Summary of the major revisions to the 2007 ART guidelines

Issue	Discussion	Reference
Guiding principles in the clinical practice of ART	The 2017 ART guidelines: • Identify and define guiding principles relevant to the clinical practice of ART. • Provide guidance for the application of these principles.	Chapters 2 & 3
Information, counselling and consent	The 2017 ART guidelines: • Acknowledge that different individuals and couples undertaking different procedures have different information and counselling needs and different requirements for consent. • Lists general requirements (i.e. those that are applicable to all individuals and couples regardless of the procedures being considered), followed by additional requirements for individuals or couples involved in specific situations. • Include appropriate cross-references to prevent duplication of information. • Emphasise the significance of the biological connection, the right to knowledge of one's genetic origins and the benefits of early disclosure. • Require that all potential consumers of ART are informed of all possible options for the use and/or disposal of their gametes/embryos – including those that are legal, but are not offered at the particular clinic. This position is seen to enhance the participants' ability to make an informed choice. • Emphasise the importance of information giving and counselling in managing potential consumer expectations. • Require decisions to be made regarding posthumous use of stored gametes or embryos before the gametes or embryos are stored. • Include the requirement for the disclosure of any financial interests of the clinician related to the services recommended. • Acknowledge the importance of having processes in place to ensure the identity of those providing consent.	Chapter 4

Use of donated gametes and embryos in reproductive treatment programs	The 2017 ART guidelines: • Acknowledge that the current acceptance of 'unknown but directed donation' is potentially discriminatory and inequitable. This type of donation is considered to be unethical. • Address the issue of 'double donation' (the use of both donor sperm and egg). • Acknowledge state/territory legislation governing donor conception practices. • Remove guidance on the creation of hybrid embryos. This practice is seldom used by clinics (not for at least the past 10 years) and the creation of such embryos is subject to the RIHE Act. • Clarify who is responsible for the decision-making about the gametes or embryos at various stages.	Chapter 5
Donors with an increased risk of infectious disease	The 2007 ART guidelines did not allow clinics to accept donations from persons who are at an increased risk of transmissible infections. A number of submissions received during public consultation identified this as potentially discriminatory to members of the LGBTI communities. The Working Committee advised that infection control is a fundamental part of a clinic's risk management policy and a person's sexual orientation is not a routine reason to deny donation. The guidance has been revised to require clinics to meet regulatory requirements on infection control and have policies and procedures in place to minimise the transmission of infectious diseases, whilst recognising that emerging evidence will impact on these policies.	Paragraph 5.2.4
Reimbursement of verifiable out-of-pocket expenses for gamete donors and surrogates	The 2017 ART guidelines: • Provide guidance on the reimbursement of verifiable out-of-pocket expenses. • Require that these expenses be verifiable. This builds on, and clarifies, the existing guidance that 'reasonable expenses' may be reimbursed.	Paragraph 5.4.1 Paragraph 8.9.1
Use of imported gametes	The 2017 ART guidelines provide guidance for the importation of donated gametes and embryos from overseas. This guidance is not included in the current ethical guidelines. The 2017 ART guidelines require that imported gametes and embryos meet Australian standards for counselling and consent, which will ensure: • persons born from these donations will have access to information about their donor • gametes and embryos are not purchased overseas for use in Australia.	Paragraph 5.5.1

Gametes donated prior to 2004 on the condition of donor anonymity	The 2017 ART guidelines clarify: • The current guidance on the use of anonymous donations prior to the introduction of the ART guidelines (pre-2004). • The role of the ART guidelines in this matter.	Paragraph 5.10 Paragraphs 5.13 – 5.15
Donation of embryos with a known genetic condition	The 2017 ART guidelines include guidance for the donation of embryos with a known genetic condition that will not severely limit the quality of life of the person born. This practice was not available to clinics under the 2007 ART guidelines.	Paragraph 6.3.1
Reallocation of donated embryos or embryos created using donated gametes	The 2017 ART guidelines provide guidance for the reallocation of an embryo that was created using donated gametes, or a donated embryo, to a new recipient. This practice was not available to clinics under the 2007 ART guidelines. The 2017 guidance acknowledges the importance of each party understanding their rights and responsibilities for making decisions for the embryo's use, storage and discard and requires clinics to advise potential gamete and embryo donors of the possibility of reallocation prior to their participation in a donor program. A case study is provided at Appendix 3 to explore this further.	Paragraph 6.1.3
Withdrawal of consent for the donation of gametes or embryos	• The point at which a gamete donor can withdraw their consent has been revised to 'any time before the creation of an embryo, or the treatment cycle of the recipient commences, whichever is sooner'. • The point at which embryo donors can withdraw their consent has been revised to 'any time before the treatment cycle of the recipient commences'.	Paragraph 5.12.1 Paragraph 6.4.1
Responsibilities of the clinic for stored gametes and embryos	The 2017 ART guidelines clearly outline the responsibilities of clinics for stored gametes and embryos, including safe storage, accurate identification and arrangements for their discard, and in various circumstances e.g. during disputes between parties and after a gamete provider has died.	Chapter 7
Maximum storage period for gametes and embryos	The maximum period of storage specified in the 2007 ART guidelines (five years, with the opportunity to increase the storage period for an additional five years) was seen to be arbitrary and not based on evidence. The 2017 ART guidelines do not include a maximum time period for the continued storage of gametes and embryos, rather it is acknowledged that the suitability of continued storage depends on both personal and clinical considerations and requires clinics to have policies in place to support the clinical decisions.	Paragraph 7.2.1

Fertility preservation	The 2017 ART guidelines address fertility preservation practices including for living persons unable to provide consent, e.g. children and people with impaired decision-making ability. Fertility preservation includes the long-term storage of gametes of gonadal tissue in an attempt to help the individual retain their ability to procreate in the future. Consideration of fertility preservation is not included in the current guidelines. The 2017 guidelines on fertility preservation are applicable regardless of whether an individual has a medical or personal/social reason for choosing to collect and store their gonadal tissue and/or gametes.	Paragraph 8.1 – 8.7
Non-commercial surrogacy	The 2007 ART guidelines preceded state/territory legislation regulating surrogacy and were developed at a time when surrogacy services were only available in the ACT. The 2017 ART guidelines: • Clarify the role and responsibilities of clinics facilitating ART treatment under a surrogacy arrangement. • Detail the information and counselling needs of all parties involved in a surrogacy arrangement. • Require that persons born by a surrogate have access to information about their birth.	Paragraphs 8.9 - 8.12
Commercial surrogacy	• The position that commercial surrogacy is ethically unacceptable is maintained in the 2017 ART guidelines. • The 2007 ART guidelines did not permit clinicians to 'facilitate' commercial surrogacy. To allay concerns that clinicians have been unable to meet their ethical obligations towards their patients, the 2017 guidelines permit clinicians to provide appropriate information to persons who have made an autonomous decision to enter into a commercial surrogacy arrangement overseas. This revision brings the guidance in line with other medical fields in which commercial and/or international arrangements can occur, e.g. organ transplantation. A case study is provided at Appendix 3 to explore this further.	Paragraph 8.8
Sex selection to reduce the risk of transmission of a genetic condition, disease or abnormality	The 2017 ART guidelines provide greater guidance for assessing the ethical acceptability of selecting the sex of a human embryo to reduce the risk of transmission of a genetic condition, disease or abnormality.	Paragraph 8.13

Sex selection for non-medical purposes	• The 2007 ART guidelines stated that *'...the admission to life should not be conditional upon a child being a particular sex. Therefore, pending further community discussion, sex selection (by whatever means) must not be undertaken except to reduce the risk of transmission of a serious genetic condition…'* • 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. • AHEC publically consulted on this issue, using case studies to illustrate the different ethical issues that need to be considered. • In considering the issue of sex selection for non-medical purposes, AHEC was cognisant of a range of relevant factors including: - The regulation and/or availability of sex selection for non-medical purposes internationally. - Whether sex selection for non-medical reasons is a valid use of medical resources. - Values inherent in Australian society that relate to freedom of choice and autonomy, particularly in 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 or a couple's cultural or personal bias, influences or desires. - 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 a 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 raised during public consultation that technology now allows for the termination of a pregnancy on the basis of sex. - The diverse opinions received during public consultation, including personal stories of the	Paragraph 8.14

	psychological impact of 'gender desire' felt by some individuals and families. - The Guiding Principles in Chapter 2. • Whilst it is AHEC's view 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 or a couple's cultural or personal bias, influences or desires, AHEC also acknowledges that the motivations of those seeking to select sex for non-medical reasons cannot be easily identified. AHEC does not endorse, or wish to perpetuate, gender stereotyping or cultural or personal biases based on biological sex, therefore the 2017 ART guidelines do not support the use of sex selection techniques for non-medical purposes. • However, AHEC recognises that many of the issues surrounding ART are as much social and political as they are ethical, and that further public debate is required. AHEC notes that the states and territories have the capacity to legislate regarding ART, including on sex selection for non-medical purposes. It is for these reasons that the ART guidelines encourage the states and territories to enact uniform legislation, and provide for paragraph 8.14 to be ignored if a state or territory were to legislate the practice. That is, a clinic would not risk their accreditation, should the state or territory in which they operate enact legislation that permits the use of sex selection techniques for non-medical purposes. **Note: Victorian and Western Australian legislation currently prohibits sex selection for non-medical purposes. All other jurisdictions are silent on the issue.**	

Preimplantation genetic testing (PGT)	The 2017 ART guidelines: • Address preimplantation genetic screening, in addition to preimplantation genetic diagnosis (PGD), as both techniques are now used in clinical practice. • Update the existing guidance on PGD. • Provide guidance for the assessment of the ethical acceptability of PGT on a case-by-case basis. • Avoid definitive statements about what constitutes a 'serious' genetic condition. Instead, guidance was provided on the relevant considerations when determining whether a genetic condition might severely limit the quality of life of the person who would be born. • Clarify when it is ethically acceptable to use PGT to select an embryo with compatible tissue for a living person.	Paragraphs 8.15 – 8.19
Posthumous use of stored gametes and embryos and the collection and use of gametes from persons who are deceased or dying	The 2017 ART guidelines separate the use of gametes stored before the death of the provider from the collection and subsequent use of gametes from a deceased person. The 2017 ART guidelines also separate the issue of dying persons who are able to give consent from deceased persons and dying persons unable to give consent.	Paragraphs 8.20 – 8.24
Record keeping and data reporting	The ART guidelines cannot mandate the establishment of a central register for ART procedures; however, the 2017 ART guidelines emphasise that the establishment of a central register is the ideal outcome. Donor conception support groups have been particularly vocal about the need to establish a central register.	Chapter 9
Innovative practice, training, quality assurance and research	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. The 2017 ART guidelines clarify what is required of clinics when considering these activities.	Chapter 10