

South Australia

# Research Involving Human Embryos Act 2003

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

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## Legislative history

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## The Parliament of South Australia enacts as follows:

### Part 1—Preliminary

#### 1—Short title

This Act may be cited as the *Research Involving Human Embryos Act 2003*.

#### 3—Interpretation

- (1) In this Act, unless the contrary intention appears—

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

- (a) the Reproductive Technology Accreditation Committee of the Fertility Society of Australia; or
- (b) if the regulations prescribe another body or other bodies in addition to, or instead of, the body mentioned in paragraph (a)—that other body or any of those other bodies, as the case requires;

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

**Commonwealth authority** means—

- (a) a body corporate established for a public purpose by or under an Act of the Commonwealth; or
- (b) a company in which a controlling interest is held by any one of the following persons, or by 2 or more of the following persons together:
  - (i) the Commonwealth;
  - (ii) a body covered by paragraph (a);
  - (iii) a body covered by either of the above subparagraphs;

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

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

**excess ART embryo** means a human embryo that—

- (a) was created, by assisted reproductive technology, for use in the assisted reproductive treatment of a woman; and
- (b) is excess to the needs of—
  - (i) the woman for whom it was created; and
  - (ii) her spouse (if any) at the time the embryo was created;

**HREC** means a Human Research Ethics Committee;

**human embryo** means a discrete entity that has arisen from either—

- (a) the first mitotic division when fertilisation of a human oocyte by a human sperm is complete; or
- (b) any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears,

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

**human reproductive material** means—

- (a) a human embryo; or
- (b) human sperm; or
- (c) a human egg; or
- (d) a thing declared by the regulations to be human reproductive material;

**human sperm** includes human spermatids;

**hybrid embryo** means—

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

- (c) a human egg into which the nucleus of an animal cell has been introduced; or
- (d) an animal egg into which the nucleus of a human cell has been introduced; or
- (e) a thing declared by the regulations to be a hybrid embryo;

**inspector** means a person appointed as an inspector under a related Commonwealth Act;

**licence** means a licence issued under Division 3 of Part 2;

**NHMRC** means the National Health and Medical Research Council established by the *National Health and Medical Research Council Act 1992* of the Commonwealth;

**NHMRC Licensing Committee** means the Committee established by section 13 of the *Research Involving Human Embryos Act 2002* of the Commonwealth;

**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 Chief Executive Officer of the NHMRC under the *National Health and Medical Research Council Act 1992* of the Commonwealth and prescribed by the regulations under the *Research Involving Human Embryos Act 2002* of the Commonwealth for the purposes of the definition of **proper consent** in that Act;

**record** means a record of any kind, including a disk, tape or other article from which information is capable of being reproduced (with or without the aid of another article or device);

**related Commonwealth Act** means—

- (a) the *Prohibition of Human Cloning for Reproduction Act 2002* of the Commonwealth; or
- (b) the *Research Involving Human Embryos Act 2002* of the Commonwealth;

**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;

**South Australian clinical practice licence** means a licence to carry out artificial fertilisation procedures issued under Part 3 of the *Reproductive Technology (Clinical Practices) Act 1988*;

**spouse**, in relation to a person, includes a person who, although not legally married to the person, is living with the person as the person's spouse on a *bona fide* domestic basis;

**State** includes the Australian Capital Territory and the Northern Territory;

**unsuitable for implantation**, in relation to a human embryo, means a human embryo that—

- (a) is diagnosed by preimplantation genetic diagnosis as unsuitable for implantation, in accordance with the *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (2004)*, issued by the Chief Executive Officer of the NHMRC; or
- (b) is determined to be unsuitable for implantation in the body of a woman, in accordance with objective criteria specified in guidelines issued by the Chief Executive Officer of the NHMRC under the *National Health and Medical Research Council Act 1992* of the Commonwealth and prescribed by the regulations under the *Research Involving Human Embryos Act 2002* of the Commonwealth for the purposes of the definition of **unsuitable for implantation** in that Act;

**use** includes develop, or development, as the case requires;

**woman** means a female human.

- (2) For the purposes of the definition of **human embryo** in subsection (1), in working out the length of the period of development of a human embryo, any period when the development of the embryo is suspended is to be disregarded.
- (3) For the purposes of paragraph (b) of the definition of **excess ART embryo** in subsection (1), a human embryo is excess to the needs of the persons mentioned in that paragraph at a particular time if—
  - (a) each such person has given written authority for use of the embryo for a purpose other than a purpose relating to the assisted reproductive technology treatment of the woman concerned, and the authority is in force at that time; or
  - (b) each such person has determined in writing that the embryo is excess to their needs, and the determination is in force at that time.
- (4) A reference in this Act to an **embryo** (including a human embryo) is a reference to a living embryo.
- (5) A reference in this Act to a **human egg** is a reference to a human oocyte.
- (6) A reference in this Act to a **human embryo** does not include a reference to—
  - (a) a hybrid embryo; or
  - (b) a human embryonic stem cell line.

#### **4—Nationally consistent scheme**

It is intended that the principal objects of this Act be achieved through a regulatory framework and a range of offences that operate in conjunction with, and in a manner that is consistent with, corresponding Commonwealth and State laws.

## **Part 2—Regulation of the use of excess ART embryos, other embryos and human eggs**

### **Division 1—Offences**

#### **5—Offence—use of excess ART embryo**

- (1) A person commits an offence if the person intentionally uses an excess ART embryo, unless—
- (a) the use by the person is authorised by a licence; or
  - (b) the use by the person is an exempt use within the meaning of subsection (2).

Maximum penalty: Imprisonment for 5 years.

- (2) A use of an excess ART embryo by a person is an exempt use for the purpose of subsection (1) if—
- (a) the use consists only of—
    - (i) storage of the excess ART embryo; or
    - (ii) removal of the excess ART embryo from storage; or
    - (iii) transport of the excess ART embryo; or
  - (b) the use consists only of observation of the excess ART embryo; or
  - (c) the use consists only of allowing the excess ART embryo to succumb; or
  - (d) the use is carried out by an accredited ART centre under a South Australian clinical practice licence and—
    - (i) the excess ART embryo is not suitable to be placed in the body of the woman for whom it was created where the suitability of the embryo is determined only on the basis of its biological fitness for implantation; and
    - (ii) the use forms part of diagnostic investigations conducted in connection with the assisted reproductive technology treatment of the woman for whom the excess ART embryo was created; or
  - (e) the use is carried out by an accredited ART centre under a South Australian clinical practice licence and is for the purposes of achieving pregnancy in a woman other than the woman for whom the excess ART embryo was created; or
  - (f) the use is of a kind prescribed by the regulations for the purposes of this paragraph.

(3) In subsection (2)—

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

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

### **5A—Offence—use of other embryos**

A person commits an offence if—

- (a) the person intentionally uses an embryo; and
- (b) the embryo is—
  - (i) a human embryo created by a process other than the fertilisation of a human egg by a human sperm; or
  - (ii) a human embryo created by a process other than the fertilisation of a human egg by a human sperm that contains genetic material provided by more than 2 persons; or
  - (iii) a human embryo created using precursor cells taken from a human embryo or a human fetus; or
  - (iv) a hybrid embryo; and
- (c) the use by the person is not authorised by a licence.

Maximum penalty: Imprisonment for 5 years.

**Note—**

The creation or development of embryos mentioned in this section is prohibited under Part 2 of the *Prohibition of Human Cloning for Reproduction Act 2003*, unless authorised by a licence under this Act.

### **5B—Offence—certain activities involving use of human eggs**

A person commits an offence if—

- (a) the person undertakes research or training involving the fertilisation of a human egg by a human sperm up to, but not including, the first mitotic division, outside the body of a woman for the purposes of research or training in ART; and
- (b) the person is not authorised by a licence to undertake the research or training.

Maximum penalty: Imprisonment for 5 years.

### **6—Offence—use of embryo that is not an excess ART embryo**

A person commits an offence if—

- (a) the person intentionally uses, outside the body of a woman, a human embryo—
  - (i) that was created by fertilisation of a human egg by a human sperm; and

- (ii) that is not an excess ART embryo; and
- (b) the use is not for a purpose related to the assisted reproductive technology treatment of a woman carried out by an accredited ART centre under a South Australian clinical practice licence, and the person knows or is reckless as to that fact.

Maximum penalty: Imprisonment for 5 years.

### **7—Offence—breaching a licence condition**

- (1) A person commits an offence if the person intentionally engages in conduct, knowing that the conduct contravenes a condition of a licence that applies to the person under this Act, or reckless as to whether the conduct contravenes a condition of such a licence.

Maximum penalty: Imprisonment for 5 years.

- (2) In this section—

*engage in conduct* means—

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

### **7A—Person not liable for conduct purportedly authorised**

- (1) To avoid doubt, a person is not criminally responsible for an offence against this Act in respect of particular conduct if—
  - (a) the conduct by the person is purportedly authorised by a provision of a 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—

*licence* includes a purported licence.

## **Division 2—Embryo Research Licensing Committee of the NHMRC**

### **8—Conferral of functions on Committee**

The NHMRC Licensing Committee has the following functions:

- (a) to perform functions in relation to licences under Division 3;
- (b) to perform functions in relation to databases under Division 4;
- (c) to perform such other functions as are conferred on it by this Act or any other law.

### **9—Powers of Committee**

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



## **Division 3—Licensing system**

### **10—Person may apply for licence**

- (1) A person may apply to the NHMRC Licensing Committee for a licence authorising 1 or more of the following:
  - (a) use of excess ART embryos;
  - (b) creation of human embryos other than by fertilisation of a human egg by a human sperm, and use of such embryos;
  - (c) creation of human embryos other than by fertilisation of a human egg by a human sperm that contain genetic material provided by more than 2 persons, and use of such embryos;
  - (d) creation of human embryos using precursor cells from a human embryo or a human fetus, and use of such embryos;
  - (e) research and training involving the fertilisation of a human egg by a human sperm up to, but not including, the first mitotic division, outside the body of a woman for the purposes of research or training in ART;
  - (f) creation of hybrid embryos by the fertilisation of an animal egg by a human sperm, and use of such embryos up to, but not including, the first mitotic division, if—
    - (i) the creation or use is for the purposes of testing sperm quality; and
    - (ii) the creation or use will occur in an accredited ART centre.
- (1a) To avoid doubt, subsection (1)(a), (b), (c) and (d) do not permit the NHMRC Licensing Committee to authorise any use of an excess ART embryo or other embryo that would result in the development of the embryo for a period of more than 14 days, excluding any period when development is suspended.
- (2) An application under subsection (1)—
  - (a) must be made in accordance with the requirements (if any) specified in writing by the NHMRC Licensing Committee; and
  - (b) must be accompanied by the fee (if any) prescribed by the regulations.

### **11—Determination of application by Committee**

- (1) This section applies if a person has made an application for a licence.
- (2) The NHMRC Licensing Committee must decide, in accordance with this section, whether or not to issue the licence.
- (3) The NHMRC Licensing Committee must not issue the licence unless it is satisfied of the following:
  - (a) that appropriate protocols are in place—
    - (i) to enable proper consent to be obtained before an excess ART embryo or human egg is used, or other embryo is created or used, under the licence; and
    - (ii) to enable compliance with any restrictions on such consent;

- (c) that the activity or project proposed in the application has been assessed and approved by a HREC that is constituted in accordance with, and acting in compliance with, the NHMRC *National Statement on Ethical Conduct in Research Involving Humans* (1999), as in force from time to time.
- (4) In deciding whether to issue the licence, the NHMRC Licensing Committee must have regard to the following:
- (a) restricting the number of excess ART embryos, other embryos or human eggs, to that likely to be necessary to achieve the goals of the activity or project proposed in the application;
  - (b) the likelihood of significant advance in knowledge or improvement in technologies for treatment as a result of the use of excess ART embryos or human eggs, or the creation or use of other embryos, proposed in the application, which could not reasonably be achieved by other means;
  - (c) any relevant guidelines, or relevant parts of guidelines, issued by the Chief Executive Officer of the NHMRC under the *National Medical and Research Council Act 1992* of the Commonwealth and prescribed by the regulations for the purposes of the corresponding provision of the *Research Involving Human Embryos Act 2002* of the Commonwealth;
  - (d) the HREC assessment of the application mentioned in subsection (3)(c);
  - (e) such additional matters (if any) as are prescribed by the regulations.

## **12—Notification of decision**

- (1) The NHMRC Licensing Committee must notify its decision on an application for a licence to the following:
- (a) the applicant;
  - (b) the HREC that assessed and approved the activity or project proposed in the application;
  - (c) any other person or body prescribed by the regulations.
- (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 subsection (1)(b) and (c).

## **13—Period of licence**

- (1) A 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 licence is not in force throughout any period of suspension.

## 14—Licence is subject to conditions

- (1) A licence is subject to the condition that before an excess ART embryo or human egg is used, or any other embryo is created or used, as authorised by the licence—
  - (a) each responsible person in relation to the excess ART embryo, human egg or other embryo must have given proper consent to that creation or use; and
  - (b) the licence holder must have reported in writing to the NHMRC Licensing Committee that such consent has been obtained, and any restrictions to which the consent is subject.
- (2) A licence is subject to the condition that the use of an excess ART embryo or human egg, or the creation or use of any other embryo, must be in accordance with any restrictions to which the proper consent under subsection (1) is subject.
- (4) A licence is subject to such other conditions as are specified in the licence.
- (5) The conditions specified in the licence may include, but are not limited to, conditions relating to the following:
  - (a) the persons authorised by the licence to use excess ART embryos or human eggs, or create or use other embryos;
  - (b) the number of excess ART embryos or human eggs authorised to be used under the licence, or the number of other embryos authorised to be created or used under the licence;
  - (c) reporting;
  - (d) monitoring;
  - (e) information to be given by the licence holder to persons authorised by the licence to use excess ART embryos or human eggs, or to create or use other embryos.
- (6) The licence conditions set out in subsections (1), (2) and (3) apply to all persons who are authorised by the licence to use excess ART embryos or human eggs, or to create or use other embryos.
- (7) Licence conditions specified in the licence apply to—
  - (a) the licence holder; and
  - (b) such other persons authorised by the licence to use excess ART embryos or human eggs, or to create or use other embryos, as are specified in the licence.
- (8) For the purposes of applying the condition referred to in subsection (1)(a)—
  - (a) a licence may provide that the guidelines referred to in the definition of *proper consent* apply in a modified form in relation to the use, under the licence, of excess ART embryos that are unsuitable for implantation; and
  - (b) if a licence so provides, the guidelines as modified by the licence have effect in relation to the giving of consent for such creation or use.

**Note—**

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

## **15—Variation of licence**

- (1) The NHMRC Licensing Committee may, by notice in writing given to the licence holder, vary a 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 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 licence in such a way that, had a person applied under this Part for the licence as varied, the Committee would not have been permitted by this Part to issue the licence.

## **16—Suspension or revocation of licence**

- (1) The NHMRC Licensing Committee may, by notice in writing given to the licence holder, suspend or revoke a licence if the Committee believes on reasonable grounds that a condition of the licence has been breached.
- (2) If a licence holder is convicted of an offence against this Act, the *Prohibition of Human Cloning for Reproduction Act 2003*, or a related Commonwealth Act, the NHMRC Licensing Committee must, by notice in writing given to the licence holder, revoke each licence held by the licence holder.

## **17—Surrender of licence**

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

## **18—Notification of variation, suspension or revocation of licence**

- (1) If the NHMRC Licensing Committee varies, suspends or revokes a licence, the Committee must notify—
  - (a) the licence holder; and
  - (b) the relevant HREC; and
  - (c) any other person or body prescribed by the regulations.
- (2) The NHMRC Licensing Committee must also notify the relevant HREC, and any other prescribed person or body, if a licence is surrendered.

## **Division 4—Reporting and confidentiality**

### **19—NHMRC Committee to make certain information publicly available**

- (1) The NHMRC Licensing Committee must maintain a database containing the following information in relation to each licence (including a licence as varied):
  - (a) the name of the person to whom the licence was issued;
  - (b) a short statement about the nature of the uses of excess ART embryos or human eggs, and creations or uses of other embryos, that are authorised by the licence;
  - (c) any conditions to which the licence is subject;

- (d) the number of ART embryos or human eggs authorised to be used under the licence, and the number of other embryos authorised to be created or used under the licence;
  - (e) the date on which the licence was issued;
  - (f) the period throughout which the licence is to remain in force.
- (2) The database is to be made publicly available.
- (3) The database may be kept and made publicly available in electronic form.
- (4) Information mentioned in subsection (1) must not be such as to disclose confidential commercial information.

**20—Confidential commercial information may only be disclosed in certain circumstances**

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

Maximum penalty: Imprisonment for 2 years.

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

Maximum penalty: Imprisonment for 2 years.

(3) In this section—

**corresponding Act** means—

- (a) the *Research Involving Human Embryos Act 2002* of the Commonwealth; or
- (b) an Act of another State that is a corresponding State law under the *Research Involving Human Embryos Act 2002* of the Commonwealth;

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

**State agency** means the following:

- (a) the Crown in right of a State;
- (b) a Minister of a State;
- (c) a State Government department;
- (d) any other agency or instrumentality of a State, including a body corporate established for a public purpose by or under a law of a State;
- (e) a company in which a controlling interest is held by any one of the following persons, or by 2 or more of the following persons together:
  - (i) the Crown in right of a State;
  - (ii) a person or body covered by paragraph (b) or (d);
  - (iii) a person or body covered by either of the above subparagraphs.

## **Division 5—Review provisions**

### **21—Interpretation**

In this Division—

**Administrative Appeals Tribunal** means the Administrative Appeals Tribunal established by the *Administrative Appeals Tribunal Act 1975* of the Commonwealth;

**Commonwealth Act** means the *Research Involving Human Embryos Act 2002* of the Commonwealth;

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

- (a) in relation to a decision under section 11 not to issue a licence—the applicant for the licence; or
- (b) in relation to a decision in respect of the period throughout which the licence is to be in force under section 13—the licence holder; or
- (c) in relation to a decision to specify a licence condition under section 14(4)—the licence holder; or
- (ca) in relation to a decision to modify guidelines under section 14(8) in respect of a licence—the licence holder; or
- (d) in relation to a decision to vary or refuse to vary a licence under section 15—the licence holder; or

- (e) in relation to a decision to suspend or revoke a licence under section 16—the person who was the licence holder immediately before the suspension or revocation;

**reviewable decision** means any of the following decisions of the NHMRC Licensing Committee:

- (a) a decision under section 11 not to issue a licence;
- (b) a decision in respect of the period throughout which the licence is to be in force under section 13;
- (c) a decision to specify a licence condition under section 14(4);
- (ca) a decision to modify guidelines under section 14(8) in respect of a licence;
- (d) a decision to vary or refuse to vary a licence under section 15;
- (e) a decision to suspend or revoke a licence under section 16;

**SACAT** means the South Australian Civil and Administrative Tribunal established under the *South Australian Civil and Administrative Tribunal Act 2013*.

## **22—Review of decisions**

- (1) An eligible person may—
  - (a) if subsection (2) applies—apply to the Administrative Appeals Tribunal for the review of a reviewable decision; or
  - (b) if subsection (2) does not apply—apply to SACAT under section 34 of the *South Australian Civil and Administrative Tribunal Act 2013* for the review of a reviewable decision.
- (2) This subsection applies if an eligible person is also—
  - (a) in relation to a reviewable decision under section 11—an applicant for a corresponding licence under the Commonwealth Act; or
  - (b) in relation to a reviewable decision under section 13, 14(4), 14(8) or 15—the holder of a corresponding licence under the Commonwealth Act; or
  - (c) in relation to a reviewable decision under section 16—a person whose corresponding licence under the Commonwealth Act has been suspended or revoked under that Act.
- (3) For the purposes of subsection (1)(a)—
  - (a) the *Administrative Appeals Tribunal Act 1975* of the Commonwealth (excluding Part IVA) and the regulations in force for the time being under that Act apply as laws of South Australia in relation to relevant reviewable decisions (and Part IVA of that Act will continue to have effect as a law of the Commonwealth); and
  - (b) a reference in a provision of the *Administrative Appeals Tribunal Act 1975* of the Commonwealth (as that provision applies as a law of South Australia) to the whole or any part of Part IVA of that Act is taken to be a reference to the whole or any part of that Part as it has effect as a law of the Commonwealth.
- (4) For the purposes of subsection (1)(b), an application for review of a reviewable decision must be made within 28 days after the making of the decision.

- (5) For the purposes of section 22 of the *South Australian Civil and Administrative Tribunal Act 2013*, there may be a panel of assessors consisting of persons who have expertise that would be of value to SACAT in relation to proceedings before SACAT on a review under this section.
- (5a) In any proceedings on a review under this section, SACAT may, if the President so determines, sit with 1 or more assessors from the panel.
- (6) Nothing in this section, or in any other provision of this Act, is intended to limit any right that a person may have under a law of the Commonwealth, or under the Constitution of the Commonwealth, to bring an action against the NHMRC Licensing Committee.
- (7) This section has effect subject to the *Administrative Appeals Tribunal Act 1975* of the Commonwealth.

## **Part 3—Inspectors**

### **23—Powers of inspectors**

- (1) An inspector may, for any purpose connected with the administration, operation or enforcement of this Act—
  - (a) enter any premises; and
  - (b) search the premises and anything on the premises; and
  - (c) inspect, examine, take measurements of, conduct tests on, or take samples of, any human reproductive or other material, or thing, at the premises; and
  - (d) take photographs, films, audio, video or other recordings, and make sketches; and
  - (e) inspect any book, record or document and, if necessary, require a person to produce any book, record or document for inspection; and
  - (f) take extracts from or make copies of any book, record or document; and
  - (g) operate any equipment at the premises, or require a person to operate any equipment at the premises; and
  - (h) take onto the premises any equipment or materials; and
  - (i) secure any equipment or material or other thing and require that it not be operated, moved, altered or used in any way until further order of an inspector or magistrate; and
  - (j) require a person to answer questions; and
  - (k) give directions reasonably required in connection with the exercise of a power conferred by any of the above paragraphs or otherwise in connection with the administration, operation or enforcement of this Act.
- (2) An inspector may, in exercising powers under this section—
  - (a) be accompanied by such police officers or other persons as the inspector thinks fit; and
  - (b) take onto premises such equipment or materials as the inspector reasonably requires.



- (3) Without limiting subsection (1), an inspector may operate equipment at premises to see whether—
- (a) the equipment; or
  - (b) a disk, tape or other storage device that—
    - (i) is at the premises; and
    - (ii) can be used with the equipment or is associated with it,
- contains information or material that is relevant to determining whether there has been compliance with this Act or the regulations.
- (4) Without limiting subsection (1) or (3), if an inspector, after operating equipment at the premises, finds that the equipment, or that a tape, disk or other storage device at the premises, contains information mentioned in subsection (3), the inspector may—
- (a) operate equipment or facilities at the premises to put the information in documentary form and copy the document so produced; or
  - (b) if the information can be transferred to a tape, disk or other storage device that—
    - (i) is brought to the premises; or
    - (ii) is at the premises,
- operate the equipment or other facilities to copy the information to the storage device, and remove the storage device from the premises.
- (5) Without limiting subsection (1), if an inspector, during a search of premises, believes on reasonable grounds that there is at the premises a human embryo, another embryo, a human egg or other material or thing that may afford evidence of the commission of an offence against this Act, the inspector may—
- (a) secure the embryo, the egg, material or other thing, pending the obtaining of a warrant to seize it; and
  - (b) seize it under the authority of a warrant to seize it obtained from a magistrate.
- (6) An inspector is not authorised to enter premises under this section unless—
- (a) the occupier of the premises has consented to the entry; or
  - (b) the occupier of the premises is carrying out activities covered by a licence under this Act, and the entry is at a reasonable time; or
  - (c) the entry is made under the authority of a warrant issued by a magistrate; or
  - (d) the inspector has reasonable grounds to believe that the circumstances require immediate entry.
- (7) An application for a warrant under this section—
- (a) may be made either personally or by telephone;
  - (b) must be made in accordance with the procedures prescribed by the regulations.
- (8) An inspector may use such force as is reasonably necessary to enter premises under subsection (6)(b), (c) or (d).

- (9) A magistrate may, on application by a person who has an interest in any equipment, material or other thing secured under paragraph (i) of subsection (1), grant an order releasing the equipment, material or thing from the requirement under that paragraph.

#### **24—Announcement before entry**

- (1) An inspector must, before entering premises without the consent of the occupier of the premises—
- (a) announce that he or she is authorised to enter the premises; and
  - (b) give any person at the premises an opportunity to allow entry to the premises.
- (2) An inspector is not required to comply with subsection (1) if the inspector has reasonable grounds to believe that immediate entry to the premises is required to ensure the effective exercise of powers under this Part.

#### **25—Inspector must produce identity card on request**

- (1) An inspector is not entitled to exercise any powers under this Part in relation to premises if—
- (a) the occupier of the premises has required the inspector to produce an identity card for inspection by the occupier; and
  - (b) the inspector fails to comply with the requirement.

- (2) In this section—

*identity card* means an identity card issued under a related Commonwealth Act.

#### **26—Compensation for damage**

- (1) The owner of equipment or other facilities is entitled to compensation for damage to the equipment or other facilities if—
- (a) the damage was caused to the equipment or other facilities as a result of it being operated by an inspector as mentioned in this Part; and
  - (b) the damage was caused as a result of insufficient care being exercised by the inspector operating the equipment or other facilities.
- (2) Compensation is payable in accordance with the regulations.
- (3) In determining the amount of compensation payable, regard is to be had to whether the occupier of the premises and his or her employees and agents, if they were available at the time, had provided any warning or guidance as to the operation of the equipment or other facilities that was appropriate in the circumstances.

#### **27—Return of seized things**

- (1) Subject to this section, if an inspector seizes any material or thing under this Part, the inspector must take reasonable steps to return it if or when the reason for its seizure no longer exists or it is decided that it is not to be used in evidence (unless the material or thing is forfeited or forfeitable to the State of South Australia under another Act or law).
- (2) An inspector is not required to return any material or thing under subsection (1) if—
- (a) the material or thing has deteriorated to the extent that it no longer has any useful purpose or any real value; or

- (b) an inspector is otherwise authorised (by a law, or an order of a court, of the State of South Australia or the Commonwealth) to retain, destroy or dispose of the material or thing.
- (3) The material or thing may be returned under subsection (1) either unconditionally or on such terms and conditions as the Minister thinks fit.
- (4) An inspector may make application to the Magistrates Court for an order for the purposes of subsection (2)(b) and a magistrate may, on such an application, if satisfied that it is appropriate to do so, make an order authorising an inspector to retain, destroy or dispose of any material or thing.
- (5) Before making an application under subsection (4), the inspector must—
  - (a) take reasonable steps to discover who has an interest in the retention of the material or thing; and
  - (b) if it is practicable to do so, notify each person whom the inspector believes to have such an interest of the proposed application.
- (6) Despite a preceding subsection, if human reproductive material has been seized and an inspector is asked to return the material because it is intended to be used at an accredited ART centre under a South Australian clinical practice licence for the purposes of achieving pregnancy in a woman, the inspector must give due consideration to the request (and seek to resolve the matter) as expeditiously as possible.

## 28—Related matters

- (1) Subject to subsection (2), a person who—
  - (a) without reasonable excuse, hinders or obstructs an inspector, or a person assisting an inspector, in the exercise of powers under this Part; or
  - (b) uses abusive, threatening or insulting language to an inspector, or a person assisting an inspector; or
  - (c) without reasonable excuse, fails to obey a requirement or direction of an inspector under this Part; or
  - (d) without reasonable excuse, fails to answer, to the best of the person's knowledge, information and belief, a question put by an inspector; or
  - (e) falsely represents, by words or conduct, that he or she is an inspector,is guilty of an offence.  
Maximum penalty: \$5 000.
- (2) A person is not obliged to answer a question if to do so might tend to incriminate the person or make the person liable to a penalty.
- (3) An inspector, or a person assisting an inspector, who, in the course of exercising powers under this Part—
  - (a) addresses offensive language to any other person; or
  - (b) without lawful authority, hinders or obstructs or uses or threatens force in relation to any other person,

is guilty of an offence.

Maximum penalty: \$5 000.

## Part 4—Miscellaneous

### 29—Commonwealth/State arrangements

- (1) The validity of any licence issued or thing done for the purposes of this Act is not affected only because it was issued or done also for the purposes of a related Commonwealth Act.
- (2) The Chairperson of the NHMRC Licensing Committee may, after consultation with the Minister, appoint as an inspector under a related Commonwealth Act a person who is appointed or employed by the State.
- (3) If—
  - (a) an act or omission is an offence against this Act and is also an offence against a related Commonwealth Act; and
  - (b) the offender has been punished for the offence under the related Commonwealth Act,the offender is not liable to be punished for the offence under this Act.
- (4) This Act does not purport to confer a function or power, or to impose a duty, on—
  - (a) the NHMRC Licensing Committee; or
  - (b) a Commonwealth authority; or
  - (c) an officer of the Commonwealth or a Commonwealth authority,to the extent to which the conferral of the function or power, or the imposition of the duty, would be beyond the legislative power of the Parliament of the State.
- (5) Subsection (4) does not limit the operation of section 22A of the *Acts Interpretation Act 1915*.

### 30—NHMRC guidelines

- (1) The Minister must cause the following documents to be laid before both Houses of Parliament:
  - (a) copies of any guidelines issued by the NHMRC that have effect under this Act on the commencement of this Act;
  - (b) copies of any alterations to any guidelines issued by the NHMRC that have effect under this Act after the commencement of this Act.
- (2) The times within which documents must be tabled under subsection (1) are as follows:
  - (a) in the case of the guidelines referred to in subsection (1)(a)—within 3 sitting days after the commencement of this Act;
  - (b) in the case of any alterations to any guidelines referred to in subsection (1)(b)—within 6 sitting days after the alterations take effect under this Act.

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- (3) Any guidelines, or alterations to guidelines, tabled under this section are referred, by force of this section, to the Social Development Committee of the Parliament for inquiry and report.
  - (4) For the purposes of this section, a guideline may be altered by the amendment, variation, addition, substitution or deletion of a guideline.

### **31—Delegations**

- (1) The Minister may, by instrument in writing, delegate any of the Minister's functions or powers under this Act or the regulations to any of the following:
  - (a) a person who is appointed or employed by the State;
  - (b) an officer of the Commonwealth or a Commonwealth authority.
- (2) The NHMRC Licensing Committee may, by instrument in writing, delegate any of the Committee's functions or powers under this Act or the regulations to any of the following:
  - (a) a person who is appointed or employed by the State;
  - (b) an officer of the Commonwealth or a Commonwealth authority.
- (3) A delegation under this section may be made to—
  - (a) a specified person; or
  - (b) a person holding or acting in a specified position.
- (4) In performing functions or exercising powers under a delegation, the delegate must comply with any directions of the Minister or the NHMRC Licensing Committee (as the case requires).
- (5) A delegation is revocable at will and does not derogate from the power of the Minister or the NHMRC Licensing Committee (as the case requires) to act in a matter.

### **32—Annual reports**

- (1) The NHMRC Licensing Committee must furnish to the Minister a copy of any report prepared under section 19(3) of the *Research Involving Human Embryos Act 2002* of the Commonwealth (insofar as the report is relevant to the operation of this Act).
- (2) The Minister must, within 12 sitting days after receipt of a report under subsection (1), cause copies of the report to be laid before each House of Parliament.

### **33—False or misleading information**

A person must not make a statement that is false or misleading in a material particular (whether by reason of the inclusion or omission of any particular) in any information provided under this Act.

Maximum penalty: \$5 000.

### **35—Evidential burden in relation to exceptions etc**

- (1) Subject to this Act, this section applies with respect to proceedings for an offence against this Act.

- (2) A defendant in proceedings who wishes to rely on any exception, exemption, excuse, qualification or justification under this Act bears an evidential burden in relation to that matter.
- (3) The exception, exemption, excuse, qualification or justification need not accompany the description of the offence.
- (4) The defendant no longer bears the evidential burden in relation to a matter if evidence sufficient to discharge the burden is adduced by the prosecution or by the court.
- (5) The question whether an evidential burden has been discharged is one of law.
- (6) In this section—

*evidential burden*, in relation to a matter, means the burden of adducing or pointing to evidence that suggests a reasonable possibility that the matter exists or does not exist.

### 36—Regulations

- (1) The Governor may make such regulations as are contemplated by, or as are necessary or expedient for the purposes of, this Act.
- (2) Without limiting the generality of subsection (1), the regulations may—
  - (a) prohibit or restrict the undertaking of a specified activity, or an activity of a specified class, relating to the use of any human reproductive material; and
  - (b) regulate any procedure associated with the use of any human reproductive material, including by providing that a person undertaking a specified activity, or an activity of a specified class, relating to the use of any human reproductive material must comply with any prescribed requirement or condition; and
  - (c) require the keeping of records, statistics and other information by any person or body who undertakes any activity that relates to the use of any human reproductive material and the provision of reports based on that information to the Minister or any other prescribed person or body; and
  - (d) require the provision of any other report, or any statement, document or other form of information, to the Minister or any other prescribed person or body; and
  - (e) prescribe fines not exceeding \$10 000 for contravention of a regulation.
- (3) Regulations under this Act—
  - (a) may be of general application or limited application; and
  - (b) may make different provision according to the matters or circumstances to which they are expressed to apply; and
  - (c) may provide that a matter or thing in respect of which regulations may be made is to be determined according to the discretion of the Minister or any other person or body prescribed by the regulations; and
  - (d) may apply or incorporate, wholly or partially and with or without modification, a code, standard or policy (as in force at the date of the particular regulations, or as in force from time to time) prepared or published by the Minister or any other person or body prescribed by the regulations.

- (4) A regulation made pursuant to subsection (2)(a) or (b) cannot take effect unless and until it has been laid before both Houses of Parliament and—
- (a) no motion for disallowance is moved within the time for such a motion; or
  - (b) every motion for disallowance of the regulation has been defeated or withdrawn, or has lapsed.

### **37—Sunset provision**

Sections 11(3)(b), 14(1)(c) and 14(3) are repealed by force of this section on 5 April 2005.

## **Schedule—Transitional provisions**

### **Part 3—Transitional provision**

#### **9—Transitional provision**

Section 36(4) does not apply with respect to a regulation made on or before the commencement of this Act that is expressed to come into operation on the day on which this Act comes into operation.

## Legislative history

### Notes

- Please note—References in the legislation to other legislation or instruments or to titles of bodies or offices are not automatically updated as part of the program for the revision and publication of legislation and therefore may be obsolete.
- Earlier versions of this Act (historical versions) are listed at the end of the legislative history.
- For further information relating to the Act and subordinate legislation made under the Act see the Index of South Australian Statutes or [www.legislation.sa.gov.au](http://www.legislation.sa.gov.au).

### Legislation amended by principal Act

The *Research Involving Human Embryos Act 2003* amended the following:

*Reproductive Technology Act 1988*

### Principal Act and amendments

New entries appear in bold.

Year	No	Title	Assent	Commencement
2003	18	<i>Research Involving Human Embryos Act 2003</i>	19.6.2003	18.12.2003 ( <i>Gazette 18.12.2003 p4526</i> )
2009	11	<i>Statutes Amendment (Prohibition of Human Cloning for Reproduction and Regulation of Research Involving Human Embryos) Act 2009</i>	2.4.2009	Pt 3 (ss 8—21) & Pt 4 (s 22)—7.5.2009 ( <i>Gazette 7.5.2009 p1702</i> )
2011	36	<i>Statutes Amendment (Directors' Liability) Act 2011</i>	22.9.2011	Pt 17 (s 22)—1.1.2012 ( <i>Gazette 15.12.2011 p4988</i> )
<b>2019</b>	<b>14</b>	<b><i>Statutes Amendment (SACAT) Act 2019</i></b>	<b>11.7.2019</b>	<b>Pt 22 (ss 143 to 146)—4.5.2020 (<i>Gazette 27.2.2020 p442</i>)</b>

### Provisions amended

New entries appear in bold.

Entries that relate to provisions that have been deleted appear in italics.

Provision	How varied	Commencement
Long title	amended under <i>Legislation Revision and Publication Act 2002</i>	7.5.2009
Pt 1		
s 2	<i>omitted under Legislation Revision and Publication Act 2002</i>	7.5.2009
s 3		
s 3(1)		
<i>District Court</i>	<i>deleted by 14/2019 s 143</i>	<b>4.5.2020</b>
human embryo	substituted by 11/2009 s 8(1)	7.5.2009



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hybrid embryo	inserted by 11/2009 s 8(2)	7.5.2009
proper consent	substituted by 11/2009 s 8(3)	7.5.2009
related Commonwealth Act	amended by 11/2009 s 8(4)	7.5.2009
responsible person	substituted by 11/2009 s 8(5)	7.5.2009
unsuitable for implantation	inserted by 11/2009 s 8(6)	7.5.2009
use	inserted by 11/2009 s 8(6)	7.5.2009
s 3(4)—(6)	inserted by 11/2009 s 8(7)	7.5.2009
Pt 2		
heading	substituted by 11/2009 s 9	7.5.2009
ss 5A and 5B	inserted by 11/2009 s 10	7.5.2009
s 6	amended by 11/2009 s 11	7.5.2009
s 7A	inserted by 11/2009 s 12	7.5.2009
s 10		
s 10(1)	substituted by 11/2009 s 13	7.5.2009
s 10(1a)	inserted by 11/2009 s 13	7.5.2009
s 11		
s 11(3)	(b) deleted: s 37	(5.4.2005)
	amended by 11/2009 s 14(1)	7.5.2009
s 11(4)	amended by 11/2009 s 14(2)—(4)	7.5.2009
s 14		
<i>s 14(1) before     substitution by     11/2009</i>	<i>(c) deleted: s 37</i>	<i>(5.4.2005)</i>
s 14(1)	substituted by 11/2009 s 15(1)	7.5.2009
s 14(2)	amended by 11/2009 s 15(2)	7.5.2009
s 14(3)	<i>deleted: s 37</i>	<i>(5.4.2005)</i>
s 14(5)	amended by 11/2009 s 15(3)—(5)	7.5.2009
s 14(6)	amended by 11/2009 s 15(6)	7.5.2009
s 14(7)	amended by 11/2009 s 15(7)	7.5.2009
s 14(8)	inserted by 11/2009 s 15(8)	7.5.2009
s 16		
s 16(2)	amended by 11/2009 s 16	7.5.2009
s 19		
s 19(1)	amended by 11/2009 s 17(1), (2)	7.5.2009
s 21		
eligible person	amended by 11/2009 s 18(1)	7.5.2009
reviewable decision	amended by 11/2009 s 18(2)	7.5.2009
<b>SACAT</b>	<b>inserted by 14/2019 s 144</b>	<b>4.5.2020</b>
s 22		
s 22(1)	<b>amended by 14/2019 s 145(1)</b>	<b>4.5.2020</b>

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s 22(2)	amended by 11/2009 s 19	7.5.2009
s 22(4)	substituted by 14/2019 s 145(2)	4.5.2020
s 22(5)	substituted by 14/2019 s 145(3)	4.5.2020
s 22(5a)	inserted by 14/2019 s 145(3)	4.5.2020
Pt 3		
s 23		
s 23(5)	amended by 11/2009 s 20(1), (2)	7.5.2009
Pt 4		
s 30		
s 30(2)	amended by 11/2009 s 21	7.5.2009
s 34	deleted by 36/2011 s 22	1.1.2012
Sch		
Pts 1 and 2	omitted under Legislation Revision and Publication Act 2002	7.5.2009

## Transitional etc provisions associated with Act or amendments

### *Statutes Amendment (Prohibition of Human Cloning for Reproduction and Regulation of Research Involving Human Embryos) Act 2009*

#### 22—Transitional provision

If an application for a licence under section 10 of the *Research Involving Human Embryos Act 2003* made before the commencement of this section has not been determined at the commencement of this section, the application is to be determined as if it had been made after that commencement.

### *Statutes Amendment (SACAT) Act 2019, Part 22*

#### 146—Transitional provisions

- (1) A right of appeal under section 22(1)(b) of the principal Act in existence before the relevant day (but not exercised before that day) will be exercised as if this Part had been in operation before that right arose, so that the relevant proceedings may be commenced before SACAT rather than the District Court.
- (2) Nothing in this section affects any proceedings before the District Court commenced before the relevant day.
- (3) In this section—

*principal Act* means the *Research Involving Human Embryos Act 2003*;

*relevant day* means the day on which this Part comes into operation;

*SACAT* means the South Australian Civil and Administrative Tribunal established under the *South Australian Civil and Administrative Tribunal Act 2013*.

## Historical versions

7.5.2009

1.1.2012

