Ethical guidelines for the clinical practice of ART – Part B of the Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research, 2007

Public consultation
March 2014
An invitation to make a submission

The National Health and Medical Research Council's (NHMRC) Australian Health Ethics Committee (AHEC) is conducting a review of Part B of the *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research, 2007* (ART guidelines).

Under Section 39 of the *National Health and Medical Research Council Act 1992* a Working Committee of experts has been established to advise AHEC on this review. The Assisted Reproductive Technology (ART) Working Committee includes:

- A Chairperson, independent of the ART consumer and provider
- Experts with an ability to identify ethical issues in relation to reproductive technology
- A person with a background in both religion and ethics
- Providers of ART services
- An expert in reproductive medicine (but not a provider of ART services)
- A person with knowledge of issues that concern people who access reproductive technology (consumer representation)
- A person with legal expertise in relation to reproductive medical practice
- A person with expertise in Reproductive Technology Accreditation Committee’s accreditation processes
- A person with an understanding of the concerns of people with a disability and/or genetic condition
The Membership of the Working Committee and their disclosed interests are publically available on the NHMRC website at www.nhmrc.gov.au/health-ethics/ethical-issues/assisted-reproductive-technology-art/review-part-b-ethical-guidelines-c

Background information about the ART guidelines is provided at Attachment A.

Public consultation

To inform the development of revised ethical guidance, the ART Working Committee is conducting a public consultation to seek comment on the current ethical guidance in Part B of the ART guidelines from a broad audience. At this stage in the review, the Working Committee has not proposed any revisions to the current ethical guidance; instead, the aim of this public consultation is to:

• determine the usefulness of the current ethical guidance,
• identify any gaps in the current ethical guidance,
• identify any new technologies, or new uses of old technology, that may require further or different ethical advice,
• inform the development of revised ethical guidance.

The Working Committee will consider all comments received regarding Part B to prepare revised ethical guidelines. The Working Committee is not seeking comment on Parts A or C of the ART guidelines and such comments will not be considered as part of this public consultation.

Further consultation will occur throughout the review process.

I am pleased to invite your feedback on Part B of the ART guidelines and encourage you to bring this public consultation to the attention of anyone with an interest in the clinical practice of ART.

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

Yours sincerely

[Signature]

Professor Warwick Anderson AM
Chief Executive Officer
Ethical guidelines for the clinical practice of ART
– Part B of the Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research, 2007

Copies of the consultation document are available from: http://consultations.nhmrc.gov.au or can be obtained by emailing ethics@nhmrc.gov.au.

The consultation document is provided at Attachment B. To assist with your submission; the Working Committee has proposed a number of questions at the beginning of each Section. You are not required to address these questions and are encouraged to comment on any aspect of Part B. If you choose to provide general comments, please be specific about which section or page of the document your comments refer to. This will avoid possible misinterpretation of your comments.

How to make your submission

Online submissions are strongly preferred via http://consultations.nhmrc.gov.au where a template for your response is available.

If online submission is not possible:

• To assist in administrative processes, it is asked that you use the template available from http://consultations.nhmrc.gov.au to complete your submission. It is also asked that you email a Word version (or equivalent) of your submission. If email is not possible, please make your submission in writing (preferably word processed) and submit it by mail.

• A form seeking authorship and other details is also included in the draft documentation. Please complete and attach the form to your submission. Submissions that do not have the completed form attached will not be accepted. Please note that it is acceptable to type your name in the signature box of the submission form as your electronic signature.

• If you would like your submission to be treated as confidential, please indicate this clearly, for example, by marking CONFIDENTIAL on each page.
As part of usual practice NHMRC places all submissions on the NHMRC website, unless individuals or organisations express any concerns about this.

If NHMRC posts submissions on the NHMRC website, all address information will be removed.

NHMRC is a Commonwealth agency subject to the Freedom of Information Act 1982 (the FOI Act). As such, your submission may be subject to an FOI request.

Where this occurs, NHMRC will need to assess whether your submission is covered by an exemption or a conditional exemption for release under the FOI Act. Where you have marked your submission as confidential, we may consult you before deciding whether to release your submission. We will consult you on whether your personal information should be excluded from the release of your submission.

For further information about the FOI Act, please visit the website at https://www.nhmrc.gov.au/about/contact/foi.htm.

Please email your submission to: email: ethics@nhmrc.gov.au or post to:

Project Officer – ART guidelines
Health & Research Ethics
Research Translation Group
National Health and Medical Research Council
GPO Box 1421
Canberra ACT 2601

Closing Date
5pm (AEDT) Wednesday 30 April 2014.

Further information

Further information can be obtained by contacting the Health & Research Ethics Section by email: ethics@nhmrc.gov.au.
Background information

NHMRC, through the work of AHEC, has been at the forefront of issuing ethical guidance on the use of assisted reproductive technology (ART) in clinical practice and research since 1992. *The Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research, 2007* (ART guidelines), in conjunction with state, territory and federal law, create a robust framework for the conduct of ART.

The ART guidelines is a principle-based document and is divided into three parts. Part A provides background and introductory material. Part B provides ethical guidelines for the clinical practice of ART and Part C provides ethical guidelines for research. Part C of the guidelines is consistent with the *Prohibition of Human Cloning for Reproduction Act 2002* (PHCR Act) and the *Research Involving Human Embryos Act 2002* (RIHE Act) (collectively ‘the Acts’).

The ART guidelines were issued in 2004 by NHMRC and updated in 2007 to reflect amendments to the Acts. These amendments were only applicable to Parts A and C of the ART guidelines.

**Interaction of the ART guidelines and the Reproductive Technology Accreditation Committee (RTAC)**

With respect to clinical practice, the ART guidelines remain fundamental in the accreditation processes for ART providers operating within Australia. As part of the national accreditation process, all ART providers in Australia adhere to the *Code of Practice for Assisted Reproductive Technology Units, 2010*, developed by the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia. The RTAC Code requires compliance with Australian laws and guidelines on the practice of ART. Accordingly, accredited ART providers consult the ART guidelines to assist in the ethical practice of ART.
Interaction of the ART guidelines and state/territory legislation

Four states have specific legislation that regulates the practice of ART. These are:

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

The first three states have each established a state regulatory body which issues licences to ART providers. In these four states, all, or part, of the ART guidelines have been incorporated into the legislation and/or regulations.


Attachment B

PART B

Ethical guidelines for the clinical practice of ART

Public consultation document
5 Ethical principles for clinical practice of ART

### QUESTIONS TO CONSIDER:

| Q1. | Have you encountered any difficulties in the interpretation and/or application of the current ethical guidance in Section 5 |
| Q2. | Do you think that there are gaps in the current ethical guidance in Section 5? |
| Q3. | Should Section 5 recognise the significance of the “biological connection” (e.g. between donor-conceived persons and the donors of gametes, between donor-conceived persons and their siblings or half-siblings, or between persons conceived from donated embryos and their genetic parents) as an additional ethical principle for the clinical practice of ART? (see also questions in relation to Paragraphs 6.1.1 and 6.1.2 and Section 9.2). |
| Q4. | Are there any further ethical principles for the clinical practice of ART which should be included in Section 5? |

#### Section 5.1

| Q5. | Is more guidance needed on what constitutes the ‘welfare of those involved’? |

#### Section 5.2

| Q6. | Paragraph 5.2.1 – Should there be exceptions to the restrictions/limitations on accumulating gametes/embryos in some situations? e.g. for fertility preservation in children, young people and adults undergoing chemotherapy, for the purposes of preimplantation genetic diagnosis, and/or for women with reduced ovarian reserve. |
| Q7. | Should there be a mandatory requirement for clinics to have policies and procedures around embryos which are excess to the requirements of patients? |

#### Section 5.3

| Q8. | Paragraph 5.3.1 – Should financial transparency be included in this list of protocols? |
5.1  **Respect all participants**

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

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

5.2  **Respect human embryos**

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

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

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

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

5.3  **Use open and consistent decision making**

Participants in ART are entitled to understand and participate in the decision making about their care. Clinics must use an open and consistent approach to ethical issues that arise in practice.
5.3.1 Clinics should maintain documented practices and procedures, identifying the line of responsibility for each. For example, specific protocols should be developed for the following:

- the range of treatments and laboratory procedures;
- access to, and eligibility for, treatment;
- gametes and embryo donation (including selection, counselling and screening of both recipients and donors);
- storage and disposal of gametes and embryos;
- information giving and counselling;
- obtaining consent to treatment;
- record keeping and data reporting;
- investigation and resolution of complaints.

5.4 Provide information and counselling

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

5.5 Obtain consent

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

5.6 Maintain privacy and confidentiality

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

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

5.8 Collect and report outcomes data

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

5.9 Respect conscientious objections

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

QUESTIONS TO CONSIDER:

Q9. Have you encountered any difficulties in the interpretation and/or application of the current ethical guidance in Section 6?

Q10. Do you think that there are gaps in the current ethical guidance in Section 6?

Section 6.1 (see also Section 7.1)

Q11. Should there be a standard way that data is collected and stored to facilitate linkage?
   • If so, how?
   • Should this guidance be included in the ART guidelines?

Q12. What is best-practice to facilitate a first contact between donor/s and the donor-conceived person?
   • Should this guidance be included in the ART guidelines?

Q13. Does the statement in Paragraph 6.1.2 need to be strengthened? (see also questions in relation to Section 5 and Section 9.2)
   • If so, in what ways?

Q14. What assistance is required to support parents in telling their children about their genetic origins?
   • Should this guidance be included in the ART guidelines?
   • How, and by whom, should this assistance be provided? e.g. Is there a role for community practitioners such as GPs and maternal-child health nurses?

Q15. Paragraph 6.1.3
   • Who should be involved in the dissemination of information to gamete donors (or gamete providers for donated embryos) about children born as a result of their donation? (see also questions in relation to Section 6.12)
   • How can gamete donors and donor-conceived persons be encouraged to register their consent to being contacted?
   • Should this guidance be included in the ART guidelines?
**Section 6.2 (also relevant to donated embryos)**

Q16. In the best interest of the child, should there be an age limit for:
   • male gamete donors?
   • female gamete donors?
   • male and female gamete providers for donated embryos?
   If so, what do you think the age limit(s) should be?

Q17. Should there be an age limit for female recipients of gamete or embryo donation?
   • If so, what do you think this age limit should be?

**Section 6.3**

Q18. Is more guidance required to enable clinics to take all reasonable steps to reduce the numbers of genetic relatives created through donor gamete programs? What guidance do you recommend?

Q19. Should paragraph 6.4.1 be revised? If so, how?

**Section 6.5**

Q20. In view of developments in other countries allowing women to receive compensation above medical and travelling expenses for donating eggs, should it be permissible for Australian women to also be compensated for the reproductive effort and risks associated with donating their eggs? (See also Section 13 Surrogacy)

Q21. Should more guidance be given about the reimbursement of legitimate expenses? What guidance would you recommend?

**Section 6.7 (see also Section 7.5)**

Q22. Are there any specific relationships that give rise to particular concerns between donor and recipient that should be included in the guidelines? e.g. egg or embryo donation from a daughter to her mother.

**Section 6.9**

Q23. Should conditional donation of sperm, eggs or embryos such as stipulating certain race or social attributes be permitted? e.g. a sperm donor not wanting his sperm to be used for a single woman, a lesbian couple, or a particular race.
### Section 6.10 – 6.11

**Q24.** Do you think that the current ethical guidance is adequate?
- Should information about the number and sex of half-siblings be available to donor-conceived persons?
- Do you think that more information about half-siblings should be available to donor-conceived persons? e.g. identifying information.

**Q25.** Do you consider 18 years of age too late to have access to this information?
- Should earlier access to the information be possible?

**Q26.** What is best-practice to facilitate a first contact between the half siblings?
- Should this guidance be included in the ART guidelines?

### Section 6.12

**Q27.** Should the donor be able to receive identifying information with the consent of the donor-conceived person?

**Q28.** Should donor and recipient information be completely confidential or do you think that this information should be available to all individuals involved?

### Section 6.14

**Q29.** Is it reasonable for a sperm donor to be able to vary or withdraw their consent for donation at any time before insemination or fertilisation? Is the point of treatment commencement or ovarian stimulation a more reasonable point at which a sperm donor can vary or withdraw their consent for donation? (see also Sections 7.3 & 9.6)
- Should the right of gamete donors (or gamete providers for donated embryos) be restricted to the time before a woman begins treatment in anticipation of using specific gametes or receiving specific embryos?

### Section 6.15 (see also Section 8.4)

**Q30.** Should restrictions on posthumous donation require written expressed direction from the donor or should the requirements allow less explicit and/or implied expressions?

**Q31.** Is it acceptable to take donations from dying or deceased persons?
- If so, under what circumstances?
- Should this rely on prior consent?

### Section 6.17

**Q32.** Do you think that Section 6.17 is still relevant to the clinical practice of ART?
Introduction

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

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

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

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

6.1 Uphold the right to knowledge of genetic parents and siblings

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

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

6.1.2 Clinics should help prospective recipients to understand the significant biological connection that their children have with the gamete donor. Recipients should be advised that their children are entitled to knowledge of their genetic parents and siblings; they should therefore be encouraged to tell their children about their origins.

6.1.3 Working with relevant professional organisations, clinics should use forums for public information to encourage people who were donors before the introduction of these guidelines, and those previously conceived using donated gametes, to contact the clinic and register their consent to being contacted by their genetic children or genetic siblings and half-siblings, respectively.

6.1.4 Clinics should not use gametes or embryos collected before the introduction of these guidelines without the consent of the gamete donor (or gamete providers for donated embryos) to the release of identifying information for any future treatments (with the exception of the circumstances given in paragraph 6.1.5).
6.1.5 The only situations in which a reproductive procedure involving donor gametes may be considered without the consent of the donor to the release of identifying information are:

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

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

6.2 Use suitable gamete donations

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

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

6.2.1 Children and young people (who are defined as ‘minors’ in each jurisdiction) should not be allowed to donate gametes for use by others in a reproductive procedure.

6.2.2 Clinics should not use gametes donated by older men and women unless the potential recipient understands the implications and increased risks of such an arrangement.

6.3 Limit the number of persons born from a single donor

Persons conceived using donor gametes, and the donors of gametes, need to be protected from the consequences of having many genetic siblings and offspring, respectively. Clinics must take all reasonable steps to reduce the numbers of genetic relatives created through donor gamete programs.
6.3.1 Gametes from one donor should be used in a limited number of families. In deciding the number of families, clinicians should take account of:

- the number of genetic relatives that the persons conceived using the donation will have;
- the risk of a person conceived with donor gametes inadvertently having a sexual relationship with a close genetic relative (with particular reference to the population and ethnic group in which the donation will be used);
- the consent of the donor for the number of families to be created; and
- whether the donor has already donated gametes at another clinic.

6.4 Minimise risk of infection

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

6.4.1 Clinics should not accept donations from people at an increased risk of transmissible infections.

6.4.2 All donors of gametes should undergo appropriate infection control surveillance.

6.5 Do not trade in human gametes

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

6.6 Respect the donor’s wishes

If the donor specifies recipients he or she knows personally, clinics must respect the wishes of the donor.
6.7 **Encourage careful consideration of donations from relatives**

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

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

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

**Unknown but directed donation**

6.9 **Respect the donor’s wishes**

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

**Entitlement to information**

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

Gamete recipients need information about gamete donors that is relevant for the care of their donor-conceived offspring. Clinics must allow recipients of donated gametes access, through either a medical practitioner or an appropriately qualified health professional, to at least the following information about gamete donors:
• details of past medical history, family history and any genetic test results that are relevant to the future health of the person born (or any subsequent offspring of that person) and the recipient of the donation;

• details of the physical characteristics of the gamete donor; and

• the number and sex of persons conceived using the gametes donated by the same gamete donor.

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

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

• all medical and family history information as specified in paragraph 6.10;

• identifying information about the gamete donor (subject to paragraph 6.1); and

• the number and sex of persons conceived using the gametes provided by the same gamete donor, the number of families involved, and any identifying information that these siblings have consented to being released (see paragraph 6.1.3).

6.12 Provide gamete donors with relevant information about their genetic offspring

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

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

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

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

- If the consent form includes permission for release of identifying information, the clinic may notify the donor and release the information to the person requesting the information.

6.13.2 When a clinic is approached by a person who was conceived using donated gametes and who now seeks identifying information about his or her genetic siblings or half-siblings, it should check its register of consent for the release of such information (see paragraph 6.1.3) and proceed as follows:

- If consent has been registered by the siblings concerned, the information may be released.

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

6.13.3 Acceptance of counselling services should be encouraged as part of the preparation for the release of identifying information.
Responsibility for gametes and resulting embryos

6.14 Maintain a consistent chain of responsibility

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

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

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

- When the gamete donor has specified a known recipient for his or her gametes, and consent for treatment has been given by the recipient, the recipient has responsibility for decision making about the use of the gametes in his or her own reproductive treatment, as well as storage and disposal, subject to any limitations expressed in the consent of the donor.

- At any time before insemination or fertilisation, gamete donors may vary or withdraw their consent to donation (see paragraph 9.6).

- Once fertilisation has taken place, the persons for whom the embryo has been created have responsibility for decision making about its use in their own reproductive treatment and the medical care of the embryo (both before and after implantation into the uterus), storage and disposal.
Posthumous use of gametes

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

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

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

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

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

6.16 Allow an appropriate period of time before attempting conception

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

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

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

6.17.2 The consent to the use of the sperm to form a hybrid embryo must meet the provisions of Section 9, ‘Information giving, counselling and consent’.
7 Use of donated embryos

Introduction

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

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

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

QUESTIONS TO CONSIDER: (In addition to questions 11 – 17 & 22 – 23)

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<td>Have you encountered any difficulties in the interpretation and/or application of the current ethical guidance in Section 7?</td>
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</table>
7.1 Uphold the right to knowledge of genetic parents and siblings

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

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

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

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

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

7.2 Maintain the integrity of genetic parenthood

Persons conceived by ART are entitled to know their genetic parents. Clinics must not use any procedures that allow the genetic parentage of persons conceived to be confused. For this reason, clinicians must not transfer embryos to the uterus of a woman from more than one source at any one time.
7.2.1 Because of the potential for difficulties in tracing genetic parents, and because of possible effects on the long-term psychosocial welfare of the persons born from embryos that have undergone serial donations, clinics should not facilitate the following procedures:

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

7.3 Ensure a consistent chain of responsibility

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

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

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

Known donations

7.4 Respect the donor’s wishes

If the donor specifies recipients he or she knows personally, and who have indicated that they wish to accept the donation, clinics must respect the wishes of the donor.
7.5  Encourage careful consideration of donations from relatives

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

Unknown but directed donation

7.6  Respect the donor’s wishes

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

QUESTIONS TO CONSIDER:

<table>
<thead>
<tr>
<th>Q36.</th>
<th>Have you encountered any difficulties in the interpretation and/or application of the current ethical guidance in Section 8?</th>
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<tbody>
<tr>
<td>Q37.</td>
<td>Do you think that there are gaps in the current ethical guidance in Section 8?</td>
</tr>
<tr>
<td>Q38.</td>
<td>Should limits apply to the duration of storage of gametes - recognising that if stored for fertility preservation purposes, they may not be used for decades?</td>
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<td>• If yes, what do you think the maximum duration should be?</td>
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<td></td>
<td>• If no, what difficulties do you perceive and how should the storage of gametes be managed?</td>
</tr>
<tr>
<td>Q39.</td>
<td>Paragraph 8.7.1 – In the case of stored embryos where the couple is in dispute, should embryos be kept in storage until the dispute is resolved or should there be time-limited storage?</td>
</tr>
<tr>
<td></td>
<td>• What do you think the maximum duration should be for time-limited storage?</td>
</tr>
<tr>
<td></td>
<td>• Should advance directives about the future of any excess ART embryos be obtained prior to the embryo being formed, so that in the event of a dispute a process for either disposal or donation is known?</td>
</tr>
</tbody>
</table>

Storage of gametes

8.1 Explain options for use and disposal of stored gametes

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

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

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

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

8.3 Limit storage

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

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

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

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

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

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

8.5 Discuss options for use or disposal of stored embryos

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

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

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

8.6 Ensure safety and identity

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

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

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

8.6.2 The labelling method used should not be susceptible to unauthorised, undetectable or accidental alteration.
8.7 Respect the wishes of the persons for whom the embryos are stored

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

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

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

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

8.8 Limit duration of storage

It is not desirable to leave embryos in storage indefinitely.

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

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

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

8.9 Dispose of embryos respectfully

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

8.9.1 The wishes of the persons for whom the embryos are stored, as to the method of disposal, should be respected.
## 9 Information giving, counselling and consent

### QUESTIONS TO CONSIDER:

| Q40. | Have you encountered any difficulties in the interpretation and/or application of the current ethical guidance in Section 9? |
| Q41. | Do you think that there are gaps in the current ethical guidance in Section 9? |

#### Section 9.2

| Q42. | Among the information which should be discussed, should there be specific reference to the significance of biological connection between donor-conceived persons and the donors of gametes, and to the right of these donor-conceived persons to knowledge of their genetic parents and siblings? (see also questions in relation to Section 5 and Paragraphs 6.1.1 and 6.1.2). |

#### Section 9.8

| Q43. | When a child or young person with stored gonadal tissue or gametes reaches adulthood, how should the ongoing consent arrangements be managed? i.e. the transition from parental consent to the consent of the individual. |

#### Section 9.9

| Q44. | Do you think that the guidance in Section 9.9 is appropriate? |
Information giving

9.1 Provide and discuss all relevant information with participants

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

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

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

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

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

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

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

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

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

- the possible implications and long-term psychosocial consequences of gamete or embryo donation for the donors, the recipients and the persons conceived;
• for participation in a donor oocyte program, the possibility that this may affect the ability of the donor to have children in the future;

• the arrangements of the clinic for collection, storage and release of identifying information;

• any difficulties in finding gamete or embryo donors, including meeting the requests of specific recipients;

• the scope of consent and the rights of each person involved to withdraw consent (see paragraphs 6.9 and 7.3);

• the responsibilities of each participant to all other participants in the proposed reproductive procedure;

• the legal status of the genetic and social parents of any persons conceived using donated gametes or embryos in the jurisdiction in which the clinic is located, or the gametes or embryos are used; and

• the options of donating embryos to other people or allowing them to be used for research (see paragraph 8.5). (For further details on allowing embryos to be used for research, see Section 17.)

Counselling

9.3 Provide counselling services

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

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

• provide an opportunity to discuss and explore issues;

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

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

Consent

9.4 Obtain consent from all participants in all procedures

Before clinical ART procedures are undertaken, clinicians must ensure that consent is obtained from all participants (and, where relevant, their spouses or partners), is informed, voluntary, competent, specific and documented, and remains current.
9.4.1 Consent should be obtained in writing, following the provision and discussion of information about the implications of proposed reproductive procedures, adequate time for consideration of the information and adequate opportunities for personal preparation (see paragraphs 9.1 to 9.3).

9.4.2 Clinics should have procedures to ensure that consent is voluntary and free from coercion.

9.4.3 Consent forms should include the following statements:

• that the participants have received the information provided about the proposed procedures;

• that counselling by a professional counsellor has been offered;

• that participants have had explained to them the procedures involved and the risks of complications and have had their questions answered;

• that participants have had explained to them any mandatory uses of data;

• whether or not the participants give permission for any additional (nonmandatory) uses or disclosures of identifying information or data collected about them;

• whether or not the participants give permission to be contacted in the future with a request for participation in follow-up research;

• the arrangements for storage and disposal of gametes or embryos;

• a signed statement by the supervising clinician that he or she has provided information about the proposed procedures; and

• that relevant participants consent to each proposed procedure.
9.5 Obtain consent from all participants in donated gamete or embryo programs

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

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

• full details of the agreed arrangements for any treatment involving donated gametes or embryos (see Sections 6 and 7);

• an acknowledgment that each participant (and spouse or partner, if any) has received and understood the information provided about gamete or embryo donation;

• a statement that the gamete or embryo donor understands and acknowledges his or her biological connection to any persons conceived using his or her donated gametes or embryos;

• a statement giving explicit permission to make the information specified in paragraphs 6.10 and 6.11 available to the recipients and any person conceived through the procedure, respectively;

• a description of the arrangements set out in paragraphs 6.14 and 7.3 for responsibility for the gametes or embryos after donation; and

• provision for signature by the participant (and his or her spouse or partner, if any).

9.5.2 Potential gamete or embryo donors and gamete or embryo recipients should be given adequate time between provision of information and obtaining consent to allow consideration of the complex issues involved.
9.6 Recognise the right of participants to withdraw or vary their consent

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

9.7 Obtain consent for the storage of gametes or embryos

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

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

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

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

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

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

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

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

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

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

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

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

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

QUESTIONS TO CONSIDER:

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<thead>
<tr>
<th>Q45.</th>
<th>Have you encountered any difficulties in the interpretation and/or application of the current ethical guidance in Section 10?</th>
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<tr>
<td>Q46.</td>
<td>Do you think that there are gaps in the current ethical guidance in Section 10?</td>
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Record keeping

10.1 Maintain integrity and privacy of personal information

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

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

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

• provision to keep records indefinitely (or at least for the expected lifetime of any persons born).

10.2 Observe, record, monitor and evaluate procedures and outcomes

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

10.2.1 Clinics should record the following information:

• full names (including previous names) and contact details of all participants and, whenever possible, the names of persons born as a result of assisted reproductive technology;

• particulars of gametes and embryos to enable staff in the clinic to trace what happens to each individual embryo, egg or sperm sample from the date of collection;

• data about outcomes of procedures to allow the clinic or accrediting body to publish relevant information to assist participants to make informed decisions about treatment options (particularly in relation to any experimental or innovative procedures);

• data to facilitate monitoring of short-term outcomes, including the live birth rate per treatment cycle commenced, the occurrence of single and multiple pregnancies, spontaneous abortion, termination of pregnancy, ectopic pregnancy, stillbirth, genetic conditions, perinatal events and any adverse effects and other side effects for the participants during treatment; and

• data to facilitate long-term follow-up studies of persons born as a result of ART procedures, and the participants (eg rates of long-term adverse outcomes and subsequent fertility).
10.3 Record information about donation, use and storage of gametes and embryos

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

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

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

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

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

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

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

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

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

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

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

10.4.3 Clinics should collate the following data annually:

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

10.5 Ensure public accountability for all activities and procedures

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

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

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

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

QUESTIONS TO CONSIDER:

Q47. Have you encountered any difficulties in the interpretation and/or application of the current ethical guidance in Section 11?

Q48. Do you think that there are gaps in the current ethical guidance in Section 11?

Section 11.1

Q49. Are there any circumstances under which it is appropriate to allow sex selection for non-medical purposes? e.g. for family balancing, to replace a lost child, for cultural purposes.

Q50. Do you think that it is ethically acceptable for ART to be available to individuals solely for non-medical sex selection purposes, e.g. for family balancing, to replace a lost child, for cultural purposes, when the individuals are neither infertile (physically or socially), nor have reduced fertility.

Q51. Is it possible to define a “serious genetic condition” for the purposes of allowing sex selection? If so, please provide a suitable definition.

11.1 Do not select sex for nonmedical purposes

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

QUESTIONS TO CONSIDER:

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<td>Q52.</td>
<td>Have you encountered any difficulties in the interpretation and/or application of the current ethical guidance in Section 12?</td>
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<tr>
<td>Q53.</td>
<td>Do you think that there are gaps in the current ethical guidance in Section 12?</td>
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Section 12.1 – 12.2

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<tr>
<td>Q54.</td>
<td>Under what situations do you think the use of preimplantation genetic diagnosis is ethically acceptable?</td>
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</table>

12.1 Carefully evaluate any use of PGD

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

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

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

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

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

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

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

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

12.3.1 The ethics committee or relevant agency should ascertain that:

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

12.4 Provide access to a geneticist and genetic counsellor

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

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

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

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

**QUESTIONS TO CONSIDER:**

<table>
<thead>
<tr>
<th>Q55.</th>
<th>Have you encountered any difficulties in the interpretation and/or application of the current ethical guidance in Section 13?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q56.</td>
<td>Do you think that there are gaps in the current ethical guidance in Section 13?</td>
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<tr>
<td>Q57.</td>
<td>In view of developments in other countries, should there be compensation, more than expenses, for gestational mothers congruent with the reproductive effort contributed?</td>
</tr>
<tr>
<td>Q58.</td>
<td>Paragraph 13.2.1 – Is this guidance still appropriate?</td>
</tr>
</tbody>
</table>

### 13.1 Do not undertake or facilitate commercial surrogacy

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

### 13.2 Noncommercial surrogacy

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

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

13.2.1 Clinicians should not advertise a service to provide or facilitate surrogacy arrangements, nor receive a fee for services to facilitate surrogacy arrangements.
14 Innovations, training and quality assurance

<table>
<thead>
<tr>
<th>QUESTIONS TO CONSIDER:</th>
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<tbody>
<tr>
<td>Q59. Have you encountered any difficulties in the interpretation and/or application of the current ethical guidance in Section 14?</td>
</tr>
<tr>
<td>Q60. Do you think that there are gaps in the current ethical guidance in Section 14?</td>
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</tbody>
</table>

14.1 Evaluate innovations before use in clinical practice

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

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

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

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

- **Safety** — an adequate number of live births, preferably from more than one centre worldwide, with no statistically significant increase in the rates of perinatal morbidity, mortality or adverse genetic conditions.

- **Efficacy** — at least one well-designed trial published in the peer-reviewed literature demonstrating the effectiveness of the intervention.
14.1.2 If there is any doubt about whether the proposed change or innovation is significant, safe or efficacious, it should be referred to an HREC for assessment.

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

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

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

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

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

14.3 **Conduct quality assurance activities**

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

An embryo that is not an excess ART embryo must not be used for any quality assurance activity unless that use is for a purpose relating to the ART treatment of a woman carried out by an accredited ART centre (RIHE Act, s 11).
14.3.1 As the distinction between quality assurance and research is not always clear, clinics should consult the National Statement and also refer to the advice in the NHMRC document *When Does Quality Assurance in Health Care Require Independent Ethical Review?* (NHMRC 2003), whether or not the quality assurance activity requires HREC approval.
Explanation of key terms

The following explanations show how key terms that have been used in Part B of the ART guidelines are to be interpreted.

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
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<tbody>
<tr>
<td>Accredited ART centre</td>
<td>A person or body accredited to carry out ART.</td>
</tr>
<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>
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<tr>
<td>Blastocyst</td>
<td>A 5 to 7 day-old embryo that has an outer layer of cells and a fluid-filled cavity in which there is a cluster of cells called the inner cell mass.</td>
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<tr>
<td>Clinic</td>
<td>Accredited ART centre.</td>
</tr>
<tr>
<td>Diagnostic investigation</td>
<td>In relation to an excess ART embryo, means any procedure undertaken on embryos for the sole purpose of diagnostic investigation for the direct benefit of the woman for whom it was created [RIHE s 10(4)] For the purposes of these guidelines, diagnostic investigation includes preimplantation genetic diagnosis. See also Preimplantation genetic diagnosis</td>
</tr>
<tr>
<td>Donated embryo</td>
<td>An embryo given by either the gamete providers or the persons for whom the embryo was created to other persons for the purpose of achieving a pregnancy. The term is also used when the gamete providers for an embryo agree to their embryo being used in research or other activities that are not intended to achieve a pregnancy. See also Embryo donor, Responsible person</td>
</tr>
<tr>
<td>Donated gametes</td>
<td>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</td>
</tr>
<tr>
<td>Embryo</td>
<td>A living entity in the earliest stage of development.</td>
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<tr>
<td>Embryo donor</td>
<td>A person who has responsibility for decisions about the use of an embryo and who donates the embryo to another person or persons for treatment, or for research or other activities. See also Responsible person</td>
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<tr>
<td>Term</td>
<td>Definition</td>
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<tr>
<td>Excess ART embryo</td>
<td>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)]</td>
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<tr>
<td>Gamete</td>
<td>A human sperm or egg (ovum or oocyte) and includes: (a) any cell that has undergone meiosis or has a haploid chromosome complement; or (b) tissue containing such cells (also referred to as gonadal tissue) See also Gonadal tissue.</td>
</tr>
<tr>
<td>Gamete donor</td>
<td>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</td>
</tr>
<tr>
<td>Gamete provider</td>
<td>The person who is the biological (that is, genetic) source of the gamete.</td>
</tr>
<tr>
<td>Gonadal tissue</td>
<td>Tissue from the ovary or testis. See also gamete.</td>
</tr>
<tr>
<td>Human egg</td>
<td>Human ovum or oocyte.</td>
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</table>
| Human embryo | The RIHE Act defines a human embryo as:
| | A discrete entity that has arisen from either:
| | (a) the first mitotic division when fertilisation of a human oocyte by a human sperm is complete; or
| | (b) any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears;
| | and has not yet reached 8 weeks of development since the first mitotic division [PHCR s 8(1), RIHE s 7(1)]
| | All aspects of these ethical guidelines applying to human embryos also apply to:
| | the single entity formed by the combination of two gametes is to be treated as an embryo for the purposes of applying these guidelines; and
| | a single cell or group of cells that is capable of reaching the stage of forming a blastocyst in vitro, because it is considered to have the potential to develop up to, or beyond, the stage at which the primitive streak appears.
| | (The significance of the previous clause is discussed in paragraph 17.1)
| | For the purposes of the definition of a human embryo, in working out the length of the period of development of a human embryo, any period when the development of the embryo is suspended is to be disregarded. [PHCR s 8]
| Human sperm | Includes human spermatids. [PHCR s 8(1)]
| Hybrid embryo | an embryo created by the fertilisation of a human egg by animal sperm; or
| | an embryo created by the fertilisation of an animal egg by human sperm; or
| | a human egg into which the nucleus of an animal cell has been introduced; or
| | an animal egg into which the nucleus of a human cell has been introduced; or
| | a thing declared by the regulations to be a hybrid embryo. [PHCR s 8(1)]
| Innovative procedure | A therapeutic, diagnostic or laboratory procedure that is aimed at improving reproductive outcomes beyond existing methods but has not been fully assessed for safety and/or efficacy.
| Objective criteria for determining the suitability of ART embryos for implantation | Criteria for use in determining that an embryo is incapable of successful implantation if transferred to the body of a woman.
| | The criteria are issued by the CEO of the NHMRC and obtainable from the NHMRC.
| **Participant** | Any person (including a gamete or cell donor) who is the subject of (or takes part in) a reproductive procedure or research or innovative procedures involving ART or research involving the formation of an embryo. In many cases ‘participant’ also includes the spouse or partner of a person undertaking the ART procedure. In cases where it is essential that the spouse or partner (if any) is included (such as in giving consent for donation of gametes), this is specified. |
| **Preimplantation genetic diagnosis (PGD)** | Technique by which embryos fertilised in vitro are tested for genetic characteristics, particularly for specific genetic disorders (e.g., cystic fibrosis). |
| **Proper consent** | The procedures and requirements for consent under these guidelines. |
| **Recipient** | A person to whom gametes or embryos are donated. |
| **Research** | Systematic investigation with the aim of increasing knowledge. |
| **Responsible person** | (a) In relation to an excess ART embryo:  
  (i) each person who provided the egg or sperm from which the embryo was created; and  
  (ii) the woman for whom the embryo was created, for the purpose of achieving her pregnancy; and  
  (iii) any person who was the spouse of a person mentioned in paragraph (a) at the time the egg or sperm mentioned in that paragraph was provided; and  
  (iv) any person who was the spouse of the woman mentioned in paragraph (b) at the time that the embryo was created; or [RHIE s 8]  
  (b) in relation to an embryo other than an excess ART embryo—each person whose reproductive material, genetic material or cell was used, or is proposed to be used, in the creation or use of the embryo; or  
  (c) in relation to a human gamete—the person who was the biological donor of the egg. |
| **Spouse or partner** | In relation to a person, includes a person who is legally married to the person (spouse), as well as a person who, although not legally married to the person, is living with the person on a bona fide domestic basis (partner). [Defined as ‘spouse’ in RHIE s 7] |
| **Treatment cycle** | A series of treatments for the purposes of in vitro fertilisation, gamete intrafallopian tube transfer or similar procedures. It is defined as beginning either on the day on which treatment by superovulatory drugs is commenced or on the first day of the patient’s menstrual cycle, and ending not more than 30 days later. |
Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tbody>
<tr>
<td>ART</td>
<td>assisted reproductive technology</td>
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<tr>
<td>HREC</td>
<td>human research ethics committee</td>
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<tr>
<td>IVF</td>
<td>in vitro fertilisation</td>
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<tr>
<td>National Statement</td>
<td>National Statement on Ethical Conduct in Human Research</td>
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<tr>
<td>PGD</td>
<td>preimplantation genetic diagnosis</td>
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