





Revised draft 'Ethical Guidelines on the use of Assisted Reproductive Technology in Clinical Practice and Research' (NHMRC 2004)

NHMRC invites comment and feedback on the draft 'Ethical Guidelines on the use of Assisted Reproductive Technology in Clinical Practice and Research' 

These ART guidelines, last published in 2004, have been reviewed by NHMRC's Australian Health Ethics Committee (AHEC) in response to the passage through the Australian Parliament of the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006 (the Act)* , in December 2006.

The Act will come into operation in June 2007, thereby amending the *Prohibition of Human Cloning Act 2002* and *Research Involving Human Embryos Act 2002* ('the legislation') and allowing researchers to apply to the NHMRC for licences to undertake an increased range of activities.

» View: Research involving human embryos and the prohibition of human cloning


The legislation requires that applications to the NHMRC must first be approved by a Human Research Ethics Committee (HREC) constituted and acting in compliance with the NHMRC's *National Statement on Ethical Conduct in Human Research*. In considering such research proposals, researchers and HREC's should have regard to these ART Guidelines.

The ART Guidelines should also be considered by Assisted Reproductive Technology clinics, HREC's and researchers in relation to the clinical application of assisted reproductive technologies and research relating to that treatment.


Researchers wishing to undertake research procedures covered by the legislation must:


- Obtain approval of their HREC which will consider the research proposal, having regard to the *National Statement on Ethical Conduct in Human Research*, the ART guidelines, and other relevant legislation or guidelines.
- Following approval by their HREC, they must then apply for a licence from the NHMRC, according to the requirements of the legislation applications are considered by the NHMRC Licensing Committee, which is required to issue licences only as permitted by the Act. In doing so, the Licensing Committee must also have regard to the ART guidelines.

The NHMRC monitors closely research that is occurring under a licence, and has powerful inspection powers under the Act, and we also rigorously follow up any allegations.

» View: *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006 (the Act)* 

The Act also specifies that the NHMRC develops objective criteria for determining in a research context^[1] when a human embryo is unsuitable for implantation.

» Download: Objective criteria (PDF, 12kb) 

» Download: Objective criteria (RTF, 10kb) 

We seek your views and comments on either the draft ART guidelines or the draft objective criteria or both documents.

» Download: Submission form (PDF, 71kb) 

» Download: Submission form (RTF, 940kb) 

Deadline for receipt of comments is 5pm AEST Friday 11 May 2007.

In Australia, ethical guidelines in human research are developed by NHMRC's AHEC and issued by the NHMRC. All submissions will be considered by AHEC, which aims to finalise the Guidelines by the end of May, for considered by NHMRC's Council.

NHMRC is committed to full consultation on all ethical and health guidelines, as described in our Act and in accord with long standing practice.

» View: *National Health and Medical Research Council Act 1992* 

» View: NHMRC Public consultation guidelines (PDF, 90kb) 

NHMRC acknowledges that there is a wide range of views on the use of human embryos in research, as reflected in the debate on the Amendment Act in the Senate and House of Representatives.

These views are likewise reflected in NHMRC's Principal Committees and Council. We are committed to implementation of the Act and to the protection afforded through NHMRC's ethics system and legislated Licensing Committee procedures. Departure from these procedures attract harsh penalties.

Professor Warwick Anderson

[1] Please note that these criteria have been developed for research purposes. They do not apply to clinical decisions relating to achieving pregnancy through assisted reproductive technology.

[top]

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Draft

**Ethical guidelines on the use of
assisted reproductive technology in
clinical practice and research**

2004 (as updated in 2007)

Consultation draft April 2007

Updated draft 'Ethical Guidelines on the use of Assisted Reproductive Technology in Clinical Practice and Research' (NHMRC 2004)

AN INVITATION TO MAKE A SUBMISSION

The National Health and Medical Research Council (NHMRC) is conducting public consultation on this updated draft document which provides ethical guidelines on the use of assisted reproductive technology in clinical practice and research. This document has been updated to take account of the new activities that are licensable under the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006*, and you are invited to make a submission about the draft. This invitation is made under section 13 (d)(iii) of the *National Health and Medical Research Council Act 1992*.

How to make your submission

Submissions should follow the instructions provided here. A template for comments has also been prepared for your guidance and use and can be accessed from the NHMRC website listed below.

Comments are sought on the changes and additions to the document that are highlighted by grey shading.

Electronic submissions using this template are strongly preferred. If this is not possible, please make your submission in writing (preferably typed or word processed) or on audio tape, and submit it by mail. Electronic submissions should be emailed to the address below.

A form seeking authorship and other details is available on the NHMRC website. Please complete and attach the form to your submission. **Submissions that do not have the completed form will not be accepted.**

Please e-mail your submission to e-mail ahec.nhmrc@nhmrc.gov.au, fax (02) 6217 9175 or post to:

Project Officer
ART Guidelines Review
Research Ethics Section
NHRMC
GPO Box 1421
CANBERRA ACT 2601

Closing date

5:00 pm AEST Friday 11 May 2007

Please draw this consultation process to the attention of anyone whom you believe would be interested in making a submission.

If you require additional copies of this document, it can be obtained from <http://www.nhmrc.gov.au/consult/index.html> or can be obtained by phone or email as listed below.

Further information

Hard copies of the draft document and forms can be obtained by contacting the Research Ethics Section on (02) 6217 9070 or by e-mail ahec.nhmrc@nhmrc.gov.au

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PART A

Introduction

1 Background

Role of the NHMRC

1.1 These guidelines (*Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research, 2007*) are issued in accordance with the *National Health and Medical Research Council Act 1992* (NHMRC Act). Under part 2, section 7(1)(a) of the NHMRC Act, the functions of the CEO are:

in the name of the NHMRC to inquire into, issue guidelines on and advise the community on matters relating to:

- (i) the improvement of health; and
- (ii) the prevention, diagnosis and treatment of disease; and
- (iii) the provision of health care; and
- (iv) public health research and medical research; and
- (v) ethical issues relating to health.

1.2 The NHMRC Act also establishes the Australian Health Ethics Committee (AHEC) as a principal committee of the NHMRC (the Council). Part 3, section 10 of the NHMRC Act ('Human research guidelines') states that:

the CEO must issue human research guidelines ... for the conduct of medical research involving humans

and that the guidelines

must be issued precisely as developed by the Australian Health Ethics Committee and provided to the Council...

1.3 Part 4 of the NHMRC Act establishes AHEC and provides its categories of membership and its terms of reference as:

- (a) to advise the Council on ethical issues relating to health; and
- (b) to develop and give the Council human research guidelines; and
- (c) any such other functions as the Minister from time to time determines in writing after consulting with the CEO; and
- (d) any other functions conferred on the Committee by this Act, the regulations or any other law.

Ethical guidelines on assisted reproductive technology

1.4 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*).

1.5 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.

1.6 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.

1.7 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

1.8 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.

1.9 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.¹ 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 2001.² 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 *Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings*, AHEC, December 1998.

² *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).

1.10 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.

1.11 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. Complementary legislation in the states and territories gives the Licensing Committee the powers necessary to undertake within those jurisdictions the functions outlined in the RIHE Act.

1.12 The RIHE Act acknowledges the importance of the application of ethical principles to research involving human embryos in several ways. A link between the Licensing Committee and AHEC is established with the requirement that there be a member in common between the two committees. 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 (section 8) as consent obtained in accordance with the NHMRC ethical guidelines on ART.

1.13 The RIHE Act (section 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 2007.

1.14 The PHC and RIHE Acts contain a requirement for review which was conducted in 2005. The report of that review, published in December 2005 as *Legislation Review: Prohibition of Human Cloning Act 2002 and Research Involving Human Embryos Act 2002*, (the Lockhart Review) recommended changes to both Acts.

1.15 In 2006, the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006 (the Amendment Act)* was enacted. It comes into force on 12 June 2007. 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)

1.16 The current revision replaces the 2004 ART guidelines, to the extent necessitated by changes to the PHC Act and the RIHE Act 2002 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.

1.17 In addition to these guidelines, researchers also need to refer to the National Statement (2007) and, in relevant circumstances, *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* (NHMRC 2003).

1.18 It is the responsibility of clinicians and researchers to be aware of any other relevant laws and regulations.

1.19 Clinicians and researchers should be aware that NHMRC ethical guidelines may impose conditions and requirements not otherwise specified by law.

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. The current revision also recognises the respect that is due to human embryos and the welfare and interests of donors of cells, gametes and embryos for research purposes involving embryos.

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;
- the need for informed decision making; and
- the importance of an ethical framework for the use of gametes and embryos in clinical practice, training and research.

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 involving embryo research
 - embryos that are intended for implantation
 - excess ART embryos
 - other embryos.

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 two appendices to the guidelines. Appendix A relates to process matters in the preparation of the guidelines and Appendix B 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 2002, the RIHE 2002 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 2007),
- *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* (currently NHMRC 2003); and
- *Australian Code for the Responsible Conduct of Research* (currently under review, NHMRC/ARC/AVCC 2007).

3.5 Human research ethics committees

Activities that require a licence (see 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.

4 Unacceptable and prohibited practices

Introduction

In 2002, the PHC and the RIHE Acts prohibited a number of practices. AHEC stated in the 2004 ART guidelines that these practices were also ethically unacceptable.

The PHCR and RIHE Acts have retained the prohibition of many of these practices. However, these Acts allow exceptions for some prohibited practices, if authorised by a licence. A condition of the issuing of a licence is that the proposal has been approved by an HREC.

In this situation, AHEC has developed, and NHMRC issues, these revised ethical guidelines. Researchers in the development of proposals, and HRECs in their review of proposals, must apply these guidelines.

Although exceptions to prohibited activities may be licensable, institutions and their HRECs have a responsibility to consider all ethical concerns of a proposal, including that embryos should only be formed to achieve pregnancy and should not be treated as mere tissue.

The RIHE Act requires the Licensing Committee to have regard to guidelines issued by the NHMRC and prescribed by regulations under the Act.

4.1 *Prohibition of Human Cloning for Reproduction Act 2002 (as amended by the Amendment Act 2006)*

Sections 9 to 21 of the PHCR Act state that the following practices³ are prohibited:

- 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 two 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 a human embryo [s 19];
- importing, exporting or placing a prohibited embryo [s 20];⁴ and

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

- commercial trading in human egg, human sperm or human embryo [s 21].

Sections 22 to 23B of the PHCR Act state that the following practices are prohibited except under licence:

- 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 [s23A];
- creating a hybrid embryo [s23B – Note: a licence to create or develop a hybrid embryo can only be issued under section 21 of the RIHE Act 2002 and only for prescribed purposes].

4.2 Research Involving Human Embryos Act 2002 (as amended by the Amendment Act 2006)

Sections 10 to 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 where the embryo 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),
- use by an accredited ART centre as 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

⁴ See ‘Explanation of key terms’ for definition of a prohibited embryo.

- created using precursor cells taken from a human embryo or human foetus, or
- using a hybrid embryo [s10A]
- undertaking research or training involving a human egg fertilised 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 [s.10B].

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 an ART treatment of a woman.

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.

5.1.2 Any person whose gametes are used for research purposes is considered to be a research participant to whom both the National Statement 2007 and these guidelines apply.

5.2 Respect human embryos

While there are different views held in our community about the moral status of a human embryo, one view that is very widely shared is that embryos are not to be treated as mere tissue. 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 6.6–6.9.

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 4.2).

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 egg provider 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 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 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

- 6.17.1 For the investigation of male infertility, sperm quality may be tested, under licence, by the production of a hybrid embryo until the stage of the first mitotic division. Hybrid embryos may not be formed for any other purpose.
- 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 difficult 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 for retrieval and storage of gonadal tissue or gametes for a child or young person

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.
- 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 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.

9.9 Obtain separate consent to the use of an excess ART embryo in research

Under the RIHE Act and corresponding state or territory legislation, 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 be used for research if the proper consent of all the persons responsible for the embryos is obtained.

Clinics must follow the procedures given in Section 17 for consent to research involving embryos, which must be separate from consent for any treatment.

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 data, including data recorded in paragraph 10.4, available to appropriate bodies to enable subsequent collation of statistical information about reproductive procedures, including both long-term and short-term outcomes.
- 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.

11 Sex selection

11.1 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.

13.1 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 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
- the fertilisation of a human egg by a human sperm up to but not including the first mitotic division.

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

- Embryos are not to be treated as mere tissue (refer 5.2)

- Such fertilisation should only be attempted for a purpose related to an ART treatment of a woman carried out by an accredited ART centre (RIHE Act, s 11)
- The welfare of a person who may be born as the result of the use of that embryo is paramount (refer 2.5).

Proper consent as defined in the amended RIHE must be obtained before any excess ART embryo or human gametes are used for licensed training activities.

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 2007 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

Research involving participants in reproductive treatments, gametes or embryos must be conducted in a way that is respectful of all the human beings involved. Researchers must therefore comply with the ethical principles provided by the NHMRC in the National Statement, 2007 and have regard to the *Ethical guidelines on organ and tissue donation (2007)*. HRECs must be aware of, and heed, advice or guidelines on research provided from time to time by AHEC and/or the Licensing Committee.

All research proposals must be approved by an HREC constituted and operating in accordance with the National Statement 2007.

15.2 Respect human embryos

While there are different views in our community about the moral status of a human embryo, one that is very widely shared is that embryos are not to be treated as mere tissue.

Research on human embryos must comply with these guidelines and with the PHCR and RIHE Acts. Under the RIHE Act, any research, training or quality assurance activities using excess ART embryos, embryos produced other than by fertilisation of a human egg with a human sperm, hybrid embryos or human gametes require a licence. 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 intended benefits from the research (see the section on risk and benefit in the National Statement 2007).

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 2007).

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 17.13 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 outcomes data

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.

Institutions that establish HRECs must submit annual compliance reports to the NHMRC in accordance with the section on accountability in the National Statement 2007.

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 prior to use, if any, they may have in the formation of embryos. Guidelines for research involving the formation of embryos are in Section 17.

16.1 Comply with National Statement 2007

Gametes, and the cells developed from them are human tissue. All research on human tissue must be conducted in accordance with the relevant sections in the National Statement 2007.

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 any risks of adverse effects to any subsequently created embryo (or to the long-term health of any person born as a result of use of the embryo to achieve a pregnancy) are minimal. This condition may be modified for licensed procedures involving embryos that are not to be used 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 the use of gametes in research, or for the use of gametes that might then be used to form an embryo. (For guidelines about obtaining consent to research involving embryos, see Section 17).

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

Research must not be conducted on human embryos when there are other reasonable alternatives available.

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 on embryos created by means other than by fertilisation of a human egg and human sperm.

Research on embryos intended for transfer to a woman to achieve a pregnancy must not harm the embryo and may 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). Research under licence on excess ART embryos and other embryos may involve harming or destroying the embryo (for example, to obtain embryonic stem cells).

17.1 Comply with the National Statement 2007

Research on human embryos must be conducted in accordance with the National Statement 2007 and be approved by an HREC.

17.2 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.

17.3 Apply criteria for licensable activity

For activities to be licensed, the following criteria must be met:

- The likely benefits are not reasonably obtainable by procedures that do not use human gametes, gonadal tissue, embryos or embryonic tissue;
- The potential benefits of the activity are sufficient to outweigh the principle that human embryos are not to be treated as mere tissue;
- The potential benefits of the activity are sufficient to outweigh the disrespect to human status in human-animal hybridisation;
- There is proof of concept that supports the activity, such as success in animal studies;

- The outcome of the research is likely to significantly advance knowledge or improve technologies for treatment

17.4 Do not use any unacceptable or prohibited practices

Research proposals involving human embryos must not include any prohibited or unacceptable practices (see Section 4).

Research on an embryo that will be used for achieving a pregnancy

17.5 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).

17.6 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 of knowledge. There must be no foreseeable harm to the embryo that would make it unfit for transfer to the woman.

17.7 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:

- 17.7.1 Where clinical care is combined with research, the risks of research should be balanced by the possibility of intended benefits for the embryo.
- 17.7.2 For research undertaken solely to develop new knowledge, any risks to the embryo should be minimal.

17.8 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.

17.8.1 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.

17.9 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.

17.10 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

17.11 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.

17.12 Use valid scientific protocols

The RIHE Act specifies important criteria that the Licensing Committee must have regard to before issuing a licence, including:

- the likelihood that the results of the use of the excess ART embryos proposed in the application offer a significant advance in knowledge or improvement in technologies for treatment, which could not reasonably be achieved by other means;
- that the number of excess ART embryos is restricted to that likely to be necessary to achieve the goals of the activity or project proposed in the application.

Paragraph 17.3 above specifies ethical guidelines for all licensable activities.

Researchers and HRECs must follow advice provided by the Licensing Committee to ensure that these criteria are met.

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 persons responsible for the embryos for consent to use their embryo in a specified research project until after a decision has been made, and confirmed in writing, by all persons responsible for the embryo is no longer needed for reproductive treatment 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.

The objective criteria for determining that an embryo is unsuitable for implantation are to be based on whether the embryo is incapable of successful implantation if transferred to the body of a woman. These criteria will be developed by the Licensing Committee.

17.15.1 If the objective criteria are met in relation to an embryo, the woman and her spouse (if any) may still decide that the embryo is not an excess ART embryo.

17.16 Obtain proper consent

Under the RIHE Act (section 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 paragraph 17.13).

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 2007, 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 2007 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.

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 Where proper consent has been given by persons responsible for an excess ART embryo that has been deemed unsuitable by the objective criteria to a use that will damage or destroy the embryo, consideration may be given by

the Licensing Committee to reducing the length of the cooling-off period to no less than 48 hours.

17.20 Keep accurate records

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 and human sperm

The PHCR and RIHE Acts allow, under certain prescribed circumstances, 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 are able to donate excess eggs from ART treatment to research. Further, women and men who are not involved in an ART program for the purpose of reproduction 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 using gametes, gonadal tissue or cells for research purposes

17.21 Respect the donors of gametes or cells for forming embryos other than by 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 2007.

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 2007 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, and
- Whenever possible, 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.

- 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 payment for gametes, gonadal tissue or cells donated 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 how such information will be handled. (See sections on human genetics in the National Statement 2007)
- 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 2007.
- 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, including the likely benefits from the research and a realistic estimate of when those benefits might be realised
 - 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 interests of researchers
- 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
- Any other information required by the National Statement 2007.

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 stem cells in the National Statement 2007.

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 are more than low risk (as defined in the National Statement 2007), including hormonal stimulation, anaesthesia or surgical procedures to obtain gametes, gonadal tissue or cells, must be reviewed by an HREC.

17.21.11 The possible 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 the donor, the HREC and the Licensing Committee must have regard to whether the person has completed his or her family.

17.21.13 In deciding whether to approve research involving donation of eggs by a woman, who is not on an ART program to achieve pregnancy, an HREC and the Licensing Committee must be satisfied that the risks associated with the donation process are justified by the direct benefits of the research to the donor or others. In reaching those decisions, HRECs and the Licensing Committee must apply the section on risk and benefit in the National Statement 2007.

17.21.14 In deciding whether to approve research involving donation of gonadal tissue, an HREC and the Licensing Committee must be satisfied that the risks associated with the donation process are justified by the direct benefits of the research to the donor or others. In reaching those decisions, HRECs and the Licensing Committee must apply the section on risk and benefit in the National Statement 2007.

17.21.15 Gamete, gonadal tissue or cell donors should be offered psychological counselling on the risks and the psychosocial and ethical implications of donation. The counsellors must be independent of the research. Counseling

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 ovarian stimulation cycles should be limited because the long-term effects are unknown.
- 17.21.17 Given the risks to donors, clinicians and clinical centres engaged in gamete or gonadal tissue retrieval should encourage studies on the medical and psychological effects of gametes or gonadal tissue donation on the donors 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 donating gametes, gonadal tissue or cells for a licensed procedure.
- 17.22.2 Gametes, gonadal tissue or cells from a dead man or woman must not be obtained or used in research unless either ante mortem-specific consent to that use had been previously obtained from the person, or they had expressed that wish to the senior next of kin.
- 17.22.3 Before consent is given to post mortem donation of gametes, gonadal tissue or cells, the donor and the senior available next of kin must have received the information that these guidelines require for donors.

Research on gametes or gonadal tissue from the human foetus, or foetal tissue, after separation

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 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 2007, 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.

Appendix A Committee membership

Membership of AHEC

2006–2009 NHMRC triennium

Professor Colin Thompson	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
Secretariat (Office of NHMRC)	
Ms Jillian Barr	Project officer
Mr Matthew Sammels	Project officer
Consultant	
Dr Alana Mitchell	Technical writer

Appendix B 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.

AHEC has not added to or altered this appendix. AHEC will consider including discussion of several new practices made possible by the amendments to the legislation. AHEC invites discussion points for and against these practices.

B1 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.

B2 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.

B3 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).

B4 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)] <i>See also</i> 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. <i>See also</i> 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. <i>See also</i> 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. <i>See also</i> Gamete provider

Embryo	<p>A living entity in the earliest stage of development.</p> <p><i>See also</i> Human, Chimeric and Hybrid embryos</p>
Embryo donor	<p>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.</p> <p><i>See also</i> Responsible person</p>
Embryonic stem cell	<p>An undifferentiated cell that is a precursor to many different cell types, obtained from the inner cell mass of a blastocyst.</p>
Embryonic stem cell line	<p>A genetically identical line of cells, derived from an embryonic stem cell, that can be propagated indefinitely in culture.</p>
Excess ART embryo	<p>A human embryo that:</p> <p>(a) was created by ART, for use in the ART treatment of a woman; and</p> <p>(b) is excess to the needs of:</p> <p style="margin-left: 20px;">(i) the woman for whom it was created; and</p> <p style="margin-left: 20px;">(ii) her spouse (if any) at the time that the embryo was created. [PHCR s 8(1); RIHE s 9(1)]</p> <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> <p>(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</p> <p>(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)]</p>
Gamete	<p>A human sperm or egg (ovum or oocyte) and includes:</p> <p>(a) any cell that has resulted from a process of meiosis; or</p> <p>(b) tissue containing such cells (referred to as gonadal tissue)</p> <p><i>See also</i> Gonadal tissue and Precursor cell</p>
Gamete donor	<p>A person who provides gametes for use:</p> <p>(a) by a person other than his or her spouse or partner in a reproductive procedure; or</p> <p>(b) for research.</p> <p><i>See also</i> Donated gametes, Gamete provider</p>

Gamete provider	The person who is the biological (that is, genetic) source of the gamete.
Gonadal tissue	Tissue from the ovary or testis. <i>See also</i> gamete.
Human egg	Human ovum or oocyte.
Human embryo	<p>A discrete entity that has arisen from either:</p> <p>(a) the first mitotic division when fertilisation of a human oocyte by a human sperm is complete; or</p> <p>(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;</p> <p>and has not yet reached 8 weeks of development since the first mitotic division [PHCR s 8(1), RIHE s 7(1)]</p> <p>For the purposes of applying this definition:</p> <p>(a) when two gametes combine to form a single cell by fertilisation the entity is to be treated as an embryo for the purposes of determining the persons responsible and for applying these guidelines; or</p> <p>(b) 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.</p> <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> <p>(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</p> <p>(b) it is not necessary to establish that the copy is an identical genetic copy. [PHCR s 8(2)]</p> <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	<p>(a) an embryo created by the fertilisation of a human egg by animal sperm; or</p> <p>(b) an embryo created by the fertilisation of an animal egg by human sperm; or</p> <p>(c) a human egg into which the nucleus of an animal cell has been introduced; or</p> <p>(d) an animal egg into which the nucleus of a human cell has been introduced; or</p> <p>(e) a thing declared by the regulations to be a hybrid embryo. [PHCR s 8(1)]</p> <p><i>See also</i> 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.</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).
Prohibited embryo	<p>(a) a human embryo created by a process other than the fertilisation of a human egg by a human sperm; or</p> <p>(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</p> <p>(c) a human embryo that contains genetic material provided by more than two persons; or</p> <p>(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</p> <p>(e) a human embryo created using precursor cells taken from a human embryo or human foetus; or</p> <p>(f) a human embryo that contains a human cell (within the meaning of section 18 of the PHCR) 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</p> <p>(g) a human embryo that was removed from the body of a woman by a person intending to collect a viable human embryo; or</p> <p>(h) a chimeric embryo or hybrid embryo.</p> <p>[PHCR s 22(4)]</p>
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	<p>(a) In relation to an excess ART embryo:</p> <p>(i) each person who provided the egg or sperm from which the embryo was created; and</p> <p>(ii) the woman for whom the embryo was created, for the purpose of achieving her pregnancy; and</p> <p>(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</p> <p>(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]</p> <p>(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</p> <p>(c) in relation to a human gamete—the person who was the biological donor of the gamete.</p>
Spouse or partner	<p>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 RHIE s 7]</p>
Treatment cycle	<p>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>A human embryo that:</p> <p>(a) is diagnosed by preimplantation genetic diagnosis as unsuitable for implantation, in accordance with these guidelines, issued by the CEO of the NHMRC; or</p> <p>(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)].</p>

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> (currently NHMRC 2007; see ‘Key information sources’)
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>

Key information sources

NHMRC guidelines

AHEC (Australian Health Ethics Committee) (1998). *Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings*. NHMRC, Canberra.
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<http://www.nhmrc.gov.au/publications/synopses/e28syn.htm> (Accessed 7 July 2004)

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<http://www.nhmrc.gov.au/research/general/nhmrcavc.htm> (Accessed 7 July 2004)

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Australian Government legislation

National Health and Medical Research Council Act 1992
<http://www.scaleplus.law.gov.au/cgi-bin/download.pl?/scale/data/comact/8/4128>
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Privacy Act 1988
<http://www.scaleplus.law.gov.au/cgi-bin/download.pl?/scale/data/comact/6/3324>
 (Accessed 7 July 2004)

Prohibition of Human Cloning Act 2002
<http://scaleplus.law.gov.au/html/comact/11/6602/pdf/1442002.pdf>
 (Accessed 7 July 2004)

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)

Research Involving Human Embryos Act 2002

<http://scaleplus.law.gov.au/html/comact/11/6603/pdf/1452002.pdf>

(Accessed 7 July 2004)

State and territory government legislation

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

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