to inspect, examine, take measurements of, conduct tests on, or take samples of, any human embryo, other embryo, human egg or thing on the premises that relates to this Act;
  (c) to take photographs, make video or audio recordings or make sketches of the premises or any thing on the premises;
  (d) to inspect any book, record or document on the premises;
  (e) to take extracts from or make copies of any such book, record or document;
  (f) to take onto the premises such equipment and materials as the inspector requires for the purpose of exercising powers in relation to the premises;
  (g) in addition to the powers mentioned in paragraphs (a) to (f), if the inspector was authorised to enter the premises by a

warrant under section 37A—to require any person in or on the premises to:

(i) answer any questions put by the inspector; and

(ii) produce any book, record or document requested by the inspector.

(2) For the purposes of this Part, monitoring powers include the power to operate equipment at premises to see whether:

(a) the equipment; or

(b) a disk, tape or other storage device that:

(i) is at the premises; and

(ii) can be used with the equipment or is associated with it;

contains information that is relevant to determining whether there has been compliance with the Act or the regulations.

(3) If the inspector, after operating equipment at the premises, finds that the equipment, or that a tape, disk or other storage device at the premises, contains information mentioned in subsection (2), the inspector may:

(a) operate equipment or facilities at the premises to put the information in documentary form and copy the document so produced; or

(b) if the information can be transferred to a tape, disk or other storage device that:

(i) is brought to the premises; or

(ii) is at the premises and the use of which has been agreed to in writing by the occupier of the premises;

operate the equipment or other facilities to copy the information to the storage device, and remove the storage device from the premises.

37 Power to secure

If an inspector, during a search of premises, believes on reasonable grounds that there is at the premises a human embryo, another embryo, a human egg or a thing that may afford evidence of the commission of an offence against this Act, the monitoring powers

include securing the embryo, the egg or the thing pending the obtaining of a warrant (whether by the inspector or by another person) to seize it.

37A Monitoring warrants

(1) An inspector may apply to a magistrate for a warrant under this section in relation to premises.

(2) Subject to subsection (3), the magistrate may issue the warrant if the magistrate is satisfied by information on oath or affirmation that it is reasonably necessary that one or more inspectors should have access to the premises for the purposes of finding out whether this Act or the regulations have been complied with.

(3) The magistrate must not issue the warrant unless the inspector or some other person has given to the magistrate, either orally or by affidavit, such further information (if any) as the magistrate requires concerning the grounds on which the issue of the warrant is being sought.

(4) The warrant must:

(a) authorise one or more inspectors (whether or not named in the warrant) with such assistance and by such force as is necessary and reasonable:

(i) to enter the premises; and

(ii) to exercise the powers set out in section 36 in relation to the premises; and

(b) state whether the entry is authorised to be made at any time of the day or night or during specified hours of the day or night; and

(c) specify the day (not more than 15 days after the issue of the warrant) on which the warrant ceases to have effect; and

(d) state the purpose for which the warrant is issued.

37B Details of warrant to be given to occupier etc.

(1) If a warrant under section 37A is being executed and the occupier of the premises or another person who apparently represents the occupier is present at the premises, the inspector must make available to that person a copy of the warrant.

(2) The inspector must identify himself or herself to that person.

(3) The copy of the warrant referred to in subsection (1) need not include the signature of the magistrate who issued the warrant.

37C Announcement before entry

An inspector must, before entering premises under a warrant:

(a) announce that he or she is authorised to enter the premises; and

(b) give any person at the premises an opportunity to allow entry to the premises.

37D Occupier entitled to be present during search

(1) If a warrant under section 37A is being executed and the occupier of the premises, or another person who apparently represents the occupier is present at the premises, the person is entitled to observe the search being conducted.

(2) The right to observe the search being conducted ceases if the person impedes the search.

(3) This section does not prevent 2 or more areas of the premises being searched at the same time.

38 Inspector must produce identity card on request

An inspector is not entitled to exercise any powers under this Part in relation to premises if:

(a) the occupier of the premises has required the inspector to produce his or her identity card for inspection by the occupier; and
(b) the inspector fails to comply with the requirement.

39 Consent

(1) Before obtaining the consent of a person for the purposes of paragraph 35(2)(a), the inspector must inform the person that he or she may refuse consent.

(2) An entry of an inspector by virtue of the consent of a person is not lawful unless the person voluntarily consented to the entry.

40 Compensation for damage

(1) The owner of equipment or other facilities is entitled to compensation for damage to the equipment or other facilities if:
(a) the damage was caused to the equipment or other facilities as a result of it being operated by an inspector as mentioned in this Part; and
(b) the damage was caused as a result of insufficient care being exercised by the inspector operating the equipment or other facilities.

(2) Compensation is payable out of money appropriated by the Parliament.

(3) In determining the amount of compensation payable, regard is to be had to whether the occupier of the premises and his or her employees and agents, if they were available at the time, had provided any warning or guidance as to the operation of the equipment or other facilities that was appropriate in the circumstances.

41 Extended operation of Part

A reference in this Part to this Act includes a reference to the *Prohibition of Human Cloning Act 2002*, and a reference in this

Part to the regulations includes a reference to regulations made under the *Prohibition of Human Cloning Act 2002*.

Part 4—Commonwealth/State arrangements

42 Operation of State laws

This Act is not intended to exclude the operation of any law of a State, to the extent that the law of the State is capable of operating concurrently with this Act.

43 Conferral of functions on Commonwealth officers and bodies

(1) A corresponding State law may confer functions, powers and duties on the following:

(a) the NHMRC Licensing Committee;

(b) a Commonwealth authority;

(c) an officer of the Commonwealth or a Commonwealth authority.

(2) If a function, power or duty is conferred on a person or body under subsection (1), the person or body may perform the function or duty or exercise the power, as the case requires.

(3) Subsection (1) does not authorise the conferral of a function or power, or the imposition of a duty, by a corresponding State law to the extent to which:

(a) the conferral or imposition, or the authorisation, would contravene any constitutional doctrines restricting the duties that may be imposed on a Commonwealth body, officer or authority; or

(b) the authorisation would otherwise exceed the legislative power of the Commonwealth.

(4) This Act is not intended to exclude or limit the operation of a corresponding State law that confers any functions or powers, or imposes any duties, on the NHMRC Licensing Committee, a Commonwealth officer or a Commonwealth authority to the extent to which that law:

(a) is consistent with subsections (1) and (2); and
(b) is capable of operating concurrently with this Act.

44 When duty imposed

(1) This section applies if a corresponding State law purports to impose a duty on the following:
(a) the NHMRC Licensing Committee;
(b) a Commonwealth authority;
(c) an officer of the Commonwealth or a Commonwealth authority.

(2) The duty is taken not to be imposed by this Act (or any other law of the Commonwealth) to the extent to which:
(a) imposing the duty is within the legislative powers of the State concerned; and
(b) imposing the duty by the corresponding State law is consistent with the constitutional doctrines restricting the duties that may be imposed on a Commonwealth body, officer or authority.

Note: If this subsection applies, the duty will be taken to be imposed by force of the corresponding State law (the Commonwealth having consented under section 43 to the imposition of the duty by the corresponding State law).

(3) If, to ensure the validity of the purported imposition of the duty, it is necessary that the duty be imposed by a law of the Commonwealth (rather than by force of the corresponding State law), the duty is taken to be imposed by this Act to the extent necessary to ensure that validity.

(4) If, because of subsection (3), this Act is taken to impose the duty, it is the intention of the Parliament to rely on all powers available to it under the Constitution to support the imposition of the duty by this Act.

(5) The duty is taken to be imposed by this Act in accordance with subsection (3) only to the extent to which imposing the duty:

(a) is within the legislative power of the Commonwealth; and
(b) is consistent with the constitutional doctrines restricting the duties that may be imposed on a Commonwealth body, officer or authority.

(6) To avoid doubt, neither this Act (nor any other law of the Commonwealth) imposes a duty on the NHMRC Licensing Committee, a Commonwealth officer or a Commonwealth authority to the extent to which imposing such a duty would:
(a) contravene any constitutional doctrine restricting the duties that may be imposed on a Commonwealth body, officer or authority; or
(b) otherwise exceed the legislative power of the Commonwealth.

(7) Subsections (1) to (6) do not limit section 43.

45 Review of certain decisions

(1) Application may be made to the Administrative Appeals Tribunal for review of a reviewable State decision.

(2) A decision made by the NHMRC Licensing Committee in the performance of a function or the exercise of a power conferred by a corresponding State law is a reviewable State decision for the purposes of this section if:
(a) the law under which the decision was made provides for review by the Administrative Appeals Tribunal; and
(b) the decision is declared by the regulations to be a reviewable State decision for the purposes of this section.

(3) For the purposes of this section, the *Administrative Appeals Tribunal Act 1975* has effect as if a corresponding State law were an enactment.

Part 5—Miscellaneous

Division 1—Arrangements relating to clinical trials of mitochondrial donation techniques

46 Arrangements relating to clinical trials of mitochondrial donation techniques

(1) The Commonwealth may make, vary or administer an arrangement:

(a) in relation to the carrying out of activities by a constitutional corporation in connection with conducting a clinical trial under a clinical trial licence referred to in section 28E, and associated activities; and

(b) for money to be payable by the Commonwealth to the constitutional corporation for that purpose.

(2) The power conferred on the Commonwealth by subsection (1) may be exercised on behalf of the Commonwealth by the Minister or the Secretary.

Note: For the power to delegate, see section 46B.

(3) In this section:

administer an arrangement includes give effect to.

arrangement includes contract, agreement or deed.

make an arrangement includes enter into.

vary an arrangement means:

(a) vary in accordance with the terms or conditions of the arrangement; or

(b) vary with the consent of the non-Commonwealth party or parties to the arrangement.

46A Terms and conditions relating to clinical trial arrangements

(1) The terms and conditions on which money may be payable by the Commonwealth under an arrangement under section 46 must be set out in a written agreement between the Commonwealth and the corporation.

(2) The corporation must comply with the terms and conditions.

(3) Without limiting subsection (1), the terms and conditions must provide for the circumstances in which the corporation must repay amounts to the Commonwealth.

(4) An agreement under subsection (1) may be entered into on behalf of the Commonwealth by the Minister or the Secretary.

Note: For the power to delegate, see section 46B.

46B Minister or Secretary may delegate powers in relation to arrangements

Delegation by the Minister

(1) The Minister may, by writing, delegate any or all of the Minister's powers under section 46 or 46A to an SES employee, or acting SES employee, in the Department who is also an official of the Department for the purposes of the *Public Governance, Performance and Accountability Act 2013*.

Note: The expressions ***SES employee*** and ***acting SES employee*** are defined in section 2B of the *Acts Interpretation Act 1901*.

(2) In exercising powers under a delegation, the delegate must comply with any directions of the Minister.

Delegation by the Secretary

(3) The Secretary may, by writing, delegate any or all of the Secretary's powers under section 46 or 46A to an SES employee, or acting SES employee, in the Department who is also an official

of the Department for the purposes of the *Public Governance, Performance and Accountability Act 2013*.

Note: The expressions ***SES employee*** and ***acting SES employee*** are defined in section 2B of the *Acts Interpretation Act 1901*.

(4) In exercising powers under a delegation, the delegate must comply with any directions of the Secretary.

46C Relationship of this Division with certain other Acts

(1) Section 23 of the *Public Governance, Performance and Accountability Act 2013* (which deals with the power of accountable authorities in relation to arrangements and commitments) does not authorise the Secretary to exercise, on behalf of the Commonwealth, a power conferred on the Commonwealth by section 46 of this Act.

(2) This Division does not, by implication, limit the operation of the *Financial Framework (Supplementary Powers) Act 1997*.

46D Executive power of the Commonwealth

This Division does not, by implication, limit the executive power of the Commonwealth.

Division 2—Other miscellaneous matters

47 Interaction with the *Gene Technology Act 2000*

(1) A mitochondrial donation technique is taken not to be gene technology for the purposes of the *Gene Technology Act 2000* when used as authorised or purportedly authorised by a mitochondrial donation licence.

(2) In this section:

mitochondrial donation licence includes a purported mitochondrial donation licence.

47A Immunity from civil actions relating to mitochondrial donation licences

(1) No civil action, suit or proceeding lies against:

(a) the Commonwealth; or

(b) a person (a ***protected person***) covered by an item of the following table;

in respect of loss, damage or injury of any kind suffered by another person as a result of anything done, or omitted to be done, by a protected person in relation to a matter mentioned in the relevant item:

Immunity from civil actions relating to mitochondrial donation licences

Item	Protected persons	Protected matters
1	any of the following persons: (a) the Minister; (b) the Secretary; (c) a person to whom powers or functions are delegated under subsection 29A(8); (d) an inspector;	the performance or purported performance, or the exercise or purported exercise, of the person's functions, duties or powers under the following in so far as they relate to mitochondrial donation licences: (a) this Act or a legislative instrument made under it;

Immunity from civil actions relating to mitochondrial donation licences		
Item	**Protected persons**	**Protected matters**
	(e) an officer or employee of the Department; (f) a member of the NHMRC Licensing Committee; (g) the CEO or an employee of the NHMRC; (h) a member of a HREC	(b) the *Prohibition of Human Cloning for Reproduction Act 2002* or a legislative instrument made under that Act
2	a person who the NHMRC Licensing Committee requests, or purportedly requests, to provide advice as mentioned in subsection 28J(4) or 28P(5A)	the provision, or purported provision, by the person of advice in response to such a request
3	a person who gives, or purportedly gives, information to the Secretary in accordance with paragraph 28R(5)(b)	the giving, or purported giving, of the information by the person

(2) Subsection (1) does not apply to an act or omission in bad faith.

(3) A reference in subsection (1) to anything omitted to be done includes a reference to a failure to make a decision.

(4) Subsection (1) is subject to section 40 (compensation for damage).

47B Review of operation of Act every 7 years

(1) The Minister must cause an independent review of the operation of this Act, in so far as it relates to the use of mitochondrial donation techniques, to be undertaken as soon as possible after the end of:

(a) the period of 7 years starting on the commencement of Schedule 1 to the *Mitochondrial Donation Law Reform (Maeve's Law) Act 2022*; and

(b) each subsequent 7-year period.

(2) A review under this section must be:

(a) undertaken by the persons who undertake the review for the relevant 7-year period required by section 25 of the *Prohibition of Human Cloning for Reproduction Act 2002*; and

(b) undertaken concurrently with the review mentioned in paragraph (a).

(3) The persons undertaking a review under this section must prepare and give to the Minister, for presentation to the Parliament, a report of the review.

(4) The report must be given to the Minister within 12 months after the end of the relevant 7-year period.

Note: See also section 34C of the *Acts Interpretation Act 1901*, which contains extra rules about periodic reports.

(5) The persons undertaking a review under this section must consult:

(a) the Commonwealth and the States; and

(b) a broad range of persons with expertise in or experience of relevant disciplines;

and the views of the Commonwealth, the States and the persons mentioned in paragraph (b) must be set out in the report to the extent that it is reasonably practicable to do so.

(6) Reports under this section and section 25 of the *Prohibition of Human Cloning for Reproduction Act 2002* may be set out in the same document.

48 Regulations

(1) The Governor-General may make regulations prescribing matters:

(a) required or permitted by this Act to be prescribed; or

(b) necessary or convenient to be prescribed for carrying out or giving effect to this Act.

(2) Before the Governor-General makes regulations under this Act, the Minister must be satisfied that:

(a) the States have been consulted in relation to the proposed regulations; and

(b) the proposed regulations have been prepared having regard to views expressed by the States in those consultations.

(3) Despite subsection 14(2) of the *Legislation Act 2003*, regulations made for the purposes of the following provisions of this Act may make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in guidelines issued by the CEO of the NHMRC under the *National Health and Medical Research Council Act 1992* as in force or existing from time to time:

(a) Division 4 (general licences) of Part 2;

(b) Division 4A (mitochondrial donation licences) of Part 2;

(c) a definition in section 7 or 8 of an expression that is used in either or both of those Divisions.

Endnotes

Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes
Endnote 2—Abbreviation key
Endnote 3—Legislation history
Endnote 4—Amendment history

Abbreviation key—Endnote 2
The abbreviation key sets out abbreviations that may be used in the endnotes.

Legislation history and amendment history—Endnotes 3 and 4
Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

Editorial changes
The *Legislation Act 2003* authorises First Parliamentary Counsel to make editorial and presentational changes to a compiled law in preparing a compilation of the law for registration. The changes must not change the effect of the law. Editorial changes take effect from the compilation registration date.

If the compilation includes editorial changes, the endnotes include a brief outline of the changes in general terms. Full details of any changes can be obtained from the Office of Parliamentary Counsel.

Misdescribed amendments
A misdescribed amendment is an amendment that does not accurately describe how an amendment is to be made. If, despite the misdescription, the amendment

can be given effect as intended, then the misdescribed amendment can be incorporated through an editorial change made under section 15V of the *Legislation Act 2003*.

If a misdescribed amendment cannot be given effect as intended, the amendment is not incorporated and "(md not incorp)" is added to the amendment history.

Endnote 2—Abbreviation key

ad = added or inserted

am = amended

amdt = amendment

c = clause(s)

C[x] = Compilation No. x

Ch = Chapter(s)

def = definition(s)

Dict = Dictionary

disallowed = disallowed by Parliament

Div = Division(s)

ed = editorial change

exp = expires/expired or ceases/ceased to have effect

F = Federal Register of Legislation

gaz = gazette

LA = *Legislation Act 2003*

LIA = *Legislative Instruments Act 2003*

(md) = misdescribed amendment can be given effect

(md not incorp) = misdescribed amendment cannot be given effect

mod = modified/modification

No. = Number(s)

o = order(s)

Ord = Ordinance

orig = original

par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)

pres = present

prev = previous

(prev…) = previously

Pt = Part(s)

r = regulation(s)/rule(s)

reloc = relocated

renum = renumbered

rep = repealed

rs = repealed and substituted

s = section(s)/subsection(s)

Sch = Schedule(s)

Sdiv = Subdivision(s)

SLI = Select Legislative Instrument

SR = Statutory Rules

Sub-Ch = Sub-Chapter(s)

SubPt = Subpart(s)

underlining = whole or part not commenced or to be commenced

Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Research Involving Human Embryos Act 2002	145, 2002	19 Dec 2002	s 3–9 and 13–48: 16 Jan 2003 (s 2(1) items 2, 4) s 10–12: 19 June 2003 (s 2(1) item 3) Remainder: 19 Dec 2002 (s 2(1) item 1)	
National Health and Medical Research Council Amendment Act 2006	50, 2006	9 June 2006	Sch 1 (items 116–121): 1 July 2006 (s 2(1) item 2)	—
Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006	172, 2006	12 Dec 2006	Sch 2 and 3: 12 June 2007 (s 2(1) item 2)	Sch 3
Same-Sex Relationships (Equal Treatment in Commonwealth Laws—General Law Reform) Act 2008	144, 2008	9 Dec 2008	Schedule 9 (item 2): 10 Dec 2008 (s 2(1) item 24)	—
Public Governance, Performance and Accountability (Consequential and Transitional Provisions) Act 2014	62, 2014	30 June 2014	Sch 11 (items 122, 123) and Sch 14: 1 July 2014 (s 2(1) items 6, 14)	Sch 14

Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
as amended by				
Public Governance and Resources Legislation Amendment Act (No. 1) 2015	36, 2015	13 Apr 2015	Sch 2 (items 7–9) and Sch 7: 14 Apr 2015 (s 2)	Sch 7
as amended by				
Acts and Instruments (Framework Reform) (Consequential Provisions) Act 2015	126, 2015	10 Sept 2015	Sch 1 (item 486): 5 Mar 2016 (s 2(1) item 2)	—
Acts and Instruments (Framework Reform) (Consequential Provisions) Act 2015	126, 2015	10 Sept 2015	Sch 1 (item 495): 5 Mar 2016 (s 2(1) item 2)	—
Statute Update Act 2016	61, 2016	23 Sept 2016	Sch 2 (items 92–94): 21 Oct 2016 (s 2(1) item 1)	—
Mitochondrial Donation Law Reform (Maeve's Law) Act 2022	26, 2022	1 Apr 2022	Sch 1 (items 9–18, 33–105, 117, 118): 1 Oct 2022 (s 2(1) item 2)	Sch 1 (items 117, 118)

Endnote 4—Amendment history

Provision affected	How affected
Part 1	
s. 3	am. No. 172, 2006
s 4	am No 26, 2022
s 7	am No 172, 2006; No 144, 2008; No 26, 2022
Part 2	
Part 2 heading	rs No 172, 2006; No 26, 2022
Division 1	
s 8	am No 50, 2006; No 172, 2006 (md incorp); No 26, 2022
Division 2	
s 10	am No 61, 2016; No 26, 2022
s 10A	ad No 172, 2006
	am No 61, 2016; No 26, 2022
s 10B	ad No 172, 2006
	am No 61, 2016; No 26, 2022
s 11	am No 172, 2006; No 61, 2016; No 26, 2022
s 11A	ad No 26, 2022
s 12	am No 61, 2016; No 26, 2022
s 12A	ad No 172, 2006
	am No 26, 2022
Division 3	
s. 13	am. No. 50, 2006; No 62, 2014
s 14	am No 26, 2022
s. 16	am. No. 172, 2006
s. 18	am. No. 50, 2006; No 62, 2014
s 19	am No 26, 2022
Division 4	
Division 4 heading	rs No 26, 2022
s 20	am No 172, 2006; No 26, 2022

Endnote 4—Amendment history

Provision affected	How affected
s 21	am No 145, 2002; No 50, 2006; No 172, 2006; No 26, 2022
s 22	am No 26, 2022
s 23	am No 26, 2022
s 24	am No 145, 2002; No 172, 2006; No 26, 2022
s 25	am No 26, 2022
s 26	am No 26, 2022
s 27	am No 26, 2022
s 28	am No 26, 2022
Division 4A	
Division 4A	ad No 26, 2022
Subdivision A	
s 28A	ad No 26, 2022
s 28B	ad No 26, 2022
s 28C	ad No 26, 2022
s 28D	ad No 26, 2022
s 28E	ad No 26, 2022
s 28F	ad No 26, 2022
s 28G	ad No 26, 2022
Subdivision B	
s 28H	ad No 26, 2022
Subdivision C	
s 28J	ad No 26, 2022
s 28K	ad No 26, 2022
s 28L	ad No 26, 2022
s 28M	ad No 26, 2022
Subdivision D	
s 28N	ad No 26, 2022
s 28P	ad No 26, 2022
s 28Q	ad No 26, 2022
Subdivision E	
s 28R	ad No 26, 2022

Provision affected	How affected
s 28S	ad No 26, 2022
s 28T	ad No 26, 2022
Subdivision F	
s 28U	ad No 26, 2022
s 28V	ad No 26, 2022
s 28W	ad No 26, 2022
s 28X	ad No 26, 2022
Division 5	
Division 5 heading	rs No 26, 2022
s 29	am No 172, 2006; No 26, 2022
s 29A	ad No 26, 2022
s 30	am No 61, 2016
Division 6	
s 31	am No 172, 2006; No 26, 2022
s 32	am No 172, 2006; No 26, 2022
Part 3	
s 34	am No 61, 2016
s 35	am No 172, 2006; No 26, 2022
s 36	am. No. 172, 2006
s 37	am. No. 172, 2006
s 37A	ad. No. 172, 2006
s 37B	ad. No. 172, 2006
s 37C	ad. No. 172, 2006
s 37D	ad. No. 172, 2006
Part 5	
Part 5 heading	rs No 26, 2022
Division 1	
Division 1	rs No 26, 2022
s 46	rs No 26, 2022
s 46A	ad No 26, 2022
s 46B	ad No 26, 2022

Endnote 4—Amendment history

Provision affected	How affected
s 46C	ad No 26, 2022
s 46D	ad No 26, 2022
Division 2	
Division 2	rs No 26, 2022
s 47	am No 50, 2006
	rs No 26, 2022
s 47A	ad No 172, 2006
	rs No 26, 2022
s 47B	ad No 172, 2006
	rs No 26, 2022
s 47C	ad No 172, 2006
	rep No 26, 2022
Division 3 heading	rep No 26, 2022
s 48	am No 26, 2022