



Australian Government

National Health and Medical Research Council

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

AUSTRALIAN HEALTH ETHICS COMMITTEE

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The content of these guidelines were informed by public consultation (see Appendix B).

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PART A: INTRODUCTION

I BACKGROUND

ROLE OF THE NHMRC

1.1 These guidelines (*Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research, 2004*) 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 NHMRC include:

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 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 2, section 8 of the NHMRC Act ('Ethics guidelines') states that:

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

and that the guidelines

must be issued precisely as developed by the principal committee known as AHEC and provided to the Council for the purpose.

1.3 Part 5 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 guidelines for the conduct of medical research involving humans; and
- (c) such other functions as the minister from time to time determines.

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*). This publication replaces the 1996 edition.
- 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 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.

NATIONAL LEGISLATION ON EMBRYO RESEARCH AND HUMAN CLONING

- 1.7 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.
- 1.8 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

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

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 This 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.

- 1.9 In 2002, the Australian Parliament passed legislation banning human cloning (*Prohibition of Human Cloning Act 2002*, referred to in these guidelines as the 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.
- 1.10 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 *Research Involving Human Embryos Act 2002* (referred to in these guidelines as 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.
- 1.11 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.
- 1.12 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; referred to in these guidelines as the National Statement).

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)

REVISED ETHICAL GUIDELINES FOR THE USE OF ART (2004)

- 1.13 These revised guidelines, which replace the 1996 guidelines, have been issued to continue to promote ethical practice in ART as follows.
- With respect to clinical practice, the guidelines will remain a key element in the accreditation processes for ART clinics.
 - With respect to research, the guidelines will be used by HRECs and researchers who apply for ethical approval of any research involving ART participants, human gametes or embryos, and by researchers who wish to make an application to the Licensing Committee for a licence.
- 1.14 In addition to these guidelines, researchers also need to refer to the National Statement and, in relevant circumstances, *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* (NHMRC 2003).
- 1.15 Clinicians and researchers should also be aware of any relevant laws and regulations. In every situation, the law will take precedence over NHMRC ethical guidelines.

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 framing these guidelines, AHEC has recognised that the welfare of people who may be born as a result of the use of ART is paramount.
- 2.6 AHEC has also taken into account the following issues:
- the autonomy and long-term welfare of individuals (both men and women) who take part in ART;
 - the need for informed decision making; and
 - the importance of an ethical framework for the use of gametes and embryos.

- 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; and
 - **research** involving
 - participants in ART
 - gametes
 - embryos that are (i) intended for implantation, (ii) excess ART 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.
- 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 by clinics and research departments.
- 2.13 The principles are supported by practical guidelines that clinicians and researchers should include in their standard operating procedures in order to ensure that they comply with the ethical principles. These practical guidelines should be followed unless there is an effective alternative option that is consistent with the relevant ethical principle.

- 2.14 To assist the reader, throughout Part B and Part C, the legal requirements and ethical principles (see paragraph 2.11 and 2.12), have first order paragraph numbering (for example, 14.1). The practical guidelines described in paragraph 2.13 all have second order paragraph numbering (for example, 14.1.1).
- 2.15 In addition, there are three appendices to the guidelines. Appendices A and B relate to process matters in the preparation of the guidelines. Appendix C aims to stimulate community discussion about a number of issues that are controversial and may need consideration by legislators.

3 REGULATORY FRAMEWORK

3.1 Legislation

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

- relevant national legislation, including the *Prohibition of Human Cloning Act 2002*, the *Research Involving Human Embryos Act 2002* and the *Privacy Act 1988*; and
- relevant state and territory legislation, including privacy legislation.

3.2 NHMRC licensing arrangements

Use of excess ART embryos for research and other activities (such as training, quality assurance) that require a licence under the RIHE Act must comply with the conditions of the licence.

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 (currently NHMRC 1999);
- *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* (currently NHMRC 2003); and
- *Joint NHMRC–Australian Vice-Chancellors' Committee Statement and Guidelines on Research Practice* (currently AVCC/NHMRC 1997).

3.5 Human research ethics committees

All proposals for research and activities requiring a licence for the use of excess ART embryos must be approved by an HREC.

Other activities, such as some quality assurance and innovative practices, may need to be considered and approved by an HREC.

4 UNACCEPTABLE AND PROHIBITED PRACTICES

4.1 Unacceptable practices

AHEC considers that it is ethically unacceptable to create a human embryo in vitro for any reason other than to achieve a pregnancy in a woman.

In 2002, the Australian Parliament passed legislation that prohibited this and other practices that AHEC agrees are unacceptable (see paragraphs 4.2 and 4.3).

4.2 *Prohibition of Human Cloning Act 2002*

Under the PHC Act (sections 9–11 and 13–23), clinicians and researchers must not engage in any of the following prohibited practices:

- creating a human embryo clone [s 9];
- placing a human embryo clone in the human body or the body of an animal [s 10];
- importing or exporting a human embryo clone [s 11];
- creating a human embryo other than by fertilisation, or developing such an embryo [s 13];
- creating a human embryo for a purpose other than achieving pregnancy in a woman [s 14];
- creating or developing a human embryo containing genetic material provided by more than two persons [s 15];
- developing a human embryo outside the body of a woman for more than 14 days (excluding any time in which its development has been suspended) [s 16];
- using precursor cells from a human embryo or a human fetus to create a human embryo, or developing such an embryo [s 17];
- intentionally altering the genome of a human cell in such a way that the alteration is heritable by descendants of the human whose cell was altered [s 18];
- collecting a viable human embryo from the body of a woman [s 19];
- creating a chimeric or hybrid embryo [s 20];
- placing a human embryo into an animal [s 21(1)];
- placing a human embryo into the body of a human, other than in a woman's reproductive tract [s 21(2)];
- placing an animal embryo into the body of a human for any period of gestation [s 21(3)];

- importing or exporting a prohibited embryo [ss 22(1) and 22(2)];³
- placing a prohibited embryo in the body of a woman [s 22(3)]; and
- commercial trading in human eggs, human sperm or human embryos [s 23].

4.3 Research Involving Human Embryos Act 2002

Under the RIHE Act (sections 10–11), clinicians and researchers must not:

- use an excess ART embryo without a licence, unless the use is an exempt use [s 10(1)]. Exempt uses of excess ART embryos are described as follows [s 10(2)]:
 - 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;
- use an embryo that is not an excess ART embryo, outside the body of a woman, for a purpose not related to ART treatment of a woman carried out by an accredited ART centre [s 11];
- breach a licence condition [s 12].

³ See ‘Explanation of key terms’ for definition of a prohibited embryo.

PART B: ETHICAL GUIDELINES FOR THE CLINICAL PRACTICE OF ART

5 ETHICAL PRINCIPLES FOR CLINICAL PRACTICE

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.

5.2 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;
- gamete 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; and
- 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 semen and oocytes 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 oocytes from close relatives

Oocytes must not be fertilised with sperm from a close genetic relative (that is, from a person for whom a sexual relationship with the oocyte 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; or
- 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.

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); and
- 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 should be respected regarding the method of disposal.

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 storage of gonadal tissue or gametes for a ‘minor’

In the event of a request to store gonadal tissue or gametes from a child or young person (defined as a ‘minor’ in each jurisdiction), consent must be obtained from the parents or guardian, or any organisation or person authorised by law.

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 *Research Involving Human Embryos Act 2002* (RIHE Act) and corresponding state or territory legislation, embryos must not be created for use in research. However, embryos that are no longer required for ART treatment (ie those defined in the RIHE Act as ‘excess ART embryos’) may be used for research if the 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 the gamete donors' 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.

II SEX SELECTION

II.1 Do not select sex for nonmedical purposes

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

12 PREIMPLANTATION GENETIC DIAGNOSIS

12.1 Carefully evaluate any use of Preimplantation Genetic Diagnosis (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 is to have another child as an addition to their family and not merely as a source of tissue.

12.4 Provide access to a geneticist and genetic counsellor

It is essential that participants in ART seeking PGD testing of embryos understand the technology and how it applies to their embryos. Clinics must ensure that people seeking PGD testing have access both to clinical geneticists and to genetic counsellors.

12.5 Provide relevant information and counselling

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

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

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

13 SURROGACY

13.1 Do not undertake or facilitate commercial surrogacy

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

13.2 Noncommercial surrogacy

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

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

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

14 INNOVATIONS, TRAINING AND QUALITY ASSURANCE

14.1 Evaluate innovations before use in clinical practice

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

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

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

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

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

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

14.2 Obtain appropriate consent from participants and/or 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.

Under the RIHE Act, a licence is required for any training 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 training 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, section 11).

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, section 11).

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

PART C: ETHICAL GUIDELINES FOR RESEARCH INVOLVING ART

15 ETHICAL PRINCIPLES FOR RESEARCH

15.1 Respect all participants

Research involving gametes, embryos and/or participants in reproductive treatments must be conducted in a way that is respectful of all the human beings involved. Researchers must therefore comply with the ethical principles provided in the National Health and Medical Research Council (NHMRC) *National Statement on Ethical Conduct in Research Involving Humans* (the National Statement). Human Research Ethics Committees 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.

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 *Research Involving Human Embryos Act 2002* (RIHE Act), which was passed by the Australian Parliament in 2002 to limit research on human embryos to specific situations. Under this legislation, any research, training or quality assurance activities using excess assisted reproductive technology (ART) embryos require a licence. See Section 17 for detailed guidelines on embryo research.

15.3 Do not engage in 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 paragraph 1.6 of the National Statement).

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

15.5 Offer separate decision-making processes for clinical care and research

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 ART research 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 ART research. Section 9 provides guidelines on obtaining consent for clinical practice; a similar range of information must be provided for research (as identified in paragraphs 1.7–1.10 of the National Statement).

Consent for the use of excess ART embryos in research must be obtained from all persons responsible for the embryos (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.

HRECs must submit annual compliance reports to the NHMRC in accordance with paragraphs 2.46–2.48 of the National Statement.

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 involving ART procedures conducted by the clinic, the clinic must allow him or her to withdraw from involvement in the research to which he or she objects. Clinics must also ensure that staff and students are not disadvantaged because of a conscientious objection.

16 RESEARCH INVOLVING GAMETES

16.1 Comply with National Statement

All research on gametes must be conducted in accordance with the ethical principles in the National Statement and in these guidelines, and must be approved by an HREC.

16.2 Do not engage in any unacceptable or prohibited practices

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

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.

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), and from any persons for whom an embryo may be created, that the gametes will be the subject of research, following which fertilisation may be attempted to create an embryo for transfer to the uterus of the recipient to achieve a pregnancy.

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'). Research on embryos intended for transfer to a woman to achieve a pregnancy 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 on excess ART embryos may involve harming or destroying the embryo (for example, to obtain embryonic stem cells).

17.1 Comply with the National Statement

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

17.2 Do not engage in 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

17.3 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).

17.4 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.

17.5 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:

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

17.6 Use valid scientific protocols

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

The number of embryos must be limited to the number necessary to achieve the defined scientific aims of the project.

17.7 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.

- 17.7.1 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.

17.8 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.

17.9 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

17.10 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.

17.11 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; and
- 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.

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

17.12 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 that it 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).

17.13 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 or partners, 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).

17.14 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, proper consent for research must be informed, competent, voluntary, specific and, for this purpose, it must be in writing. Researchers must comply with the National Statement in respect of all these conditions, and must also follow the specific guidance provided in paragraphs 17.16 and 17.17 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.

17.15 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.

17.16 Provide all relevant information

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

- 17.16.1 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.
- 17.16.2 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.

17.17 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.

17.18 Keep accurate records

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

APPENDIX A COMMITTEE MEMBERSHIP

Committee to Revise the Ethical Guidelines on Assisted Reproductive Technology (CREGART)

2000–2003 NHMRC triennium

Dr Bernadette Tobin, Chair	Member of AHEC
Professor Geoffrey Bishop	An expert in reproductive medical practice but not necessarily IVF
Professor John Mattick	Member of AHEC with experience in medical research
Dr Sandra Webb	Member of AHEC with experience in public health research
Mr Henry Wellsmore	A person with knowledge of issues that concern people who access reproductive technology
Dr Peter Illingworth	A provider of IVF services
Emeritus Professor Douglas Saunders (from April 2003)	A provider of IVF services
Rev Bill Uren (November–December 2001)	Member of AHEC with knowledge of the ethics of medical research
Ms Belinda Byrne	Member of AHEC (corresponding member)

Secretariat (Office of NHMRC)

Mr Ian Denley	Project officer (November 2001 – February 2002)
Ms Nerida Lawrentin	Project officer (February 2002 – April 2003)

Consultants

Dr Janet Salisbury	Technical writer
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The 2000–2003 NHMRC triennium finished on 22 May 2003, and all committees were disbanded from that date. CREGART was reconstituted for the 2003–2005 NHMRC triennium and held its first meeting in August 2003. At this time, AHEC made special arrangements to ensure continuity between the two triennia. Membership of Dr Tobin as co-chair of the committee was retained. To meet AHEC's policy that chairs of AHEC subcommittees should be members of AHEC, Dr Breen, the chair of AHEC, was appointed co-chair of CREGART.

2003–2005 NHMRC triennium

Dr Kerry Breen Chair of AHEC	Co-chair of GREGART
Dr Bernadette Tobin	Co-chair of CREGART
Professor Geoffrey Bishop	Obstetrician (an expert in medical practice but not necessarily IVF)
Professor Bryan Campbell	Member of AHEC with knowledge of the regulation of the medical profession
Dr Christopher Cordner	Member of AHEC with knowledge of the ethics of medical research
A/Professor Robert McLachlan	A person with research expertise in a relevant area
Ms Sharon Phillips	A nurse with experience in the clinical practice area of reproductive health
Dr Sandra Webb	A person with knowledge of national, state and territory legislation in this area
Mr Henry Wellsmore	A person with knowledge of issues that concern people who access reproductive technology
Emeritus Professor Douglas Saunders	A provider of IVF services

Secretariat (Office of NHMRC)

Ms Francesca Baas Becking	Project officer
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Consultants

Dr Janet Salisbury	Technical writer
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APPENDIX B PROCESS REPORT

BACKGROUND

In developing and issuing guidelines, the Council of the National Health and Medical Research Council (NHMRC) and its principal committees are obliged under the *National Health and Medical Research Council Act 1992* (sections 13 and 14A) to release draft guidelines for public consultation. To develop draft guidelines, the Australian Health Ethics Committee (AHEC) establishes working parties that include some members of AHEC and others with relevant expertise.

In 2001, AHEC appointed a working party to review the NHMRC *Ethical Guidelines on Assisted Reproductive Technology* 1996 (the 1996 Guidelines). This committee, the Committee to Revise the Ethical Guidelines on Assisted Reproductive Technology (CREGART), included members with expertise in assisted reproductive technology (clinical and research), counselling in infertility, and state regulation of in vitro fertilisation. CREGART met for the first time on 20 November 2001. The members of CREGART and support staff are given in Appendix A.

PROCESS

INITIAL CONSULTATION ON 1996 GUIDELINES

CREGART has undertaken extensive consultation of public, community and professional stakeholders during the review of the guidelines, as outlined below.

Two rounds of public consultation have been undertaken in the course of the review of the ethical guidelines.

AHEC conducted the first round of public consultation from September to November 2001. The public were invited to submit comments on issues relevant to the review of the 1996 Guidelines. A total of 61 submissions were received.

PUBLIC CONSULTATION ON DRAFT REVISED GUIDELINES

It was initially envisaged that the draft revised guidelines would be released for public consultation in July 2002. However, AHEC considered that it was appropriate to delay further consultation on the draft guidelines until after the conclusion of Parliamentary debate on the Research Involving Embryos and Prohibition of Human Cloning Bill 2002.

Following completion of that debate, AHEC released draft *Ethical Guidelines on the Use of Reproductive Technology in Clinical Practice and Research* in February 2003 for public consultation. Over 100 submissions were received from individuals, community groups, professional groups, state and territory regulatory bodies and other relevant government departments.

FURTHER CONSULTATION WITH STATE AND TERRITORY GOVERNMENTS

After due consideration of the submissions received, CREGART agreed that specific submissions raised significant issues with respect to the interface of the guidelines with state and territory legislation. Where particular issues needed further discussion and clarification, the relevant state and territory departments and organisations were invited to meet with CREGART.

During October 2003, meetings were held with the Infertility Treatment Authority of Victoria, the New South Wales Department of Health and the then New South Wales Cabinet BioUnit, and the South Australian Council on Reproductive Technology and the South Australian Department of Human Services.

PREPARATION OF REVISED DRAFT GUIDELINES

From late 2003 to July 2004, CREGART redrafted the guidelines to take account of the public submissions and further consultations.

CONSULTATION WITH STATES AND TERRITORIES, THE AUSTRALIAN GOVERNMENT AND THE LICENSING COMMITTEE

Given that all, or parts, of the guidelines were to be prescribed via the Regulations under the *Research Involving Human Embryos Act 2002*, and that most states and territories were enacting or had enacted legislation related to assisted reproductive technology matters, AHEC considered it to be important that all jurisdictions were provided with an opportunity to preview the guidelines. Consequently, AHEC agreed to circulate an in-confidence 'exposure' draft of the revised guidelines to state and territory representatives.

A preview copy of the revised guidelines was also circulated to the NHMRC Embryo Research Licensing Committee (the Licensing Committee).

Representatives of the Australian Government, the jurisdictions, and the Licensing Committee (as an observer) were also invited to a meeting with members of CREGART in July 2004 to discuss the 'exposure' draft.

ENDORSEMENT

After the meeting with government and Licensing Committee representatives, the guidelines were finalised and forwarded to AHEC for final approval and endorsement at its meeting on 25–26 August 2004.

The AHEC-endorsed guidelines were forwarded to the NHMRC Council for consideration at its meeting on 16–17 September 2004.

APPENDIX C ISSUES FOR FURTHER COMMUNITY DISCUSSION

This appendix provides a brief discussion of three controversial issues in the use of assisted reproductive technology (ART), namely the use of genetic technology associated with ART; sex selection; and surrogacy. 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.

C1 APPROACH TO CONTROVERSIAL ISSUES

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

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

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

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

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

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

C2 GENETIC TECHNOLOGY ASSOCIATED WITH ART

Introduction

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

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

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

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

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

- Use of genetic technology implies that admission to life is no longer unconditional.
- Use of genetic technology may foster reproductive discrimination.
- Use of genetic technology establishes the principle that parents may choose the qualities their children have.
- The handling, testing and manipulation of embryos in genetic technology procedures may expose them to significant risk of harm. (The weight of this consideration may depend on the seriousness of the outcome that the technology is being used to avert.)
- The likelihood that the social effects of general acceptance of ART (with genetic technology) as an alternative to natural reproduction will include a diminished tolerance for difference.

- Though avoidance of serious disease may be a reasonable use of genetic technology, shaping babies to parents' ideas of perfection (were this to prove possible) is not.
- Otherwise normal (so-called 'carrier') embryos that would be expected to have a normal life will be discarded.

C3 SEX SELECTION

Introduction

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

Reasons given in support of the availability of sex selection

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

Reasons given for opposing the availability of sex selection

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

C4 SURROGACY

Introduction

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

Reasons given in support of allowing surrogacy arrangements

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

Reasons given for opposing 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 Act 2002* (PHC 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.
Chimeric embryo	A human embryo into which a cell, or any component part of a cell, of an animal has been introduced. [PHC s 8 (1a)] <i>See also</i> Hybrid embryo
Clinic	Accredited ART centre.
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 donor	A person who has responsibility for decisions about the use of an embryo and who donates the embryo to another person or persons for treatment, or for research or other activities. <i>See also</i> Responsible person
Embryonic stem cell	An undifferentiated cell, obtained from the inner cell mass of a blastocyst, that is a precursor to many different cell types.

Embryonic stem cell line	A genetically identical line of cells, derived from an embryonic stem cell, that can be propagated indefinitely in culture.
Excess ART embryo	<p>A human embryo that:</p> <ul style="list-style-type: none">(a) was created by ART, for use in the ART treatment of a woman; and(b) is excess to the needs of:<ul style="list-style-type: none">(i) the woman for whom it was created; and(ii) her spouse (if any) at the time that the embryo was created. [PHC s 8(1); RIHE s 9(1)] <p>For the purposes of paragraph (b), a human embryo is excess to the needs of the persons mentioned in that paragraph at a particular time if:</p> <ul style="list-style-type: none">(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(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. [PHC s 8(5); RIHE s 9(2)]
Gamete	<p>A human sperm or egg cell (oocyte).</p> <p>In these guidelines, unless otherwise specified, the term ‘gamete’ is also used to include gonadal tissue.</p>
Gamete donor	<p>A person who provides gametes for use by a person other than his or her spouse or partner in a reproductive procedure.</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.
Human cell	For the purposes of the PHC Act [s 18] (heritable alterations to genome), ‘human cell’ includes a human embryonal cell, a human fetal cell, human sperm or a human egg.

Human embryo	<p>A live embryo that has a human genome or an altered human genome and that has been developing for less than eight weeks since the appearance of two pronuclei or the initiation of its development by any other means (not including any period when its development was suspended for any reason) [PHC s 8(1); RIHE s 7(1)].</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. [PHC s 3]</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 [PHC s 8(1)].</p> <p>For the purposes of establishing that a human embryo clone is a genetic copy of a living or dead human:</p> <ul style="list-style-type: none"> (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 (b) it is not necessary to establish that the copy is an identical genetic copy. [PHC s 8(2)] <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. [PHC s 8(4)]</p>
Human sperm	Includes human spermatids. [PHC s 8(1)]
Hybrid embryo	<ul style="list-style-type: none"> (a) an embryo created by the fertilisation of a human egg by animal sperm; or (b) an embryo created by the fertilisation of an animal egg by human sperm; or (c) a human egg into which the nucleus of an animal cell has been introduced; or (d) an animal egg into which the nucleus of a human cell has been introduced; or (e) a thing declared by the regulations to be a hybrid embryo. [PHC s 8(1)] <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.
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 donor) who is the subject of (or takes part in) a reproductive procedure, or research, or innovative procedures involving ART.</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. [PHC 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	<ul style="list-style-type: none">(a) a human embryo created by a process other than the fertilisation of a human egg by a human sperm; or(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(c) a human embryo that contains genetic material provided by more than two persons; or(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(e) a human embryo created using precursor cells taken from a human embryo or human fetus; or

	<ul style="list-style-type: none"> (f) a human embryo that contains a human cell (within the meaning of section 18 of the PHC) whose genome has been altered in such a way that the alteration is heritable by human descendants of the human whose cell was altered; or (g) a human embryo that was removed from the body of a woman by a person intending to collect a viable human embryo; or (h) a chimeric embryo or hybrid embryo. [PHC s 22(4)]
Recipient	A person to whom gametes or embryos are donated.
Research	Systematic investigation with the aim of increasing knowledge.
Responsible person	<p>In relation to an excess ART embryo:</p> <ul style="list-style-type: none"> (a) each person who provided the egg or sperm from which the embryo was created; (b) the woman for whom the embryo was created, for the purpose of achieving her pregnancy; (c) 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 (d) any person who was the spouse of the woman mentioned in paragraph (b) at the time that the embryo was created. [RIHE s 8]
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).</p> <p>[Defined as 'spouse' in RIHE s 7]</p>
Treatment cycle	A series of treatments for the purposes of in vitro fertilisation, gamete intrafallopian tube transfer or similar procedures. It is defined as beginning either on the day on which treatment by superovulatory drugs is commenced or on the first day of the patient's menstrual cycle, and ending not more than 30 days later.

ABBREVIATIONS AND ACRONYMS

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 1999; 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>
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.

<http://www.nhmrc.gov.au/issues/clonelnk.htm> (Accessed 7 July 2004)

House of Representatives Standing Committee on Legal and Constitutional Affairs (2001). *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research*. Parliament of the Commonwealth of Australia, Canberra (Andrews Report).

NHMRC (1996). *Ethical Guidelines on Assisted Reproductive Technology*. NHMRC, Canberra.

<http://www.nhmrc.gov.au/publications/synopses/e28syn.htm> (Accessed 7 July 2004)

NHMRC (1999). *National Statement on Ethical Conduct in Research Involving Humans*.

<http://www.nhmrc.gov.au/publications/synopses/e35syn.htm> (Accessed 7 July 2004)

NHMRC (2003a). *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*. NHMRC, Canberra.

<http://www.nhmrc.gov.au/publications/synopses/e52syn.htm> (Accessed 7 July 2004)

NHMRC (2003b). *When Does Quality Assurance in Health Care Require Independent Ethical Review? Advice to Institutions, Human Research Ethics Committees and Health Care Professionals*. NHMRC, Canberra.

<http://www.nhmrc.gov.au/publications/synopses/e46syn.htm> (Accessed 7 July 2004)

NHMRC/AVCC (Australian Vice-Chancellors' Committee) (1997). *Joint NHMRC/AVCC Statement and Guidelines on Research Practice*, NHMRC, Canberra.

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

LEGISLATION

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>
(Accessed 7 July 2004)

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)

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.