Feedback form

Please provide your contact details below.

Name:	**John Kleinsman PhD & Sue Buckley**
If this feedback is on behalf of an organisation, please name the organisation:	**The Nathaniel Centre:** **The New Zealand Catholic Bioethics Centre**
Please provide a brief description of the organisation if applicable:	
Address/email:	**PO Box 12243** **Wellington 6144** email: **administrator@nathaniel.org.nz**
Interest in this topic (e.g. user of fertility services, health professional, researcher, member of public):	**The Nathaniel Centre is an agency of the New Zealand Catholic Bishops' Conference. Its role is to address bioethical and biotechnology issues on behalf of the Catholic Church in New Zealand.**

Please refer to page v for information about:

- Publication of feedback on ACART's website
- Official Information Act requests – possible release of you feedback
- Official Information Act requests – possible release of you name and contact details

We will acknowledge all feedback.

☐ I **request** that my feedback be withheld in full or part from publication on ACART's website. (If you wish a part to be withheld, please clearly indicate which part.)

☐ I **do not** give permission for my name to be published on ACART's website.

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If you consider that your feedback, or your name and contact details (if you are submitting on behalf of an organisation), should be withheld under the Act, please state the reasons here:

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Questions for response

Question 1

Refer to sections 3 and 4.

(a) Do you agree with ACART's assessment of the known risks and benefits to health associated with the use of cryopreserved ovarian tissue to restore ovarian function?

Yes [√] No [ ]

Please give reasons for your views.

The Consultation document provided a balanced overview informed by a thorough independent report.

(b) Are there any risks and/or benefits associated with the use of cryopreserved ovarian tissue to restore ovarian function that ACART has not identified or assessed?

Yes [ ] No [√]

If yes, please list below.

Question 2

Refer to section 4.

(a) Do you agree with ACART's conclusion that the risks associated with the use of cryopreserved ovarian tissue to restore ovarian function falls within a level that is acceptable in New Zealand?

Yes [√] No [ ]

Please give reasons for your views.

[ ]

(b) Please note any other comments below.

[n. 84, p. 18, mentions 'risk reduction measures', but these are not identified. While we agree with the conclusion that the known risks associated with the use of cryopreserved ovarian tissue fall within an acceptable limit, we would like to see 'risk reduction measures' identified and considered with a view to promoting consistency of practice according to the highest possible standards throughout New Zealand. We believe this should be part of the ongoing monitoring brief taken on by ACART (n. 102, p. 23).

Even though the equipment for the procedure is readily available in New Zealand and relatively "low cost", we would like to see serious consideration given to the suggestion that one laboratory carry out the actual cryopreservation procedure for the whole country in order to maximise the necessary expertise and experience required and rather than "many centres doing a few cases and nobody obtaining good experience and expertise" (see D.23, p. 59).]

Question 3

Refer to section 4.

(a) Has ACART identified all the relevant areas to monitor the use of cryopreserved ovarian tissue to restore ovarian function?

Yes [√] No [ ]

Please give reasons for your views.

(b) Are there any other areas ACART should monitor?

Yes [√] No [ ]

Please give reasons for your views.

We understand that there is still some uncertainty surrounding the procedures related to a lack of information about long-term outcomes. For this reason it is critically important that ACART continue to monitor international developments (n. 77, 102) including long-term follow-up and data collection on outcomes. We would also like to see ACART (or another health-related body) take on the role of collecting and reporting on specific data on treatment outcomes within New Zealand including, as far as is possible, future fertility rates (even if it will be impossible to determine if subsequent pregnancies derive from the endogenous stores of follicles or from the transplanted tissue – see C.20.4.2, p. 55).

Question 4

Refer to section 5.

(a) Has ACART identified all the ethical issues relevant to the use of cryopreserved ovarian tissue to restore ovarian function?

Yes [ ] No [√]

Please give reasons for your views.

It appears that ovarian tissue freezing is still not publicly funded and that women seeking fertility preservation after diagnosis will continue to be referred to private fertility clinics. There is, clearly, a financial incentive for these clinics to encourage women to store ovarian tissue. In view of this, our preference is that the storage of tissue be handled within the public health system.

We believe that this will also be more equitable for women who might otherwise lack the financial resources necessary to pay for storage costs. A woman's future fertility, as well as the other benefits of ovarian storage and transplantation, should not depend on her socio-economic status (see our additional comments in Question 7, below).

(b) Do you agree with ACART's ethical analysis that there are no significant ethical issues associated with the use of cryopreserved ovarian tissue to restore ovarian function?

Yes [√] No [ ]

Please give reasons for your views.

The processes associated with providing full information and gaining consent will be particularly important to consider in cases where children are involved and where there is the potential for disagreement between parents/guardians and a child/young person or between parents/guardians of a child/young person regarding the necessity (or even affordability) of such treatment. The implications for future fertility decisions are permanent and of such a serious nature that thought should be given to providing independent counselling in these cases.

Question 5

Refer to section 6.

(a) Do you agree that the use of cryopreserved ovarian tissue to restore ovarian function should become an established procedure?

Yes [√] No [ ]

Please give reasons for your views.

The Consultation Document notes that the benefits of restoring ovarian function are much wider than the restoration of fertility. Consequently, as the procedure becomes more common worldwide, and presuming there are no significant negative outcomes discovered, we believe there will be a good case for regarding the removal, storage and transplantation of ovarian tissue as a standard part of the 'treatment' of all women undergoing cancer treatments that are potentially gonadotoxic (see also our comments in Question 7 below).

(b) Please note any other comments below.

An *unintended* consequence of making the procedure an "established" one is that it might send a message to women that there are few if any risks involved when in fact the information that we currently have is based on a relatively small number of cases over a relatively short time span.

While we agree that, on balance, the benefits outweigh the risks, it is critically important that women are fully informed about the current level of uncertainty. The information they receive at the time of surgery (both removal and transplantation) should reflect the latest developments related to cryopreservation and transplantation – both the broader health benefits as well as information concerning pregnancy rates and the known outcomes for children born from cryopreserved ovarian tissue.

In addition, because the information is currently limited, we believe there should be a system of notification/communication set up whereby women who have *previously* gone through the process of having excised tissue transplanted back *continue to be provided with any new information as it comes to hand*, particularly any potentially significant developments relating to risks and benefits.

Question 6

Refer to section 6.

Do you agree with ACART's position that the scope for the use of cryopreserved ovarian tissue to restore ovarian function be limited to the woman from whom the tissue was excised, for her own treatment?

Yes [√] No [ ]

Please give reasons for your views.

There are clear medical reasons for limiting the use of cryopreserved ovarian tissue to the woman from whom the tissue was excised, specifically the potential for introducing malignant cells into a woman's body that could lead to cancer.

In addition, a situation involving the transplantation of donated ovarian tissue from a 'healthy' woman to a third party raises additional and unique ethical issues of a medical, ethical, cultural and spiritual nature related to the introduction of a genetic 'third party' that are not fully explored in the Consultation Document. While third party gamete donation for IVF is already allowed in New Zealand, it should not be assumed that the issues related to consent and knowledge of genetic origins would be exactly the same in the case of donated ovarian tissue donation. Such issues would need to be explored as part of a separate consultation.

Question 7

Refer to section 6.

Do you have any further comments to share with ACART?

In some parts of the Consultation Document, including in the title, the gathering, storage and transplantation of ovarian tissue is referred to in terms of 'restoring ovarian function'. In other parts of the Document the procedure is described more narrowly as 'fertility preservation'. As noted above, given the multiple health benefits of tissue removal and then transplantation – most notably the return of endocrine function and the regaining of menstrual cycles which can assist in delaying the onset of osteoporosis and other menopausal related conditions (n. 48) – we believe there is a strong case for regarding the process as a standard part of the 'treatment' for all women requiring health interventions that are potentially gonadotoxic. For this reason we suggest that the procedure should ultimately be more broadly promoted as an element of the 'best practice' treatment in such circumstances, *rather than as a specialised procedure aimed primarily at restoring the fertility of women for whom fertility is important*.

This constitutes for us a further reason why the storage of such tissue should be handled within the public health system rather than directly by Fertility Clinics (see Question 4a above).

We are particularly concerned that, if freezing and storage costs associated with the procedure are <u>not</u> covered by a DHB, as currently seems to be the case, the benefits of ovarian tissue transplantation (both fertility and other health-related benefits) may be available only to those with the financial means to pay such costs. This we think constitutes an unjust state of affairs. We would like to see both the surgical and storage costs covered by the New Zealand health system for all women likely to benefit from the transplantation of cryopreserved ovarian tissue.