Australian Government
National Health and Medical Research Council

NHMRC

Mitochondrial Donation

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

DRAFT (for public consultation 9 November to 19 December 2022)

BUILDING A HEALTHY AUSTRALIA

S1. 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 man and a woman (the prospective mother and father)
- mitochondria in an egg donated by another woman (the mitochondrial donor).

This approach minimises the risk of a prospective mother transmitting mitochondrial disease to her child, where the mother carries mitochondria that mean her child is likely to inherit severe mitochondrial disease.

It cannot, however, be used to cure people with existing mitochondrial disease or to prevent mitochondrial disease caused by mutations in an individual's nuclear DNA.

In March 2022, the Australian Parliament passed a Bill to allow the introduction of this ART technique in Australia, through a staged approach and under strict regulatory conditions, to prevent transmission of severe mitochondrial disease. The *Mitochondrial Donation Law Reform (Maeve's Law) Act 2022* came into effect on 2 October 2022 and amended the *Research Involving Human Embryos Act 2002* (the 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 new section 28P(4) of the RIHE Act, ERLC must not grant approval for a licence unless it is satisfied:

(a) 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

(b) 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

(c) 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.

Other uses of mitochondrial donation techniques 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.

This Supplementary Section aims to support the legislation by providing an ethical framework 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 or Part C 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.

S2. Abbreviations

Table 1. List of abbreviations

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

S3. 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.

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	In the mitochondrial donation process, carryover arises when mitochondria are transferred from the mother's affected egg along with the nucleus 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. See also 'Reversion'
Deoxyribonucleic acid (DNA)	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. See also 'Mitochondrial DNA'
Donor	If a particular use of a mitochondrial donation technique results in the creation of a zygote that: (a) has nuclear DNA from a woman and a man; and (b) contains mitochondria from a human egg of a different woman the woman mentioned in paragraph (b) is the ***donor*** in relation to that use of the technique. [RIHE Act ss28R(2)]

Key term	Explanation
Haplotype or haplogroup matching	**Haplogroup**: Corresponds to the common maternal origins of a species as defined by the haplotypes. **Haplotype:** A set of markers (identified DNA sequences) on the mitochondrial DNA or the nuclear DNA that tend to be inherited together transgenerationally. 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. Mitochondrial-nuclear interactions refer to the potential ways that components of the cell nucleus could affect the functioning of the mitochondria within that cell, or vice-versa. Mitochondrial donation will result in the intending mother's cell nucleus being paired with the donor mitochondrial DNA haplogroup, which may be different to the intending mother's haplogroup. There has been some concern that this mismatch could have negative consequences for the child born following mitochondrial donation. A number of new [2020] studies have examined aspects of mitochondrial-nuclear interactions resulting from mitochondrial donation. These publications have not provided a consensus on the importance of haplogroup matching or the risks of mis-matching. However, there is evidence from some studies to suggest that haplogroup matching may be important and that this area warrants further consideration. - Excerpt from the *Mitochondrial Donation Expert Working Committee Statement to the NHMRC CEO on the science of mitochondrial donation*[1], March 2020. Available from the NHMRC website at: www.nhmrc.gov.au/mitochondrial-donation
Licence holder	The entity responsible for a licence issued under section 28J of the RIHE Act.
Mitochondrial DNA	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. See also 'Deoxyribonucleic acid (DNA)', 'Nuclear DNA'
Mitochondrial donation licence	A mitochondrial donation licence means: (a) a pre-clinical research and training licence [RIHE Act s28C]; or (b) a clinical trial research and training licence [RIHE Act s 28D]; 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].

[1] National Health and Medical Research Council, *Mitochondrial Donation Expert Working Committee Statement to the NHMRC CEO on the science of mitochondrial donation* (March 2020) Available from: https://www.nhmrc.gov.au/mitochondrial-donation#download

Key term	Explanation
Mitochondrial donation technique	A technique, prescribed by the regulations for the purposes of this definition, that: (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: (i) has nuclear DNA from the woman and a man; and (ii) contains mitochondria from a human egg of a different woman; and (c) does not involve: (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 *Prohibition of Human Cloning for Reproduction Act 2002*) or a hybrid embryo. [RIHE Act s8] The following are mitochondrial donation techniques: (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]. [Research Involving Human Embryos Regulations 2017 s7A]
Must	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. See also 'Should'
Nuclear DNA	The genetic material in the nucleus of a cell. 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. See also 'Deoxyribonucleic acid (DNA)', 'Mitochondrial DNA'
Patient	A woman whose pregnancy is sought to be achieved using a mitochondrial donation technique under a clinical practice licence. [RIHE Act s8] See also 'Trial participant'
Responsible person	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. [RIHE Act s28N]

Key term	Explanation
Reversion	Reversion is where a child born following mitochondrial donation develops mitochondrial DNA disease later in life, perhaps as a result of the carried-over mitochondrial DNA replicating more efficiently than donor mitochondrial DNA. See also 'Carryover'
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'
Trial participant	A woman whose pregnancy is sought to be achieved using a mitochondrial donation technique under a clinical trial licence. [RIHE Act s8] See also 'Patient'

S4. Guiding principles

The guiding principles of the ART Guidelines inform this Supplementary Section and aim to support the clinical practice of mitochondrial donation 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.

S4.1 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.

S5. Information giving and counselling

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

S5.1 Ensure the provision of relevant information

S5.1.1 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 – 4.2.2 and 4.2.6 (if relevant).

S5.1.2 Clinical risks should be communicated to a trial participant or patient with regard to their predisposition to mitochondrial disease. Trial participants and patients should receive:

- 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.

S5.1.3 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.

S5.2 Ensure effective counselling of all responsible persons

S5.2.1 Licence holders must provide counselling services that meet the requirements outlined in 4.3.1.

S5.2.2 A trial participant or patient (and their spouse, if any) or a donor must have attended counselling with an appropriately qualified 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 impact of haplotype matching
- the risks involved in using mitochondrial donation techniques, including the possibility of reversion and carry-over of mitochondria containing the mutated DNA from the mother
- the potential for mitochondrial disease to re-emerge in future generations, or mitochondrial disease or developmental abnormalities to occur despite mitochondrial donation techniques
- 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 on the basis of sex)
- the impact of ongoing monitoring on the child and family (trial participant or patient and their spouse, if any; not applicable to the donor) and the existence and implications of the donor register.

S5.2.3 Due to the complex nature of the issues involved, a trial participant or patient (and their spouse, if any), or a donor, should participate in counselling by an ANZICA-accredited fertility counsellor (who may or may not be the genetic counsellor in paragraph S4.1.2). 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 donor's right to make informed decisions about their own medical care, including hormonal stimulation and egg retrieval processes
- that their reproductive material can only be used for the specific purpose that consent is provided for (that is, 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 destroyed 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.

S5.2.4 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.

S5.2.5 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.

S5.2.6 A licence holder must ensure that appropriate protocols are in place to facilitate the information giving and counselling as described in this section.

S6. 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).

S6.1 Obtain consent from all relevant parties in line with processes described in Part B of the ART Guidelines

S6.1.1 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).

6.1.1.1 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.

S6.1.2 Mitochondrial donation that is authorised under a clinical trial licence is classified as research but gives rise to ethical issues that 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.

S6.1.3 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.

S6.2 Recognise the right of individuals to withdraw or vary their consent

S6.2.1 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.

S6.3 Guidance for HRECs

S6.3.1 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.

S7. 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 recipient who is known to the donor ('known donation') or a trial participant or patient 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.

S7.1 Protect the interests of the donor

S7.1.1 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.

S7.1.2 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.

S7.2 Limit the number of families created from each donor

S7.2.1 Despite a donor not contributing nuclear DNA to offspring born following a mitochondrial donation technique, licence holders must take all reasonable steps to minimise the number of families created using eggs from each specific donor, in line with paragraph 5.3.

S7.3 Support the exchange of information between relevant parties

S7.3.1 There should be voluntary exchange of information between persons born from mitochondrial donation techniques, donors and trial participants or patients, with the valid consent of all parties.

S7.3.2 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.

S8. 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.

S9. 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 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 mitochondrial donor. The donor will also have access to information on the register about themselves and whether 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.

S9.1 Maintain appropriate records

S9.1.1 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.

S9.2 There must be protocols for monitoring

S9.2.1 Licence holders must have protocols 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).

S9.2.2 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.

S9.2.3 Licence holders must encourage the ongoing engagement of trial participants, 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.

S9.2.4 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.

S9.2.5 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.

S9.3 Privacy and confidentiality must be protected

S9.3.1 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.

S9.3.2 Licence holders should make non-identified data available to appropriate bodies, to enable subsequent collation of national statistical information.

S9.3.3 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.

S10. Sex selection

Mitochondria are passed to offspring through the maternal line. 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).

S10.1 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.