





# **Mitochondrial Donation Law Reform (Maeve's Law) Act 2022**

**No. 26, 2022**

**An Act to amend the law relating to human cloning  
and research involving human embryos, and for  
related purposes**

Note: An electronic version of this Act is available on the Federal Register of Legislation  
(<https://www.legislation.gov.au/>)



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**An Act to amend the law relating to human cloning  
and research involving human embryos, and for  
related purposes**

[Assented to 1 April 2022]

The Parliament of Australia enacts:

## **1 Short title**

This Act is the *Mitochondrial Donation Law Reform (Maeve's Law) Act 2022*.

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## 2 Commencement

- (1) Each provision of this Act specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

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Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. Sections 1 to 3 and anything in this Act not elsewhere covered by this table	The day this Act receives the Royal Assent.	1 April 2022
2. Schedule 1	A single day to be fixed by Proclamation. However, if the provisions do not commence within the period of 6 months beginning on the day this Act receives the Royal Assent, they commence on the day after the end of that period.	

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Note: This table relates only to the provisions of this Act as originally enacted. It will not be amended to deal with any later amendments of this Act.

- (2) Any information in column 3 of the table is not part of this Act. Information may be inserted in this column, or information in it may be edited, in any published version of this Act.

## 3 Schedules

Legislation that is specified in a Schedule to this Act is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this Act has effect according to its terms.

Note: The provisions of a legislative instrument (the *principal instrument*) amended or inserted by this Act, and any other provisions of the principal instrument, may be amended or repealed by a legislative instrument made under the enabling provision for the principal instrument (see subsection 13(5) of the *Legislation Act 2003*).

## **Schedule 1—Mitochondrial donation**

### **Part 1—Main amendments**

#### ***Prohibition of Human Cloning for Reproduction Act 2002***

##### **1 Subsection 8(1)**

Insert:

***general licence*** has the same meaning as in Part 2 of the *Research Involving Human Embryos Act 2002*.

***mitochondrial donation licence*** means any of the following licences issued under section 28J of the *Research Involving Human Embryos Act 2002*:

- (a) a pre-clinical research and training licence;
- (b) a clinical trial research and training licence;
- (c) a clinical trial licence;
- (d) a clinical practice research and training licence;
- (e) a clinical practice licence.

***mitochondrial donation technique*** has the same meaning as in Part 2 of the *Research Involving Human Embryos Act 2002*.

##### **2 Section 12 (at the end of the heading)**

Add “**or the purposes of a mitochondrial donation licence**”.

##### **3 Subsection 12(1)**

Omit all of the words after “body of a woman,” (not including the penalty), substitute:

unless either or both of the following apply:

- (a) the person’s intention in creating the embryo is to attempt to achieve pregnancy in a particular woman;
- (b) the creation of the embryo by the person is permitted under section 28B of the *Research Involving Human Embryos Act 2002* (carrying out activities authorised by mitochondrial donation licences).

#### **4 After paragraph 13(b)**

Insert:

- ; and (c) the creation or development of the human embryo by the person is not permitted under section 28B of the *Research Involving Human Embryos Act 2002* (carrying out activities authorised by mitochondrial donation licences).

#### **5 After paragraph 15(1)(b)**

Insert:

- ; and (c) the alteration of the genome by the person is not permitted under section 28B of the *Research Involving Human Embryos Act 2002* (carrying out activities authorised by mitochondrial donation licences).

#### **6 At the end of subsection 20(3) (before the penalty)**

Add:

, unless:

- (a) the embryo is a prohibited embryo under paragraph (a), (c) or (f) of the definition of that expression in subsection (4); and
- (b) the placement of the embryo by the person is permitted under section 28B of the *Research Involving Human Embryos Act 2002* (carrying out activities authorised by mitochondrial donation licences).

#### **7 At the end of section 20**

Add:

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

#### **8 Paragraphs 22(b) and 23(c)**

Omit “a licence”, substitute “a general licence or permitted under section 28B of the *Research Involving Human Embryos Act 2002* (carrying out activities authorised by mitochondrial donation licences)”.

## ***Research Involving Human Embryos Act 2002***

### **9 Subsection 7(1)**

Insert:

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

***Secretary*** means the Secretary of the Department.

### **10 Section 8**

Insert:

***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.

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

***general licence*** means a licence issued under section 21.

***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.

***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.

***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).

### **11 Paragraph 10(1)(a)**

Repeal the paragraph, substitute:

- (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

### **12 Paragraph 10(2)(e)**

Repeal the paragraph, substitute:

- (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

### **13 Paragraph 10A(c)**

Omit “licence”, substitute “general licence or, if subparagraph (b)(i) or (ii) applies, permitted under section 28B (carrying out activities authorised by mitochondrial donation licences)”.

### **14 Paragraph 10B(b)**

Repeal the paragraph, substitute:

- (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.

## **15 After paragraph 11(b)**

Insert:

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

## **16 After section 11**

Insert:

### **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.

## **17 After Division 4 of Part 2**

Insert:

### **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;

## Schedule 1 Mitochondrial donation

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- (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.

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<b>Responsible persons for material</b>		
<b>Item</b>	<b>Column 1 Material</b>	<b>Column 2 Responsible persons</b>
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

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<b>Responsible persons for material</b>		
<b>Item</b>	<b>Column 1 Material</b>	<b>Column 2 Responsible persons</b>
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 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

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- (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.

**18 After section 29**

Insert:

**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.

## ***Research Involving Human Embryos Regulations 2017***

### **19 Section 5**

Insert:

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*first polar body transfer* has the meaning given by section 7F.

*germinal vesicle transfer* has the meaning given by section 7E.

*maternal spindle transfer* has the meaning given by section 7C.

*pronuclear transfer* has the meaning given by section 7D.

*second polar body transfer* has the meaning given by section 7G.

## 20 After section 7

Insert:

## Division 2—Provisions relating to mitochondrial donation licences

### 7A Definition of mitochondrial donation technique

For the purposes of the definition of *mitochondrial donation technique* in section 8 of the Act, the following are mitochondrial donation techniques:

- (a) maternal spindle transfer;
- (b) pronuclear transfer;
- (c) germinal vesicle transfer;
- (d) first polar body transfer;
- (e) second polar body transfer.

### 7B Definition of permitted technique

For the purposes of the definition of *permitted technique* in section 8 of the Act, a mitochondrial donation technique mentioned in an item in the following table is declared to be a permitted technique for a mitochondrial donation licence mentioned in that item.

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Definition of permitted technique		
Item	For this kind of mitochondrial donation licence ...	the permitted techniques are ...
1	a pre-clinical research and training licence	the following:

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<b>Definition of permitted technique</b>		
<b>Item</b>	<b>For this kind of mitochondrial donation licence ...</b>	<b>the permitted techniques are ...</b>
		(a) maternal spindle transfer; (b) pronuclear transfer; (c) germinal vesicle transfer; (d) first polar body transfer; (e) second polar body transfer
2	a clinical trial research and training licence or a clinical trial licence	the following: (a) maternal spindle transfer; (b) pronuclear transfer

### **7C Definition of maternal spindle transfer**

*Maternal spindle transfer* is a technique that involves taking the following steps, without intentionally modifying any nuclear DNA or mitochondrial DNA:

- (a) removing the maternal spindle from a human egg (*egg A*) of a woman;
- (b) removing the maternal spindle from a human egg (*egg B*) of a different woman;
- (c) implanting into egg B the maternal spindle removed from egg A, while seeking to minimise carryover of mitochondria from egg A to egg B;
- (d) fertilising egg B with a human sperm to create a zygote.

### **7D Definition of pronuclear transfer**

*Pronuclear transfer* is a technique that involves taking the following steps, without intentionally modifying any nuclear DNA or mitochondrial DNA:

- (a) fertilising, with a human sperm, a human egg of a woman to create a zygote (*zygote A*);
- (b) removing the pronuclei from zygote A;
- (c) fertilising, with a human sperm, a human egg of a different woman to create another zygote (*zygote B*);

- (d) removing the pronuclei from zygote B;
- (e) implanting the pronuclei from zygote A into zygote B, while seeking to minimise carryover of mitochondria from zygote A to zygote B.

#### **7E Definition of germinal vesicle transfer**

*Germinal vesicle transfer* is a technique that involves taking the following steps, without intentionally modifying any nuclear DNA or mitochondrial DNA:

- (a) removing the germinal vesicle from a maturing human egg (*egg A*) of a woman;
- (b) removing the germinal vesicle from a maturing human egg (*egg B*) of a different woman;
- (c) implanting the germinal vesicle removed from egg A into egg B, while seeking to minimise carryover of mitochondria from egg A to egg B;
- (d) maturing egg B in vitro to the stage ready for fertilisation;
- (e) fertilising egg B with a human sperm to create a zygote.

#### **7F Definition of first polar body transfer**

*First polar body transfer* is a technique that involves taking the following steps, without intentionally modifying any nuclear DNA or mitochondrial DNA:

- (a) removing the first polar body from a human egg (*egg A*) of a woman;
- (b) removing the maternal spindle from a human egg (*egg B*) of a different woman;
- (c) fusing the first polar body to, or implanting the first polar body into, egg B;
- (d) fertilising egg B with a human sperm to create a zygote.

#### **7G Definition of second polar body transfer**

*Second polar body transfer* is a technique that involves taking the following steps, without intentionally modifying any nuclear DNA or mitochondrial DNA:

- (a) fertilising, with a human sperm, a human egg of a woman to create a zygote (*zygote A*);
- (b) fertilising, with a human sperm, a human egg of a different woman to produce another zygote (*zygote B*);
- (c) removing the second polar body from zygote A;
- (d) removing the female pronucleus from zygote B;
- (e) transferring the second polar body from zygote A to zygote B.

#### **7H Determination by NHMRC Licensing Committee of mitochondrial donation licence applications—prescribed guidelines**

For the purposes of paragraph 28J(3)(b) of the Act, the following guidelines are prescribed:

- (a) the ART Guidelines;
- (b) the National Statement.

#### **7J Definition of proper consent—prescribed guidelines**

For the purposes of the definition of *proper consent* in subsection 28N(8) of the Act, the ART Guidelines are prescribed.

#### **7K Keeping records—prescribed period**

For the purposes of subsection 28R(4) of the Act, the period for which a record must be kept is 25 years after the creation of the record.

#### **7L Notifying adverse events—form of notification**

For the purposes of subsection 28S(4) of the Act, a notification for the purposes of subsection 28S(3) of the Act must:

- (a) be in the form approved by the CEO of the NHMRC; and
- (b) contain any information required by the form.

#### **7M Definition of adverse event**

For the purposes of the definition of *adverse event* in subsection 28S(8) of the Act, an adverse event is:

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- (a) for a trial participant or a patient—any of the following in connection with a pregnancy achieved in the trial participant or patient as a result of using a mitochondrial donation technique:
  - (i) a failed embryo development;
  - (ii) a miscarriage;
  - (iii) a premature birth of a child;
  - (iv) the birth of a child with a birth defect, a genetic abnormality or a diagnosis at birth of mitochondrial disease; and
- (b) for a child of a trial participant—a diagnosis at any time of mitochondrial disease.

## **Part 2—Other amendments**

### ***Freedom of Information Act 1982***

#### **21 Subsection 38(2)**

Omit “subsection (3)”, substitute “subsections (3) and (3A)”.

#### **22 After subsection 38(3)**

Insert:

- (3A) This section applies in relation to a document so far as it contains personal information about a person if:
- (a) the person requests access to the document; and
  - (b) disclosure of the document, or information contained in the document, is prohibited under subsection 29A(7) of the *Research Involving Human Embryos Act 2002*.

#### **23 Schedule 3**

After:

*Private Health Insurance Act 2007*, sections 323-1 and 323-40

insert:

*Research Involving Human Embryos Act 2002*, subsection 29A(7).

### ***Prohibition of Human Cloning for Reproduction Act 2002***

#### **24 At the end of subsection 4(1)**

Add:

Note: See also section 28B of the *Research Involving Human Embryos Act 2002* in relation to mitochondrial donation licences.

#### **25 Subsection 8(1) (definition of *licence*)**

Repeal the definition.

#### **26 Division 1 of Part 2 (heading)**

Repeal the heading.

**27 Division 2 of Part 2 (heading)**

Repeal the heading.

**28 Paragraph 23A(b)**

Omit “licence”, substitute “general licence”.

**29 Subsection 23B(3)**

Omit “licence”, substitute “general licence”.

**30 Subsection 23B(3) (note)**

Omit “licence”, substitute “general licence”.

**31 After section 23B**

Insert:

**23BA 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 a 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 22, 23, 23A or 23B; or
- (b) for a mitochondrial donation licence—an offence against section 12, 13 or 15, subsection 20(3), or section 22 or 23.

***mitochondrial donation licence*** includes a purported mitochondrial donation licence.

## **32 Sections 25 and 25A**

Repeal the sections, substitute:

### **25 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 is to be undertaken by persons chosen by the Minister, with the agreement of each State.
- (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.

## ***Research Involving Human Embryos Act 2002***

### **33 At the end of subsection 4(1)**

Add:

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

**34 Subsection 4(2) (definition of *constitutional corporation*)**

Repeal the definition.

**35 At the end of subsection 4(2)**

Add:

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

**36 Subsection 7(1) (paragraph (a) of the definition of *unsuitable for implantation*)**

Omit “the *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (2004)*, issued by the CEO of the NHMRC”, substitute “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”.

**37 Part 2 (heading)**

Repeal the heading, substitute:

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

**38 Section 8**

Insert:

*engage in conduct* means:

- (a) do an act; or
- (b) omit to perform an act.

**39 Section 8 (definition of *licence*)**

Repeal the definition.

**40 Section 8**

Insert:

*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>).

#### **41 Section 8 (definition of *proper consent*)**

Repeal the definition, substitute:

***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).

#### **42 Section 8 (definition of *responsible person*)**

Repeal the definition, substitute:

***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).

#### **43 Section 10A (note)**

Omit “licence under this Act”, substitute “general licence under this Act, or if subparagraph (b)(i) or (ii) applies, permitted under section 28B of this Act”.

#### **44 Paragraph 10B(a)**

Omit “ART”, substitute “assisted reproductive technology”.

#### **45 Section 12 (heading)**

Omit “licence”, substitute “**general licence or mitochondrial donation licence**”.

#### **46 Subsection 12(1)**

Omit “(1)”.

**47 Subsection 12(1)**

Omit “licence” (first occurring), substitute “general licence or mitochondrial donation licence”.

**48 Subsection 12(2)**

Repeal the subsection.

**49 Subsection 12A(1)**

Omit “an offence against this Act”, substitute “a licence offence”.

**50 Paragraph 12A(1)(a)**

Omit “licence”, substitute “general licence or mitochondrial donation licence”.

**51 Subsection 12A(2)**

Repeal the subsection, substitute:

(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.

**52 Paragraph 14(a)**

Omit “licences”, substitute “general licences”.

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**53 After paragraph 14(a)**

Insert:

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

**54 Paragraph 14(b)**

Omit “Division 5”, substitute “section 29”.

**55 Paragraph 19(3)(e)**

Omit “licences”, substitute “general licences and mitochondrial donation licences”.

**55A At the end of section 19**

Add:

- (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).

**56 Division 4 of Part 2 (heading)**

Repeal the heading, substitute:

**Division 4—General licences**

**57 Section 20 (heading)**

Repeal the heading, substitute:

## 20 Applying for a general licence

### 58 Subsection 20(1)

After “licence”, insert “(a *general licence*)”.

### 59 Paragraph 20(1)(e)

Omit “ART”, substitute “assisted reproductive technology”.

### 60 After subsection 20(1A)

Insert:

(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.

### 61 Subsection 21(1)

Omit “a licence”, substitute “a general licence”.

### 62 Paragraph 21(3)(c)

Omit “NHMRC *National Statement on Ethical Conduct in Research Involving Humans* (1999), as in force from time to time”, substitute “National Statement”.

### 63 Subsection 22(1)

Omit “a licence”, substitute “a general licence”.

### 64 Section 23 (heading)

Repeal the heading, substitute:

## 23 Period of a general licence

### 65 Subsections 23(1) and (2)

Omit “A licence”, substitute “A general licence”.

**66 Section 24 (heading)**

Repeal the heading, substitute:

**24 Conditions of general licences**

**67 Subsections 24(1), (2) and (4)**

Omit “A licence”, substitute “A general licence”.

**68 Subsection 24(6)**

Omit “(1), (2) and (3)”, substitute “(1) and (2)”.

**69 Paragraph 24(8)(a)**

Omit “a licence may provide that the guidelines referred to in the definition of *proper consent* apply”, substitute “a general licence may provide that the guidelines referred to in the definition of *proper consent* in subsection (9) apply”.

**70 Paragraph 24(8)(b)**

Omit “a licence”, substitute “a general licence”.

**71 At the end of section 24**

Add:

(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.

**72 Section 25 (heading)**

Repeal the heading, substitute:

**25 Variation of a general licence**

**73 Subsections 25(1), (2) and (4)**

Omit “a licence”, substitute “a general licence”.

**74 Subsection 25(4)**

Omit “Part”, substitute “Division”.

**75 Section 26 (heading)**

Repeal the heading, substitute:

**26 Suspension or revocation of a general licence**

**76 Subsection 26(1)**

Omit “a licence”, substitute “a general licence”.

**77 Subsection 26(2)**

Omit “each licence”, substitute “each general licence”.

**78 Section 27 (heading)**

Repeal the heading, substitute:

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**27 Surrender of a general licence**

**79 Section 27**

Omit “a licence”, substitute “a general licence”.

**80 Section 28 (heading)**

Repeal the heading, substitute:

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

**81 Subsections 28(1) and (2)**

Omit “a licence”, substitute “a general licence”.

**82 Division 5 of Part 2 (heading)**

Repeal the heading, substitute:

**Division 5—Protection and disclosure of information**

**83 Subsection 29(1)**

Omit “each licence”, substitute “each general licence and each mitochondrial donation licence”.

**84 Paragraph 29(1)(b)**

Before “a short statement”, insert “for a general licence—”.

**85 After paragraph 29(1)(b)**

Insert:

- (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;

**86 Paragraph 29(1)(c)**

Repeal the paragraph.

**87 Paragraph 29(1)(d)**

Omit “the number of ART”, substitute “for a general licence—the number of excess ART”.

**88 Paragraphs 29(1)(e) and (f)**

Repeal the paragraphs, substitute:

- (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.

**89 Section 31 (paragraph (a) of the definition of *eligible person*)**

After “21”, insert “or 28J”.

**90 Section 31 (paragraph (b) of the definition of *eligible person*)**

After “23”, insert “or 28M”.

**91 Section 31 (paragraph (c) of the definition of *eligible person*)**

After “24(4)”, insert “or 28N(4)”.

**92 Section 31 (paragraph (d) of the definition of *eligible person*)**

After “25”, insert “or 28U”.

**93 Section 31 (paragraph (e) of the definition of *eligible person*)**

After “26”, insert “or subsection 28V(1) or (2)”.

**94 Section 31 (at the end of the definition of *eligible person*)**

Add:

- ; 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.

**95 Paragraph 32(1)(a)**

After “21”, insert “or 28J”.

**96 Paragraph 32(1)(b)**

After “23”, insert “or 28M”.

**97 Paragraph 32(1)(c)**

After “24(4)”, insert “or 28N(4)”.

**98 Paragraph 32(1)(d)**

After “25”, insert “or 28U”.

**99 Paragraph 32(1)(e)**

After “26”, insert “or subsection 28V(1) or (2)”.

**100 At the end of subsection 32(1)**

Add:

- ; (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.

**101 Paragraph 35(2)(b)**

After “21”, insert “or 28J”.

**102 Part 5 (heading)**

Repeal the heading, substitute:

## Part 5—Miscellaneous

### 103 Divisions 1 and 2 of Part 5

Repeal the Divisions, substitute:

### 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:

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**Immunity from civil actions relating to mitochondrial donation licences**

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<b>Item</b>	<b>Protected persons</b>	<b>Protected matters</b>
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; (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	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; (b) the <i>Prohibition of Human Cloning for Reproduction Act 2002</i> 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

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- (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.

#### **104 Division 3 of Part 5 (heading)**

Repeal the heading.

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### **105 At the end of section 48**

Add:

- (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.

### ***Research Involving Human Embryos Regulations 2017***

#### **106 Section 5 (after the heading)**

Insert:

- Note: A number of expressions used in this instrument are defined in the Act, including the following:
- (a) National Statement;
  - (b) the NHMRC.

#### **107 Section 5 (definition of *ART Guidelines*)**

Repeal the definition, substitute:

***ART Guidelines*** means 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.

- Note: The ART Guidelines could in 2021 be viewed on the website of the NHMRC (<https://www.nhmrc.gov.au>).

#### **108 Section 5 (definition of *National Statement*)**

Repeal the definition.

**109 Section 5 (definition of *Objective Criteria for Unsuitable Embryos*)**

Repeal the definition, substitute:

*Objective Criteria for Unsuitable Embryos* means the *Objective Criteria for determining embryos that are unsuitable for implantation*, 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 Objective Criteria for Unsuitable Embryos could in 2021 be viewed on the website of the NHMRC (<https://www.nhmrc.gov.au>).

**110 Part 2 (heading)**

Repeal the heading, substitute:

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

**Division 1—Provisions relating to general licences**

**111 After section 6**

Insert:

**6A Determination by NHMRC Licensing Committee of general licence applications—prescribed guidelines**

For the purposes of paragraph 21(4)(c) of the Act, the following guidelines are prescribed:

- (a) the ART Guidelines;
- (b) the National Statement.

**112 Section 7**

Omit “section 8”, substitute “subsection 24(9)”.

**113 Before section 8**

Insert:

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### **Division 3—Other provisions**

#### **114 Section 9**

Repeal the section.

#### **115 Part 4**

Repeal the Part.

### ***Therapeutic Goods (Excluded Goods) Determination 2018***

#### **116 Schedule 2 (after table item 4D)**

Insert:

4E	goods that are:	when used in carrying out an activity
	(a) human eggs; or	as authorised or purportedly
	(b) human sperm	authorised by a mitochondrial
		donation licence under the <i>Research</i>
		<i>Involving Human Embryos Act 2002</i>

## Part 3—Application and transitional provisions

### 117 Reports to Parliament

- (1) For the purposes of a report that is required to be tabled in a House of the Parliament under subsection 19(3) of the *Research Involving Human Embryos Act 2002* during the period of 6 months starting on the commencement of this Schedule, the following are to be disregarded:
  - (a) the amendments of that Act made by this Schedule;
  - (b) any mitochondrial donation licences issued under that Act as amended by this Schedule.
- (2) However, any information that would have been required to be included in a report under that subsection apart from subitem (1) must be included in the first report required to be tabled under that subsection after the end of that 6-month period.

### 118 Determination of pre-commencement general licence applications

- (1) This item applies in relation to an application for a licence made under subsection 20(1) of the *Research Involving Human Embryos Act 2002*, but not finally determined, before the commencement of this Schedule.
- (2) Despite the amendments made by this Schedule, the following provisions, as in force immediately before that commencement, continue to apply on and after that commencement in relation to the application:
  - (a) paragraph 21(3)(c) of the *Research Involving Human Embryos Act 2002*;
  - (b) the following provisions of the *Research Involving Human Embryos Regulations 2017*:
    - (i) the definitions of **ART Guidelines** and **National Statement** in section 5 of those regulations;
    - (ii) sections 7 and 9 of those regulations.

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*[Minister's second reading speech made in—  
House of Representatives on 24 March 2021  
Senate on 2 December 2021]*

(43/21)