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

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Abbreviations

AHEC	Australian Health Ethics Committee
ART	assisted reproductive technology
HREC	Human Research Ethics Committee
Licensing Committee	Embryo Research Licensing Committee
National Statement	<i>National Statement on Ethical Conduct in Human Research</i>
NHMRC	National Health and Medical Research Council
NHMRC Act	<i>National Health and Medical Research Council Act 1992</i>
PGT-M	preimplantation genetic testing for single gene (monogenetic) disorders
PGT-SR	preimplantation genetic testing for structural rearrangements
PGT-A	preimplantation genetic testing for aneuploidy
PGT	preimplantation genetic testing
PHCR Act	<i>Prohibition of Human Cloning for Reproduction Act 2002</i>
RIHE Act	<i>Research Involving Human Embryos Act 2002</i>
RTAC	The Reproductive Technology Accreditation Committee of the Fertility Society of Australia

Explanation of key terms

The following explanations show how key terms are to be interpreted in the context of these Ethical 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 referenced.

Key term	Explanation
Activity / ART activity	An assisted reproductive technology (ART) treatment or procedure.
Altruistic surrogacy	Refers to an arrangement where a surrogate receives no payment or inducement, beyond the reimbursement of verifiable out-of-pocket expenses directly associated with the surrogacy procedure or pregnancy. See also 'Commercial surrogacy'
Assisted reproductive technology (ART)	The application of laboratory or clinical techniques to gametes and/or embryos for the purposes of reproduction.
Blastocyst	A 5 to 7 day-old embryo that has an outer layer of cells and a fluid-filled cavity in which there is a cluster of cells called the inner cell mass.
Clinic	A person or body accredited to carry out ART by: (a) the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia; or (b) if the Research Involving Human Embryos Regulations 2003 prescribe another body or other bodies in addition to RTAC, that other body or any of those other bodies, as the case requires. [RIHE Act s8]
Clinical team	Refers to any person involved in the care of individuals or couples undergoing ART and/or the handling of gametes or embryos, within the ART clinic's remit.
Commercial surrogacy	Refers to an arrangement where a surrogate receives payment or inducement above and beyond the reimbursement of verifiable out-of-pocket expenses directly associated with the surrogacy procedure or pregnancy. See also 'Altruistic surrogacy'
Commissioning parent(s)	The individual or couple who seeks to have a baby through an arrangement with a surrogate.

Key term	Explanation
Donated embryo(s)	<p>Embryos given to an individual or couple for their reproductive use.</p> <p>The term is also used when embryos are donated for use in research, training or quality assurance activities.</p> <p>See also 'Embryo donor(s)', 'Embryo donation'</p>
Donated gametes	<p>Sperm or egg(s) given to an individual or couple for their reproductive use.</p> <p>The term is also used when gametes are donated for use in research, training or quality assurance activities.</p> <p>See also 'Gamete donation', 'Gamete donor(s)', 'Double donation'</p>
Double donation	<p>The use of both donated sperm and donated eggs to create embryos for the reproductive use of an individual or couple. The intended parent(s) will not be the genetic parents of the person born.</p>
Embryo	<p>See 'Human embryo'</p>
Embryo donation	<p>The giving of any excess ART embryo to another individual or couple for their reproductive use, or to research, without payment or inducement, beyond the reimbursement of verifiable out-of-pocket expenses directly associated with the donation.</p> <p>See also 'Donated embryo(s)', 'Embryo donor(s)', 'Excess ART embryo'</p>
Embryo donor(s)	<p>Person(s) who has responsibility for decisions about the use of an embryo and who donates the embryo to another individual or couple for reproductive use, or to research.</p> <p>In reference to the reallocation of human embryos, the term 'embryo donor' may include the recipient who is further donating an embryo that was previously donated to them.</p> <p>See also 'Donated embryo(s)', 'Embryo donation', 'Reallocation', 'Responsible party(ies)'</p>
Embryonic stem cell	<p>An undifferentiated cell that is a precursor to many different cell types, obtained from the inner cell mass of a blastocyst.</p> <p>See also 'Blastocyst', 'Embryonic stem cell line'</p>
Embryonic stem cell line	<p>A genetically identical line of cells, derived from an embryonic stem cell, which can be propagated indefinitely in culture.</p> <p>See also 'Embryonic stem cell'</p>
Embryo transfer	<p>Refers to a specialised technique in which an embryo created in vitro is transferred to a uterus for the purposes of reproduction.</p>

Key term	Explanation
Excess ART embryo	<p>A human embryo that:</p> <ul style="list-style-type: none"> (a) was created by ART, for use in the ART treatment of a woman, and (b) is excess to the needs of: <ul style="list-style-type: none"> (i) the woman for whom it was created, and (ii) her spouse (if any) at the time that the embryo was created. <p>[PHCR Act s8(1); RIHE Act s9(1)]</p> <p>For the purposes of paragraph (b), a human embryo is excess to the needs of the persons mentioned in that paragraph at a particular time if:</p> <ul style="list-style-type: none"> (a) each such person has given written authority for the use of the embryo for a purpose other than a purpose relating to the ART treatment of the woman concerned, and the authority is in force at that 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. <p>[PHCR Act s8(5); RIHE Act s9(2)]</p>
Gamete	<p>A human sperm or egg (ovum or oocyte) and includes:</p> <ul style="list-style-type: none"> (c) any cell that has resulted from a process of meiosis, or (d) tissue containing such cells (also referred to as gonadal tissue). <p>See also 'Gonadal tissue', 'Human egg', 'Human embryo', 'Human sperm'</p>
Gamete donation	<p>The giving of sperm or egg(s) to another individual or couple for their reproductive use, or to research, without payment or inducement, beyond the reimbursement of verifiable out-of-pocket expenses directly associated with the donation.</p> <p>See also 'Donated gametes', 'Gamete donor(s)'</p>
Gamete donor(s)	<p>A person who gives sperm or egg(s) for use by a person other than their spouse or partner in a reproductive procedure, or to research.</p> <p>See also 'Donated gametes', 'Gamete provider(s)'</p>
Gamete provider(s)	<p>Refers to the persons whose sperm and egg were used (or are to be used) to create an embryo.</p>
Gonadal tissue	<p>Tissue from the ovary or testis.</p> <p>See also 'Gamete'</p>
Human egg	<p>A female reproductive cell - a human ovum or oocyte.</p>

Key term	Explanation
Human embryo	<p>A discrete entity that has arisen from either:</p> <p>(a) the first mitotic division when fertilisation of a human oocyte by a human sperm is complete, or</p> <p>(b) any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears</p> <p>and has not yet reached 8 weeks of development since the first mitotic division.</p> <p>[RIHE Act s7(1)]</p>
Human sperm	<p>A male reproductive cell - includes human spermatids.</p> <p>[PHCR Act s8(1)]</p>
Independent body	<p>An institution, group or person involved in decision- or policy-making who is able to provide an 'independent' or 'disinterested' opinion or advice.</p> <p>May include a clinical ethics committee, a regulatory body or board, a tribunal or a magistrate, a Human Research Ethics Committee, a counsellor, or another relevant expert. The appropriateness of the body will be determined by the particular circumstances, and may be prescribed by legislation.</p>
Infertility	<p>Generally seen as a delay of greater than 12 months to achieve a planned pregnancy; however, these Ethical Guidelines acknowledge that in some contexts, such as advanced maternal age, it may be appropriate that a diagnosis of infertility is made in a lesser time period.</p> <p>See also 'Social infertility'</p>
Innovative practice	<p>A therapeutic, diagnostic or laboratory practice that is aimed at improving reproductive outcomes beyond existing methods but has not been fully assessed for safety and/or efficacy.</p>
Intended parent(s)	<p>The individual or couple who seeks to have a baby using ART.</p>
Legal advice	<p>Professional advice/information provided by a registered legal practitioner, preferably with expertise in the law relating to reproductive medicine.</p>
Licensable activities	<p>Activities which require a general licence under the RIHE Act or the PHCR Act.</p>
General licence	<p>A licence issued under section 21 of the RIHE Act.</p>

Key term	Explanation
Mitochondrial donation	<p>Mitochondrial donation may allow women with mitochondrial disease, caused by mutations or errors in their mitochondrial DNA, to have biological children without transmitting the disease to their children.</p> <p>The term refers to several specific techniques aimed at ensuring only healthy mitochondria are passed on to an embryo. Mitochondrial donation techniques allow reproductive technology specialists to create an embryo which contains the: nuclear DNA from a sperm and an egg (from the prospective parent/s), and mitochondria in an egg donated by another person (the mitochondrial donor).</p> <p>See the Mitochondrial Donation Supplementary Section.</p>
Must	<p>Identifies ethical standards which are the minimal standards of ethically acceptable practice. These standards often relate to external or observable behaviour and practices, and either prohibit or restrict some behaviours and practices. From an ethical perspective, these standards are mandatory.</p> <p>See also 'Should'</p>
National Statement	<p>Means the <i>National Statement on Ethical Conduct in Human Research</i>, issued by the CEO of the NHMRC under the <i>National Health and Medical Research Council Act 1992</i>, as existing from time to time.</p> <p>Note: The National Statement could in 2021 be viewed on the NHMRC website (https://www.nhmrc.gov.au).</p>
Objective criteria	<p>The objective criteria do not apply to clinical practice, but must be used to determine whether specific excess ART embryos can be used under a general licence in circumstances described in subsection 24(8) of the RIHE Act.</p> <p>In these specific circumstances, the objective criteria are used to determine that an embryo is incapable of successful implantation if transferred to the body of a woman.¹</p> <p>The criteria are issued by the CEO of the NHMRC, as required by section 7 of the RIHE Act.</p> <p>See also 'Unsuitable for implantation', 'Unsuitable for transfer', 'Excess ART embryo'</p>
Observation	<p>In relation to an excess ART embryo, includes taking a photograph of an embryo, or taking a recording of the embryo from which a visual image can be produced.</p> <p>[RIHE Act s10(4)]</p>

¹ These Ethical Guidelines use gender neutral language. However, the term 'woman' is used where its use is necessitated by existing Commonwealth legislation or the National Statement.

Key term	Explanation
Participant	<p>In Part C of these Ethical Guidelines, ‘participant’ refers to any individual (including a gamete donor) who is the subject of (or takes part in) ART activities for research purposes, or research involving the formation of an embryo.</p> <p>In some circumstances, the law may require that the spouse or partner of an individual undertaking an ART procedure also be considered a ‘participant’ (see the definition of ‘responsible person’ in section 8 of the RIHE Act). Where this is required, this is specified in Part C of these Ethical Guidelines.</p>
Precursor cell	<p>A cell that has the potential to develop into a human egg or human sperm.</p> <p>[PHCR Act s8(1)]</p>
Preimplantation genetic testing for single gene (monogenic) disorders (PGT-M)	<p>A procedure used prior to embryo transfer to detect serious genetic conditions, diseases or abnormalities, which the gamete provider(s) are known to be at risk, to carry or to be predisposed. In rare circumstances PGT-M is used to select an embryo with compatible tissue for subsequent stem cell therapy for a parent, sibling or other relative. In some circumstances PGT-M may also be used to select an embryo of a particular sex.</p> <p>See also ‘Preimplantation genetic testing for aneuploidy (PGT-A)’, ‘Preimplantation genetic testing for structural rearrangements (PGT-SR)’, ‘Preimplantation genetic testing (PGT)’</p>
Preimplantation genetic testing for structural rearrangements (PGT-SR)	<p>A test to verify if there are any structural chromosome rearrangements. When a parent has a modified chromosome structure, the test can detect missing or excessive genetic material in an embryo.²</p> <p>See also ‘Preimplantation genetic testing for single gene (monogenic) disorders (PGT-M)’, ‘Preimplantation genetic testing for aneuploidy (PGT-A)’, ‘Preimplantation genetic testing (PGT)’.</p>
Preimplantation genetic testing for aneuploidy (PGT-A)	<p>A procedure used to test embryos for unspecified and multiple genetic or chromosomal abnormalities where the gamete providers are not known to have any genetic condition, disease or abnormality, or who do not carry a known causative abnormality. PGT-A may be undertaken to improve live birth rates (by improving pregnancy rates from embryo transfer and reducing incidence of miscarriage) and may be suitable in cases of advanced maternal age and repeated implantation failure.</p> <p>See also ‘Preimplantation genetic testing for single gene (monogenic) disorders (PGT-M)’, ‘Preimplantation genetic testing for structural rearrangements (PGT-SR)’, ‘Preimplantation genetic testing (PGT)’</p>

2 Fertility Society of Australia and New Zealand, Genetic Testing, available from: <https://www.fertilitysociety.com.au/preimplantation-genetic-testing-australia-new-zealand/>

Key term	Explanation
Preimplantation genetic testing (PGT)	<p>PGT refers to a number of techniques, including PGT-M, PGT-SR and PGT-A.</p> <p>See also 'Preimplantation genetic testing for single gene (monogenic) disorders (PGT-M)', 'Preimplantation genetic testing for structural rearrangements (PGT-SR)', 'Preimplantation genetic testing for aneuploidy (PGT-A)'.</p>
Proper consent	<p>The term 'proper consent' is used in the RIHE Act to describe the consent requirements for the use of an excess ART embryo, a human egg, or the creation or use of any other embryo, in licensable or licensed activities.</p> <p>Subsection 24(9) of the RIHE Act defines 'proper consent' as consent obtained in accordance with guidelines issued by the CEO of NHMRC as prescribed in the RIHE regulations.' The RIHE Regulations prescribe the ART guidelines, as updated from time to time.</p> <p>In the context of these Ethical Guidelines, the term 'valid consent' is used instead of the term proper consent, and has equivalent meaning.</p> <p>See also 'Excess ART embryo', 'Valid consent'</p>
Reallocation	<p>In relation to a human embryo, means the subsequent donation of:</p> <p>(a) a donated embryo, or</p> <p>(b) an embryo created using donated gametes (sperm and/or egg) from a recipient to another individual or couple.</p>
Reasonable effort(s)	<p>Implies that what can be done should be done, given the particular circumstances. What is reasonable in the circumstances will depend on the context.</p>
Recipient(s)	<p>A person to whom gametes or embryos are donated.</p>
Relevant party(ies)	<p>In varying circumstances, the 'relevant party(ies)' might include the individual or couple involved in the ART procedure, the gamete donor(s), the embryo donor(s), the gamete provider(s), the surrogate, the spouse or partner of the donor(s) or surrogate, the person who would be born as a result of an ART procedure or any child within the family unit(s) who may be affected by that birth.</p>
Research	<p>Systematic investigation with the aim of increasing knowledge.</p>
Responsible party(ies)	<p>The individual or couple responsible for decision-making.</p> <p>[In the context of the 'responsible person' in relation to an excess ART embryo refer explicitly to the definition provided in subsection 24(9) of the RIHE Act]</p> <p>See also 'Excess ART embryo'</p>

Key term	Explanation
Sex selection	The selection and transfer of an embryo on the basis of genetic sex.
Should	Identifies ethical standards which are the optimal standards of ethical practice. These standards often relate to attitudes, behaviours and practices which are complex, and therefore less easily measured and assessed by external observers. These are not optional standards. Rather, they are standards which every member of the clinical team has an ethical obligation to understand and strive to practise. See also 'Must'
Sibling	Each of two or more offspring having one or both parents (genetic or social) in common.
Social infertility	The inability to have children because of social factors, rather than medical reasons, e.g. same-sex relationships, single individuals. See also 'Infertility'
Sperm	See 'Human sperm'
Spouse or partner	In relation to a person, includes a de facto partner of the person within the meaning of the <i>Acts Interpretation Act 1901</i> . [Defined as 'spouse' in section 7 of the RIHE Act]
Surrogacy	See 'Altruistic surrogacy' and 'Commercial surrogacy'
Surrogate	A general term that refers to an individual who carries a pregnancy for another individual.
Transfer	See 'Embryo transfer'
Treatment cycle	Monitoring and procedures for the purposes of intrauterine insemination, in vitro fertilisation or similar procedures.
Unsuitable for embryo transfer	The criteria for determining that an embryo is unsuitable for transfer are based on whether there is a low likelihood of implantation according to the clinic's established policies and procedures for grading embryos. These embryos may or may not be classified as excess ART embryos under section 9 of the RIHE Act. Note: This term is used to denote the clinical context and should not be confused with the term 'unsuitable for implantation' as used in the RIHE Act. See also 'Excess ART embryos', 'Unsuitable for implantation'

Key term	Explanation
Unsuitable for implantation	<p>This term is used by the RIHE Act to describe the use of an embryo in circumstances described in subsection 24(8). This should not be confused with the term ‘unsuitable for transfer’, which is applicable in the clinical context.</p> <p>Under subsection 7(1) of the RIHE Act, an embryo that is unsuitable for implantation is a human embryo that:</p> <ul style="list-style-type: none"> (a) is diagnosed by preimplantation genetic diagnosis as unsuitable for implantation, in accordance with the Ethical Guidelines on the use of assisted reproductive technology in clinical practice and research , issued by the CEO of the NHMRC, or (b) is determined to be unsuitable for implantation in the body of a woman, in accordance with objective criteria specified in guidelines issued by the CEO of the NHMRC under the <i>National Health and Medical Research Council Act 1992</i> and prescribed by the regulations for the purposes of this paragraph. <p>See also ‘Objective criteria’, ‘Unsuitable for transfer’</p>
Valid consent	<p>For consent to be valid:</p> <ul style="list-style-type: none"> • the person giving consent must be considered to have the capacity to provide consent • the decision to consent to the treatment or procedure must be made without undue pressure • all relevant requirements regarding the provision of information and counselling requirements must be satisfied • the consent must be specific, and is effective only in relation to the treatment or procedure for which information has been given.

PART A: INTRODUCTION

1 Introduction to these guidelines

Since its inception, advances in assisted reproductive technology (ART) have aided millions of people worldwide to achieve pregnancy. With an estimated 1 in 6 couples in Australia experiencing some measure of infertility,³ and the increasing use of ART by same-sex couples and single individuals, ART plays an important role in assisting people to grow their families and reduce the burden of psychological distress associated with infertility.

Once an innovative and cutting edge treatment, many aspects of ART are now standard medical practice, with 1 in 20 individuals who gave birth in Australia in 2020 using some form of ART to do so.⁴ Nevertheless, the use of ART is not without controversy and there remain important ethical considerations in both the clinical and research contexts.

The National Health and Medical Research Council (NHMRC) has a well-established role in the provision of ethical advice for ART. See Appendix 1 for a history of NHMRC's involvement.

Role of the Ethical Guidelines

These Ethical Guidelines provide an overarching framework for the conduct of ART in both clinical practice and research and, when read in conjunction with federal and state or territory legislation, create a robust framework for the conduct of ART in Australia.

The guiding principles in this document are in line with community expectations that ART activities will be conducted in a manner that shows respect, minimises potential harms and supports the ongoing wellbeing of all parties, including persons born as a result of ART. These Ethical Guidelines also support the right to fair and reasonable access to health care, including ART.

These Ethical Guidelines have been developed primarily for ART clinicians, clinic nurses, embryologists, counsellors and administrators, researchers, Human Research Ethics Committees (HRECs) and governments, identifying guiding principles that should inform the conduct of clinicians and researchers and the procedures developed in clinics and research facilities. These guiding principles are supported by practical guidelines that clinicians and researchers should include in their standard operating procedures to ensure that they comply with the principles. These practical guidelines should be followed unless there is an effective alternative option that is consistent with the relevant principle.

All activities referred to in these Ethical Guidelines must be carried out in compliance with existing laws and regulatory frameworks. The activities must also comply with relevant professional and accreditation standards.

In addition to this document, researchers need to refer to the current version of the *National Statement on Ethical Conduct in Human Research*, and any other relevant ethical guideline.

³ Health Direct (2020) [Infertility](#), Health Direct, accessed 27 March 2023 .

⁴ Australian Institute of Health and Welfare 2022 . National Perinatal Data Collection annual update 2020.Cat. no.PER101. Canberra: AIHW. Available from: <https://www.aihw.gov.au/reports/mothers-babies/australias-mothers-babies/data>

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
 - practices that raise specific ethical issues
 - licensable activities under the *Research Involving Human Embryos Act 2002* (RIHE Act) that occur in the clinical practice setting. For example, the use of excess ART 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 13).

Structure of the Ethical Guidelines

These Ethical Guidelines are divided into three parts:

- Part A provides introductory information, clarifying the role and scope of these guidelines.
- Part B provides guiding principles for the clinical practice of ART and practical guidelines in order to apply such principles. This part of the Ethical Guidelines remains a key element in the accreditation process for ART clinics.
- Part C provides ethical guidelines for research involving ART and other practices. It is intended for use by 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 general licence to undertake such research.

Part C is consistent with Commonwealth legislation on embryo research and human cloning and was updated in 2007 to the extent required by changes to the *Prohibition of Human Cloning Act 2002* (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* (the Amendment Act). The Amendment Act extended the range of licensable activities and changed the title of the PHC Act to the *Prohibition of Human Cloning for Reproduction Act 2002*.

Following the enactment of the *Mitochondrial Donation Law Reform (Maeve's Law) Act 2022*, these Ethical Guidelines also address mitochondrial donation in the Mitochondrial Donation Supplementary Section (Part D). The Supplementary Section does not sit neatly within Part B or Part C of the ART Guidelines, and should be read with reference to the relevant sections of Part B and/or Part C. The Supplementary Section has been developed primarily for medical specialists, patients, researchers, mitochondrial donation licence holders, ART clinicians, counsellors, research coordinators, and Human Research Ethics Committees (HRECs), who are involved, or considering involvement, in mitochondrial donation programs in Australia. The Supplementary Section is intended for use by researchers when applying to the NHMRC Embryo Research Licensing Committee for a mitochondrial donation licence.

Further information about the national legislation for embryo research and human cloning is at Appendix 2.

Review of the Ethical Guidelines

Since these Ethical Guidelines were developed in 2004, they have been subject to rolling review. This means that parts of the guidelines will be updated as required, in place of a whole-of-document review at a specific point in time.

Year of release	Impetus for the review
2007	Part C - to the extent required by changes to the PHC and RIHE Acts brought about by the Amendment Act.
2017	Parts A and B - to ensure ongoing relevance and contemporary guidance. Consequential editorial revisions were made to Part C.
2023	Added Part D (Mitochondrial Donation Supplementary Section) to facilitate the ethical introduction of mitochondrial donation, following enactment of the <i>Mitochondrial Donation Law Reform (Maeve's Law) Act 2022</i> . Consequential editorial revisions to update the process narrative, provide information about the updated legislation and update the terminology used in the pre implantation genetic testing section so that it reflects contemporary ART practice.

PART B: ETHICAL GUIDELINES FOR THE CLINICAL PRACTICE OF ART

2 Guiding principles in the clinical practice of ART

Assisted reproduction raises significant issues for individuals, families and communities. It can be a controversial topic, with opinions influenced by a wide range of political, cultural, religious, ethical, scientific, professional and legal factors. Some may regard assisted reproduction as standard medical practice that should be available with minimal constraints, in the interest of scientific progress and out of respect for an individual's or a couple's reproductive choices. Others, in contrast, may regard it as ethically problematic, raising a number of issues and dilemmas that challenge humanity's core values, putting the needs and wants of the intended parent(s) above those of the potential child. Some may regard ART to be a direct contradiction of their religious faith. For some, ART may raise questions about the extent to which medicine should 'interfere with nature' or the manner in which medical technology may empower or disempower individuals and the control they have over their own lives, bodies and reproductive futures.

Despite these varied views, ART has an established place in modern health care systems. For individuals or couples facing infertility, assisted reproduction may offer the best, or in some cases, the only option to conceive a much-wanted child. Consequently, those who require ART do not want to face unnecessary obstacles. Rather they desire care that optimises outcomes and minimises risks to both themselves and the child who may be born.

In developing these Ethical Guidelines, the Australian Health Ethics Committee (AHEC) was cognisant of the:

- cultural and social importance attached to reproduction and to children
- complex biological connections and social relationships that occur in the context of, or as a result of, ART
- difficulty in balancing the needs, concerns, and interests of all relevant parties, which may include the intended parent(s), gamete or embryo donor(s), a surrogate, the person who may be born and/or any child within the family unit who may be affected by that birth
- different views regarding the status attributed to human embryos and the moral acceptability of ART itself
- risks involved in ART, and the inevitable uncertainties around outcomes that exist where scientific progress is rapid and is quickly translated into clinical practice
- possibility that scientific progress and clinical practice may outpace community debate and legal frameworks.

The guiding principles below inform these Ethical Guidelines and aim to support the clinical practice of ART so that health professionals have an ethical framework to guide clinical consideration and decision-making. While all of these principles are important, they will not always be equally important in any given situation and are therefore not listed in any particular order of importance. Judgments will always be needed as to what weight should be attached to each principle and how the obligations arising from each principle should be satisfied. This will require explicit consideration of the context in which ART is being pursued and the salient interests of all relevant parties.

Guiding principles

1. ART activities must be conducted in a way that shows respect to all involved.
2. The interests and wellbeing of the person who may be born as a result of an ART activity must be an important consideration in all decisions about the activity.
3. ART activities must be undertaken in a manner that minimises harm and maximises the benefit to each individual or couple involved in the ART activity, any persons who may be born as a result of the activity, and any other child within the family unit who may be affected by that birth.
4. 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 as a result of the ART activity.
5. Decision-making in the clinical practice of ART must recognise and respect the autonomy of all relevant parties, promoting and supporting the notion of valid consent as a fundamental condition of the use of ART.
6. Decision-making in the clinical practice of ART must recognise that social relationships and social context may affect an individual's or a couple's decision-making and be sensitive to cultural and spiritual differences.
7. Processes and policies for determining an individual's or a couple's eligibility to access ART services must be just, equitable, transparent and respectful of human dignity and the natural human rights of all persons, including the right to not be unlawfully or unreasonably discriminated against.
8. The provision of ART must be underpinned by policies that support effective and efficient practices that minimise interventions not supported by evidence of successful clinical outcomes.
9. 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, to the degree that is protected by law.

The status of the human embryo

There are different views held in the Australian community about the status attributed to a human embryo. To different individuals the same embryo can be seen as a living human entity in the earliest stage of development, a potential life, or a group of cells. Some argue that the value and significance of an embryo is best determined by the individual or couple for whom it was created, based on their individual or collective set of values, preferences, and beliefs.

Nevertheless, under Commonwealth legislation, the human embryo is given a special status. The *Research Involving Human Embryo Act 2002* and the *Prohibition of Human Cloning for Reproduction Act 2002* regulate the creation and use of human embryos outside of the human body, providing sanctions for those who misuse embryos. The Acts, and these Ethical Guidelines, recognise that the creation and use of a human embryo requires serious consideration.

3 Application of guiding principles in the clinical practice of ART

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

A range of parties may be involved in ART, including the intended parent(s), gamete or embryo donor(s), a surrogate, persons who may be born as a result of ART and any child within the family unit(s) who may be affected by that birth.⁵ The interests of these parties are invariably interrelated and interdependent and may be competing. In decision-making about ART every effort should be made to consider the interests of all relevant parties in order to reconcile, as far as possible, these individual and collective interests.

3.2 The interests and wellbeing of the person who may be born as a result of an ART activity must be an important consideration in all decisions about the activity.

All competent adult participants exercise a choice about their involvement in ART activities. The person who may be born as a result of the activity does not. Although the same can be said when conception is natural, some ART activities offer the potential for greater influence of the desires of the intended parent(s).

Some argue that the child would not exist without the desire of the intended parent(s) to become parents and that it is in a child's best interest to be born. Nevertheless, ART may have serious consequences for the person born. Therefore, ART activities should not commence without serious consideration of the interests and wellbeing of the person who may be born as a result of that activity.

3.3 ART activities must be undertaken in a manner that minimises harm and maximises the benefit to each individual or couple involved in the ART activity, any persons who may be born as a result of the activity, and any other child within the family unit who may be affected by that birth.

Decisions regarding any procedures or the use of gametes or embryos should take into account any potential harm to any relevant party, the views of the intended parent(s), any medically relevant factors, and the likelihood of a successful live birth.

In deciding whether to proceed, clinics should carefully consider potential harms to the person who may be born, or any child who may be affected by that birth.

Clinics may refuse or delay treatment (pending further review by the clinical team) if there are concerns about the physical, psychological and/or social wellbeing of any relevant party.

⁵ These parties are not listed in order of importance.

3.4 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 as a result of the ART activity.

The significance ascribed to a biological connection varies considerably from person to person. For some people, their connection to their biological parents, surrogate, siblings or other biological family members is very significant. For others, some or all of these biological connections have 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 or an embryo 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 of biological connections and social relationships is important for prospective gamete donors or providers, and for those considering the use of donated gametes, donated embryos, surrogacy, or the posthumous use of gametes or embryos. In each of these cases, counselling by a professional with the appropriate training, skills, experience and competency to counsel in reproduction is required to assist those involved in their decision-making and to explore the possible implications of such decisions.

3.5 Decision-making in the clinical practice of ART must recognise and respect the autonomy of all relevant parties, promoting and supporting the notion of valid consent as a fundamental condition of the use of ART.

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. To support their decision-making, individuals and couples seeking ART are entitled to the provision of detailed, accurate, contemporary and relevant information about proposed procedures or treatment and access to counselling about the potential consequences or risks, by a professional with the appropriate training, skills, experience and competency to counsel in reproduction.

Valid consent must be obtained from all relevant parties for each specific procedure or treatment. The process of obtaining consent for ART activities is ongoing 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, people with impaired decision-making capacity, or the deceased), a representative (as defined by relevant legislation, or as identified by the Ethical Guidelines) must be involved in the discussions and decision-making.

Although it is important to respect autonomy, an individual's or a couple's autonomy may be constrained by ethical and legal parameters.

3.6 Decision-making in the clinical practice of ART must recognise that social relationships and social context may affect an individual's or a couple's decision-making and be sensitive to cultural and spiritual differences.

It is important to recognise that social relationships and social context may enable, shape, or constrain an individual's or a couple's autonomy (i.e. autonomy is relational).

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, or those of their family and/or community.

Whilst it is important that the clinical team recognise the role that social factors play in decision-making, assumptions should not be made based on the personal circumstances, cultural background or spiritual beliefs of an individual or a couple seeking ART.

3.7 Processes and policies for determining an individual's or a couple's eligibility to access ART services must be just, equitable, transparent and respectful of human dignity and the natural human rights of all persons, including the right to not be unlawfully or unreasonably discriminated against.

In determining an individual's or a couple's eligibility to access ART services, there must be no unlawful or unreasonable discrimination, for example, on the basis of:

- race, religion, sex, sexual orientation, relationship status, gender identity or intersex status, social status, disability or age⁶
- the reason(s) for seeking assisted conception
- refusal to participate in research.

The right of an individual or a couple to accept or reject specific procedures or treatments should be respected. However, where the choice of an individual or a couple is in conflict with current clinical evidence and practice, is likely to have an adverse effect on the person who would be born, or has demonstrable adverse social impacts (e.g. the transfer of multiple embryos at the one time), then it is appropriate that these factors are taken into account in decision-making regarding the procedure. There are circumstances where it is reasonable for a clinician to delay treatment or decline to treat an individual or couple.

Conscientious objection

A member of staff or a 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, so long as the objection does not contravene relevant anti-discrimination laws and does not compromise the clinical care of the patient (e.g. the patient is referred to someone without a conscientious objection and is willing to accept their care). The clinic must allow a member of staff or a student who expresses a lawful conscientious objection to withdraw from involvement and ensure that the member of staff or student is not disadvantaged because of their lawful conscientious objection.

3.8 The provision of ART must be underpinned by policies that support effective and efficient practices that minimise interventions not supported by evidence of successful clinical outcomes.

The principle of effectiveness requires that waste is reduced, practices that clearly do not work are not used, and proven measures that are likely to succeed are implemented. Effectiveness is linked to the concept of efficiency, which requires that limited resources be used in the most productive manner possible.

⁶ In considering the meaning of these terms, the following Acts are relevant: *Age Discrimination Act 2004 (Cth)*; *Disability Discrimination Act 1992 (Cth)*; *Sex Discrimination Act 1984 (Cth)*; *Australian Human Rights Commission Act 1986 (Cth)*; and similar state and territory legislation.

3.9 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, to the degree that is protected by law.

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

Clinics must maintain policies for each treatment and procedure available at the clinic. These policies must identify the line of responsibility in each circumstance. For example, specific policies should be developed and implemented in relation to:

- the range of treatments and procedures available
- 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 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.

Clinics must also have processes in place for the audit and/or peer review of clinical decisions.

Conflicts of interest

There is a need to ensure that the safety and wellbeing of patients takes priority over the commercial, financial, personal or other interests of the clinic or clinician. Clinics and clinicians should therefore avoid interactions that do not further patient care and which have the potential to bias professional judgment.

Clinics should ensure that the clinical team discloses any interests, including any commercial, financial or personal interests, relating to the services provided by the clinic or any treatment or procedure recommended by the treating clinician(s). Disclosure of interests is necessary in order to assess any relevant conflicts; however, disclosure alone does not resolve a conflict. Clinics must maintain documented practices and procedures for the disclosure of interests and management of conflicts of interests.

Privacy

The right to privacy is not absolute in Australia. However, all individuals and couples involved in ART activities, including gamete and embryo donors, and persons born, are entitled to privacy to the degree that is protected by law.

ART clinics hold large amounts of personal, sensitive or health information. Where an ART clinic operates as a private sector health service provider, it is considered an 'Australian Privacy Principle (APP) entity' under the *Privacy Act 1988 (Cth)* and is required to comply with the Privacy Act and the Australian Privacy Principles (APPs). It is a requirement for APP entities to take reasonable steps to secure this information from misuse, interference, loss and from unauthorised access, modification or disclosure. ART clinics in the private sector should seek advice from the relevant federal body⁷ in order to understand best practice and how to comply with the APPs when it comes to handling and storing this information.

ART clinics that operate as a public health service provider must comply with the relevant state or territory privacy legislation. Clinics must have a privacy policy that ensures compliance with the relevant legislation.

⁷ At the time of publication [2017], this would be the Office of the Australian Information Commissioner.

4 Information, counselling and consent

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 activities is informed decision-making which involves provision of accurate and contemporary information relevant to the circumstances. Decision-making must be supported by the provision of access to counselling by a professional with the appropriate training, skills, experience and competency to counsel in reproduction.

Information giving

4.1 Provide and discuss information – General requirements

- 4.1.1** Clinics must ensure that 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 undue pressure or inducement.
- 4.1.2** Clinics must ensure that the following information is discussed, at a minimum:
- 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, any clinically relevant outcomes and success rates and, where applicable, an explanation that certain procedures may be undertaken by persons other than the individual's or couple's treating clinician
 - whether any training activities are intended to be conducted in the course of the treatment, including where a member of the clinical team will be supervised by more experienced staff whilst undertaking a procedure (see paragraph 10.6)
 - any interests of the clinician, including any commercial, financial or personal 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 3.9)

- an explanation of all costs involved for relevant parties. Clinics must provide individuals or couples with sufficient information regarding the likely fees and the associated out-of-pocket expenses so that they are able to make an informed financial decision
- the clinic's privacy and record keeping policies, including an explanation of any mandatory uses or reporting of data
- 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 facilitate 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 at the particular clinic. Options include:

- use in their own or their partner's reproductive treatment (including the potential for posthumous use – see paragraph 8.22)
- donation to another individual or couple for use in reproductive treatment (see Chapters 5 and 6) and the potential for this donation to be reallocated to a subsequent individual or couple (see paragraph 6.1.3)
- use in research (see Part C of these Ethical Guidelines)
- use in training or quality assurance activities (see paragraphs 10.3 – 10.6)
- 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 The provision of information should be separated from the process of seeking consent, to allow the individual or couple sufficient time to consider the information discussed and the opportunity to seek further information and/or participate in counselling, before consent is provided.

4.2 Provide and discuss all relevant information – Specific situations

Individuals 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 individuals and couples undergoing ART is sufficient to facilitate an accurate understanding of the following issues:
- the likelihood of the individual becoming pregnant other than through ART
 - the likelihood of the individual becoming pregnant via the proposed reproductive procedures, referencing conditional factors including the individual's age, the number of cycles previously undertaken and recent and meaningful success and failure rates relevant to the particular individual or couple
 - the potential that treatment will produce embryos that are considered unsuitable for transfer and the potential that such embryos may be used in training and quality assurance activities, or discarded (see paragraphs 4.5.1 and 10.3 – 10.6)

- any potential short or long-term physical and psychosocial implications for the person who would be born, the individual or couple, acknowledging that these may be uncertain
- the currently available published data on morbidity, and short and long-term outcomes for persons born through ART, including for future generations.

4.2.2 The provision of accurate and contemporary information to individuals and couples undergoing ART activities is ongoing and not a single event prior to the commencement of treatment. Clinics should document the information provided in relation to paragraph 4.2.1 and reassess the accuracy of the information before the commencement of a new cycle, or following any clinically significant change in circumstances.

Individuals and couples involved in donor conception programs

4.2.3 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
- the scope of consent, decision-making responsibilities and the rights of each person involved to withdraw consent (see paragraphs 5.11 – 5.12, 6.2 and 6.4) including the possibility that there may be unused gametes or embryos at the completion of the recipient's treatment and the possible options for these gametes or embryos
- the ongoing responsibilities of each party to all other parties (see paragraphs 5.6 – 5.9)
- the 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
- the possibility that egg donation may affect the egg donor's own fertility.

4.2.4 In addition to the information outlined in paragraph 4.2.3, potential gamete or embryo recipients need information about the potential gamete donor (or gamete providers in the case of embryos) that is relevant to the care of the person who would be born. Clinics must allow recipients of donated gametes or embryos 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 existing 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 already born from the gametes provided by the same gamete donor and the number of families involved.

4.2.5 Where a potential gamete donor has a spouse or partner, clinics should encourage the potential donor to include their spouse or partner in the discussions about their gamete donation, acknowledging the benefits of open disclosure and the potential impact of the decision on the spouse or partner, the couple's relationship and/or the family unit.

Individuals and couples seeking to store gametes or embryos

4.2.6 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 for the particular clinic
- the currently available information about outcomes for persons born from stored gametes or embryos
- any limitations on use, specific to the clinic or the state or territory
- any limitations on storage times, specific to the clinic or the state or territory
- any circumstances under which the clinic may dispose of the gametes or embryos before the end of the consent period, including the clinic's policy for managing disputes that may arise between a couple for whom an embryo is stored (see paragraphs 7.2, 7.4 and 7.6)
- the responsibilities of each party (including the clinic's) for stored gametes or embryos (see paragraphs 5.11, 6.2 and Chapter 7).

Individuals and couples seeking ART 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 or are illegal under Australian legislation.

- 4.2.7** Clinics and clinicians must not promote or recommend practices which contravene these Ethical Guidelines or Australian legislation, nor enter into contractual arrangements with overseas providers who offer such practices.
- 4.2.8** Clinics approached by an individual or a couple for advice on undertaking ART overseas have an ethical obligation to advise the individual or couple of any concerns about the standard of care in the overseas clinic or acknowledge where the standard of care is unknown.

- 4.2.9** Where an individual or couple has made an autonomous decision to seek ART overseas, clinics may provide information aimed at the reduction of harm to the intended parent(s) and the person who would be born. This may include advice aimed at reducing the likelihood of ovarian hyperstimulation, the promotion of single embryo transfer and supporting the right of persons born from donated gametes or embryos to know the details of their genetic origins.
- 4.2.10** Where an individual or couple has made an autonomous decision to seek ART overseas, a clinician may feel they have an ethical obligation to participate in elements of the treatment of the individual or couple in order to minimise potential harms, however:
- clinicians have no obligation to participate in such treatment (see paragraph 3.7 – Conscientious objection)
 - clinicians should be aware of the relevant legislation in the relevant state or territory before participating in the treatment in such circumstances.

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 procedures.

4.3 Provide counselling services – General requirements

- 4.3.1** Clinics must provide accessible counselling services from 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 potential personal and social implications for the person who may be 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 professionals who are independent of the clinic, who have specific expertise with appropriate training, skills, experience and competency to support individuals and couples in making decisions about their treatment.

- 4.3.2** Clinics should be satisfied that 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, 8.10.2 and 8.18).
- 4.3.3** Clinics should ensure that the time period between counselling and obtaining consent for treatment is sufficient to enable consideration of the issues. Conversely, the time elapsed should not be so great that the information discussed and the issues explored during counselling are no longer relevant or contemporary.

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 and any other child within the family unit(s) who may be affected by that birth
 - 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 potential long-term psychological implications for a person born from an embryo that has undergone multiple reallocations (see paragraph 6.1.3)
 - 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** In addition to the requirements outlined in paragraph 4.4.1, counselling for potential gamete or embryo donors must explore the reason(s) why they wish to be involved in a donated gamete program. Clinics should document the reason(s) for the future information of any person born from the donation.
- 4.4.3** Where a potential donor has a spouse or partner, the clinic should encourage the potential donor to include their spouse or partner in counselling exploring the topics described in 4.4.1, due to the potential impact on the spouse or partner, the couple's relationship and/or the family unit.
- 4.4.4** 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 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
- preimplantation 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 ongoing 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 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 to have the capacity to provide consent
- the decision to consent to the treatment or procedure must be made without undue pressure
- all relevant requirements regarding the provision of information and counselling requirements must be satisfied (see paragraphs 4.1 – 4.4 and Chapter 8)
- the consent must be specific, and is effective only in relation to the treatment or procedure for which information has been given
- consent must be sought for all training and quality assurance activities conducted on embryos, including where an embryo is deemed unsuitable for transfer (see Chapter 10).

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 professional with the appropriate training, skills, experience and competency (see paragraphs 4.3 and 4.4).

- 4.5.3 Clinics must have procedures to verify the identity of those providing consent and to ensure the validity of the consent.
- 4.5.4 Consent must be obtained in writing and documentation must include a signed statement by the treating clinician confirming that all relevant provision of information and counselling requirements have been satisfied (see paragraphs 4.1 – 4.4 and Chapter 8).
- 4.5.5 All relevant parties must be provided with a copy of the signed consent form for each specific treatment or procedure.

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 Consent for participation in a donor conception program must include:
 - provision of full details of the agreed arrangements including any limitations the donor(s) have placed on the use, storage or discard of the embryos (including reallocation) (see Chapters 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 3.4)
 - 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), including an acknowledgement of the decision-making responsibilities of each party, as described in paragraphs 5.11 and 6.2
 - obtaining specific consent from the donor to make relevant information available to the recipients and any person born as a result of the donation (see paragraphs 4.2.4 and 5.9)
 - obtaining specific consent 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 paragraph 5.7.1).
- 4.6.2 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

- 4.6.3** In addition to the requirements for obtaining consent outlined in paragraph 4.5, clinics must obtain specific consent from each relevant party before gametes or embryos are stored.
- 4.6.4** Consent must 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 withdrawing consent, or fail(s) to give further instructions at the expiry of the period of storage specified in the consent form.

Non-mandatory uses of data

- 4.6.5** In addition to the requirements for obtaining consent outlined in paragraph 4.5, clinics must 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).

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 5.12 and 6.4), individuals and couples have the right to withdraw or vary their consent for ART activities.

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, and quality assurance activities are outlined in Chapter 10.

5 Use of donated gametes in ART activities

Introduction

The gametes used in ART activities can either be provided by the person receiving treatment, their spouse or partner, or provided by a donor or donors. 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 they know personally (known donation), clinics must respect the wishes of the donor unless the donation is prohibited by law or is contrary to these Ethical Guidelines (see paragraph 5.2.2).
- 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 to individuals or couples from particular ethnic or social groups can only do so through known donation. This also applies to gametes and embryos in storage that were not allocated to a specific individual or couple prior to the introduction of these Ethical Guidelines [2017].⁸

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

Children and young people

- 5.2.1 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.

⁸ Where a clinic has unallocated 'unknown directed' donations in storage, the clinic should recontact the relevant donors to update their consent to either unknown or known donation.

Donation from a relative

The donation of gametes between relatives (e.g. between sisters, from daughter to mother) may offer benefits to all parties involved, including the person who may be born. However, due to the possible influence the relationship, or the family, could have on the potential donor's decision to donate and the impact of potentially confusing family relationships, this practice requires special consideration.

- 5.2.2** Clinics must not create embryos from gametes derived from close genetic relatives, as defined by relevant legislation.

Older donors

- 5.2.3** 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 risks of proceeding with such an arrangement for the person who would be born.

Donors with an increased risk of infectious disease

- 5.2.4** 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 must be reviewed in light of new evidence.

5.3 Limit the number of families created from a single donor

- 5.3.1** Clinics must take all reasonable steps to minimise the number of families created through donated gamete treatment programs.

- 5.3.2** Gametes from a single donor must be used to create only a limited number of families. In the absence of specific state or territory legislation, clinics must take account of the following factors when deciding on an appropriate number of families to be created:

- the number of persons already born from the donor's gametes
- 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 on the number of families expressed as part of the consent of the donor
- whether the donor has already donated gametes at another clinic.

- 5.3.3** In the absence of a national registry for gamete donation, to encourage disclosure of multiple donations at multiple clinics, potential gamete donors should be reminded of the importance of limiting the number of families created from a single donor. Prior to donation, clinics must:

- 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 legislation. This position reflects concerns about the potential exploitation of donors (particularly egg donors) and the potential risks to all parties.

- 5.4.1** While direct or indirect inducements are prohibited, it is reasonable to provide reimbursement of verifiable out-of-pocket expenses directly associated with the donation, including, but not limited to:
- medical and counselling costs, both before and after the donation
 - travel and accommodation costs within Australia
 - loss of earnings⁹
 - insurance
 - child care costs when needed to allow for the donor's attendance at donation related appointments and procedures
 - legal advice.

5.5 Use of imported gametes

- 5.5.1** Treatment in Australia using gametes donated by persons living in another country must not take place unless it can be established that the gametes were obtained in a manner consistent with any Commonwealth legislation and any relevant state or territory legislation, accreditation body guidelines and these Ethical Guidelines.
- Where a recipient has had a child born¹⁰ before the introduction of these Ethical Guidelines [2017] and gametes or embryos are in storage, within Australia, for the recipient's future use, the gametes or embryos may be used in the treatment of the recipient provided that the relevant requirements outlined in paragraph 4.4.1 are satisfied.

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 donor conception program.

For donations allocated prior to the introduction of the 2004 edition of these Ethical Guidelines, please refer to paragraphs 5.10 and 5.13–5.15.

⁹ Donors who access paid leave during the donation process cannot be reimbursed for loss of earnings. Loss of earnings can be demonstrated by the donor providing payslips verifying that unpaid leave was taken.

¹⁰ Or has had an embryo transferred before the introduction of these Ethical Guidelines, and the birth of the resulting child is pending.

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. Counselling received by potential gamete recipients must explore 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 (see paragraph 4.4.1). Whilst recipients cannot be forced to disclose this information to their children, clinics have a role in encouraging and supporting early disclosure.

- 5.6.1 Clinics must not use donated gametes in reproductive procedures unless the donor has consented to the release of their identifying information to the person(s) born as a result of the donation (see paragraphs 4.6.1 and 5.5.1).
- 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 uncertain. This includes the attempted fertilisation of a human egg by human sperm from more than one donor at a time.
- 5.6.3 Clinics must:
 - encourage gamete recipients to disclose to their children their genetic origins
 - provide ongoing support to parents, to help them to understand the potential significance of the biological connection and the benefits of early disclosure
 - assist parents to find effective ways of disclosing to their children their genetic origins
 - provide persons born from donated gametes with a supportive environment within which to explore the possibility of meeting with the donor(s) and/or siblings (see paragraph 5.9).

5.7 Provide gamete donors with relevant information concerning persons born using their donated gametes

Gamete donors are entitled to some information about any persons born as a result of their donation (in particular, to prepare them for possible future approaches by the persons born).

- 5.7.1 Clinics should provide gamete donors, on request, with non-identifying information about the number, age and sex of any persons born as a result of their donation.

5.8 Encourage the update of relevant information

- 5.8.1 Clinics should inform potential gamete donors (or gamete providers for donated embryos) that it is a donor's ethical responsibility to keep the clinic informed about any changes to their health that may be relevant to any person born or the recipients of their donation and about changes to their contact details.
- 5.8.2 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.

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

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

- 5.9.1** A clinic that is approached by a person born from gametes donated at that clinic, who has reached the age of 18, must arrange for counselling by a professional with the appropriate training, skills, experience and competency to support their decision-making, prior to providing the following information, as a minimum:
- all information specified in paragraph 4.2.4
 - identifying information about the gamete donor (see paragraph 5.6.1)
 - any identifying information that any person born from the gametes of the same donor has consented to being released (see paragraph 5.10.2).
- 5.9.2** A clinic that is approached by a person born from gametes donated at that clinic, who has not yet reached the age of 18, must arrange for counselling by a professional with the appropriate training, skills, experience and competency to support their decision-making and make a determination of the person's maturity and ability to appreciate the significance of the request (including any implications for any younger siblings).
- 5.9.3** Should the person born from donated gametes be assessed as sufficiently mature, the clinic must provide the information listed in 5.9.1, as a minimum.

5.10 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 to the degree that is protected by law (see paragraph 3.9).

- 5.10.1** When approached by a person who was born from donated gametes who now seeks identifying information about their gamete donor, the clinic must 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 5.14), the clinic should make all reasonable efforts, consistent with the original consent document and the privacy rights of the donor, to contact the gamete donor and request their consent to the release of their information.
 - If the consent form includes permission for release of identifying information, the clinic should make all reasonable efforts to notify the gamete donor of the request prior to the release of the information. This process should not, however, unreasonably delay the release of such information to the person born.

- 5.10.2** 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 must 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 must not release identifying information or contact the individual(s).
- 5.10.3** Clinics must provide the donor with access to counselling by a professional with the appropriate training, skills, experience and competency, as part of the preparation for the release of identifying information.

Responsibility for gametes

5.11 Ensure that all parties are aware of who is responsible for decision-making about the use, storage and discard of donated gametes¹¹

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 their consent for donation also needs to be protected (see paragraph 5.12).

- 5.11.1** 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 their gametes (unknown donation), the clinic has responsibility for decision-making about the allocation, storage and discard of the gametes, subject to any directions or limitations expressed in the consent of the donor. Once allocated, the responsibility for decision-making is transferred to the recipient (see paragraph 6.2).
 - When the gamete donor has specified a recipient for their gametes (known donation), and consent for treatment has been given by the recipient, the recipient has responsibility for decision-making about the use, storage and discard of the gametes or resulting embryos, subject to any directions or limitations expressed in the consent of the donor (see paragraph 6.2).
 - The clinic is responsible for maintaining the appropriate storage of donated gametes (see Chapter 7).

Withdrawal of consent for donation

5.12 Recognise the right of an individual to withdraw or vary their consent

- 5.12.1** 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.

¹¹ The RIHE Act specifically denotes who the responsible parties are, and therefore which parties need to provide consent for the donation of gametes and embryos for research purposes. Clinics accepting donation for research purposes must act in accordance with this legislation.

Gametes donated prior to 2004 on the condition of anonymity

Prior to the introduction of the 2004 edition of these guidelines, many donations across Australia were provided 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.

5.13 Use of gametes collected before 2004

- 5.13.1** Clinics should not use gametes collected before the introduction of the 2004 edition of these Ethical Guidelines without the consent of the gamete donor to the release of identifying information for any future treatments.
- 5.13.2** The only situations in which these gametes 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.
- 5.13.3** In both circumstances described paragraph 5.13.2, the recipients must be given detailed information and offered further counselling to explore the benefits and risks associated with this arrangement for the persons born from donated gametes without consent to release of identifying information.

5.14 Encourage and promote consent for the release of information

- 5.14.1** Organisations that have responsibility for the welfare of individuals born from donated gametes must use public forums to encourage former donors to consider registering their consent for the release of information about themselves (as outlined in paragraph 5.9.1) to persons born from the donated gametes. Such encouragement must not be coercive or create undue pressure on the donors, should they decide to remain anonymous.

5.15 Maintain appropriate records

- 5.15.1** Clinics must ensure that all existing information about parties involved in donor conception programs prior to the introduction of the 2004 edition of these Ethical Guidelines is maintained in accordance with paragraph 9.2.

6 Additional guidelines for the use of donated embryos

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. Additionally, where a recipient individual or couple no longer requires a donated embryo for their own reproductive treatment, the donated embryo may be reallocated to another individual or couple.

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 builds upon the guidelines in Chapter 5 to provide additional guidelines for the use of donated embryos.

Allocation of donated embryos

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

- 6.1.1 Donated embryos (including those obtained from overseas, see paragraph 5.5.1) must only be used in reproductive treatment if all of the requirements in Chapter 5 for donated gametes are satisfied.
- 6.1.2 Clinics must ensure that the genetic origin of the person who would be born is certain. This includes not transferring multiple embryos, at any one time, where the embryos have different genetic origins.
- 6.1.3 Where a donated embryo (including one created using donated gametes) is no longer required by the individual or couple to whom the embryo was donated, the embryo may be reallocated to another individual or couple, subject to any directions or limitations expressed as part of the consent from the embryo donor(s) (see paragraph 4.6.1), or imposed by law or paragraph 5.1.2 (see paragraphs 6.2.1 and 7.1).

Responsibility for donated embryos

6.2 Ensure that all parties are aware of who is responsible for decision-making about the use, storage and discard of 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 rights of the embryo donor(s) to place limitations on the use, storage and discard of the donated embryos and to withdraw their consent for donation also need to be protected (see paragraphs 4.6.1 and 6.4).

Clinics must have 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 to another 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 an individual or couple.
- Once a recipient individual or couple has accepted a donated embryo, they are responsible for decision-making about its use, storage and discard, including decisions about the reallocation of an embryo (see paragraph 6.1.3), subject to any directions or limitations expressed in the consent of the donor(s) or imposed by law.
- When an embryo is reallocated to a subsequent individual or couple, and they have accepted an embryo, that individual or couple is responsible for decision-making about its use, storage and discard, including decisions about the reallocation of embryos (see paragraph 6.1.3), subject to any directions or limitations expressed in the consent of the embryo donor(s) or imposed by law.

Donation of embryos with a known genetic condition, disease or abnormality

6.3 Carefully consider the implications when facilitating the donation of an embryo known to be affected by a genetic condition, disease or abnormality

The donation of an embryo known to be affected by a genetic condition, disease or abnormality should not be routinely dismissed.

- 6.3.1** When an embryo is known to be affected by a genetic condition, disease or abnormality that will not severely limit the quality of life of the person who would be born, a clinic may facilitate the donation of the embryo if the potential recipient:
- is aware of the status of the embryo and understands and accepts the potential implications for the person who may be born
 - has received and considered all appropriate information and has undergone counselling (see paragraph 8.18).
- 6.3.2** Clinics must not facilitate the donation of embryos known to be affected by a genetic condition, disease or abnormality that would severely limit the quality of life of the person who would be born.

Withdrawal of consent for donation

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

- 6.4.1** The embryo donor(s) can withdraw or vary consent for donation (or reallocation) 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 or embryos may need to make difficult decisions about the use, continued storage or discard of these stored gametes or embryos. This may include 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 4.2.6). Clinics must have obtained valid consent for the storage of gametes and embryos (see paragraphs 4.6.3 – 4.6.5).

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

Individuals and couples responsible for stored gametes or 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 must ensure that all reasonable efforts are made to keep gametes and embryos in safe storage for the period of storage specified in the consent form. After this time, 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 or embryos, in accordance with the clinic's policy (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 or embryos may depend entirely on the personal preferences of the responsible party(ies).

- 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 needed for their own reproductive purposes. The options listed in paragraph 4.1.3 should then be offered.¹²

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

- 7.4.1 Clinics must have clear policies for managing disputes that may arise between individuals for whom an embryo is stored.
- 7.4.2 When a dispute arises, a clinic may suspend the expiry of the period of storage specified in the consent form (see paragraph 4.6.4) at the request of either party. Such a suspension should be notified in writing to both parties and should be reviewed by the clinic every five years. Any subsequent discard of the embryos, without the consent of both parties, must be in accordance with the clinic's policy, which should have been clearly articulated to the responsible couple before the storage initially occurred (see paragraphs 4.2.6 and 7.6).

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

The use of stored gametes or embryos for reproductive purposes following the death of a gamete provider requires the valid consent of the gamete provider or in some situations, their spouse or partner (see paragraph 8.22).

- 7.5.1 Clinics must have clear policies for the management of stored gametes or embryos following the death of a gamete provider.
- 7.5.2 Unless prohibited by law, if a clinic receives confirmation that a gamete provider has died, the gametes or embryos should remain stored and made available for use, or be discarded, in accordance with the wishes of the deceased expressed in the consent for storage (see paragraphs 4.6.4 and 8.22).

¹² From this point on, these embryos are considered 'excess ART embryos' in accordance with the RIHE Act.

7.6 Manage the discard of stored gametes and embryos

- 7.6.1** Clinics must have policies and procedures in place for discarding stored gametes and embryos. These policies should provide for the responsible party(ies) to determine the means of removal or discard of the embryos from the clinic, including those which are legal, but are not available at the particular clinic (see paragraph 4.1.3).
- 7.6.2** Clinics may, in limited circumstances, and in line with the clinic's policy, discard stored gametes or embryos without the consent of the individual or couple for whom the gametes or embryos are stored (see paragraphs 4.2.6, 7.1.2, 7.2.1 and 7.4.2).
- 7.6.3** Before a clinic may discard stored gametes or embryos without the consent of the responsible party(ies), clinics must make all reasonable efforts, and document all attempts, to notify the responsible party(ies) and allow reasonable time for the responsible party(ies) to take action.

8 Practices that raise specific ethical issues

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
- surrogacy
- sex selection
- preimplantation genetic testing
- the collection and use of gametes from persons who are deceased or dying and/or the posthumous use of stored gametes or embryos

Each of these practices warrants serious ethical consideration and may also be subject to specific state and territory legislation.

Fertility preservation

Introduction

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.

An individual may have medical and/or personal or social reasons for choosing to collect and store their gonadal tissue and/or gametes. For example, certain medical conditions and/or treatments can harm a person's fertility, and some individuals may have personal or social reasons for delaying parenthood beyond their most fertile years, increasing their risk of age-related infertility.

The guidelines below emphasise the guidelines in Chapter 4 and the importance of informed decision-making and the management of expectations within the context of the available clinical evidence.

Guidelines for the collection and storage of gonadal tissue or gametes for fertility preservation from persons unable to provide valid consent are also included below.

8.1 Manage the collection and storage of gonadal tissue or gametes for fertility preservation

- 8.1.1** Clinics should have a policy in place to manage the collection and storage of gonadal tissue or gametes for fertility preservation, including from persons unable to provide valid consent.

Information giving, counselling and consent

8.2 Provide relevant information and counselling

- 8.2.1** Clinics must ensure that those considering the collection and storage of their gonadal tissue and/or gametes are provided with all relevant information in accordance with paragraphs 4.1, 4.2.1 – 4.2.2 and 4.2.6.
- 8.2.2** Clinics must provide those considering the collection and storage of their gonadal tissue and/or gametes with access to counselling by a professional with appropriate training, skills, experience and competency to support their decision-making, in accordance with paragraph 4.3.1.

8.3 Obtain valid consent

- 8.3.1** Clinics must ensure that valid consent for each specific procedure is obtained in accordance with paragraphs 4.5, 4.6.3 – 4.6.5 and 4.7.

Persons unable to provide consent

There may be situations in which it is ethically acceptable to collect and store the gonadal tissue or gametes of persons who are unable to provide consent in accordance with paragraphs 4.5 – 4.6. Assessments should be made on a case-by case basis.

Children and young people

8.4 Assess the ethical acceptability of the proposed collection and storage of gonadal tissue or gametes for a child or young person

- 8.4.1** 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 best means of preserving the fertility of the child or young person
 - the risks and discomfort of the procedure to the child or young person can be minimised
 - the child or young person, if capable, and their parent(s), guardian or otherwise authorised person consents to the proposed collection and storage (see paragraphs 8.5 and 8.6)
 - the collection and storage is not for the reproductive needs of another individual (see paragraphs 5.2.1 and 8.24).
- 8.4.2** Where there is any doubt about the ethical acceptability of the proposed collection and storage of gonadal tissue or gametes for a child or young person, a clinician should seek advice from an independent body.

8.5 Provide relevant information and counselling and obtain valid consent

- 8.5.1 Clinics must ensure that person(s) authorised to consent to the collection and storage of gonadal tissue or gametes from a child or young person are provided with all relevant information and have access to appropriate counselling services (see paragraph 8.2).
- 8.5.2 Clinics must ensure that 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 paragraph 8.3).

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

- 8.6.1 Clinics must respect the developing capacity of children and young people to be involved in decisions about the collection or ongoing storage of their 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.
- 8.6.2 Where appropriate, clinics must ensure that the child or young person is also provided with all relevant information and has access to appropriate counselling services.
- 8.6.3 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 person(s) authorised to consent, to the individual. The individual's valid consent must be obtained for the continued storage of their gonadal tissue or gametes (see paragraphs 4.6.3 and 4.6.4).

People with impaired decision-making ability

8.7 Provide relevant information and counselling and obtain valid consent

- 8.7.1 Clinics must 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 the principles outlined in paragraphs 8.4 – 8.6.

Surrogacy

Introduction

There is legislation governing surrogacy in all Australian states and territories. All persons involved in surrogacy must ensure that they are familiar with the relevant legislation and operate within the law. For ART activities requested under a surrogacy arrangement, the guidelines provided below should be followed, unless there is a legal impediment to doing so.

Surrogacy arrangements are between the commissioning parent(s) and the surrogate and should be entered into with each party having appropriate legal representation. It is not the role of clinics to provide legal advice to potential surrogates and/or commissioning parents, however, clinics do have an ethical obligation to ensure that a legal arrangement is in place, before proceeding with the required ART treatment.

Commercial surrogacy

Commercial surrogacy, where the surrogate receives financial compensation above and beyond expenses associated with the surrogacy procedure and pregnancy, is ethically unacceptable because it raises concerns about the commodification and exploitation of the surrogate, the commissioning parent(s) and any person born as a result of the surrogacy arrangement.

8.8 Do not practise, promote or recommend commercial surrogacy

- 8.8.1 Clinics and clinicians must not practise, promote or recommend commercial surrogacy, nor enter into contractual arrangements with commercial surrogacy providers (see paragraphs 4.2.7 - 4.2.10).
- 8.8.2 It is ethically unacceptable to provide, or offer to provide, direct or indirect inducements for surrogacy services.

Altruistic surrogacy

The term 'altruistic 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, pregnancy or birth.

8.9 Confirm that the surrogacy arrangement is ethically acceptable

- 8.9.1 Clinics must not facilitate ART treatment under a surrogacy arrangement if there are concerns about whether the arrangement is ethical and/or legal. This includes the arrangement for reimbursement of verifiable out-of-pocket expenses.

Arrangements for any reimbursement of verifiable out-of-pocket expenses should be between the commissioning parent(s) and the surrogate and each party should be encouraged to seek legal advice before reimbursements are given or received to ensure compliance with relevant state or territory legislation.

It is reasonable for the commissioning parent(s) to reimburse a surrogate's verifiable out-of-pocket expenses directly associated with the procedure or pregnancy, which may include:

- medical and counselling costs, before, during, and after the pregnancy or birth
- travel and accommodation costs within Australia
- loss of earnings¹³
- insurance
- child care costs when needed to allow for attendance at appointments and procedures related to the surrogacy arrangement
- legal advice.

Note: There may be state or territory legislation that regulates what out-of-pocket expenses can and cannot be reimbursed under a surrogacy arrangement.

8.9.2 In an effort to reduce the potential for harm for the surrogate, clinics must:

- ensure that the potential surrogate is medically and psychologically suitable to undertake the requested ART activity
- perform only a single embryo transfer.

Information giving, counselling and consent

8.10 Ensure the provision of relevant information and counselling

8.10.1 Clinics must ensure that sufficient information about the ART treatment is provided to meet the requirements outlined in paragraphs 4.1 and 4.2.1 – 4.2.2.

8.10.2 Individuals and couples involved in an altruistic surrogacy arrangement must undergo counselling before, during and after ART treatment 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 may be born and any other child within the family unit(s) who may be affected by that birth
- the reason(s) why the potential surrogate wants to become involved in a surrogacy program
- the surrogate's right to make informed decisions about their own medical care, including before and during the pregnancy and birth
- the possibility that the surrogate may need medical and/or psychological assistance following the birth and that the pregnancy may affect the surrogate's own health
- the potential significance of the gestational connection and the right of persons born to know the details of their birth, and the benefits of early disclosure

¹³ Surrogates who access paid leave during the pregnancy and birth cannot be reimbursed for loss of earnings. Loss of earnings can be demonstrated by the surrogate providing payslips verifying that unpaid leave was taken.

- the possibility that persons born may learn about their birth from other sources (for example from other family members) and may independently access information about their birth
- the possibility that persons born may attempt to make contact with the surrogate in the future.

8.10.3 Where a potential surrogate has a spouse or partner, the clinic should encourage the potential surrogate to include their spouse or partner in the discussions about the potential surrogacy arrangement, acknowledging the benefits of open disclosure and the potential impact of the decision on the spouse or partner, the couple's relationship and/or the family unit.

8.10.4 Clinics must not proceed with ART treatment to facilitate an altruistic surrogacy arrangement without first being satisfied that a legal arrangement is in place.

8.11 Obtain consent from all relevant parties

8.11.1 Clinics must obtain valid consent, in accordance with the requirements outlined in paragraph 4.5, from the relevant party(ies) for each specific treatment or procedure required. Clinics are not responsible for obtaining consent for the surrogacy arrangement itself as this is a legal arrangement between the commissioning parent(s) and the intended surrogate.

8.11.2 Clinics must respect the autonomy of surrogates to make informed decisions about their own medical care.

8.11.3 All relevant parties should be allowed adequate time for consideration of information and the complex issues involved before consent is provided.

Exchange of information between all relevant parties

There should be voluntary exchange of information between persons born via a surrogate, the surrogate and the commissioning parent(s), with the valid consent of all parties. The guidelines in this section specify the minimum level of information that should be accessible to all relevant parties.

8.12 Provide persons born with information about the surrogate

8.12.1 Persons born via a surrogacy arrangement are entitled to know the details of their birth and to have the opportunity to determine the significance of their gestational connection with the surrogate, in accordance with the principles outlined in paragraphs 5.6, 5.9 and 5.10.

Sex selection

In the context of ART, the term 'sex selection' refers to the selection and transfer of an embryo on the basis of genetic sex. Intended parents seeking to select the sex of an embryo may have genetic or non-medical reasons for doing so. The ART guidelines have long considered that the use of sex selection techniques may be ethically acceptable when used to reduce the risk of transmission of a serious genetic condition, disease or abnormality.

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, or those of their family and/or community. In recent years, there has been an increasing public and professional debate regarding whether intended parents should be permitted to make an autonomous decision regarding sex selection for non-medical purposes. However, a significant voice against the practice also remains.

Sex selection to reduce risk of transmission of a genetic condition, disease or abnormality

8.13 Assess the ethical acceptability of selecting the sex of a human embryo to reduce the risk of transmission of a genetic condition, disease or abnormality

- 8.13.1** Sex selection techniques may be used to reduce the risk of transmission of a genetic condition, disease or abnormality that would severely limit the quality of life of the person who would be born, when there is evidence to support:
- claims that the condition, disease or abnormality affects one sex significantly more than the other (see paragraph 8.16)
 - that the risk of transmission is greater than the general risk of the condition, disease or abnormality occurring within the general population.
- 8.13.2** Sex selection techniques may not be used unless the intended parent(s) have been provided with relevant information and counselling, in accordance with paragraph 8.18.

Sex selection for non-medical purposes

In considering the issue of sex selection for non-medical purposes, the Australian Health Ethics Committee (AHEC) was cognisant of a range of relevant factors, including:

- Existing state and territory legislation regulating ART.
State and territory governments are responsible for regulating the clinical practice of ART.
- The regulation and/or availability of sex selection for non-medical purposes internationally.
At the time of consideration, sex selection for non-medical purposes was being considered in other jurisdictions internationally.
- Concerns about the standard of care in international clinics.
Some international 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.
This becomes an increased concern when considering fertile individuals or couples using ART solely for the purposes of sex selection.
- Developing evidence that some ART activities may increase health risks in women.
This also becomes an increased concern when considering fertile individuals or couples using ART solely for the purposes of sex selection.
- Whether sex selection for non-medical reasons is a justifiable use of medical resources.
- Whether some attitudes towards sex selection for non-medical purposes are influenced by whether or not the procedure would be publicly or privately-funded.
- Values inherent in Australian society that relate to freedom of choice and autonomy, particularly in relation to reproductive choices.
- Whether there is an ethical difference between a desire to introduce variety to the existing sex ratio of offspring within a family and the desire to design the sex of the offspring based on the preferential selection of a particular sex due to an individual's or couple's cultural or personal bias, influences or desires.
- The importance that some individuals or couples place on having both male and female children for the intended family or for the parenting experience, with the possibilities and challenges that this may bring.¹⁴
- The possibility that sex selection for non-medical reasons may validate or reinforce gender stereotyping and discriminatory attitudes, 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 open the way to the selection of other characteristics such as eye or hair colour, based on an individual's or couple's preferences.
- The possibility that access to sex selection for non-medical purposes may reduce potential harms to a family and society by minimising potential family size.
- Concerns that the termination of a pregnancy may be used as an alternative sex selection technique.

¹⁴ The terms 'male' and 'female' are used here to describe the chromosomal sex of the person who would be born. This chapter is not intended to apply to the gender of the person born, nor their intersex status.

AHEC does not endorse, nor wish to perpetuate, gender stereotyping, or cultural or personal biases based on biological sex.

Following lengthy consideration, and the application of the guiding principles in Chapter 2 of these Ethical Guidelines, AHEC concluded that in some circumstances, sex selection for non-medical purposes is consistent with the guiding principles. AHEC's majority view is that there is an ethical difference between a desire to introduce variety to the existing sex ratio of a family and the desire to design the sex of the offspring based on the preferential selection of a particular sex due to an individual's or a couple's cultural or personal bias, influences or desires.

At the same time, AHEC acknowledges that the motivations of those seeking to use sex selection for non-medical purposes cannot be easily identified. What is presented as a desire to introduce variety could conceal cultural and/or personal biases.

AHEC also recognises that many of the issues surrounding ART are as much social and political as they are ethical. With any controversial practice, society's readiness to accept a practice is a relevant and important consideration. At the time of publication [2017], there is limited research into the question of whether Australians support the use of sex selection for non-medical purposes.

It is also recognised that the states and territories have the capacity to legislate regarding ART, including on sex selection for non-medical purposes. At the time of publication [2017], only four Australian states have legislation regulating the clinical practice of ART, with sex selection for non-medical purposes prohibited in two Australian states.¹⁵

Therefore, despite AHEC's majority view that there may be some circumstances where there is no ethical barrier to the use of sex selection for non-medical purposes, paragraph 8.14 applies until such time that wider public debate occurs and/or state and territory legislation addresses the practice.

8.14 Sex selection for non-medical purposes is not currently supported

- 8.14.1** Sex selection techniques may not be used unless it is to reduce the risk of transmission of a genetic condition, disease or abnormality that would severely limit the quality of life of the person who would be born (see paragraph 8.13).

¹⁵ See Appendix One for further information.

Preimplantation genetic testing

Introduction

Preimplantation genetic testing (PGT) comprises a range of techniques. The most common are:

- preimplantation genetic testing for single gene (monogenic) disorders (PGT-M)
- preimplantation genetic testing for structural rearrangements (PGT-SR)
- preimplantation genetic testing for aneuploidy (PGT-A).

Ethical acceptability

8.15 Assess the ethical acceptability of PGT

8.15.1 PGT may only be used to:

- select against genetic conditions, diseases or abnormalities that would severely limit the quality of life of the person who would be born
- select an embryo with compatible tissue for subsequent stem cell therapy intended for a parent, sibling or other relative
- increase the likelihood of a live birth.

8.15.2 PGT may not be used to preferentially select in favour of a genetic condition, disease or abnormality that would severely limit the quality of life of the person who would be born.

8.16 Assess the ethical acceptability of PGT to select against a genetic condition, disease or abnormality that would severely limit the quality of life of the person who would be born

The use of PGT to select against a genetic condition, disease or abnormality requires serious ethical consideration because:

- opinions regarding quality of life differ and may change over time as new treatments become available
- there are differing perceptions of genetic conditions, diseases and abnormalities held within the community
- the practice of selecting against some genetic conditions, diseases or abnormalities may threaten the status of, and equality of opportunity for, people who have that condition, disease or abnormality, and lead to stigmatisation and discrimination
- the technology has technical limitations (such as the failure/inability to identify the condition, disease or abnormality of interest).

8.16.1 It is not possible to list the genetic conditions, diseases or abnormalities for which the use of PGT is ethically acceptable, as context is important and the assessment may change over time. 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, disease or abnormality on the quality of life of the person who would be born, including the anticipated symptoms, age-of-onset and the degree/spectrum or severity of the condition, disease or abnormality
- the concerns of the intended parent(s) about their ability to care for a person born with the condition, disease or abnormality
- the availability and accessibility of therapies or interventions to reduce the severity, delay onset or minimise the impact of the condition, disease or abnormality
- the limitations of the technology, including the likelihood of false positive and false negative results
- the experiences of individuals and families living with the condition, disease or abnormality
- the potential for stigma to influence the perceived impact of the condition, disease or abnormality on the quality of life of the person who would be born
- the extent of social support available to the intended parent(s) and to the person who would be born.

8.16.2 Where there is any doubt about the ethical acceptability of a potential use of PGT, clinics should seek advice from an independent body.

8.17 Assess the ethical acceptability of PGT to select an embryo with compatible tissue for subsequent stem cell therapy for a parent, sibling or other relative

The use of PGT for the purposes of tissue typing an embryo for subsequent stem cell therapy for a parent, sibling or other relative may be ethically acceptable as this practice recognises biological relatedness, is beneficial to the recipient and the subsequent collection of stem cells from umbilical cord blood does not cause physical harm to the person who would be born.

8.17.1 PGT may only be used to select an embryo with compatible tissue for subsequent stem cell therapy for the planned treatment of an intended parent, sibling or other relative.

8.17.2 Clinicians must seek advice from an independent body before undertaking PGT to select an embryo with compatible tissue for subsequent stem cell therapy. The independent body should be satisfied that:

- there is no evidence to suggest that the person who would be born would not be a welcomed, respected member of the family unit
- the use of PGT will not significantly affect the welfare and interests of the person who would be born
- the medical condition of the intended parent, sibling or other relative to be treated is serious and stem cell treatment is the medically recommended management of the condition.

Information giving, counselling and consent

8.18 Provide relevant information and counselling

To make informed decisions, it is essential that individuals or couples who seek PGT understand the technology and the potential risks and benefits of using the technology.

- 8.18.1** Due to the complex nature of the issues involved, and to promote the consideration of the interests and welfare of the person who may be born, individuals and couples seeking PGT must undergo counselling before they may consent to the procedure.
- 8.18.2** In addition to the requirements outlined in paragraphs 4.1 and 4.2, clinics must provide individuals or couples who seek PGT with sufficient information to facilitate an understanding of the limitations of the technology, including the likelihood of false positive and false negative results and the potential for developmental abnormalities to occur despite PGT.
- 8.18.3** In addition to the requirements outlined in paragraph 4.3, clinics must ensure that individuals or couples seeking PGT are aware that they have the option to see a genetic counsellor.
- 8.18.4** In the interest of promoting the consideration of the interest and welfare of the person who may be born, clinics should promote an environment of positive acceptance and non-discrimination.

Individuals and couples seeking PGT to select against a genetic condition, disease or abnormality that would severely limit the quality of life of the person who would be born.

- 8.18.5** In addition to the requirements outlined in paragraphs 8.18.2 and 8.18.3, clinics must ensure that the following information is discussed:
- current evidence and expert opinion on the impact of the condition, disease or abnormality on the quality of life of the person who would be born, including the anticipated symptoms, age-of-onset and the degree/spectrum or severity of the condition disease or abnormality
 - the available therapies or interventions to reduce the severity, delay onset or minimise the impact of the condition, disease or abnormality
 - the experiences of individuals and families living with any relevant condition, disease or abnormality
 - the potential for stigma to impact on the perceived seriousness of the condition, disease or abnormality
 - the extent of social support available to the intended parent(s) and the person who would be born
 - the potential impact the decision to use PGT may have on any child within the family unit who may be affected by that decision
 - the possibility that all of the embryos may be affected by a genetic condition, disease or abnormality that would severely limit the quality of life of the person who would be born

- that the genetic cause of some conditions, diseases or abnormalities is currently unknown and some of the genetic information obtained by PGT may be of unknown significance at the time
- that the clinic will continue to store the PGT results in accordance with the requirements of Chapter 9 of these Ethical Guidelines, and the clinic's policy for the management of PGT results, including whether the clinic will communicate the ongoing significance of any results in light of new evidence/research
- the potential for PGT to identify genetic conditions, diseases or abnormalities that were not the subject of the testing, nor for which the intended parent(s) were counselled (an incidental finding) and the clinic's policy for handling such an event.

Incidental findings and record keeping

8.19 Maintain appropriate policies and procedures to support the ethical use of PGT and associated record keeping

- 8.19.1** Clinics should have policies and procedures for the management of PGT results and the handling of incidental findings in line with current best practice and should seek advice from an independent body where the appropriate action is unclear.
- 8.19.2** Where an incidental finding is to be disclosed to the intended parent(s), and the genetic condition, disease or abnormality may severely limit the quality of life of the person who would be born, clinics should ensure that the relevant requirements of paragraph 8.18.5 are satisfied, and arrange for additional counselling.

The collection and use of gametes from persons who are deceased or dying and/or the posthumous use of stored gametes or embryos

Introduction

The possibility that an individual might be conceived following the death of one of their parents is understandably controversial. This situation might arise via the:

- use of gametes or embryos collected and stored prior to death of a spouse or partner
- collection of gametes from a deceased person, or a person who is dying and their subsequent use.

In such situations, clinicians are faced with a number of considerations, including:

- relevant state or territory legislation
- respect for the deceased or dying person
- respect for the desire of the surviving spouse or partner to have a child
- possible (and unknown) effects on the welfare of the person to be born, having been conceived following a parent's death
- possible (and unknown) effects on the welfare of existing children within the family unit who may be affected by that birth.

Collection and storage of gametes from a person who is dying and has the capacity to provide valid consent

8.20 Obtain valid consent

- 8.20.1** Clinics may facilitate the collection of gametes from a person who is dying if the person has the capacity to provide valid consent (see paragraph 4.5) and consents to the storage of gametes and their use for reproductive purposes after their death (see paragraphs 4.6.3 – 4.6.5).

Collection and storage of gametes from a deceased person or a person who is dying and lacks the capacity to provide valid consent

8.21 Obtain valid consent from a spouse or partner

The acceptability of a spouse or partner making decisions regarding the collection of gametes 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). For these reasons, court authority is required before a clinician may facilitate the collection of gametes from a person who is deceased or is dying and lacks the capacity to provide valid consent.

8.21.1 With appropriate legal authority, 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:

- the request to do so has come from the spouse or partner of the deceased or dying person, and not from any other relative
- the gametes are intended for use by the surviving spouse or partner for the purposes of reproduction
- there is some evidence that the dying or deceased person would have supported the posthumous use of their gametes by the surviving partner, or at the very least, there is no evidence that the deceased or dying person had previously expressed that they do not wish for this to occur
- the surviving spouse or partner provides valid consent for the collection and storage of the gametes (see paragraphs 4.5 and 4.6.3 – 4.6.5)
- the proposed collection and storage has been approved by an appropriate court authority.

Posthumous use of stored gametes or embryos

In accordance with paragraph 4.1.3, before gametes are collected or embryos are created, clinics must ensure that all responsible parties are provided with sufficient information to facilitate an understanding of the options they will have regarding the use, storage and discard of the gametes or embryos, including the potential for posthumous use (see paragraph 4.6.4). Therefore, following the introduction of these Ethical Guidelines [2017], consent to store gametes and embryos should include the relevant individual's clearly articulated position on the posthumous use of their stored gametes or embryos.

However, for gametes and embryos stored prior to the introduction of these Ethical Guidelines [2017], the relevant individual's position on the posthumous use of their stored gametes or embryos may be unknown or undocumented.

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

Regardless of the relevant individual's position on the posthumous use of their stored gametes or embryos, there may be a legal impediment to such use in some states or territories and a court order may first be required.

- 8.22.1** 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 such use following their death (see paragraph 4.6.4)
 - the request to do so has come from the spouse or partner of the deceased person, and not from any other relative
 - the gametes are intended for use by the surviving spouse or partner
 - the conditions of paragraph 8.23 are satisfied.
- 8.22.2** Where the deceased person has left clearly expressed directions that object to the posthumous use of their stored gametes or embryos, clinics must respect this objection and not facilitate the posthumous use of the stored gametes or embryos to achieve pregnancy.
- 8.22.3** Where the deceased person has not left clearly expressed directions regarding the posthumous use of their stored gametes or embryos, where permitted by law, clinics may facilitate the posthumous use of stored gametes or embryos to achieve pregnancy, if:
- the request to do so has come from the spouse or partner of the deceased or dying person, and not from any other relative
 - the gametes are intended for use by the surviving spouse or partner for the purposes of reproduction
 - there is some evidence that the dying or deceased person would have supported the posthumous use of their gametes by the surviving partner, or at the very least, there is no evidence that the deceased or dying person had previously expressed that they do not wish this to occur
 - the surviving spouse or partner provides valid consent (see paragraph 4.5)
 - the conditions of paragraph 8.23 are satisfied.

8.23 Allow sufficient time before attempting conception and/or pregnancy

- 8.23.1** Given the enduring consequences of the decision, clinics should not attempt conception or a pregnancy using stored gametes or embryos unless:
- sufficient time has passed so that grief and related emotions do not interfere with decision-making
 - in addition to the requirements outlined in paragraph 4.1, the surviving prospective parent (the spouse or partner) is provided with sufficient information to facilitate an accurate understanding of the potential social, psychological and health implications of the proposed activity for the person who may be born
 - the surviving prospective parent (the spouse or partner) has undergone appropriate counselling (see paragraph 4.3)
 - an independent body has reviewed the circumstances and supports the proposed use.

8.24 Posthumous use of gametes or gonadal tissue collected from a child or young person for the purpose of fertility preservation

- 8.24.1** Gametes or gonadal tissue collected from a child or young person for the purpose of fertility preservation (see paragraphs 8.4 – 8.6) can only be used posthumously if the person for whom they were stored reached adulthood before their death and the conditions of paragraphs 8.22 – 8.23 are satisfied.

9 Record keeping and data reporting

Introduction

Record keeping and data reporting is an integral part of the clinical practice of ART. Clinics have 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 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 (e.g. similar to bone marrow and transplant registries). At the time of publication [2017], no such register exists on a national scale.

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
 - for the collation of clinic-specific and national statistics about reproductive treatments and procedures, to assist individuals and couples considering ART to make informed decisions (see paragraphs 4.1.2, 4.2.1, 4.2.6 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)
 - where applicable, the exchange of information between a surrogate, the commissioning parent(s) and person born as a result of the surrogacy arrangement (see paragraph 8.12).
- 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 accreditation or regulation 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 and preservation.

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, a record of participation in counselling services, and the information provided to fulfil the relevant requirements of Chapter 4
- 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 7.1.1)
- the outcomes of the activity for the embryo, the person born and the individuals or couples involved. This data should be recorded in an easily accessible form that can 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, ovarian hyperstimulation syndrome, miscarriage, termination of pregnancy, ectopic pregnancy, stillbirth, genetic conditions or perinatal events
 - any serious adverse effects and other side effects for the individual undergoing ART or for the person born.
- 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 and surrogacy arrangements

- 9.2.1** Clinics must ensure that all relevant information about parties involved in donor conception programs or surrogacy arrangements are 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** Information about all parties involved in a donor conception program or surrogacy arrangement must be kept indefinitely (or at least for the expected lifetime of any persons born); in a way that is secure but is accessible to any relevant party (see paragraphs 4.2.4, 5.7 – 5.9, 5.15.1 and 8.12).

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 must 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 is subject to the consent of the individuals or couples involved (see paragraph 4.6.5).

10 Innovative practice, training and quality assurance

Introduction

To ensure high standards of clinical care, it is important that clinics undertake training and quality assurance activities. In the course of providing treatment, clinics may also determine that the use of innovative practices may improve the clinical outcomes for individuals or couples undergoing ART treatment and/or the person who would be born. There are a number of important ethical and legal considerations when undertaking these activities in the context of clinical practice.

Innovative practice

10.1 Evaluate innovative practices before routine use in clinical practice

There is an expectation that, in routine clinical practice, clinics utilise interventions supported by evidence of successful clinical outcomes (see paragraph 3.8). The introduction of changes to clinical treatment, or the use of innovative practices, may have short or long-term consequences for the person born and/or the individual or couple undergoing the treatment.

- 10.1.1 Clinics must not introduce changes in clinical treatment, or innovative practices, into routine clinical practice without prior evaluation of safety and efficacy and consideration of legal and ethical issues.
- 10.1.2 Advice should be sought from an independent body before the introduction of an innovative practice, or a proposed change to routine clinical practice, as this may constitute research, even where only one individual or couple is involved.

10.2 Provide relevant information and obtain valid consent

- 10.2.1 Where an innovative practice is proposed, clinics must ensure that all relevant information is discussed with all relevant parties, and valid consent is obtained from all relevant parties for each specific procedure (see paragraphs 4.1.2 and 4.5).

Training and/or quality assurance

The RIHE and PHCR Acts regulate certain practices associated with ART, including training, quality assurance and research involving human embryos or gametes. These activities may also be subject to additional state and territory legislation.

Under the RIHE and PHCR Acts, the use of human embryos or gametes in training or quality assurance activities can be classified as either:

- permitted uses without a licence, for example, training or quality assurance undertaken whilst creating human embryos for the purposes of achieving pregnancy, carried out at an accredited ART clinic, or
- uses authorised under a general licence issued by the NHMRC Embryo Research Licensing Committee (Licensing Committee), for example, the use of excess ART embryos (see 'Explanation of key terms') in training or quality assurance activities.

These Acts also prohibit certain practices. For example, the creation of a human embryo *solely* for the purposes of training or quality assurance is not permitted and would be an offence.

It is important that clinics are aware of their legal obligations when undertaking any training or quality assurance activities. Where there is any uncertainty in relation to the licensing requirements, clinics should seek their own legal advice or contact the Licensing Committee for further information.

10.3 Facilitate ongoing training of the clinical team

- 10.3.1** Clinics must have a training policy and an ongoing training program for the clinical team involved in the ART activities available at the clinic.

10.4 Conduct quality assurance activities

- 10.4.1** Clinics must conduct regular quality assurance activities.
- 10.4.2** As the distinction between quality assurance and research is not always clear, clinics should consult the National Statement and NHMRC guidance on quality assurance activities¹⁶ for advice on whether or not the quality assurance activity requires ethical approval.

10.5 Obtain a licence for the use of an excess ART embryo for training or quality assurance activities

- 10.5.1** Under the RIHE Act, a general licence is required for any training activities that involve the fertilisation of a human egg by a human sperm up to, but not including, the first mitotic division where the fertilised egg is created solely for the purposes of training.
- 10.5.2** Under the RIHE Act, a general licence may be required for training or quality assurance activities that involve the use of an excess ART embryo.¹⁷

¹⁶ At the time of publication [2017], the current guidance is NHMRC's Ethical Considerations in Quality Assurance and Evaluation Activities in 2014.

¹⁷ A licence may not be required if the activity is an exempt use under subsection 10(2) of the RIHE Act. Where there is any uncertainty in relation to the licensing requirements, clinics should seek their own legal advice or contact the Licensing Committee for further information.

10.6 Provide relevant information and obtain valid consent

- 10.6.1** Clinics must ensure that all relevant information about the proposed training or quality assurance activity is discussed with all relevant parties (see paragraph 4.1).
- 10.6.2** Clinics must ensure that valid consent is obtained (see paragraph 4.5) for any training or quality assurance activities undertaken:
- during an individual's or couple's reproductive treatment
 - involving an individual's or couple's gametes or embryos which are deemed unsuitable for transfer (see 'Explanation of key terms' and additional guidance published by the Licensing Committee)
 - using an excess ART embryo under a general licence (see paragraphs 4.1.3, 7.3.2 and 10.5.2). This consent must be separate from consent for any treatment and must be obtained after an individual or couple have advised that the embryo is excess to their needs
 - involving the fertilisation of a human egg by a human sperm under a general licence (see paragraph 10.5.1).

PART C: ETHICAL GUIDELINES FOR RESEARCH

11 Ethical principles in ART research

11.1 Respect all participants

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

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

11.2 Respect human embryos

The fact that the use of embryos warrants very serious moral consideration was recognised by the Australian Parliament in the PHCR and RIHE Acts. Therefore, research on human embryos can only be performed in conformity with these Ethical Guidelines and the conditions imposed by those Acts. See Chapter 13 for detailed guidelines on embryo research.

11.3 Do not use any unacceptable or prohibited practices

The research proposal must not include any prohibited or unacceptable practices (refer to the Commonwealth RIHE and PHCR Acts and any relevant state or territory legislation).

11.4 Minimise risks

Researchers must ensure that any risks of involvement in the research are appropriate for the type of research (see paragraphs 3.1 – 3.3 of these Ethical Guidelines and the section on risk and benefit in the National Statement).

- 11.4.1 Where clinical care is combined with research, the risks of research should be balanced by the possibility of expected benefits from the research.
- 11.4.2 For research undertaken solely to develop new knowledge, any risks (particularly any long-term risks to persons born) should be minimal.

11.5 Offer separate decision-making processes

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

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

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

11.6 Provide information

Participants in research are often vulnerable and can easily misunderstand the purpose and nature of the research. Researchers must provide information to participants, at their level of comprehension, about the purpose, methods, demands, risks, inconveniences, discomforts and possible consequences of the research (including the likelihood and form of publication of the research results). Chapter 4 provides guidelines on information giving and counselling for clinical practice; the same principles must be applied to research.

11.7 Obtain consent

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

Chapter 4 provides guidelines on obtaining consent for clinical practice; a similar range of information must be provided for research (as identified in the sections on consent in the National Statement).

Consent for the use of excess ART embryos or human gametes or human genetic material or other embryos in research must be obtained from all responsible persons (see paragraph 13.14 for further information).

11.8 Keep detailed records

Good record keeping is an essential component of research. Researchers must keep accurate records of their research, including records of all gametes and embryos in their care, and the outcomes of the research. Chapter 9 provides guidelines on record keeping for clinical practice. The same principles must be applied to research.

11.9 Collect and report data on outcomes

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

Data relevant to licensed activities must be collected in accordance with paragraph 9.3.

11.10 Assess and monitor outcomes for all participants (present and future)

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

11.11 Disclose financial interests

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

11.12 Respect conscientious objections

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

12 Research involving gametes

This section provides guidelines for research involving gametes intended for use in the formation of embryos. See Chapter 13 for guidelines for research involving the formation of embryos.

12.1 Comply with the National Statement

Gametes are human tissue and all research on human tissue must be conducted in accordance with the relevant sections in the National Statement (see 'Explanation of key terms').

12.2 Do not use any unacceptable or prohibited practices

The research proposal must not include any prohibited or unacceptable practices (refer to the Commonwealth RIHE and PHCR Acts and any relevant state or territory legislation).

12.3 Use valid scientific protocols

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

12.4 Minimise risks

Researchers must ensure that the use of gametes in research is not contrary to the best interests of any person born as a result of the use of those gametes to achieve a pregnancy (see paragraph 3.2).

12.5 Provide information

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

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

12.6 Obtain consent

Researchers must obtain consent from the gamete providers (and their spouses or partners, if any) for research involving gametes intended for use in the formation of embryos. See Chapter 13 for guidelines about obtaining consent to research involving embryos.

12.7 Keep accurate records, and collect and report data about outcomes

Researchers must comply with paragraphs 11.8 to 11.10 of these Ethical Guidelines.

13 Research involving embryos

Introduction

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

The RIHE Act requires that research on certain human embryos may only be conducted under a licence issued by the Embryo Research Licensing Committee of the NHMRC (the Licensing Committee), which must be satisfied that the research proposal has been assessed and approved by an HREC acting in compliance with the National Statement and these Ethical Guidelines.

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

13.1 Identify human embryo

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

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

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

However, there is an ethical need to recognise that the two gametes that formed the embryo ceased to exist as gametes when they fused almost a day earlier than the first mitotic division.

To ensure that there is no hiatus in the application of ethical guidelines that apply to gametes and those that apply to human embryos as defined by the Act, all aspects of these Ethical Guidelines applying to human embryos also apply to this single entity formed by the combination of two gametes.

An embryo formed other than by fertilisation of a human oocyte by a human sperm, is *"a discrete entity that has arisen from ... any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears"*.¹⁸

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

¹⁸ Note that these Ethical Guidelines take into account the technologies that were available at the time of publication [2017]. Novel methods for creating a 'other embryos', such generation of embryo-like structures from somatic cells, are not specifically addressed in these Ethical Guidelines.

13.2 Comply with the National Statement

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

13.3 Fulfil essential ethical criteria for a licensable research activity

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

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

13.4 Restrict the number of embryos or eggs

For any licensable activity, the number of excess ART embryos, other embryos or human eggs should be restricted to that likely to be necessary to achieve the goals of the activity [RIHE Act, s21(4)].

13.5 Do not use any prohibited practices

Research proposals involving human embryos must not include any practices prohibited by the legislation (refer to the Commonwealth RIHE and PHCR Acts and any relevant state or territory legislation).

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

13.6 Ensure that the research relates to reproductive treatment

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

13.7 Respect the embryo and all relevant parties

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

13.8 Minimise risks

Researchers must ensure that any risks to the embryo from the research (and to the long-term health of the person who may be born) are appropriate for the type of research.

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

13.9 Provide information

Researchers must provide the intended parent(s) with all relevant information about the research, including how it relates to clinical care, including the clinical care of the embryo.

- 13.9.1** The information provided should include a full explanation of:
- whether the research has intended benefits for the embryo or will not benefit the embryo or themselves but is intended to improve scientific knowledge or technical application
 - any risks involved for the individual undergoing ART and/or the embryo after transfer, and how they are balanced by any potential benefits
 - the expected consequences for the embryo and the person who may be born.

13.10 Obtain separate, specific consent

Researchers must obtain consent from all participants that is separate from the consent for clinical care and specific for the proposed research procedure(s)

(see paragraph 11.5).

Researchers must also ensure that the intended parent(s) are assured that their clinical care, or the clinical care of their embryo, will not be prejudiced in any way if they do not wish to be involved.

13.11 Keep accurate records

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

Research involving excess ART embryos

13.12 Obtain a licence

Under the RIHE Act, researchers must obtain a general licence for any research involving an excess ART embryo that is not an exempt use under the RIHE Act. Researchers must comply with the requirements of the Embryo Research Licensing Committee of the NHMRC (the Licensing Committee) in making an application, as well as with all conditions of a licence (see paragraph 13.3)

13.13 Ensure that the embryo has been declared an excess ART embryo

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

13.14 Identify all persons responsible for the embryo

Under the RIHE Act, the persons responsible for an excess ART embryo include: the gamete providers; their spouses or partners (if any, at the time the gametes were donated); and the individual or couple for whom the embryo was created, (if different from the gamete providers) [RIHE Act s8].

13.15 Apply the objective criteria

The RIHE Act defines an embryo that is unsuitable for implantation ([RIHE Act s7(1)]; see 'Explanation of key terms') as an embryo that:

- is diagnosed by preimplantation genetic diagnosis as unsuitable for implantation, in accordance with the *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical practice and Research (2004)*, or
- is determined to be unsuitable for implantation in the body of a woman, in accordance with objective criteria (see 'Explanation of key terms') specified in guidelines issued by the CEO of the NHMRC under the *National Health and Medical Research Council Act 1992* and prescribed by the regulations for the purposes of this paragraph.

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

- 13.15.1** The individual or couple responsible for decision-making may decide that an embryo that meets the objective criteria is not an excess ART embryo and is not available for research.

13.16 Obtain consent

Under the RIHE Act (s21), before a licence can be issued for the use of an excess ART embryo in research, the Licensing Committee must be satisfied that appropriate protocols are in place to obtain *proper consent* from each person responsible for the embryo (see 'Explanation of key terms' and paragraph 13.14).

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

Under the terms of the National Statement, consent for research must be informed, competent, voluntary, specific and, for this purpose, it must be in writing. Researchers must comply with the National Statement in respect of all these conditions, and must also follow the specific guidance provided in paragraphs 13.18 and 13.19 of these Ethical Guidelines.

As for all other ART research (see paragraph 11.5), the process of providing information and obtaining consent for research on excess ART embryos must be clearly separated from the clinical care of the embryos or embryo donors.

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

The RIHE Act permits, in certain circumstances, the modification of the guidelines in relation to the giving of proper consent [RIHE Act s24(8)].

13.17 Specify the purpose of the research

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

13.18 Provide all relevant information

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

- 13.18.1** Researchers should provide an oral explanation, supported by written information in plain language and in sufficient time for it to be taken away, read and considered before consent is given.
- 13.18.2** The explanation should be given with sensitivity to the individual needs of the patient (including language) and include a full explanation of:
- the proposed research (including the proposed method and its scientific aims)
 - why the research would represent a significant advance in knowledge or improvement in technologies for treatment
 - what will happen to each embryo, including, where applicable, that embryonic stem cells may be derived from the embryo and that any cells or cell lines so derived may be kept for some years
 - whether the results of research will have commercial potential (see paragraph 11.11) (the embryo donors should be informed that they will not receive financial or any other benefits from any such future commercial development)
 - the procedures for raising concerns, obtaining further information about the research and making complaints
 - the inspection procedures that will be conducted by the NHMRC to ensure compliance with the RIHE Act.

13.19 Allow for withdrawal of consent

A person responsible for an embryo must be free at any time to withdraw consent to further involvement in the research.

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

- 13.19.1** If a modification of the guidelines relating to proper consent is made, as noted in paragraph 13.16, and the modification involves a change in the cooling-off period, any such change must provide for a period that is long enough to allow the persons responsible to consult others important to them and counsellors before making a considered decision whether or not to withdraw consent [RIHE Act s24(8)].

13.20 Keep accurate records

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

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

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

Accordingly, an individual may choose to donate gametes from ART treatment to research. Further, individuals who are not involved in ART activities for the purpose of achieving a pregnancy may choose to donate their gametes for research purposes.

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

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

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

An individual who agrees to donate gametes or gonadal tissue, cells or genetic material to research is a research participant for the purposes of the National Statement.

Such tissue is human tissue, containing human genetic material, and the relevant sections in the National Statement particularly apply.

- 13.21.1** When obtaining gametes or cells from a donor involves the donor receiving treatment, there must be separation of clinical and research roles.
- The clinician treating the donor should not be an investigator in the intended research.

- Persons other than members of the research team should obtain consent to research from the potential donor. When the involvement of researchers is unavoidable, their role in the research must be made known to a donor.
 - Members of the research team should be available to discuss the involvement of the gamete or gonadal tissue donor in the research protocol. In doing so, researchers should use appropriate language and graphics to convey accurate, clear information.
- 13.21.2** There should be no payments or other inducements for the donation of gametes, gonadal tissue or cells for research that is subject to these Ethical Guidelines. The reimbursement of reasonable out-of-pocket expenses associated with the procedures is acceptable. In research to which these Ethical Guidelines apply, reimbursement does not cover compensation, including compensation for time.
- 13.21.3** Gametes, gonadal tissue or cells donated for research must not be used for any other purpose.
- 13.21.4** If genetic screening and disease testing related to gamete or cell donation is to be done, there must be an ethically defensible plan for the disclosure or withholding of such information, in accordance with the National Statement.
- 13.21.5** Protocols for recruitment must ensure that the donation of gametes, gonadal tissue or cells is voluntary and free from exploitation or coercion. Where participation involves non-therapeutic interventions of more than low risk, recruitment should exclude potential participants who are in dependent relationships. Such dependent relationships include those between researchers and students or those working within the research institution, and between clinician researchers and patients.¹⁹
- 13.21.6** For the purpose of consent, the potential donor should be provided with the following information in written and oral form:
- a brief description of the project in lay language and its contribution to the potential benefits of the overall research program
 - a clear statement that the provision of gametes, gonadal tissue or cells to the project is voluntary
 - a description of the intended use of the gametes, gonadal tissue or cells and any products derived from them
 - that any value from the gamete, gonadal tissue or cell donation for research, such as by the development of a cell-based treatment for a disease, may only be realised in the long term
 - a description of the retrieval process for gametes, gonadal tissue or cells, including what will be done, where the procedures will be done and by whom
 - a statement of the potential risks of retrieving and donating gametes, gonadal tissue or cells
 - a description of how to withdraw from gamete, gonadal tissue or cell donation
 - the right of a donor to refuse donation for a specific project, but agree to donation for another

¹⁹ For explanation of 'low risk' and 'dependent relationship', see the National Statement.

- a statement about the availability of counselling resources
- how donor privacy will be protected
- a statement of the potential financial and non-financial interests of researchers
- a statement that the donor will receive no financial benefit
- a statement that the donation will not be used for any other purpose
- a statement of any future financial gains that the researcher may receive if the research gives rise to a commercial product
- any other information required by the National Statement.

- 13.21.7** Consent to the use of stem cells developed from donated gametes, gonadal tissue or cells must meet the requirements of the National Statement.
- 13.21.8** The donor may withdraw consent to use the donated gametes, gonadal tissue or cells up to the time of their actual use in research.
- 13.21.9** The donor is entitled to know the outcome of research involving donated gametes, gonadal tissue or cells.
- 13.21.10** Research involving procedures that carry significant risk of harm, including hormonal stimulation, anaesthesia or surgical procedures to obtain gametes, gonadal tissue or cells, must be reviewed by an HREC.
- 13.21.11** The risks of long-term consequences for fertility of hormonal stimulation of the ovaries and surgical collection of eggs must be disclosed to potential donors.
- 13.21.12** When the donation involves risks to the fertility of donors, the HREC and the Licensing Committee must have regard to whether the donors have been fully informed about the risks to fertility and have given consent.
- 13.21.13** In deciding whether to approve research involving donation of eggs by women who are not on an ART program to achieve pregnancy, an HREC must be satisfied that the potential benefits are sufficient to justify the risks associated with the donation process (see paragraph 13.21.11). In deciding whether there is sufficient benefit, HRECs must apply the guidelines on risk and benefit in the National Statement.
- 13.21.14** In deciding whether to approve research involving donation of gonadal tissue, an HREC must be satisfied that the potential benefits are sufficient to justify the risks associated with the donation process (see paragraph 13.21.11). In deciding whether there is sufficient benefit HRECs must apply the guidelines on risk and benefit in the National Statement.
- 13.21.15** Gamete, gonadal tissue or cell donors should be offered counselling on the risks and the psychosocial and ethical implications of donation. The counsellors must be independent of the research. Counselling should be available at any time from before the procedures for retrieval of gametes, gonadal tissue or cells are commenced to the time they are used in research.
- 13.21.16** The number of cycles and intensity of ovarian stimulation should be limited (see the RTAC Code of Practice) because it is known to be associated with harmful effects.

- 13.21.17** Clinicians and clinical centres engaged in gamete or gonadal tissue retrieval should encourage studies on the medical and psychological effects on the donors of the donation of gametes or gonadal tissue, with a view to achieving a more accurate evaluation of risks and benefits.

13.22 Respect persons who have died

- 13.22.1** Registering consent to be a donor on the Australian Organ Donor Register does not constitute consent to the donation of gametes, gonadal tissue or cells for a licensed procedure.
- 13.22.2** Gametes, gonadal tissue or cells from a person who has died must not be used in a licensed activity unless that person had previously given specific consent to that use.
- 13.22.3** Before that consent is given, the donor must have received the information that these Ethical Guidelines require for donors.
- 13.22.4** The needs of relatives of the deceased must be respected in accordance with ethical guidelines on organ and tissue donation, issued by NHMRC.

Research involving creation of human embryos using precursor cells from a human embryo or a human fetus [RIHE Act s20(1)(d); PHCR Act s23A]

The RIHE and PHCR Acts permit the issue of a licence to conduct research involving the creation of human embryos using precursor cells from the human embryo or human fetus. The following guidelines are intended to inform the ethical review and approval of such research, where it involves gametes, gonadal tissue or cells obtained from the human fetus.

Research involving human fetal tissue must also comply with the relevant sections in the National Statement.

13.23 Respect the human fetus

- 13.23.1** Those conducting research involving gametes, gonadal tissue or cells obtained from the human fetus ex utero, after spontaneous miscarriage or termination of pregnancy, should have no involvement in the clinical care of the woman²⁰ from whom the fetus or fetal tissue was derived, and no financial or legal relationships with those who are so involved. Such research should be conducted in a location that maintains a separation of the woman's clinical care from research.
- 13.23.2** Researchers should demonstrate in their proposals that there are no suitable alternatives by which the aims of research using the fetal gametes, gonadal tissue or cells can be achieved.
- 13.23.3** There should be no trade in human fetal gametes, gonadal tissue or cells.
- 13.23.4** Where research involves a separated fetus or fetal gametes, gonadal tissue or cells, researchers should ask the woman whether, in her decisions about the research, she wishes to involve others such as family members, for whom the research may have implications.

²⁰ The term woman is used here, as this is the terminology used in the National Statement.

- 13.23.5** A fetus or fetal gametes, gonadal tissue or cells may become available for research as the result of termination. The process through which the woman is approached, informed about, and her consent sought for research on that fetus should be separate from the process under which she decides whether to terminate her pregnancy, and should not begin until a decision to terminate has been made. Consenting to the research must not compromise the woman's freedom to change that decision.
- 13.23.6** Where research involves her separated fetus or its gametes, gonadal tissue or cells, arrangements should be made for the woman to have access to counselling and support.
- 13.23.7** Research on a terminated fetus or its gametes, gonadal tissues or cells, including the timing and content of the process of seeking the woman's consent for the research, should be designed so as not to compromise the woman's decisions about the timing and method of termination.
- 13.23.8** Consideration of a woman's wishes and her physical, psychological and emotional welfare should inform:
- a decision whether to approach her about proposed research involving her separated fetus or its tissue, and, if she is approached
 - the way information is provided about the research and the way her consent is sought.
- 13.23.9** In addition to information required to be disclosed under the consent sections in the National Statement, the woman should also be informed:
- that she should consider whether to seek consent to the proposed research from any other person
 - about the possibility of storing the fetus or fetal tissues for later use in research
 - that she is free to withdraw her consent to the research at any time, whether before or after a termination or other loss of a fetus
 - about any potential commercial application of outcomes of the research, including the development of cell lines
 - that she will not be entitled to a share in the profits of any commercial applications
 - if fetal tissues or stem cell lines developed from them will be exported to another country.
- 13.23.10** A fetus delivered alive is a child, and should be treated as a child and receive the care that is due to a child.
- 13.23.11** Gametes, gonadal tissue and cells for use in research may not be removed from a fetus delivered dead, unless:
- the woman and any others she wishes to involve (see paragraph 13.23.4) have given consent to the removal and the research
 - the fetus is available for research only as a result of separation by natural processes or by lawful means
 - the death of the fetus has been determined by a registered medical practitioner who has no part (or financial interest) in the research.

PART D: MITOCHONDRIAL DONATION SUPPLEMENTARY SECTION

14 Introduction

Mitochondrial donation is an assisted reproductive technology (ART) which can help some women to avoid transmitting mitochondrial disease to their biological children. The term collectively refers to a number of specific techniques aimed at ensuring only healthy mitochondria are passed on to an embryo. Used in conjunction with in-vitro fertilisation (IVF), mitochondrial donation techniques allow an embryo to be created which contains the:

- nuclear DNA from a sperm and an egg (from the prospective parent/s)
- mitochondria in an egg donated by another person (the donor).

This approach is intended to minimise the risk of a prospective mother transmitting mitochondrial disease to her child, where the prospective mother carries mitochondria with changes or variations to the mitochondrial DNA that mean her child is likely to inherit mitochondrial disease.

Mitochondrial donation cannot be used to cure people with existing mitochondrial disease or to prevent mitochondrial disease caused by changes or variations in an individual's nuclear DNA.

In March 2022, the Australian Parliament passed a Bill to allow the introduction of mitochondrial donation in Australia, through a staged approach and under strict regulatory conditions, to minimise the risk of a woman's offspring inheriting mitochondria from that woman, that would predispose the offspring to mitochondrial disease that would result in a serious illness or other serious medical condition. The *Mitochondrial Donation Law Reform (Maeve's Law) Act 2022* came into effect on 1 October 2022 and amended the *Research Involving Human Embryos Act 2002* (RIHE Act) and the *Prohibition of Human Cloning for Reproduction Act 2002* (PHCR Act).

The legislation allows the prescribed mitochondrial donation techniques to be used only to reduce the risk of inheriting mitochondrial disease. The allowed mitochondrial donation techniques can only be used under the relevant licence issued by NHMRC's Embryo Research Licensing Committee (ERLC). Under section 28P(4) of the RIHE Act, ERLC must not grant approval to conduct mitochondrial donation (with a licence) unless it is satisfied:

- that there is a particular risk of the woman's offspring inheriting mitochondria from the woman that would predispose the offspring to mitochondrial disease; and
- that there is a significant risk that the mitochondrial disease that would develop in those offspring would result in a serious illness or other serious medical condition; and
- that other available techniques that could potentially be used to minimise the risks referred to in paragraphs (a) and (b) would be inappropriate or unlikely to succeed.

Mitochondrial donation must be conducted in accordance with the specific purposes and requirements of the legislation, with a mitochondrial donation licence. Other uses of mitochondrial donation techniques, such as oocyte supplementation for fertility decline, are not permitted.

The legislation introduces mitochondrial donation in a staged and closely monitored way. Under the first stage, mitochondrial donation will be legalised for certain research and training purposes, including for the purpose of undertaking a clinical research trial of the use of mitochondrial donation techniques as part of human ART (that is, attempting to achieve pregnancy and birth). The aim of this approach is to build an Australian evidence base on the safety and efficacy of mitochondrial donation techniques, and associated issues such as feasibility, service delivery, cost and impacts, before a decision is made on introducing the use of the techniques more broadly into clinical practice. A decision to broaden the scope of the legislation would require legislative change enacted through the Parliament of Australia.

This Supplementary Section aims to support the legislation by providing ethical guidelines for the conduct of mitochondrial donation that protects the physical, psychological and social wellbeing of all people involved in the process. This Supplementary Section has been developed primarily for medical specialists, patients, researchers, licence holders, ART clinicians, counsellors, research co-ordinators, and Human Research Ethics Committees (HRECs), who are involved, or considering involvement, in mitochondrial donation programs in Australia.

This Supplementary Section contains summaries and explanations designed to assist in interpreting the provisions of the legislation and associated legal requirements. It should not be relied on as either a comprehensive or authoritative statement of the law and, in particular, should not be taken as a substitute for reading the relevant legislation. You are advised to seek your own independent legal advice before making any decisions or undertaking any course of activity, or if you are in any doubt about particular provisions of the law. If there is a potential contradiction between the legislation and this Supplementary Section, the legislation takes precedence.

This Supplementary Section on mitochondrial donation does not sit neatly within Part B (clinical practice) or Part C (research) of the *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* (ART Guidelines), as the clinical trial phase is classified as research, but gives rise to ethical issues that arise in clinical treatment as the clinical trial aims to achieve a successful pregnancy. Therefore, this Supplementary Section should be read with reference to the relevant sections of Part B and/or Part C.

15 Abbreviations

Table 1. List of abbreviations

Abbreviation	Expanded term
AHEC	Australian Health Ethics Committee
ART	assisted reproductive technology
ART Guidelines	<i>Ethical guidelines on the use of assisted reproductive technology in clinical practice and research</i>
HREC	Human Research Ethics Committee
ERLC	Embryo Research Licensing Committee
Maeve's Law	<i>Mitochondrial Donation Law Reform (Maeve's Law) Act 2022</i>
National Statement	<i>National Statement on Ethical Conduct in Human Research</i>
NHMRC	National Health and Medical Research Council
NHMRC Act	<i>National Health and Medical Research Council Act 1992</i>
PHCR Act	<i>Prohibition of Human Cloning for Reproduction Act 2002</i>
RIHE Act	<i>Research Involving Human Embryos Act 2002</i>

16 Explanation of key terms

The following explanations show how key terms are to be interpreted in the context of the ART Guidelines. For consistency with national legislation, where the terms have been used in either the RIHE Act or the PHCR Act, the same definitions have been used here and the relevant section of legislation referenced. This Supplementary Section aims to use gender inclusive language. However, the term 'woman' and/or 'man' is used where its use is necessitated by Commonwealth legislation and/or the National Statement.

Table 2. List of key terms

Key term	Explanation
Assisted reproductive technology (ART)	The application of laboratory or clinical techniques to gametes and/or embryos for the purposes of reproduction.
Carryover	<p>In the mitochondrial donation process, carryover arises when mitochondria are transferred from the prospective mother's affected egg along with the cytoplasm containing the nuclear DNA. This is of concern because it is not yet known what level of carryover may lead to a risk of mitochondrial DNA disease in the future child.</p> <p>Reversion or carryover could occur in subsequent generations; the child born following mitochondrial donation may be at low risk of mitochondrial disease, but the offspring of the daughters could have a further increase in the level of mutant mitochondrial DNA.</p> <p>See also 'Reversion'</p>
Deoxyribonucleic acid (DNA)	<p>A molecule which is composed of four different types of chemical compounds (called nucleotides). The sequence of these nucleotides encodes the genetic instructions for the development, functioning, growth and reproduction of all known organisms. Changes (or 'mutations') to the sequence can introduce errors into the genetic instructions.</p> <p>See also 'Mitochondrial DNA', 'Nuclear DNA'</p>
Donor	<p>If a particular use of a mitochondrial donation technique results in the creation of a zygote that:</p> <ul style="list-style-type: none"> (a) has nuclear DNA from a woman [egg] and a man [sperm]; and (b) contains mitochondria from a human egg of a different woman <p>the woman mentioned in paragraph (b) is the donor in relation to that use of the technique.</p> <p>[RIHE Act ss28R(2)]</p>

Key term	Explanation
Haplotype or haplogroup matching	<p>Haplogroup: Corresponds to the common maternal origins of a species as defined by the haplotypes.</p> <p>Haplotype: A set of markers (identified DNA sequences) on the mitochondrial DNA or the nuclear DNA that tend to be inherited together transgenerationally.</p> <p>Haplotype matching: the process of matching the haplotypes of the trial participant or patient and the donor.</p> <p>Mitochondrial DNA is maternally inherited. People from different haplotypes have different mitochondrial DNA. A haplogroup corresponds to the common maternal origins of a species. In humans, there are about 25 different major variations of the mitochondrial DNA sequence and they largely correspond to continental population groups. Each haplogroup contains subcategories, called haplotypes.</p>
Licence holder	The entity responsible for a licence issued under section 28J of the RIHE Act.
Mitochondrial DNA	<p>The DNA that resides in the mitochondria rather than the nucleus of a cell. Unlike nuclear DNA, mitochondrial DNA is only inherited from the mother.</p> <p>See also 'Deoxyribonucleic acid (DNA)', 'Nuclear DNA'</p>
Mitochondrial Donation Donor Register	<p>A register kept by the Secretary of the Department (e.g. the Commonwealth Department of Health as existing from time to time), that contains specific information about the donor and child born following mitochondrial donation. The information that is required to be in the Mitochondrial Donation Donor Register is specified in the RIHE Act and can only be disclosed to specific people under specific circumstances.</p> <p>[RIHE Act s29A]</p>
Mitochondrial donation licence	<p>A mitochondrial donation licence means:</p> <ul style="list-style-type: none"> (a) a pre-clinical research and training licence [RIHE Act s28C]; or (b) a clinical trial research and training licence [RIHE Act s28D]; or (c) a clinical trial licence [RIHE Act s28E]; or (d) a clinical practice research and training licence [RIHE Act s28F]; or (e) a clinical practice licence [RIHE Act s28G].

Key term	Explanation
Mitochondrial donation technique	<p>A technique, prescribed by the regulations for the purposes of this definition, that:</p> <ul style="list-style-type: none"> (a) can be used to minimise the risk of a woman's offspring inheriting mitochondria from that woman that would predispose the offspring to mitochondrial disease; and (b) involves using assisted reproductive technology to create a zygote that: <ul style="list-style-type: none"> (i) has nuclear DNA from the woman [an egg] and a man [a sperm]; and (ii) contains mitochondria from a human egg of a different woman; and (c) does not involve: <ul style="list-style-type: none"> (iii) intentionally modifying nuclear DNA or mitochondrial DNA; or (iv) using any cell, or any component part of a cell, of an animal; or (v) creating a chimeric embryo (within the meaning of the <i>Prohibition of Human Cloning for Reproduction Act 2002</i>) or a hybrid embryo. <p>[RIHE Act s8]</p> <p>The following are mitochondrial donation techniques:</p> <ul style="list-style-type: none"> (a) maternal spindle transfer [RIHE Regs s7C]; (b) pronuclear transfer [RIHE Regs s7D]; (c) germinal vesicle transfer [RIHE Regs s7E]; (d) first polar body transfer [RIHE Regs s7F]; (e) second polar body transfer [RIHE Regs s7G]. <p>[Research Involving Human Embryos Regulations 2017 s7A]</p>
Must	<p>Identifies ethical standards which are the minimal standards of ethically acceptable practice. These standards often relate to external or observable behaviour and practices, and either prohibit or restrict some behaviours and practices. From an ethical perspective, these standards are mandatory.</p> <p>See also 'Should'</p>
Nuclear DNA	<p>The genetic material in the nucleus of a cell. Nuclear DNA is assembled into chromosomes. A human cell usually has 46 chromosomes, 23 from each parent. Sperm cells and egg (oocyte) cells each have 23 chromosomes.</p> <p>See also 'Deoxyribonucleic acid (DNA)', 'Mitochondrial DNA'</p>
Patient	<p>A woman whose pregnancy is sought to be achieved using a mitochondrial donation technique under a clinical practice licence.</p> <p>[RIHE Act s8]</p> <p>See also 'Trial participant'</p>

Key term	Explanation
Proper consent	<p>The term ‘proper consent’ is used in the RIHE Act to describe the consent requirements for the use of an excess ART embryo, a human egg, or the creation or use of any other embryo, in licensable or licensed activities.</p> <p>Section 8 Subsection 24(9) of the RIHE Act defines ‘proper consent’ as ‘consent obtained in accordance with guidelines issued by the CEO of NHMRC as prescribed in the RIHE regulations.’ The RIHE Regulations prescribe the ART guidelines, as updated from time to time and should be consulted to determine which version of the ART guidelines is prescribed.</p> <p>In the context of these Ethical Guidelines, the term ‘valid consent’ is used instead of the term proper consent, and has equivalent meaning.</p> <p>See also ‘Excess ART embryo’, ‘Valid consent’</p>
Responsible person	<p>Each person whose reproductive material, genetic material or cell was used, or is proposed to be used, in the creation, development, production or use of the material produced as authorised by a mitochondrial donation licence.</p> <p>[RIHE Act s28N]</p>
Reversion	<p>Reversion is the phenomenon of carried over mitochondrial DNA increasing in amount, which could potentially result in mitochondrial disease if the extent of reversion was sufficient.</p> <p>Reversion or carryover could occur in subsequent generations; the child born following mitochondrial donation may be at low risk of mitochondrial disease, but the offspring of the daughters could have a further increase in the level of mutant mitochondrial DNA.</p> <p>See also ‘Carryover’</p>
Should	<p>Identifies ethical standards which are the optimal standards of ethical practice. These standards often relate to attitudes, behaviours and practices which are complex, and therefore less easily measured and assessed by external observers. These are not optional standards. Rather, they are standards which every member of the clinical team has an ethical obligation to understand and strive to practise.</p> <p>See also ‘Must’</p>
Trial participant	<p>A woman whose pregnancy is sought to be achieved using a mitochondrial donation technique under a clinical trial licence.</p> <p>[RIHE Act s8]</p> <p>For the purposes of this Supplementary Section, a child born following mitochondrial donation is not defined as a trial participant.</p> <p>See also ‘Patient’</p>

17 Guiding principles

The guiding principles of the ART Guidelines inform this Supplementary Section and aim to support the use of mitochondrial donation in research, training and clinical practice, so that health professionals have an ethical framework to guide clinical consideration and decision-making. Many of the ethical principles in ART research (Chapter 11) are also relevant. For reference, the Guiding Principles as they appear in Chapter 2 are below.

17.1 Mitochondrial donation techniques must be conducted in a way that aligns with the guiding principles as specified in Chapter 2.

Guiding principles

1. ART activities must be conducted in a way that shows respect to all involved.
2. The interests and wellbeing of the person who may be born as a result of an ART activity must be an important consideration in all decisions about the activity.
3. ART activities must be undertaken in a manner that minimises harm and maximises the benefit to each individual or couple involved in the ART activity, any persons who may be born as a result of the activity, and any other child within the family unit who may be affected by that birth.
4. 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 as a result of the ART activity.
5. Decision-making in the clinical practice of ART must recognise and respect the autonomy of all relevant parties, promoting and supporting the notion of valid consent as a fundamental condition of the use of ART.
6. Decision-making in the clinical practice of ART must recognise that social relationships and social context may affect an individual's or a couple's decision-making and be sensitive to cultural and spiritual differences.
7. Processes and policies for determining an individual's or a couple's eligibility to access ART services must be just, equitable, transparent and respectful of human dignity and the natural human rights of all persons, including the right to not be unlawfully or unreasonably discriminated against.
8. The provision of ART must be underpinned by policies that support effective and efficient practices that minimise interventions not supported by evidence of successful clinical outcomes.
9. 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, to the degree that is protected by law.

18 Information giving and counselling

Trial participants and patients wishing to use mitochondrial donation techniques must meet legislated requirements, including eligibility criteria, the provision of specific information and participation in mandatory counselling. Some trial participants and patients may seek mitochondrial donation after significant investigation of other reproductive options or within the context of serious illness.

18.1 Ensure the provision of relevant information

- 18.1.1** Licence holders must ensure that sufficient information about the IVF components of mitochondrial donation treatment (for example, hormone stimulation, egg retrieval, embryo transfer) is provided to the donor and trial participant or patient to meet the requirements outlined in paragraphs 4.1 and 4.2.1 to 4.2.2 and 4.2.6 (if relevant).
- 18.1.2** Clinical risks, including the potential for unknown risks, should be communicated to a trial participant or patient with regard to their predisposition to mitochondrial disease and the predisposition of their offspring to mitochondrial disease. The clinical team should provide trial participants and patients with:
- detailed written information with respect to the risks to both themselves and any offspring, including those specific to mitochondrial disease
 - an appreciation of the risk of mortality, permanent disability or other serious morbidities that may result from ART procedures, and from medical complications in any resulting pregnancy, including those specific to mitochondrial disease.
- 18.1.3** Licence holders, clinicians and counsellors should use clear and consistent terminology to ensure that responsible persons and their families have the vocabulary to talk and think about issues relevant to mitochondrial donation, and to avoid language that is potentially discriminatory or harmful to those involved. Science should be communicated in an easy-to-understand way using plain language and avoiding jargon where possible. Written information may be supported by multi-media tools such as videos or infographics, if it is non-directive and helps responsible persons to understand the relevant concepts.

18.2 Ensure effective counselling of all responsible persons

- 18.2.1** Licence holders must provide counselling services that meet the requirements outlined in paragraph 4.3.1.
- 18.2.2** A trial participant or patient (and their spouse or partner, if any) or a donor must have attended counselling with an appropriately qualified and Human Genetics Society of Australasia certified genetic counsellor before commencement of treatment, and been fully informed of the following:
- alternatives to using mitochondrial donation techniques, such as: the use of donor eggs without using a mitochondrial donation technique, adoption or fostering, or not having children
 - detailed information about the science and process of mitochondrial donation, including the implications of haplotype/haplogroup matching
 - the risks, including potential unknown risks, involved in using mitochondrial donation techniques, including the possibility of carry-over and reversion of mitochondria containing the mutated DNA from the prospective mother
 - the potential for mitochondrial disease to re-emerge in future generations, or mitochondrial disease or developmental abnormalities to occur despite mitochondrial donation techniques being used
 - the impact of the sex of the embryo on the heritability of changes to the mitochondrial genome (noting the legislative prohibition on the selection of an embryo for implantation on the basis of sex)
 - the impact of ongoing monitoring on the child and family (trial participant or patient and their spouse or partner, if any; not applicable to the donor) and the existence and implications of the Mitochondrial Donation Donor Register.
- 18.2.3** Due to the complex nature of the issues involved, a trial participant or patient (and their spouse or partner, if any), or a donor, must participate in counselling by a fertility counsellor who is a fully accredited member of the Australian and New Zealand Infertility Counsellors Association (ANZICA) (who may or may not be the genetic counsellor in paragraph 18.2.2). The counselling should include a detailed discussion of the following:
- the potential long-term psychosocial implications for each individual and each family involved, including the person who may be born and any other child within the family unit(s) who may be affected by that birth
 - the reason(s) why they want to become involved in a mitochondrial donation program, including any familial or undue pressure on the donor to participate
 - the trial participant or patient's expectations regarding likelihood of success of the technique
 - the donor's right to make informed decisions about their own medical care, including hormonal stimulation and egg retrieval processes, recognising the individuals' rights to withdraw or vary their consent as described in paragraph 19.2.1

- that their reproductive material can only be used for the specific purpose that consent is provided for (e.g. for in vitro research and training in the pre-clinical trial phase or by the trial participant in the clinical trial phase) and will need to be disposed of if it is not used for that specific purpose. For the donor, this should specifically address the partial use of their egg/s and disposal of the nuclear DNA.
- the potential emotional significance of the contribution of mitochondrial DNA and the right of persons born to know the details of their conception, and the benefits of early disclosure
- the possibility that persons born may learn that they were conceived using mitochondrial donation from other sources (for example from other family members) and may independently access information about their conception
- that any children born as a result of a pregnancy achieved by using the technique will be able to obtain information about the donor in accordance with the rules for disclosure of information on the Mitochondrial Donation Donor Register
- the possibility that persons born may attempt to make contact with the donor in the future
- the obligation to provide personal information (for example, name, date of birth) to a licence holder, including for each child born alive as a result of a pregnancy achieved using a mitochondrial donation technique
- the purpose of ongoing, comprehensive monitoring as well as the benefits involved for personal, clinical and research purposes.

18.2.4 In order for the counselling to be effective and give sufficient time for reflection, the counselling described in this section should be conducted during a minimum of two sessions, separated by at least one week.

18.2.5 Where the donor is known to the trial participant or patient and/or their spouse or partner all parties must also participate in an additional joint counselling session, separated by at least one week from the counselling detailed in paragraphs 18.2.2 and 18.2.3.

18.2.6 Where a potential donor has a spouse or partner, licence holders should encourage the potential donor to include their spouse or partner in the discussions about their egg donation, acknowledging the benefits of open disclosure and the potential impact of the decision on the spouse or partner, the couple's relationship and/or the family unit.

18.2.7 A licence holder must ensure that appropriate protocols are in place to facilitate the information giving and counselling as described in this section.

19 Consent

All participants involved in mitochondrial donation techniques have the right to make informed personal decisions on whether to take part in the proposed activities or not.

The term ‘proper consent’ is used in the RIHE Act to describe the consent requirements for the use of a human egg or the creation of an embryo in licenced mitochondrial donation activities. Proper consent must be given by each ‘responsible person’ involved in a licensed mitochondrial donation activity. This includes “each person whose reproductive material, genetic material or cell was used, or is proposed to be used, in the creation, development, production or use of the material” (ss28N(8) RIHE Act). The legislation defines ‘proper consent’ as that prescribed in the ART Guidelines. In these ART Guidelines, the term ‘valid consent’ is used instead of the term ‘proper consent’ and has equivalent meaning.

In these ART Guidelines, ‘valid consent’ requires: the person giving consent to have capacity to provide consent, the decision to consent to the treatment or procedure must be made without undue pressure, all relevant requirements regarding the provision of information and counselling requirements must be satisfied, and the consent must be specific and is effective only in relation to the treatment or procedure for which information has been given (paragraph 4.5).

19.1 Obtain consent from all relevant parties in line with processes described in Part B of the ART Guidelines

- 19.1.1 The consent processes for all types of mitochondrial donation licences must be in line with the comprehensive and stringent standards in Part B (clinical practice) of the ART Guidelines (see paragraph 4.5).
 - 19.1.1.1 A pre-clinical research and training licence or a clinical trial research and training licence could be seen to align with general ART research as described in Part C (research) of the ART Guidelines. However, the research authorised by these licences are different to other forms of ART research due to the disposal of the identity-forming nuclear DNA. On this basis, consent requirements for a research and training licence must reflect the more comprehensive and stringent standards in Part B (clinical practice) of the ART Guidelines.
- 19.1.2 Mitochondrial donation that is authorised under a clinical trial licence is classified as research. However, the ethical issues it gives rise to are more aligned with ethical issues that arise in clinical treatment, as the clinical trial aims to achieve a successful pregnancy. Therefore, consent requirements for these licence types must reflect the more comprehensive and stringent standards in Part B (clinical practice) of the ART Guidelines.
- 19.1.3 In addition to the processes for obtaining consent to discard material, responsible persons should receive information on the differences between mitochondrial DNA and nuclear DNA in the context of mitochondrial donation, to assist them to make an informed decision about the use and disposal of their reproductive material. Patient Information Sheets and Consent Forms should explicitly state how the different forms of the responsible persons’ DNA will be used and discarded.

19.2 Recognise the right of individuals to withdraw or vary their consent

- 19.2.1** A responsible person can withdraw or vary consent for their participation in a mitochondrial donation technique at any time before the creation of an embryo. This takes into account the scientific, social and emotional complexities that are involved with mitochondrial donation and the many points of informed decision-making that occur throughout the process.

19.3 Guidance for HRECs

- 19.3.1** An HREC assessing a mitochondrial donation licence application must ensure that the proposed research complies with the requirements of this Supplementary Section, and the ART Guidelines and *National Statement on Ethical Conduct in Human Research* more broadly, as applicable.

20 Use of donated gametes

The RIHE Act uses the term ‘donor’ to refer to the woman who donated an egg and whose mitochondria (but not nuclear DNA) are contained in the zygote that is created by mitochondrial donation. The intention underlying the legislation is that the donor would not legally become a parent solely because a child is born of the use of their donated materials using a mitochondrial donation technique. This is not dealt with expressly under the legislation but is dealt with in general laws dealing with parentage.

Eggs for mitochondrial donation techniques may be donated to a specific trial participant or patient who is known to the donor (‘known donation’) or who is not known to the donor and receiving mitochondrial donation techniques (‘unknown donation’).

Commercial trading in human gametes or the use of direct or indirect inducements is prohibited by the PHCR Act. This position reflects concerns about the potential exploitation of donors (particularly egg donors) and the potential risks to all parties. The ART Guidelines state that it is reasonable to provide reimbursement of verifiable out-of-pocket expenses directly associated with the donation, including medical and counselling costs and travel and accommodation costs within Australia.

20.1 Protect the interests of the donor

- 20.1.1 Licence holders must consider the physical, psychological and social wellbeing of each party when accepting or allocating gamete donations, as specified in paragraph 5.2.
- 20.1.2 Guidance in Chapter 5 on reducing the potential for commercialisation and exploitation of women for their eggs, including reimbursement for verifiable out-of-pocket expenses directly associated with donation of eggs (paragraph 5.4), applies to mitochondrial donation. In addition, licence holders should make efforts to ensure that a donor is not subject to non-commercial exploitation in the form of emotional persuasion, particularly if the donor is known to the trial participant or patient.

20.2 Limit the number of families created from each donor

- 20.2.1 Despite a donor not contributing nuclear DNA to offspring born following a mitochondrial donation technique, licence holders must take all reasonable steps to limit the number of families created using eggs from each specific donor, in line with paragraph 5.3.

20.3 Support the exchange of information between relevant parties

- 20.3.1 There should be voluntary exchange of information between persons born from mitochondrial donation techniques, donors and trial participants or patients, with the consent of all parties.
- 20.3.2 Licence holders must implement the principles and processes in paragraphs 5.6 – 5.10 for the exchange of information, with minor alterations to account for the specific requirements of the RIHE Act in relation to mitochondrial donation, and any other relevant legislation.

21 Responsibilities of the licence holder for stored gametes and embryos

Licence holders must ensure that processes are in place, and complied with, to ensure the safe and ethical storage of gametes and embryos, in line with Chapter 7.

22 Record keeping and data reporting

The legislation provides for the collection, storage, security, use, disclosure and publication of personal information. In particular, section 28R of the RIHE Act requires a holder of a clinical trial licence or a clinical practice licence to collect information about donors and children born as a result of mitochondrial donation techniques. It also requires them to share this information with the Secretary of the Department of Health for inclusion in the Mitochondrial Donation Donor Register (s29A RIHE Act). The Mitochondrial Donation Donor Register will not be publicly available and will allow any person over 18 born as a result of mitochondrial donation to access identifiable information regarding their donor. The donor will have access to information on the register about themselves and will be able to infer, by the presence of their information on the Mitochondrial Donation Donor Register, that a child has been born of their donation, but will not be able to access any details about the child.

In addition to the considerations in Chapter 9 of the ART Guidelines, section 4.2 of the National Statement addresses ethical considerations that are specific to the participation of children and young people in research. The principles of this chapter are relevant to the ongoing monitoring of a child conceived using mitochondrial donation techniques.

22.1 Maintain appropriate records

- 22.1.1 Licence holders must maintain appropriate records in accordance with the requirements of paragraphs 9.1 – 9.2, in addition to any records required by a Licence or legislation.

22.2 There must be protocols for monitoring

- 22.2.1 Licence holders must have protocols in place for certain monitoring of trial participants, patients and children born as a result of mitochondrial donation techniques, in line with legislative requirements (for example, s28S(2) RIHE Act).
- 22.2.2 A key purpose of monitoring should be to understand any risks that may result from using mitochondrial donation techniques so that they can be managed or mitigated, and to provide data to inform ongoing improvements to the safety and efficacy of mitochondrial donation techniques.
- 22.2.3 Licence holders must have protocols in place to seek the ongoing engagement of trial participants or patients and children born as a result of mitochondrial donation techniques, for example by explaining the benefits to themselves and others of their participation in monitoring.

22.2.4 Licence holders must adhere to the principles and standards set out in the National Statement when developing protocols for ongoing monitoring of trial participants, patients and children born as a result of mitochondrial donation techniques.

22.2.5 Usual privacy and patient confidentiality policies should apply in relation to a trial participant or patient dealing with clinical specialists in their antenatal care team.

22.3 Privacy and confidentiality must be protected

22.3.1 Licence holders and clinics must stringently protect the identities of donors, trial participants, patients and children born through mitochondrial donation techniques, reflecting the high standards of confidentiality and privacy that are already implemented with other donor registries.

22.3.2 Licence holders should make non-identified data available to appropriate bodies as prescribed by the RIHE Act, to enable subsequent collation of national statistical information.

22.3.3 Reporting of data must 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 is subject to the consent of the individuals or couples involved.

23 Sex selection

The legislation includes a condition of licence that “a human embryo created for a woman using a licensed mitochondrial donation technique is not to be selected for implantation in that woman on the basis of the sex of the embryo” (s28Q(d) RIHE Act).

23.1 An embryo is not to be selected for implantation on the basis of the sex of that embryo.

Further guidance on sex selection outside the context of mitochondrial donation techniques is at paragraphs 8.13 and 8.14.

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 *National Health and Medical Research Council Act 1992* came into force.

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*
- *Ethical Guidelines on the use of assisted reproductive technology in clinical practice and research, 2004 (revised 2007, 2017, 2023).*

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). Parts A and B were revised in 2017 to ensure ongoing relevance and contemporary guidance. The Mitochondrial Donation Supplementary Section was added in 2023 to facilitate the ethical introduction of mitochondrial donation, following enactment of the *Mitochondrial Donation Law Reform (Maeve's Law) Act 2022*.

Accreditation of ART clinics

All persons and bodies offering ART services must be accredited by the recognised accreditation body, the Reproductive Technology Accreditation Committee, established by the Fertility Society of Australia, or another body prescribed by the Research Involving Human Embryos Regulations 2017. 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 relevant legislation 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 publication [2017], only four Australian states have such legislation:²¹

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.

²¹ Note: states and territories may have specific legislation concerning certain ART practices, including surrogacy and the donation of human gametes or embryos.

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 the individual or couple responsible for the embryo ('excess ART embryos').

The RIHE Act also established the Embryo Research Licensing Committee (the Licensing Committee) as a principal committee of the National Health and Medical Research Council (NHMRC).

The functions of the Licensing Committee include:

- the consideration of applications for general licences to conduct research on excess ART embryos
- the consideration of applications for mitochondrial donation licences
- 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.

The *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (the Amendment Act) came into effect on 12 June 2007. The Amendment Act extended the range of licensable activities and changed the title of the PHC Act to the *Prohibition of Human Cloning for Reproduction Act 2002*.

The *Mitochondrial Donation Law Reform (Maeve's Law) Act 2022* came into effect on 1 October 2022. The amendments to the RIHE and PHCR Acts allow the introduction of mitochondrial donation techniques in Australia, through a staged approach and under strict regulatory conditions, to prevent transmission of severe mitochondrial disease. Further information can be found in the Mitochondrial Donation Supplementary Section.

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 (<https://www.nhmrc.gov.au/>).

3 Case studies

Case Study One – Individuals and couples seeking ART treatment or procedures overseas

Paragraphs 4.2.7 – 4.2.10

A couple have been receiving treatment through an ART clinic for two years with no success. They decide to attempt treatment with the help of an egg donor, and make an autonomous decision to seek the services of a commercial egg donor overseas. They present at their Australian clinic and explain their plans to their clinician. The couple are unsure about the overseas clinic's procedures for egg donation, as they have only had email contact. They express excitement that the overseas clinic has suggested they transfer three embryos, to give them the 'best possible chance' of falling pregnant.

Issues to consider

The couple may not have a good understanding of the differences in the standard of care and donor arrangements between Australia and their destination country. The clinician has an ethical obligation to raise any concerns about the standard of care in the overseas clinic or acknowledge where the standard of care is unknown.

Whilst the clinician must not promote or recommend practices which contravene these Ethical Guidelines or Australian legislation, the clinician may provide information in the interest of minimising the potential for harm to the couple and the person(s) to be born, and to assist the couple in making an informed decision. This information may include:

- a list of questions for the couple to ask the clinic, to seek further information about their standard of care and donor conception practices, such as:
 - What are the qualifications and experience of the clinical team at the clinic?
 - What pre-donation testing is conducted, to ensure donors are free from communicable disease?
 - Will identifying information about the donor be available to the person(s) born?
 - What counselling is available to both the donor and themselves?
- advice regarding the recommended testing and treatment protocol for the couple's embryo transfer and follow up care
- the risks associated with multiple births, and advice about the recommended number of embryos to transfer to minimise this risk, based on the couple's circumstances
- information about Australian donor conception practices, including the information outlined in paragraphs 4.4 and 5.6 of these Ethical Guidelines.

In addition to providing this information, the clinician may feel they have an ethical obligation to participate in elements of the treatment of the individual or couple in order to minimise potential harms. However, the clinician is under no ethical obligation to participate in such treatment and should be aware of any relevant legislation before commencing any such treatment (see paragraph 4.2.10).

Any information or services provided by the clinician should promote current Australian best practice.

Case Study Two – Reallocation of donated embryos

Paragraphs 6.1.3 – 6.2.1

Couple 1 have completed their family and have embryos remaining in storage. In deciding whether to donate or discard their embryos, Couple 1 is advised of their options and upon choosing to donate their embryos, undergo the required counselling.

Scenario A

Couple 1 wish to donate their embryos to Couple 2 and is comfortable with the possibility that once Couple 2 has completed their treatment, they could choose to reallocate any remaining excess embryos to another party. Couple 1's consent for donation does not include any restrictions on the use or discard of the embryos.

Couple 2 are informed and counselled, consent to receiving these embryos and proceed to treatment.

Couple 2 complete their family and have embryos remaining in storage. As there were no restrictions on the use or discard placed on the consent for donation by Couple 1, Couple 2 is advised of their options.

Couple 2 decide to reallocate the remaining embryos. However, they are not comfortable with the possibility that their children could have siblings spread over more than three family units. As a result, Couple 2 donates their remaining embryos to Couple 3 on the condition that the embryos are either used by Couple 3, or discarded.

During the consent process, Couple 3 is informed of the above condition and counselled regarding the implications. Couple 3 accepts the conditions of the donation and proceed to treatment.

Couple 3 have one embryo remaining in storage once they have completed their family, and consent for the remaining embryo to be discarded, in line with the conditions Couple 2 placed on the donation.

Scenario B

Couple 1 wish to donate their embryos to their friends (Couple 2) but are not comfortable with the possibility that once Couple 2 has completed their treatment, they could choose to discard any remaining embryos. As a result, Couple 1 donates their remaining embryos to Couple 2 on the condition that the embryos are either used by Couple 2, or reallocated to another individual or couple.

During the consent process, Couple 2 is informed of the above conditions and counselled regarding the implications. Couple 2 had only planned to have one child and do not feel comfortable with the possibility that their child could have siblings spread over more than two family units.

Couple 2 therefore do not consent to receiving these embryos.

Issues to consider

- This case study demonstrates the importance of information giving, counselling and consent before participation in a donor conception program.
- This case study demonstrates the complexity of information giving, counselling and consent in the reallocation of donated embryos.
- Counselling prior to donation is critical to ensure that potential donors and recipients understand the potential uses of the embryos, particularly the potential for reallocation.
- Donors have the right to place limitations on the use, storage and discard of donated embryos.
- Consent for donation should be explicit regarding the permitted uses for the donated embryos, including reallocation.
- Donors and recipients need to know who is responsible for decision-making about their donated embryos throughout the entire process.
- The rights of donors to withdraw their consent for donation need to be protected.
- With reallocation, there will be multiple donors and multiple recipients whose rights and responsibilities must be considered.
- All recipients have an interest in the future use of the embryos as the offspring of each couple will have a biological connection.
- Clear and transparent processes will:
 - support each donor and recipient's decision-making
 - manage expectations
 - minimise the potential for harm to all parties, including the persons born.
- The reallocation of donated embryos created using donated gametes will add greater complexity to the information giving, counselling and consent requirements.
- All parties should be counselled on the potential impact of multiple reallocations on the person(s) born.
- The reallocation of donated embryos (including those created using donated gametes) may be prohibited by law in some states/territories.

Responsibilities in donor conception programs and the reallocation of donated embryos^{22,23}

Couple 1 donates their excess embryos.

- Couple 1 is responsible for decision-making about the use, storage and discard of the embryos whilst they are in storage awaiting donation to an identified individual or couple (known donation), or to another individual or couple (unknown donation).
- Couple 1 can place a limitation on the number of recipients.
- The clinic is responsible for maintaining the appropriate storage of the embryos and record keeping.
- In unknown donation, the clinic is also responsible for the allocation of the embryos.

²² Subject to any limitations imposed by law and these Ethical guidelines (see paragraph 6.1.3).

²³ Where an embryo has been created using donated gametes, additional considerations apply.

A recipient couple (Couple 2) accepts the donation.

- Subject to any limitations expressed in the consent of Couple 1, Couple 2 is responsible for decision-making about the use, storage and discard of the embryos.
- Couple 1 retains the right to withdraw consent at any time before the treatment cycle of the recipient commences.
- The clinic is responsible for maintaining the appropriate storage of the embryos and record keeping.

Couple 2 completes their treatment and excess embryos are able to be reallocated.

- Subject to any limitations expressed in the consent of Couple 1, Couple 2 is responsible for decision-making about the use, storage and discard of the embryos whilst they are in storage awaiting reallocation.
- Subject to any limitations expressed in the consent of Couple 1, Couple 2 can place a limitation on the number of recipients.
- The clinic is responsible for maintaining the appropriate storage of the embryos and record keeping.
- In unknown donation, the clinic is also responsible for the reallocation of the embryos to another individual or couple.

Another recipient couple (Couple 3) accepts the donation.

- Subject to any limitations expressed in the consent of Couple 1 or the consent of Couple 2, Couple 3 is responsible for decision-making about the use, storage and discard of the embryos.
- The clinic is responsible for maintaining the appropriate storage of the embryos and record keeping.
- Couple 1 and Couple 2 retain the right to withdraw consent at any time before the treatment cycle of the recipient commences.

Exchange of information between relevant parties.

As a minimum:

- Persons born as a result of the donated embryos are entitled to know the details of their genetic origins (as per paragraphs 5.6 and 5.9).
- Couple 1 are entitled to some information about any persons born as a result of their donation (i.e. the offspring of Couple 2 and Couple 3) (as per paragraph 5.7).
- Couple 2 are entitled to some information about any persons born as a result of their donation (i.e. the offspring of Couple 3) (as per paragraph 5.7).

Persons born may register their consent to have their identifying information released to other individuals born from donations made by the same donors (as per paragraph 5.10.2).

4 Process Report

These Ethical Guidelines are subject to rolling review. This means that parts of the guidelines are updated as required, in place of a whole-of-document review at a specific point in time.

2017 Update

In 2013, NHMRC commenced a review of Part B – Ethical guidelines for the clinical practice of ART. The review of Part B necessitated changes to Part A – Introduction. Only consequential editorial revisions (e.g. cross-references, chapter numbers and consistent language) were made to Part C – Ethical guidelines for research.

Assisted Reproductive Technology (ART) Working Committee

Following the provision of nominations from relevant organisations, NHMRC formally established the Assisted Reproductive Technology (ART) Working Committee under section 39 of the NHMRC Act and members were appointed on 16 April 2013.

The ART Working Committee was chaired by a member of AHEC and included members with relevant knowledge and expertise in ethics, reproductive technology, reproductive law and regulation, religion and consumer issues.

The Terms of Reference for the ART Working Committee were to advise AHEC on the review of Part B of the ART guidelines.

Member	Membership Category
Professor Ian Olver AM	Chairperson
Dr Clare Boothroyd	Provider of ART services
Professor David Coman	Person with an understanding of the concerns of people with a disability or genetic condition
Professor Sheryl de Lacey	Expert with an ability to identify ethical issues in relation to reproductive technology
Mr Keith Harrison	Person with expertise in RTAC Accreditation processes
Professor Ian Kerridge	Expert with an ability to identify ethical issues in relation to reproductive technology
Professor William Ledger	Provider of ART services
Reverend Kevin McGovern	Person with a background in both religion and ethics
Ms Kay Oke OAM	Person with knowledge of issues that concern people who access reproductive technology (consumer representation)
Professor Loane Skene	Person with legal expertise in relation to reproductive medical practice
Professor Robin Mortimer AO <i>until 30 June 2015</i>	Expert in reproductive medicine (but not a provider of ART services)

Disclosure of interest and management of conflicts of interest

A robust and transparent system was used for disclosure and management of interests throughout the development of these Ethical Guidelines, in accordance with the requirements of the NHMRC Act, NHMRC's *Policy on the disclosure of interests requirements for prospective and appointed NHMRC committee members*, and from 1 July 2014, the *Public Governance, Performance and Accountability Act 2013*.

Members of the ART Working Committee were required to disclose their interests before their appointment and advise any changes to their interests throughout the development of these Ethical Guidelines. Consideration of disclosed interests was a standing item at every meeting of the ART Working Committee. The process involved members considering all disclosed interests and agreeing to a management strategy for any interest that was identified as being a real or perceived conflict of interest. There were no instances in the development process where an interest was identified as a perceived or real conflict of interest that required a management strategy.

A record of interests was maintained by NHMRC and relevant information was made publicly available on the NHMRC website to ensure transparency.

Consumer representation

Consumer engagement was a fundamental part of the public consultation process and many consumer organisations were specifically contacted for comment during both consultations. The consumer representative on AHEC 2012 – 2015 was included in the membership of the ART Working Committee that developed these Ethical Guidelines.

NHMRC Project Team

Alana Lucas (2012 – 2017)

Jennifer Campaign (2015 – 2017)

Zoë Thomas (2015 – 2017)

Sarah Renwick (2016 – 2017)

Jillian Barr (2012 – 2015)

Mary Bate (2014 – 2015)

Key steps in the process

- Establishment of the Assisted Reproductive Technology (ART) Working Committee to advise AHEC on the review of Part B of the ART guidelines.
- Preparation of the initial public consultation document.
- Initial public consultation (11 March – 30 April 2014), with 65 submissions received. The aim of this public consultation was to:
 - determine the usefulness of the existing ethical guidance
 - identify any current gaps in the existing ethical guidance
 - identify any new technologies, or new uses of old technology, that may require further or different ethical guidance
 - inform the development of revised ethical guidance.

- Consideration of the submissions received during the initial public consultation and the development of revised ethical guidelines for further public consultation.
- Subsequent public consultation (23 July – 17 September 2015), with 186 submissions received.
- Consideration of the submissions received during the subsequent public consultation and the development of revised ethical guidelines.
- Consideration and approval of the revised ethical guidelines by AHEC.
- Consideration of the revised ethical guidelines by Council, in accordance with subsection 10(2) of the NHMRC Act.

At its 210th session on 15 March 2017, Council advised NHMRC's CEO that the final document should be issued. The CEO issued the *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research, 2017* under subparagraph 7(1)(a)(v) of the NHMRC Act on 20 April 2017.

AHEC 2012-2015	AHEC 2015-2018
Professor Ian Olver AM – Chairperson	Professor Ian Olver AM – Chairperson
Dr Gary Allen	Associate Professor Mark Arnold
Professor Vicki Anderson	Ms Rebecca Davies
Professor Samar Aoun	Emeritus Professor Anne Edwards
Professor Susan Dodds	Professor Helen Edwards
Associate Professor Ian Kerridge	Associate Professor Clara Gaff
Dr Tammy Kimpton	Professor Louisa Jorm
Rabbi Aviva Kipen	Associate Professor Karen Liu
Reverend Kevin McGovern	Associate Professor Daniel McAullay
Professor John McGrath AM	Reverend Kevin McGovern
Dr Eleanor Milligan	Professor Dianne Nicol
Professor Robin Mortimer AO	Professor Peter Procopis
Ms Kay Oke OAM	Dr Sarah Winch
Professor Margaret Otlowski	Professor Ingrid Winship
Professor Debra Rickwood	
Professor Wendy Rogers	
Professor Loane Skene	

2023 Mitochondrial Donation Supplementary Section

In 2022, following the passage of the *Mitochondrial Donation Law Reform (Maeve's Law) Act 2022*, NHMRC commenced a review of the ART Guidelines to identify amendments that may be required to the ART Guidelines as a result of the introduction of mitochondrial donation in Australia.

ART Guidelines (Mito) Review Working Committee

NHMRC established the ART Guidelines (Mito) Review Working Committee under section 39 of the NHMRC Act. Members were appointed for the period 5 July 2022 to 31 December 2022.

The ART Guidelines (Mito) Review Working Committee was chaired by a member of AHEC and included members with relevant knowledge and expertise in ethics, reproductive technology, reproductive law and regulation and consumer issues.

The Terms of Reference for the ART Guidelines (Mito) Review Working Committee were to provide advice to the Chief Executive Officer of the National Health and Medical Research Council (NHMRC), and to the 2021-2024 Australian Health Ethics Committee (AHEC), on amendments that may be required to the ART Guidelines as a result of the introduction of mitochondrial donation in Australia.

Member	Membership Category
Associate Professor Bernadette Richards	Chair. Expertise in health law, including mitochondrial donation law reform and regulation.
Ms Mia Bell	Expertise in consumer issues relating to mitochondrial disease
Professor Jackie Leach Scully	Expertise in the ethical considerations relating to mitochondrial donation
Ms Cal Volks	Expertise in consumer issues relating to ART consent and counselling
Professor Steve Robson	Expertise in assisted reproductive technology (ART)

Disclosure of interest and management of conflicts of interest

A robust and transparent system was used for disclosure and management of interests throughout the development of the Supplementary Section, in accordance with the requirements of the NHMRC Act, NHMRC's *Policy on the disclosure of interests requirements for prospective and appointed NHMRC committee members*, and the *Public Governance, Performance and Accountability Act 2013*.

Members of the ART Guidelines (Mito) Review Working Committee were required to disclose their interests before commencement of their duties and advise any changes to their interests throughout the development of the Supplementary Section. Consideration of disclosed interests was a standing item at every meeting of the ART Guidelines (Mito) Review Working Committee. The process involved members considering all disclosed interests and agreeing to a management strategy for any interest that was identified as being a real or perceived conflict of interest. There were no instances in the development process where an interest was identified as a perceived or real conflict of interest that required a management strategy.

A record of interests was maintained by NHMRC and relevant information was made publicly available on the NHMRC website to ensure transparency.

Consumer representation

Consumer engagement was a fundamental part of the public consultation process. A number of key consumer organisations were specifically contacted for comment during the public consultation. The ART Working Committee that developed these Ethical Guidelines included a Member with expertise in consumer issues relating to mitochondrial disease, and a Member of AHEC 2021-2024 with significant expertise in bioethics with a particular focus on people with disability and other marginalised communities.

Key steps in the process

- Establishment of the ART Guidelines (Mito) Review Working Committee to advise the NHMRC CEO and AHEC on the requirements to address mitochondrial donation in the ART Guidelines.
- The ART Guidelines (Mito) Review Working Committee engaged in detailed workshop discussions on counselling, consent, record keeping and reporting in the context of mitochondrial donation.
- Public consultation (9 November 2022 – 19 December 2022), with 19 submissions received.
- Consideration of the submissions received during the public consultation and the development of revised Supplementary Section.
- Consideration and approval of the revised ethical guidelines by AHEC.
- Consideration of the revised ethical guidelines by Council, in accordance with subsection 10(2) of the NHMRC Act.

On 8 March 2023, Council reached an out-of-session decision to advise NHMRC's CEO that the final document should be issued. The CEO issued the Ethical guidelines on the use of assisted reproductive technology in clinical practice and research 2017 (updated 2023) under subparagraph 7(1)(a)(v) of the NHMRC Act on 17 April 2023.

The members of AHEC 2021-2024 can be found on the NHMRC website (<https://www.nhmrc.gov.au/>).

5 Issues for further consideration in the clinical practice of ART

This appendix provides a brief discussion of issues that are either outside of the scope of these Ethical Guidelines, are issues identified in these Ethical Guidelines, or are issues on the horizon that may require consideration in the future.

The importance of enacting nationally consistent legislation to facilitate harmonisation in the ART industry

The Australian Health Ethics Committee (AHEC) conducted public consultation on the advice of the Assisted Reproductive Technology (ART) Working Committee during 2014, and again in 2015. The importance of enacting nationally consistent legislation to ensure harmonisation in the ART industry was evident in the submissions received. Issues identified through the public consultations included:

- The lack of ART legislation in some states/territories and the significant variations in ART legislation between the other states/territories.
- The different approaches in the states/territories regarding access to information about a person's genetic origins.
- The variation between states/territories in how surrogacy arrangements are made, and who can access surrogacy services.

Whilst the ART Working Committee recognised that the public consultations identified salient concerns, it also recognised that the regulation of health care is a state/territory responsibility. Since the 1996 edition, the ART guidelines have strongly recommended that uniform legislation be enacted in all Australian states and territories.

Sex selection for non-medical purposes

These Ethical Guidelines recognise that there are differences of opinion about the acceptability of sex selection practices. As detailed in Section 8 of the Ethical Guidelines, the majority view of AHEC is that there may be some circumstances where there is no ethical barrier to the use of sex selection for non-medical purposes. However, as with any controversial practice, Australian society needs to be ready, both socially and politically, for there to be a change in its availability. AHEC recommends further public debate and broad social and political discussion on the potential to permit access to sex selection for non-medical purposes, in some circumstances.

Notwithstanding the social and political considerations, AHEC saw merit in permitting access to ART activities to select the sex of a human embryo prior to embryo transfer to introduce variety to the sex ratio of offspring within a family, where:

- the intended parent(s) have (collectively) two or more offspring of the one sex and no offspring of the opposite sex
- the intended parent(s) have been provided with relevant information and counselling, in accordance with paragraphs 8.17 – 8.18
- the decision to permit access is made on a case-by-case basis, following consideration of the guiding principles in Chapter 2 of these Ethical Guidelines in the context of the individual family.

With this in mind, the following scenarios could, or could not, be supported:

Scenario	Using the above criteria, could the use of sex selection be supported?	Comment
An individual or couple would like to choose the sex of their first child	No	This is an example of family design
An individual or couple has one male child and would like their second child to be female	No	This is an example of family design
An individual or couple has one biological son and one adopted daughter. The individual or couple would like to have a biological daughter	No	This is an example of family design, as there is already variety in the sibship
An individual or couple has two daughters and would like a son	Yes – subject to appropriate information giving, counselling and consent requirements	This is an example of introducing variety to the sibship of the family
An individual or couple has two daughters and one son, and would like another son	No	This is an example of family design, as there is already variety in the sibship
A couple have a blended family, consisting of two male children (who are step-brothers). The couple would like a daughter	Yes – subject to appropriate information giving, counselling and consent requirements	This is an example of introducing variety to the sibship of the family
A couple have a blended family, consisting of two male children (who are step-brothers). The couple would like another son	No	This is an example of family design

The complexity of this issue emphasises the need for uniform legislation across all Australian states and territories.

The importance of establishing registries for donor conception

The importance of establishing registries for donor conception has long been recognised by the ART guidelines. The purpose of such registries is to facilitate the exchange of information, through a centralised register, between donors, recipients and persons born as a result of gamete donation. The establishment of donor registries may be of particular assistance to individuals involved in donor conception programs prior to 2004. At the time of publication [2017], such registries have been established in New South Wales, Victoria and Western Australia.

The ART Working Committee agreed that there would likely be practical difficulties in the establishment and maintenance of a national registry due to the complexities of Australian privacy legislation and the state/territory responsibility for the management of health records. It is outside the remit of these Ethical Guidelines to establish a national registry; however, the ART Working Committee sought to reinforce the importance of each state/territory establishing its own registry for donor conception. These Ethical Guidelines acknowledge the importance of the biological connection and support the right of an individual to know their genetic origins. The voluntary exchange of information between the donor, recipient and the persons born, facilitated by donor registries, is central to upholding this right.

Affordability of ART services

The affordability of ART services may affect an individual's or couple's ability to access treatment. At the time of publication [2017], Medicare rebates are available for a range of ART services in Australia.

While the ART Working Committee noted the ethical importance of promoting equitable access to health services, it was not within the scope of these Ethical Guidelines to comment on Medicare funding.

The compensation of gamete donors for the reproductive effort and risks associated with the donation

In Australia, trade in human gametes is prohibited by Commonwealth, and state and territory law. However, the reimbursement of verifiable out-of-pocket expenses directly associated with the donation is permitted.

Following the 2014 public consultation, the ART Working Committee looked to policies regarding compensation of gamete donors in countries with similar ethical and legal foundations to Australia, including the United Kingdom (UK). Since 1 April 2012, women in the UK have been able to receive a fixed rate of moderate compensation, and the reimbursement of expenses incurred above and beyond this amount, for the donation of eggs. 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 ART Working Committee considered whether it could be ethical for Australian women to receive compensation for the reproductive effort and risks associated with donating their eggs.

AHEC and the ART Working Committee sought to further explore attitudes relating to compensation for egg donors through public consultations during 2014 and 2015. The main themes of these submissions are summarised below:

- Compensation for the donation of gametes acknowledges the risk and reproductive efforts of the donor.
- Compensation for the donation of gametes is exploitative and is not compatible with the concept of altruistic donation.
- Compensation may increase the number of Australian donors, and could therefore be considered a harm minimisation strategy as it may reduce the demand for international donor arrangements.
- The fine distinction between compensation and inducement. Even a modest amount of compensation may act as an inducement for some individuals.
- Compensation may diminish a person's ability to provide valid consent due to the coercive potential.
- In the interest of equality, compensation for sperm donors should also be considered.

The ART Working Committee concluded it may be ethical to provide compensation for reproductive risk and effort, provided that the amount of compensation would not act as an inducement for the individual. The ART Working Committee recognised the practical difficulties in identifying what would constitute an inducement for different individuals and that compensation may be at odds with the *Prohibition of Human Cloning for Reproduction Act 2002*. Under this Act, it is an offence to offer or receive valuable consideration for human gametes or embryos. The ART Working Committee recommended further, in-depth consideration of this issue.

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. AU\$67) per clinic visit, and egg donors a fixed sum of up to £750 (approx. AU\$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 key findings from 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 to match the recipient's requests, leading, in some cases, to the importation of sperm.
- Egg donation has increased; this might be because of a combination 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 individuals and couples 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: <https://www.hfea.gov.uk/>. Further analysis on the impact of this regulatory change, including both quantitative and qualitative data is anticipated by 2018.

The compensation of surrogates for the reproductive effort and risks associated with the provision of surrogacy services

Public consultation raised the issue of compensation payments to surrogates for the reproductive effort and risks associated with pregnancy and birth. The ART Working Committee considered:

- whether compensation for surrogacy services represented exploitation or opportunity
- the difficulty in establishing the difference between compensation and payment/trade
- whether allowing for greater compensation could be considered a harm minimisation strategy as it may reduce trans-border surrogacy arrangements
- the emotional and physical demand of conception and pregnancy as being a significant part of the surrogate's experience
- that the provision of a set compensation rate may recognise the significant act provided by the surrogate
- existing state and territory legislation relating to surrogacy.

The ART Working Committee considered a report by the Surrogacy UK Working Group on Surrogacy Law Reform (the UK Report), which sought to identify current practice and regulation of surrogacy in the United Kingdom (UK).²⁴ The ART Working Committee acknowledged that the UK report demonstrated a genuine attempt to collect data relating to surrogacy arrangements in the UK and noted that it found that most surrogates in the United Kingdom were compensated between £0 and £15,000, but a breakdown of this sum was not provided.

On 2 December 2015, the Australian House of Representatives Social Policy and Legal Affairs Committee (the HoR Committee) began an inquiry into the regulatory and legislative aspects of domestic and international surrogacy. A report outlining the HoR Committee's findings and recommendations was released on 4 May 2016. The report identified a range of legal, social and financial issues relating to surrogacy arrangements and made a number of recommendations. One recommendation was 'the need for adequate reimbursement for the birth mother for legal, medical and other expenses incurred as a consequence of the surrogacy'.²⁵ The HoR Committee suggested that it may be within the scope of the Australian Law Reform Commission to further explore reimbursement for surrogates and the possible parameters for a national scheme.

²⁴ <https://surrogacyuk.org/legal-reform/>

²⁵ http://www.aph.gov.au/Parliamentary_Business/Committees/House/Social_Policy_and_Legal_Affairs/Inquiry_into_surrogacy/Report

The establishment of an Australian donor egg bank

In Australia, there may be egg banks established within individual ART clinics or within a group of affiliated clinics. At the time of publication [2017], there is no formally established or national egg bank in Australia. Donor egg banks are established in both the United Kingdom (UK)²⁶ and the United States of America (USA).²⁷

The ART Working Committee considered that 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 persons born via donated gametes
- reduce the number of embryos discarded.

Public consultations conducted in 2014 and 2015 identified the following issues:

- whether it is the responsibility of government to facilitate or fund a donor egg bank
- whether involvement from industry could leave donors and recipients vulnerable to commercialisation
- concerns regarding the costs involved, including establishment and ongoing management
- that the egg bank would be responsible for managing the donors' information and this could lead to the establishment of central donor registries.

The establishment of a donor egg bank is not within the scope of these Ethical Guidelines. The ART Working Committee acknowledged that the use of donated gametes in Australia, including the availability of donor gametes, remains an issue requiring further consideration.

²⁶ e.g. <http://www.ngdt.co.uk/become-an-egg-donor>

²⁷ e.g. <https://www.theworlddeggandspermbank.com/>

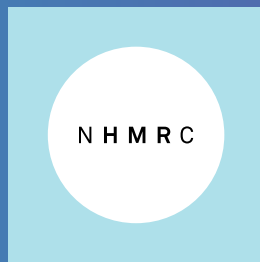
Emerging technologies

The emergence of new technologies and techniques has the potential to raise additional ethical considerations not yet addressed by these Ethical Guidelines. At the time of publication [2017], the research occurring internationally that might raise additional ethical issues includes:

- next-generation DNA sequencing
- mitochondrial donation to prevent of the transmission of mitochondrial disease²⁸
- editing of the embryonic genome
- in vitro maturation of oocytes
- the impact of stem cell research on the clinical practice of ART
- in vitro derived gametes
- prolonged culture of embryos
- mitochondrial transfer for the replenishment of older oocytes.

In some of these examples, the translation of this research into clinical practice is constrained by existing Australian legislation and/or these Ethical Guidelines. These Ethical Guidelines do not address technology which, at the time of publication [2017], is neither clinically validated nor permitted by Australian legislation.

²⁸ Following the enactment of the *Mitochondrial Donation Law Reform (Maeve's Law) Act 2022*, the Mitochondrial Donation Supplementary Section was added to these Guidelines in 2023.



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