ecart
Ethics Committee on
Assisted Reproductive Technology

25 September 2015

Martin Kennedy
Senior Analyst
Advisory Committee on Assisted Reproductive Technology
PO Box 5013
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Dear Martin

ECART has reviewed the proposed advice from ACART to the Minister of Health on Informed Consent and Assisted Reproductive Technology (ART). ECART is pleased that ACART is considering this area formally as informed consent is an especially important aspect of ART and further development and strengthening of this area would benefit all parties involved in the use of these technologies. ECART would like to thank ACART for providing this document for its consideration. As the committee that makes ethical decisions on applications for use of assisted reproductive technologies, ECART can offer comment informed by a practical experience for ACART's consideration.

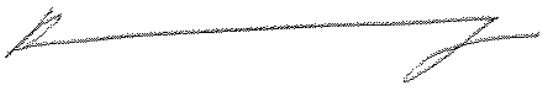
Overall, ECART agrees with ACART's advice throughout this document, namely that there is no issue about compliance from Fertility Service Providers and that current practice seems successful and well developed. However ECART considers that strengthening the area of informed consent would be valuable to all parties involved, especially with a view to reducing the risk of harm to donors, patients, their families, and whanau.

In considering this document, ECART notes the importance of keeping in mind the specific circumstances faced by those using ART technologies. The use of ART is emotionally fraught and costly, particularly for those who do not meet the funding criteria, have limited personal funds, and/or (for example) require several IVF cycles. ART is a hugely emotional and ethically complex area, and some people go to great lengths to have children. ECART stresses that any regulations or guidelines must be compassionate to the circumstances of those using ART.

Further, ECART notes that the impact of the use of these technologies has a substantial impact not only on the individuals using them and their family and Whanau, but also imposes a specific set of circumstances on children - not only the children created by the use of these technologies, but also the existing children of the donors or intending parents. One of the key principles of the HART Act 2004 (s 4(a)) is that the well-being of children born as a result of ART should be an important consideration in all decisions about that procedure. ECART suggests that evidence that children have been considered in the development of ACART's proposals is important and should be reflected in ACART's advice on informed consent to the Associate Minister of Health.

Again, ECART appreciates being involved in the consultation process and would welcome any further opportunity to comment on specific recommendations to the Associate Minister of Health.

Yours sincerely,



Iris Reuvecamp
Chairperson
Ethics Committee on Assisted Reproductive Technology

Question 1: Access to information that must be disclosed to patients and donors prior to consent

(a) Do you agree there is a need for better access to the information that must be disclosed to patients and donors prior to consent?

(b) Is there other information that should be given to patients and donors as part of the informed consent process?

Not only is consent to of the use of ART essential, it is important that this consent is fully informed. ECART agrees with ACART's emphasis on the importance of the availability of information to patients and donors as part of the informed consent process. This helps to ensure that consent is fully informed and facilitates protection of the interests of all parties to the processes of ART.

In general, ECART agrees that there should be ready access, at no cost to the individual, to information that must be disclosed to patients and donors prior to consent. However, ECART is of the view that simply making the Fertility Services Standard (The Standard) available may not be sufficient to ensure informed consent. The Standard is limited in its ability to facilitate informed consent for patients and donors as it is aimed at a professional rather than lay audience.

The Standard is not in a readily accessible format for public use as it is a facility provision service standard, not a guideline for service users. Further, ECART notes that the current Standard is copyright to Standards New Zealand and it would need to be made freely available for this to be practical. In any event, ECART suggests that the information already identified in The Standard as being required to be provided to consumers of fertility services should be considered a minimum requirement.

ECART suggests that, although in principle The Standard should be made freely available, it is also important to ensure more relevant guidelines are developed regarding the other information that should be provided to patients and donors as part of the informed consent process. ECART suggests that this type of information should be nationally standardised to ensure that all patients and donors are provided with the information necessary to ensure their consent is fully informed. This information should be aimed directly at patients and donors to ensure it is easily understandable.

ECART suggests that to develop information on the informed consent process ACART should consult widely, including with Fertility Service Providers, Child Youth and Family, the Ministry of Social Development, the Children's Commissioner, and the Health and Disability Commissioner. Potentially, such consultation may aid the inclusion of views of those who have undergone these procedures, as well as information specifically from the children created with ART.

In summary, ECART agrees with ACART's proposal that all essential information needed to help people make a decision should be available to patients and donors as part of the informed consent process. Although The Standard contains important information that should be available to all patients and donors about the standard of service provision, ECART argues that it is not sufficient to facilitate informed consent and should be combined with nationally standardised information that is directly aimed at recipients and donors (i.e. consumers of ART services), to ensure that all information necessary for fully informed consent is available. It is noted that along with standardised information true informed consent requires specific information that has been tailored to inform the actual parties involved (refer Right 5 of the Code).

Question 2: Form of consent

(a) Do you agree that consent to all assisted reproductive processes, where consent is required, must be in writing?

ECART agrees that all consent, any variation in consent and withdrawal of consent, should be in writing, with a provision for people who are unable to sign. It is important that significant thought is given to what should be included in consent forms in order to guide providers and consumers in addressing specific matters such as the parameters of consent. Therefore, it may be appropriate for specific guidelines or templates to be developed to ensure consistency across fertility service providers. Although ECART recognises that it is currently considered best practice by clinics to obtain written consent, it would help to protect everyone involved in ART for this to be an explicit requirement.

A nationally agreed consent form and information sheet could be combined. Whether they are then added to the Standard is another question as the Standard is a copyright provider developed and funded document.

ECART is interested to know whether ACART intends for any agreed national consent form to have the force of law or to be an industry agreed standard?

Question 3: Donor consent to use gametes or embryos for training purposes

(a) Do you agree that the consent of gamete and embryo donors should be obtained if their gametes, or embryos created from their gametes, may be used for training purposes?

Fully informed consent is essential to protect the welfare of donors, as well as to protect clinics. ECART agrees that donors must be informed of, and consent to, all of the ways in which their tissue may be used, including when it is used for training purposes. Therefore, ECART agrees that consent should be obtained for the use of gametes or embryos for training purposes.

Failing to obtain fully informed consent seems to conflict with Right 6, the right to be fully informed, of the HDC Code of rights (specifically right 6(1)(d) "Notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval"). Further ECART suggests that it also seems to conflict with Right 7 and 9 (Right to Make an Informed Choice and Give Informed Consent and Right in Respect of Teaching or Research).

ECART considers that it would be useful to clarify the circumstances in which gametes or embryos would be used for training purposes. For example, do they relate to all sperm, egg, or embryo donations, or just non-viable gametes and embryos? Could people opt out of the use of their gametes or embryos for training purposes?

ECART also considers that it would be useful to define 'Training Purposes' to ensure that this term is distinguishable from 'Research Purposes'. It is important that this distinction is clearly made to ensure donors understand how their gametes and embryos may be used. ECART also suggests it is important that donors understand what will happen to their gametes and embryos after training, specifically that they will be discarded and how. ECART suggests that ACART may wish to consult with the Royal Australian and New Zealand College of Obstetricians and Gynaecologists about what is considered current best practice.

In summary, ECART agrees with ACART's proposal that donor consent to the use of gametes or embryos for training purposes should be required, with the recommendation that 'Training

Purposes' is made clearly distinct from 'Research Purposes', and the definition of 'donor' is also clarified. Fully informed consent is an essential aspect of the provision of all health services, and is especially important in an area as emotionally and ethically complex as the use of ART.

Question 4: Placing conditions on donor consent

(a) Do you agree that donors should continue to be able to place conditions on their consent?
(b) If so, should there be any limits on the conditions placed?

Although the attitudes that lie behind discrimination are unethical and ought not to be supported within the health care system, gamete and embryo donation raises a particular set of circumstances. Because there is an expectation that donation will be open, and a possibility that any resulting child will have future contact with the donor, if the donation is made to recipients that the donor disapproves of for whatever reason, the potential for harm to individuals and relationships is very high. For these reasons ECART agrees that gamete and embryo donors should be able to continue to place conditions on their consent and that these conditions should be captured in the consent form. ACART may wish to include a provision that these conditions need to be reasonable and practical for action.

An alternative to allowing conditions to be placed on donations is to refuse donations that come with conditions. However, a restriction on who can donate may have an undesirable effect on:

(1) the donors, who may then need to dispose of embryos when they do not consider it appropriate to do so
(2) the availability of donor gametes and embryos, and
(3) the potential to cause donors to feel coerced into agreeing to donations to people that they would prefer to not donate to, which may have adverse effects on later relationships and potentially on any resulting child.

Therefore, although ECART may not agree with the reasons donors may have for discriminating by placing conditions on their consent, in practice, ECART agrees that there should not be limits on the conditions donors can place on their consent (except that they must be reasonable and practical).

ACART may wish to consider further the legal status of any conditions imposed on donation, including who is responsible for compliance with the conditions imposed; how compliance is monitored; and how any breaches are dealt with.

Question 5: Ongoing information for donors on the use of their gametes

(a) Do you agree that gamete donors should be given the option of receiving ongoing information on the use of their gametes for the following situations:

(i) if the gamete is about to be used?

(ii) on the outcome(s) of the donation?

(b) Is there any other information that you think should be offered to gamete donors after consent has been given?

ECART understands that this question is about the ongoing provision of information and that it is not necessarily related to the ability of the donor to withdraw their consent after 'the point of no return'.

ECART agrees that donors should receive ongoing information each time a recipient has a child and that this be an 'opt- in' option for donors rather than a requirement for fertility providers to contact donors.

ECART notes that section 60 of the HART Act provides that fertility providers must tell donors, at a donor's request, about any known births using their donation and also the sex of the child and ECART understands that this is current clinical practice.

ECART notes that placing the onus on fertility providers to inform the donor each time their donation was about to be used in treatment would be impractical and not reasonable for either the recipient of the donation or the fertility provider and would place an administrative burden on the fertility provider.

Providing donors with ongoing information about children born of their donation would also emphasise the necessity to get fully informed consent from donors at key decision points in the IVF process, especially to ensure that they are fully informed regarding the 'point of no return' after which they can no longer withdraw or vary their consent.

Question 6: Withdrawal or variation of consent by donors

(a) Do you agree that gamete donors should be able to withdraw or vary consent to the use of their gametes up to the point of fertilisation?

(b) If not, when do you consider the 'point of no return' should be?

ECART agrees that the current 'point of no return' provisions work well and that gamete donors should be able to withdraw or vary their consent up to the point of fertilisation and embryo donors, up to the point of transfer to the uterus.

However, although in practice this 'point of no return' seems to work, ECART considers that it would be beneficial to have the arguments for fertilisation being considered the 'point of no return' more fully explored and documented and a formal definition given. The definition should be provided and explained to all donors as part of the informed consent process.

ECART notes that donors may have an ongoing interest in the outcome of their donations, especially as they can create ongoing intergenerational relationships. Although it is possible that any given donor's views on their consent may not change, it is equally possible that due to changes in their circumstances and personal beliefs their views on the use of their gametes may change and they should be offered all information necessary to alter or withdraw their consent should this occur.

Question 7: Consent of a partner, family or whānau to donation or use of donor gametes

(a) Do you agree that the consent of partners to the donation or use of a donor's gametes should not be required?

(b) Do you agree that the consent of family or whānau to the donation or use of a donor's gametes should not be required?

Donation of gametes

The use of ART and donation of gametes is often deeply personal, involving complicated emotions and motivations. Although the inclusion of partners, families, and whanau should be encouraged, ECART agrees that an individual's autonomy over the use of their body and gametes should not be restricted by the lack of consent from another party. Individual autonomy

currently underpins our health system and a requirement that consent be obtained from partners, family or whanau would fundamentally undermine that principle.

ECART feels that in the case of the donation of gametes, partner, family, or Whanau consent should not be required. Although it is considered that consultation with a donor's partner, family or Whanau is desirable, a decision not to do so should not prevent an individual donating their gametes.

Donation of gametes does have some risk of harm to a non-consenting partner, family, or Whanau (for example, the donation may lead to their partner becoming infertile, or to a child being created who later wishes to develop a relationship to their biological family), however, this risk of harm is not sufficient to warrant restricting an individual's autonomy.

Use of donated gametes

ECART recognises that the use of donated gametes without consent from partners, families, or whanau has a greater potential for harm, not just to these non-consenting parties but also to the child who is created from these donated gametes. This risk of harm especially threatens the autonomy of the non-consenting partner as it may cause them to become a parent against their will. Although the non-consenting partner would not necessarily become a legal parent against their will (our understanding is that The Status of Children Act 1969 18(1) (c) states that the woman's partner is the legal parent of a child created with donated gametes only if they consent to the woman undergoing the procedure); social and emotional parenthood may be forced upon them. Further, there may be an unreasonable burden of proof on the unwilling partner as the Status of Children Act 1969 (27(1)) suggests that the partner's consent is presumed unless evidence to the contrary is produced.

ECART recognises that an individual who does not require the use of ART and donated gametes could become pregnant without their partner's consent, and that requiring the consent of partners for the use of ART could restrict some individual's autonomy more than others. However, they also recognise the significant potential for harm to both the non-consenting partner and the child created if an individual becomes pregnant without the partner's consent. This harm could be further increased if the non-consenting partner is not biologically related to the child created, such as through the use of donated gametes. Therefore, ECART argues that ACART should carefully consider the ethical principles involved in such circumstances when developing its guidelines.

ECART suggests that the views of Child Youth and Family, the Children's Commissioner, and the Ministry of Social Development should be sought, as well as others, once ACART begins to consider the development of its guidelines, as they will have a particular insight into the impact of these technologies, including the expanding definitions of family. In our view, their input would benefit the discussion regarding informed consent and ART.

Question 8: Couple disputes about the future use of embryos

(a) Do you agree that where one party in a couple disputes the future use of embryos that have been created for them, there should be a 'cooling-off' period of 12 months – and if not, why not?

(b) Do you agree that, if the couple cannot agree about the use of the embryos within that period, the embryos should be disposed of – and if not, why not?

ECART notes that this is a particularly contentious area as individuals using ART are often at the end of a long and emotional road. They may have suffered through infertility and/or traumatic pregnancies, have invested significant time and financial resources, and at the stage where this proposal becomes relevant may be at the end of a meaningful relationship. Destroying embryos

against the wishes of one of the intending parents could deprive an individual of their only chance of having a biological child. However, this must be balanced against the harm of forcing one partner to become a parent against their will. Therefore, although ECART realises that there is also a practical aspect of this discussion, any decision regarding these cases needs to be particularly sensitive to the individual's circumstances.

ECART agrees with the idea of a 'cooling off' period when a couple disputes the future use of embryos. ECART is interested to know when the cooling off period might be reasonably expected to commence within the IVF process and requests that the commencement and ending of such a period needs defining.

ECART notes that a cooling off period, if implemented, could result in other difficulties. For example, one party may hold this period as a threat to achieve other gains in a relationship breakdown. ECART thinks that a 12 month period seems too short considering the potential circumstances (for example, a couple dealing with the grief and stress of infertility combined with a marriage breakdown). Therefore, ECART suggests a cooling off period alone may also be insufficient to avoid the potential harms from dispute over the future use of embryos. Accordingly, ECART suggested that any cooling off period should be combined with the requirement for the couple to attend mediation or counselling to attempt to reach a mutually agreeable resolution.

ECART suggests that another possible solution may be the retention of gametes from both partners at the time of collection to retain the options for future use of personal genetic material should the relationship break down. However, ECART understands that the functional and technical difficulties that this suggestion may raise could make it unachievable.

The ECART Secretariat also notes that the practical implications of any such cooling-off period could be substantial. For example, if this cooling-off period coincides with the storage limits for gametes and embryos this could cause significant difficulties if both partners do not agree to their extended storage. It would be impractical, and undesirable, to continue storing embryos beyond their lawful storage period if the couple cannot agree on their use. Therefore, the options become allowing them to be used by the individual wishing to use them, and forcing unwanted parenthood on the objecting individual, or discarding the embryos. ECART agrees that if the couple cannot agree about the use of the embryos within a lawful period, the embryos should be disposed of. Although this may cause some harm to the individual unable to use these embryos, especially since they may hold their last opportunity to have biological children, ECART considers this harm less than that would be caused to their ex-partner if they were forced into parenthood.

Similarly, consideration should be given to the person responsible for paying for continued storage. The costs associated with counselling and/or mediation, and who would be responsible for those, would also need to be considered.

Question 9: Form of requirements for informed consent

(a) Do you agree that requirements for informed consent should be set out in regulations?

ECART feels that it would be more appropriate to have the requirements for informed consent set out in formal guidelines, which can be more easily modified as new technologies are developed. Specifically, ECART notes that a complaint and enforcement regime would need to be established which is potentially costly and may create a burdensome regulatory environment.

Question 10: Comments or suggestions

(a) Do you have any general comments or suggestions about the requirements for informed consent?

(b) Do you have any other comments or suggestions about the issues discussed in this consultation document?

The use of ART is emotionally fraught and costly, particularly for those who don't meet the funding criteria, have limited personal funds, and/or require several IVF cycles. The use of ART is a hugely emotional and ethically complex area. Some people go to great extents to have a child and they are likely to experience emotional, physical and financial turmoil. Therefore, ECART stresses that any regulations or guidelines must be compassionate to the circumstances of those using ART.

One of the key principles of the HART Act 2004 (s 4(a)) is that the well-being of children born as a result of ART should be an important consideration in all decisions about that procedure. However, there is little mention of this principle in the consultation document. ECART suggests formal consultations with other organisations, such as the Children's Commissioner, is considered, if it has not yet occurred.