**NEW ZEALAND’S ASSISTED REPRODUCTIVE TECHNOLOGY REGULATORY FRAMEWORK – ASSOCIATED PAPER 4**

**THE HUMAN ASSISTED REPRODUCTIVE TECHNOLOGY ACT 2004 (HART ACT)**

1. The HART Act is the key law that regulates human assisted reproductive technology and human reproductive research in New Zealand. Important features of the HART Act include:

* Guiding Principles: the health and well-being of children conceived from assisted reproduction; the health, safety and dignity of future generations; health and well-being of women; informed consent; access by donor offspring to information about genetic origins; consideration and respect for the needs, values and beliefs of Māori; and consideration and respect for ethical, spiritual and cultural perspectives in society (s.4).
* Prohibitions against certain actions including commercial supply of gametes and embryos; commercial surrogacy arrangements; sex selection of embryos for social reasons; storing gametes and embryos for longer than 10 years without ethical approval; and the use of hybrid and cloned embryos (Part 2, Subpart 1; Schedule 1).
* Registers to preserve information about gamete and embryo donors, and about people born from donated embryos or donated cells, so donor offspring have the ability to find out about their genetic origins (Part 3).
* Processes and institutional arrangements that allow for a flexible system that is able to make some changes without Parliament’s involvement. The HART Act delegates to ACART responsibility for establishing the requirements for using some procedures. ACART is required to undertake public consultation and consult with the Minister of Health before issuing new guidelines or making significant changes to guidelines (Part 2, Subpart 3).
* Enabling regulations to be made about both specific issues (eg, informed consent, importing and exporting gametes and embryos) and any other matters necessary for giving full effect to the HART Act (s.76).

1. The HART Act is the responsibility of the Minister of Justice. The Ministry of Justice, the Ministry of Health and the Department of Internal Affairs all contribute to the administration of the legislation. The Customs Service also has some functions under the HART Act.

**ART activities that require ethical approval**

1. ACART develops and issues guidelines for activities requiring case by case approval by the Ethics Committee on Assisted Reproductive Technology (ECART) which is a specialist ethics committee. ECART’s functions, membership and relationship with ACART are set out in the HART Act.
2. ACART guidelines fall under three categories: assisted reproductive procedures; extending the storage period of gametes and embryos; and human reproductive research. The activities requiring ECART approval are generally seen to be more ethically complex.
3. ACART has issued or has responsibility for the following guidelines:

***Assisted reproductive procedures***

* Surrogacy involving assisted reproductive procedures
* Embryo donation for reproductive purposes
* Creation and use, for reproductive purposes, of an embryo created from donated eggs in conjunction with donated sperm
* Donation of eggs or sperm between certain family members
* Preimplantation genetic diagnosis with human leucocyte antigen tissue typing (selecting an embryo which is compatible with an existing seriously ill sibling, with view to using donated cord blood or bone marrow from resulting child)
* Storage, use and disposal of sperm from a deceased man (issued before the HART Act and still in force).

***Extending storage of gametes and embryos***

* Extending the storage period of gametes and embryos.

***Human reproductive research***

* Research on gametes and non-viable embryos (issued before the HART Act and still in force).

1. ACART’s guidelines and ECART’s decisions only cover assisted reproductive procedures in New Zealand where they are carried out by a New Zealand fertility services provider.

**THE HUMAN ASSISTED REPRODUCTIVE TECHNOLOGY ORDER 2005 (HART ORDER)**

1. The HART Order sets out procedures that are declared to be “established procedures”. An established procedure does not require ethical approval and is not covered by ACART guidelines.
2. The majority of procedures are established procedures. Established procedures include *in vitro* fertilisation; collection and use of sperm for donation; cryopreservation of eggs; and cryopreservation of embryos.
3. The HART Order also sets out some exceptions where the use of specific procedures is subject to ACART guidelines and ECART approval. Examples are sperm or egg donation between certain family relationships, and the use of cryopreserved ovarian tissue.

**FERTILITY SERVICES STANDARD**

1. The Fertility Services Standard sets out the requirements for the safety and quality of fertility services in New Zealand. Providers are audited and certified against the Standard which is administered by the Ministry of Health. ACART does not have any responsibility for the Standard, though is consulted by the Ministry of Health when reviewing the Standard.

**CODE OF HEALTH AND DISABILITY SERVICES CONSUMERS’ RIGHTS**

1. Patients of fertility services providers are protected by the Code of Health and Disability Services Consumers’ Rights.