



## Proposed minor administrative amendments to the ART Guidelines

AHEC is making some minor administrative changes to the main body of the *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research*. This summary of proposed changes, available on the National Health and Medical Research Council (NHMRC) website from 9 November 2022 until 19 December 2022, fulfills the notification requirements in accordance with section 9 of the of the National Health and Medical Research Council Regulation 2016.

Table 1. ART Guidelines - anticipated amendments

ART Guideline reference	Anticipated amendment
Abbreviations	Remove PGD. Add PGT-M and PGT-SR. Remove PGS. Add PGT-A.
Explanation of Key Terms	Add 'Mitochondrial Donation':  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.
	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 woman and a man (the prospective mother and father), and mitochondria in an egg donated by another woman (the mitochondrial donor).  See the Mitochondrial Donation Supplementary Section.
	Amend 'National Statement' as the legislation now refers to the National Statement as existing from time to time, rather than a specific (outdated) version of the National Statement.
	Replace words "Preimplantation genetic diagnosis (PGD)" with "Preimplantation genetic testing for single gene (monogenic) disorders (PGT-M)".



ART Guideline reference	Anticipated amendment
	Add 'Preimplantation genetic testing for structural rearrangements (PGT-SR)':
	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. <sup>1</sup>
	See also 'Preimplantation genetic testing for single gene (monogenic) disorders (PGT-M)', 'Preimplantation genetic testing for aneuploidy (PGT-A)', Preimplantation genetic testing (PGT)'.
	Replace words "Preimplantation genetic screening (PGS)" with "Preimplantation genetic testing for aneuploidy (PGT-A)".
	Amending various references to sections of the RIHE and PHCR Acts following enactment of Maeve's law.
Introduction	Update statistic about the number of individuals who gave birth in Australia using some form of ART to do so (change from 1 in 25 in 2012, to 1 in 20 in 2020, according to National Perinatal Data Collection annual update).
	Add description of the Mitochondrial Donation Supplementary Section, including its intended audience.
	Add row to table for 2023 review of the Ethical Guidelines.
Preimplantation genetic testing	Revise terminology in introduction so that the term PGD is replaced with PGT-M and PGT-SR, and PGS is replaced with PGT-A.
	No changes to the ethical guidance in this section (paras 8.15 - 8.19.2).
Research involving human embryos (13.1)	Add footnote to fifth paragraph:
	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.

 $<sup>^{\</sup>rm 1}$  Fertility Society of Australia and New Zealand, Genetic Testing



ART Guideline reference	Anticipated amendment
Appendix 1: A history of NHMRC's involvement in developing ethical guidelines for ART	Add sentence about 2017 update and 2023 mitochondrial donation update.  Add paragraph about the operation of the mitochondrial donation licensing system.
Appendix 4: Process Report	Add several paragraphs about the development of the 2023 Mitochondrial Donation Supplementary Section, including terms of reference and membership of the working committee, and key dates for finalisation of the revised ART Guideline through AHEC and Council.
Various	Amend 'licence' to 'general licence' where appropriate to distinguish from mitochondrial donation licence, following enactment of Maeve's Law.