



Australian Government

National Health and Medical Research Council

# **ETHICAL GUIDELINES ON THE USE OF ASSISTED REPRODUCTIVE TECHNOLOGY IN CLINICAL PRACTICE AND RESEARCH**

2004 (AS REVISED IN 2007 TO TAKE INTO ACCOUNT  
THE CHANGES IN LEGISLATION)

JUNE 2007

WORKING TO BUILD A HEALTHY AUSTRALIA



**Australian Government**

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**National Health and Medical Research Council**

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## **PREFACE**

The previous version of this document was developed in 2004 to provide ethical guidelines for clinical practice and research involving assisted reproductive technology.

In addition, the guidelines were designed to take into account the legal requirements of the 2002 legislation, the *Research Involving Human Embryos Act 2002* and the *Prohibition of Human Cloning Act 2002*, in relation to prohibited and licensable activities.

In 2007, the guidelines have been revised only to the extent made necessary by amendments to those Acts and to account for changes to the *National Health and Medical Research Council Act 1992*. This revision to the guidelines, which included public consultation, was developed by AHEC and presented to the NHMRC Council on 12 June 2007. It was then referred to the Chief Executive Officer (CEO) of the NHMRC and is now issued.

The document will, in due course, be fully revised, in keeping with the NHMRC policy of 5-yearly reviews.

## **PART A**

### INTRODUCTION

# I BACKGROUND

## ETHICAL GUIDELINES ON ASSISTED REPRODUCTIVE TECHNOLOGY

- 1.1 The NHMRC first issued guidelines on ethical aspects of research related to assisted reproductive technology (ART) as Supplementary Note 4 (*In Vitro Fertilisation and Embryo Transfer*) to the then *Statement on Human Experimentation* (NHMRC 1992). These guidelines were not continued when the NHMRC Act came into force and AHEC developed a new edition of the guidelines during 1993–96, which were published in 1996 (*Ethical Guidelines on Assisted Reproductive Technology*).
- 1.2 The 1996 ART guidelines stated that all reproductive medicine units offering ART services must obtain accreditation by a recognised accreditation body and that such accreditation was to include consideration of compliance with NHMRC guidelines. The recognised accreditation body was then, and remains, the Reproductive Technology Accreditation Committee, a committee established by the Fertility Society of Australia.
- 1.3 In the 1996 ART guidelines, it was also noted that only three states (Victoria, South Australia and Western Australia) had enacted legislation to regulate ART. AHEC recommended strongly that legislation be enacted in the other states and territories. Many of the issues surrounding ART (including surrogacy, eligibility, consent for posthumous use, preimplantation genetic diagnosis and sex selection) were as much social and political issues as they were ethical issues. In addition, it was noted that, without uniform legislation, regulation of national data collection, maintenance of a centralised database and monitoring of research could not be achieved. At the time of preparation of these current guidelines, uniform legislation has not been enacted.
- 1.4 In 2004, the NHMRC published *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research*. The guidelines revised and replaced the 1996 guidelines and also took account of the *Prohibition of Human Cloning Act 2002* (PHC Act) and the *Research Involving Human Embryos Act 2002* (RIHE Act).

## NATIONAL LEGISLATION ON EMBRYO RESEARCH AND HUMAN CLONING

- 1.5 Since 1996, there have been scientific developments that are relevant to the existing guidelines and laws relating to ART, such as:
- the development of somatic cell nuclear transfer, which was first announced with the cloning of Dolly the sheep; and
  - the development of methods of extracting and propagating embryonic stem cells from a 5-day-old embryo created in vitro.
- 1.6 In 1998, in response to widespread concern about the possible use of somatic cell nuclear transfer to clone humans, the then Australian Minister for Health and Ageing requested AHEC to prepare an urgent report on human cloning.<sup>1</sup> That report was referred to the House of Representatives Standing Committee on Legal and Constitutional Affairs, which conducted a public inquiry and handed down its report in August 2001.<sup>2</sup> The latter report was considered by the Council of Australian Governments (COAG) and contributed to the development of new Australian legislation banning human cloning and regulating the use of human embryos that are no longer required for ART treatment.
- 1.7 In 2002, the Australian Parliament passed legislation banning human cloning (PHC Act). Through COAG, the states and territories agreed that each jurisdiction would introduce complementary laws and progressively amend or introduce new legislation to provide for corresponding prohibition on cloning humans and other unacceptable practices.
- 1.8 The Australian Parliament also passed legislation to regulate certain uses of embryos that have been deemed to be no longer needed in an ART program ('excess ART embryos'). The RIHE Act also established the Embryo Research Licensing Committee (referred to in these guidelines as the Licensing Committee) as a new principal committee of the NHMRC. The functions of the Licensing Committee include the consideration of applications for licences to conduct research on excess ART embryos, to grant licences in conformity with the RIHE Act, to appoint inspectors for monitoring and compliance, to maintain a public database and to report to the Australian Parliament on a regular basis.

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<sup>1</sup> *Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings*, AHEC, December 1998.

<sup>2</sup> *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research*, House of Representatives Standing Committee on Legal and Constitutional Affairs, Canberra, August 2001 (Andrews Report).

- 1.9 The RIHE Act acknowledges the importance of the application of ethical principles to research involving human embryos in several ways. The RIHE Act requires that, before an excess ART embryo is used under licence, ‘responsible persons’, as defined by the legislation, must give proper consent to that use. Proper consent is defined in the RIHE Act (s 8) as 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.
- 1.10 The RIHE Act (s 21) states that the Licensing Committee must not issue a licence unless satisfied that the activity or project proposed in the application has been assessed and approved by a human research ethics committee (HREC) constituted in accordance with, and acting in compliance with, the *National Statement on Ethical Conduct in Research Involving Humans* (NHMRC 1999), now *The National Statement on Ethical Conduct in Human Research 2007*, referred to in these guidelines as the National Statement.
- 1.11 The PHC and RIHE Acts contain a requirement for review which was conducted in 2005. The report of that review, conducted by a committee chaired by the late Justice John Lockhart, was published in December 2005 as *Legislation Review: Prohibition of Human Cloning Act 2002 and Research Involving Human Embryos Act 2002*, (the Lockhart Review) and recommended changes to both Acts.
- 1.12 In 2006, the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (the Amendment Act) was enacted. The Amendment Act comes into effect on 12 June 2007. These amendments extend the range of licensable activities. The Amendment Act changed the title of the PHC Act to the *Prohibition of Human Cloning for Reproduction Act 2002* (PHCR Act).

## REVISED ETHICAL GUIDELINES FOR THE USE OF ART (2007)

- 1.13 The current revision replaces the 2004 ART guidelines, to the extent necessitated by changes to the PHC Act and the RIHE Act brought about by the Amendment Act. With respect to clinical practice, the ART guidelines remain a key element in the accreditation processes for ART clinics. With respect to research, they will be used by HRECs and researchers who apply for ethical approval of any proposed research involving participants in ART, human eggs, sperm and/or embryos, and by researchers applying to the Licensing Committee for a licence.
- 1.14 In addition to these guidelines, researchers also need to refer to the National Statement and, in relevant circumstances, *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* (NHMRC 2003).

- 1.15 It is the responsibility of clinicians and researchers to be aware of any other relevant laws and regulations.
- 1.16 NHMRC ethical guidelines, in conjunction with the law, create a robust framework for the conduct of research or practice. For example, the National Statement sets ethical guidelines for the conduct of all human research.
- 1.17 This document contains revised ethical guidelines for the conduct of clinical practice or research in ART, including research involving human embryos. For an explanation of the role of these guidelines in relation to licensable activities, see Section 4.

## 2 INTRODUCTION TO THESE GUIDELINES

### ETHICAL BASIS OF GUIDELINES

- 2.1 Ethics is sometimes thought to be merely a matter of individual preference or cultural convention. Although ethical judgments may indeed express personal preferences, and may be connected in complicated ways with cultural conventions, ethics itself is a form of rational inquiry that concerns how we should live and what we should do. Some ethical issues are matters of debate: people of goodwill can reason about them but still reach differing practical conclusions.
- 2.2 The best way of reasoning about ethical issues is itself a matter of debate. Some people emphasise the moral undesirability of *certain acts* (such as deliberate deception) in and of themselves and the moral desirability of *certain standards of conduct* (such as integrity in one's relationships with others) in and of themselves. Others emphasise the moral significance of anticipating the likely *consequences* of proposed acts (for example, the likely consequences for a woman who gestates a child for another woman).
- 2.3 Similarly, some people emphasise the *duties* we owe to each other (for example, the duty to respect another's personal autonomy). Others emphasise the *moral claims* we are entitled to make against each other (for example, a child's moral entitlement to knowledge of his or her genetic parents). All of these kinds of considerations matter, even if there can be reasonable disagreement among people about how they are to be balanced.
- 2.4 In preparing these guidelines, AHEC has tried to be sensitive to all the relevant ethical dimensions of ART: to recognise the basic human goods at stake; to distinguish goals and purposes from means chosen; to clarify relevant moral principles and motives; to distinguish the moral evaluation of human acts themselves from the moral evaluation of their likely consequences; to identify the virtues or character traits that facilitate responsible conduct in ART; and, to recognise that, while related in complicated ways, ethical questions cannot be wholly separated from social and political questions.
- 2.5 In these guidelines, AHEC has recognised that the welfare of people who may be born as a result of the use of ART is paramount.

- 2.6 AHEC has also taken into account the following issues:
- the autonomy and long-term welfare of individuals (both men and women) who take part in ART or research;
  - the need for informed decision making;
  - the importance of an ethical framework for the use of gametes and embryos in clinical practice, training and research; and
  - the recognition in the strict licensing procedures imposed by National Legislation that the embryo warrants very serious moral consideration.
- 2.7 In addition, AHEC has recognised the potential benefits from the responsible pursuit of medical and scientific knowledge.

## SCOPE

- 2.8 These guidelines cover all activities associated with ART as they occur in:
- **clinical practice**, including:
    - routine practice associated with fertility treatment using ART
    - training, quality assurance and innovative practices
    - the use of excess embryos for training purposes
    - the creation or use of hybrid embryos for sperm testing, and
  - **research** involving:
    - participants in ART
    - donors of human gametes or cells involved in embryo research
    - embryos that are intended for implantation
    - excess ART embryos
    - other human embryos (See Section 17).
- 2.9 These guidelines are primarily for ART practitioners, researchers, infertility clinic administrators, HRECs, and state and national government officials.

## STRUCTURE AND USE OF THE GUIDELINES

- 2.10 These guidelines are divided into three parts:
- Part A provides introductory information about the development of the guidelines and their ethical and legal basis.
  - Part B provides ethical guidelines for clinical practice involving ART.
  - Part C provides ethical guidelines for research involving ART and other practices.
- 2.11 For all issues raised in the guidelines, clinicians and researchers must comply with relevant national and/or state/territory legislation.

- 2.12 In addition, AHEC has identified ethical principles that must inform the conduct of clinicians and researchers and the procedures developed in clinics and research facilities.
- 2.13 The ethical principles are supported by practical guidelines that clinicians and researchers should include in their standard operating procedures in order to ensure that they comply with the ethical principles. These practical guidelines should be followed unless there is an effective alternative option that is consistent with the relevant ethical principle.
- 2.14 To assist the reader, throughout Part B and Part C, the legal requirements and ethical principles (see paragraph 2.11 and 2.12), have first order paragraph numbering (for example, 14.1). The practical guidelines described in paragraph 2.13 all have second order paragraph numbering (for example, 14.1.1).
- 2.15 In addition, there are three appendices to the guidelines. Appendix A lists the members of AHEC, Appendix B relates to process matters in the preparation of the revised guidelines and Appendix C aims to stimulate community discussion about a number of issues that are controversial and may need consideration by legislators.

## 3 REGULATORY FRAMEWORK

### 3.1 Legislation

Clinical practice, research and all other activities referred to in these guidelines must comply with:

- relevant national legislation, including the PHCR Act, the RIHE Act and the *Privacy Act 1988*; and
- relevant state and territory legislation, including privacy legislation.

### 3.2 NHMRC licensing arrangements

Activities that require a licence are specified under the RIHE Act and must comply with the conditions of the licence and these guidelines.

### 3.3 Professional and accreditation standards

Clinical practice, research and all other related activities referred to in these guidelines must conform to standards established by the relevant professional and accreditation bodies, including certification and maintenance of appropriate professional standards, and maintenance of quality management systems for laboratory and clinical work.

### 3.4 NHMRC guidelines

Clinical practice, research and all other related activities using ART are to adhere to these ethical guidelines as follows:

- they must comply with all relevant legislation relating to the activities described in these guidelines;
- they must conform with ethical principles outlined in Parts B and C of the guidelines; and
- they should follow the practical guidelines provided in Parts B and C to ensure conformity with ethical principles (see paragraph 2.13).

Research using ART should also conform to the most recent editions of other relevant NHMRC guidelines (see 'Key information sources'), including:

- the National Statement;
- *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*; and
- *Australian Code for the Responsible Conduct of Research*.

### **3.5 Human research ethics committees**

Activities that require a licence (see paragraph 4.2) and all proposals for human research must be approved by an HREC.

Other activities, such as some quality assurance and innovative practices, may also need to be considered and approved by an HREC. (See National Statement.)

### **3.6 Monitoring**

Research institutions have the responsibility for monitoring all human research. See the section on monitoring approved research in the National Statement.

## 4 ETHICS AND LICENSABLE PRACTICES

### INTRODUCTION

In general, ethical guidelines issued under the *NHMRC Act 1992* for human research provide guidance to researchers, HRECs and institutions. They are not, in themselves, legally binding. However, they have legal effect, for example, when the agreements with the Commonwealth bodies require compliance. In some areas of research, the ethical guidelines may be given legal force by State or Commonwealth statute, which is the case for research involving the formation or use of human embryos. The Fertility Society of Australia also endorses the NHMRC ART guidelines as part of its accreditation process.

The PHC and RIHE Acts in 2002 provided a list of prohibited practices. Accordingly, the 2004 guidelines did not contain any guidance for HRECs reviewing proposals involving these practices. Changes to these Acts have introduced exceptions by which certain otherwise prohibited practices are now permissible if authorised by a licence. This revised document includes ethical guidelines for the implementation of these changes to the Acts.

A condition of the issuing of a licence is that the proposal has been approved by an HREC. Section 21(3)(c) of the RIHE Act states that the NHMRC Licensing Committee must not issue a licence unless it is satisfied that the activity or project has been assessed and approved by an HREC that is constituted in accordance with, and acting in compliance with, the National Statement. For research involving human gametes or embryos, the National Statement states that such research is governed by, and subject to the ART guidelines (see sections on human tissue samples and human stem cells).

In relation to clinical practice, the ART guidelines provide ethical guidance. However, in relation to licensable activities under the RIHE Act, compliance with the ART guidelines is also a legal requirement to the extent required by the Act.

Accordingly, AHEC has developed, and the CEO of the NHMRC issues, these revised ethical guidelines. Researchers, in the design and conduct of research, and HRECs, in their review of proposals, must apply these guidelines. In accordance with the National Statement, HRECs are required to have regard to the values and principles of ethical conduct: research merit and integrity, justice, beneficence and respect.

AHEC has developed guidelines on obtaining human ova and other aspects of research involving the formation and/or use of human embryos for research purposes. AHEC has not developed guidelines on the intrinsic issues involved in the formation of human embryos and human-animal hybrid embryos and their use in research. Whether these activities are ethically acceptable in the context of a specific research proposal is a judgement assigned by legislation to the HREC prior to the application for a licence.

#### **4.1 PROHIBITION OF HUMAN CLONING FOR REPRODUCTION ACT 2002**

Sections 9 to 21 of the PHCR Act prohibit certain practices under the following headings<sup>3</sup> as used in the Act:

- placing a human embryo clone in the human body or the body of an animal [s 9];
- importing or exporting a human embryo clone [s 10];
- creating a human embryo for a purpose other than achieving pregnancy in a woman [s 12];
- creating or developing a human embryo by fertilisation that contains genetic material provided by more than 2 persons [s 13];
- developing a human embryo outside the body of a woman for more than 14 days [s 14];
- heritable alterations to genome [s 15];
- collecting a viable human embryo from the body of a woman [s 16];
- creating a chimeric embryo [s 17];
- developing a hybrid embryo [s 18];
- placing of an embryo [s 19] ;
- importing, exporting or placing a prohibited embryo [s 20]<sup>4</sup>; and
- commercial trading in human eggs, human sperm or human embryo [s 21].

Sections 22 to 23B of the PHCR Act prohibit certain practices unless authorised by a licence, under the following headings:

- creating a human embryo other than by fertilisation, or developing such an embryo [s 22];
- creating or developing a human embryo containing genetic material provided by more than 2 persons [s 23];
- using precursor cells from a human embryo or a human foetus to create a human embryo, or developing such an embryo [s 23A];
- creating a hybrid embryo [s 23B – Note: a licence to create or develop a hybrid embryo can only be issued under the RIHE Act (s 21) and only for prescribed purposes].

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<sup>3</sup> The full definition of the practices can be found in the identified sections of the PHCR Act.

<sup>4</sup> See 'Explanation of key terms' for definition of a prohibited embryo.

## 4.2 RESEARCH INVOLVING HUMAN EMBRYOS ACT 2002<sup>5</sup>

Sections 10 and 11 of the RIHE Act state that the following uses of excess ART embryos are exempt and therefore do not require a licence:

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

Sections 10A and 10B of the RIHE Act state that the following practices are prohibited unless authorised by a licence:

- using a human embryo:
  - created by a process other than the fertilisation of a human egg by a human sperm; or
  - created by a process other than fertilisation that contains genetic material of more than 2 persons; or
  - created using precursor cells taken from a human embryo or human foetus, or
- using a hybrid embryo; and
- undertaking 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.

Section 11 of the RIHE Act prohibits the use, outside the body of a woman, of a human embryo created by fertilisation of a human egg by a human sperm that is not an excess ART embryo for a purpose unrelated to the ART treatment of a woman.

<sup>5</sup> The following summarises sections 10, 11, 10A and 10B of the RIHE Act.

**PART B**

ETHICAL GUIDELINES FOR THE CLINICAL  
PRACTICE OF ART

## **5 ETHICAL PRINCIPLES FOR CLINICAL PRACTICE OF ART**

### **5.1 Respect all participants**

Assisted reproductive technology (ART) procedures must be conducted in a way that is respectful of all involved. Clinical decisions must respect, primarily, the interests and welfare of the persons who may be born, as well as the long-term health and psychosocial welfare of all participants, including gamete donors.

5.1.1 According to the National Statement, any person whose gametes are used for research purposes is considered to be a research participant.

### **5.2 Respect human embryos**

While there are different views held in our community about the moral status of a human embryo, one very widely shared view is that embryos warrant very serious moral consideration. At all times, any embryos created must be dealt with according to these guidelines and accepted standards of clinical and laboratory practice.

In the course of clinical practice, clinicians must limit the number of embryos created to those likely to be needed by the participants in the course of their treatment.

5.2.1 To limit the number of embryos created, clinicians should:

- minimise ovarian stimulation;
- limit the number of ova fertilised and embryos stored; and
- not start new treatment cycles for patients when clinically suitable embryos are in storage.

### **5.3 Use open and consistent decision making**

Participants in ART are entitled to understand and participate in the decision making about their care. Clinics must use an open and consistent approach to ethical issues that arise in practice.

5.3.1 Clinics should maintain documented practices and procedures, identifying the line of responsibility for each. For example, specific protocols should be developed for the following:

- the range of treatments and laboratory procedures;
- access to, and eligibility for, treatment;
- gametes and embryo donation (including selection, counselling and screening of both recipients and donors);

- storage and disposal of gametes and embryos;
- information giving and counselling;
- obtaining consent to treatment;
- record keeping and data reporting;
- investigation and resolution of complaints.

#### **5.4 Provide information and counselling**

Participants in ART are entitled to detailed information about proposed procedures and any alternatives and to receive counselling about the consequences of those procedures. Clinicians must strive to ensure that all participants (and, where relevant, their spouses or partners) in ART are informed about all aspects of the procedures and receive professional counselling. Section 9 provides guidelines on information giving and counselling.

#### **5.5 Obtain consent**

Participants in ART have the right to decide for themselves whether or not to take part in the proposed procedures. Clinics must obtain the consent of all participants in ART procedures (and, where relevant, their spouse or partner). Section 9 provides guidelines on obtaining consent.

#### **5.6 Maintain privacy and confidentiality**

All participants in ART are entitled to privacy. Clinics must respect the privacy of participants and confidentiality of all records and must have a privacy policy that ensures compliance with relevant legislation and guidelines.

#### **5.7 Keep detailed records**

Good record keeping is an essential component of clinical practice and vital for ART because of the long-term consequences of procedures involving ART on the health and psychosocial wellbeing of the persons who are born and on the participants in ART procedures themselves (and their spouses and partners, if any). Clinics must keep accurate records of all gametes and embryos in their care in accordance with Section 10.

#### **5.8 Collect and report outcomes data**

Participants in ART are entitled to accurate information about the risks of the procedures they will undergo. To monitor the short-term and long-term risks of ART procedures, and to provide accurate information for prospective participants, clinics must collect and make public data on the outcomes of ART procedures in accordance with Section 10.

## **5.9 Respect conscientious objections**

Conscientious objectors are not obliged to be involved in the procedures or programs to which they object. If any member of staff or student expresses a conscientious objection to the treatment of any individual patient or to any ART procedures conducted by the clinic, the clinic must allow him or her to withdraw from involvement in the procedure or program to which he or she objects. Clinics must also ensure that staff and students are not disadvantaged because of a conscientious objection.

## 6 USE OF GAMETES IN REPRODUCTIVE TREATMENT PROGRAMS

### INTRODUCTION

The gametes used in ART can either be provided by the spouse or partner of the person receiving treatment or donated by a third party. In these guidelines, the term ‘donated gametes’ is used when the gametes are provided by a third person who, while being the genetic parent of the person born, will not be the social parent (see ‘Explanation of key terms’).

Most of the guidelines in this section refer to donated gametes. However, paragraphs 6.15 and 6.16 refer to collection of gametes from either a spouse or partner, or from a gamete donor, for use in ART procedures.

Gametes may be donated for use by anyone who is receiving ART treatment at the clinic where the donation is made (‘unknown donation’). However, some gamete donors may donate their gametes for use only by certain individuals, such as those from a particular ethnic or social group (‘unknown but directed donation’), or for use by a specified recipient who is known to the donor, such as a relative or friend (‘known donation’). Most of the guidelines in this section refer to unknown donations, but some specific issues relating to unknown but directed donation and known donation are included in paragraphs 6.6 to 6.9.

Voluntary exchange of information between persons conceived using donated gametes, gamete donors and gamete recipients, with the consent of all parties, is desirable. The guidelines in this section specify the minimum level of information that should be accessible to participants in a donated gamete treatment program. Access to further information may occur only with the consent of all parties involved or as specified by the law.

### DONATION OF GAMETES

#### 6.1 Uphold the right to knowledge of genetic parents and siblings

Persons conceived using ART procedures are entitled to know their genetic parents. Clinics must not use donated gametes in reproductive procedures unless the donor has consented to the release of identifying information about himself or herself to the persons conceived using his or her gametes. Clinics must not mix gametes in a way that confuses the genetic parentage of the persons who are born.

- 6.1.1 Clinics should help potential gamete donors to understand and accept the significance of the biological connection that they have with the persons conceived using their gametes. Donors should be advised that the persons conceived are entitled to knowledge of their genetic parents and siblings.

- 6.1.2 Clinics should help prospective recipients to understand the significant biological connection that their children have with the gamete donor. Recipients should be advised that their children are entitled to knowledge of their genetic parents and siblings; they should therefore be encouraged to tell their children about their origins.
- 6.1.3 Working with relevant professional organisations, clinics should use forums for public information to encourage people who were donors before the introduction of these guidelines, and those previously conceived using donated gametes, to contact the clinic and register their consent to being contacted by their genetic children or genetic siblings and half-siblings, respectively.
- 6.1.4 Clinics should not use gametes or embryos collected before the introduction of these guidelines without the consent of the gamete donor (or gamete providers for donated embryos) to the release of identifying information for any future treatments (with the exception of the circumstances given in paragraph 6.1.5).
- 6.1.5 The only situations in which a reproductive procedure involving donor gametes may be considered without the consent of the donor to the release of identifying information are:
- where the recipient has a child who was born before the introduction of these guidelines using the same gamete donor; or
  - where embryos created using donated gametes have been stored before the introduction of these guidelines but the donor cannot be contacted.

In such circumstances, the recipients should be given detailed information (and offered further counselling, if required) about the benefits and risks associated with this transitional arrangement for the persons conceived using donated gametes without consent to release of identifying information.

## 6.2 Use suitable gamete donations

In using gamete donations, clinicians must carefully consider the physical, psychological and social wellbeing of the person to be born and the participants.

Treatment in Australia using either gametes donated overseas or embryos created from gametes donated overseas must not take place unless all the relevant conditions of these guidelines and any relevant legislation have been fulfilled.

- 6.2.1 Children and young people (who are defined as ‘minors’ in each jurisdiction) should not be allowed to donate gametes for use by others in a reproductive procedure.
- 6.2.2 Clinics should not use gametes donated by older men and women unless the potential recipient understands the implications and increased risks of such an arrangement.

### **6.3 Limit the number of persons born from a single donor**

Persons conceived using donor gametes, and the donors of gametes, need to be protected from the consequences of having many genetic siblings and offspring, respectively. Clinics must take all reasonable steps to reduce the numbers of genetic relatives created through donor gamete programs.

- 6.3.1 Gametes from one donor should be used in a limited number of families. In deciding the number of families, clinicians should take account of:
- the number of genetic relatives that the persons conceived using the donation will have;
  - the risk of a person conceived with donor gametes inadvertently having a sexual relationship with a close genetic relative (with particular reference to the population and ethnic group in which the donation will be used);
  - the consent of the donor for the number of families to be created; and
  - whether the donor has already donated gametes at another clinic.

### **6.4 Minimise risk of infection**

Clinics must take all appropriate steps to reduce the risk of transmission of infection.

- 6.4.1 Clinics should not accept donations from people at an increased risk of transmissible infections.
- 6.4.2 All donors of gametes should undergo appropriate infection control surveillance.

### **6.5 Do not trade in human gametes**

Gamete donation must be altruistic. Commercial trading in human gametes and/or the use of direct or indirect inducements, must not be undertaken (see paragraph 17.21.2).

## KNOWN DONATION

### 6.6 Respect the donor's wishes

If the donor specifies recipients he or she knows personally, clinics must respect the wishes of the donor.

### 6.7 Encourage careful consideration of donations from relatives

If clinics provide treatment involving gamete donation from a relative, they must encourage very careful consideration of all relevant issues (in particular, that it is unethical to mislead a child about the identity of his or her genetic parent(s), and that relationships within families can be confused by cross-generational donations).

### 6.8 Do not allow fertilisation of eggs from close relatives

Eggs must not be fertilised with sperm from a close genetic relative (that is, from a person for whom a sexual relationship with the female donor would legally be considered to be incest).

## UNKNOWN BUT DIRECTED DONATION

### 6.9 Respect the donor's wishes

Some gamete donors may wish to donate their gametes for use only by certain individuals, such as those from a particular ethnic or social group. This type of directed donation is illegal in some jurisdictions. Clinics in those states must not accept such donations. In the remaining states and territories, clinics must not use the gametes in a way that is contrary to the wishes of the donor.

## ENTITLEMENT TO INFORMATION

### 6.10 Provide gamete recipients with relevant medical history of gamete donor

Gamete recipients need information about gamete donors that is relevant for the care of their donor-conceived offspring. Clinics must allow recipients of donated gametes access, through either a medical practitioner or an appropriately qualified health professional, to at least the following information about gamete donors:

- details of past medical history, family history and any genetic test results that are relevant to the future health of the person born (or any subsequent offspring of that person) and the recipient of the donation;
- details of the physical characteristics of the gamete donor; and
- the number and sex of persons conceived using the gametes donated by the same gamete donor.

### **6.11 Provide donor-conceived persons with information about their gamete donor**

People conceived using donated gametes are entitled to know their genetic parents. On request, clinics must arrange for either a medical practitioner, or an appropriately qualified health professional, to provide at least the following information, to a person conceived through ART procedures, provided that he or she has either reached the age of 18 years or acquired sufficient maturity to appreciate the significance of the request (including any implications for his or her younger siblings):

- all medical and family history information as specified in paragraph 6.10;
- identifying information about the gamete donor (subject to paragraph 6.1); and
- the number and sex of persons conceived using the gametes provided by the same gamete donor, the number of families involved, and any identifying information that these siblings have consented to being released (see paragraph 6.1.3).

### **6.12 Provide gamete donors with relevant information about their genetic offspring**

Gamete donors are entitled to some information about the recipients of their gametes and the offspring born (in particular, to prepare them for future approaches by their genetic offspring). Clinics may provide gamete donors, on request, with nonidentifying information about gamete recipients, including the number and sex of persons born.

### **6.13 Respect the privacy of all persons involved in ART procedures**

People have a right to privacy. Clinics must not release identifying information to another person without the consent of the person to be identified.

6.13.1 When approached by a person who was conceived using donated gametes and who now seeks identifying information about his or her genetic parents, the clinic should examine the consent form of the gamete donor and proceed as follows:

- If the consent form does not include permission for release of identifying information (because the donation was made before the introduction of these guidelines and the gamete donor has not come forward in response to the public information campaign outlined in paragraph 6.1.3), the clinic should make an appropriate effort, consistent with the original consent document and the privacy rights of the donor, to contact the gamete donor and obtain his or her consent to the release of information.

- If the consent form includes permission for release of identifying information, the clinic may notify the donor and release the information to the person requesting the information.
- 6.13.2 When a clinic is approached by a person who was conceived using donated gametes and who now seeks identifying information about his or her genetic siblings or half-siblings, it should check its register of consent for the release of such information (see paragraph 6.1.3) and proceed as follows:
- If consent has been registered by the siblings concerned, the information may be released.
  - If consent has not been registered, clinics should not release identifying information or contact the siblings.
- 6.13.3 Acceptance of counselling services should be encouraged as part of the preparation for the release of identifying information.

## RESPONSIBILITY FOR GAMETES AND RESULTING EMBRYOS

### 6.14 Maintain a consistent chain of responsibility

Participants in ART procedures involving donated gametes need to know who is responsible for the gametes and resulting embryos used in their treatment. At the same time, the right of the donor to withdraw his or her consent for donation also needs to be protected.

Clinics must maintain clear procedures for the transfer of responsibility for gametes and the resulting embryos at each stage of the program as follows:

- When the gamete donor has not specified a recipient for his or her gametes, the clinic has responsibility for decision making about the use, storage and disposal of the gametes, subject to any limitations expressed in the consent of the donor.
- When the gamete donor has specified a known recipient for his or her gametes, and consent for treatment has been given by the recipient, the recipient has responsibility for decision making about the use of the gametes in his or her own reproductive treatment, as well as storage and disposal, subject to any limitations expressed in the consent of the donor.
- At any time before insemination or fertilisation, gamete donors may vary or withdraw their consent to donation (see paragraph 9.6).
- Once fertilisation has taken place, the persons for whom the embryo has been created have responsibility for decision making about its use in their own reproductive treatment and the medical care of the embryo (both before and after implantation into the uterus), storage and disposal.

## POSTHUMOUS USE OF GAMETES

### 6.15 Use of gametes from deceased or dying persons or from persons in postcoma unresponsive state

When either parent dies before the birth of a child, this is generally regarded by society as tragic in that the child will not know that parent. The facilitation of conception in circumstances where the child born will never know one of his or her genetic parents is, by analogy, a serious act of profound significance for the person born. In addition, state or territory legislation may prohibit the use of gametes after a person has died.

Clinics must not facilitate use of gametes to achieve pregnancy in such circumstances, unless all of the following conditions are met:

- a deceased person has left clearly expressed and witnessed directions consenting to the use of his or her gametes; or
- a person in a postcoma unresponsive state ('vegetative state') prepared clearly expressed and witnessed directions, before he or she entered the coma, consenting to the use of his or her gametes; or
- a dying person prepares clearly expressed and witnessed directions consenting to the use, after death, of his or her gametes; and
- the prospective parent received counselling about the consequences of such use; and
- the use does not diminish the fulfilment of the right of any child who may be born to knowledge of his or her biological parents.

6.15.1 As these situations arise infrequently and involve serious ethical issues, clinics should ensure that those involved seek advice and guidance from a clinical ethics committee on the ethical issues raised above and, if necessary, seek advice regarding the application of relevant laws.

### 6.16 Allow an appropriate period of time before attempting conception

The loss of a spouse or partner will be followed by a period of grief. Clinics must allow adequate time for this grieving process and ensure that counselling is available to the surviving spouse or partner before assisting in conception attempts using gametes collected from persons described in paragraph 6.15.

## CREATION OF HYBRID EMBRYOS FOR PURPOSES OF TESTING SPERM QUALITY

### **6.17 Limit the formation of hybrid embryos to sperm testing in an accredited ART centre (see RIHE Act s 20(1)(f))**

6.17.1 For the investigation of male infertility, sperm quality may be tested, under licence, by the fertilisation of an animal egg by a human sperm, and use of such embryo up to, but not including, the first mitotic division. Hybrid embryos may not be formed for any other purpose and their creation or use must occur in an accredited ART centre.

6.17.2 The consent to the use of the sperm to form a hybrid embryo must meet the provisions of Section 9, 'Information giving, counselling and consent'.

## 7 USE OF DONATED EMBRYOS

### INTRODUCTION

Embryos that are no longer needed for reproductive treatment by the persons for whom they were created may be donated to another couple for their reproductive treatment (see ‘Explanation of key terms’). The implications of embryo donation for the persons born and the donors are similar to those in adoption. Neither the birth mother nor the social father of the person born is the genetic parent.

Embryos may be donated for use by anyone who is receiving ART at the clinic where the donation is made (‘unknown donation’). However, some embryo donors may donate their embryos for use only by certain individuals, such as those from a particular ethnic or social group (‘unknown but directed donation’) or for a specified person who is known to the donor, such as a relative or friend (‘known donation’).

Most of this section refers to unknown donations, but some specific issues relating to known donations (paragraphs 7.4 and 7.5) and to unknown but directed donations (paragraph 7.6) are included.

#### 7.1 Uphold the right to knowledge of genetic parents and siblings

As for adopted people, persons born from reproductive procedures using donated embryos are entitled to know their genetic parents and of the existence of any genetically related siblings.

Donated embryos, or embryos created using donated gametes, must therefore only be used in an ART procedure to achieve a pregnancy if all the principles in Section 6 for donated gametes are followed both for the gamete providers whose gametes were used to create the embryo and for the recipients of the embryo.

The only situations in which a reproductive procedure involving donor embryos may be considered without the consent of the gamete providers to the release of identifying information are:

- where the recipient has a child who was born before the introduction of these guidelines using the same embryo donor(s); or
- where embryos created using donated gametes have been stored before the introduction of these guidelines but the donor cannot be contacted.

In such circumstances, the recipients should be given detailed information (and offered further counselling, if required) about the benefits and risks associated with this transitional arrangement for the person conceived using a donated embryo without consent to release of identifying information.

## 7.2 Maintain the integrity of genetic parenthood

Persons conceived by ART are entitled to know their genetic parents. Clinics must not use any procedures that allow the genetic parentage of persons conceived to be confused. For this reason, clinicians must not transfer embryos to the uterus of a woman from more than one source at any one time.

7.2.1 Because of the potential for difficulties in tracing genetic parents, and because of possible effects on the long-term psychosocial welfare of the persons born from embryos that have undergone serial donations, clinics should not facilitate the following procedures:

- donation of an embryo that has been created using a donated gamete or gametes; or
- on-donation of a donated embryo to another couple.

## 7.3 Ensure a consistent chain of responsibility

People undertaking ART procedures using donated embryos need to know who is responsible for the embryos involved in their treatment. At the same time, the right of the donors to withdraw their consent for donation also needs to be protected.

Clinics must maintain clear procedures for the transfer of responsibility for embryos at each stage of the program as follows:

- Once the embryo donors have specified a recipient who has accepted their embryo for implantation, the nominated embryo recipient (and her spouse or partner, if any) has responsibility for decision making about its use in her reproductive treatment and the embryo's medical care, storage and disposal, subject to any limitations expressed in the consent of the donor or imposed by law.
- If the embryo donors have not specified a recipient for their embryos, clinics should keep or place the embryos in storage until suitable recipients are selected by the clinic for treatment.
- At any time before transfer of the embryo into the uterus of the recipient, embryo donors may vary or withdraw their consent to donation (see paragraph 9.6).

## KNOWN DONATIONS

### 7.4 Respect the donor's wishes

If the donor specifies recipients he or she knows personally, and who have indicated that they wish to accept the donation, clinics must respect the wishes of the donor.

### 7.5 Encourage careful consideration of donations from relatives

If clinicians provide treatment involving embryo donation from a relative, they must encourage careful consideration of all relevant issues (in particular, that it is unethical to mislead a child about the identity of his or her genetic parent(s), and that relationships within families can be confused by cross-generational donations).

## UNKNOWN BUT DIRECTED DONATION

### 7.6 Respect the donor's wishes

Some embryo donors may wish to donate their embryos for use only by certain individuals, such as those from a particular ethnic or social group. This type of directed donation is illegal in some jurisdictions. Clinics in those states must not accept such donations. In the remaining states and territories, clinics must not use the embryos in a way that is contrary to the wishes of the donor.

## **8 STORAGE OF GAMETES AND EMBRYOS**

### **STORAGE OF GAMETES**

#### **8.1 Explain options for use and disposal of stored gametes**

The persons for whom gametes are stored are entitled to know the options for future use and disposal of their gametes. Clinics must ensure that, at the time that gametes are stored, the people who are responsible for them are given sufficient information to understand the future options they will have for the gametes.

#### **8.2 Ensure safety and identity**

Persons for whom gametes are stored and persons who use stored gametes are entitled to certainty about the safety and identity of the gametes. Clinics must therefore ensure the safe storage and accurate identification of all gametes.

8.2.1 The identity and location of any gametes or gonadal tissue in storage should be recorded in detail.

8.2.2 The labelling method should not be susceptible to unauthorised, undetectable or accidental alteration.

#### **8.3 Limit storage**

It is not desirable to leave gametes in storage indefinitely. Clinics must have clear policies that limit the duration of storage of gametes.

8.3.1 Gametes should be kept in safe storage for up to the maximum time specified in the consent (see paragraph 8.8), after which, if the gamete provider has not consented to further storage arrangements, clinics may dispose of the gametes.

8.3.2 In accepting gametes (including gonadal tissue) for storage, clinicians should clearly outline to each gamete provider his or her responsibilities and any circumstances under which the clinic may dispose of the gametes before the end of the consent period.

#### **8.4 Do not store gametes from deceased or dying persons or from persons in a postcoma unresponsive state**

The use of gametes for conception requires the consent of the gamete provider or donor. Clinics must not store or use gametes from deceased persons or from persons who are unable to consent to the procedure, for example, due to postcoma unresponsiveness ('vegetative state'), unless there is a clearly expressed and witnessed directive from the person that gives his or her consent to the use of the gametes.

If the clinic receives confirmation that a gamete provider or donor has died, it must dispose of the stored gametes, unless there is a clearly expressed and witnessed directive to the contrary.

### **STORAGE OF EMBRYOS**

#### **8.5 Discuss options for use or disposal of stored embryos**

The persons for whom embryos are stored will, from time to time, have to make difficult decisions about the future of their embryos. Clinics must ensure that, at the time that embryos are stored, all the people who are responsible for them (including the persons for whom they are stored and the gamete providers for the embryos) are given sufficient information to understand the future options they will have for the embryos.

8.5.1 Clinics should provide information about the following options for the future use of stored embryos:

- use in reproductive treatment for the original participant;
- donation to another recipient for reproductive treatment, in which case clinics would explore options for the embryos to be used by other participants in reproductive procedures (see Section 7);
- removal from storage, in which case clinics would arrange for disposal of the embryo (see paragraph 8.9);
- use in research (see Section 17);
- use in training or quality assurance activities (see Section 14).

## **8.6 Ensure safety and identity**

Persons for whom embryos are stored are entitled to certainty about the safety and identity of their embryos.

Clinics must therefore ensure the safety and accurate identification of all embryos stored.

8.6.1 The identity, number and location of any embryos in storage should be recorded in detail.

8.6.2 The labelling method used should not be susceptible to unauthorised, undetectable or accidental alteration.

## **8.7 Respect the wishes of the persons for whom the embryos are stored**

At any time during the period of storage, the persons for whom the embryo is stored, in consultation with their clinician, may decide that the embryo is no longer needed for their treatment.

If the embryo is no longer needed for treatment, clinicians must obtain a declaration in writing that the embryo is no longer required for any clinical treatment. The other four options noted in paragraph 8.5.1 may then be offered.

8.7.1 If a dispute arises between the members of a couple for whom the embryo is stored, and either person requests continued storage, the embryo should be kept in storage until the dispute is resolved or until the maximum period of storage has been reached (see paragraph 8.8).

8.7.2 If both members of a couple for whom an embryo is stored die, any reasonable, clearly expressed and witnessed directive from them should be followed. If there is no such directive, or it cannot be followed, clinics should arrange for disposal of the embryo.

## **8.8 Limit duration of storage**

It is not desirable to leave embryos in storage indefinitely.

Clinics must have clear policies that limit the duration of storage of embryos.

8.8.1 The maximum time for which embryos may be kept in storage should be five years with the option to renew consent for a further five years.

8.8.2 If, after the maximum period of storage, the embryos have not been used, donated or allowed for use in research (see paragraph 8.5), and no alternative arrangements have been made by the persons for whom the embryos are stored, clinics should arrange for the disposal of the embryos.

## **8.9 Dispose of embryos respectfully**

Clinics must have protocols in place for the respectful disposal of embryos.

8.9.1 The wishes of the persons for whom the embryos are stored, as to the method of disposal, should be respected.

## **9 INFORMATION GIVING, COUNSELLING AND CONSENT**

### **INFORMATION GIVING**

#### **9.1 Provide and discuss all relevant information with participants**

To make informed decisions about their treatment, participants in ART need to understand all the procedures involved, including any health risks and psychosocial consequences associated with them. Clinics must give up-to-date, objective, accurate information about treatment options and the procedures involved to all potential participants in ART procedures and discuss it with them.

9.1.1 The information discussed should allow participants to develop an accurate understanding of the following issues:

- the likelihood of the woman becoming pregnant other than through ART;
- recent success and failure rates relevant to the particular participants;
- any significant risks involved in the proposed procedures;
- the likelihood and significance of potential short-term or long-term physical and psychosocial implications for the person born and the participants;
- the currently available published data on morbidity, and both long-term and short-term outcomes, for persons born through ART;
- whether the proposed procedure is accepted practice or an innovative procedure (see paragraph 14.1);
- options for use, storage, donation and disposal of gametes and embryos (see Sections 6, 7 and 8);
- an explanation of all costs involved;
- the clinic's privacy policy; and
- any planned or possible follow-up studies and/or the possibility of later contact and request to take part in such studies.

9.1.2 Clinics should provide and discuss information about storage of gametes (including gonadal tissue) and/or embryos.

The information should include:

- the survival rate and suitability for transfer of gametes and embryos after freezing and thawing for the particular clinic;
- the live-birth rate following the use of the thawed gametes, tissues and embryos;
- available information about outcomes for persons conceived using stored gametes or embryos;
- any legal or other limitations to use, including posthumous use; and
- the maximum storage times.

9.1.3 Clinics should provide and discuss information in a way that is appropriate to, and sufficient for, informed decision making.

The information should be given:

- verbally, supported by written information in plain language;
- with sensitivity to cultural diversity and religious beliefs;
- in a way that is accessible to those with low literacy or disability, and/or whose first language is not English;
- in a way that avoids any coercion or inducement; and
- without emotive imagery (such as images of babies and young children) or emotive language.

## **9.2 Consider the information needs of all parties in donated gamete or embryo programs**

Donors and recipients in gamete or embryo donor programs (see Sections 6 and 7) each have complex information needs. Clinics must consider the information needs of both donors and recipients.

9.2.1 Clinics should provide and discuss information on the following issues:

- the possible implications and long-term psychosocial consequences of gamete or embryo donation for the donors, the recipients and the persons conceived;
- for participation in a donor oocyte program, the possibility that this may affect the ability of the donor to have children in the future;
- the arrangements of the clinic for collection, storage and release of identifying information;
- any difficulties in finding gamete or embryo donors, including meeting the requests of specific recipients;

- the scope of consent and the rights of each person involved to withdraw consent (see paragraphs 6.9 and 7.3);
- the responsibilities of each participant to all other participants in the proposed reproductive procedure;
- the legal status of the genetic and social parents of any persons conceived using donated gametes or embryos in the jurisdiction in which the clinic is located, or the gametes or embryos are used; and
- the options of donating embryos to other people or allowing them to be used for research (see paragraph 8.5).  
(For further details on allowing embryos to be used for research, see Section 17.)

## COUNSELLING

### 9.3 Provide counselling services

ART involves complex decision making and participants may find it an emotional and stressful experience. Clinics must provide readily accessible services from accredited counsellors to support participants in making decisions about their treatment, before, during and after the procedures.

9.3.1 Clinics should therefore provide counselling services, with professionals who have appropriate training, skills, experience and accreditation necessary for their counselling role. The counselling services should:

- provide an opportunity to discuss and explore issues;
- explore the personal and social implications for the persons born and for the participants;
- provide personal and emotional support for participants, including help in dealing with unfavourable results;
- provide advice about additional services and support networks;
- reflect an integrated, multidisciplinary approach, including medical, nursing, scientific and counselling staff; and
- provide participants with information, when requested, about professional counsellors who are independent of the clinic.

- 9.3.2 For participants in a gamete or embryo donation program, counselling should include a detailed discussion of the complex issues relating to gamete or embryo donation, including the following specific aspects:
- the long-term psychosocial implications for each individual and each family involved;
  - the psychosexual implications;
  - the motives of the gamete or embryo provider for becoming involved in a donated gamete program;
  - the need to ensure that gamete or embryo donors make their own independent decision to participate and that this decision is reached free from coercion in any form; and
  - the right of persons born to have identifying information about their genetic parents and information about the possibility that they will make contact in the future.

## CONSENT

### 9.4 Obtain consent from all participants in all procedures

Before clinical ART procedures are undertaken, clinicians must ensure that consent is obtained from all participants (and, where relevant, their spouses or partners), is informed, voluntary, competent, specific and documented, and remains current.

- 9.4.1 Consent should be obtained in writing, following the provision and discussion of information about the implications of proposed reproductive procedures, adequate time for consideration of the information and adequate opportunities for personal preparation (see paragraphs 9.1 to 9.3).
- 9.4.2 Clinics should have procedures to ensure that consent is voluntary and free from coercion.
- 9.4.3 Consent forms should include the following statements:
- that the participants have received the information provided about the proposed procedures;
  - that counselling by a professional counsellor has been offered;
  - that participants have had explained to them the procedures involved and the risks of complications and have had their questions answered;
  - that participants have had explained to them any mandatory uses of data;

- whether or not the participants give permission for any additional (nonmandatory) uses or disclosures of identifying information or data collected about them;
- whether or not the participants give permission to be contacted in the future with a request for participation in follow-up research;
- the arrangements for storage and disposal of gametes or embryos;
- a signed statement by the supervising clinician that he or she has provided information about the proposed procedures; and
- that relevant participants consent to each proposed procedure.

## **9.5 Obtain consent from all participants in donated gamete or embryo programs**

The donation of gametes or embryos is associated with a range of difficult ethical, social and legal considerations for participants. Clinics must obtain a separate consent form from each participant in gamete or embryo donation programs and their spouse or partner (if any).

9.5.1 Consent forms for the donation of gametes or embryos should include:

- full details of the agreed arrangements for any treatment involving donated gametes or embryos (see Sections 6 and 7);
- an acknowledgment that each participant (and spouse or partner, if any) has received and understood the information provided about gamete or embryo donation;
- a statement that the gamete or embryo donor understands and acknowledges his or her biological connection to any persons conceived using his or her donated gametes or embryos;
- a statement giving explicit permission to make the information specified in paragraphs 6.10 and 6.11 available to the recipients and any person conceived through the procedure, respectively;
- a description of the arrangements set out in paragraphs 6.14 and 7.3 for responsibility for the gametes or embryos after donation; and
- provision for signature by the participant (and his or her spouse or partner, if any).

9.5.2 Potential gamete or embryo donors and gamete or embryo recipients should be given adequate time between provision of information and obtaining consent to allow consideration of the complex issues involved.

## **9.6 Recognise the right of participants to withdraw or vary their consent**

Clinics must recognise that, with the exception of some specific issues relating to the donation of gametes and embryos (see paragraphs 6.14 and 7.3), participants have the right to withdraw or vary their consent at any time.

## **9.7 Obtain consent for the storage of gametes or embryos**

The storage of gametes or embryos is associated with a range of ethical, social and legal considerations for all participants. Clinics must obtain a separate consent form from persons responsible for stored gametes or embryos (and, where relevant, their spouses or partners).

9.7.1 Consent forms for the storage of gametes or embryos should include:

- the maximum period of storage; and
- for embryos, a clearly expressed and witnessed directive as to what should be done with the embryos if either or both the person(s) for whom they are stored die(s), become(s) incapable of varying or revoking the consent, or fail(s) to give further instructions at the expiry of the maximum period of storage.

## **9.8 Obtain consent to retrieve and store a child's or young person's gonadal tissue or gametes**

The retrieval of gonadal tissue or gametes from a child or young person for storage in anticipation of their future need is associated with a range of difficult ethical, social and legal considerations. Decisions to permit the retrieval and storage of gonadal tissue or gametes for a child or young person are ethically acceptable only when:

- the risks and discomfort to the child or young person are minimal;
- storage is the only means of maintaining the benefit of the reproductive capacity of the child or young person;
- there is an independent judgement that the storage is in the child's or young person's overall best interests;
- the child or young person, if capable, and their parents or guardian agree to the storage;
- where required by law, a court or tribunal authorisation has been obtained to undertake a non-therapeutic procedure on the child or young person on the basis that the procedure is in their interests; and
- information about and consent to the retrieval and storage of gametes or gonadal tissue from a child or young person should follow the requirements of Section 9.4.

9.8.1 When the child or young person is not legally competent but sufficiently understands the issues, clinicians should encourage him or her to take part in the decision process.

9.8.2 Any research involving gametes from children or young people are subject to the National Statement (See the section on children and young people) and Section 16 of these guidelines.

### **9.9 Obtain consent to retrieve and store the gonadal tissue or gametes of people with impaired decision-making ability**

The conditions in 9.8 apply to consent for the retrieval and storage of gonadal tissue for people with impaired decision-making ability, such as cognitive impairment, intellectual disability or a mental illness. (See relevant section of the National Statement).

### **9.10 Obtain separate consent to the use of an excess ART embryo in research**

Under the RIHE Act and corresponding state or territory legislation, the persons responsible for embryos that are no longer required for ART treatment (ie those defined in the RIHE Act as 'excess ART embryos'), as well as other embryos, may consent to the use of those embryos in research.

Clinics must apply the principles in Section 15 and follow the procedures in Section 17 for consent to research involving embryos. Such consent must be separate from consent for any treatment and be obtained after the embryos have been deemed excess.

## **10 RECORD KEEPING AND DATA REPORTING**

### **RECORD KEEPING**

#### **10.1 Maintain integrity and privacy of personal information**

Clinical records contain sensitive personal information. Clinics must manage records so that the integrity and privacy of the information complies with all requirements of relevant national, state or territory legislation and accrediting bodies, and conforms with the ethical principles defined in these guidelines.

10.1.1 Clinics should have the following overall arrangements for record keeping:

- a privacy policy that complies with the requirements of the relevant national, state or territory privacy legislation;
- procedures to collect, record and report information about persons, treatments and results that ensure maximum security, integrity and effectiveness;
- arrangements to store relevant information about participants in a procedure involving the use of donated gametes or embryos in a way that is secure but accessible to the persons born as a result of the procedures, and the participants, under the conditions described in paragraphs 6.10 to 6.13;
- arrangements to ensure transfer of records to a suitable person or location when a clinic closes or a practitioner ceases to practise (such arrangements should ensure that records stay with the gametes and embryos to which they relate); and
- provision to keep records indefinitely (or at least for the expected lifetime of any persons born).

#### **10.2 Observe, record, monitor and evaluate procedures and outcomes**

Good record keeping is essential for short-term and long-term follow-up of procedures. Clinics must therefore keep detailed clinical and laboratory records that are appropriate to the practice of ART and allow monitoring of procedures and their short-term and long-term outcomes:

10.2.1 Clinics should record the following information:

- full names (including previous names) and contact details of all participants and, whenever possible, the names of persons born as a result of assisted reproductive technology;
- particulars of gametes and embryos to enable staff in the clinic to trace what happens to each individual embryo, egg or sperm sample from the date of collection;

- data about outcomes of procedures to allow the clinic or accrediting body to publish relevant information to assist participants to make informed decisions about treatment options (particularly in relation to any experimental or innovative procedures);
- data to facilitate monitoring of short-term outcomes, including the live birth rate per treatment cycle commenced, the occurrence of single and multiple pregnancies, spontaneous abortion, termination of pregnancy, ectopic pregnancy, stillbirth, genetic conditions, perinatal events and any adverse effects and other side effects for the participants during treatment; and
- data to facilitate long-term follow-up studies of persons born as a result of ART procedures, and the participants (eg rates of long-term adverse outcomes and subsequent fertility).

### **10.3 Record information about donation, use and storage of gametes and embryos**

In order to facilitate the exchange of information between donors, recipients and the persons conceived by gamete or embryo donation (as required by paragraphs 6.10 to 6.12), clinics must have appropriate arrangements/systems for data collection, data storage and information release.

10.3.1 Clinics should collect the following information from gamete donors (or gamete providers for donated embryos):

- name, any previous name, date of birth and most recent address;
- details of past medical history, family history, and any genetic test results that are relevant to the future health of the person conceived by gamete donation (or any subsequent offspring of that person) or the recipient of the donation; and
- details of physical characteristics.

10.3.2 Clinics should tell gamete donors (or gamete providers for donated embryos) that it is their ethical responsibility to keep the clinic informed about any changes to their health that may be relevant to the persons born or the recipients of their donation, and about changes to their contact details.

10.3.3 Clinics should keep records of the number of persons born using gametes or embryos provided by the same person(s), the sex of each person born and the number of families into which they have been born. Clinics should ensure that gamete donors (or gamete providers for donated embryos) consent to this information being collected and released to the persons born and/or recipients, as appropriate.

10.3.4 Clinics should store all relevant information about participants in a donated gamete or embryo treatment program indefinitely (see 10.1.1), in a way that is secure but is accessible to all the participants under the conditions described in paragraphs 6.10 to 6.12).

#### **10.4 Monitor the number of embryos created and stored**

Clinics must limit the number of embryos created to those that are likely to be needed to achieve a pregnancy. Clinics must maintain records that are adequate to allow monitoring of the number of embryos created and stored (see paragraph 5.2) and to comply with requirements of legislation or relevant authorities (see paragraph 10.5.2).

10.4.1 Clinics should record the following data for each collection cycle:

- the number of eggs collected;
- the number of eggs exposed to sperm;
- the number of embryos created;
- the date that each embryo is created; and
- the number of embryos placed in storage.

10.4.2 Clinics should record the following data for each frozen embryo transfer:

- the number of embryos removed from storage for transfer into the woman for whom the embryos were stored;
- the number of embryos removed from storage for donation to another person for treatment;
- the number of embryos removed from storage for research purposes; and
- the number of embryos removed from storage and disposed of.

10.4.3 Clinics should collate the following data annually:

- mean number of eggs collected at egg collection cycles;
- proportion of egg collection cycles where more than 20 eggs were collected;
- mean number of eggs exposed to sperm in each fertilisation cycle;
- mean number of embryos created in each fertilisation cycle;
- total number of embryos put into storage following fertilisation cycles in the clinic during the previous calendar year; and
- total number of embryos removed from storage for frozen embryo transfer in the clinic during the previous calendar year.

## REPORTING OF DATA

### 10.5 Ensure public accountability for all activities and procedures

Reporting of data must be adequate to ensure open communication of, and accountability for, the clinic's activities to the participants and the general public.

10.5.1 Clinics should make all non-identified data referred to in Section 10 available to appropriate bodies to enable subsequent collation of national statistical information about reproductive procedures, including both long-term and short-term outcomes for the embryos, the children born and the participants.

10.5.2 Reporting of data should comply with requirements of relevant privacy legislation, any state or territory legislation, NHMRC guidelines and, where necessary, be subject to the consent of the participants.

10.5.3 All data relevant to licensed activities, including both long-term and short-term outcomes for the participants, must be kept and made available to appropriate bodies to enable subsequent collation of national statistical information about these activities.

## **II SEX SELECTION**

### **II.1 Do not select sex for nonmedical purposes**

Sex selection is an ethically controversial issue. The Australian Health Ethics Committee believes that admission to life should not be conditional upon a child being a particular sex. Therefore, pending further community discussion, sex selection (by whatever means) must not be undertaken except to reduce the risk of transmission of a serious genetic condition. See also paragraphs 12.1 and 12.2 on the use of preimplantation genetic diagnosis (PGD) for sex selection.

## **12 PREIMPLANTATION GENETIC DIAGNOSIS**

### **12.1 Carefully evaluate any use of PGD**

PGD is currently used to detect serious genetic conditions, to improve ART outcomes and, in rare circumstances, to select an embryo with compatible tissue for a sibling. These uses have profound ethical significance including:

- what counts as a serious genetic condition is controversial;
- there are different perceptions of disability;
- the practice of selecting against some forms of abnormality may threaten the status and equality of opportunity of people who have that form of abnormality;
- the procedures involve the disposal of some healthy embryos; and
- the procedures have technical limitations (such as the failure to identify the genetic abnormality of interest)

Clinics must ensure careful evaluation of these and all other relevant issues before the use of PGD (see also paragraph 12.5.1).

### **12.2 Restrict the use of PGD**

Pending further community discussion (see Appendix C), PGD must not be used for:

- prevention of conditions that do not seriously harm the person to be born;
- selection of the sex of an embryo except to reduce the risk of transmission of a serious genetic condition; or
- selection in favour of a genetic defect or disability in the person to be born.

### **12.3 Seek advice before using PGD to select an embryo with compatible tissue for a sibling**

Except in the case of siblings, PGD must not be used to select a child to be born with compatible tissue for use by another person.

When requested to select an embryo with tissues compatible with a sibling of a child to be born, clinics must seek advice from a clinical ethics committee (or relevant state or territory regulatory agency).

12.3.1 The ethics committee or relevant agency should ascertain that:

- the use of PGD will not adversely affect the welfare and interests of the child who may be born;
- the medical condition of the sibling to be treated is life-threatening;
- other means to manage the medical condition are not available; and
- the wish of the parents to have another child as an addition to their family and not merely as a source of tissue.

## 12.4 Provide access to a geneticist and genetic counsellor

It is essential that participants in ART seeking PGD testing of embryos understand the technology and how it applies to their embryos.

Clinics must ensure that people seeking PGD testing have access both to clinical geneticists and to genetic counsellors.

## 12.5 Provide relevant information and counselling

To make informed decisions about their treatment, participants in ART seeking PGD need to understand all the procedures involved. Clinics must give up-to-date, objective, accurate information in line with the guidelines provided in paragraphs 9.1 and 9.2.

12.5.1 In dealing with a specific situation, the people seeking testing should be encouraged to consider the following factors when deciding the appropriateness of PGD:

- information about the likelihood of false positive and false negative results;
- genetic and clinical information about the specific condition;
- their previous reproductive experience;
- the distinction between the genotypic and phenotypic expression of the condition, disease or abnormality;
- the variable range of effects of the condition, disease or abnormality, including the likely rate of degeneration in the case of progressive disorders;
- the experiences of families living with the condition;
- the likely availability of effective therapy or management now and in the future; and
- the extent of social support available.

## **13 SURROGACY**

### **13.1 Do not undertake or facilitate commercial surrogacy**

It is ethically unacceptable to undertake or facilitate surrogate pregnancy for commercial purposes. Clinics must not undertake or facilitate commercial surrogacy arrangements.

### **13.2 Noncommercial surrogacy**

Noncommercial surrogacy (whether partial surrogacy or full surrogacy) is a controversial subject (see Appendix C) and is prohibited in some states and territories. In other states and territories, clinics must not facilitate surrogacy arrangements unless every effort has been made to ensure that participants:

- have a clear understanding of the ethical, social and legal implications of the arrangement; and
- have undertaken counselling to consider the social and psychosocial significance for the person born as a result of the arrangements, and for themselves.

13.2.1 Clinicians should not advertise a service to provide or facilitate surrogacy arrangements, nor receive a fee for services to facilitate surrogacy arrangements.

## **14 INNOVATIONS, TRAINING AND QUALITY ASSURANCE**

### **14.1 Evaluate innovations before use in clinical practice**

Changes to clinical treatment methods, or introduction of innovative procedures, may have short-term or long-term consequences for the persons born and/or the participants in the treatment.

Clinics must not introduce changes in treatment methods or innovative procedures in ART into routine clinical practice without prior evaluation of safety and efficacy and consideration of legal and ethical issues.

Significant changes or innovations in procedures, practices or therapies must be considered as research and formal HREC approval obtained, even where only one person or couple is involved.

14.1.1 Innovations should be considered significant (and therefore referred to an HREC for assessment) when they have not been assessed or have been assessed and found not to comply with the following criteria.

- *Safety* — an adequate number of live births, preferably from more than one centre worldwide, with no statistically significant increase in the rates of perinatal morbidity, mortality or adverse genetic conditions.
- *Efficacy* — at least one well-designed trial published in the peer-reviewed literature demonstrating the effectiveness of the intervention.

14.1.2 If there is any doubt about whether the proposed change or innovation is significant, safe or efficacious, it should be referred to an HREC for assessment.

### **14.2 Obtain appropriate consent from participants and/or a licence for training activities**

To ensure high standards of clinical care, ART clinics need to run an ongoing training program for clinicians and other staff involved in the ART procedures used. Clinics must inform participants about, and obtain consent for, any clinical training activities undertaken during their care.

14.2.1 Under the RIHE Act, a licence is required for any training activity that involves the use of an excess ART embryo or the fertilisation of a human egg by a human sperm up to, but not including, the first mitotic division.

14.2.2 The following ethical considerations apply to the design, licensing and conduct of training activities:

- Proper consent must be obtained before any excess ART embryo or human eggs are used for licensed training activities;
- The importance of human eggs to participants in ART programs for the purposes of achieving pregnancy must be respected; and
- The use of embryos warrants very serious moral consideration.

### 14.3 Conduct quality assurance activities

To ensure high standards of clinical care, ART clinics need to run regular quality assurance activities. Under the RIHE Act, a licence is required for any quality assurance activity that involves the use of an excess ART embryo, whether or not harm is likely to result to the embryo.

An embryo that is not an excess ART embryo must not be used for any quality assurance activity unless that use is for a purpose relating to the ART treatment of a woman carried out by an accredited ART centre [RIHE Act s 11].

14.3.1 As the distinction between quality assurance and research is not always clear, clinics should consult the National Statement and also refer to the advice in the NHMRC document *When Does Quality Assurance in Health Care Require Independent Ethical Review?* (NHMRC 2003), whether or not the quality assurance activity requires HREC approval.

## **PART C**

### ETHICAL GUIDELINES FOR RESEARCH

## 15 ETHICAL PRINCIPLES

### 15.1 Respect all participants

All human research must be conducted with regard to the values of research merit and integrity, justice, beneficence and respect for human beings. Researchers must therefore comply with the ethical principles provided by the NHMRC in the National Statement. Researchers using gametes and gonadal tissue must also have regard to the *Ethical guidelines on organ and tissue donation (2007)*.

All research proposals must be approved by an HREC constituted and operating in accordance with the National Statement. HRECs must comply with these and other human research guidelines issued by the NHMRC.

### 15.2 Respect human embryos

The fact that the use of embryos warrants very serious moral consideration was recognised by the Australian Parliament in the PHCR and RIHE Acts. Therefore, research on human embryos can only be performed in conformity with these guidelines and the conditions imposed by those Acts. See Section 17 for detailed guidelines on embryo research.

### 15.3 Do not use any unacceptable or prohibited practices

The research proposal must not include any prohibited or unacceptable practices (see Section 4).

### 15.4 Minimise risks

Researchers must ensure that any risks of involvement in the research are appropriate for the type of research.

15.4.1 Where clinical care is combined with research, the risks of research should be balanced by the possibility of expected benefits from the research (see the section on risk and benefit in the National Statement).

15.4.2 For research undertaken solely to develop new knowledge, any risks (particularly any long-term risks to persons born) should be minimal.

### 15.5 Offer separate decision-making processes

It is unethical to coerce potential research participants in any way into taking part in the research. Consent must be freely given and be explicit for the proposed research. Any concealment of the purposes of a study from the persons responsible is unethical and excludes informed and voluntary consent.

Proposals for research must include procedures to ensure that the process of providing information and obtaining consent for involvement in the research is clearly separated from clinical care.

Information sheets for research projects must be completely separate from, and capable of being read independently of, written information provided to a patient in the course of routine clinical care.

### **15.6 Provide information**

Participants in research are often vulnerable and can easily misunderstand the purpose and nature of the research. Researchers must provide information to participants, at their level of comprehension, about the purpose, methods, demands, risks, inconveniences, discomforts and possible consequences of the research (including the likelihood and form of publication of the research results). Section 9 provides guidelines on information giving and counselling for clinical practice; the same principles must be applied for research.

### **15.7 Obtain consent**

Participants in research involving ART processes, embryos, human gametes or human genetic material have the right to decide for themselves whether or not to take part in the proposed research. Researchers must therefore obtain the consent of all participants in any such research.

Section 9 provides guidelines on obtaining consent for clinical practice; a similar range of information must be provided for research (as identified in the sections on consent in the National Statement).

Consent for the use of excess ART embryos or human gametes or human genetic material or other embryos in research must be obtained from all responsible persons (see paragraph 17.14 for further information).

### **15.8 Keep detailed records**

Good record keeping is an essential component of research. Researchers must keep accurate records of their research, including records of all gametes and embryos in their care, and the outcomes of the research. Section 10 provides guidelines on record keeping for clinical practice. The same principles must be applied for research.

### **15.9 Collect and report data on outcomes**

Researchers and HRECs must, subject to appropriate requirements for privacy and confidentiality, make information about research projects involving participants, gametes or embryos available to the NHMRC on request and as part of annual reporting compliance.

Data relevant to licensed activities must be collected in accordance with paragraph 10.5.

### **15.10 Assess and monitor outcomes for all participants (present and future)**

All clinical research requires evaluation. For research involving participants in reproductive treatment, researchers must assess, evaluate and monitor outcomes for all participants (including any persons conceived using reproductive procedures, their siblings, where relevant, and the gamete or embryo donors).

### **15.11 Disclose financial interests**

The participants in research are entitled to know about any financial benefits that the researcher or clinic may gain from the research. Researchers must disclose in the project proposal to be submitted to the HREC, any financial interests they have in the research. The HREC must consider the extent to which disclosure of relevant financial aspects of research should be made known to the participants. For example, where researchers plan to request donation of embryos with the intention of undertaking research that may ultimately yield commercial profit, this must be made clear to the donors before consent is obtained.

### **15.12 Respect conscientious objections**

Conscientious objectors are not obliged to be involved in the procedures or programs to which they object. If any member of staff or student expresses a conscientious objection to the research conducted by an ART clinic or a research facility they must be allowed to withdraw from involvement in the research to which he or she objects. Clinics or research facilities must also ensure that staff and students are not disadvantaged because of a conscientious objection.

## **16 RESEARCH INVOLVING GAMETES**

This section provides guidelines for research involving gametes intended for use in the formation of embryos. See Section 17 for guidelines for research involving the formation of embryos.

### **16.1 Comply with National Statement**

Gametes are human tissue and all research on human tissue must be conducted in accordance with the relevant sections in the National Statement.

### **16.2 Do not use any unacceptable or prohibited practices**

The research proposal must not include any prohibited or unacceptable practices.

### **16.3 Use valid scientific protocols**

Research must be justified in terms of its potential contribution to knowledge or technical application.

### **16.4 Minimise risks**

Researchers must ensure that the use of gametes in research is not contrary to the best interests of any person born as a result of the use of those gametes to achieve a pregnancy.

### **16.5 Provide information**

Researchers must give gamete providers (and their spouses or partners, if any), and any persons for whom an embryo may be created, all relevant information about the research.

16.5.1 The information provided should include a full explanation of any consequences and risks involved for any embryo created and any person born after implantation of the embryo, and how they are balanced by potential benefits.

### **16.6 Obtain consent**

Researchers must obtain consent from the gamete providers (and their spouses or partners, if any) for research involving gametes intended for use in the formation of embryos. See Section 17 for guidelines about obtaining consent to research involving embryos.

### **16.7 Keep accurate records, and collect and report data about outcomes**

Researchers must comply with paragraphs 15.8 to 15.10 of these guidelines.

## 17 RESEARCH INVOLVING EMBRYOS

### INTRODUCTION

The fact that the use of embryos warrants very serious moral consideration was recognised by the Australian Parliament in the PHCR and RIHE Acts. That recognition is expressed in the special conditions imposed on human embryo research.

The RIHE Act requires that research on certain human embryos may only be conducted under a licence issued by the Licensing Committee, which must be satisfied that the research proposal has been assessed and approved by an HREC acting in compliance with the National Statement and these guidelines (See the introduction to Section 4 for a full explanation).

The RIHE Act distinguishes between embryos intended for transfer to a woman to achieve a pregnancy and embryos that have been deemed to be no longer needed in an ART program ('excess ART embryos'). The PHCR and RIHE Acts permit research on excess ART embryos, including those that are unsuitable for implantation, and embryos created by means other than by fertilisation of a human egg and human sperm.

#### 17.1 Identify human embryo

There is a need to determine when an embryo exists and the features that distinguish an embryo from any other cell or cluster of cells.

The RIHE Act defines an embryo as an entity arising either from fertilisation or from other processes.

An embryo arising from fertilisation is "a discrete entity that has arisen from ... the first mitotic division when the fertilisation of a human oocyte by a human sperm is complete". Because cleavage to yield the second cell is a verifiable event, this definition is sufficient for the purposes of proving an offence under the Act.

However, there is an ethical need to recognise that the two gametes that formed the embryo ceased to exist as gametes when they fuse almost a day earlier than the first mitotic division. To ensure that there is no hiatus in the application of ethical guidelines that apply to gametes and those that apply to human embryos as defined by the Act, all aspects of these ethical guidelines applying to human embryos also apply to this single entity formed by the combination of two gametes.

An embryo formed other than by fertilisation of a human oocyte by a human sperm, is “a discrete entity that has arisen from ... 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”.

The formation of a primitive streak normally happens after, and is dependent on, implantation in the uterus of a woman. However, the Act requires that embryos formed other than by fertilisation of a human oocyte by a human sperm may not be implanted. Since it will never be known whether they have the capacity to form a primitive streak, there is an ambiguity concerning these embryos. To provide clarity in these ethical guidelines, a single cell or group of cells that is capable of reaching the stage of forming a blastocyst in vitro is considered to have the potential to develop up to, or beyond, the stage at which the primitive streak appears.

## **17.2 Comply with the National Statement**

Research on human embryos must be conducted in accordance with the National Statement and be approved by an HREC. Researchers and HRECs are required to have regard to the values and principles of ethical conduct: research merit and integrity, justice, beneficence and respect.

## **17.3 Fulfil essential ethical criteria for licensable research activity**

In deciding whether a research proposal meets the requirements of the National Statement and these guidelines, an HREC must be satisfied that:

- There is sufficient evidence that the likely benefits of the proposed research cannot be achieved without using human embryos;
- There is proof of concept, such as success in animal studies;
- The research is justifiable by its potential benefit in improving technologies for treatment of, or knowledge about, human diseases. This benefit must be sufficient in the light of the very serious moral consideration due to human embryos.

## **17.4 Restrict the number of embryos or eggs**

For any licensable activity, the number of excess ART embryos, other embryos or human eggs should be restricted to that likely to be necessary to achieve the goals of the activity [RIHE Act, s 21(4)].

## **17.5 Do not use any prohibited practices**

Research proposals involving human embryos must not include any practices prohibited by the legislation (see Section 4).

## RESEARCH ON AN EMBRYO THAT WILL BE USED FOR ACHIEVING A PREGNANCY

### 17.6 Ensure that the research relates to reproductive treatment

The research must be for a purpose relating to the reproductive treatment of a woman, carried out by an accredited ART centre (see RIHE Act).

### 17.7 Respect the embryo and all persons involved

Respect for the dignity and wellbeing of the mother and the embryo must take precedence over any expected benefits. Research on embryos intended for transfer to a woman to achieve a pregnancy must not harm the embryo or make it unfit for transfer. In addition, the research may only be undertaken either to trial a new procedure that is expected to bring benefits to the embryo concerned (such as a trial to compare two culture media) or to advance knowledge without direct benefit to the embryo (such as microscopic observation of the embryo during its development before transfer to the woman).

### 17.8 Minimise risks

Researchers must ensure that any risks to the embryo from the research (and to the long-term health of any person born after implantation of the embryo) are appropriate for the type of research:

17.8.1 Where clinical care is combined with research, the risks of research should be balanced by the possibility of intended benefits for the embryo.

17.8.2 For research undertaken solely to develop new knowledge, any risks to the embryo should be minimal.

### 17.9 Provide information

Researchers must provide the persons for whom an embryo is to be used to achieve a pregnancy with all relevant information about the research, including how it relates to clinical care, which includes the clinical care of the embryo.

17.9.1 The information provided should include a full explanation of:

- whether the research has intended benefit for the embryo or will not benefit the embryo or themselves but is intended to improve scientific knowledge or technical application;
- any risks involved for the mother and/or the embryo after implantation of the embryo, and how they are balanced by any potential benefits; and
- the expected consequences for the embryo and the person born after implantation of the embryo.

### **17.10 Obtain separate, specific consent**

Researchers must obtain consent from all participants that is separate from the consent for clinical care and specific for the proposed research procedures (see paragraph 15.7).

Researchers must also ensure that the persons for whom the embryo is to be used to achieve a pregnancy are assured that their clinical care, or the clinical care of their embryo, will not be prejudiced in any way if they do not wish to be involved.

### **17.11 Keep accurate records**

Researchers must keep accurate records of the source, use and outcome of each embryo included in the research project.

## **RESEARCH INVOLVING EXCESS ART EMBRYOS**

### **17.12 Obtain a licence**

Under the terms of the RIHE Act, researchers must obtain a licence for any research involving an excess ART embryo that is not an exempt use under the RIHE Act. Researchers must conform with the requirements of the Embryo Research Licensing Committee of the NHMRC (the Licensing Committee) in making an application, as well as with all conditions of a licence. (See paragraph 17.3)

### **17.13 Ensure that the embryo has been declared an excess ART embryo**

The decision to allow an embryo to be used for research is a difficult one for many people. Researchers must not approach the woman (and her spouse, if any) for consent to use the embryo in a specified research project until she (they) has decided, and confirmed in writing, that the embryo is no longer needed to achieve pregnancy and that it is therefore an excess ART embryo (as defined by the RIHE Act; see 'Explanation of key terms').

### **17.14 Identify all persons responsible for the embryo**

Under the RIHE Act, the persons responsible for an embryo include the gamete providers for the embryo and their spouses, and the woman for whom the embryo was created (for the purpose of achieving her pregnancy) and her spouse or partner (if different from the gamete provider).

### 17.15 Apply objective criteria

The RIHE Act defines an embryo that is unsuitable for implantation as an embryo that:

- is diagnosed by preimplantation genetic diagnosis as unsuitable for implantation, in accordance with these guidelines; or
- is determined to be unsuitable for implantation in the body of a woman, in accordance with objective criteria specified in guidelines issued by the CEO of the NHMRC under the *National Health and Medical Research Council Act 1992* and prescribed by the regulations for the purposes of this paragraph [RIHE s 7(1)].

The objective criteria for determining that an embryo is unsuitable for implantation are based on whether the embryo has a low likelihood of implantation if transferred to the body of a woman. The criteria are available from the NHMRC.

17.15.1 The woman and her spouse (if any) may decide that an embryo that meets the objective criteria is not an excess ART embryo and is not available for research.

### 17.16 Obtain proper consent

Under the RIHE Act (s 21), before a licence can be issued for the use of an excess ART embryo in research, the Licensing Committee must be satisfied that appropriate protocols are in place to obtain proper consent from each person responsible for the embryo (as defined in the RIHE Act; see also paragraph 17.14).

Researchers must report in writing to the Licensing Committee that such consent has been obtained and must disclose any restrictions to which the consent is subject. The protocols must also enable compliance with any restrictions of the consent.

Under the terms of the National Statement, proper consent for research must be informed, competent, voluntary, specific and, for this purpose, it must be in writing. Researchers must comply with the National Statement in respect of all these conditions, and must also follow the specific guidance provided in paragraphs 17.18 and 17.19 of these guidelines.

As for all other ART research (see paragraph 15.5), the process of providing information and obtaining consent for research on excess ART embryos must be clearly separated from the clinical care of the embryos or embryo donors.

If a dispute arises or a responsible person dies without leaving clearly expressed and witnessed directions, the embryos must not be used in research.

The RIHE Act permits in certain circumstances, the modification of the guidelines in relation to the giving of proper consent [s 24(8)].

### **17.17 Specify the purpose of the research**

The consent form must be specific for the purpose, nature and scope of, and rationale for, the research. In the case of destructive embryo research, it must be made clear to the persons responsible for the embryo that it may not be possible to report the fate of individual embryos. For example, if stem cells were to be harvested from a given embryo, the persons responsible would be consulted about that use of the embryo, but, for the purpose of giving the proper consent required under the RIHE Act, would not need to be consulted about the subsequent use of those stem cells.

### **17.18 Provide all relevant information**

Researchers must ensure that all persons responsible for the embryo are given all relevant information about the proposed research.

17.18.1 Researchers should provide an oral explanation, supported by written information in plain language and in sufficient time for it to be taken away, read and considered before consent is given.

17.18.2 The explanation should be given with sensitivity to the individual needs of the patient (including language) and include a full explanation of:

- the proposed research (including the proposed method and its scientific aims);
- why the research would represent a significant advance in knowledge or improvement in technologies for treatment;
- what will happen to each embryo, including, where applicable, that embryonic stem cells may be derived from the embryo and that any cells or cell lines so derived may be kept for some years;
- whether the results of research will have commercial potential (see paragraph 15.11) (the embryo donors should be informed that they will not receive financial or any other benefits from any such future commercial development);
- the procedures for raising concerns, obtaining further information about the research and making complaints; and
- the inspection procedures that will be conducted by the NHMRC to ensure compliance with the RIHE Act.

### 17.19 Allow for withdrawal of consent

A person responsible for an embryo must be free at any time to withdraw consent to further involvement in the research. In view of the fact that once an embryo has been destroyed it cannot be restored, it is recommended that the consent of the persons responsible to a use that will damage or destroy an embryo must not be acted upon until a suitable fixed period of time for reconsideration has been allowed, normally at least two weeks after their consent to such research. This 'cooling-off' period before consent becomes effective must be explained to the persons responsible when consent is obtained.

17.19.1 If a modification of the guidelines relating to proper consent is made, as noted in 17.16, and the modification involves a change in the cooling-off period, any such change must provide for a period that is long enough to allow the persons responsible to consult others important to them and counsellors before making a considered decision whether or not to withdraw consent. [RIHE Act s 24(8)].

### 17.20 Keep accurate records whether or not to withdrawal their consent

The researchers must keep accurate records of the source, use and outcome of each embryo used in the project.

## RESEARCH ON EMBRYOS CREATED BY MEANS OTHER THAN BY FERTILISATION OF A HUMAN EGG BY HUMAN SPERM

Under certain prescribed circumstances, the RIHE Act allows the creation of human embryos other than by fertilisation of a human egg by a human sperm (eg human embryo cloning), and the use of such embryos for purposes authorised by a licence.

Accordingly, women may choose to donate eggs from ART treatment to research. Further, women and men who are not involved in an ART program for the purpose of achieving a pregnancy may choose to donate gametes for purposes unrelated to reproduction, or to the treatment of infertility.

Important ethical considerations in the use of human gametes and embryos in research include:

- the empowerment of potential donors to make informed decisions on whether to participate; and
- the significance to many members of the community of the formation of an embryo for research purposes using gametes, gonadal tissue or cells.

## **17.21 Respect the donors of gametes or cells used to form embryos by means other than fertilisation**

A person who agrees to his or her gametes or gonadal tissue, cells or genetic material being used in research is a research participant for the purposes of the National Statement.

Such tissue is human tissue and contains human genetic material. The sections on human tissue samples, human genetics and human stem cells in the National Statement particularly apply.

17.21.1 When obtaining gametes or cells from a donor involves the donor receiving treatment, there must be separation of clinical and research roles.

- The clinician treating the donor should not be an investigator in the intended research;
- Persons other than members of the research team should obtain consent to research from the potential donor. When the involvement of researchers is unavoidable, their role in the research must be made known to a donor; and
- Members of the research team should be available to discuss the involvement of the gamete or gonadal tissue donor in the research protocol. In doing so, researchers should use appropriate language and graphics to convey accurate, clear information.

17.21.2 There should be no payments or other inducements for the donation of gametes, gonadal tissue or cells for research that is subject to these guidelines. The reimbursement of reasonable out-of-pocket expenses associated with the procedures is acceptable. In research to which these guidelines apply, reimbursement does not cover compensation, including compensation for time.

17.21.3 Gametes, gonadal tissue or cells donated for research must not be used for any other purpose.

17.21.4 If genetic screening and disease testing related to gamete or cell donation is to be done, there must be an ethically defensible plan for the disclosure or withholding of such information. (See section on human genetics in the National Statement.)

17.21.5 Protocols for recruitment must ensure that donation of gametes, gonadal tissue or cells is voluntary and free from exploitation or coercion. Where participation involves non-therapeutic interventions of more than low risk, recruitment should exclude potential participants who are in dependent relationships.

Such dependent relationships include those between researchers and students or those working within the research institution, and between clinician researchers and patients. (For explanation of 'low risk' and 'dependent relationship', see the National Statement.)

17.21.6 For the purpose of consent, the potential donor should be provided with the following information in written and oral form:

- a brief description of the project in lay language and its contribution to the potential benefits of the overall research program;
- a clear statement that the provision of gametes, gonadal tissue or cells to the project is voluntary;
- a description of the intended use of the gametes, gonadal tissue or cells and any products derived from them;
- that any value from the gamete, gonadal tissue or cell donation for research, such as by the development of a cell-based treatment for a disease, may only be realised in the long term;
- a description of the retrieval process for gametes, gonadal tissue or cells, including what will be done, where the procedures will be done and by whom;
- a statement of the potential risks of retrieving and donating gametes, gonadal tissue or cells;
- a description of how to withdraw from gamete, gonadal tissue or cell donation;
- the right of a donor to refuse donation for a specific project, but agree to donation for another;
- a statement about the availability of counselling resources;
- how donor privacy will be protected;
- a statement of the potential financial and non-financial interests of researchers;
- a statement that the donor will receive no financial benefit;
- a statement that the donation will not be used for any other purpose;
- a statement of any future financial gains that the researcher may receive if the research gives rise to a commercial product; and
- any other information required by the National Statement.

- 17.21.7 Consent to the use of stem cells developed from donated gametes, gonadal tissue or cells must meet the requirements of the section on human stem cells, in the National Statement.
- 17.21.8 The donor may withdraw consent to use the donated gametes, gonadal tissue or cells up to the time of their actual use in research.
- 17.21.9 The donor is entitled to know the outcome of research involving donated gametes, gonadal tissue or cells.
- 17.21.10 Research involving procedures that carry significant risk of harm, including hormonal stimulation, anaesthesia or surgical procedures to obtain gametes, gonadal tissue or cells, must be reviewed by an HREC.
- 17.21.11 The risks of long-term consequences for fertility of hormonal stimulation of the ovaries and surgical collection of eggs must be disclosed to potential donors.
- 17.21.12 When the donation involves risks to the fertility of donors, the HREC and the Licensing Committee must have regard to whether the donors have been fully informed about the risks to fertility and have given consent.
- 17.21.13 In deciding whether to approve research involving donation of eggs by women who are not on an ART program to achieve pregnancy, an HREC must be satisfied that the potential benefits are sufficient to justify the risks associated with the donation process (see 17.21.11). In deciding whether there is sufficient benefit, HRECs must apply the guidelines on risk and benefit in the National Statement.
- 17.21.14 In deciding whether to approve research involving donation of gonadal tissue, an HREC must be satisfied that the potential benefits are sufficient to justify the risks associated with the donation process (see 17.21.11). In deciding whether there is sufficient benefit HRECs must apply the guidelines on risk and benefit in the National Statement.
- 17.21.15 Gamete, gonadal tissue or cell donors should be offered counselling on the risks and the psychosocial and ethical implications of donation. The counsellors must be independent of the research. Counselling should be available at any time from before the procedures for retrieval of gametes, gonadal tissue or cells are commenced to the time they are used in research.

- 17.21.16 The number of cycles and intensity of ovarian stimulation should be limited (see RTACT code of Practice) because it is known to be associated with harmful effects.
- 17.21.17 Clinicians and clinical centres engaged in gamete or gonadal tissue retrieval should encourage studies on the medical and psychological effects on the donors of the donation of gametes or gonadal tissue, with a view to achieving a more accurate evaluation of risks and benefits.

## 17.22 Respect persons who have died

- 17.22.1 Registering a consent to be a donor on the Australian Organ Donor Register does not constitute consent to the donation of gametes, gonadal tissue or cells for a licensed procedure.
- 17.22.2 Gametes, gonadal tissue or cells from a person who has died must not be used in a licensed activity unless that person had previously given specific consent to that use.
- 17.22.3 Before that consent is given, the donor must have received the information that these guidelines require for donors.
- 17.22.4 The needs of relatives of the deceased must be respected in accordance with *NHMRC Organ and Tissue Donation after Death for Transplantation: Guidelines for Ethical Practice for Health Professionals (2007)*.

## RESEARCH INVOLVING CREATION OF HUMAN EMBRYOS USING PRECURSOR CELLS FROM A HUMAN EMBRYO OR A HUMAN FOETUS [RIHE ACT S 20(1)(D)]

The RIHE and PHCR Acts permit the issue of a licence to conduct research involving the creation of human embryos using precursor cells from the human embryo or human foetus. The following guidelines are intended to inform the ethical review, approval and licensing of such research.

### 17.23 Respect the human foetus

- 17.23.1 Those conducting research involving gametes, gonadal tissue or cells obtained from the human foetus ex utero, after spontaneous miscarriage or termination of pregnancy, should have no involvement in the clinical care of the woman from whom the foetus or foetal tissue was derived, and no financial or legal relationships with those who are so involved. Such research should be conducted in a location that maintains a separation of the woman's clinical care from research.

- 17.23.2 Researchers should demonstrate in their proposals that there are no suitable alternatives by which the aims of research using the foetal gametes, gonadal tissue or cells can be achieved.
- 17.23.3 There should be no trade in human foetal gametes, gonadal tissue or cells.
- 17.23.4 Where research involves a separated foetus or foetal gametes, gonadal tissue or cells, researchers should ask the woman whether, in her decisions about the research, she wishes to involve others such as family members, for whom the research may have implications.
- 17.23.5 A foetus or foetal gametes, gonadal tissue or cells may become available for research as the result of termination. The process through which the woman is approached, informed about, and her consent sought for research on that foetus should be separate from the process under which she decides whether to terminate her pregnancy, and should not begin until a decision to terminate has been made. Consenting to the research must not compromise the woman's freedom to change that decision.
- 17.23.6 Where research involves her separated foetus or its gametes, gonadal tissue or cells, arrangements should be made for the woman to have access to counselling and support.
- 17.23.7 Research on a terminated foetus or its gametes, gonadal tissues or cells, including the timing and content of the process of seeking the woman's consent for the research, should be designed so as not to compromise the woman's decisions about the timing and method of termination.
- 17.23.8 Consideration of a woman's wishes and her physical, psychological and emotional welfare should inform:
- a decision whether to approach her about proposed research involving her separated foetus or its tissue; and, if she is approached,
  - the way information is provided about the research and the way her consent is sought.
- 17.23.9 In addition to information required to be disclosed under the consent sections in the National Statement, the woman should also be informed:
- that she should consider whether to seek consent

to the proposed research from any other person;

- about the possibility of storing the foetus or foetal tissues for later use in research;
- that she is free to withdraw her consent to the research at any time, whether before or after a termination or other loss of a foetus;
- about any potential commercial application of outcomes of the research, including the development of cell lines;
- that she will not be entitled to a share in the profits of any commercial applications; and
- if foetal tissues or stem cell lines developed from them will be exported to another country.

17.23.10 A foetus delivered alive is a child, and should be treated as a child and receive the care that is due to a child.

17.23.11 Gametes, gonadal tissue and cells for use in research may not be removed from a foetus delivered dead, unless:

- the woman and any others she wishes to involve (see paragraph 17.23.4) have given consent to the removal and the research;
- the foetus is available for research only as a result of separation by natural processes or by lawful means; and
- the death of the foetus has been determined by a registered medical practitioner who has no part (or financial interest) in the research.

## **APPENDICES**

## APPENDIX A COMMITTEE MEMBERSHIP

### MEMBERSHIP OF AHEC

#### 2006–2009 NHMRC triennium

Professor Colin Thomson	Chair
Dr Rosanna Capolingua	A person who has expertise in clinical medical practice
Ms Sharon Caris	A person with understanding of health consumer issues
Mr Christopher Coyne	A person who has expertise in law
A/Professor Terry Dunbar	A person with expertise relevant to the functions of the committee
Rev Dr Gerald Gleeson	A person who has expertise in religion
Professor Paul Griffiths	A person who has expertise in philosophy
Mr Barry Maley	A person who has experience in social science research
Prof Margaret O'Connor, AM	A person who has expertise in nursing or allied health practices
Dr Gregory Pike	A person with knowledge of the ethics of medical research
A/Professor Peter Sainsbury	A person who has experience in public health research
Dr Marian Scarrabelotti	A person with knowledge of the regulation of the medical profession
Dr Nicholas Tonti-Filippini	A person with understanding of the concerns of people with a disability
Dr Nikolajs Zeps	A person who has experience in medical research
<b>NHMRC STAFF</b>	
Ms Jillian Barr	Project officer
Mr Matthew Sammels	Project officer
<b>CONSULTANT</b>	
Dr Alana Mitchell	Technical writer

## **APPENDIX B PROCESS REPORT**

In developing and issuing guidelines, the National Health and Medical Research Council and its principal committees are obliged under the *National Health and Medical Research Council Act 1992* (sections 13 and 14A) to release draft guidelines for public consultation.

The changes made to the 2004 guidelines, as required by the new legislation, were developed by a sub-group of the Australian Health Ethics Committee and released for public consultation between 11 May 2007 and 11 April 2007. Ninety-three submissions were received.

The submissions were analysed by a sub-group of AHEC and AHEC considered a revised draft of the guidelines at a meeting on 29-30 May 2007. The Council considered the draft guidelines at a special meeting on 4 June 2007 and again on 12 June 2007.

## APPENDIX C ISSUES FOR FURTHER COMMUNITY DISCUSSION

*This appendix provides a brief discussion of three controversial issues in the use of assisted reproductive technology (ART), namely the use of genetic technology, sex selection and surrogate motherhood. In each instance, the Australian Health Ethics Committee (AHEC), having carefully weighed these matters, considers that they require further community debate and consideration by elected governments. Where appropriate, Part B of these guidelines contains relevant guidelines for clinics concerning these issues. The following brief discussion summarises some of the arguments around these issues. It is included to foster and assist community debate.*

*Further discussion of these issues can be found in the philosophical and bioethical literature, as well as in reports and guidelines developed by government agencies internationally.*

*In the revision of these guidelines, AHEC has not added to or altered this appendix.*

### CI APPROACH TO CONTROVERSIAL ISSUES

New knowledge, scientific discoveries and technical advances frequently stimulate controversy. This is the case for the study of biology, genetics and reproduction, where techniques developed for one purpose may be used for other purposes and, in particular, where techniques developed for therapeutic purposes (that is, preventing and curing diseases, reversing disabilities and alleviating suffering associated with lack of good health) may be used for nontherapeutic, but otherwise desired, purposes (for example, for sex selection).

National, state and territory legislation reflects the variation in opinion and lack of consensus on many of these issues. In general, developments in biotechnology deserve careful consideration in order to determine whether they should be welcomed enthusiastically, tolerated within limits, met with disquiet or even prohibited by law.

Good regulation (in particular, good legislation) depends in part on a well-informed public discussion of potential benefits, possible risks, potential abuses and other areas of concern. AHEC therefore wishes to ensure that public discussion is well-informed and, in particular, is not dominated by any particular interest group.

To that end, AHEC sets out, in summary form, what it considers to be some of the more substantial considerations in favour of, and against, three relatively new and/or controversial applications of reproductive technologies:

- genetic technology associated with ART (Section C2);
- sex selection (Section C3); and
- surrogacy (Section C4).

Each of these practices affects people other than the person who has decided to use the technology. Each is properly a matter for community debate and discussion. Community regulation may be necessary, but the justification for such intervention will need to be decided for each issue based on such community debate and discussion.

## **C2 GENETIC TECHNOLOGY ASSOCIATED WITH ART**

### **Introduction**

Genetic technology associated with ART currently has the capacity to be put to a number of uses (eg preimplantation genetic diagnosis; see Section 12). Other, more ethically controversial applications of the technology, such as the detection of susceptibility to late-onset conditions, are on the horizon. In the future, genetic technology may also have the potential to be used to increase the chances that a child is born 'biologically advantaged'; for example, brighter, taller or more athletic.

This section outlines some ethical considerations in favour of and against these various uses.

### **Reasons given in support of allowing the use of genetic technologies associated with ART**

- Compassion for the suffering of those afflicted with genetic diseases.
- The wish to spare families the tragedy of having, and the burden of caring for, children with deadly and devastating illnesses in the next and, in some cases, future generations.
- Sympathy for couples who might otherwise forgo having children, for fear of passing on heritable disorders.
- An interest in reducing the economic and social costs of caring for the incurable.
- Hope for progress in the overall health and fitness of human society.
- The belief that other people are not entitled to stop those who wish to use genetic technology.

### Reasons given for opposing or limiting the use of genetic technologies associated with ART

- Use of genetic technology implies that admission to life is no longer unconditional.
- Use of genetic technology may foster reproductive discrimination.
- Use of genetic technology establishes the principle that parents may choose the qualities their children have.
- The handling, testing and manipulation of embryos in genetic technology procedures may expose them to significant risk of harm. (The weight of this consideration may depend on the seriousness of the outcome that the technology is being used to avert.)
- The likelihood that the social effects of general acceptance of ART (with genetic technology) as an alternative to natural reproduction will include a diminished tolerance for difference.
- Though avoidance of serious disease may be a reasonable use of genetic technology, shaping babies to parents' ideas of perfection (were this to prove possible) is not.
- Otherwise normal (so-called 'carrier') embryos that would be expected to have a normal life will be discarded.

## C3 SEX SELECTION

### Introduction

Selection by sex can serve medical goals (for example, to prevent the transmission of sex-linked genetic diseases; see Sections 11 and 12 of these guidelines). The focus of the discussion in this section is on the nonmedical use of selection by sex, that is to say, sex selection for the purpose of choosing the sex of a future child.

### Reasons given in support of the availability of sex selection

- Sex selection permits 'family balancing'.
- Sex selection may enable parents to fulfil religious obligations or cultural expectations.
- Sex selection is properly thought of as a matter for individual autonomy.

### **Reasons why people are opposed to the availability of sex selection**

- Sex selection is incompatible with the parent–child relationship being one that involves unconditional acceptance.
- Sex selection may be an expression of sexual prejudice, in particular against girls. As practised today around the world, it generally reflects and contributes to bias and discrimination against women.
- Sex selection harms men in some cultural groups (by contributing to the shortage of women for men to marry).

## **C4 SURROGACY**

### **Introduction**

Surrogacy is the arrangement by which one woman (the surrogate mother) carries and bears a child for another woman or couple (the commissioning mother, or commissioning parents) to whom she will transfer custody at or shortly after birth. The discussion in this section sets out some considerations in favour of and against the availability of noncommercial (both partial and full) surrogacy. It should be read against the background of Section 13.

### **Reasons given in support of allowing surrogacy arrangements**

- Surrogacy enables women who would not otherwise be able to have children to do so.
- There are sometimes good reasons for transferring the burdens and risks associated with pregnancy from one woman to another. For example, the use of a surrogate mother who is also the genetic mother can prevent the transmission of serious genetic diseases by allowing a commissioning mother who is the carrier of that disease to avoid pregnancy.
- The strength of any bond between surrogate mothers and the children they carry does not outweigh the benefits to be gained by permitting surrogacy arrangements.

### **Reasons why people are opposed to allowing surrogacy arrangements**

- The surrogate mother is reduced to the status of an incubator of another couple's child.
- Surrogacy confuses the relationship of the child to his or her parents.
- Surrogacy risks interfering with the surrogate mother's own personal relationships.

- There is often an unequal social relationship between the commissioning parents and the surrogate mother, making it unlikely that surrogacy arrangements will be fair and just.
- Surrogate mothers are sometimes reluctant to hand over the child whose birth has been commissioned.
- Surrogacy is less about the autonomous choices of the women involved than about enabling men to have children with whom they have a genetic connection.

## EXPLANATION OF KEY TERMS

The following explanations show how key terms that have been used in these guidelines are to be interpreted. For consistency with national legislation, where the same terms have been used in either the *Research Involving Human Embryos Act 2002* (RIHE Act) or the *Prohibition of Human Cloning for Reproduction Act 2002* (PHCR Act), the same definitions have been used here and the relevant section of legislation is given in square brackets.

Accredited ART centre	A person or body accredited to carry out ART.
Assisted reproductive technology (ART)	The application of laboratory or clinical techniques to gametes and/or embryos for the purposes of reproduction.
Blastocyst	A 5 to 7 day-old embryo that has an outer layer of cells and a fluid-filled cavity in which there is a cluster of cells called the inner cell mass.
Clinic	Accredited ART centre.
Chimeric embryo	A human embryo into which a cell, or any component part of a cell, of an animal has been introduced. [PHCR s 8(1)]  See also Hybrid embryo
Diagnostic investigation	In relation to an excess ART embryo, means any procedure undertaken on embryos for the sole purpose of diagnostic investigation for the direct benefit of the woman for whom it was created [RIHE s 10(4)].  For the purposes of these guidelines, diagnostic investigation includes preimplantation genetic diagnosis.  See also Preimplantation genetic diagnosis
Donated embryo	An embryo given by either the gamete providers or the persons for whom the embryo was created to other persons for the purpose of achieving a pregnancy.  The term is also used when the gamete providers for an embryo agree to their embryo being used in research or other activities that are not intended to achieve a pregnancy.  See also Embryo donor; Responsible person
Donated gametes	Gametes given for use by a person other than the gamete provider or his or her spouse or partner in a reproductive procedure.  The term is also used when gametes are provided for research or other activities.  See also Gamete provider
Embryo	A living entity in the earliest stage of development.  See also Human, Chimeric and Hybrid embryos
Embryo donor	A person who has responsibility for decisions about the use of an embryo and who donates the embryo to another person or persons for treatment, or for research or other activities.  See also Responsible person
Embryonic stem cell	An undifferentiated cell that is a precursor to many different cell types, obtained from the inner cell mass of a blastocyst.
Embryonic stem cell line	A genetically identical line of cells, derived from an embryonic stem cell, which can be propagated indefinitely in culture.

## Explanation of key terms

Excess ART embryo	<p>A human embryo that:</p> <ul style="list-style-type: none"> <li>(a) was created by ART, for use in the ART treatment of a woman; and</li> <li>(b) is excess to the needs of: <ul style="list-style-type: none"> <li>(i) the woman for whom it was created; and</li> <li>(ii) her spouse (if any) at the time that the embryo was created. [PHCR s 8(1); RIHE s 9(1)].</li> </ul> </li> </ul> <p>For the purposes of paragraph (b), a human embryo is excess to the needs of the persons mentioned in that paragraph at a particular time if:</p> <ul style="list-style-type: none"> <li>(a) each such person has given written authority for the use of the embryo for a purpose other than a purpose relating to the ART treatment of the woman concerned, and the authority is in force at the time; or</li> <li>(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. [PHCR s 8(5); RIHE s 9(2)]</li> </ul>
Gamete	<p>A human sperm or egg (ovum or oocyte) and includes:</p> <ul style="list-style-type: none"> <li>(a) any cell that has resulted from a process of meiosis or has a haploid chromosome complement; or</li> <li>(b) tissue containing such cells (also referred to as gonadal tissue)</li> </ul> <p>See also Gonadal tissue and Precursor cell</p>
Gamete donor	<p>A person who provides gametes for use:</p> <ul style="list-style-type: none"> <li>(a) by a person other than his or her spouse or partner in a reproductive procedure; or</li> <li>(b) for research.</li> </ul> <p>See also Donated gametes, Gamete provider</p>
Gamete provider	The person who is the biological (that is, genetic) source of the gamete.
Gonadal tissue	<p>Tissue from the ovary or testis.</p> <p>See also gamete.</p>
Human egg	Human ovum or oocyte.
Human embryo	<p>The RIHE Act defines a human embryo as:</p> <p>A discrete entity that has arisen from either:</p> <ul style="list-style-type: none"> <li>(a) the first mitotic division when fertilisation of a human oocyte by a human sperm is complete; or</li> <li>(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 [PHCR s 8(1), RIHE s 7(1)]</li> </ul> <p>All aspects of these ethical guidelines applying to human embryos also apply to:</p> <ul style="list-style-type: none"> <li>• the single entity formed by the combination of two gametes is to be treated as an embryo for the purposes of applying these guidelines; and</li> <li>• a single cell or group of cells that is capable of reaching the stage of forming a blastocyst in vitro, because it is considered to have the potential to develop up to, or beyond, the stage at which the primitive streak appears. (The significance of the previous clause is discussed in paragraph 17.1)</li> </ul> <p>For the purposes of the definition of a human embryo, 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. [PHCR s 8]</p>

Human embryo clone	<p>A human embryo that is a genetic copy of another living or dead human, but does not include a human embryo created by the fertilisation of a human egg by a human sperm [PHCR s 8(1)].</p> <p>For the purposes of establishing that a human embryo clone is a genetic copy of a living or dead human:</p> <ul style="list-style-type: none"> <li>(a) it is sufficient to establish that the set of genes in the nuclei of the cells of the living or dead human has been copied; and</li> <li>(b) it is not necessary to establish that the copy is an identical genetic copy; [PHCR s 8(2)]</li> </ul> <p>For the purposes of the definition of a human embryo clone, a human embryo that results from the technological process known as embryo splitting is taken not to be created by a process of fertilisation of a human egg by a human sperm. [PHCR s 8(4)]</p>
Human sperm	Includes human spermatids. [PHCR s 8(1)]
Hybrid embryo	<ul style="list-style-type: none"> <li>(a) an embryo created by the fertilisation of a human egg by animal sperm; or</li> <li>(b) an embryo created by the fertilisation of an animal egg by human sperm; or</li> <li>(c) a human egg into which the nucleus of an animal cell has been introduced; or</li> <li>(d) an animal egg into which the nucleus of a human cell has been introduced; or</li> <li>(e) a thing declared by the regulations to be a hybrid embryo. [PHCR s 8(1)]</li> </ul> <p>See also Chimeric embryo</p>
Innovative procedure	A therapeutic, diagnostic or laboratory procedure that is aimed at improving reproductive outcomes beyond existing methods but has not been fully assessed for safety and/or efficacy.
Objective criteria for determining the suitability of ART embryos for implantation	<p>Criteria for use in determining that an embryo is incapable of successful implantation if transferred to the body of a woman.</p> <p>The criteria are issued by the CEO of the NHMRC and obtainable from the NHMRC.</p>
Observation	In relation to an excess ART embryo, includes taking a photograph of an embryo, or taking a recording of the embryo from which a visual image can be produced. [RIHE s 10(4)]
Participant	<p>Any person (including a gamete or cell donor) who is the subject of (or takes part in) a reproductive procedure or research or innovative procedures involving ART or research involving the formation of an embryo.</p> <p>In many cases 'participant' also includes the spouse or partner of a person undertaking the ART procedure. In cases where it is essential that the spouse or partner (if any) is included (such as in giving consent for donation of gametes), this is specified.</p>
Precursor cell	A cell that has the potential to develop into a human egg or human sperm. [PHCR s 8(1)]
Preimplantation genetic diagnosis (PGD)	Technique by which embryos fertilised in vitro are tested for genetic characteristics, particularly for specific genetic disorders (eg cystic fibrosis).

## Explanation of key terms

Prohibited embryo	<ul style="list-style-type: none"> <li>(a) a human embryo created by a process other than the fertilisation of a human egg by a human sperm; or</li> <li>(b) a human embryo created outside the body of a woman, unless the intention of the person who created the embryo was to attempt to achieve pregnancy in a particular woman; or</li> <li>(c) a human embryo that contains genetic material provided by more than two persons; or</li> <li>(d) a human embryo that has been developing outside the body of a woman for a period of more than 14 days, excluding any period when development is suspended; or</li> <li>(e) a human embryo created using precursor cells taken from a human embryo or human foetus; or</li> <li>(f) a human embryo that contains a human cell (within the meaning of section 18 of the PHC) whose genome has been altered in such a way that the alteration is heritable by human descendants of the human whose cell was altered; or</li> <li>(g) a human embryo that was removed from the body of a woman by a person intending to collect a viable human embryo; or</li> <li>(h) a chimeric embryo or hybrid embryo. [PHCR s 22(4)]</li> </ul>
Proper consent	The procedures and requirements for consent under these guidelines
Recipient	A person to whom gametes or embryos are donated.
Research	Systematic investigation with the aim of increasing knowledge.
Responsible person	<ul style="list-style-type: none"> <li>(a) In relation to an excess ART embryo: <ul style="list-style-type: none"> <li>(i) each person who provided the egg or sperm from which the embryo was created; and</li> <li>(ii) the woman for whom the embryo was created, for the purpose of achieving her pregnancy; and</li> <li>(iii) any person who was the spouse of a person mentioned in paragraph (a) at the time the egg or sperm mentioned in that paragraph was provided; and</li> <li>(iv) any person who was the spouse of the woman mentioned in paragraph (b) at the time that the embryo was created; or [RIHE s 8]</li> </ul> </li> <li>(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</li> <li>(c) in relation to a human egg—the person who was the biological donor of the egg.</li> </ul>
Spouse or partner	In relation to a person, includes a person who is legally married to the person (spouse), as well as a person who, although not legally married to the person, is living with the person on a bona fide domestic basis (partner). [Defined as 'spouse' in RIHE s 7]
Treatment cycle	A series of treatments for the purposes of in vitro fertilisation, gamete intrafallopian tube transfer or similar procedures. It is defined as beginning either on the day on which treatment by superovulatory drugs is commenced or on the first day of the patient's menstrual cycle, and ending not more than 30 days later.

<p>Unsuitable for implantation</p>	<p>A human embryo that:</p> <ul style="list-style-type: none"> <li>(a) is diagnosed by preimplantation genetic diagnosis as unsuitable for implantation, in accordance with these guidelines, issued by the CEO of the NHMRC; or</li> <li>(b) is determined to be unsuitable for implantation in the body of a woman, in accordance with objective criteria specified in guidelines issued by the CEO of the NHMRC under the <i>National Health and Medical Research Council Act 1992</i> and prescribed by the regulations for the purposes of this paragraph. [RIHE s 7(1)]</li> </ul>
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## ABBREVIATIONS

AHEC	Australian Health Ethics Committee
ART	assisted reproductive technology
COAG	Council of Australian Governments
CREGART	Committee to Review the Ethical Guidelines on Assisted Reproductive Technology
HREC	human research ethics committee
IVF	in vitro fertilisation
Licensing Committee	Embryo Research Licensing Committee (NHMRC)
National Statement	<i>National Statement on Ethical Conduct in Research Involving Humans</i>
NHMRC	National Health and Medical Research Council
NHMRC Act	<i>National Health and Medical Research Council Act 1992</i>
PGD	preimplantation genetic diagnosis
PHC Act	<i>Prohibition of Human Cloning Act 2002</i>
PHCR Act	<i>Prohibition of Human Cloning for Reproduction Act 2002</i>
RIHE Act	<i>Research Involving Human Embryos Act 2002</i>

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### LEGISLATION

#### Australian Government legislation

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[http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/0/23029FDD3FCC3FD7CA25719C008331D3/\\$file/NatHeaMedResCou1992WD02.pdf](http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/0/23029FDD3FCC3FD7CA25719C008331D3/$file/NatHeaMedResCou1992WD02.pdf) (Accessed 14 June 2007)

***Privacy Act 1988***

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(Accessed 14 June 2007)

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

[http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/0/647EBC139FB39FDDCA2572F7007B272E/\\$file/ProhibHumanCloningforRep2002\\_WD02.pdf](http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/0/647EBC139FB39FDDCA2572F7007B272E/$file/ProhibHumanCloningforRep2002_WD02.pdf) (Accessed 14 June 2007)

***Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006***

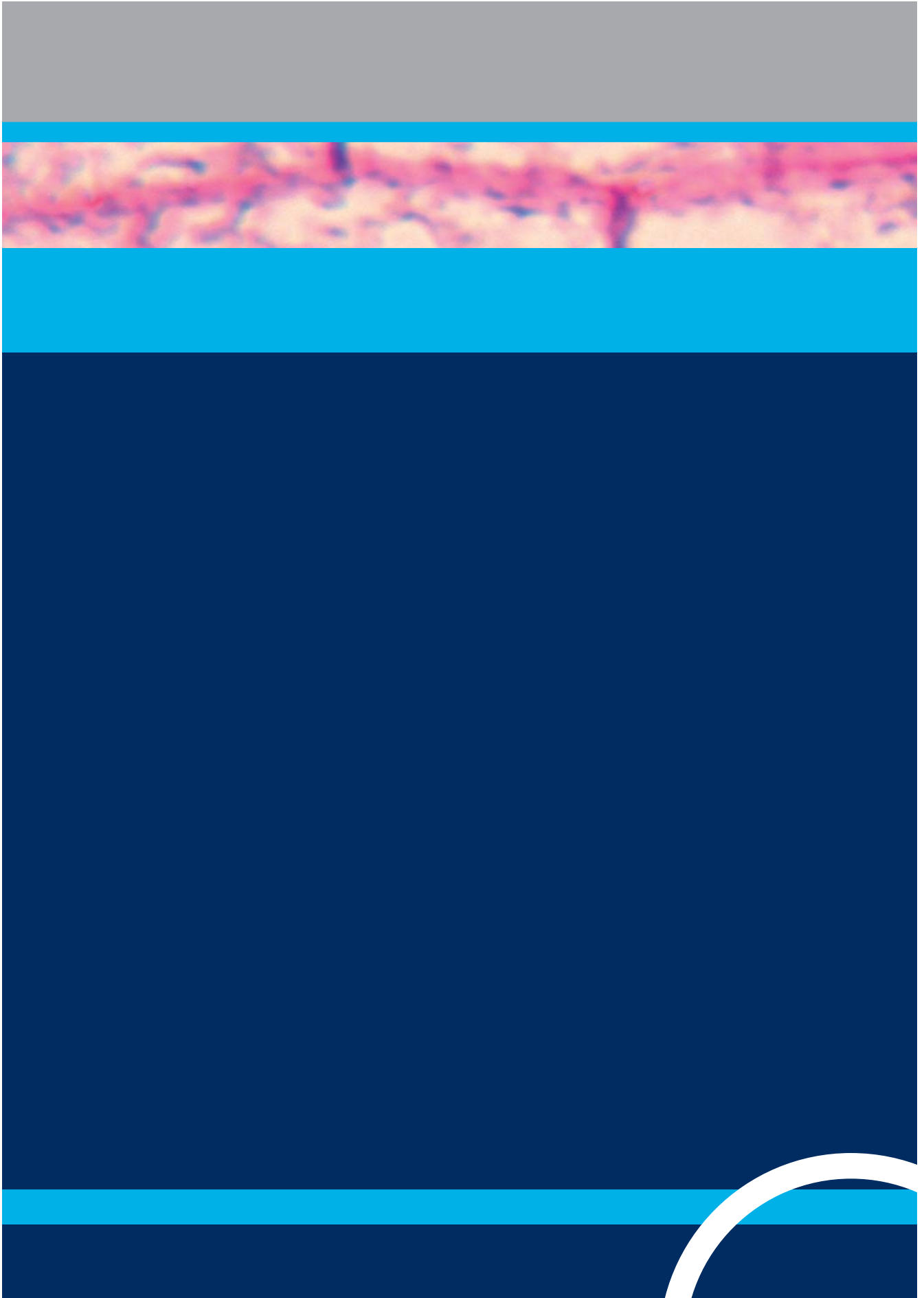
[http://www.comlaw.gov.au/ComLaw/Legislation/Act1.nsf/0/71AC9EAE45677788CA2572440012F18A/\\$file/1722006.pdf](http://www.comlaw.gov.au/ComLaw/Legislation/Act1.nsf/0/71AC9EAE45677788CA2572440012F18A/$file/1722006.pdf)  
(Accessed 14 June 2007).

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

[http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/0/03F95E485D04231DCA2572F80003B1C3/\\$file/ResearchInvolvingHumanEmbryosAct2002\\_WD02.pdf](http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/0/03F95E485D04231DCA2572F80003B1C3/$file/ResearchInvolvingHumanEmbryosAct2002_WD02.pdf) (Accessed 14 June 2007)

**State and territory government legislation**

Information about relevant state and territory legislation is available on state/territory government websites.



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