ecart
Ethics Committee on
Assisted Reproductive Technology

19 July 2016

ACART Secretariat
Advisory Committee on Assisted Reproductive Technology
PO Box 5013
WELLINGTON

Dear ACART secretariat,

ECART has reviewed the proposed advice from ACART to the Minister of Health on the use of cryopreserved ovarian tissue to restore ovarian function and that it become an established procedure. As the decision-making committee that reviews the ethics on assisted reproductive procedures and research, ECART is pleased to have the opportunity to give its views on your proposed advice.

ECART appreciates the quality of advice in the document that ACART has summarised and ACART's consideration of the issues, and overall, supports ACART's advice to make the use of cryopreserved ovarian tissue to restore ovarian function an established procedure. ECART agrees with ACART's analysis that the identified risks and ethical issues are acceptable, and would not require ethical oversight by ECART. ECART would like to note that although established procedures are by definition unlikely to raise significant ethical issues, ECART is able to provide non-binding ethical advice to clinics on established procedures when requested.

ECART agrees with ACART's position that at this time the scope for the use of cryopreserved ovarian tissue to restore ovarian function be limited to women from whom the tissue was excised for their own treatment.

Section 5: Ethical Analysis

ECART agrees with ACART's view that the use of cryopreserved ovarian tissue to restore ovarian function is consistent with the ethical principles of the HART Act 2004, despite there being unconfirmed implications and data uncertainties for the health and wellbeing of women and children born.

ECART notes a key ethical issue is in regard to informed consent, particularly in relation to the areas of risk and benefit analysis where much is yet unknown, (as detailed in the ACART consultation document). However, provided that the risks, benefits and uncertainties are made clear to patients as part of the consent process, ECART would support the proposed use becoming an established procedure as recommended by ACART.

ECART supports fully a robust informed consent process and would like to be reassured that all essential information needed to help people make a decision be made available to patients from the time that the taking and cryopreserving of the tissue is presented as an option. ECART notes that true informed consent requires information to be communicated in a form, language, and manner that enables the consumer to understand the information provided (refer Right 5 of the Health and Disability Commissioner Code of Rights).

As well as echoing inclusion of the points of discussion detailed in paragraph 89 of ACART's document, ECART suggests that the information presented include the storage and use costs involved as well as the probabilities of success, benefits and risks. ECART notes that given that it is likely that some time will elapse between the taking of tissue and using it, costs may accrue for the woman and or her family. There will also be emotional investment in the hope that the tissue will restart the hormonal cycle with its benefits of fertility and avoiding early menopause. In ECART's response to ACART's Informed Consent and Assisted Reproductive Technology consultation document (Question 9: Form of requirements for informed consent), we recommended that the requirements for informed consent be set out in formal guidelines, which can be easily modified as new uses of assisted reproductive technology are developed.

For the reasons relating to the risk and benefit analysis set out in ACART's document, ECART agrees with ACART's position that the scope for use of cryopreserved ovarian tissue to restore ovarian function be limited to women from whom the tissue was excised for their own treatment at this time.

With reference to the document's discussion around 'Justice and equality', set out in paragraph 96, ECART notes that while the issue of equity around people being able to afford to store and use cryopreserved ovarian tissue is briefly discussed, this paragraph could be seen as minimalizing or ignoring the fact that the storage and use of ovarian treatment may be an option for only those who can afford to pay.

ECART acknowledges that while resource allocation itself lies outside of ACART's jurisdiction, if ACART has not already done so, it may wish to seek parallel Ministry advice on funding and accessibility of this treatment service from an oncology service to IVF perspective, including potential future demand. If there are exceptions on clinical grounds, e.g. Leukaemia, then this should be explained as part of any planned funding criteria.

Section 6: Conclusion: Proposed advice to the Minister of Health

ECART notes in the executive summary the statement that if the Minister approves the use of cryopreserved ovarian tissue to restore ovarian function as an established procedure, ACART will keep a watching brief on international developments and reported findings in the use of cryopreserved ovarian tissue.

ECART would like to add that given that this is a relatively new addition to the repertoire of ART related practices, ACART should encourage NZ fertility clinics to work with oncologists and IVF specialists to collect as much information as they are able to over time to provide further information about the uptake of this procedure and its success or otherwise in the New Zealand context. ECART anticipates as part of routine clinical practice, audit will be conducted for this new procedure.

ECART notes the document states at paragraph 100 that a woman may choose to donate her stored cryopreserved ovarian tissue for research purposes and that the subsequent use of ovarian tissue for human reproductive research will require further ECART approval; and notes its understanding that the current research guidelines are limited to research on non-viable gametes and embryos at this time.

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

Yours sincerely,