An invitation to make a submission

The National Health and Medical Research Council is reviewing Part B of the Ethical guidelines on the use of assisted reproductive technology in clinical practice and research, 2007 (the ART guidelines) which provide ethical guidance for the clinical practice of ART. The review has also necessitated revision to Part A (the introduction) of the ART guidelines. Part C (ethical guidelines for research) is not currently under review.

The Australian Health Ethics Committee (AHEC) is overseeing the review, with the assistance of the Assisted Reproductive Technology (ART) Working Committee.

I am pleased to release the DRAFT Ethical guidelines on the use of assisted reproductive technology in clinical practice and research (Parts A and B) (the draft guidelines) for public consultation.

The draft guidelines provide ethical principles that must inform the conduct of clinicians and the development and use of procedures in ART clinics. These ethical principles are supported by practical guidelines on topics such as:

- use and storage of human eggs, sperm and embryos
- specific situations such as fertility preservation, surrogacy, preimplantation genetic testing, the collection and use of eggs and sperm from persons who are deceased or dying, and the use of stored eggs, sperm and embryos after the death of a person
- information giving, counselling and consent requirements.

Comments are particularly invited on the following issues:

- sex-selection for non-medical purposes
- compensation of Australian women for the reproductive effort and risks associated with donating their eggs
- establishment of an Australian donor egg bank.

NHMRC is keen to ensure that the Australian community has the best opportunity to participate in developing guidance on matters of health ethics and now seeks your comments on these proposed guidelines. I encourage you to bring this public consultation to the attention of anyone whom you believe would be interested in providing comment.

AHEC and the ART Working Committee look forward to receiving your comments.

Yours sincerely

[Signature]

Professor Anne Kelso AO
Chief Executive Officer

Date: 15 July 2015
Draft

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

Public consultation - 2015
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## Abbreviations

<table>
<thead>
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<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AHEC</td>
<td>Australian Health Ethics Committee</td>
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<tr>
<td>ART</td>
<td>assisted reproductive technology</td>
</tr>
<tr>
<td>HREC</td>
<td>Human Research Ethics Committee</td>
</tr>
<tr>
<td>Licensing Committee</td>
<td>Embryo Research Licensing Committee (NHMRC)</td>
</tr>
<tr>
<td>National Statement</td>
<td>National statement on ethical conduct in human research&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
</tr>
<tr>
<td>NHMRC Act</td>
<td>National Health and Medical Research Council Act 1992</td>
</tr>
<tr>
<td>RIHE Act</td>
<td>Research Involving Human Embryos Act 2002</td>
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</tbody>
</table>

<sup>1</sup> At the time of publication, the current version is the National statement on ethical conduct in human research, 2007 - updated March 2014. Where in reference to the Research Involving Human Embryos Act 2002, the 'National Statement' refers to the National Statement on Ethical Conduct in Research Involving Humans, 1999.
**Explanation of key terms used in this public consultation document**

**TERMS USED EXCLUSIVELY IN PART C OF THE ART GUIDELINES ARE NOT LISTED IN THIS PUBLIC CONSULTATION DOCUMENT. THESE TERMS WILL BE INCLUDED IN THE FINAL VERSION.**

The following explanations show how key terms are to be interpreted in the context of Parts A and B of these Ethics Guidelines. For consistency with national legislation, where the same terms have been used in either the Research Involving Human Embryos Act 2002 (RIHE Act) or the Prohibition of Human Cloning for Reproduction Act 2002 (PHCR Act), the same definitions have been used here and the relevant section of legislation provided.

<table>
<thead>
<tr>
<th>Activity / ART activity</th>
<th>An ART treatment or procedure.</th>
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<tbody>
<tr>
<td>Assisted reproductive technology (ART)</td>
<td>The application of laboratory or clinical techniques to gametes and/or embryos for the purposes of reproduction.</td>
</tr>
</tbody>
</table>
| Clinic | A person or body accredited to carry out ART by:
(a) the Reproductive Technology Accreditation Committee of the Fertility Society of Australia; or
(b) if the regulations prescribe another body or other bodies in addition to, or instead of, the body mentioned in paragraph (a)—that other body or any of those other bodies, as the case requires [RIHE s8] |
| Donated embryo | An embryo given by either the gamete providers or the persons for whom the embryo was created to other persons for the purpose of achieving a pregnancy.

The term is also used when the gamete providers for an embryo agree to their embryo being used in research or other activities that are not intended to achieve a pregnancy.

See also Embryo donor |
| Donated gametes | Gametes given for use by a person other than the gamete provider or his or her spouse or partner in a reproductive procedure.

The term is also used when gametes are provided for research or other activities.

See also Gamete provider |
| Double donation | The use of both donor sperm and a donor egg to create an embryo. |
| Embryo | A living entity in the earliest stage of development. |
| See also Human embryo |
| Embryo donor | A person who donates an embryo to another person or persons for treatment, or for research or other activities. |
| **Excess ART embryo** | A human embryo that:  
(a) was created by ART, for use in the ART treatment of a woman; and  
(b) is excess to the needs of:  
(i) the woman for whom it was created; and  
(ii) her spouse (if any) at the time that the embryo was created [PHCR s 8(1); RIHE s 9(1)].  
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:  
(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 [PHCR s 8(5); RIHE s 9(2)]. |
| --- | --- |
| **Gamete** | A human sperm or egg (ovum or oocyte) and includes:  
(a) any cell that has resulted from a process of meiosis; or  
(b) tissue containing such cells (also referred to as gonadal tissue)  
See also Gonadal tissue |
| **Gamete donor** | A person who provides gametes for use:  
(a) by a person other than his or her spouse or partner in a reproductive procedure; or  
(b) for research.  
See also Donated gametes, Gamete provider |
| **Gamete provider** | The person who is the biological (that is, genetic) source of the gamete. |
| **Gonadal tissue** | Tissue from the ovary or testis.  
See also gamete. |
<p>| <strong>Human egg</strong> | Human ovum or oocyte. |</p>
<table>
<thead>
<tr>
<th><strong>Human embryo</strong></th>
<th>The RIHE Act [s7(1)] defines a human embryo as:</th>
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<tr>
<td></td>
<td>A discrete entity that has arisen from either:</td>
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<tr>
<td></td>
<td>(a) the first mitotic division when fertilisation of a human oocyte by a human sperm is complete; or</td>
</tr>
<tr>
<td></td>
<td>(b) any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears;</td>
</tr>
<tr>
<td></td>
<td>and has not yet reached 8 weeks of development since the first mitotic division</td>
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<table>
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<tr>
<th><strong>Human sperm</strong></th>
<th>Includes human spermatids. [PHCR s 8(1)]</th>
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<tr>
<th><strong>Innovative procedure</strong></th>
<th>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.</th>
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<table>
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<tr>
<th><strong>Licensable activities</strong></th>
<th>Activities which require a licence under the RIHE Act or the PHCR Act.</th>
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<thead>
<tr>
<th><strong>License</strong></th>
<th>A license issued under section 21 of the RIHE Act [PHCR s 8(1)].</th>
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<table>
<thead>
<tr>
<th><strong>Reallocation</strong></th>
<th>In relation to a human embryo, means the further donation of:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(a) a donated embryo</td>
</tr>
<tr>
<td></td>
<td>(b) an embryo created using donated gametes (sperm and/or egg).</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th><strong>Recipient</strong></th>
<th>A person to whom gametes or embryos are donated.</th>
</tr>
</thead>
</table>

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<thead>
<tr>
<th><strong>Relevant party/ies</strong></th>
<th>In varying circumstances, the ‘relevant party/ies’ might include the individual or couple involved in the ART procedure, the gamete donor, the embryo donors, the surrogate, the spouse or partner of the donor or surrogate or the person who would be born as a result of an ART procedure.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Research</strong></th>
<th>Systematic investigation with the aim of increasing knowledge.</th>
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<table>
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<tr>
<th><strong>Sex selection</strong></th>
<th>Choosing the sex of an embryo prior to implantation.</th>
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</table>

<table>
<thead>
<tr>
<th><strong>Spouse or partner</strong></th>
<th>In relation to a person, includes a person who is legally married to the person (spouse), as well as a person who, although not legally married to the person, is living with the person on a bona fide domestic basis (partner). [Defined as ‘spouse’ in RHIE s 7]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment cycle</td>
<td>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.</td>
</tr>
<tr>
<td>-----------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Valid consent</td>
<td>For consent to be valid:</td>
</tr>
<tr>
<td></td>
<td>• the person giving consent must be considered by the treating clinician to have the capacity to provide valid consent</td>
</tr>
<tr>
<td></td>
<td>• the decision to consent to the treatment or procedure must be made without undue pressure</td>
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<tr>
<td></td>
<td>• sufficient information about the treatment or procedure must be made available, including the benefits and risks</td>
</tr>
<tr>
<td></td>
<td>• the consent must be specific, and is valid only in relation to the treatment or procedure for which information has been given.</td>
</tr>
</tbody>
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PART A

Introduction
# 1 Introduction to these guidelines

The National Health and Medical Research Council (NHMRC) has a well-established role in the provision of ethical advice for assisted reproductive technology (ART); with the first ethical guidelines for ART released in 1996. There have been a number of revisions to this ethical guidance between 1996 and 2015. A history of NHMRC’s involvement in developing ethical guidelines for ART is at Appendix 1.

These Ethical Guidelines are divided into three parts:

- **Part A** provides introductory information about these guidelines, including the role and scope of these guidelines.
- **Part B** provides ethical principles for the clinical practice of ART and practical guidelines in order to apply such principles.
- **Part C** provides ethical guidelines for research involving ART and other practices.

In this current revision of the Ethical Guidelines (2015):

- Parts A, B and the appendices have been revised.
- No changes have been made to Part C.

Part B of the Ethical Guidelines remains a key element in the accreditation process for ART clinics. Part C of the Ethical Guidelines is intended for use by Human Research Ethics Committees (HRECs) and researchers in reviewing, or applying for ethical approval of, proposed research involving:

- individuals or couples undertaking ART activities
- human eggs, sperm and/or embryos

Part C of the Ethical Guidelines is also intended for use by researchers when applying to the NHMRC Embryo Research Licensing Committee for a license to undertake such research.


Further information on national legislation on embryo research and human cloning is at Appendix 2.

**Role of the Ethical Guidelines**

The Ethical Guidelines provide an overarching framework for the conduct of ART in both clinical practice and research. The ethical principles in this document are in line with community expectations that human rights and the right to reasonable access to health care, including assisted reproductive services are respected and protected.

The Ethical Guidelines identify ethical principles that must inform the conduct of clinicians and researchers and the procedures developed in clinics and research facilities.

The ethical principles are supported by practical guidelines that clinicians and researchers should include in their standard operating procedures 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.
All activities referred to in these Ethical Guidelines must be carried out in compliance with existing law, legislation and regulatory frameworks. The activities must also comply with relevant professional and accreditation standards and the maintenance of appropriate quality assurance.

These Ethical Guidelines, in conjunction with federal and state/territory law, create a robust framework for the conduct of ART in Australia.

In addition to these Ethical Guidelines, researchers need to refer to the current version of the National statement on ethical conduct in human research\(^2\), and any other relevant ethical guideline.

**Scope of the ethical guidelines**

These Ethical Guidelines cover all activities associated with ART as they occur in:

- **clinical practice**, including:
  - routine practice associated with ART treatment
  - practices with specific ethical issues
  - licensable activities under the RIHE Act that occur in the clinical practice setting. For example, the use of excess embryos for training purposes.

- **research involving**:
  - individuals or couples involved in ART activities, including donors of human gametes or embryos involved in embryo research
  - embryos that are intended for implantation
  - excess ART embryos
  - other human embryos (See Chapter 17\(^3\)).

These Ethical Guidelines have been developed primarily for ART clinicians, researchers, ART clinic administrators, HREC’s, and governments.

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\(^2\)At the time of publication, the current version is National statement on ethical conduct in human research, 2007 - updated March 2014.

\(^3\)Note: Part C (including Chapter 17) is not included in this public consultation pack.
PART B

Ethical guidelines for the clinical practice of ART
2 Ethical principles in the clinical practice of ART

2.1 Human rights, ethical principles and values

A rights-based framework, and in particular, respect for human rights is relevant to the development and implementation of health policies, laws and practices, including those that relate to assisted reproduction.

Human rights are best conceived of as a moral claim against a government or health provider to a particular good or service. They are most often articulated, and are most easily enforceable, where they are stated negatively, for example, as the right not to be discriminated against. Rights may also be stated in positive terms, however, as a claim to access to health care, education or legal representation. Positive rights, where they are not legally enforceable, are more aspirational. The strength of rights-based claims is generally a function of the social services and political structures that people have access to i.e. they are more salient for individuals or populations who are disadvantaged in their access to basic services.

The right to a standard of living adequate for the health and well-being of a person and their family has been broadly protected in international law since the inception of the United Nations (UN) and is recognised in The universal declaration of human rights. This general protection was further interpreted by the UN Committee on Economic, Social and Cultural Rights in declaring that people have a right to access quality health care and that states have basic duties, within the availability of resources, to provide their citizens with access to adequate and affordable health care.5

As is the case with human rights, fundamental ethical principles and values may be used to guide the development and assessment of health care systems, policies and practices. These principles and values include respect, justice, solidarity, altruism, transparency and effectiveness and efficiency.6 While all of these principles and values are important, they will not always be equally important in any given situation. Judgments will always be needed as to what weight should be attached to each principle or value and how the obligations arising from each principle or value should be satisfied.

These principles and values may be defined as follows.

**Respect** — The right of all individuals to be treated with dignity and to have their autonomy respected (i.e. respect for self-determination based on an individual’s particular set of values, preferences, and beliefs).

In the context of ART, the principle of respect extends to all individuals or couples involved in ART activities, individuals or couples considering ART activities and the persons who would be born as a result of ART.

**Justice** — Justice is concerned with equality and fairness and is one of the core principles upon which society and its institutions (including health care systems) are based. Forms of justice relevant to the provision of health care include:

- distributive justice: fair, equitable, and appropriate distribution of benefits and burdens in society determined by justified norms that structure the terms of social cooperation
- social justice: the exercise of justice within a society, including recognition of causes of social inequality and the moral necessity to address them
- procedural justice: fairness in the processes that allocate resources and resolve disputes, which provides a means for making health resource decisions even where there is disagreement about which principles should govern priority setting and what constitutes justice in health care.

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Solidarity — The concept of ‘standing together’ as a group, community or nation, which reflects a collective commitment to share ‘costs’ (financial, social, emotional or otherwise) to assist others.

Altruism — The principle or practice of seeking the welfare of others, with no expectation of personal reward or gain.

Transparency — The open disclosure of clear and accurate information about activities and decision-making processes.

Effectiveness and efficiency — The principle of effectiveness requires that waste is reduced, practices that clearly don’t work are not used, and proven measures that are likely to succeed are implemented. Effectiveness, or utility, is linked to the concept of efficiency, which requires that limited resources be used in the most productive manner possible.
3 Application of ethical principles in the clinical practice of ART

The nature of ART raises a number of particular ethical issues and dilemmas. This is because of:

- the cultural and social importance attached to reproduction and to children
- the complex biological connections and social relationships that occur in the context of, or as a result of, ART
- the difficulty in balancing the needs and concerns of individuals or couples, donors and persons born as a result of ART
- the different views regarding the status attributed to human embryos and the moral acceptability of ART itself
- the risks involved in ART, and the inevitable uncertainties that exist where scientific progress is rapid and is quickly translated into clinical practice.

The clinical practice of ART should therefore ensure the balanced consideration of all relevant ethical principles. These Ethical Guidelines recognise that ethical questions cannot be completely separated from their social, economic, technological, cultural and political context and so may be addressed differently in different situations and at different times.

The ethical principles in Chapter 2 aim to support the clinical practice of ART so that, regardless of the situation, health professionals have an ethical framework to guide clinical consideration and decision-making. More than one principle may need to be considered in a specific situation.

3.1 ART activities must be conducted in a way that shows respect to all involved.

Clinical decisions must respect:

- women and intended parents
- gamete and embryo donors
- persons born as a result of ART.

While there are different views held in the Australian community about the status attributed to a human embryo, there is wide agreement that embryos warrant serious moral consideration.

3.2 Decision-making in the clinical practice of ART must be undertaken in a manner that protects from harm each individual or couple involved in ART activities and any persons who would be born.

Before, during and after treatment, the individual’s or couple’s psychological and physical wellbeing should be supported as far as possible. With their consent, this may include access to counselling facilitated by a health professional with the appropriate training, skills, experience and competency to counsel in reproduction.

Decisions regarding any procedures or the use of gametes or embryos, should take into account any potential harm to the person who would be born, the views of the intended parent/s, any medically relevant factors, and the likelihood of a successful live birth.

In the course of clinical practice, clinicians must limit the number of embryos created to those likely to be needed by the individual or couple in the course of their treatment.
ART may have serious consequences for the person born. An individual or couple considering undertaking ART should therefore give serious consideration to the psychological and physical wellbeing of the person who would be born.

3.3 Decision-making in the clinical practice of ART must recognise and take into account the biological connections and social relationships that exist or may be formed.

The significance ascribed to a biological connection varies considerably from person to person. For some people, their connection to their biological parents, surrogate, half-siblings and other biological family members is very significant. For others, this biological connection has little or no significance.

If a person born as a result of ART is deprived of knowledge about their biological connections, they are also deprived of the ability to decide the level of significance these connections will hold for them. When a person born from donated gametes wants to establish contact with their biological parent(s) and/or their other biological family members, but is unable to do so, the effect on that person may be substantial.

Consideration about biological connections and social relationships is important for potential gamete donors, and for those considering the use of donated gametes, donated embryos, and/or surrogacy, or considering the posthumous use of gametes.

3.4 Decision-making about ART activities must recognise and respect the autonomy of each individual or couple involved

Individuals and couples involved, or considering involvement in, ART activities have the right to decide for themselves whether or not to take part in the proposed activities. It is important to recognise that social relationships and social context may enable, shape, or constrain an individual’s or couple’s autonomy (i.e. autonomy is relational).

Individuals or couples involved, or considering involvement in, ART activities are entitled to the provision of detailed, accurate, contemporary and relevant information about proposed procedures or treatment and to receive appropriate counselling about the consequences or risks of those procedures or treatment.

Valid consent must be obtained from all relevant parties for each specific procedure or treatment. The process of obtaining consent for ART activities is an ongoing process and not a single event.

When the individual involved does not have the capacity, or is not able, to provide valid consent (e.g. children, adult with impaired decision-making capacity), a representative should be involved in the discussions and decision-making.

3.5 Processes and policies for determining an individual’s or couple’s eligibility to access ART services must be just, equitable and respectful of the inherent dignity and of the equal and inalienable rights of all persons.

Decision-making about access to ART must include explicit evaluation of the risks and benefits to the individual or couple as well as the person who would be born.

There must be no unlawful or unreasonable discrimination against an individual or couple on the basis of:

- race, religion, sex, marital status, sexual preference, social status, disability or age
- the reason(s) for seeking assisted conception
- refusal to participate in research.

The right of an individual or couple to accept or reject specific procedures or treatments should be respected. However, where the choice of an individual or couple is likely to have an adverse effect on the person who would be born, or have demonstrable adverse social impacts (e.g. the transfer of
multiple embryos at the one time), then it is appropriate that these potential adverse effects are taken into account in the decision-making regarding the procedure.

3.6 Donation of gametes or embryos or the provision of surrogacy services is an act of altruism and solidarity that provides significant benefits to those requiring assisted conception.

The availability of donor gametes and embryos and surrogacy services to members of the Australian community is wholly dependent on the preparedness of individuals or couples to consent to the altruistic donation of gametes or surrogacy services.

Gametes or embryos used for donor conception or the provision of surrogacy services must be obtained without undue pressure or inducement. While reimbursement of reasonable verifiable out-of-pocket expenses is ethically acceptable, providing payment that acts as an incentive is ethically unacceptable. It is unethical for individuals, or couples, to purchase, offer to purchase or sell gametes or embryos or surrogacy services.

3.7 The provision of ART must be transparent and open to scrutiny, while ensuring the protection of the privacy of all individuals or couples involved in ART and persons born.

Clinics must use an open and consistent approach to ART activities.

Clinics should maintain documented practices and procedures, identifying the line of responsibility for each. For example, specific protocols should be developed and implemented in relation to:

- the range of treatments and laboratory procedures
- access to, and eligibility for, treatment
- gametes and embryo donation (including allocation, counselling and eligibility of both donors and recipients)
- use, storage and discard of gametes and embryos
- provision of information and counselling to assist decision-making
- obtaining consent for treatment
- record keeping and data reporting
- investigation and resolution of complaints.

Detailed records must be maintained so that the short-term and long-term outcomes of ART activities can be assessed in order to document benefit and harm. The objectives of this are to maximise the availability of data for research, monitoring and professional oversight and to identify risks — and facilitate their correction — in order to minimise harm to all parties, including to the persons born.

Processes must be in place for audit and peer review of clinical decisions.

Conflicts of interest

There is a need to ensure that treatment remains patient centred, and not profit driven. Clinics should ensure the disclosure of any interests, including any financial interests, of the clinician(s) relating to the services provided by the clinic or any treatment or procedure recommended by the clinician.

Privacy

All individuals and couples involved in ART activities, including gamete and embryo donors, and persons born, are entitled to privacy. Clinics must respect the privacy of each party and the confidentiality of all records and must have a privacy policy that ensures compliance with relevant legislation.

Conscientious objection

A member of staff or student who expresses a conscientious objection to the treatment of an individual patient or to an ART procedure is not obliged to be involved in that treatment or procedure. The clinic...
must allow him or her to withdraw from involvement and ensure that he or she is not disadvantaged because of a conscientious objection.
INTRODUCTION

Individuals and couples involved, or considering involvement, in ART activities are entitled to participate in decision-making about such involvement. In the context of ART, it is important to recognise that social relationships and social context may enable, shape, or constrain an individual’s or couple’s decision-making. Valid consent must be obtained from each relevant party for each specific treatment or procedure. Central to the provision of valid consent for ART procedures is informed decision-making which involves provision of accurate and contemporary information relevant to the circumstances. Decision-making should be supported by the provision of access to counselling by a health professional with the appropriate training, skills, experience and competency to counsel in reproduction.

INFORMATION GIVING

4.1 Provide and discuss all relevant information - General requirements

4.1.1 Clinics must ensure that all relevant information is discussed 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, religious beliefs and personal circumstances
- in a way that is accessible to those with low literacy or disability, or whose first language is not English
- in a way that avoids any pressure or inducement.

4.1.2 Clinics must ensure that appropriate information is discussed, for example:

- options for the use or discard of gametes or embryos, including options that are legal, but may not be offered at the particular clinic (see paragraph 4.1.3)
- whether the proposed procedure or treatment is accepted practice or an innovative practice, acknowledging areas of uncertainty (see paragraph 10.1)
- the experience of the clinic and the clinician with the procedure and clinically relevant outcomes and success rates
- any interests of the clinician, including financial interests, relating to services provided by the clinic or any treatment or procedure recommended by the clinician, which may reasonably be perceived as a conflict of interest (see paragraph 3.7)
- an explanation of all costs involved for relevant parties. Clinics should provide the patient with sufficient information regarding the likely fees and the associated out-of-pocket expenses so that the patient is able to make an informed financial decision
- the clinic’s privacy and record keeping policies, including an explanation of any mandatory uses of data (see paragraphs 4.6.9 - 4.6.10)
- any planned or possible clinical follow-up
- options for participation in a current research study or any possibility of future requests for participation in research studies.

4.1.3 Before gametes are collected or embryos are created, clinics must ensure that all responsible parties are provided with sufficient information to allow an understanding of the options they
will have regarding the use, storage and discard of the gametes or embryos, including those which are legal, but are not available are the particular clinic. Options include:

- use in their own or their partner’s reproductive treatment (including the potential for posthumous use - see paragraph 8.16)
- donation to another individual or couple for use in reproductive treatment (see Chapters 5 and 6) and the potential for this donation to be re-allocated to a subsequent individual or couple (see paragraph 6.2.1)
- use in research (see Part C of these Ethics guidelines)
- use in training or quality assurance activities (see paragraphs 10.4 and 10.7)
- transfer to another clinic in cases where the desired option for the use or discard is not available at the initial clinic
- discard of the gamete or embryo.

4.1.4 Individuals and couples should be allowed adequate time for consideration of the information discussed and have the opportunity to seek further information, before consent is provided.

4.2 Provide and discuss all relevant information - Specific situations

Women and couples undergoing ART

4.2.1 In addition to the requirements outlined in paragraph 4.1, clinics should ensure that the information discussed with women and couples undergoing ART is sufficient to facilitate an accurate understanding of the following issues:

- the likelihood of the woman becoming pregnant other than through ART
- the likelihood of the woman becoming pregnant via the proposed reproductive procedures, referencing conditional factors including the woman’s age, the number of cycles previously undertaken and recent and meaningful success and failure rates relevant to the particular woman or couple
- any risks involved in the proposed procedures to either the woman or embryo to be created
- the likelihood and significance of potential short-term or long-term physical and psychosocial implications for the person who would be born and the woman or couple
- the currently available published data on morbidity, and long-term and short-term outcomes for persons born through ART, including for future generations.

Individuals and couples involved in donor conception programs

4.2.2 Clinics must consider the information needs of both donors and recipients. In addition to the requirements outlined in paragraph 4.1, clinics should ensure that the following information is discussed:

- the possible implications and long-term psychosocial consequences of gamete or embryo donation for the donor/s and their families, the recipient/s and their families, and the person who would be born
- the arrangements of the clinic for collection, storage and release of identifying information
- any difficulties in finding gamete or embryo donors, including those related to specific preferences expressed by recipients
- Draft -

- the scope of consent, decision-making responsibilities and the rights of each person involved to withdraw consent (see paragraphs 5.10 – 5.11, 6.2 and 6.4)

- the responsibilities of each party to all other parties in the proposed reproductive procedure

- the legal rights and responsibilities of the gamete or embryo donor and the intended parent/s in the jurisdiction in which the clinic is located, or the gametes or embryos are used

- for women considering participation in a donor egg program, the possibility that this may affect her own fertility.

4.2.3 In addition to the information outlined in paragraph 4.2.2, potential gamete or embryo recipients need information about the history of the gamete donor (or gamete providers in the case of embryos) that is relevant for the care of the person who would be born. 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:

- medical history, family history and any genetic test results that are relevant to the future health of the person who would be born (or any subsequent offspring of that person) or the recipient of the donation

- details of the physical characteristics of the gamete donor

- the number, age and sex of persons born from the gametes provided by the same gamete donor and the number of families involved.

Individuals and couples seeking to store gametes or embryos

4.2.4 In addition to the requirements outlined in paragraph 4.1, clinics should ensure that the following information is discussed:

- 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

- the currently available information about outcomes for persons born from stored gametes or embryos

- any legal or other limitations to use, including posthumous use

- any limitations on storage times, and any circumstances under which the clinic may dispose of the gametes before the end of the consent period (see paragraphs 7.2 and 7.6)

- the responsibilities of each party (including the clinic’s) for stored gametes or embryos (see paragraphs 5.10, 6.2 and Chapter 7).

Individuals and couples seeking ART treatment or procedures overseas

Overseas clinics may operate in an environment that does not adhere to Australian standards of care, and the clinical services available may perpetuate donor anonymity, or include treatments or procedures which are considered unethical under these Ethical Guidelines.

4.2.5 Where an individual or a couple has made an autonomous decision to seek ART treatment or procedures overseas, the Australian clinician’s ethical obligation to provide appropriate advice and health care to his/her patient/s remains. The Australian clinician should provide advice regarding any concerns about the standard of care in the overseas clinic, or acknowledge where the standard of care is unknown.
COUNSELLING

ART involves complex decision-making and individuals and couples may find it an emotional and stressful experience. Clinics have an ongoing responsibility to provide access to counselling services to support the individuals involved and their decision-making. The types of counselling required may change throughout the treatment process or between each procedure.

4.3 Provide counselling services - General requirements

4.3.1 Clinics must provide readily accessible counselling services from health professionals with appropriate training, skills, experience and competency to support individuals and couples in making decisions about their treatment, before, during and after the procedures. Clinics should actively encourage participation and keep a record of participation. The counselling services should:

• provide an opportunity to discuss and explore issues
• explore the personal and social implications for the person/s born and for the individual or couple
• provide personal and emotional support for the individual or couple, including help in dealing with adverse or undesired results
• provide advice about additional services and support networks
• reflect an integrated, multidisciplinary approach, including medical, nursing, scientific and counselling staff
• provide individuals or couples with information, when requested, about professional counsellors who are independent of the clinic or who have specific expertise (e.g. genetic counselling).

4.3.2 Clinics should ensure each individual makes their own independent decision to participate in counselling and that this decision is reached without undue pressure. In some circumstances, participation in counselling is mandatory (see paragraphs 4.4, 8.9.2 and 8.15.2).

4.3.3 The provision of counselling should be differentiated from the assessment of suitability to participate in an ART treatment program.

4.4 Provide counselling services - Specific situations

Individuals and couples involved in donor conception programs

4.4.1 Individuals and couples involved in a donor conception program must undergo counselling because of the complex nature of the issues involved. In addition to the requirements outlined in Paragraph 4.3, counselling must include a detailed discussion of the following:

• the potential long-term psychosocial implications for each individual and each family involved, including the person who would be born
• the reason/s why the gamete or embryo provider had become involved in a donated gamete program
• the potential significance of the biological connection, the right of persons born to know the details of their genetic origins, and the benefits of early disclosure
• the possibility that persons born may learn about their genetic origins from other sources (for example from family members or pathology testing) and may independently access information about their conception
• the possibility that persons born may attempt to make contact with the donor/s in the future.
4.4.2 The use of an embryo created using both donor sperm and a donor egg (double donation) may have an increased psychological impact on the person who would be born due to the range of biological connections and social relationships that would be created and the potential significance of these for any persons born. When double donation is being considered, counselling should acknowledge the complexity of this practice.

**Individuals and couples involved in the reallocation of an embryo**

4.4.3 All relevant parties involved in the reallocation of a human embryo should undergo specialised counselling to support decision-making, with consideration given to the potential long-term psychological implications for a person born from an embryo that has undergone multiple reallocations.

**Individuals and couples involved in ART activities that require specific ethical consideration**

Chapter 8 provides information on additional counselling requirements for ART activities which require specific ethical consideration, including the collection, storage and use of gametes from:

- children and young persons
- people who are dying and unable to give consent
- deceased persons

and for individuals or couples seeking:

- surrogacy
- pre-implantation genetic testing.

**VALID CONSENT**

Individuals and couples involved in ART activities have the right to decide for themselves whether or not to take part in the proposed activities. Valid consent must be obtained from all relevant parties for each specific treatment or procedure. The process of obtaining consent for ART activities is an ongoing process and not a single event.

4.5 Obtain consent from all relevant parties for each specific procedure - General requirements

4.5.1 Clinics must ensure that the valid consent for each specific procedure is obtained from all relevant parties and remains current. For consent to be valid:

- the person giving consent must be considered by the treating clinician to have the capacity to provide valid consent
- the decision to consent to the treatment or procedure must be made without undue pressure
- sufficient information about the treatment or procedure must be made available, including the benefits and risks
- the consent must be specific, and is valid only in relation to the treatment or procedure for which information has been given.

4.5.2 The process of seeking consent should include:

- provision of all relevant information about the proposed treatment or procedure to the individual or couple, and discussion of this information (see paragraphs 4.1 and 4.2)
- provision of access to counselling by a health professional with the appropriate training, skills, experience and competency has been offered (see paragraphs 4.3 and 4.4)
4.5.3 Clinics should have procedures to verify the identity of those providing consent and to ensure the validity of the consent.

4.5.4 Consent should be obtained in writing and documentation should include a signed statement by the supervising clinician confirming that he or she has provided and discussed all relevant information with all relevant parties, and provided access to appropriate counselling services.

4.6 Obtain consent from all relevant parties for each specific procedure - Specific situations

Individuals and couples involved in donor conception programs

4.6.1 In addition to obtaining the valid consent of the parties involved with each specific procedure (see paragraph 4.5), clinics must ensure that, where appropriate, valid consent for the donation of gametes is obtained from a potential donor’s spouse or partner, due to the potential implications for that couple’s existing or future children.

4.6.2 Consent for the donation of gametes or embryos should include:

- provision of full details of the agreed arrangements for any treatment involving donated gametes or embryos (see Chapter 5 and 6)
- provision of advice to all parties about the donor’s biological connection to any person who would be born using donated gametes or embryos, the potential significance of this connection to the person born and the benefits of early disclosure (see paragraph 3.3)
- obtaining an acknowledgment from each party that they have received and understood the information provided about gamete or embryo donation (see paragraphs 4.1 and 4.2.2-4.2.3), including an acknowledgement of the decision-making responsibilities of each party, as described in paragraphs 5.10 and 6.2
- obtaining explicit permission from the donor to make relevant information available to the recipients and any person born as a result of the procedure (see paragraphs 4.2.3 and 5.8).
- obtaining explicit permission from the potential recipient/s to make the information available, on request, to the donor and an acknowledgement of their responsibility to the donor (see paragraphs 5.7.1 - 5.7.2).

4.6.3 Potential gamete or embryo donors and gamete or embryo recipients should be allowed adequate time for consideration of information and the complex issues involved before consent is obtained.

Individuals and couples seeking to store gametes or embryos

4.6.4 In addition to the requirements for obtaining consent outlined in paragraph 4.5, clinics must obtain separate consent from each relevant party before gametes or embryos can be stored.

4.6.5 Consent should include consideration of:

- the duration of storage
- the use, storage or discard of gametes or 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 specified in the consent form.

4.6.6 Clinics should ensure that consent is regularly reviewed by the person(s) responsible for the stored gametes or embryos to ensure that it remains current.
Non-mandatory uses of data

4.6.7 In addition to the requirements for obtaining consent outlined in Paragraph 4.5, clinic should ensure that specific consent is obtained from individuals or couples involved in ART for any planned or future non-mandatory uses or disclosures of identifying information or data collected about them (see Paragraph 4.1.2).

Additional situations

Additional consent requirements for the collection, storage and use of gametes from children and young persons, people who are dying and unable to give consent, and deceased persons are outlined in Chapter 8.

Additional consent requirements for innovative practice, training activities, quality assurance activities, and research are outlined in Chapter 10.

4.7 Recognise the right of individuals or couples to withdraw or vary their consent

4.7.1 Clinics must recognise that, with the exception of some specific issues relating to the donation of gametes and embryos (see paragraphs 5.11.1 and 6.4.1), individuals and couples have the right to withdraw or vary their consent for ART activities at any time.
5 Use of donated gametes in reproductive treatment programs

INTRODUCTION

The gametes used in ART activities can either be provided by the spouse or partner of the person receiving treatment, or provided by a donor. This chapter provides ethical guidelines for the use of donated gametes.

Gametes may be donated to a specific recipient who is known to the donor (‘known donation’) or to anyone who is receiving ART treatment (‘unknown donation’).

ACCEPTING AND ALLOCATING GAMETE DONATIONS

5.1 Respect the donor’s wishes

5.1.1 If the donor specifies recipients he or she knows personally (known donation), clinics must respect the wishes of the donor.

5.1.2 Clinics must not accept donations from any donor who wishes to place conditions on the donation that the gametes are for the use only by individuals or couples from particular ethnic or social groups, or not to be used by particular ethnic or social groups. This type of donation (‘unknown directed donation’) is considered unethical on the basis that it is discriminatory and inequitable.

5.1.3 Donors wishing to direct their donations can only do so through known donation.

5.2 Consider the physical, psychological and social wellbeing of each party when accepting or allocating gamete donations

5.2.1 In accepting gamete donations, or when allocating donated gametes to potential recipients, clinicians must carefully consider the physical, psychological and social wellbeing of the person who would be born, the gamete recipient/s and gamete donor/s. Clinics may refuse treatment or delay treatment (pending further review) if there are concerns about the physical, psychological and/or social wellbeing of any party.

Children and young people

5.2.2 Clinics must not accept donations from children and young people (who are defined as ‘minors’ in each jurisdiction) for use by others in a reproductive procedure.

Donation from a relative

The donation of gametes between relatives (e.g. between sisters, from daughter to mother) requires special consideration because of the possible influence the relationship, or the family, will have on the potential donor’s decision to donate and the impact of potentially confusing family relationships.

5.2.3 Clinics should not fertilise an egg with sperm that is equivalent to a sexual relationship with a close genetic relative, as defined by relevant legislation.

Older donors

5.2.4 The risk of an abnormality occurring in the person who would be born increases with the advancing age of the gamete donor. Therefore, clinics should not use gametes provided by older donors unless the potential recipient understands and accepts the implications and increased risks of proceeding with such an arrangement.
Donors with an increased risk of infectious disease

5.2.5 Clinics must meet regulatory requirements and have policies and procedures in place to minimise transmission of infectious diseases from the donor to the recipient or the person who would be born. These policies and procedures will change in response to emerging evidence.

5.3 Limit the number of persons born from a single donor

5.3.1 Clinics must take all reasonable steps to minimise the numbers of genetic relatives created through donated gamete treatment programs to protect persons born through the use of donor gametes, and the donors of gametes, from the potential harms of having a sexual or long-term romantic relationship with an unknown genetic relative.

5.3.2 Gametes from a single donor should be used to create a limited number of families. Where specific legislation does not exist, clinics should take account of the following factors when deciding on an appropriate the number of families:

- the number of genetic relatives that the persons born from the donation will have
- the risk of a person born from 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)
- any limitations expressed as part of the consent from the donor
- whether the donor has already donated gametes at another clinic.

5.3.3 To encourage their disclosure of multiple donations at multiple clinics, potential gamete donors should be reminded of the importance of limiting the number of persons born from a single donor. Prior to donation, clinics should:

- ask potential donors whether they have donated at other clinics
- obtain consent from potential donors to contact other clinics about any previous donations

ACQUISITION OF DONATED HUMAN GAMETES

5.4 Provide reimbursement of verifiable out-of-pocket expenses

The current situation in Australia is that gamete donation must be altruistic, and that commercial trading in human gametes or the use of direct or indirect inducements is prohibited by law. This reflects concerns about the potential exploitation of donors (particularly women), the potential risks to all parties and that this could constitute the commodification of reproduction.

5.4.1 While direct or indirect inducements are currently prohibited, it is reasonable to provide reimbursement of verifiable out-of-pocket expenses associated with the donation, including:

- medical and counselling costs
- loss of earnings
- travel and accommodation costs
- insurance directly related to the donation
- legal advice.
5.5 **Use of imported gametes**

5.5.1 Treatment in Australia using gametes donated by people living in another country must not take place unless it can be established that the gametes were obtained in a manner consistent with any relevant Australian legislation, any relevant guidelines of any accreditation body and that all the requirements described in these guidelines are fulfilled.

**EXCHANGE OF INFORMATION BETWEEN ALL RELEVANT PARTIES**

There should be voluntary exchange of information between persons born from donated gametes, gamete donors and gamete recipients (the parents), with the valid consent of all parties. The guidelines in this section specify the minimum level of information that should be accessible to all parties in a donated gamete treatment program.

*For donations made prior to the introduction of the 2004 edition of these guidelines, please refer to paragraphs 5.12 – 5.13*

5.6 **Support the right to know the details of one’s genetic origins**

Persons born from donated gametes are entitled to know the details of their genetic origins, including the donor's medical and family history and identifying information about the donor/s and a safe process within which to explore the possibility of meeting with the donor/s.

Issues relating to disclosure of genetic origins are complex and require sensitive consideration of a range of salient ethical principles including: respect, privacy and confidentiality (see Chapter 2). The right of certain parties to know must be balanced against the rights of other parties to privacy.

5.6.1 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 person/s born from his or her gametes.

5.6.2 Clinics must not mix gametes in a way that allows the genetic origins of the person who would be born to be confused. This includes the attempted fertilisation of a human egg by human sperm from more than one donor at a time.

5.6.3 Clinics should help potential gamete donors to understand and accept the biological connection that they have with the person/s born from his or her gametes, acknowledging that the significance ascribed to a biological connection varies considerably from person to person. Potential gamete donors should be advised that persons born from his or her gametes are entitled to know the details of their genetic origins.

5.6.4 Potential recipients of donated gametes should be advised that persons born from donated gametes are entitled to know the details of their genetic origins.

5.6.5 Potential recipients should also be advised that persons born from donated gametes may learn about their genetic origins from other sources (for example from family members or pathology testing) and may independently access information about their conception.

Mandating that potential recipients disclose to their children their genetic origins is ethically problematic and is practically difficult and counterproductive. A more productive way to encourage this disclosure is for clinics to provide ongoing opportunities to support parents, to help them to understand the potential significance of the biological connection and the benefits of early disclosure, and to assist parents to find effective ways of disclosing to their children their genetic origins.

**5.7 Provide gamete donors with relevant information concerning persons born using his or her donated gametes**

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

5.7.2 Clinics should encourage gamete recipients to disclose to the clinic any information about the person born that might be relevant to the health of the donor, the donor’s offspring, or other persons born from the donated gametes.

5.8 Provide persons born from donated gametes with information about the gamete donor

People born from donated gametes are entitled to know the details of their genetic origins.

5.8.1 On request, clinics must arrange for either a medical practitioner, or an appropriately qualified health professional, to provide information to a person born from donated gametes, provided that he or she has either reached the age of 18 years or acquired sufficient maturity to appreciate the significance of the request (including any implications for his or her younger siblings). The following information must be provided as a minimum:

- all information specified in paragraph 4.2.3
- identifying information about the gamete donor, that the gamete donor has consented to being released (see paragraph 5.6.1)
- any identifying information that any person born from the gametes of the same donor have consented to being released (see paragraph 5.13.1).

5.9 Respect the privacy of all parties involved in ART procedures

All individuals and couples involved in ART activities, including gamete donors, and persons born, are entitled to privacy.

5.9.1 When approached by a person who was born from donated gametes who now seeks identifying information about his or her gamete donor, the clinic should examine the consent from 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 the 2004 edition of these Ethical Guidelines and the gamete donor has not come forward in response to the public information campaign, see paragraph 5.13), 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 should notify the gamete donor and release the information to the person requesting the information.

5.9.2 When approached by a person who was born from donated gametes who now seeks identifying information about others born from gametes donated from the same donor, the clinic examine the consent from the individual/s involved and proceed as follows:

- If consent has been registered by the individual/s concerned, the information may be released.

- If consent has not been registered, clinics should not release identifying information or contact the individual/s.

5.9.3 Clinics should encourage all individuals affected to accept counselling services as part of the preparation for the release of identifying information.
RESPONSIBILITY FOR GAMETES

5.10 Ensure that all parties are aware of who is responsible for donated gametes

Recipients of 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 gamete donor to withdraw his or her consent for donation also needs to be protected.

5.10.1 Clinics must maintain clear procedures for the transfer of responsibility for gametes and the resulting embryos at each stage.

- When the gamete donor has not specified a recipient for his or her gametes (unknown donation), the clinic has responsibility for decision-making about the use, storage and discard of the gametes, subject to any directions or limitations expressed in the consent of the donor.

- When the gamete donor has specified a recipient for his or her gametes (known donation), 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, the re-allocation of any excess embryos created using the donated gametes (see paragraph 6.1.3), and decisions regarding the storage and discard of the gametes or resulting embryo, subject to any directions or limitations expressed in the consent of the donor.

- The clinic is responsible for maintaining the appropriate storage of donated gametes (see Chapter 7).

WITHDRAWAL OF CONSENT FOR DONATION

5.11 Recognise the right of an individual to withdraw or vary his or her consent

5.11.1 A gamete donor can withdraw or vary consent for donation at any time before the treatment cycle of the recipient commences, or at any time before the creation of an embryo, whichever is sooner.

GAMETES DONATED PRIOR TO 2004 ON THE CONDITION OF ANONYMITY

Prior to the introduction of the 2004 edition of these guidelines, many donations received across Australia were done so on the condition of donor anonymity. It is recognised that there are conflicts between the rights of the persons born to know the details of their genetic origins and the rights of the donor to remain anonymous.

5.12 Use of gametes or embryos collected before 2004

5.12.1 Clinics should not use gametes or embryos collected before the introduction of the 2004 edition of these Ethical Guidelines without the consent of the gamete donor (or gamete providers for donated embryos) to the release of identifying information for any future treatments.

5.12.2 The only situations in which these gametes or embryos may be considered for use 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 the 2004 edition of these Ethical Guidelines using the same gamete donor, or

- where embryos created using donated gametes have been stored before the introduction of the 2004 edition of these Ethical Guidelines but the donor cannot be contacted.
5.12.3 In both circumstances described paragraph 5.12.2, the recipients should be given detailed information and offered further counselling about the benefits and risks associated with this arrangement for the persons born from donated gametes without consent to release of identifying information.

5.13 Establish and promote consent register for the release of information

5.13.1 Working in collaboration with relevant professional organisations, clinics should use forums for public information to encourage people who were gamete donors before the introduction of the 2004 edition of these Ethical Guidelines, and those born from these donated gametes, to consider contacting the clinic and registering their consent for the release of information about themselves (as outlined in paragraphs 4.2.3 and 5.8) to persons born from the donated gametes or genetic siblings and half-siblings, respectively.
INTRODUCTION

Embryos that are no longer required by the individual or couple for whom they were created may be donated to another individual or couple for use in their reproductive treatment.

Embryos may be donated to a specific recipient who is known to the donor (‘known donation’) or to anyone who is receiving ART (‘unknown donation’).

This chapter is to be read in conjunction with the guidelines in Chapter 5.

ALLOCATION OF DONATED EMBRYOS

6.1 Support the right to know the details of one’s genetic origins

6.1.1 Persons born from donated embryos are entitled to know the details of their genetic origins. Donated embryos (including those obtained from overseas, see paragraph 5.5.1), must therefore only be used in reproductive treatment if all of the requirements in Chapter 5 for donated gametes are met.

6.1.2 Clinicians must not practice any procedure that may confuse the genetic origin of the person who would be born, including the transfer to the uterus of a woman of embryos that include genetic material from more than one man and one woman, at any one time.

6.1.3 Where an embryo (including one created using donated gametes) is no longer required by the individual or couple for whom the embryo was created, clinics may re-allocate the embryo to another individual or couple, subject to any directions or limitations expressed as part of the consent from the embryo donor, or imposed by law and paragraph 4.4.3 (see also paragraph 6.2.1).

RESPONSIBILITY FOR DONATED EMBRYOS

6.2 Provide advice on who is responsible for donated embryos

Recipients of donated embryos need to know who is responsible for decision-making about the embryos used in their treatment. At the same time, the right of the gamete providers to withdraw consent for donation also needs to be protected.

6.2.1 Clinics must maintain clear procedures for the transfer of responsibility for embryos at each stage.

- The embryo donors are responsible for decision-making about the use, storage and discard of an embryo whilst it is in storage awaiting donation to an identified individual or couple (known donation), or allocation to an otherwise suitable individual or couple (unknown donation).

- The clinic is responsible for maintaining the appropriate storage of an embryo, as outlined in Chapter 7.

- In circumstances involving unknown donation, the clinic is also responsible for the allocation of an embryo to a suitable individual or couple.

- Once a recipient individual or couple has accepted an embryo for implantation they are responsible for decision-making about its use, storage and discard, including decisions
about the re-allocation of an embryo (see paragraph 6.1.3), subject to any directions or limitations expressed in the consent of the donor or imposed by law.

- When an embryo is reallocated to a subsequent individual or couple, and they have accepted an embryo for implantation, that individual or couple is responsible for decision-making about its use, storage and discard, including decisions about the re-allocation of embryos (see paragraph 6.1.3), subject to any directions or limitations expressed in the consent of the embryo donors or imposed by law.

DONATION OF EMBRYOS WITH A KNOWN GENETIC CONDITION

6.3 Encourage careful consideration when accepting the donation of an embryo known to be affected by a genetic condition

The donation of embryos known to be affected by a genetic condition should not be arbitrarily prohibited.

6.3.1 Clinics may use donated embryos with a known genetic condition only if the potential recipient understands and accepts the implications and potential risks associated with such an arrangement. These types of arrangements should proceed only after appropriate genetic counselling.

WITHDRAWAL OF CONSENT FOR DONATION

6.4 Recognise the right of individuals or couples to withdraw or vary their consent

6.4.1 The responsible party can withdraw or vary consent for donation (or reallocation) of an embryo at any time before the treatment cycle of the recipient commences.
7 Responsibilities of the clinic for stored gametes and embryos

INTRODUCTION

Individuals or couples responsible for stored gametes and embryos may need to make difficult decisions about the use, continued storage or discard of the stored gametes or embryos, including options that are legal, but may not be offered at the particular clinic. Before accepting gametes or embryos for storage, clinics must have ensured that the information discussed with the individual or couple responsible for the gametes or embryos was sufficient to facilitate their understanding of the future decisions they will face (see paragraphs 4.1.3 and 4.2.4). Clinics must have obtained valid consent for the storage of gametes and embryos (see paragraphs 4.6.4 – 4.6.6).

7.1 Maintain the safe storage and accurate identification of all gametes and embryos

Individuals and couples responsible for stored gametes and embryos are entitled to certainty about the safety and identity of the gametes or embryos.

7.1.1 Clinics must have procedures in place to ensure all reasonable efforts are taken to maintain the safe storage and accurate identification of all gametes and embryos. All procedures should be consistent with current best practice.

7.1.2 Clinics should keep gametes and embryos in safe storage for up to the maximum time specified in the consent form, after which, if the individual or couple responsible for the stored gametes and embryos cannot be contacted to provide further direction and consent, clinics may discard the gametes (see paragraph 7.6).

7.2 Assess the suitability for continued (long term) storage of gametes and embryos

Decisions about the continued (long term) storage of gametes or embryos involve both personal and clinical considerations. The suitability of gametes or embryos for continued storage is a clinical determination, however, if there is no evidence of deterioration, decisions about the continued storage of gametes may depend entirely on the personal preferences of the individual or couple responsible for the stored gametes or embryos.

7.2.1 Clinics should have policies that guide the clinical determination for continued storage of gametes and embryos.

7.3 Manage embryos no longer needed by an individual or couple for their own reproductive purposes

At any time during the period of storage of an embryo, the individual or couple for whom the embryo is stored, in consultation with their clinician, may decide that the embryo is no longer needed for their own reproductive purposes.

7.3.1 Clinics must have policies in place that document the basis of discussion about embryos no longer needed by an individual or couple for their own reproductive purposes.

7.3.2 Clinics must obtain a declaration in writing, from the individual or couple for whom the embryo is stored, that the embryo is no longer required for any clinical treatment. The options noted in paragraph 4.1.3 may then be offered.

7.4 Manage disputes between members of a couple for whom an embryo is stored

7.4.1 Clinics should have clear policies for managing disputes that may arise between a couple for whom an embryo is stored.

7.4.2 If a dispute involves the request from either party for continued storage, any maximum time limit for storage specified in the consent form (see paragraph 4.6.5) may be suspended at the request of either party. Such a suspension may be for a maximum of five years from when the
dispute arises, or until the dispute is resolved, whichever is sooner. If a resolution is not achieved within five years, the clinic should arrange for the embryos to be discarded.

7.5 Manage stored gametes or embryos following the death of a gamete provider

The use of gametes in reproduction requires the valid consent of the gamete provider or another party with appropriate legal authority (see paragraph 4.5).

7.5.1 Clinics should have clear policies for the management of stored gametes or embryos following the death of a gamete provider.

7.5.2 Clinics must not facilitate the use of a deceased individual’s stored gametes, or a stored embryo created using gametes from the deceased individual (subject to 6.2.1), unless:

- the individual left a clearly expressed directive that gives his or her consent to the posthumous use of the gametes; or
- another party with the appropriate legal authority provides his or her consent (see paragraph 8.16).

7.5.3 If the clinic receives confirmation that a gamete provider has died, the gametes or embryos must be stored and made available for the use or discarded, in accordance with the wishes of the deceased or another party with the appropriate legal authority to make such decisions (see Chapter 8).

7.6 Manage the discard of stored gametes or embryos

7.6.1 Clinics must have policies and procedures in place for discarding stored gametes and embryos. These policies should provide for individuals or couples responsible for the stored embryos to remove the embryos from the clinic for private burial.

7.6.2 Clinics may, in limited circumstances, discard stored gametes or embryos without the consent of the individual or couple for whom the gametes or embryos are stored (see paragraphs 4.2.4, 7.4.2 and 7.5.3).

7.6.3 Before a clinic may discard stored gametes or embryos without the consent of the individual or couple responsible for the stored gametes or embryos, clinics must document all attempts to notify the individual or couple and provide reasonable time for the individual couple to take action.
Some ART practices require specific ethical guidance, in addition to the guidelines provided in Chapters 4 – 7.

The following chapter provides additional ethical guidelines for:

- fertility preservation for living persons unable to provide consent
- surrogacy
- sex selection
- preimplantation genetic testing
- posthumous use of stored gametes and embryos and the collection and use of gametes from persons who are deceased or dying

Each of these practices warrants serious ethical consideration and may also be subject to specific state and territory legislation.
Fertility preservation for living persons unable to provide consent

INTRODUCTION

Certain medical conditions and/or treatments can harm a person's fertility. Fertility preservation is the collection and storage of a person’s gonadal tissue and/or gametes in an attempt to help the person retain their ability to procreate. This section provides guidelines for fertility preservation for living persons unable to provide valid consent.

8.1 Manage the collection and storage of gonadal tissue or gametes from persons unable to provide valid consent

8.1.1 Clinics should have policies in place for the collection and storage of gonadal tissue or gametes from persons unable to provide valid consent.

CHILDREN AND YOUNG PEOPLE

8.2 Assess ethical acceptability

8.2.1 The collection and storage of gonadal tissue or gametes for a child or young person may be ethically acceptable if:

- storage of the gonadal tissue or gametes is the only means of preserving the fertility of the child or young person
- the risks and discomfort of the non-therapeutic procedure to the child or young person are minimal
- there is an independent judgement that the collection and storage is in the child’s or young person’s overall best interests
- the child or young person, if capable (see paragraphs 8.4 and 8.5), and their parents, guardian or otherwise authorised person consents to the proposed collection and storage
- where required by law, a court or tribunal authorisation has been obtained
- the collection and storage is not for the reproductive needs of another individual (see paragraph 5.2.2).

8.3 Provide relevant information and counselling

8.3.1 Clinics should ensure that all relevant information is discussed with the person authorised to consent for the collection and storage of gonadal tissue or gametes from a child or young person (see paragraphs 4.1, 4.2.1 and 4.2.4).

8.3.2 In addition to the general requirements detailed in paragraph 4.3, clinics must provide readily accessible counselling services from health professionals with appropriate training, skills, experience and competency to support the authorised person/s responsible for making decisions on behalf of the child or young person.

8.3.3 Where appropriate, clinics should ensure that the child or young person has access to relevant information and appropriate counselling services (see paragraph 8.5).
8.4 Obtain valid consent

8.4.1 Clinics must ensure that the valid consent for each specific procedure is obtained from the person/s authorised to consent to the collection and storage of gonadal tissue or gametes from a child or young person (see paragraphs 4.5 and 4.6.4 - 4.6.6).

8.5 Respect the developing capacity of a child or young person to participate in decision-making

8.5.1 Clinics must respect the developing capacity of children and young people to be involved in decisions about the collection or ongoing storage of his or her gonadal tissue or gametes. When the child or young person is not legally competent but sufficiently understands the issues, clinicians should encourage the child to take part in the decision-making process.

8.5.2 When the child or young person reaches the appropriate age of consent, as determined by relevant legislation, clinics must manage the transition of responsibility for the stored gametes from the parents, guardian or otherwise authorised person. The individual’s valid consent must be obtained for the continued storage of his or her gonadal tissue or gametes (see paragraph 4.5).

PEOPLE WITH IMPAIRED DECISION-MAKING ABILITY

8.6 Obtain valid consent

8.6.1 Clinics should ensure that the collection and storage of gonadal tissue or gametes from a person with impaired decision-making ability, such as with a cognitive impairment, intellectual disability or a mental illness, is conducted in accordance with paragraphs 8.2 - 8.5.
Surrogacy

INTRODUCTION

‘Surrogate’ is a general term that refers to a woman who carries a pregnancy for another person. The person or couple who wishes to have a baby with a surrogate's help is known as the intended, or commissioning, parent or parents.

These guidelines apply where surrogacy arrangements require ART services.

There is legislation governing surrogacy in all Australian states and in the Australian Capital Territory. All persons involved in surrogacy must ensure they are familiar with relevant legislation and operate within the law.

The term commercial surrogacy refers to an arrangement where the surrogate receives financial compensation above and beyond expenses associated with the surrogacy procedure and pregnancy.

The term non-commercial surrogacy refers to an arrangement where the surrogate receives no financial compensation or inducement, beyond the reimbursement of verifiable out-of-pocket expenses directly associated with the surrogacy procedure or pregnancy.

The following terms address different surrogacy arrangements:

- **Traditional surrogacy** is where the woman carrying the child is also the egg donor. Her egg is usually fertilised with sperm from an intended male parent.

- **Gestational surrogacy** is where the woman carrying the child is not the egg donor. Gestational surrogacy is also called IVF surrogacy, host surrogacy or full surrogacy.

  In gestational surrogacy, the sperm and egg may be provided by one or both of the intended parents, or donated by a donor (or donors) known, or unknown to the intended parents. The egg is then fertilised using ART, and any resulting embryo is transferred to the gestational surrogate.

8.7 **Do not practice, promote or recommend commercial surrogacy**

Commercial surrogacy is ethically unacceptable because it has the potential for exploitation and to commodify the reproductive process. Commercial surrogacy is illegal in Australia.

8.7.1 Clinics and clinicians must not practice, promote or recommend commercial surrogacy, nor enter into contractual arrangements with commercial surrogacy providers.

8.7.2 Where an individual or a couple has made an autonomous decision to enter into a surrogacy arrangement at a clinic overseas (commercial or otherwise), the Australian clinician’s ethical obligation to provide appropriate advice and health care to his/her patient/s remains. The Australian clinician should provide advice regarding any concerns about the standard of care in overseas clinics, or acknowledge where the standard of care is unknown (see paragraph 4.2.5).

8.8 **Assess the ethical acceptability of non-commercial surrogacy**

8.8.1 Clinics should ensure that arrangements for non-commercial surrogacy are ethically evaluated on a case-by-case basis. Evaluation of a traditional surrogacy arrangement should include the possible increased risks to the wellbeing of all parties involved, including the person who would be born. Traditional surrogacy is currently illegal in some Australian states and territories.
INFORMATION GIVING, COUNSELLING AND CONSENT

8.9 Provide relevant information and counselling

8.9.1 In addition to the requirements outlined in paragraph 4.1, in any non-commercial surrogacy arrangement, clinics must ensure that each party:

- is provided with sufficient information to facilitate an accurate understanding of the ethical, social and legal implications of the arrangement, including any state or territory specific legal implications
- is fully informed about their medical, psychological and social risks and benefits under the arrangement

8.9.2 Individuals and couples involved in a non-commercial surrogacy arrangement must undergo counselling because of the complex nature of the issues involved. In addition to the requirements outlined in Paragraph 4.3, counselling must include a detailed discussion of the following issues:

- the social and psychological implications for the person who would be born as a result of the arrangement
- the potential significance of biological connections for the person born as a result of the arrangement.

8.10 Obtain consent from all relevant parties

8.10.1 In addition to obtaining the valid consent of the parties involved with each specific procedure (see paragraph 4.5), clinics must ensure that, where appropriate, valid consent for the surrogacy arrangement is obtained from a potential surrogate’s spouse or partner, due to the potential implications for that couple’s existing or future children.

ACQUISITION OF SURROGACY SERVICES

8.11 Provide reimbursement of verifiable out-of-pocket expenses

8.11.1 While direct or indirect inducements for surrogacy services are currently prohibited in Australia, it is reasonable to provide reimbursement of verifiable out-of-pocket expenses associated with the procedure or pregnancy, including:

- medical and counselling costs
- loss of earnings
- travel and accommodation costs
- insurance directly related to the procedure or pregnancy
- legal advice.

Arrangements for any reimbursement should be between the intended parent/s and the surrogate and each party should be encouraged to seek independent legal advice before reimbursements are given or received.

EXCHANGE OF INFORMATION BETWEEN ALL RELEVANT PARTIES

8.12 Provide persons born with information about the surrogate

8.12.1 The minimum level of information detailed in paragraph 5.8 should also be available to a person born as a result of a surrogacy arrangement.
Sex selection

Please refer to Appendix 3 - 'Issues for further discussion in the clinical practice of ART'.
Preimplantation genetic testing

INTRODUCTION

Preimplantation genetic testing (PGT) comprises two techniques:

• preimplantation genetic diagnosis

• preimplantation genetic screening.

Preimplantation genetic diagnosis (PGD) is currently used to detect serious genetic conditions of which the intended parent/s are known to be at risk, to carry or to be predisposed. In rare circumstances PGD is used to select an embryo with compatible tissue for subsequent stem cell therapy for a sibling. PGD is commonly recommended for intended parents with chromosomal translocation and with known carrier status of serious genetic conditions.

Preimplantation genetic screening (PGS) is used to screen for unspecified and multiple genetic or chromosomal anomalies in embryos from parents who do not have any diagnosed genetic condition. It may be performed to improve live birth rates (by improving pregnancy rates from embryo transfer and reducing incidence of miscarriage) and has been used in cases of advanced maternal age and repeated implantation failure.

PGT may be used to:

• prevent conditions that would seriously harm the person who would be born

• select the sex of an embryo to reduce the risk of transmission of a serious genetic condition

• improve ART outcomes.

PGT may not be used to select in favour of a genetic defect in the person who would be born.

8.13 Assess the ethical acceptability of PGT to select against a serious genetic condition

8.13.1 The use of preimplantation genetic testing requires serious ethical consideration because:

• what might be considered a ‘serious genetic condition’ is controversial and may change over time as new effective treatments become available

• there are differing perceptions of genetic conditions held within the community

• the practice of selecting against some conditions may threaten the status of, and equality of opportunity for, people who have that condition

• the procedures may involve the unnecessary discard of some healthy embryos

• the procedures have technical limitations (such as the failure to identify the condition of interest).

8.13.2 It is not possible to definitively assign genetic conditions as ‘serious’ or ‘non-serious’ as context is important. Clinicians should consider the following criteria when assessing the ethical acceptability of the use of PGT:

• current evidence and expert opinion on the impact of the condition of the life of the person who would be born, including the anticipated symptoms, age-of-onset and the degree/spectrum or severity of the condition

• the concerns of the intended parent/s about their ability to financially and emotionally care for a person born with the condition
the available therapies or interventions to reduce the severity, delay onset or minimise the impact of the condition

the likelihood of false positive and false negative results

the distinction between the genotypic and phenotypic expression of the condition

the variable range of effects of the condition, 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 of the condition now and in the future

the extent of social support available to the intended parent/s and to the person who would be born.

8.13.3 Clinicians should seek advice from a clinical ethics committee, where appropriate.

8.14 Assess the ethical acceptability of PGT to select an embryo with compatible tissue for a sibling

The use of PGT for the purposes of tissue typing an embryo for subsequent stem cell therapy for a sibling may be ethically acceptable as this practice recognises biological relatedness, is beneficial to the recipient and does not result in physical harm to the person who would be born.

8.14.1 PGT to select an embryo with compatible tissue for subsequent stem cell therapy must not be used for the planned treatment of a person other than a sibling.

8.14.2 Clinicians must seek advice from a clinical ethics committee (or relevant state or territory regulatory agency) before undertaking PGT to select an embryo with compatible tissue for subsequent stem cell therapy. The clinical ethics committee or relevant agency should ascertain that:

• the wish of the parents is to have another child as an addition to their family and not merely as a source of stem cells

• the use of PGT will not adversely affect the welfare and interests of the person who would be born

• the medical condition of the sibling to be treated is life-threatening and other means to manage the medical condition are not available.

INFORMATION GIVING AND COUNSELLING

8.15 Provide relevant information and counselling and access to a genetic counsellor

To make informed decisions, it is essential that women or couples who seek PGT understand the technology and how it applies to their embryos.

8.15.1 In addition to the requirements outlined in paragraph 4.1, clinics should ensure that the following information is discussed:

• the limitations of the technology, including the likelihood of false positive and false negative results

• genetic and clinical information about any relevant condition, disease or abnormality

• their previous reproductive experience
• the distinction between the genotypic and phenotypic expression of relevant condition, disease or abnormality

• the variable range of effects of any relevant condition, disease or abnormality, including the likely rate of degeneration in the case of progressive disorders

• the experiences of families living with any relevant condition, disease or abnormality

• the likely availability of effective therapy or management of relevant condition, disease or abnormality now and in the future

• the extent of social support available to them and their offspring.

8.15.2 In addition to the requirements outlined in paragraph 4.3, clinics must ensure that women or couples seeking PGT have access to a genetic counsellor.
Posthumous use of stored gametes and embryos and the collection and use of gametes from persons who are deceased or dying

POSTHUMOUS USE OF STORED GAMETES OR EMBRYOS

8.16  Respect the wishes of the person for whom the gametes or embryos were stored

After a person has died, the use of their stored gametes or embryos may be prohibited by state or territory legislation.

8.16.1  Where permitted by law, clinics may facilitate the posthumous use of stored gametes or embryos to achieve pregnancy, if the deceased person left clearly expressed directions consenting to the use after death of his or her stored gametes, or a stored embryo created using his or her gametes (see paragraphs 4.6.5 and 7.5). Clinics must ensure the provision of relevant information and access to counselling (see paragraph 8.20.1).

COLLECTION OF GAMETES FROM A PERSON WHO IS DYING AND HAS THE CAPACITY TO PROVIDE VALID CONSENT

8.17  Obtain valid consent

8.17.1  Clinics may facilitate the collection of gametes from a person who is dying if he or she has the capacity to give clearly expressed directions and has consented to the use of their gametes for reproductive purposes after their death (see paragraph 4.5). Clinics must ensure the provision of relevant information and access to counselling (see paragraph 8.20.1) prior to the collection of the gametes.

COLLECTION OF GAMETES FROM A DECEASED PERSON OR A PERSON WHO IS DYING AND LACKS THE CAPACITY TO PROVIDE VALID CONSENT

8.18  Obtain valid consent from a spouse or partner with the legal authority to do so

In many circumstances, it is generally accepted that close relatives are able to make decisions for a relative who has died, or is dying, and is unable to or lacks the capacity to provide valid consent. This includes decisions regarding health care and the donation of organs and tissues. The acceptability of a spouse or partner making decisions regarding the collection of gametes however warrants serious ethical consideration because of the enduring consequences of these decisions on any person who would be born and the potential for the spouse or partner to have a conflict of interest (i.e. a grieving spouse or partner may be focussed on their own desire to have a child, rather than the broader implications for the person who would be born, or the wishes of the person who is deceased or dying).

8.18.1  Where permitted by law, clinics may facilitate the collection of gametes from a deceased person or a person who is dying and lacks the capacity to provide valid consent if:

- at a minimum, there is no evidence that he or she has previously expressed that they do not wish this to occur
- his or her spouse or partner provides valid consent (see paragraph 4.5) to the collection of the gametes
- the proposed collection has been reviewed and authorised by an independent body with the legal authority to do so
- prior to the collection of the gametes, relevant information and access to counselling is provided (see paragraph 8.20.1).
USE OF GAMETES FROM A DECEASED PERSON OR A PERSON WHO IS DYING

8.19 Allow sufficient time for grieving and counselling before attempting conception

8.19.1 The decision to collect gametes from a deceased or dying person is usually made in a relatively brief time frame. Given the enduring significance of the decision to use these gametes, a final decision about the use of the gametes should be made only after:

- sufficient time has passed so that grief and related emotions do not interfere with decision-making
- the surviving prospective parent (the spouse or partner) receives relevant information and access to counselling (see paragraph 8.20.1)
- an independent body with the legal authority to do so has reviewed the circumstances and confirmed that the conditions above have been satisfied.

INFORMATION GIVING AND COUNSELLING

8.20 Provide relevant information and counselling

8.20.1 In addition to the requirements outlined in Paragraph 4.1 clinics must ensure that the surviving prospective parent (the spouse or partner):

- is provided with sufficient information to facilitate an accurate understanding of the ethical, social and legal implications of the proposed activity, including any state or territory specific legal implications
- has access to appropriate counselling services (see paragraph 4.3)
- gives consideration to the social and psychological implications for the person who will be born after the death of a parent.

8.20.2 Clinicians should seek advice from a clinical ethics committee, where appropriate, and, if necessary, advice regarding the application of relevant laws.
9 Record keeping and data reporting

INTRODUCTION

Record keeping and data reporting is an integral part of the clinical practice of ART. There is a duty of care to all parties, especially to the persons born, to ensure that there is appropriate maintenance of records and data. Good record keeping is also essential for short-term and long-term follow-up of procedures and to facilitate the sharing of information between relevant parties.

Ideally data should be collected and maintained in a centralised register as is the case with bone marrow and transplant registries. At the time of writing, such a register does not exist.

RECORD KEEPING

9.1 Maintain appropriate records - general requirements

9.1.1 Clinics must have appropriate policies and procedures for the collection, storage and release of data related to ART activities.

9.1.2 Clinics must maintain records that are adequate to allow:

- monitoring of, and access to data regarding the creation, storage, use and discard of embryos (see paragraph 3.2)

- collation of clinic specific and national statistics about reproductive treatments and procedures, to assist individuals and couples considering ART to make informed decisions about their involvement in ART activities (see paragraphs 4.1.2, 4.2.1, 4.2.4 and 9.1.5).

- where applicable, the exchange of information between a gamete donor, recipient and person born as a result of donation (see paragraph 9.2)

9.1.3 Clinics must manage records so that the integrity and privacy of the records comply with all requirements of relevant commonwealth, state or territory legislation and any requirements of applicable accrediting bodies.

9.1.4 Clinics should have procedures for record keeping that include:

- the collection, recording and reporting of data about persons, treatments, procedures and results

- arrangements to ensure transfer of records to a suitable person or location (e.g. a central register or another clinic) when a clinic closes, a clinician ceases to practice or gametes or embryos are transferred to a sperm, egg or embryo bank or another clinic (see paragraph 4.1.3)

- provision to keep records indefinitely (or at least for the expected lifetime of any persons born), including the regular review of the format in which the records are stored to ensure their ongoing accessibility.

9.1.5 As a minimum, the following information should be recorded for each ART activity:

- full names (including previous names) and contact details of all individuals and couples involved and, whenever possible, the names of any person born as a result of the activity

- consent forms, and record of participation in counselling services
• identification details of gametes and embryos so that the clinical status or outcome for each individual embryo, egg or sperm sample can be followed from the date of collection (see paragraph 7.1)

• the outcomes of the activity (including innovative practice) for the embryo, the person born and the individuals or couples involved. This data should be recorded in a form that will facilitate the collation of national statistics about reproductive treatments and procedures (see paragraph 9.1.2). The recorded outcomes should include:
  - the live birth rate per treatment cycle commenced
  - the occurrence of single and multiple pregnancies, miscarriage, termination of pregnancy, ectopic pregnancy, stillbirth, genetic conditions or perinatal events
  - any serious adverse effects and other side effects for the woman or fetus during treatment

• data to facilitate long-term follow-up studies of persons born as a result of ART activities, and the individuals or couples involved (e.g. rates of long-term adverse outcomes and subsequent fertility).

9.2 Maintain appropriate records - Donor conception programs

9.2.1 Clinics must ensure that all relevant information about parties involved in donor conception programs (see 4.2.3, 5.7.1 and 5.8) is recorded so that this information is available to potential recipients of the donation, any persons born and/or the gamete or embryo donors.

9.2.2 Clinics should have procedures in place to inform potential gamete donors (or gamete providers for donated embryos) that it is his or her ethical responsibility to keep the clinic informed about any changes to his or her health that may be relevant to any person born or the recipients of their donation, and about changes to their contact details (see also paragraph 5.7.2).

9.2.3 Information about all parties involved in a donor conception program must be kept indefinitely, in a way that is secure but is accessible to any relevant party (see paragraphs 4.2.3, 5.7 and 5.8).

REPORTING OF DATA

9.3 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 all parties involved, including persons born as a result of ART and to the general public.

9.3.1 Clinics should make non-identified data, including data relevant to licensable activities (see Chapter 10), available to appropriate bodies, to enable subsequent collation of national statistical information (see paragraph 9.1.2).

9.3.2 Reporting of data should comply with requirements of relevant privacy legislation, state or territory legislation, NHMRC guidelines, and any accrediting bodies. Any non-mandatory use or reporting of data should be subject to the consent of the individuals or couples involved (see paragraph 4.6.9 and 4.6.10).
10 Innovative practice, training, quality assurance and research

INNOVATIVE PRACTICE

10.1 Evaluate innovations before routine use in clinical practice

The introduction of changes to clinical treatment, or the use of innovative procedures, may have short-term or long-term consequences for the persons born and/or the individual or couple undergoing the treatment.

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

10.1.2 Significant changes to routine clinical practice, for example, those that may place any patient, gamete, embryo and/or person who would be born at any increased risk, or innovations in procedures, practices or therapies must be considered as research and formal approval of the research must be obtained from a Human Research Ethics Committee (HREC), even where only one individual or couple is involved.

10.1.3 If there is any doubt about whether a proposed practice change constitutes research, this should be referred to an HREC for advice.

10.1.4 Any change in routine clinical practice should be subject to audit.

10.2 Provide relevant information and obtain valid consent

10.2.1 Where an innovative treatment or procedure is proposed, clinics must ensure that all relevant information is discussed with all relevant parties, and valid consent is obtained (see paragraphs 4.1.2 and 4.5).

TRAINING

10.3 Facilitate ongoing training of clinicians and laboratory staff

10.3.1 To ensure high standards of clinical care, clinics must have an ongoing training program for clinicians and laboratory staff involved in the ART activities available at the clinic. Training activities may:

• occur as part of the clinical treatment of an individual or couple (see paragraphs 4.6.11 – 4.6.14)

• involve the use of an excess ART embryo

• involve the fertilisation of a human egg by a human sperm up to, but not including, the first mitotic division.

10.4 Obtain valid consent

10.4.1 Clinics must ensure that valid consent is obtained for any training activities undertaken during an individual or couple’s reproductive treatment (see paragraph 4.5).

10.4.2 Where an embryo is no longer required by the individual or couple responsible for the embryo (see paragraphs 4.1.3 and 7.3.2), and the excess embryo is made available for use in training, clinics must ensure that specific consent is obtained for such use. This consent must be separate from consent for any treatment and must be obtained after the embryo has been deemed excess.
10.5 Obtain a license for the use of an excess ART embryo, or the creation of an embryo, for training activities

10.5.1 Under the Research Involving Human Embryos Act 2002 (RIHE Act), a licence is required for any training activity that involves the use of an excess ART embryo or the fertilisation of a human egg by a human sperm up to, but not including, the first mitotic division (RIHE Ast, s10). Consent, in accordance with the National Statement, must be obtained before any excess ART embryo or human eggs are used for licensed training activities.

QUALITY ASSURANCE

10.6 Conduct quality assurance activities

10.6.1 To ensure high standards of clinical care, clinics must conduct regular quality assurance activities.

10.6.2 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.

10.6.3 As the distinction between quality assurance and research is not always clear, clinics should consult the National Statement and the NHMRC document Ethical Considerations in Quality Assurance and Evaluation Activities, 2014 for advice on whether or not the quality assurance activity requires the approval of a Human Research Ethics Committee.

10.7 Obtain valid consent

10.7.1 Clinics must ensure that valid consent is obtained for any quality assurance activities undertaken during an individual or couple’s reproductive treatment (see paragraph 4.5).

10.7.2 Where an embryo is no longer required by the individual or couple responsible for the embryo (see paragraphs 4.1.3 and 7.3.2), and the excess embryo is made available for use in quality assurance activities, clinics must ensure that specific consent is obtained for such use. This consent must be separate from consent for any treatment and must be obtained after the embryo has been deemed excess.

10.8 Obtain a license for the use of an excess ART embryo, or the creation of an embryo, for quality assurance activities

10.8.1 Clinics must ensure that a licence is obtained for any quality assurance activity that involves the use of an excess ART embryo.

RESEARCH

10.9 Obtain valid consent

10.9.1 Clinics should ensure that separate consent is obtained from individuals or couples regarding future contact for participation in follow-up research (see paragraph 4.1.2).

10.9.2 Where an embryo is no longer required by the individual or couple responsible for the embryo (see paragraphs 4.1.3 and 7.3.2), and the embryo is made available for use in research, clinics must ensure that consent is obtained for such use. This consent must be separate from consent for any treatment and be obtained after the embryo has been deemed excess. Use of an embryo in research may be a licensable activity under the RIHE Act (see Part C of these Ethical Guidelines for further guidance).

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PART C

Ethical guidelines for research

Part C of the Ethical Guidelines is not under review. Editorial revisions (e.g. cross-references, chapter numbers) will be made to Part C once Parts A and B have been finalised.

AHEC is not seeking comment on Part C of the ART guidelines and such comments will not be considered as part of this consultation.
APPENDICES
1 A history of NHMRC’s involvement in developing ethical guidelines for ART and the role of the ART guidelines in the regulation of the clinical practice of ART

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 1966). These guidelines were rescinded when the NHMRC Act came into force in 1992.

Since 1992, the Australian Health Ethics Committee (AHEC) has developed and revised the following ethical guidelines

- Ethical Guidelines on Assisted Reproductive Technology, 1996
- Ethical Guidelines on the use of assisted reproductive technology in clinical practice and research, 2004

The 2004 guidelines took account of the Prohibition of Human Cloning Act 2002 (PHC Act) and the Research Involving Human Embryos Act 2002 (RIHE Act). These guidelines were revised in 2007 to the extent necessitated by changes to the PHC Act and the RIHE Act brought about by the Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006 (refer to Appendix 2 for further information).

Accreditation of ART clinics

All persons and bodies offering ART services must obtain accreditation by the recognised accreditation body, the Reproductive Technology Accreditation Committee, established by the Fertility Society of Australia. The accreditation of ART clinics is the basis of a nationally consistent approach for overseeing ART clinical practice.

Following a recommendation in the 1996 ethical guidelines, accreditation requires ART clinics to comply with government laws and guidelines concerning the practice of ART, including NHMRC guidelines.

State and Territory ART legislation

The regulation of the clinical practice of ART is the responsibility of the state and territory governments. At the time of writing, only four Australian states have such legislation:8

- Victoria – Assisted Reproductive Treatment Act 2008
- New South Wales – Assisted Reproductive Technology Act 2007
- Western Australia – Human Reproductive Technology Act 1991
- South Australia – Assisted Reproductive Treatment Act 1988

Since 1996, AHEC has recommended that legislation be enacted in the all states and territories, noting that without uniform legislation, the regulation of national data collection and the maintenance of a centralised registry cannot be achieved.

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8 Note: states and territories may have specific legislation concerning certain ART practices, including surrogacy and donor conception.
2 National legislation on embryo research and human cloning

In 2002, the Australian Parliament passed the Prohibition of Human Cloning Act 2002 (PHC Act) and the Research Involving Human Embryos Act 2002 (RIHE Act) to prohibit human cloning and regulate certain uses of an embryo that is no longer required by an individual or couple responsible for the embryo ('excess ART embryos').

The RIHE Act also established the Embryo Research Licensing Committee (referred to in these Ethical Guidelines as the Licensing Committee) as a new principal committee of the National Health and Medical Research Council (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.


Further information on the national legislation on embryo research and human cloning, licensable activities and the NHMRC Embryo Research Licensing Committee can be found on the NHMRC website (www.nhmrc.gov.au).
## 3 Issues for further consideration in the clinical practice of ART

### INTRODUCTION

Many of the issues surrounding ART are as much social and political issues as they are ethical issues. Attitudes towards some of the more controversial practices and aspects of ART differ considerably, and are shaped by an individual’s own particular set of values, preferences, and beliefs.

In general, a significant change to current practice deserves careful consideration in order to determine whether the change should be welcomed enthusiastically, tolerated within limits, met with disquiet or even prohibited by law.

This appendix provides a brief outline of three such issues in the clinical practice of assisted reproductive technology:

- the use of sex selection for non-medical purposes
- the compensation of Australian women for the reproductive effort and risks associated with donating their eggs
- the establishment of an Australian donor egg bank.

In each instance, the Australian Health Ethics Committee (AHEC), having carefully considered these matters, agreed that further public consultation is required. Each issue affects people other than the person who wishes to use the practice, are subject to Commonwealth and/or state and territory legislation and are matters for community debate and discussion.

With regard to the first issue, the use of sex selection for non-medical purposes, AHEC agrees that public consultation on this matter would be enhanced through the exploration of some of the complex ethical and social issues raised by non-medical sex selection, through the use of illustrative case studies. Case studies have been presented to demonstrate and highlight the complexities associated with introducing non-medical sex selection in Australia and to provide interested members of the public with an understanding of these complexities in a public policy context.

AHEC is also seeking comment on whether or not to compensate Australian women for the reproductive effort associated with donating their eggs. The current draft of the public consultation document has guidance for the reimbursement of verifiable out-of-pocket expenses and AHEC would like to explore whether compensation for reproductive effort is a matter for a future version of these guidelines.

Lastly, AHEC wishes to explore the ethical issues that might arise if a donor egg bank was to be established in Australia.

AHEC wishes to ensure that the discussion of these issues is well-informed and, in particular, is not dominated by any particular interest group.
3a Sex selection for non-medical purposes

Background information

The current guidelines on the use of assisted reproductive technology in clinical practice and research (ART guidelines) prevent the use of sex selection for non-medical 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” (paragraph 11.1, 2007 edition).

This current 2007 guidance on sex selection was subject to public comment during the first round of consultation that took place on these guidelines in 11 March - 30 April 2014. The comments received on this matter were mixed, with some respondents supporting the use of sex selection for non-medical purposes, while others did not.

In considering the matter of sex selection as part of the review of the current guidelines, the Working Committee recognised that the current situation in Australia may need to be reconsidered.

The Committee also recognised that there are practical and ethical reasons to support continuing with the current position of not allowing sex selection for non-medical reasons.

In considering the matter of sex selection following public consultation, the Committee was cognisant of a range of relevant factors, including:

- Existing state and territory legislation regulating ART. The state and territory governments are responsible for regulating of the clinical practice of ART.

- The regulation of sex selection internationally. Sex selection for non-medical purposes is illegal in four states in America, in Europe, New Zealand and in parts of Asia. The current Australian position is not out of step internationally.

- International travel for sex selection. Sex selection is available in some countries and Australians are accessing sex selection at overseas clinics. Some of these clinics do not have the same standard of care that exists in Australia and people may be exposing themselves, and possibly the person who would be born as a result, to risks and harms.

- Evidence that some adverse events may be slightly increased in children conceived following ART compared to natural conceptions.

- Values inherent in Australian society that relate to freedom of choice and autonomy, particularly in relation to reproductive choices.

- Whether sex selection for non-medical reasons is a valid use of medical resources.

- The possibility that sex selection for non-medical reasons may reinforce gender stereotyping, and create pressure on the person born to conform to parental expectations regarding gender.

- The possibility that allowing sex selection for non-medical reasons may lead to a slippery slope of allowing testing to take place for other characteristics such as height, intelligence and sporting prowess.
Comment invited

AHEC is seeking further public comment on the matter of non-medical sex selection in a more focussed way. The Working Committee has developed a range of case studies that illustrate the issues that arise.

While comment is sought on the entire content of the draft Ethical Guidelines, AHEC is particularly interested in your views as to whether the current position on sex selection should be relaxed and, if so, what boundaries should be on the practice and why. Issues and questions are raised at the end of each case study to prompt further thought and reflection. You are welcome to comment directly on the questions raised or about the topic more generally.

Case Studies

Case study 1 - family balancing

**Scenario A**
The couple have no children and are planning to have two children. They have decided that they wish to have only boys. They would like to use sex selection techniques to ensure the sex of both children will be male.

**Scenario B**
The couple have a daughter, and wish to have only two children. They would like to use sex selection techniques to ensure that their second child is male.

**Scenario C**
A couple have two male children and wish to have a third child. They would like to use sex selection to ensure that their third child is female.

**Scenario D**
A husband and wife are part of a group which preferentially values one gender as part of their culture. The wife feels vulnerable because the two children they have are not of their preferred gender. She is anxious that they cannot afford more than three children and that if the next child is the same sex as their first two, she will be seen as a failure by her own and her husband’s wider family. The couple are seeking to use sex selection techniques for their next child.

**Issues:**
Family balancing is a term that is hard to define. If sex selection was allowed for family balancing then some guidance around what constitutes ‘family balancing’ would need to be included in the guidelines.

1. Is sex selection more appropriate in one of these scenarios than another?
2. As Scenario C is the most common example of ‘family balancing’ would it be ethically acceptable to allow sex selection for Scenario C, but not the other scenarios?
Case study 2 – replacement of a child

A couple had a daughter, who dies in a car accident at the age of three. Two years after the death of their daughter, the couple wish to have another child. They have had extensive counselling to help manage their grief. They appreciate that another child will not replace their loss, and that every child is unique who will grow into a unique adult, and have covered this in counselling.

Scenario A
The couple enjoyed having a daughter, and they now wish to use sex selection techniques to have another daughter.

Scenario B
The couple do not wish to have another daughter because she will remind them of their loss, and they now wish to use sex selection techniques to have a son.

Issues
3. Is the use of sex selection techniques ethically acceptable in these scenarios?
4. Does the need to respect the wishes of the intended parents override the need to respect the child who would be born?

Case study 3 – travelling overseas for sex selection

Scenario A
A couple travel to an overseas clinic where the woman becomes pregnant. On return to Australia, the woman is hospitalised for several months to treat infection acquired at the clinic overseas. Once recovered, the pregnancy proceeds without any further complications and a healthy girl is born.

Scenario B
A couple travel to an overseas clinic for sex selection. Because of the man’s infertility, they also use donor sperm. The pregnancy proceeds with no complications, and a healthy girl is born. The family talk openly about the fact that the daughter was donor conceived. In her late teenage years, the daughter wishes to learn about her genetic origins. She is devastated to discover that, because the donation was made on the condition of anonymity, she is prevented from accessing any information about the sperm donor.

Scenario C
Following an ART procedure overseas involving sex selection, and the transfer of three embryos, scans confirm that the woman is carrying triplets and the pregnancy is now considered high risk. The triplets are born early and one baby has severe neurological defects as a complication from the premature birth. The couple is traumatised by the experience and are concerned about their long term health care costs.

Issues
Some overseas clinics do not have the same standard of care that exists in Australia and people may be exposing themselves, and possibly the child/ren who would be born as a result, to risks and harms.
5. Should the only option available to Australians who feel strongly about parenting a particular sex be to have sex selection performed overseas?
6. Should the children that are born as a result of ART conducted overseas be exposed to practices that are not ethical in Australia, such as the right to know their genetic parents and or multiple embryo transfer?
Case study 4 - respecting parental autonomy

Scenario A
Brendan was 18 when his parents told him that they had chosen his sex before his birth. He was shocked and angry. “I shouldn’t be surprised!” he said to his best friend Erin. “Mum and Dad have always controlled everything about my life. I’ve always said that when you look up ‘helicopter parents,’ there’s a picture of my folks. So I shouldn’t be surprised that even before my birth they were already controlling me.”

Scenario B
A couple have two sons. Whilst the mother loves both her sons, she longs for the mother-daughter relationship that she didn’t have with her own mother. The mother’s mental health has diminished as she mourns the loss of a daughter she’s never had. She feels the only path to happiness is through the birth of a daughter.

The couple access sex selection technology overseas and are delighted at the birth of their daughter. As the daughter grows, it becomes clear that she will not fulfil the ‘girly’ dreams of the mother and has not formed the mother-daughter bond that the mother desired. The mother’s mental health remains diminished and this has now affected the mental health of her daughter.

Issue
There is a lack of empirical evidence to demonstrate that sex selection is either damaging or not damaging to children born as a result of the procedure. However, children who discover that their sex was predetermined by their parents may experience negative psychological reactions/feelings, particularly if they feel they are not living up to their expectations.

7. Should parents have this much control over the children they are proposing to bring into the world?
8. Should parental autonomy be respected over the need to respect the child who would be born and their right to an open future?

Case study 5 - other potential uses of sex selection

A couple have a four-year old boy who is severely affected by autism. They wish to have another child. However, they are anxious that their second child may also be affected by autism. They have been advised by their clinician that the occurrence of autism has a bias towards males (1 in 63 children, 1 in 42 boys), and that because they have one child who is severely affected, there is chance that their subsequent children will also be affected.

As the genetic causes of autism are not known, the couple is unable to use PGD to select against autism. The couple wishes to use sex selection to select a female embryo, to reduce the risk of autism in their second child. However, sex selection is unavailable to them for this purpose. The couple conceive naturally and have a boy who is also severely affected by autism.

Issues
Had the family been able to choose the sex of their child, their chances of having a child with autism may have been reduced.

9. Is the use of sex selection techniques ethically acceptable in this scenario?
3b Compensation of Australian women for the reproductive effort and risks associated with donating their eggs

Background information

In Australia, trade in human gametes is prohibited by state and territory and Commonwealth law. However, the 2007 ART guidelines permit the ‘reimbursement of reasonable out-of-pocket expenses associated with [ART] procedures’ for gamete donors.

The 2007 guidelines do not specify what out-of-pocket expenses may be appropriate and between March - April 2014 when the guidelines underwent public consultation, comments were sought on the following two questions:

1) Should more guidance be given about the reimbursement of expenses?

2) Should it be permissible for Australian women to be compensated for the reproductive effort and risks associated with donating their eggs?

The 2014 public consultation submissions supported defining and/or clarifying what types of expenses could or could not be reimbursed. Based on this feedback, specific guidance as to what ‘reasonable out-of-pocket expenses’ might include has been provided in the revised draft Ethical Guidelines (see paragraphs 5.4.1 and 8.11.1). For example:

- medical and counselling costs
- loss of earnings
- travel and accommodation
- insurance directly related to the procedure
- legal advice.

The draft Ethical Guidelines also require such expenses to be verifiable.

Following the 2014 public consultation, AHEC looked to policies regarding compensation of gamete donors in countries with similar ethical and legal foundations to Australia, including the United Kingdom (UK). Women in the UK have been able to receive a fixed rate of moderate compensation, in addition to the reimbursement of reasonable, verifiable out-of-pocket expenses, for the donation of eggs since 1 April 2012. The UK Human Fertilisation and Embryology Authority (HFEA) was consulted to obtain any available data on the success, harm or impact of the capped payment system for human eggs since its introduction in the UK (see Box 1 for further information).

The Committee considered whether it could be ethical for Australian women to receive compensation for the reproductive effort and risks associated with donating their eggs and whether such compensation would constitute ‘reimbursement’.

Opinions on the compensation of Australian egg donors received during the 2014 public consultation were varied and are summarised below:

Reasons given in support of allowing Australian women to receive compensation for the reproductive effort and risks associated with donating their eggs

- Compensation may increase the number of Australian egg donors, and therefore the number of donor eggs available; leading to a reduction in the number of Australian’s undertaking ART
overseas. This outcome may be desirable as:

- It may lead to a reduction in the potential exploitation of unregulated international markets.

- Procurement of a human egg within Australia, and its subsequent use in reproductive treatment would be regulated by the existing ART guidelines and relevant legislation. For example, the person born would be able to know their genetic origins.

- Overseas clinics may operate in an environment that does not adhere to Australian standards of care.

- Compensation of a modest, capped amount for each attempt to collect eggs from a woman (not per egg collected) may recognise the burden and risk faced by a woman donating her eggs. The woman would be compensated for undergoing the procedure, and not for the eggs themselves. Therefore the woman would be compensated regardless of whether the procedure was successful or how many eggs were collected. The amount of compensation would not be of such significance that it acts as an inducement and compromises valid consent.

- The establishment of an egg bank in Australia, in a manner similar to existing cord blood banks, could allow for greater regulation of compensation and reduce the potential exploitation of the system (see also Appendix 3c).

**Reasons given for opposing compensation for the reproductive effort and risks associated with donating eggs**

- Compensation of a modest, capped amount may act as an inducement and compromise valid consent. An inducement provides the potential for the exploitation of vulnerable women, particularly those with no or low income.

- Compensation is not compatible with the notion of altruism, and is akin to the trade in human gametes.

**Comment invited**

These Ethical Guidelines do not include a proposal to compensate Australian women for the reproductive effort and risks associated with donating their eggs. While comment is sought on the entire content of the draft Ethical Guidelines, AHEC is interested in your views on whether Australia should consider the introduction of compensation for reproductive effort, similar to the United Kingdom, in the future.
Box 1 - Compensation in the United Kingdom (UK)

The Human Fertilisation and Embryology Authority (HFEA) undertook public consultation on its donation policies in 2011. Views were sought from clinics, the public and other interested stakeholders on various issues, including the compensation of gamete donors.

As a result of public consultation, from 1 April 2012 clinics in the UK have been able to compensate sperm donors a fixed sum of up to £35 (approx. A$67) per clinic visit, and egg donors a fixed sum of up to £750 (approx. A$1440) per cycle of donation.

The HFEA has recently carried out a preliminary assessment of the impact of this regulatory change. Although the assessment was limited in scope, some highlights of this assessment included:

- total number of donor cycles increased.
- sperm donation steadily increased year on year, though there may not be as good awareness of it as egg donation.
- the number of imported sperm increased, most likely because it is an easy and efficient process for UK clinics
- there continues to be difficulty for clinics to find the right type of donor that the patient requests, this is partly why clinic import sperm
- egg donation has increased, this might be because of increased compensation, awareness and marketing by clinics.

On the basis of this assessment, and other anecdotal evidence, the HFEA believes that the regulatory change has resulted in:

- a reduction in waiting times for donor gametes at some clinics
- a surplus of donors available at some clinics, with some clinics no longer referring patients overseas to access egg donors.

HFEA has also advised that:

- clinics rarely compensate donors for excess expenses, suggesting that the amount is set at the right level
- although compensation is a factor when considering donation, the desire to help others is seen as the key motivation for donors.

Further information is available: [http://www.hfea.gov.uk/9370.html](http://www.hfea.gov.uk/9370.html). Further analysis on the impact of this regulatory change, including both quantitative and qualitative data is anticipated to occur by 2018.
3c Establishment of an Australian donor egg bank

Background information

Although there may be eggs banks established within individual Australian clinics, or within a group of affiliated clinics, currently, there is no formally established or national donor egg bank in Australia. Donor egg banks are established in both the United Kingdom (UK)⁹ and the United States of America (USA)¹⁰.

The establishment of a donor egg bank in Australia may:

- increase the availability of donor eggs in Australia, thereby reduce the number of Australians travelling overseas for reproductive treatment
- facilitate greater regulation of a reimbursement and/or compensation system and reduce the potential exploitation of such a system
- facilitate a centralised register for donation records, and make access to such records easier for donor-conceived individuals
- reduce the number of embryos discarded.

In theory, there are three methods by which a woman can donate her eggs:

- donation of any stored eggs following completion of a woman’s own reproductive treatment
- undertaking ART to produce and collect eggs for the sole purpose of donation
- agreement between a woman and a clinic to donate a proportion of eggs collected for her own reproductive treatment, in exchange for a reduction in the cost of her own ART treatment (known as ‘egg sharing’).

In the UK, egg sharing is commonly practiced and is licenced by the Human Fertilisation and Embryology Authority (HFEA). Egg sharing is often used by women/couples in the UK to fund their reproductive treatment when the woman/couple is not eligible for government funding, or has reached funding limits. However, in Australia, under Medicare, there is no limit on the number of funded treatment cycles and egg sharing is not currently practiced nor encouraged. The Australian Health Ethics Committee (AHEC) does not support the practice of egg sharing in Australian clinics.

AHEC wishes to further explore the ethical issues that might arise if a donor egg bank was to be established in Australia.

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⁹ e.g. http://www.ngdtc.co.uk/become-an-egg-donor
¹⁰ e.g. https://www.donoreggbankusa.com/, http://www.theworldeggbank.com/
Illustrative Case Studies

Case study 1 - profit from the supply of donated eggs
A woman has twice undergone ART to produce and collect eggs for the sole purpose of donation. Each donation included the collection of twenty mature eggs. She contacts the egg bank and is told that five families have been established as a result of her donations and a number of embryos have been created and are being stored for these families’ future use.

Scenario A
The woman was reimbursed for the verifiable out-of-pocket expenses associated with her donations. The woman donated her eggs altruistically, and is satisfied that five families have benefited from her donations.

Scenario B
The woman was reimbursed for the verifiable out-of-pocket expenses associated with her donations, however, the woman feels exploited and has some regrets about her donations when she realises that the egg bank and clinic have profited from the services provided as a result of her donations.

Scenario C
The woman was reimbursed for the verifiable out-of-pocket expenses associated with her donations, and received a modest, capped amount for each attempt to collect eggs. The woman does not feel exploited or coerced as she received compensation for her reproductive effort.

Scenario D
The woman was reimbursed for the verifiable out-of-pocket expenses associated with her donations, and received a modest, capped amount for each attempt to collect eggs. Upon reflection, the woman feels that she was exploited and the receipt of compensation for her reproductive effort acted as an inducement for her donations.

Scenario E
The egg bank is able to recover the costs involved with the procedure to collect the eggs and costs incurred for the storage, processing, transport and administration of the donation. These costs are recovered from the clinic involved in the recipient’s treatment. The clinic providing treatment to the recipient is then able to recover all costs from the recipient.

In this scenario, neither the donor, egg bank nor the clinic profited financially from the supply of the eggs.

Case study 2 - eggs previously stored for fertility preservation purposes
A 29 year-old woman chooses to have some of her eggs collected and stored on the grounds that she has not yet met a suitable reproductive partner and in hope of preserving her fertility. She paid to have twenty eggs collected and paid for ten years storage upfront.

At the age of 34, she met her partner and naturally conceived two children with him. After deciding that their family is complete, she decides to donate the twenty stored eggs to the egg bank but asks that the egg bank reimburse her for the costs incurred in storing the eggs at the clinic, arguing that this is a verifiable out-of-pocket expenses incurred in her donation.
Case study 3 – collection of a small number of eggs

Scenario A
A woman decides to donate eggs to the egg bank and produces four eggs suitable for storage and donation. Because eggs are allocated only in groups of six, the egg bank discards the woman’s four eggs. The egg bank is not able to recover costs involved with the procedure to collect the eggs from a recipient.

In this scenario, as compensation is for undergoing the procedure, and not for the eggs themselves, the woman is compensated with a modest, capped amount. When she asks to donate again, the clinic tells her that she is not a suitable donor because of the small number of eggs previously collected.

Scenario B
Instead of discarding the four eggs collected in Scenario 1, the egg bank has the alternative of combining this donation with the donation of an additional two eggs collected from another donor and providing the combined donation of six eggs to a clinic for a suitable recipient. Processes are in place to ensure that the genetic origins of the eggs remain traceable and the clinic will know which egg was successfully implanted. A potential recipient undergoes counselling and it is explained that any siblings born may have different genetic origins. The potential recipient requests that the clinic make these eggs available to her at a reduced price of two-thirds of the usual fee. The clinic advises that the costs incurred in providing the eggs are per donation rather than per eggs and as such the fee stands.