

**Report on the Regulatory
Framework Governing
Assisted Reproductive Technologies
in New Zealand
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Executive Summary

This report provides the Advisory Committee (ACART) with an overview of the regulatory context within which assisted reproductive technologies are carried out in New Zealand and how other laws interface with the Human Assisted Reproductive Technology Act 2004 (the HART Act) and the Advisory Committee's functions under the Act.

The report is divided into two parts. Sections 1-4 explain the regulatory framework of the HART Act. Regulation is carried out in three ways: by prohibition of certain ART procedures and research, by an ethical review and policy framework, and through the establishment of an information-keeping regime for donors and donor off-spring.

The ethical review and policy framework is complex, partly due to the separation of the ethics and policy advice functions into two committees. The jurisdiction of the Ethics Committee (ECART) is limited to assisted reproductive procedures and human reproductive research covered by ACART's guidelines or advice. Clarification of the relationship between the Ethics Committee and the Advisory Committee would assist the Advisory Committee in carrying out its functions to ensure that all relevant ART procedures and research are captured by the HART Act.

A potential regulatory gap exists where a new emerging technology is not an established procedure and does not fall within the activities regulated by the HART Act as it is neither prohibited nor a procedure which is covered by the guidelines or advice of the Advisory Committee. The report identifies the steps the Advisory Committee can take in identifying new technologies and providing advice when fulfilling its monitoring role under the Act.

Sections 5-10 provide an overview of the regulatory landscape within which the HART Act operates. There are a number of laws and multiple agencies that are relevant to assisted reproductive procedures and research, some of which overlap with the ethical review framework and functions of the Advisory Committee.

The HART Act has now aligned the regulation of providers of fertility services to the Health and Disability Services (Safety) Act 2001 through professional standards.

Regulation of health and disability research is covered by several pieces of legislation and bodies concerned with its oversight. The ethical review and advice framework in the HART Act operates largely independently of the ethical review system for health and disability ethics committees. The work of the Advisory Committee overlaps with the National Ethics Advisory Committee and there are other bodies which have an input into research policy and advice.

The development of policy on research on human embryos and human embryonic stem cells illustrates the overlap between the HART Act and other legislation. The jurisdictional boundaries between the HART Act and the Human Tissue Act, the Hazardous Substances and New Organisms Act, and the Medicines Act are discussed.

Consumer protection laws and how they impact on the rights of consumers of assisted reproductive technologies are discussed. These laws include: The Health Information Privacy Code, the Code of Health and Disability Consumers' Rights and anti-discriminatory laws in the Human Rights Act and the New Zealand Bill of Rights Act. Some of these laws and codes apply not only to providers, but also to public bodies. The Advisory Committee will need to ensure compliance with anti-discriminatory laws when developing its guidelines and advice.

The family law framework provides a statutory regime for the protection of children born through assisted reproductive procedures. An overview is provided of the Care of Children Act (parenting orders and guardianship), the Status of Children Act (the legal status of children and their biological and social parents) and the Births, Deaths and Marriages Act (the Registrar-General's role). The developments in this area of the law and the Law Commission's recommendations for changes will be important for the Advisory Committee when revising its guidelines.

Introduction

The purpose of this report is to provide the Advisory Committee (ACART) with an overview of the regulatory context within which assisted reproductive technologies (ART) are carried out in New Zealand and how other laws interface with the Human Assisted Reproductive Technology Act 2004 (the HART Act).

The HART Act is a regulatory response to emerging technologies and practices in the field of assisted reproductive technology. For the first time in New Zealand legislation specifically establishes a regulatory framework for the conduct of assisted reproductive procedures and human reproductive research. For the purpose of this report, *regulation* means the legislative mechanisms that operate in this context, such as statutes, regulations and codes of practice. This report is not so concerned with the underlying common law principles and case law that underpin the legislation.

In the first part of the report (Sections 1-4) the regulated activities within the HART Act are analysed to provide a baseline for comparison with other legislation. The HART Act *regulates* in three ways: by prohibition, by a framework for ethical review and policy advice, and through establishing rules of operation for an information-keeping regime for donors and donor off-spring. Each of these kinds of regulation are analysed for the purpose of describing the operation of the HART Act. The focus of this analysis is on understanding the processes involved for ACART to carry out its functions, rather than the content of specific guidelines and issues arising in assisted reproductive technologies.

The regulatory framework of the HART Act is not an exhaustive regime and there are other existing laws which are relevant to the conduct of assisted reproductive procedures and human reproductive research. The second part of the report (Sections 5-10) identifies legislation that is relevant to the regulatory context of assisted reproductive technologies in New Zealand and how these laws overlap with the activities regulated by the HART Act and the role of the Advisory Committee. There are multiple systems and a number of agencies involved. This report is concerned however with the general regulatory environment within which ART operates, much of which existed prior to the enactment of the HART Act. These areas of law and associated legislation are not static and are part of a continuum of review and change. The laws currently under review and the implications for ART will be highlighted. This section is divided into five areas for consideration: providers of fertility services; health and disability research; research on human embryos and human embryonic stem cells; health sector consumer protections; and family law legislation.

Some areas of law are touched upon briefly, and ACART may require a more in-depth analysis for the purpose of preparing its guidelines and advice. This report provides a starting point in identifying the regulatory framework for assisted reproductive technologies.

Acknowledgments

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The Regulatory Framework of the Human Assisted Reproductive Technology Act 2004

1. Scheme of the HART Act

The HART Act has a number of purposes described in Section 3 which includes the general purpose:

- (a) to secure the benefits of assisted reproductive procedures, established procedures, and human reproductive research for individuals and for society in general by taking appropriate measures for the protection and promotion of the health, safety, dignity, and rights of all individuals, but particularly those of women and children, in the use of these procedures and research:

The intention of the Act is to secure the benefits of assisted reproductive technologies not only at an individual level but for society as a whole. Other purposes include prohibition of certain activities, provision of a comprehensive information keeping regime, and “to provide a robust and flexible framework of regulating and guiding the performance of assisted reproductive procedures”¹.

Section 4 sets out the underlying principles to the Act by which “all persons exercising powers or performing functions under this Act must be guided”. These are:

- (a) the health and well-being of children born as a result of the performance of an assisted reproductive procedure or an established procedure should be an important consideration in all decisions about that procedure:
- (b) the human health, safety, and dignity of present and future generations should be preserved and promoted:
- (c) while all persons are affected by assisted reproductive procedures and established procedures, women, more than men, are directly and significantly affected by their application, and the health and well-being of women must be protected in the use of these procedures:
- (d) no assisted reproductive procedure should be performed on an individual and no human reproductive research should be conducted on an individual unless the individual has made an informed choice and given informed consent:
- (e) donor offspring should be made aware of their genetic origins and be able to access information about those origins:
- (f) the needs, values, and beliefs of Maori should be considered and treated with respect:
- (g) the different ethical, spiritual, and cultural perspectives in society should be considered and treated with respect.

¹ Section 3(d) HART Act.

There are potentially a number of competing interests to be taken into account when applying these principles to decision making including: children born from assisted reproductive technologies (ART), women, Maori, and present and future generations. Of note, there is no paramountcy principle that applies to children born from ART, rather the health and well-being of children born as a result of ART should be an important consideration in all decisions about a procedure.

The HART Act has been described as providing a means for the provision of ART within a “flexible protective framework”². The means of achieving this is by regulation operating in different ways. Regulation under the Act falls into three main categories:

1. Prohibited actions (Part 2 Subpart 1);
2. Framework for ethical review and policy advice (Part 2 Subpart 2 and Subpart 3); and
3. Information-keeping regime on donors and donor offspring (Part 3).

These categories of regulation are not exclusive and there are some areas of overlap. For example, performing research or procedures without prior approval from the Ethics Committee in the context of the ethical review framework is a prohibited activity and creates an offence. The Advisory Committee operates within the framework for ethical review and policy advice. In carrying out its advisory function however, it may recommend that certain ART procedures are prohibited and the Committee’s role impacts on other regulation carried out under the Act.

2. Prohibited Actions

2.1 Part 2, Subpart 1

For the first time in New Zealand, certain activities in relation to assisted reproductive technologies are prohibited by law. Part 2 Subpart 1 of the HART Act is concerned with meeting the purposes set out in Section 3(b), (c) and (e) as follows:

- (b) to prohibit unacceptable assisted reproductive procedures and unacceptable human reproductive research;
- (c) to prohibit certain commercial transactions relating to human reproduction;
- (e) to prohibit the performance of assisted reproductive procedures (other than established procedures) or the conduct of human reproductive research without the continuing approval of the ethics committee.

² Choosing genes for future children; regulating pre-implantation genetic diagnosis, Human Genome Research Project, Dunedin 2006, p.334.

The prohibited actions are set out in Schedule 1 and are shown in [Table 1](#).

[Table 1](#) – Prohibited Action (Schedule 1 HART Act 2004)

Prohibited Actions

1. Artificially form, for reproductive purposes, a cloned embryo. For the purposes of this item, a cloned embryo is not formed by splitting, on 1 or more occasions, an embryo that has been formed by the fusion of gametes.
2. Artificially form, for reproductive purposes, a hybrid embryo.
3. Implant into a human being a cloned embryo.
4. Implant into a human being an animal gamete or embryo.
5. Implant into a human being a hybrid embryo.
6. Implant into an animal a human gamete or human embryo.
7. Implant into an animal a hybrid embryo.
8. Implant into a human being a genetically modified gamete, human embryo, or hybrid embryo.
9. Implant into a human being gametes derived from a foetus, or an embryo that has been formed from a gamete or gametes derived from a foetus.

2.2 Offences

An offence is committed if a person takes an action described in Schedule 1. These offences extend to importing into, or exporting from, New Zealand, an in vitro gamete, in vitro embryo, in vitro foetus, or an in vitro being if formed by a prohibited action described in Schedule 1³ and any person who knowingly has possession without reasonable excuse, that gamete, embryo, foetus or being⁴. An “in vitro being” is not defined in the Act and is a curious term although the definition of “in vitro” does include a cell that is outside a living organism.

[Table 2](#) lists the range of offences in relation to prohibited activities.

[Table 2](#) – Offences in relation to prohibited activities

- Taking a prohibited action: Section 8;
- The duty to stop development of in vitro human or hybrid embryos: Section 9;
- Storage of human in vitro embryos and human in vitro gametes for more than ten years (except with permission by the Ethics Committee);
- Restrictions on sex selection of human embryos: Section 11;
- Restriction on obtaining gametes from minors: Section 12;
- Commercial supply of human embryos or human gametes prohibited: Section 13;
- Prohibition of commercial surrogacy arrangements; Section 14;
- Advertising for illegal action: Section 15;

For the first time in New Zealand, offences have been created and substantial penalties can be imposed where procedures or research are carried out without the approval of the Ethics Committee or are subject to a moratorium.

³ Section 8(2) HART Act.

⁴ Section 8(3) HART Act.

Table 3 shows offences in relation to procedures and research.

Table 3 – Offences in relation to procedures and research

- Assisted reproductive procedures and human reproductive research that is performed or conducted without prior approval of the Ethics Committee: Section 16;
- Assisted reproductive procedures and human reproductive research subject to a moratorium: Sections 24 and 26

2.3 Enforcement

The enforcement provisions are set out in Part 4. There are wide ranging powers for search and seizure of gametes, embryos and related equipment which may form part of the prohibited actions and offences. This includes the powers of authorised persons (designated by the Director-General of Health) to detain persons for questioning or arrest under the Act. The Ministry of Health administers and enforces these provisions.

Customs Officers are given authority to detain (not seize) a cloned or hybrid embryo and its container at the border. Various provisions of the Customs and Excise Act 1996 apply in this context⁵. The New Zealand Customs Service has interpreted this requirement to be limited to the detention only of cloned and hybrid embryos and any further steps would be transferred over to the person designated by the Ministry of Health. Realistically, it is difficult to imagine how a Customs Officer would establish a reasonable cause for detention given the potential difficulty of identifying what is a cloned or hybrid embryo. Interestingly, there are no custom controls on the importation of human bodies and body parts including “normal” human embryos⁶.

3. Framework for Ethical Review and Policy Advice

3.1 Definitions

Part 2 Subpart 3 of the Act sets out the ethical review and policy advice framework. The establishment of the Ethics Committee (Ethics Committee or ECART) and the Advisory Committee (Advisory Committee or ACART) with their respective role and functions is set out in this part of the Act.

The definitions of “assisted reproductive procedure” and “human reproductive research” in the preliminary provisions of the Act are important because both procedures and research form the basis of the activities regulated by the Act. These definitions are set out in Section 5:

⁵ Section 73(4) HART Act 2004.

⁶ New Zealand Customs Service, Prohibited Imports: Cloned and Hybrid Embryos GM POL122, 2 November 2005.

“assisted reproductive procedure” or procedure—

- (a) means a procedure performed for the purpose of assisting human reproduction that involves—
 - (i) the creation of an in vitro human embryo; or
 - (ii) the storage, manipulation, or use of an in vitro human gamete or an in vitro human embryo; or
 - (iii) the use of cells derived from an in vitro human embryo; or
 - (iv) the implantation into a human being of human gametes or human embryos; but
- (b) does not include an established procedure.

“human reproductive research” means research that uses or creates a human gamete, a human embryo, or a hybrid embryo.

An established procedure is further defined:

“established procedure” means any procedure, treatment, or application declared to be an established procedure under section 6.

“Procedures” fall into three categories: those which are prohibited (Part 2 Subpart 1); those which are declared an “established procedure” (HART Order 2005); and those which are an “assisted reproductive procedure” and require ethical review (Part 2 Subpart 3).

3.2 Established Procedures

The Advisory Committee may advise the Minister of Health that certain procedures should be declared by Order in Council to be established procedures⁷. In tendering advice to the Minister, the Advisory Committee must provide a report setting out a scientific and ethical analysis of the proposed established procedure including an assessment of the known risks and benefits to health of the procedure or treatment. This risk assessment is concerned with demonstrating that an existing procedure or treatment (and its application) has become an accepted practice within the context of ART and is no longer considered innovative on either scientific or ethical grounds⁸.

The significance of the distinction between what is declared an established procedure and what is not is that those procedures which are established procedures for the purpose of the definition of assisted reproductive procedure do not require the approval of the Ethics Committee under the Act. The Advisory Committee must however continue to monitor the outcomes of an established procedure and it may recommend that an established procedure should be modified or cease being an established procedure⁹.

⁷ Section 6.

⁸ Where a new emerging technology or procedure is identified and there has been no previous advice or Guidelines issued by ACART, see Section 3.4.3 and Table 8 setting out steps ACART can take in identifying a new procedure and providing advice.

⁹ Section 35(1)(b)(iii).

Table 4 is a list of established procedures as set out in Part 1 of the Schedule to the Human Assisted Reproductive Technology Order 2005 (SR 2005/181).

Table 4 – Declared Established Procedures (Section 6 HART Act and HART Order 2005)

- Artificial insemination;
- Assisted hatching;
- Blastocyst culture;
- Collection of eggs for purposes of donation;
- Collection of sperm for purposes of donation;
- Egg cryopreservation;
- Embryo cryopreservation;
- Gamete Intro Fallopian Transfer (GIFT);
- Intracytoplasmic Sperm Injection (ICSI);
- In vitro Fertilisation (IVF);
- Ovarian tissue cryopreservation;
- Pre-implantation Genetic Diagnosis (PGD);
- Sperm cryopreservation.

The Schedule to the Order in Council describes the established procedures in Part 1 but then in Part 2 excludes certain purposes or uses for which each procedure is not an established procedure, thereby describing exceptions to each established procedure.

Table 4 is a summary of these exceptions described in Part 2.

Table 4 – Exceptions to established procedures

- Use of donated eggs or donated sperm that have been donated from someone other than a family member (Part 2(1), (2)).
- Use of ovarian tissue or eggs that have previously undergone cryopreservation (Part 2(3)).
- The collection of immature eggs or the use of eggs that have been matured by in vitro maturation (Part 2(4)).
- Use of sperm from a deceased person without prior consent to use of sperm before person's death (Part 2(4)).
- Use of pre-implantation genetic diagnosis for purposes other than the prevention or treatment of a genetic disorder or disease by
 - (a) diagnosis of familial single-gene disorder
 - (b) sex determination
 - (c) diagnosis of familial chromosomal disorders
 - (d) diagnosis of non-familial chromosomal disorders (aneuploidy testing)(Part 2(6))

As an example, donation of eggs from a non-family member or from a sister or cousin is considered an established procedure. If however, the donation is by other family members (not a sister or cousin) it would not be an established procedure. For example, intergenerational donation from a niece to an aunt falls in this latter category.

If an exception applies, the procedure then falls into the residual category of an “assisted reproductive procedure” and will require an application for approval

before the Ethics Committee. The interpretation of the procedures declared as established procedures and whether any given procedure used for a particular purpose falls within the exception provisions in the Order of Council will require clarification and advice from the Advisory Committee.

3.3 Ethics Committee

3.3.1 Status

Part 2 Subpart 2 of the Act sets out the framework for ethical review of procedures and research by establishing the Ethics Committee (ECART or Ethics Committee), a committee designated by the Minister of Health under Section 27 of the HART Act. This Minister must ensure that the Ethics Committee complies in its composition with “any applicable standard governing ethics committees as determined by the national advisory committee appointed under Section 16(1) of the New Zealand Public Health and Disability Act 2000¹⁰. This, in effect, refers to the Operational Standard for Ethics Committees (Operational Standard). The recent revision of the Operational Standard (April 2006) has removed any reference to the composition of ethics committees as health and disability committees are now appointed by the Minister of Health. Therefore, this requirement in the HART Act has no application save that the committee must have one or more members with expertise in assisted reproductive procedures and research¹¹.

An additional general requirement is that ECART is “subject to applicable ethical standards” namely, the Operational Standard for Ethics Committees¹². The terms of reference for ECART state that only parts 1-4 of the Operational Standard apply, and, on any point of conflict, the guidelines issued by ACART will have precedence over the Operational Standard. The relevant part of the Operational Standard is confined to the general ambit of ethical review and applicable principles. It has been suggested that the terms of reference for ECART is ultra vires (beyond its powers) as they permit decision making on the basis of a two thirds majority, contrary to the Operational Standard which requires consensus decision making and its terms of reference are silent on review and appeal rights¹³. ECART is not subject to the administrative procedures in the Operational Standard and the revised Operational Standard (2006) no longer requires consensus decision making by ethics committees. There are however, no rights of review or appeal by researchers against ECART’s decisions which apply to health and disability ethics committees and are set out in the Operational Standard¹⁴. This apparent contradiction between ECART’s terms of reference and its designation as an ethics committee subject to the ethical standards under the HART Act will require clarification.

¹⁰ This is the National Advisory Committee on Health and Disability Support Services Ethics (NEAC).

¹¹ Section 27(3)(b) HART Act.

¹² Section 27(4) HART Act.

¹³ Choosing genes for future children; regulating pre-implantation genetic diagnosis, Human Genome Research Project, Dunedin 2006, page 262.

¹⁴ The Ministry of Health has indicated that the issue of appeal rights was raised with the Select Committee at the time of the passing of the HART Act and is yet to be addressed, personal communication.

The degree of alignment of ECART's terms of reference with the Operational Standard may have policy implications as to whether there should be consistency between the operation of ECART and health and disability ethics committees generally. The relationship between the Ethics Committee and Advisory Committee and the extent to which the Ethics Committee is accountable to the Advisory Committee is an important issue. Duties imposed on the Ethics Committee include operating expeditiously and in accordance with the guidelines of the Advisory Committee¹⁵ and all approvals and the relevant proposal must be forwarded to the Advisory Committee¹⁶. The Ethics Committee's annual report to the Minister of Health is, among other things, required to report any areas of review that caused difficulty for ECART in making a decision on any particular protocols and any questions on policy or other matters ECART referred to ACART for comment or guidance¹⁷.

3.3.2 *Role and Function*

The primary function of ECART is to consider and determine applications for approvals for the performance of assisted reproductive procedures (procedures) or the conduct of human reproductive research (research) and to keep under review any approvals previously given¹⁸. A distinctive feature of the Ethics Committee is the limits placed on its jurisdiction and decision making capacity. In carrying out its functions the Ethics Committee must operate in accordance with any guidelines or advice issued by the Advisory Committee. Where the kind of activity is not covered in guidelines or the proposed activity is inconsistent with relevant guidelines or advice, the Ethics Committee must decline the application and refer it to the Advisory Committee¹⁹. Specifically, the Ethics Committee's power to approve procedures or research is limited under Section 19(2):

- (2) The ethics committee may not give an approval unless it is satisfied that the activity proposed to be undertaken under the approval is consistent with relevant guidelines or relevant advice issued or given by the advisory committee.

A potential gap exists in the regulation of a new procedure or research where the procedure or research is neither an established procedure nor a prohibited activity, and, is not an activity which falls within the guidelines or advice issued by ACART, (the only basis upon which ECART can consider applications for approval). In this situation, ECART must decline an application for approval as it does not fall within existing guidelines and refer the matter to ACART: Section 18(2). This requirement is reinforced in Section 19(2).

This limitation on what ECART can consider for approval could discourage providers from submitting new procedures or research for ethical review where no guideline or advice that contemplates the procedure or research exists. This could include an existing procedure which has a guideline applicable to it but the

¹⁵ Section 29 HART Act.

¹⁶ Section 30 HART Act.

¹⁷ ECART, Terms of Reference, reporting requirements.

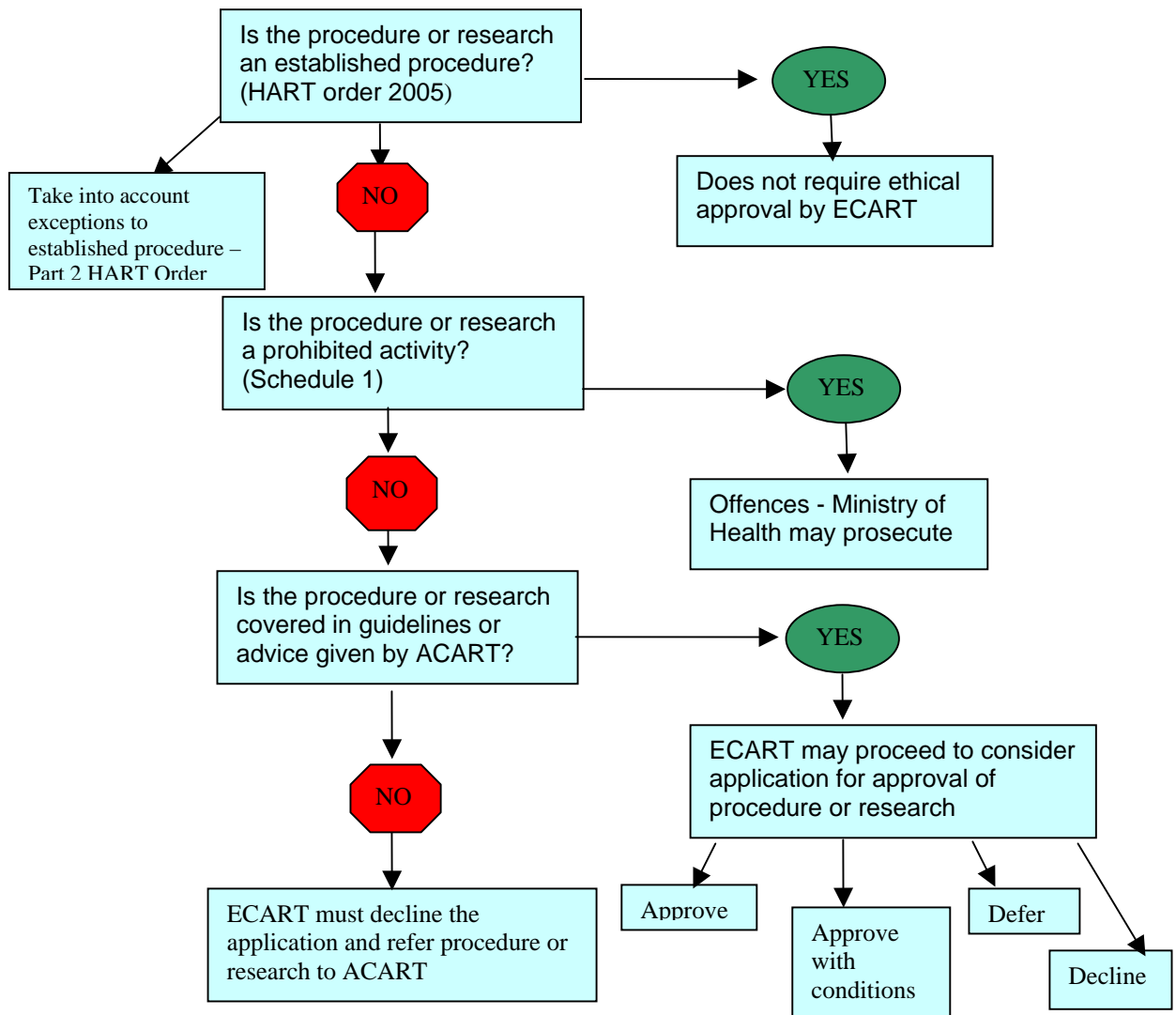
¹⁸ Section 28(a), (b) HART Act.

¹⁹ Section 18(2), 19(2) HART Act.

provider or researcher proposes a substantial variation to the procedure which would require an amendment to the guidelines by ACART.

Figure 1 sets out the process ECART follows in determining whether it can consider an application for approval of a procedure or research.

Figure 1 – Process for ECART in determining approvals for procedures or research



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To date, the Ethics Committee has considered the procedures shown in Table 5:

Table 5 - Procedures considered by ECART to date

Procedures subject to Guidelines:

- IVF Surrogacy
- Within family gamete donation

Procedures that could not be considered because no guidelines and not established procedures in the HART Order:

- In vitro maturation of oocytes

- Use of ovarian tissue
These procedures were forwarded to the Advisory Committee: section 18(2)

The definition of “human reproductive research” has been interpreted narrowly by the Ethics Committee. Two research applications have been received by ECART. On the basis that both research proposals were clinical trials and had a focus on human participants, rather than the use or creation of gametes or embryos *in vitro*, ECART considered these proposals needed ethical approval from a health and disability ethics committee. The researcher was told the applications would have to be submitted to the relevant health and disability ethics committee as ECART considered they did not fall within the definition of “human reproductive research”²⁰. Applying this interpretation *human* reproductive research is a misnomer as the definition has been interpreted to be restricted to the use or creation of gametes and not research with gametes and embryos on humans. To exclude this kind of research is contrary to the purpose of the Act which includes providing a “robust and flexible framework for regulating and guiding... the conduct of human reproductive research”²¹. Both the Ethics Committee and the Advisory Committee have an interest in the outcome of such research, involving the manipulation of embryos and their use on human participants yet it appears the Ethics Committee did not seek advice from the Advisory Committee on this jurisdictional issue.

ECART also has a monitoring role and is required to keep under review any approvals previously given, including approvals prior to the existence of ECART, and, “without limitation, to monitor the progress of any assisted reproductive procedures performed or any human reproductive research conducted under current approvals”²². This general monitoring role overlaps with the Advisory Committee in keeping a watching brief over the progress of ART procedures and research.

3.4 Advisory Committee

3.4.1 Role and Function

The Advisory Committee on Assisted Reproductive Procedures and Human Reproductive Research (ACART or Advisory Committee) is established, appointed and its functions are set out within Part 2 Subpart 3. ACART is an advisory committee to the Minister of Health and its composition and appointment of members is provided for in the HART Act. Subject to directions of the Minister, it may regulate its own procedures. A member of the Ethics Committee may attend the meeting of the Advisory Committee in an *ex officio* capacity (and vice versa) and this encourages a working relationship between the two committees²³.

²⁰ ECART minutes 28 November 2005. Applications E05/08; randomised trial to assess the efficacy of assisted hatching on cryopreserved-thawed embryos and E05/09:Antioxidants for infertility clinical trial. It is not clear why assisted hatching on cryopreserved – thawed embryos that were created *in vitro* are not “use of embryos” for the purpose of the definition even if the research participants are “human”. A possible difficulty is the required certification by an ethics committee for ACC indemnity as ECART is not an approved ethics committee for this purpose.

²¹ Section 30(d) HART Act.

²² Section 28(1)(b) HART Act.

²³ Section 33 HART Act.

There are extensive consultation and reporting requirements to ensure that information about the Advisory Committee is available to the public. The Committee must submit its annual report to the Minister of Health after which the Minister must present the report to the House of Representatives²⁴.

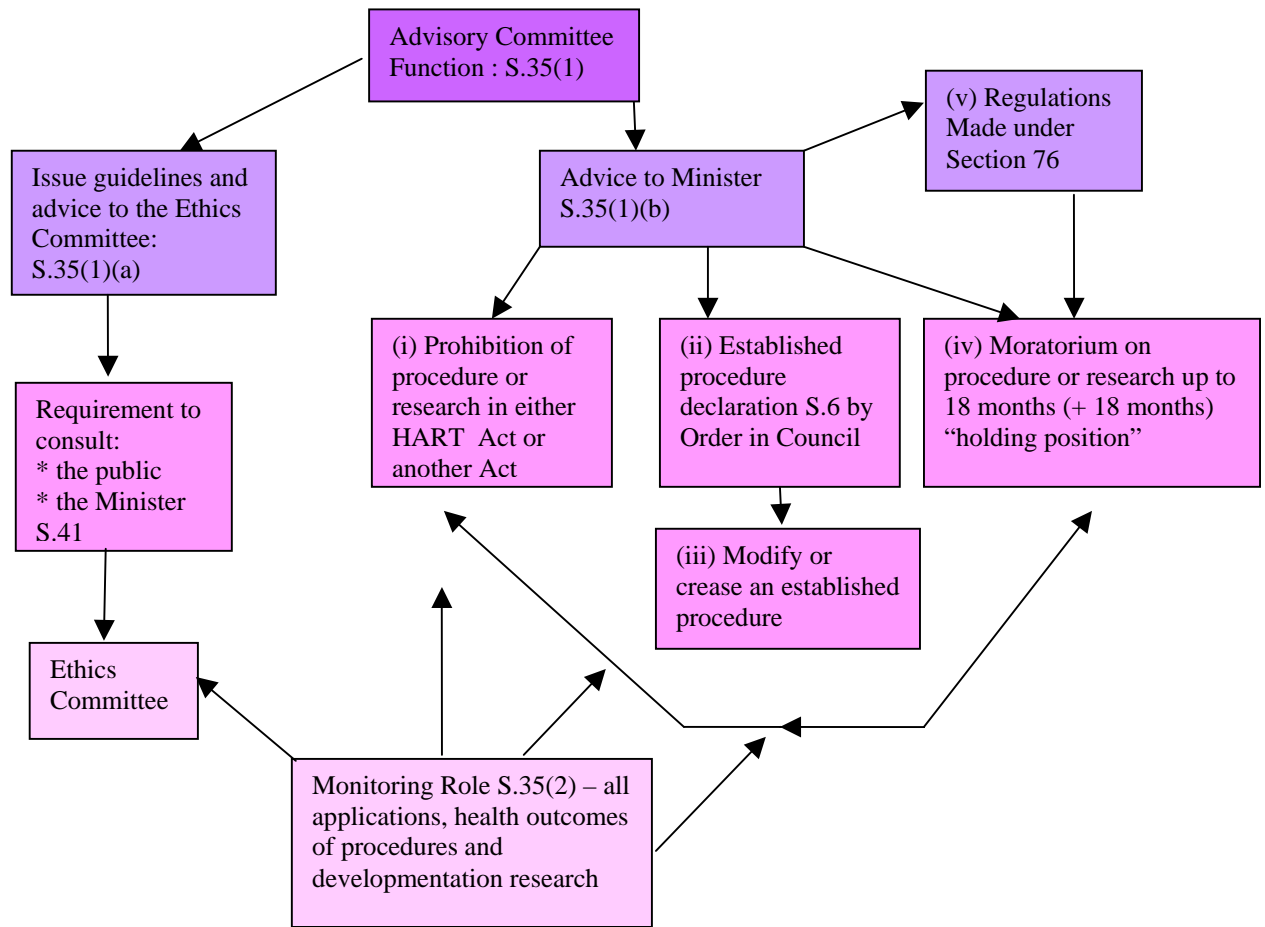
ACART is not subject to the Operational Standard and is not an ethics committee. Its decision making is concerned with the direction of policy and advice to the Minister of Health on a range of aspects of ART and the issue of guidelines to the Ethics Committee. The functions of ACART as set out in Section 35(1)(a) and (b) are concerned with its regulatory role. The functions of ACART include:

- to issue guidelines and advice to the Ethics Committee Section 35(1)(a); and
- to provide the Minister with advice on the regulatory issues of procedures or research, e.g. further prohibition, declaration of an established procedure; or modification, whether a moratorium should be imposed and whether regulations of the performance of any kind of procedure or research should be made²⁵.

²⁴ Section 42(3), (4) HART Act.

²⁵ Section 35(1)(b)(i)-(v) HART Act.

Figure 2 – Advisory Committee Functions



3.4.2 Guidelines

The Transitional Provisions in the Act provide for a three year period (the interim period) whereby, documents mainly the guidelines previously developed by the National Ethics Committee on Assisted Human Reproduction (NECAHR), may be gazetted by the Minister. The Ethics Committee is required to treat these as interim guidelines issued by the Advisory Committee. The guidelines must be reviewed or new guidelines issued by the Advisory Committee before the end of the interim period, 21 November 2007.

Table 6 – List of interim guidelines approved by the Minister of Health.

Table 6

- Guidelines for the storage, use and disposal of sperm from a deceased man;
- Guidelines on pre-implantation genetic diagnosis;
- Guidelines on IVF surrogacy;
- Guidelines of within-family gamete donation;
- Guidelines on embryo donation for reproductive purposes;
- Guidelines for search on gametes and non-viable embryos.

ACART may only issue guidelines to ECART after it has given interested parties and members of the public a reasonable opportunity to make submissions on the proposed guidelines and takes those submissions into account. It must also provide the Minister of Health with the proposed guidelines who, in turn must present them to the House of Representatives²⁶. The guidelines are enforceable through the operation of ECART ethically reviewing any application for approval subject to the guidelines.

If ACART seeks to make a minor change to existing guidelines, it will be a matter of discretion as to whether such changes are sufficiently significant to require the consultation process. It would be reasonable to expect that ACART would consult with interested parties (Section 41). Strictly speaking, changes to the guidelines are not “advice” but an assessment as to whether any proposed change is of significant public interest under Section 39(1)(b) may be warranted²⁷.

3.4.3 Advice

The Advisory Committee’s function of providing advice arises in two different situations. First, ACART is required to issue both guidelines and advice to the ECART²⁸. This could include clarification of existing guidelines where there may be more than one interpretation or advice to ECART as to whether a research proposal or procedure falls within the jurisdiction of the HART Act²⁹.

Second, ACART is required to provide advice to the Minister on wide ranging regulatory aspects of procedures and research under Section 35(1)(b) and specific advice to the Minister within an agreed timeframe under Sections 37 and 38.

Table 7 is a list of specific advice the Advisory Committee must provide to the Minister of Health and its current status:

Table 7: Human Reproductive Research, Section 37(1):

- (1) The advisory committee must, within time frames agreed with the Minister, provide the Minister with information, advice, and, if it thinks fit, recommendations on the following matters in relation to the use of gametes and embryos in human reproductive research:
 - (a) cloned embryos:
 - (b) donations of human embryos:
 - (c) genetic modification of human gametes and human embryos:
 - (d) human gametes derived from fetuses or deceased persons:
 - (e) hybrid embryos:
 - (f) requirements for informed consent:
 - (g) the import into, or export from, New Zealand of in vitro human gametes or in vitro human embryos.”

²⁶ Sections 41 and 42 HART Act.

²⁷ See discussion below paragraph 3.4.3 on the requirement of ACART to consult when giving advice.

²⁸ Section 35(1)(a) HART Act.

²⁹ Such as the research application example described in Section 3.3.2.

Current status: ACART is preparing a discussion document on embryo and gamete research (October 2006): Section 37(a)-(f). Section 37(g) will be addressed in document on Clinical Uses of ART.

Human assisted reproductive technology: Section 38:

38. Advisory committee to provide specific advice in respect of human assisted reproductive technology—

The advisory committee must, within time frames agreed with the Minister, provide the Minister with information, advice, and, if it thinks fit, recommendations on the following matters in relation to human assisted reproductive technology:

- (a) donations of embryos:
- (b) embryo splitting:
- (c) gametes derived from deceased persons:
- (d) requirements for informed consent:
- (e) selection of embryos using pre-implantation genetic analysis:
- (f) the import into, or export from, New Zealand of in vitro donated cells or in vitro donated embryos.”

Current status: ACART will publicly consult on discussion document, Clinical Uses of ART, early 2007: Section 38(a)-(f) and Section 37(1)(g).

If the Advisory Committee gives advice under Sections 37 and 38 (shown in Table 7 above) or significant advice, namely advice of “significant public interest but is not required on a matter of urgency” (Section 39(1)(b)), then it must follow procedural requirements such as, calling for, and considering submissions, and consulting on the proposed advice.

A “matter of urgency” is not defined in the Act although where the advice involves an addition to the list of established procedures, it is not considered a “matter of urgency”³⁰. The negative effect of Section 39 is to create another category of advice, this, is *urgent significant advice*.

An example of where urgent significant advice has previously been sought was when the National Ethics Committee on Assisted Human Reproduction (NECAHR) considered a request from a fertility provider for the cryopreservation of eggs and ovarian tissue of a minor about to undergo cancer treatment. This kind of advice had to be dealt with expeditiously and within a short timeframe.

There is no express requirement to consult with the Minister on *urgent significant advice*³¹. The requirement to consult is only in relation to non-urgent advice to the Minister (Sections 35(1)(b), 37 and 38) and for the issue of guidelines to the Ethics Committee (Section 35(1)(a)). The Advisory Committee has however, a discretion in this situation to consult with appropriate persons. In a short timeframe consultation could be limited to the clinic seeking the advice and relevant experts.

The Advisory Committee has an oversight role and must monitor the application, and health outcomes, of assisted reproductive procedures and established

³⁰ Section 39(3) HART Act.

³¹ Section 41 HART Act.

procedures together with the developments in human reproductive research³². This monitoring role is important because not only does it allow the Advisory Committee to monitor changes to existing procedures and research but it also allows it to be proactive in identifying emerging technologies where it has not previously given advice. Thus, the regulatory gap referred to above can be remedied to some extent by the Advisory Committee undertaking its monitoring role and identifying emerging technologies and developments in research and giving advice on them. The Ethics Committee may give an approval consistent with relevant guidelines but also “relevant advice given or issued by the Advisory Committee”³³. “Relevant advice” could include clarification of existing guidelines or advice on matters of urgency.

Table 8 sets out the procedural steps the Advisory Committee can take in identifying a new procedure or research and providing advice.

Table 8

ACART identifies emerging procedure or research not previously considered in guidelines or advice.

1. ACART must monitor the application and health outcomes of procedures and developments in research; (Section 35(2))
2. Advice and recommendation to Minister may fall into one of three categories:
 - (a) Specific advice regarding the use of gametes and embryos in human reproductive research; (Section 37)
 - (b) Specific advice regarding those matters listed in relation to human assisted reproductive technology; (Section 38)
 - (c) Significant advice, that is, of significant public interest but is not required as a matter of urgency and is not covered in the advice provided for in Sections 37 and 38; (Section 39(1)(b))
There are no particular requirements as to the extent of scientific and ethical assessment that might be carried out when ACART provides advice on a newly identified technology under these provisions. ACART could carry out a similar kind of risk assessment as required for established procedures set out in Section 6.
 - (d) Urgent significant advice. Advice is of significant public interest but is required as a matter of urgency.
3. Categories (a), (b) and (c). ACART is required to:
 - i. Issue a discussion paper and have an opportunity for submissions. (Section 39(2)(a)).
 - ii. The submissions are to be taken into account; (Section 39(2)(b))
 - iii. Hold public meetings (if criteria for holding a public meeting is met) on proposed advice. (Section 40)
 - iv. A requirement to consult the public and the Minister of Health. (Section 41)
4. If category (d), urgent significant advice, then neither Section 39 nor the requirements of a public meeting apply. Consultation may be limited to appropriate persons within the short timeframe and need not include the Minister.

Where urgent significant advice is required, it would be reasonable to expect the Advisory Committee at a later stage to revisit any interim advice given under urgent circumstances and to apply the procedural steps set out in Step 3 above. There are no particular requirements as to the extent of scientific and ethical assessment that might be carried out when ACART provides advice on a newly

³² Section 35(2) HART Act.

³³ Section 19(2) HART Act.

identified technology under these provisions. ACART could carry out a similar kind of risk assessment as required for established procedures in Section 6.

If there is an issue of allowing time for the development of advice or guidelines, or both, the Minister, on the advice of the Advisory Committee may recommend that the research or procedure be subject to a moratorium for a period of 18 months with a possible extension of another 18 months) but the Advisory Committee must provide advice to the Minister within agreed timeframes³⁴. No moratorium has been imposed to date under these provisions.

4. Information-keeping Regime on Donors and Donor Offspring

4.1 Rules of Operation

Part 3 of the Act is concerned with an information sharing regime of donors and donor offspring³⁵. The stated purpose of the information-keeping regime is set out in Section 3:

3. (f) To establish a comprehensive information-keeping regime to ensure that people born from donated embryos or donated cells can find out about their genetic origins.

Certain information-keeping duties are placed on both providers and the Registrar-General³⁶. Fees are payable for certain actions taken by the Registrar-General as set out in the Schedule to the Human Assisted Reproductive Technology (Fees) Regulations 2005. Providers must give advice to prospective donors and guardians about the information-keeping regime. Where a donor donates an embryo or cell through a provider, the donor's information must be accepted and kept by the provider. Where the birth of living donor offspring results, the provider must give the information about the donor to the Registrar-General at the earliest date of either 50 years after the date of birth, or the provider ceases to provide services where there is no successor provider. The Registrar-General then must keep the information indefinitely. Access to information about donors is restricted to those persons authorised by the Act and where a medical practitioner requests medical information for the medical treatment or advice of the person³⁷. Providers must also notify the Registrar-General about the birth of donor offspring and have systems in place to do so promptly.

³⁴ Section 24 HART Act.

³⁵ Both "donors" and "donor offspring" are defined in Section 5 HART Act.

³⁶ The Registrar-General is the person appointed under Section 79(1) of the Births, Deaths and Marriages Registration Act 1995.

³⁷ Section 51(c).

Both donors and donor offspring have access to information about donors and donor offspring kept by providers and the Registrar-General. The donor offspring must be 18 years of age, unless an order is obtained from the Family Court where the donor offspring is 16 or 17 years of age, for the access provision to apply³⁸. Access by donor offspring to information about siblings (offspring from the same donor) is provided for on condition of consent from the other offspring (or their guardian if under 18 years). Donor offspring may consent to disclosure of identifying information to a donor but access by donors to such information either held by providers or the Registrar-General may be withheld if they are satisfied, on reasonable grounds, that to do so is likely to endanger any person³⁹.

The information-keeping regime does not apply retrospectively but a parallel regime is established with a voluntary register maintained by the Registrar for any donor or donor offspring formed prior to the commencement of the Act.

4.2 Application of the Privacy Act 1993

Access to the complaint procedures of the Privacy Commissioner is specifically referred to in Section 66 of the Act. If a person is dissatisfied with any decision, action, or failure to act by a provider or the Registrar-General in relation to requests and access to information under the HART Act they may make a complaint and the same timeframes apply as under the Privacy Act for decisions on requests (20 working days unless extension to time limit). The complaint procedure, proceedings by the Privacy Commissioner and the ability of the Privacy Commissioner to consult with other agencies, for example, the Health and Disability Commissioner for the purposes of carrying out an investigation, will apply to any privacy complaint made in respect of a provider or the Registrar-General in the HART Act.

The privacy of individuals and clear procedures for the access to, and the disclosure of, information are integral to the operation of the information-keeping regime in the HART Act. These rules of operation are consistent with the privacy principles and expressly recognise the complaints procedure in the Privacy Act⁴⁰.

Legislation Relevant to Assisted Reproductive Technologies in New Zealand

5. Introduction

The following sections look beyond the HART Act to provide an overall picture of

³⁸ Section 65.

³⁹ Sections 60 and 61.

⁴⁰ See paragraph 9.1.1 below.

the regulatory environment in which ART is carried out and the interface between other legislation relevant to ART and the operation of the HART Act. There are five areas for consideration:

1. Providers of Fertility Services;
2. Health and Disability Research;
3. Research on Embryos and Human Embryonic Stem Cells;
4. Health Sector Consumer Protection Laws;
5. Family Law Legislation;

In New Zealand there is a range of legislation that applies generally to regulating activities, including the provision of fertility services, carried out in the health system. Providers of fertility services are subject not only to professional oversight but also legal obligations that apply to those working in the field of health and disability research.

There are a number of statutory bodies and ministerial committees, which together, form the basis of the ethical review framework and determine rules for operation of ethics committees. The development of policy applicable to research on embryos and human embryonic stem cells will be discussed to illustrate the interface between the HART Act and other legislation relevant to this emerging technology.

The legal framework is based around protecting the rights of consumers and providing avenues for complaint procedures. Consideration will be given also to the extent to which the advisory and ethics committees are subject to scrutiny by the consumer protection laws. The family law framework is an important part of the overall picture. Whereas the HART Act is concerned with assisted conception, the family law framework provides a protective regime for children born from ART and acknowledges the status of their biological and social parents.

6. Providers of Fertility Services

6.1 Professional Standards for Fertility Service Providers

Professional oversight of fertility service providers in New Zealand is an accreditation system carried out by the Reproductive Technology Accreditation Committee (RTAC). RTAC is the accreditation body of the Fertility Society of Australia. The HART Act is not concerned with professional oversight of providers but deems fertility services to be included in the definition of “specified health or disability services” in Section 4(1) of the Health and Disability Services (Safety) Act 2001 (HDS(S) Act)⁴¹. The purpose of the HDS(S) Act is to promote the safe provision of health and disability services and to establish standards for providers of health and disability services⁴².

The transitional provisions in the HART Act allow time for a New Zealand Fertility Standard to be developed and providers to comply with those standards (as provided for in the HDS(S) Act)⁴³. Standards New Zealand is in the process of working with the sector and consumer groups to develop the Standard⁴⁴. The Standard focuses on the safety and quality of fertility services (and promotes ongoing quality assurance by fertility clinics), and sets out the minimum requirements clinics must meet in order to gain certification under the HDS(S) Act. The Standard will refer to and be consistent with legislative and other requirements (for example, ethical guidelines) covering fertility services. Once the Standard is approved by the Ministry of Health, affected providers will be given a reasonable time to comply with the Standards, that is, no earlier than 12 months. It will apply to all fertility service providers in public and private settings and once finalised will be gazetted. Fertility service providers will need to be certified against this Standard.

During the interim period, the provision of fertility services by a person is deemed to comply with the HDS(S) Act if:

1. The Director-General has approved any organisation (RTAC) to act as the auditing agency to accredit a person for the purposes of the interim period; and
2. If the person who provides those services has:
 - been the subject of an audit report completed, for the purposes of the person’s accreditation, by an organisation approved to act as an auditing agency (RTAC) by the Director-General; and
 - given the Director-General a copy of that audit report; and
 - complies with any standards approved by the Director-General under section 82 (during the interim period, the Director-

⁴¹ Section 80 HART Act.

⁴² Section 3 Health and Disability Services (Safety) Act 2001.

⁴³ Section 81 HART Act.

⁴⁴ NZS 8181 Fertility Services Standard and Audit Workbook (currently a draft as at 14 June 2006).

General may, by written notice describing by name the standards concerned, approve standards for providing fertility services).

The Director-General of Health certified RTAC as an audit agency on 8 November 2004. All six fertility service providers in New Zealand are currently accredited by RTAC, and are thus deemed to be in compliance with the Health and Disability Services (Safety) Act.

Providers are audited at least once every three years. The providers meet any additional compliance costs arising from the audit. Providers who fail to comply with approved Standards can have a cessation or closing order imposed on them by the Director-General of Health.

6.2 Other Laws Affecting Providers

The general regulatory environment for health and disability service research and consumer protection laws that apply to providers are discussed in Sections 7 and 9. Below is a brief mention of other laws that affect the liability of providers:

- *Health Practitioners Competence Assurance Act 2003*

This Act establishes the Health Practitioners Disciplinary Tribunal and provides a framework for professional disciplinary proceedings against health professionals where there has been professional misconduct.

- *Criminal Liability*

The Crimes Act 1961 contains a number of serious offences which could apply to providers, such as assault, criminal nuisance and medical manslaughter. It imposes legal duties tending to the preservation of life, which, if breached, could result in the criminal liability of providers. They include a legal duty on everyone who undertakes (except in the case of necessity), to administer surgical or medical treatment to have and to use reasonable knowledge, skill and care in doing any such act⁴⁵. There is also a duty on persons doing dangerous acts, or in charge of dangerous things which could include viruses and other dangerous organisms⁴⁶. An important qualification to these duties was made in a 1997 amendment to the Crimes Act. Liability for criminal negligence in this context applies “only if, in the circumstances of the particular case the omission or neglect is a major departure from the standard of care expected of a reasonable person to whom that legal duty applies in those circumstances”⁴⁷.

The Police are the prosecuting authority under the Crimes Act whereas the prohibited activities in the HART Act are prosecuted by the Ministry of

⁴⁵ Section 155 Crimes Act 1961.

⁴⁶ Section 156 Crimes Act 1961.

⁴⁷ Section 150A Crimes Act 1961.

Health. Criminal sanctions are also imposed in other health law legislation, for example, trading in blood and “controlled human substances” is a criminal offence punishable with 6 months imprisonment or a fine not exceeding \$5,000.00⁴⁸.

- *Injury Prevention, Rehabilitation and Compensation Act 2001*

Personal injury law and the accident compensation scheme (ACC) is covered by the Injury Prevention, Rehabilitation and Compensation Act 2001 (IPRC Act). Where personal injury occurs for which there is cover under the IPRC Act there is a statutory bar to Court proceedings for damages arising directly or indirectly from personal injury. There is, however, a limited ability to sue for exemplary (punitive) damages. “Treatment injury” now replaces the medical misadventure provisions that apply to health professionals and is consistent with the overall non-fault approach of the ACC Scheme. In certain circumstances, the treatment injury provisions in the IPRC Act will provide ACC cover and possibly compensation, to participants harmed in a clinical trial. For ACC cover to apply, it must be shown that the injured participant did not agree in writing to participate in the trial or an ethics committee certified that it was satisfied that the trial was *not* to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being studied⁴⁹. For a clinical trial to be covered by this provision, the ethics committee must be accredited by the Director-General of Health or the Health Research Council. As noted above, ECART is not accredited for these purposes and therefore is limited in the type of research it can consider⁵⁰.

- *Common Law Claims*

Claims in negligence against a provider for wrongful birth or wrongful life are a possibility but are limited by the IPRC Act. Such actions are excluded if the cause of action involves personal injury caused by a treatment injury. Other civil claims could include an action for breach of contract against a provider, or breach of a statutory duty enforced by a Government agency⁵¹.

7. Health and Disability Research

Regulation of health and disability research generally is carried out through the operation of the ethical review framework in New Zealand. This section considers the statutory instruments that create ethics committees and the ethical standards

⁴⁸ Section 92B Health Act 1956.

⁴⁹ Section 32 IPRC Act 2001.

⁵⁰ *Ibid*, fn 20.

⁵¹ For a fuller discussion on liability of providers carrying out research see *The Law of Research A Guide*, edited by J Dawson and N Peart, 2003, chapter 17, *Liability for Misconduct in Research*.

that apply. There are also international codes and ethical guidelines that provide an international framework on which New Zealand ethical standards are based⁵².

7.1 New Zealand Public Health and Disability Act 2000

Section 16 of the New Zealand Public Health and Disability Act 2000 (NZPHD Act) provides for the establishment of the National Advisory Committee on Health and Disability Support Services Ethics (NEAC). NEAC is a ministerial advisory committee and is accountable to the Minister of Health. Its statutory functions are to:

1. provide advice to the Minister of Health on ethical issues of national significance in respect of the health and disability matters (including research and health services); and
2. determine nationally consistent ethical standards across the health and disability sector and provide scrutiny for national health research and health services.

NEAC has an oversight role of the ethical framework for ethics committees. This role includes “to monitor and review the operation of health and disability ethics committees for the purposes of providing direction, guidance and leadership to ensure the ongoing quality and consistency of ethical review in the health and disability sector⁵³. NEAC’s work programme to date has included a review of the system of ethical review in New Zealand, developing ethical guidelines for observational studies, a project on the ethics of intervention studies and innovative practice. NEAC is also developing a governance framework for health and disability research ethics. This project will clarify responsibilities in the ethical conduct of research and related activity. The ethical framework under the HART Act and its overlap with ethical review of health and disability ethics will be relevant to this project.

The development of the Operational Standard for Ethics Committees forms part of NEAC’s statutory function in determining nationally consistent ethical standards.

NEAC’s terms of reference provide for the establishment of a sub-committee on appeals (the SCA)⁵⁴. Whereas the main statutory function of NEAC is to advise the Minister of Health on ethical issues of national significance regarding health and disability, the functions of its sub-committee on appeals is to review particular proposals appealed by researchers. The SCA is responsible for hearing appeals from decisions of the health and disability ethics committees and the multi-region ethics committee established under Section 11 of the New Zealand Public Health and Disability Act 2000. The SCA may only hear appeals in cases where a second opinion from the Health Research Council Ethics Committee has been

⁵² For example, the Declaration of Helsinki, World Medical Association, 1962 (revised 2002).

⁵³ NEAC Terms of Reference.

⁵⁴ This Sub-Committee has not been convened to date.

sought by either the original ethics committee or the researcher and such appeals are heard by way of re-hearing, focusing on specific alleged errors of judgment or reasoning in the original decision. No appeal against an ethics committee's decision has been heard to date. ECART is not subject to this appeal procedure⁵⁵. The Ministry of Health is separately considering an appeals process in relation to ECART decisions⁵⁶.

In comparison, ACART is a committee established by the Minister of Health under Section 32 of the HART Act and is not subject to the oversight provided by NEAC under the NZPHDA Act 2000 or the Operational Standard. Both NEAC and ACART are however, advisory committees to the Minister of Health and therefore their accountability lies with the Minister.

The NZPHD Act also provides for the establishment of the seven health and disability ethics committees (including one multi-region ethics committee) by the Minister of Health⁵⁷. It is important to note that while there is legislative recognition of ethics committees, there is no legislative mechanism that requires researchers to submit their research to a health and disability ethics committee. The requirement to submit proposals for ethical review is derived in a number of ways, including: in order to obtain funding from many sources, ACC certification, professional codes of conduct and for research to be published in peer-reviewed journals.

7.2 Operational Standard for Ethics Committees

The Operational Standard for Ethics Committees April 2006 (Operational Standard) applies to ethics committees that review the ethics of research and innovative practice, and provides advice on issues relating to the delivery of health and disability services. These seven health and disability ethics committees are required to operate in accordance with their terms of reference, which contain requirements around membership, approval, meetings and decisions, as well as stating they must comply with the Operational Standard. The Operational Standard derives its authority from the terms of reference of ethics committees established by the Minister of Health under Section 11 of the NZPHDA Act. If there is any point of conflict, the terms of reference of those ethics committees have precedence over the Operational Standard⁵⁸.

The Operational Standard is designed to:

- i. Protect participants in research and innovative practice and consumers of health and disability services;

⁵⁵ See paragraph 3.3.1 as to the extent ECART is subject to ethical standards determined by NEAC.

⁵⁶ Personal Communication from the Ministry of Health.

⁵⁷ Section 11 New Zealand Public Health and Disability Act 2000. The health and disability ethics committees were previously appointed independently under the Operational Standard but are now appointed under this empowering provision by the Minister of Health.

⁵⁸ Substantial changes were made to the previous Operational Standard (2002), including the provision giving precedence of ethics committees' Terms of Reference over the Operational Standard and the procedural rules for the operation of ethics committees.

- ii. Achieve consistency of ethical review throughout New Zealand;
- iii. Provide researchers and purchasers of research with guidance on the processes for ethical review;
- iv. Promote awareness of the Code of Health and Disability Services Consumers' Rights 1966.
- v. Promote awareness of the Health Information Privacy Code 1994;
- vi. Respect the principles of the Treaty of Waitangi by ensuring Maori ethical practices and standards are included in review.

Health and disability research requiring ethical review is broadly defined to include investigations that involve human participants, whether health and disability service consumers, health volunteers or members of the community at large, and the investigation (among other things) “compares an established procedure, whether therapeutic, non-therapeutic or diagnostic with other procedures that are not recognised as established either by virtue of their recent development, discovery or use in a new unfamiliar way”⁵⁹.

“Innovative practice” is defined as:

An innovative practice involves the provision of a clinical intervention (diagnostic, therapeutic or prophylactic), be it a therapeutic drug, medical device or clinical procedure, that is untested, unproven or not in common use and therefore poses its own unique set of characteristics and issues.

An “assisted reproductive procedure” as defined in the HART Act has been interpreted as an “innovative procedure” for the purpose of explaining the framework of the HART Act to members of the Advisory Committee⁶⁰. It may be confusing to introduce new terminology into the HART Act, however the point is that an “assisted reproductive procedure” is by definition not an established procedure and would fall within the general concept of “innovative practice” in the Operational Standard.

7.3 Health Research Council Ethics Committee

The Health Research Council Ethics Committee (HRC Ethics Committee) was the first statutory human ethics committee established under Section 24 of the Health Research Council Act 1990. Section 25 of the Act sets out the functions of the HRC Ethics Committee. It is primarily concerned with giving ethical advice to the Health Research Council and to ensure that research funded by the HRC has received ethical scrutiny. Under the Operational Standard the HRC Ethics Committee also has the role of accrediting health and disability ethics committees and institutional ethics committee which provide the ethical review framework for health and disability research in New Zealand.

⁵⁹ Operational Standard for Ethics Committees, Chapter 3 – Matters requiring ethical review.

⁶⁰ Innovative Practice under the HART Act 2004, ACART Member’s Handbook, Ministry of Health.

7.4 Toi te Taio : the Bioethics Council

The Bioethics Council is not a regulatory body but has a watching brief on all aspects of biotechnology, including ART and health and disability research. The Council is a ministerial advisory committee with the role of:

1. providing independent advice to Government on biotechnological issues involving significant cultural, ethical and spiritual dimensions.
2. promoting and participating in public dialogue on cultural ethical and spiritual aspects of biotechnology and to enable public participation in the Council's activities.
3. providing information on the cultural, ethical and spiritual aspects of biotechnology⁶¹.

To this end, the Council has a work programme which includes a project on "Human Embryos for Research". This project involves public discussion and has been developed in the knowledge that ACART will be advising the Minister of Health about embryo research. The Council has offered to work in partnership with ACART by raising public awareness and discussion on such issues. As an independent body the Council can explore critical and often controversial issues. It can advise and make recommendations to the Government on issues relevant to ART in New Zealand.

7.5 The Treaty of Waitangi

The Treaty of Waitangi and, in particular, the application of Treaty principles, is relevant to how health and disability is conducted in New Zealand. Although not part of the regulatory regime the emphasis or otherwise on Treaty principles forms part of the policy context in which research is carried out. Generally speaking, health legislation does not enshrine the Treaty of Waitangi but often incorporates the Treaty principles which are usually referred to as those of partnerships, participation and protection.

The HART Act principles require those performing functions under the Act must be guided by principles including:

The needs, values and beliefs of Maori should be considered and treated with respect⁶².

The Advisory Committee has a wide ranging requirement to consult on its proposed advice and guidelines with members of the public and other persons or groups that the Committee considers appropriate⁶³. The composition of the Advisory Committee must include:

⁶¹ Toi te Taio : The Bioethics Council, Terms of Reference, www.bioethics.org.nz.

⁶² Section 4(f) HART Act.

⁶³ Section 41 HART Act.

One or more Maori members with expertise in Maori customary values and practice and the ability to articulate issues from a Maori perspective⁶⁴.

Members of the committee as a whole must comprise people from a range of backgrounds and ethnicities. All members of the Advisory Committee are expected to have an understanding of how the health sector responds to Maori issues and their application to ethical review⁶⁵.

These references to Maori in the HART Act are similar to some secondary legislation or rules such as, for example, the Health and Disability Commissioner Code of Rights. Right 1(3) requires respect for “the needs, values, and beliefs of Maori”. The Operational Standard for Ethics Committees is designed to (among other things) “respect the principles of the Treaty of Waitangi by ensuring ethical practices and standards are included in review”.

There is no general legislation that requires Treaty compliance with health and disability research but Treaty consistency generally is expected of government bodies and agencies that fund or are concerned with research. An example where Treaty principles have been applied in practice is the work of the Environmental Risk Management Authority (ERMA New Zealand). ERMA has established guidelines on working with Maori under the Hazardous Substances and New Organisms Act when seeking approval to import or develop new organisms or hazardous substances. The National Ethics Advisory Committee (NEAC) is also working on the development of a Maori framework for health and disability research ethics.

8. Research on Human Embryos and Human Embryonic Stem Cells

The regulatory system applicable to research on human embryos and human embryonic stem cells (HESC) illustrates the overlap between the HART Act and other legislation relevant to these activities. In New Zealand, research involving human cells is carried out using immortalized human adult or foetal cell lines and is regarded as a non-controversial practice and is not generally subject to ethical approval⁶⁶. Currently, no research with HESCs is occurring in New Zealand although there are a number of researchers working with animal stem cell research.

No therapeutic cloning of human embryos has been carried out in New Zealand. Researchers have indicated that they wish to undertake research using HESCs

⁶⁴ Section 34(4) HART Act.

⁶⁵ Terms of Reference, ACART.

⁶⁶ Francois, F. Regulatory Issues Concerning the Use of Human Embryonic Stem Cells in New Zealand, Ministry for the Environment, May 2006, p17. Immortalised human cells lines are derived naturally from tumours taken from patients and can be immortalized in the laboratory.

lines from Australia in the future and this has initiated a government policy response to this emerging area of research⁶⁷.

8.1 The HART Act and Human Reproductive Research on Embryos

Human reproductive research is defined in the HART Act as:

Research that uses or creates a human gamete, a human embryo, or a hybrid embryo.

Research on human embryos is not prohibited under the Act but is limited by the 14 day development rule, namely, there is a prohibition against an in vitro embryo or an in vitro hybrid embryo developing outside the body of a human being beyond 14 days after its formation⁶⁸. Before this stage, embryos may be used in human reproductive research, imported and exported and developed in vitro outside the human body. Research on human embryos or hybrid embryos will require ethical approval from the Ethics Committee on the basis that this activity is consistent with relevant guidelines or relevant advice issued by the Advisory Committee⁶⁹. The HART Act also limits the storage of embryos for no longer than 10 years in the absence of an ethics committee approving a longer storage period⁷⁰. It has been suggested that the effect of this provision will be the large-scale destruction of human embryos in New Zealand as it is unlikely that all stored embryos will be implanted and given a chance to develop past the 14 day stage⁷¹.

“Embryo” is defined in the Act as follows:

Embryo includes a zygote and a cell or a group of cells that has the capacity to develop into an individual; but does not include stem cells derived from an embryo. (emphasis added)

The significance of this exclusion of stem cells derived from an embryo is that research that falls within the jurisdiction of the Act is limited to the use of embryos to *derive* embryonic stem cells but would not include the use of cells from *established* embryonic stem cell lines. Therefore, the derivation of stem cells from human embryos in New Zealand is regulated under the HART Act even if their subsequent use is not regulated by the HART Act. The discussion document by the Ministry of Health “*Guidelines on Using Cells from Established Human Embryonic Stem Cell Lines for Research*” recognises that an appropriate degree of consistency must be ensured between regulating research that uses established embryonic stem cells and regulating human reproductive research.⁷²

⁶⁷ Ministry of Health (2005) Guidelines Using Cells from Established Human Embryonic Stem Cell Lines for Research, p.19.

⁶⁸ Section 9(2)(d) HART Act.

⁶⁹ There are interim guidelines for research on gametes and non-viable embryos and the Advisory Committee is currently generating a discussion document on embryo and gamete research.

⁷⁰ Section 10 HART Act 2004. This limitation on storage of embryos does not operate retrospectively and the 10 year period runs from August 2004.

⁷¹ Ministry of Health (2005) Guidelines Using Cells from Established Human Embryonic Stem Cell Lines for Research, p.19.

⁷² Ministry of Health 2005.

The proposed guidelines will require HESC lines to be derived from surplus IVF embryos only and will require imported HESC lines to have ethics committee approval. They suggest that, except where legislation requires otherwise (presumably ethical oversight in the HART Act), the health and disability ethics committee will have jurisdiction over HESC research as the broad definition of research in the Operational Standard covers basic biological research, including HESCs.

The generation of embryonic stem cell lines involves the destruction of human embryos and consequently, there are a number of ethical issues to be considered. The Advisory Committee will provide guidance on the research use of human embryos including their use to derive stem cell lines. Once established, HESCs are not embryos and therefore fall outside the jurisdiction of the HART Act. There are three other regulatory regimes that then become relevant: the Human Tissue Act 1964 and review, the Hazardous Substances and New Organisms Act (HSNO Act 1996) and the Medicines Act 1981 and associated review.

8.2 The Human Tissue Act 1964

The Human Tissue Act 1964 regulates the collection and use of human tissue samples. Due to its age, the Act is currently under review, with new legislation expected to be introduced during 2006. The new legislation to replace the Human Tissue Act will address, among other things, the use of all human tissue in research, including issues of consent for both therapeutic and non-therapeutic (education or research) uses of human tissue primarily from deceased people, the import and export of human tissue, and the ethical review of research that uses human tissue from both living and deceased people. Part 3A of the Health Act which regulates trading in donated blood and controlled human substances will be revoked and incorporated in the new human tissue legislation.

The definition of human tissue will include cellular material, tissue specimens, cell lines, foetal material, stillborn children, parts of whole organs and other human body parts. Human sperm, eggs and embryos outside of the human body will not be included and the new legislation will specifically exclude material covered by the HART Act⁷³. The definition of human tissue will include HESCs, the regulation of such research and the use of stem cell therapies and gene therapies will fall within this jurisdiction.

8.3 The Hazardous Substances and New Organisms Act 1996

The Hazardous Substances and New Organisms (HSNO) Act 1996 is concerned with protecting the environment and the health and safety of people in communities by preventing or managing the adverse effects of hazardous substances and new organisms. In October 2003, the definition of “new organisms” was extended to include the genetic modification of human cells (but

⁷³ Ministry of Health, Review of Regulation of Human Tissue and Tissue-Based Therapies, Cabinet Paper.

not human beings). The HSNO Act is therefore relevant to research using HESCs where those cells have been genetically modified or where research involves genetic modification.

Where HESC research involves importing or developing genetically modified cells, approval is required from the Environmental Risk Management Authority (ERMA) New Zealand. ERMA New Zealand approval is additional to other forms of approval and review that may be required. Researchers wanting to use New Zealand embryos to create stem cell lines will first require ethics committee approval under the HART Act. ERMA approval would then be required to genetically modify the resulting cell line. An application to ERMA to genetically modify or import genetically modified HESCs or human embryos (the latter being outside the jurisdiction of the HART Act) would consider the environmental and public health risks of the genetic modification procedure. It is noted that failure to gain ERMA New Zealand approval where it is required is a serious offence, punishable by a fine up to \$500,000.00 and up to three months imprisonment.

ERMA applications are categorised into either low-risk genetic modification regulations with delegated decision making authority for rapid assessment, or alternatively and in view of the likelihood of significant public interest, ERMA has discretion to publicly notify an application to genetically modify HESCs⁷⁴. In addition, the Minister for the Environment has power to “call-in” applications and make a decision instead of ERMA when the decision will have “significant cultural, economic, environmental, ethical, health, international, or spiritual effects”⁷⁵.

At this stage, it is unclear whether ethics committee approval (from either ECART or a health and disability ethics committee) will be required before or after an approval from ERMA. For example, if a researcher wished to make HESC lines from human embryos produced by therapeutic cloning, both ECART and ERMA approval would be required. In practical terms an application would not be dealt with concurrently by both bodies and is more likely to be considered on a step by step basis. As therapeutic cloning is a new technology, the approval process would probably begin under the HART Act.

8.4 The Medicines Act 1981 and Associated Review

The primary concern of the Medicines Act 1981 is the safety of medicines and medical devices. Under this Act, a medicine is defined as, amongst other things,

any substance or article, other than a medical device that is manufactured, imported, sold or supplied wholly or principally –

(a) For administering to one or more human beings for a therapeutic purpose.⁷⁶

⁷⁴ For a fuller discussion of the preparedness of the HSNO Act to address issues around emerging Technologies see “Regulatory Issues Concerning the Use of Human Embryonic Stem Cells in New Zealand”, Dr Fleur Francois, Ministry for the Environment, May 2006.

⁷⁵ Section 68(1)(a) Hazardous Substances and New Organisms Act 1996.

⁷⁶ Section 3 Medicines Act 1981.

A therapeutic purpose includes:

- “(a) Treating or preventing disease; or
- (b) Diagnosing disease or ascertaining the existence, degree, or extent of a physiological condition.”⁷⁷

In light of these definitions it is likely that the Medicines Act would cover the research of embryos using gene therapy if this becomes possible in the future. Because the substance used in gene therapy is likely to have been subjected to a manufacturing process and would be administered to the embryo through the mother it would, in effect, be a medicine (under Section 3) provided to the mother, for the purposes of treating or preventing disease (Section 4). The pre-market approval system for medicines is managed by the Medicines and Medical Devices Safety Authority (Medsafe). A pre-market approval is required for both totally new medicines and medicines to which changes have been made.

Medsafe already regulates gene therapy products as medicines. The definition of what constitutes a medicine is being reconsidered for the proposed joint therapeutic products agency with Australia to:

- (a) make it clearer that technology such as gene therapy is to be considered as medicine; and
- (b) to allow Ministers to declare a new technology to either be, or not be, a therapeutic product in terms of the terms of legislation.

This will allow new technologies to be covered by existing legislation⁷⁸.

Clinical trials to test the safety and effectiveness of new medicines in humans require an exemption under the Medicines Act. For this to occur, the Standing Committee on Therapeutic Trials (SCOTT) of the Health Research Council must perform a scientific assessment of the proposed clinical trial. Clinical trials involving the introduction of nucleic acids (genetically manipulated or synthesised in the laboratory) genetically modified organisms, viruses or cells into human subjects require assessment by the Gene Technology Advisory Committee (GTAC). In addition to assessment by GTAC and SCOTT, any clinical trial must also be assessed by a human ethics committee⁷⁹.

8.5 Summary of Interface Between Relevant Legislation

Research involving human embryos, including the generation of human embryonic stem cells falls within the statutory control of the Ethics Committee and Advisory Committee under the HART Act 2004. The HART Act is concerned with the overall ethical and safety framework for research and clinical procedures

⁷⁷ Section 4 Medicines Act 1981.

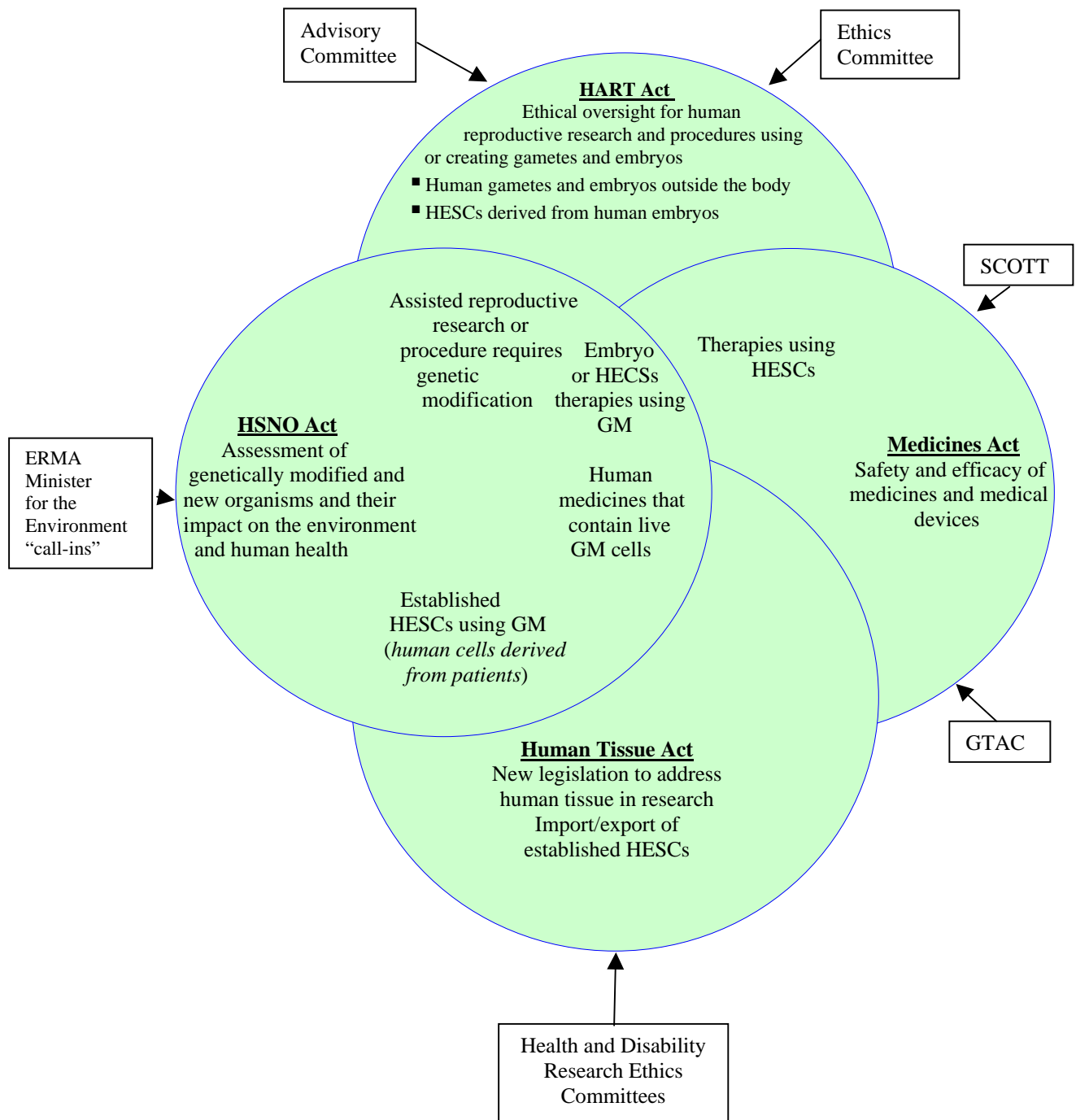
⁷⁸ Personal Communication from the Ministry of Health.

⁷⁹ Guidelines of Ethics and Health Research, Health Research Council of New Zealand, October 2002.

involving gametes, embryos or hybrid embryos. Stem cells derived from an embryo are excluded from the definition of embryo under the HART Act. Therefore, a distinction is made between the use of embryos to derive embryonic stem cells (under HART Act control) and the use of cells from established embryonic stem cell lines (outside the control of the HART Act). As has already been recognised by the discussion documents and guidelines available to date, there is an inevitable overlap between the HART Act and other legislation. The review of the Human Tissue Act will provide a regulatory regime of all human tissue in research, except for those matters already regulated under the HART Act. If the research involves genetic modification, an approval under the HSNO Act would also be required. The HSNO Act considers the environmental and public health risks of the genetic modification procedure. If the procedure or research has a therapeutic use, an assessment will be required under the Medicines Act.

The interface between the HART Act, Human Tissue Act, HSNO Act and Medicines Act is shown in [Figure 3](#).

Figure 3: Research on embryos and human embryonic stem cells (HESCs).
Interface between the HART Act and other legislation⁸⁰.



⁸⁰ Adapted from diagrams prepared by Karla Falloon, (Ministry of Research Science and Technology) and Fleur Francois (Ministry for the Environment).

9. Health Consumer Protection Laws

This section is concerned with three main areas of consumer protection law that operate in the health sector. They are:

- privacy and health information (Health Information Privacy Code);
- the rights of health and disability consumers (Code of Health and Disability Services Consumers' Rights);
- unlawful discrimination (Human Rights Act and New Zealand Bill of Rights Act).

These rights-based laws (and associated legislation) are concerned with promoting and protecting the rights of individuals, which, in the context of the HART Act, will include consumers of fertility services. There are corresponding obligations on providers of fertility services and also public bodies such as the Advisory Committee operating under the framework of the HART Act.

9.1 Privacy and Health Information

9.1.1 *The Privacy Act 1993 and the Health Information Code 1994*

The Privacy Act is primarily concerned with good personal information-handling practices. It gives the Privacy Commissioner the power to issue codes of practice that become part of the law. The Act sets out a complaints mechanism whereby the Privacy Commissioner can investigate breaches of the Act or applicable codes. If the Commissioner considers that a complaint has substance but cannot resolve the matter by conciliation, the complaint may go to the Human Rights Review Tribunal, which may grant remedies including damages for loss of injury to feelings.

Part 2 of the Act contains twelve information privacy principles which cover collection, storage, use and disclosure of personal information and access to it. They do not override other laws which govern the collection, use or disclosure of personal information.

The Health Information Privacy Code 1994 ("the Privacy Code") applies specific rules to agencies in the health sector to ensure the protection of individual privacy. The Privacy Code substitutes the 12 information privacy principles with health information privacy rules. It applies to all agencies providing health and disability services. The Ministry of Health and committees such as ACART are subject to the requirements of the Privacy Code, particularly in respect of releasing or withholding health information.

For the Privacy Code to apply in relation to ART procedures and research, the provider of the procedure or research must be a "health agency" and the

information must be “health information”. Where the information in question is not health information (for example, financial details) the Privacy Act will apply as personal information is involved. The definition of health information is broad and includes:

- the person’s medical history;
- any disabilities the person has or has had;
- health and disability services provided to that individual;
- his or her donation of any body part or bodily substance, or information derived from the testing or examination of any body part or bodily substance of that individual;
- information about the individual which is collected before, or in the course of, and incidental to, the provision of any health and disability service to the person⁸¹.

The rules in the Privacy Code are particularly relevant to procedures and research that are concerned with the collection, use and disclosure of health information. In summary these, are:

- Collection of health information: Rules 1-4, 12;
- Use of health information: Rules 5, 8, 9 and 10;
- Disclosure of health information: Rules 6, 7 and 11.

Health information may be collected for research purposes from sources other than the individual concerned if approval by an ethics committee (if required) has been given and so long as it will not be published in a form that could reasonably be expected to identify the individual concerned⁸². The reasons for not seeking consent should be justified to the ethics committee. These reasons may be scientific, practical or ethical. ECART, may therefore receive an application for approval which considers these aspects of the Privacy Code in relation to research and procedures carried out under the HART Act. As an application to ECART could include individual health information and a copy of the approval and the relevant proposal is required to be forwarded to ACART, the Privacy Code will also apply to ACART.

The express reference to the Privacy Act in Section 66 of the HART Act reinforces the operation of the Privacy Act and the role of the Privacy Commissioner specifically in relation to decisions and actions taken by a provider or the Registrar-General where there is a request for access to information or wrongful disclosure under the information-keeping regime for donors and donor offspring.

⁸¹ Health Information Privacy Code 1994, 4(1).

⁸² Rule 2(2)(g)(3).

9.1.2 Official Information Act 1982

The Official Information Act governs access to information held by public sector agencies. “Official information” is any information held by a Government Department, a Minister and a range of public sector organisations. The Ministry of Health and ACART are subject to the Official Information Act. Official information refers to information about an organisation’s management, operation, business practices, internal policies, guidelines, forms and fact sheets. It also includes personal information where someone other than the individual concerned makes the request.

Official information is not confined to written documents. In addition, it can include tape recordings, electronic files and materials, e-mails, books, maps, drawings, video tapes and films.

The basic principle of the Official Information Act is that all information held by public sector agencies should be made available to the public, unless a good reason exists for withholding it. Mechanisms exist in the Act to protect information which, if disclosed, would prejudice a particular interest such as an individual’s privacy, or that it would not be in the public interest to do so. Section 9(1) provides that the grounds for withholding information can be outweighed by the public interest. The legislation specifies the reasons that are appropriate for an agency to withhold requested information⁸³.

Most of the information held by the Advisory Committee as an example, is official information, and is subject to the Official Information Act. This does not mean however that information may or should be disclosed. Information held by the Advisory Committee or the Ethics Committee regarding a research proposal would need to be considered under any request. This may include specifically, the research proposal, the final report and correspondence in relation to the investigation but does not necessarily include the evaluative material of the application before the Ethics Committee.

The Official Information Act is also concerned with requests for personal information, defined as “any information held about an identifiable person” and therefore the Official Information Act and the Privacy Act (and the Privacy Code) overlap to some extent. Generally speaking, where requests are made by a person for personal information about themselves, the Privacy Act will apply whereas requests for personal information by organisations about themselves or requests by persons for personal information about another individual, are considered under the Official Information Act.

If a request for official information is refused, the agency must give the applicant the reason and, if the applicant requests, the grounds to support that reason. The applicant must also be informed of their right to make a complaint to the

⁸³ Sections 6 and 9 Official Information Act 1982.

Ombudsman to seek an investigation and review of the refusal. The review may result in a binding recommendation being made against the agency.

9.1.3 Health Act 1956

Section 22B-22H of the Health Act 1956 sets out mandatory rules of disclosure by health agencies (given the same meaning as under the Privacy Act). Examples include disclosure of health records on the request of other health professionals treating the same person, or at the request of the person's representative, unless reasonable grounds to believe the patient does not approve, or that would be against the patient's interest⁸⁴.

There are also specific provisions that permit a health agency to disclose information to third parties without a patient's consent, for example, disclosure to the Ministry of Health for the purpose of administering the Health Act and compiling statistics for health purposes⁸⁵.

9.1.4 The Health (Retention of Health Information) Regulations 1996

These regulations require identifiable health information to be kept for at least ten years. Health information collected as part of a research investigation will have to be kept for this period of time. This regulation overrides Rule 9 of the Health Information Privacy Code which states that a health agency must not keep health information for longer than is required for the purposes for which the information may lawfully be used. In addition, agencies can still keep any health information for the purposes of providing health and disability services to an individual.

9.2 The Rights of Health and Disability Consumers

9.2.1 Code of Health and Disability Services Consumers' Rights

The Health and Disability Commissioner Act 1994 established the office of the Health and Disability Commissioner and provided for the drafting of the Code of Health and Disability Services Consumers' Rights ("HDC Code of Rights"). The HDC Code of Rights confers 10 rights on consumers of health and disability services in New Zealand and therefore applies to people receiving fertility services. Providers of those services have a duty to give effect to these rights. Application of the HDC Code of Rights is very wide and extends to all individuals and organisations providing or holding themselves out as providing health and disability services, both public and private. It includes all health professionals and the places in which they work.

⁸⁴ Section 22(f) Health Act 1956.

⁸⁵ Section 22C(2)(g) Health Act 1956.

The 10 rights in the Code are:

- Right 1: To be treated with respect
- Right 2: Freedom from discrimination, coercion, harassment, and exploitation
- Right 3: Dignity and independence
- Right 4: Services of an appropriate standard
- Right 5: Effective communication
- Right 6: To be fully informed
- Right 7: To make an informed choice and give informed consent
- Right 8: Support
- Right 9: In respect of teaching and research
- Right 10: To complain

The rights are not absolute. A provider is not in breach of the HDC Code of Rights if they take reasonable actions in the circumstances to give effect to the rights and comply with duties in the Code. The onus is on the provider to show that such action has been taken. Importantly, the Code of Rights does not override other legislation. Clause 5 provides:

Other Enactments

Nothing in this Code shall require a provider to act in breach of any duty or obligation imposed by any enactment or prevents a provider doing an act authorised by any enactment.

Therefore, if the HART Act required a provider to do something inconsistent with the HDC Code of Rights that requirement would prevail. In addition, a provider may refuse to provide a service that is prohibited under the HART Act. For example, there are restrictions on a provider performing Pre-implantation Genetic Diagnosis on the basis of sex selection⁸⁶. A refusal to carry out this procedure would not be in breach of Right 4(1), namely, that services must be provided that comply with legal, professional, ethical and other standards. The provider, however, could still be subject to a complaint on the basis of other breaches of the Code of Rights. For example, Right 1, the right to be treated with respect and Right 6, the right to be fully informed. In particular, under Right 6, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including (but not limited to): an explanation of his or her condition; an explanation of the options available, including an assessment of the expected rights, side effects, benefits and costs of each option; notification of any proposed participation in teaching and research, including whether the research requires and has received ethical approval.

The Ethics and Advisory Committees are not subject to the HDC Code of Rights but providers of fertility services and associated health professionals are, and how they respond to complaints will have an impact on the utilisation of fertility services and the ART procedures carried out. As with other anti-discriminatory laws, complaints against providers could be referred to the Advisory Committee if

⁸⁶ Section 11 HART Act and HART Order 2005.

the provider defends their position on the grounds that they are complying with guidelines issued by the Advisory Committee.

Some health legislation specifically permits the provision of services without an individual's consent. For example, the Health Act 1956 allows for treatment of infectious diseases without a person's consent to stop the spread of an infectious disease. By comparison, the principles of informed choice and informed consent underpin the scheme of the HART Act and are expressly referred to in the principles to the Act (section 4(d)). Furthermore, the Advisory Committee must make recommendations to the Minister on the requirements of informed consent (section 37(1) (f)). The scheme of the HART Act therefore, is consistent with the consumer protection framework in the HDC Code of Rights.

9.2.2 Informed Consent – Retention and Use of Body Parts and Bodily Substances

The law governing informed consent is largely found in Rights 6 and 7 of the HDC Code of Rights. The rights in the Code also extend to teaching and research in Right 9. Of particular relevance to procedures and research undertaken in the context of the HART Act are Rights 7(9) and 7(10), with respect to decisions about the return, disposal, storage or use of any body parts and bodily substances.

- 9) Every consumer has the right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a health care procedure.
- 10) No body part or bodily substance removed or obtained in the course of a health care procedure may be stored, preserved, or used otherwise than
 - (a) with the informed consent of the consumer; or
 - (b) For the purposes of research that has received the approval of an ethics committee; or
 - (c) For the purposes of 1 or more of the following activities, being activities that are each undertaken to assure or improve the quality of services;
 - (i) a professionally recognised quality assurance programme
 - (ii) an external audit of services:
 - (iii) an external evaluation of services.

In 2004 a change to Right 7(10) allowed strictly limited exceptions to the right to informed consent where use of body parts and bodily substances is for research approved by an ethics committee or, for the purpose of quality assurance, external audit, or evaluation.

The reason for these changes was that it was not always reasonably practicable to obtain informed consent because a donor can no longer be traced and the particular use was not contemplated (and therefore consent was not sought) at

the time of the organ or tissue removal. In addition, there are certain research situations where the research use is known in advance and it is possible to seek a patient's informed consent, but to do so would invalidate the proposed research⁸⁷.

The Health and Disability Commissioner has stated that it is unlikely that the HDC Code of Rights would extend to the act of donating a surplus embryo⁸⁸. An embryo created in a laboratory and outside of a woman's uterus (in vitro) is unlikely to be regarded as a body part or bodily substance of either the genetic mother or father. Accordingly, Right 7(10) is unlikely to apply to the use (including donation) of surplus embryos. The Health and Disability Commissioner has stated that gametes – sperm or eggs – would be considered “bodily substances” under Right 7(10)⁸⁹. Gametes are arguably more likely to be “bodily substances” in this context. There may therefore be situations where informed consent is not required from a consumer for research or audit activities on their gametes under Right 7(10).

Rights 7(9) and (10) overlap with the requirements of ethical review of research and the laws regulating the conduct of research. The Operational Standard for Ethics Committees requires that if tissue is to be taken from living people for research purposes, then ethical approval is required for the particular research proposal. Failure to do so could be a breach of the Code under Right 4(2) – the right to have services provided that comply with legal, professional, ethical, and other relevant standards. While embryos may not fall within the definition of body parts and bodily substances under Rights 7(9) and (10), the requirement for informed consent is a cornerstone to the safeguards and protections provided for in the HART Act. An ethics committee is likely to be cautious in waiving the requirement of informed consent under Rights 7(9) and (10) where the research involves the use of gametes.

9.2.3 *Informed Consent by a Consumer*

An obvious limitation of the HDC Code of Rights in the context of ART, as with other rights based legislation, is that it only confers rights on health consumers at the time they receive treatment. A health consumer includes any *person* on or in respect of whom a health care procedure is carried out. Therefore no rights are conferred on the embryo created from ART procedures as they have no legal status as a “person”⁹⁰. A person whose gametes or embryos are used and upon

⁸⁷ Paterson, R Body Parts – Changing the Code of Patients' Rights, *New Zealand Doctor*, 30 June 2004.

⁸⁸ Health and Disability Commissioner, Submission on Draft Guidelines for the Practice of Embryo Donation for Reproductive Purposes.

⁸⁹ Communication from the Chief Legal Advisor, Office of The Health and Disability Commissioner to the Ministry of Health, 28 August 2003.

⁹⁰ It is beyond the scope of this discussion to consider the legal status of the embryo. In brief, a foetus is not a “person” in the eyes of the law and therefore an embryo cannot be a person either. Note that in a recent New Zealand decision, known as *Nikki's Case*, the High Court found that Nikki's unborn child in utero was a “person” for the purposes of the Guardianship Act 1968, but the decision is probably limited to its particular facts: *Re A Unborn Child* [2003] 1 NZLR 115, Heath J.

whom an ART procedure is carried out, however, is a consumer for the purposes of the HDC Code of Rights.

The rights are premised on informed consent by a consumer who is a competent living adult. The Code does not apply to a dead person, and so the Health and Disability Commissioner has no power to investigate a complaint in respect of anything done to a dead body. This requirement places limits on the jurisdiction of the Health and Disability Commissioner where the lawfulness of a decision to retrieve gametes for posthumous use without prior consent of the deceased person is at issue⁹¹.

When the person from whom the body part or bodily substance lacks competence to consent, the definition of consumer is extended for the purposes of Right 7(10) to include a person entitled to give consent on that person's behalf. Right 7(4) sets out the procedure to ascertain the views of the consumer. The provider must establish that the decision is in the best interests of the consumer. The authority of a welfare guardian or enduring attorney to consent on behalf of the other person to research other than for therapeutic or diagnostic purposes under the Protection of Personal and Property Rights Act 1988 is limited. Such decisions must be in best interests of that person and may be prohibited if consent to that person is for taking part in a "medical experiment"⁹². The ability to consent on someone else's behalf is therefore strictly limited.

9.3 Unlawful Discrimination

9.3.1 Unlawful discrimination by providers

The Human Rights Act 1993 provides for basic human rights protections in New Zealand by promoting freedom from certain specified forms of discrimination in a number of areas. Section 21 includes a number of grounds for discrimination, some of which are relevant to determining who may receive fertility treatment or services. These include discrimination on the grounds of disability, sexual orientation, family status, age and marital status. The same anti-discrimination grounds are found in Section 19 of the New Zealand Bill of Rights Act 1990.

The provision of fertility treatment services falls within the meaning of "goods, facilities or services" referred to in Section 44 of the Human Rights Act and providers under the HART Act will be subject to the compliance with anti-discriminatory practices. Section 44 provides that:

⁹¹ Guidelines for the Storage, use and Disposal of Sperm from a Deceased Man, National Ethics Committee on Assisted Human Reproduction, February 2000. A further development of this issue has been raised where the Auckland Coroner, acting on the requests of the lawyer for the deceased man's wife, ordered the removal of sperm from a dead man. It is questionable whether the Coroner's order was legally justified in the context of his narrow powers to make enquiries or examinations under Section 12 Coroners Act 1988. See Daniels K, Report on the Collection, Storage, Disposal and Use of Gametes, Ministry of Health, July 2006.

⁹² Sections 18, 98 Protection of Personal and Property Rights Act 1988.

- “44. (1) It shall be unlawful for any person who supplies goods, facilities, or services to the public or to any section of the public—
- (a) To refuse or fail on demand to provide any other person with those goods, facilities, or services; or
 - (b) To treat any other person less favourably in connection with the provision of those goods, facilities, or services than would otherwise be the case,—

by reason of any of the prohibited grounds of discrimination.”

When considering the grounds of discrimination from a rights perspective, it becomes apparent that interested parties may have conflicting rights and that consideration must be given to balancing or prioritising these rights. The rights most obviously in potential conflict in the ART context are the rights of the prospective parents and the rights of the child. The general concern may be that while consideration of the rights of the child born from ART procedures is essential, these issues can be subject to prejudice regarding single or same sex parents or less conventional family circumstances or environments⁹³. Individual cases will need to be examined to see whether there has indeed been unlawful discrimination and whether discrimination to protect the child may in the particular circumstances be justified.

Some of New Zealand legislation gives paramouncy to the rights and welfare of children, for example, the Care of Children Act 2004. The HART Act states only that the welfare of the child should be taken into consideration along with other factors. Persons exercising powers under the Act must be guided by the principles set out in Section 4 including:

- (a) the health and well-being of children born as a result of the performance of an assisted reproductive procedure or an established procedure should be an important consideration in all decisions about that procedure.

To some extent positive discrimination for women is included in the principles to the HART Act as women are recognised as being “directly and significantly” affected by the application of ART procedures and Section 4 also provides:

- (c) while all persons are affected by assisted reproductive procedures and established procedures, women, more than men, are directly and significantly affected by their application, and the health and well-being of women must be protected in the use of these procedures:

⁹³ Submission of the Human Rights Commission to the Ministerial Committee on Assisted Reproductive Technologies, Human Rights Commission, April 1994.

If a practice of a provider is prima facie (on the face of it) in breach of Section 44 of the Human Rights Act, the Human Rights Commission may receive a complaint of discrimination which could result in action being taken against the provider at the Human Rights Review Tribunal and possibly the High Court.

9.3.2 *Unlawful Discrimination by Public Bodies*

The issue of compliance with anti-discriminatory law and practice applies to Acts done by any person or body in the performance of any public function, power, or duty conferred or imposed by or pursuant to law⁹⁴. As an advisory committee to the Minister of Health carrying out a public function, ACART would be considered to be subject to this law. The 2001 amendment to the Human Rights Act has the effect that the executive arm of Government and those bodies and persons performing public functions are no longer exempt from compliance with anti-discrimination protections but must however comply with the anti-discrimination standard in the New Zealand Bill of Rights Act 1990. This standard essentially states that discrimination on the grounds set out in the Human Rights Act is permitted within reasonable limits prescribed by law *as may be demonstrably justified in a free and democratic society*⁹⁵.

If a complaint is laid against a provider for a discriminatory practice, that provider may in turn assert that practice was in compliance with the guidelines issued by ACART. In issuing guidelines, ACART will need to give consideration to where discrimination may be present and whether a limit on a right is reasonable. For example, a guideline limiting the age of women to receive fertility services may prima facie be discriminatory when the recipient's age presents no substantial conflict with the rights of the potential child. In this situation denial of services on proper medical grounds may be justified⁹⁶.

A possible mechanism to determine the scope and the meaning of the Human Rights Act or the New Zealand Bill of Rights Act is the Declaratory Judgments Act 1908. This Act provides a procedure for obtaining a ruling by the High Court on the interpretation of the activities undertaken by an individual or body. A declaration does not involve the paying over of damages but merely facilitates a determination of law to be made. The Human Rights Act empowers the Human Rights Commissioner to seek such declarations and in some circumstances, it may be a useful way to clarify the law.

The Ministry of Justice has issued guidelines for the public sector on how to apply the New Zealand Bill of Rights Act which will be relevant to the operation of both

⁹⁴ Sections 20(I), 20(J) Human Rights Amendment Act 2001 and Section 3 New Zealand Bill of Rights Act 1990.

⁹⁵ Section 5, New Zealand Bill of Rights Act 1990.

⁹⁶ The National Ethics Committee on Assisted Human Reproduction (NECAHR) received a complaint on similar grounds in 1999 and the complaint was settled at mediation.

the Ethics Committee and Advisory Committee in carrying their functions under the HART Act⁹⁷. There are likely to be aspects of the Advisory Committee's guidelines and advice which, prima facie, may infringe a particular right. Consideration should be given to identifying whether the guidelines comply with the anti-discriminatory laws and to determining whether any limitations on a right are reasonable.

10. Family Law Legislation

The HART Act expressly recognises that the health and wellbeing of children born as a result of an ART procedure is an important consideration in all decisions about that procedure. The HART legislation considers the interests of children along with other competing interests in the context of assisted conception. After the child is born, however, the family law framework provides a statutory regime which ensures the best interests and welfare of the child is the paramount consideration.

The family law legislation in New Zealand is now spread between a variety of statutes. The main family law statutes and their relevance to assisted reproductive technologies are as follows:

- *Adoption Act 1955*

Adoptive parents become the child's parents for all purposes and the child's legal link with his or her birth mother or genetic parents is severed. The Department of Child, Youth and Their Families is involved in the administration of this Act.

- *Adult Adoption Information Act 1985*

This Act provides for access by adult adoptees to information about birth parents and access by birth parents to information about children placed with adoptive parents. The Act is administered by the Registrar-General.

- *Births, Deaths, and Marriages Registration Act 1995*

Recording of information regarding births, deaths and marriages and access to that information administered by the Registrar-General.
Discussed Below

⁹⁷ The Guidelines on the New Zealand Bill of Rights Act 1990: A Guide to the Rights and Freedoms in the Bill of Rights Act for the Public Sector, Ministry of Justice, 2004.

- *Care of Children Act 2004*

Replaces the Guardianship Act 1968 with the aim of modernising the law relating to guardianship, care of children, Family Courts procedures and parental status. Discussed below

- *Child Support Act 1991*

Financial support for children. Clarifies who is liable to pay child support where a child is conceived as a result of any ART procedure.

- *Civil Union Act 2004*

Creates a new status of civil union available to same-sex and different-sex couples aged 16 years or older, and sets out the procedures for entering into a civil union. Provides legal status for couples in a same-sex or de facto relationship in relation to parenting matters.

- *Domestic Violence Act 1995*

Enables the Family Court to make protection orders to give children and partners protection from partners or persons with whom they are or have been in a domestic relationship. The Act extends to cover biological parents. An identified sperm donor may be considered a partner of the sperm recipient for the purposes of the Act.

- *Family Proceedings Act 1980*

Provides for counselling, conciliation and mediation and establishes procedures for proving paternity of children.

- *Status of Children Act 1969*

Establishes a presumption that the husband of a woman who gives birth to a child during her marriage is the father of the child. It also sets rules determining the parental status of gamete donors and recipients and their spouses or partners in respect of children born as a result of assisted reproductive technology. This Act also impacts on inheritance rights and succession law. Discussed below

- *The United Nations Convention On The Rights Of The Child*

New Zealand ratified the United Nations Convention on the Rights of the Child in 1993. In doing so, New Zealand made a commitment to assure to every child the rights set forth in the Convention, particularly regarding welfare, identity and access to information⁹⁸.

⁹⁸ Brookers Child Law, Wellington, 2003.

10.1 The Care of Children Act 2004

The Care of Children Act 2004 (“COCA”) replaces the Guardianship Act 1968. The purpose of COCA is to promote children’s welfare and best interests and to ensure that appropriate arrangements are in place for their guardianship and care.

The main changes the Care of Children Act 2004 introduced are as follows:

1. The child’s welfare is now paramount in the new legislation and must be considered together with the child’s best interests.
2. The previous terminology of “custody” and “access” has been removed. The Act introduces parenting orders which sets out who has the “day to day care” of the child and who has “contact” with the child.
3. Guardianship is defined and guardians must act jointly on guardianship matters by consulting wherever practicable. Parents and guardians can appoint eligible step-parents and partners as additional guardians to the child.

10.2 Parenting Orders

Parenting Orders set out the times when specified persons have the role of providing day to day care or contact with the child.

The Act expressly allows for a child’s family, whanau or other recognised family groups to apply for a parenting order⁹⁹. The Act recognises that it is not only biological parents who may care for a child. The intending parents of a surrogacy arrangement can apply to the Court for a Parenting Order after a child is born to confirm they are responsible for the child’s day to day care.

10.3 Parenting Agreements

Section 41 of COCA provides for parenting agreements to be drafted between parents and ART donors.

This section was drafted as a result of the case of *P v K* [2003] 2 NZLR 787. The case involved a sperm donor and his male partner, and the woman who conceived the child and her female partner. A man agreed to provide his sperm to assist a woman to conceive a child which she and her female partner would parent. An agreement was drawn up that gave the donor the right for the donor and his male partner to have contact with the child. There was a falling out between the couples and the mother of the child and her partner refused the man

⁹⁹ Section 47 Care of Children Act 2004.

and his partner any further contact. The donor encountered legal difficulties in trying to enforce the agreement.

An Agreement made under Section 41 cannot be enforced under the Act. The Court may, however, with the consent of all parties, make an order that embodies some or all of the terms of the Agreement.

10.4 Guardianship

The term “guardianship” refers to the powers rights and responsibilities in relation to the upbringing of a child. This is distinct from parenthood.

The COCA allows any person to make an application to be made a guardian of a child. There are different procedures available depending on the relationship of the person to the child. The COCA allows sperm donors to apply for guardianship, together with same-sex partners and step-parents. There are different procedures available to be appointed as an additional guardian under the Act, but all require a formal application to be filed with the Family Court.

10.5 Status of Children Act 1969

The Act defines the status of children conceived as a result of ART procedures (referred to as AHR procedures). Since 1987, New Zealand has had a policy in place which recognises the status of children born as a result of assisted reproductive technologies. The 2004 Amendment has updated this approach by the inclusion and recognition of same sex couples.

The Act provides that a woman who becomes pregnant as a result of a donor embryo implantation procedure is the mother of the child. If the mother is married or living in a same sex or de facto relationship, and her husband or partner has consented to the procedure, the mother’s partner is also deemed to be the parent of the child.

All parental rights and responsibilities of the donors are removed.

The Law Commission has recommended that known donors of gametes have the ability to be recognised as parents in some circumstances. This is a reversal of earlier policy which was to extinguish parental rights of donors. The Government is now being asked to consider the right of donors to have contact with children born through ART. The Ministry of Justice considers that further policy work and consultation is required before drawing any conclusions on this issue¹⁰⁰.

The Status of Children conceived as a result of ART procedures is set out in Part 2 of the Act and is attached in **Appendix One**. This provides a full explanation of parental status through ART procedures.

¹⁰⁰ Overview of Government Response, <http://w.w.w.justice.govt.nz/pubs/reports/2006/govt-response-law-commission-legal-parenthood/index.html>.

10.6 Surrogacy Arrangements

A definition of “surrogacy arrangement” is set out in Section 5 of the Human Assisted Reproductive Technology Act 2004:

***surrogacy arrangement** means an arrangement under which a woman agrees to become pregnant or to seek to become pregnant; for the purpose of surrendering custody of a child born as a result of the pregnancy.*

Surrogacy arrangements were unregulated by legislation until the passage of the HART Act. The Act prohibits commercial surrogacy arrangements and provides that only reasonable and necessary expenses can be paid to the surrogate mother. Section 14(1) of the Act recognises the principle that surrogacy arrangements are unenforceable¹⁰¹. To force such an arrangement to take place is contrary to public policy and impacts upon human rights.

The surrogate mother is the child’s legal parent at birth, regardless of the type of surrogacy arrangement. Even if the intending mother is the child’s genetic parent, she will not have status as a parent at law. If a child has been conceived by way of insemination of the intending father’s sperm, the intending father will be considered a donor and will not have any parental status. This means that the intending parents do not have any of the rights and responsibilities to parenthood even if both are the genetic parents of the child¹⁰².

To complete a surrogacy arrangement, the commissioning parents need to either adopt the child or apply for Parenting and Additional Guardianship Orders under the Care of Children Act. Without these steps, the child retains its legal ties with the birth mother and the child may have no rights of maintenance or inheritance against the commissioning parents.

The Law Commission has recommended that a legal framework be implemented to transfer legal parenthood both on an interim and final basis to the intending parents in certain circumstances. The Law Commission has also recommended that the Family Court should be empowered to issue a Parenting Order at any time from 21 days post-birth to 6 months post-birth¹⁰³.

10.7 Births, Deaths and Marriages Registration Act

The HART Act provides that when a live birth occurs from a donor’s gametes or embryo, the fertility clinic must pass information about the donor offspring and the donor to the Registrar-General of Births, Deaths and Marriages. The information

¹⁰¹ Section 14 (1) HART Act states that “A surrogacy arrangement is not of itself illegal, but is not enforceable by or against any person”.

¹⁰² Brookers Child Law, Wellington, 2003.

¹⁰³ Law Commission, *New Issues in Legal Parenthood*, April 2005.

retained by the Registrar-General is to be available to the donor offspring at 18 years, unless an order is obtained from the Family Court where they are 16 or 17 years of age¹⁰⁴.

The Notice of Birth form under the Births, Deaths and Marriage Registration Act requires information about the date and place of birth and ethnic group of the child, the full names, date and place of birth, name at birth, current name, address and ethnic group of the mother, and in some cases the same details of the father. This may cause difficulties with children born as a result of ART.

The Law Commission has recommended that the law be changed so that birth certificates include a statement to indicate that the Births, Deaths and Marriages Register contains other information that may be accessed by the person whose certificate it is. This would allow the donor offspring to be provided with greater information as to their genetic background. This raises privacy issues in relation to the quality and availability of the information to be stored. The Law Commission have also recommended that the Registrar-General allows parents to choose to have an annotation on the birth certificate stating that the child was born by “donor”¹⁰⁵. The Government considers that more policy work is required on these issues.

10.8 Key Family Law Legislation

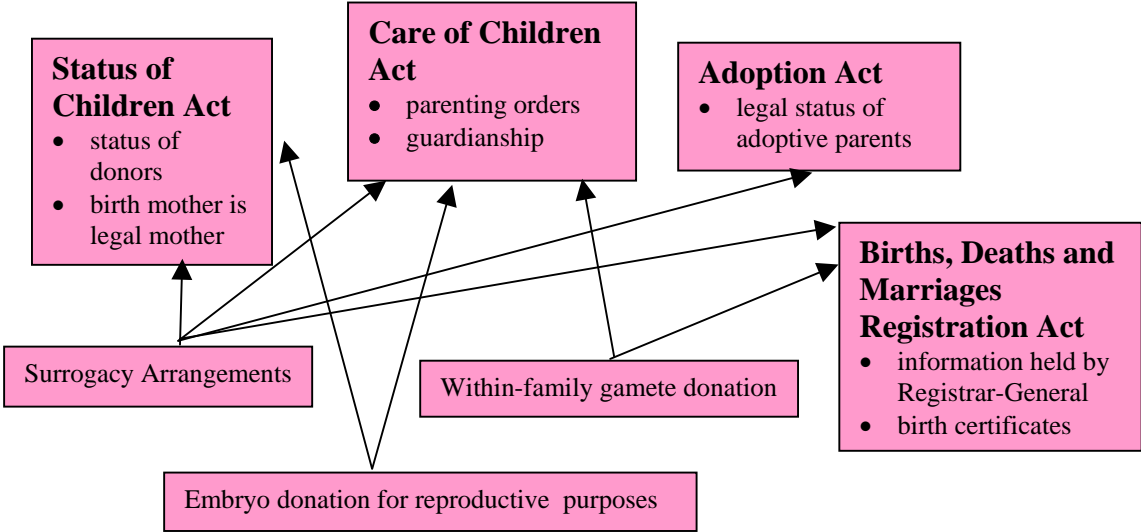
The legal framework regulating parenting is complex and impacts upon the interests of many parties. In its response to the Law Commission the Government has advised that it will be considering amending the above legislation particularly with regard to transferring legal parenting in surrogacy arrangements and allowing parenthood to be allocated to “known” donors of sperm or eggs. The Government is also considering the information contained on birth certification applications to alert more people to the possibility they may be donor conceived¹⁰⁶. **Figure 4** shows family law legislation relevant to the Advisory Committee’s guidelines.

¹⁰⁴ Section 65 HART.

¹⁰⁵ Law Commission, *New Issues in Legal Parenthood*, April 2005.

¹⁰⁶ *Ibid* 100.

Figure 4 Family law legislation relevant to the Advisory Committee’s guidelines.



Discussion and Conclusion

The introduction of the HART Act has provided the opportunity to bring together all aspects of assisted reproductive technologies in New Zealand under a single regulatory framework. The workability of the Act, like all new legislation, is in the process of being tested. The HART Act was not created in a legal vacuum. Regulation of assisted reproductive technologies has been covered by a complex overlapping system of legislation, codes of practice and professional oversight. The HART Act now provides the central focus of regulation of assisted reproductive technologies. There continues to be legislation and associated bodies concerned with the regulation of health and disability research in the health sector. The task for the Advisory Committee is to be aware of the existing laws and their interface with the HART Act so that they can be taken into account and applied when implementing its policy functions under the HART Act.

The first part of this report has provided an analysis of the regulatory framework of the HART Act. As this legislation is new, there will inevitably be a period of uncertainty as to the legal interpretation of some aspects of the Act and how it should be implemented. Regulation under the Act is carried out in three ways; by prohibition of certain ART procedures and research, by an ethical review and policy framework, and through the establishment of an information-keeping regime for donors and donor offspring.

Although some procedures and research are expressly prohibited, the regulatory regime is to some extent permissive as it allows the Advisory Committee to recommend that certain procedures be declared as established procedures on the basis of scientific and ethical analysis by ACART, thereby removing the requirement for ethical scrutiny of those procedures. In addition, the regulation of procedures and research is carried out through the ethical review of applications to the Ethics Committee applying the guidelines issued by the Advisory Committee. There are a number of checks and balances in the process to be undertaken by the Advisory Committee in issuing guidelines and advice to both the Ethics Committee and the Minister of Health. The structure of the ethical review framework is prescribed by the HART Act, however, how the Advisory Committee carries out its functions is discretionary and will impact on creating a workable system of ethical review of research and procedures.

The ethical review and advice framework is complex, partly due to the separation of ethics and policy functions into two committees. Clarification of the following issues may assist the Advisory Committee in carrying out its functions:

- The relationship between the Ethics Committee and the Advisory Committee is unclear and, in particular, (1) the overlap of functions between the Advisory Committee and the Ethics Committee and, (2) the extent to which the Ethics Committee is accountable to the Advisory Committee. There is no specific oversight of the Ethics Committee by the Advisory Committee in the HART Act. The Ethics Committee is only

accountable to the Advisory Committee to the extent that the Ethics Committee's jurisdiction is limited to the guidelines and advice issued by the Advisory Committee. This raises questions as to the scope of the Ethics Committee jurisdiction and in what circumstances it must seek advice and guidance from the Advisory Committee.

- A “regulatory gap” exists for new emerging technologies where a procedure or research is neither an established procedure nor a prohibited activity and, is not a procedure or research which falls within existing guidelines or advice issued by the Advisory Committee. In carrying out its monitoring role the Advisory Committee will identify emerging technologies that don't fall within the existing categories provided for in the Act. The gap in the framework can be filled to the extent that once identified as a new procedure, the Advisory Committee can identify the kind of advice that is required. A scientific and ethical analysis (along similar lines as required for established procedures) may form part of the Committee's process in providing advice to the Minister.

The second part of the report has provided an overview of the regulatory landscape within which the HART Act operates. There are a number of laws and multiple agencies that are relevant to assisted reproductive procedures and research, some of which overlap with the ethical review framework and functions of the Advisory Committee. They have been considered in five categories as follows:

- Providers of fertility services. Previously, a system of professional oversight operated by way of an accreditation system of fertility service providers. The HART Act has now aligned the regulation of providers under the Health and Disability Services (Safety) Act 2001. There are also a number of general laws that affect both criminal and civil liability of providers.
- Health and disability research. The ethical review framework in the HART Act is part of the overall ethical review system for all health and disability research in New Zealand but largely operates independently of it. A policy issue arises as to whether the Ethics Committee should be more aligned with its counterpart health and disability ethics committees. The Advisory Committee works alongside this framework and it has areas of interest and overlap with the National Ethics Advisory Committee. Other bodies which have an input into research policy and advice include the Health Research Council Ethics Committee and the independent role of the Bioethics Council in promoting public discussion.
- Research on human and human embryonic stem cells. Regulation of this area of research is a good example of the overlap between the HART Act and other legislation. The exclusion of stem cells derived from an embryo in the definition of “embryo” in the Hart Act means that there will be jurisdictional boundaries depending on the proposed research. The Advisory Committee will be part of policy development between

Government agencies and will need to develop a position as to what research is covered by the HART Act and how ethical review of such research is to be carried out under applicable legislation.

- Health consumer protection laws. The implications and likely interpretation of three areas of consumer protection law have been outlined. They include: the Health Information Privacy Code (and its express recognition in the HART Act) and the Official Information Act, The Code of Health and Disability Services Consumers' Rights (particular implications for the waiver of informed consent under Right 7 (9) and (10)) and, the anti discriminatory laws set out in the Human Rights Act and New Zealand Bill of Rights Act. Some of these laws apply not only to providers but also public bodies such as the Advisory Committee. In developing its guidelines the Advisory Committee will need to ensure compliance with anti discriminatory laws and whether any limitations on these rights are reasonable.
- Family law legislation. The family law framework provides a statutory regime to ensure the best interests and welfare of children born through assisted reproductive procedures. Of particular relevance is the operation of the Care of Children Act, (parenting orders and guardianship) the Status of Children Act (the legal status of children and their biological and social parents) and the Births Deaths and Marriages Act (the Registrar-General's role and interface with the HART Act). The developments in this area of the law and the Law Commission's recommendations for changes will be important for the Advisory Committee to consider when revising its guidelines in relation to IVF surrogacy, embryo donation for reproductive purposes and within-family donation.

There is a large amount of law for the Advisory Committee to take into account when developing policies on assisted reproductive technologies. This report provides a starting point in undertaking this task. In carrying out its advisory role the Advisory Committee will want to keep in mind the overall aim of the HART Act, namely, to secure the benefits of assisted reproductive procedures and human reproductive research not only for individuals but for society as a whole.

Appendix One

Status of Children Act 1969

PART 2 - STATUS OF CHILDREN CONCEIVED AS RESULT OF AHR PROCEDURES

13. Purpose of this Part—

The purpose of this Part is to—

- (a) remove uncertainty about the status of children conceived as a result of AHR procedures; and
- (b) replace the Status of Children Amendment Act 1987 with provisions that continue the effects of that Act (except for the status of father without the rights and liabilities of a father), but also extend the status of parent to a woman living as a de facto partner of a birth mother.

14. Interpretation—

- (1) In this Part, unless the context otherwise requires,—

“AHR procedure” has the meaning given to it by section 14A

“partner”,—

- (a) in relation to a woman who is married or in a civil union and to whom paragraph (b) does not apply, means the woman's husband or civil union partner; and
- (b) in relation to a woman (“woman A”) who is married or in a civil union but is living with a man, or with another woman, as a de facto partner, means the man or other woman who is living with woman A as a de facto partner (and so does not mean woman A's husband or civil union partner); and
- (c) in relation to a woman (“woman A”) who is not married or in a civil union but is living with a man, or with another woman, as a de facto partner, means the man or other woman who is living with woman A as a de facto partner]

“partnered woman” means a woman who—

- (a) is married or in a civil union; or
- (b) is married or in a civil union, but is living with a man, or with another woman, as a de facto partner; or
- (c) is not married or in a civil union but is living with a man, or with another woman, as a de facto partner]

“woman acting alone” means a woman—

- (a) who is not a partnered woman; or
- (b) who is a partnered woman, but has undergone an AHR procedure without her partner's consent.

- (2) A woman who is not the birth mother of a child but who, by operation of this Part, is a parent of the child must, for the purposes of an enactment or rule of law (other than this Part) that refers to, or contemplates, a mother and a father of, or 2 parents of, a child, be treated so far as practicable in the same manner as the father of, or as the other parent of, the child.
- (3) A reference in any of sections 17 to 22 to ``any child of the pregnancy" is a reference to ``any child of the pregnancy (whether born or unborn)".

15. AHR procedure defined—

- (1) In this Part, unless the context otherwise requires, ``AHR procedure" means one of the following assisted human reproduction procedures (regardless of where, or how (for example, with whose help) the procedure is carried out):
 - (a) an artificial insemination procedure:
 - (b) a donor semen implantation procedure:
 - (c) a donor ovum or donor embryo implantation procedure:
 - (d) a donor semen intra-fallopian transfer procedure:
 - (e) a donor ovum intra-fallopian transfer procedure:
 - (f) a donor embryo intra-fallopian transfer procedure:
 - (g) an embryo (donor semen) intra-fallopian transfer procedure:
 - (h) an embryo (donor ovum) intra-fallopian transfer procedure.

- (2) In this section,—

``artificial insemination procedure" means a procedure of artificial insemination of a woman where the semen used for the artificial insemination—

 - (a) is produced by a man who is not her partner; or
 - (b) is a mixture of semen part of which is produced by a man who is not her partner and part of which is produced by her partner

``donor semen implantation procedure" means a procedure of implanting in the womb of a woman an embryo derived from an ovum produced by her and fertilised outside her body by the use of semen produced by a man who is not her partner

``donor ovum or donor embryo implantation procedure" means a procedure of implanting in the womb of a woman (``woman A") an embryo derived from an ovum produced by another woman (``woman B") (whether or not woman B is woman A's partner), being an ovum that has been fertilised by the use of semen produced—

- (a) by woman A's partner; or
- (b) by a man who is not woman A's partner

``donor semen intra-fallopian transfer procedure" means a procedure of transferring into the fallopian tubes of a woman an ovum produced by her together with semen produced by a man who is not her partner

``donor ovum intra-fallopian transfer procedure" means a procedure of transferring into the fallopian tubes of a woman (``woman A") an ovum produced by another woman (``woman B") (whether or not woman B is woman A's partner) together with semen produced—

- (a) by woman A's partner; or
- (b) by a man who is not woman A's partner

“donor embryo intra-fallopian transfer procedure” means a procedure of transferring into the fallopian tubes of a woman (“woman A”) an embryo derived from an ovum produced by another woman (“woman B”) (whether or not woman B is woman A's partner), being an ovum that has been fertilised by the use of semen produced by a man who is not woman A's partner

“embryo (donor semen) intra-fallopian transfer procedure” means a procedure of transferring into the fallopian tubes of a woman (“woman A”) an embryo derived from an ovum produced by woman A, being an ovum that has been fertilised by the use of semen produced by a man who is not woman A's partner

“embryo (donor ovum) intra-fallopian transfer procedure” means a procedure of transferring into the fallopian tubes of a woman (“woman A”) an embryo derived from an ovum produced by another woman, being an ovum that has been fertilised by the use of semen produced by woman A's partner.

16. **Application of Part—**

- (1) This Part applies in respect of a pregnancy referred to in any of sections 17 to 22,—
 - (a) whether the pregnancy occurred before or after the commencement of this Part:
 - (b) whether or not the pregnancy resulted from a procedure carried out in New Zealand.
- (2) This Part applies in respect of a child born of a pregnancy referred to in any of sections 17 to 22,—
 - (a) whether the child was born before or after the commencement of this Part:
 - (b) whether or not the child was born in New Zealand.
- (3) Nothing in this Part affects the vesting in possession or in interest of any property that occurred before the commencement of this Part.

Rule about maternity

- 17. Woman who becomes pregnant is mother even though ovum is donated by another woman—
 - (1) This section applies to the following situation:
 - (a) a woman (“woman A”) becomes pregnant as a result of an AHR procedure:
 - (b) the ovum or embryo used for the procedure was produced by or derived from an ovum produced by another woman (“woman B”).
 - (2) In that situation, woman A is, for all purposes, the mother of any child of the pregnancy.

Rule about when non-donor partner is parent

18. When woman's non-donor partner is parent, and non-partner semen donor or ovum donor is not parent—

- (1) This section applies to the following situation:
 - (a) a partnered woman ("woman A") becomes pregnant as a result of an AHR procedure:
 - (b) the semen (or part of the semen) used for the procedure was produced by a man who is not woman A's partner or, as the case requires, the ovum or embryo used for the procedure was produced by, or derived from an ovum produced by, a woman who is not woman A's partner:
 - (c) woman A has undergone the procedure with her partner's consent.
- (2) In that situation, woman A's partner is, for all purposes, a parent of any child of the pregnancy.

Rules about donors of genetic material

19. Partnered woman: ovum donor not parent unless mother's partner at time of conception—

- (1) This section applies to the following situation:
 - (a) a partnered woman ("woman A") becomes pregnant as a result of an AHR procedure:
 - (b) the ovum or embryo used for the procedure was produced by, or derived from an ovum produced by, another woman ("woman B").
- (2) In that situation, woman B is not, for any purpose, a parent of any child of the pregnancy unless woman B is, at the time of conception, woman A's partner.

20. Woman acting alone: non-partner ovum donor not parent unless later becomes mother's partner—

- (1) This section applies to the following situation:
 - (a) a woman acting alone ("woman A") becomes pregnant as a result of an AHR procedure:
 - (b) the ovum or embryo used for the procedure was produced by or derived from an ovum produced by another woman ("woman B") who is not woman A's partner.
- (2) In that situation, woman B is not, for any purpose, a parent of any child of the pregnancy unless woman B becomes, after the time of conception, woman A's partner (in which case the rights and liabilities of woman B, and of any child of the pregnancy, are determined in accordance with section 23).

21. Partnered woman: non-partner semen donor not parent—

- (1) This section applies to the following situation:
 - (a) a partnered woman becomes pregnant as a result of an AHR procedure:

- (b) the semen (or part of the semen) used for the procedure was produced by a man ("man A") who is not her partner.
- (2) In that situation, man A is not, for any purpose, a parent of any child of the pregnancy.

22. Woman acting alone: non-partner semen donor not parent unless later becomes mother's partner—

- (1) This section applies to the following situation:
 - (a) a woman acting alone becomes pregnant as a result of an AHR procedure:
 - (b) the semen used for the procedure was produced by a man ("man A") who is not her partner.
- (2) In that situation, man A is not, for any purpose, a parent of any child of the pregnancy unless man A becomes, after the time of conception, the woman's partner (in which case the rights and liabilities of man A, and of any child of the pregnancy, are determined in accordance with section 24).

Rights and liabilities if non partner donor later becomes mother's partner

23. Non-partner ovum donor—

If, in the situation to which section 20 applies, woman B becomes, after the time of conception, woman A's partner,—

- (a) woman B has, in relation to any child of the pregnancy, the rights and liabilities of a parent of the child, but, in the absence of agreement to the contrary, those liabilities do not include liabilities incurred before woman B becomes woman A's partner:
- (b) any child of the pregnancy has, in relation to woman B, the rights and liabilities of a child of woman B, but, in the absence of agreement to the contrary, those liabilities do not include liabilities incurred before woman B becomes woman A's partner.

24. Non-partner semen donor—

If, in the situation to which section 22 applies, man A becomes, after the time of conception, the woman's partner,—

- (a) man A has, in relation to any child of the pregnancy, the rights and liabilities of a parent of the child, but, in the absence of agreement to the contrary, those liabilities do not include liabilities incurred before man A becomes the woman's partner:
- (b) any child of the pregnancy has, in relation to man A, the rights and liabilities of a child of man A, but, in the absence of agreement to the contrary, those liabilities do not include liabilities incurred before man A becomes the woman's partner.

25. **Only first non-partner donor to later become mother's partner becomes parent—**

Despite sections 20(2) and 22(2), a person cannot become a parent of a child under one of those provisions if another person has already done so through the application of the other of those provisions.

Glossary and Abbreviations

ACART or Advisory Committee	Advisory Committee on Assisted Reproductive Technology established under Section 32 of the Human Assisted Reproductive Technology Act 2004 as the Advisory Committee on Assisted Reproductive Procedures and Human Reproductive Research
ACC	Accident Compensation Corporation
ART	Assisted Reproductive Technology
COCA	Care of Children Act 2004
HDC Code of Rights	Code of Health and Disability Services Consumers' Rights
ECART or Ethics Committee	Ethics Committee on Assisted Reproductive Technology designated under Section 27 of the Human Assisted Reproductive Technology Act 2004
ERMA	Environmental Risk Management Authority New Zealand
GTAC	Gene Technology Advisory Committee of the Health Research Council
HART Act	Human Assisted Reproductive Technology Act 2004
HDS(S) Act	Health and Disability Services (Safety) Act 2001
HESC	Human Embryonic Stem Cells
HRC Ethics Committee	Health Research Council Ethics Committee
HSNO Act	Hazardous Substances and New Organisms Act 1996
IPRC Act	Injury Prevention, Rehabilitation and Compensation Act 2001
NEAC	National Ethics Advisory Committee established under Section 16 of the New Zealand Public Health and Disability Act 2000
NECAHR	National Ethics Committee on Assisted Human Reproduction
NZPHDA Act	New Zealand Public Health and Disability Act 2000
Operational Standard	Operational Standard for Ethics Committees, April 2006
Privacy Code	Health Information Privacy Code 1994
RTAC	Reproductive Technology Accreditation Committee, accreditation body of the Fertility Society of Australia
SCA	Sub-committee on Appeals convened by the National Ethics Advisory Committee
SCOTT	Standing Committee on Therapeutic Trials of the Health Research Council

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