ACART Consultation on Informed Consent.
Submission by Anne Else.

Feedback form

FROM DR ANNE ELSE, MNZM
Please provide your contact details below.

Name:	Dr Anne Else
If this feedback is on behalf of an organisation, please name the organisation:	This is my individual response. I am also a member of Adoption Action Inc.
Please provide a brief description of the organisation if applicable:	
Address/email:	
Interest in this topic (eg, user of fertility services, health professional, researcher, member of the public):	Researcher and writer on adoption and ART

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Questions for response

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?

To ensure informed consent as far as possible, those giving consent need to be informed, and be seen to be informed, about particular points of essential information. This requires standardised consent forms. The form of consent needs to make it as clear as possible that the donor (whether of gametes, embryos, or pregnancy and birth – see below) has been given and has understood the information. All clinics must have an obligation to provide this information, which needs to include areas other than medical, e.g., legal information.

Yes [X] No [ ]

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

It is not at all clear what information is currently given, particularly in areas other than medical. Even the sub-report on "Informed consent: clinic policies, rules and processes" (March 2015) (the sub-report) does not cover this clearly. See comments below and on Question 2.

Yes [X] No [ ]

Please give reasons for your views.

The extracts from the Standard included in the consultation document make it difficult to get a clear idea of what information is currently given and the sub-report does not make this clear either. I would like to see examples of the information currently given, to see what is conveyed about, for example, donor identification or consequences following surrogacy.
The glaring omission in both the consultation document and the sub-report is surrogacy. Intending surrogates' clearly informed consent to undergoing the procedures required, on the basis of being fully informed about these and also about the consequences of pregnancy, gestation and birth in this situation, is just as important, if not even more so, as it is for gametes or embryo donors. The birth mother is in fact donating the reproductive process itself. There is no clear indication in this document or the sub-report of what information is currently given to women being asked to act as surrogates, or what proof of their informed consent is required before applications are approved by ECART (other than simply being told by the applicants that the woman has been fully informed and has freely given her consent – a process very similar to the consent provisions in the 1955 Adoption Act, which completely fail to meet current concepts of informed consent.)

Question 2: Form of consent

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

Fully informed consent in writing is of central importance to all forms of medical treatment. The Cartwright Inquiry established very clearly that the use of all medical procedures, and of human materials, must have the written informed consent of those on whom they are performed and/or from whom they are obtained. In the case of ART, where that treatment involves the use of other people's gametes and/or their reproductive capacities for the creation of a child, thereby creating permanent genetic or biological links, fully informed consent is even more important.

Yes [x] No [ ]

(b) Do you have any other comments?

A standard form of consent, which includes a list of the basic items of essential information provided, is urgently required. This does not preclude clinics adding other items if they wish, and of course if legislation alters, the forms may need to be revised.

Yes [x] No [ ]

The form of consent also needs to includes an “I” statement that the person consenting has been fully informed about the stated list of the major points, including the legal ones, relating to the proposed procedure(s) and the outcomes, and has understood this information and its implications. In the case of surrogacy, the required information must include the legal provisions. This is already indicated in the Guidelines on Surrogadcy involving Assisted Reproduction Procedures (the Guidelines) – see concluding comments.

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?

Yes [x] No [ ]

(b) Do you have any other comments?

The overall issue of what information donors receive, or are offered, or understand that they have a right to receive if they so wish, about the subsequent use of their gametes stands out in the sub-report as an area needing urgent attention.

Yes [x] No [ ]

Please give reasons for your views.

See responses on question 5.

Question 4: Placing conditions on donor consent

(a) Do you agree that donors should continue to be able to place conditions on their consent?

Yes [x] No [ ]

(b) If so, should there be any limits on the conditions placed?

I agree with the limits suggested in the discussion document.

Yes [x] No [ ]

(c) Do you have any other comments?

Donating gametes and embryos, and providing gestation and birth for others which includes the birth mother's own egg, create permanent genetic links to future children. A lasting biological and personal history connection is created by surrogacy. Both donors and intending surrogates therefore need to be able to place conditions on their consent.

Yes [ ] No [ ]

Please give reasons for your views.

See last box c. above.

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?

They also need to know that they have a right to this information, and their avowal that they have been told of this right should be included in the consent form.

Yes [x] No [ ]

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

They also need to know that they have a right to this information, and their avowal that they have been told of this right should be included in the consent form.

Yes [x] No [ ]

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

All donors (not a limited subset chosen by the clinic, as shown in the sub-report) should also be able to receive some information about the recipients where offspring result, and should have this explained to them as part of the consent process. The donor's right to information about uses, outcomes and recipients needs to be explained to them as part of the information process, and also included in the consent form itself, although they may of course choose not to exercise this right.

Yes [x] No [ ]

Please give reasons for your views.

According to the evidence in the sub-report, informing donors about uses and outcomes, and also about recipients, or even informing them about their right to obtain such information, appear to have no consistency in current practice. The information given also appears to vary, at the clinics' discretion, between egg donors and sperm donors (based perhaps on vague assumptions about gender differences – no reasons for this variance are given). The provision of information about recipients, in particular, appears to be inconsistent and confused, varying according to the gender of the donor and also whether it is gametes or embryos which are being donated.
None of this appears to ensure that all donors fully understand the implications of donating in order for a child to be created (though this may not eventuate). It is not well designed to ensure that donors understand the provisions of the HART Act, or fully convey the fact that if offspring result, a permanent genetic link is created which the offspring may wish to know more about in the future. Donors also need to have the right to be informed about what happens to their gametes if they are not used, or are used for training purposes (as discussed above). Information gathered from donors appears to be another grey area which does not ensure that the rights and interests of donors, recipients or future offspring are well served.

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?

Yes [x] No [ ]

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

Yes [ ] No [ ]

Please give reasons for your views.

The reasons are well argued in the consultation document and seem to be well considered in the sub-report.

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?

I agree, with the important proviso that, in cases where the two people concerned are already the joint parents of other children, that other parent definitely needs to know what is proposed, as any resulting children will be related to the existing ones. Clinics need to ensure that the other parental partner has been informed.
In cases of surrogacy, however, the consent of a co-parent living with the family does need to be obtained as surrogacy has major impacts on the family and may have major unforeseen consequences.

Yes [x] No [ ]

(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?

In the case of existing children, their knowledge is required rather than their consent. However, as definitions of "family" and "whanau" vary considerably, informing adult family members other than co-parents needs to be left up to the donors or intending surrogates.

Yes [x] No [ ]

Please give reasons for your views.

Where an intending donor or surrogate already has children (as all intending surrogates will, according to the Guidelines), the creation of genetically related children affects both the partners and their existing children. The children need to know what is happening (although their consent is not required) and in this case the other parent also needs to know. In the ECART minutes, many of the applications comment on the need for existing children to know what is going to take place. It is not feasible to imagine that children can be told, but their other parent does not need to know. There seems to be currently no provision for ensuring that intending donors and/or intending surrogate birth mothers do in fact inform their children and parental partners. In my view, evidence that they have done so (and provision of counselling services if wanted) should be required. Family secrets have long bedevilled adoption and done much harm. They should be avoided as much as possible in ART situations.

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?

A cooling off period could be helpful – however, it may not resolve the situation.

Yes [x] No [ ]

(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?

Yes [x] No [ ]

Please give reasons for your views.

It is not in anyone's interests for children to be born, or embryos donated, against a genetic parent's wishes. Difficult situations will arise, such as where one or other partner has had their fertility destroyed by illness (or treatment), so that the existing embryos are their only hope of their own genetically related child. But even so, unless there is agreement from the other partner (whose child it will also be), the embryos should not be used.

Question 9: Form of requirements for informed consent

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

Yes, as fully and clearly as possible. I was really shocked to find that this had not yet been done for ART procedures. In particular, simply reporting that fully informed consent has been obtained is not sufficient. This must be shown via an "I" statement to that effect being included in the signed consent form. The requirements must include a comprehensive list of the basic information given.

Yes [x] No [ ]

(b) Do you have any other comments?

ECART needs to be satisfied there has been no coercion, and this is recorded in the minutes. However, I was unclear as to how this is determined. There is no indication in the sub-report as to how this is actually done at clinic level (though it is noted as being very important). One useful approach would be to have consent forms include a clear "I" statement declaring that no coercion was involved and that the person is consenting of their own free will.

Yes [x] No [ ]

Please give reasons for your views.

While it is never possible to ensure beyond all possible doubt that consent is indeed freely given and is fully informed, clear regulations about the forms of consent required, preferably with outline forms and fully including surrogacy, would go as far as possible toward ensuring that this is the case.

Question 10: Comments or suggestions

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

As the consultation document notes, ART donations are different from others, because they may lead to the creation of a new person. It is in the interests of donors, the resulting children, the intending parents and society generally that the genetic links created through ART are recognised, rather than being automatically hidden (as the now superseded legislation on donation originally ensured).

Surrogacy involves the donation of pregnancy and birth; however, intending surrogates were excluded from the "donor" category in the ART legislation. The ECART committee minutes make it clear that the committee is now dealing with a considerable number of surrogacy applications – a total of 21 in 2014, for example. Yet they are scarcely mentioned in the consultation document or in the sub-report on clinic policies, rules and processes.

Agreeing to become involved in surrogacy requires agreeing to invasive medical procedures and subsequently donating pregnancy and birth. Even where this involves an embryo which has no genetic connection to the birth mother, it is in fact a major, complex form of ART-related donation. The complexities are clearly revealed in the ECART minutes. Some of the reservations apparent in the minutes, such as concern over the ramifications of using an adopted daughter as a surrogate, could be dealt with more transparently if comprehensive forms of consent were prescribed. The consent form signed by the intending surrogate needs to show that when she consented to her involvement and to the procedures she was fully informed of the implications and possible problems.

The Guidelines on Surrogacy involving Assisted Reproductive Procedures include this paragraph:

(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;

But they give no guidance as to how this should be done in relation to the complexities of surrogacy. There appears to be undue reliance on the consent to adoption required in such cases.

Nor do they indicate how ECART is to ascertain "whether legal reports indicate that the parties clearly understand the legal issues associated with surrogacies" (see Guidelines). There is cause for concern in this respect, since the sub-report does not indicate that legal aspects are routinely and effectively covered at present. A comprehensive signed consent form incorporating "I" statements is the best form of evidence that this is the case.

With regard to the prohibition on commercial surrogacy and on payment of anything other than reasonable costs, the consent forms should also be required to include a declaration by those centrally concerned – the woman and the intending parents – as to what payment, if any, has been made and what it covers.

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

ECART and surrogacy

The ART legislation implied that ECART's approval was required in all proposed uses of surrogacy. Yet with regard to socalled "natural" surrogacy, which involves the birth mother's own egg, I understand that ECART's approval is in fact now not required, because this is seen as an established procedure. The committee is asked to give advice only. It is not clear, however, whether ECART's advice in such cases is in fact required to be sought.

"Natural" surrogacy is not an established procedure in any sense other than the strictly technical. It is arguably even more complex, in terms of psychology and social relationships, than surrogacy which does not involve use of the birth mother's egg. Meticulous checking of fully informed consent is just as important in such cases as in any other form of ART procedure overseen by the committee, yet this is apparently not required. The concerns raised by ECART about some of the applications before it – for example, with regard to the birth mother's health, or family relationships and knowledge - would seem to be just as likely to arise in cases of "natural" surrogacy. There is, in my view, a strong case for regulation relating to this situation – for example, ECART routinely being required to ascertain, at the very least, that the intending "natural" surrogate has indeed been fully informed and has freely consented to proceed, by the provision of a comprehensive signed consent form.

Some of the applications proposed involving overseas intending surrogates, and this was accepted. Commercial surrogacy, like commercial gametes donation, is common overseas, and unlike in NZ, such arrangements commonly exclude any consideration of the child's need in future to identify his or her progenitors. I am surprised to see ECART's apparent lack of concern about approving such applications, beyond mentioning the need to heed immigration requirements. There seems to be a need for some kind of clear statement about the reasons for the NZ provisions on donor identification and the adoption of children born through surrogacy, with regard to their protecting the right to know the identity of (a) one's progenitors and (b) one's offspring or birth children.

However, reform of the 1955 Adoption Act is also urgently required in this respect. Adoption law continues to provide for new birth certificates showing the adoptive parents as the child's original birth parents, one of the many outdated and dysfunctional provision in the 1955 Act. Unfortunately this also applies in cases where the birth mother is acting as a surrogate for the intending parents; however, at least the provisions of the Adult Adoption Information Act ensure (provided the child knows of the adoption) that the birth mother's identity will be available if required. I support a form of full birth certificate (available only to those directly concerned) which clearly shows the involvement of all donors, including birth mothers acting as surrogates and in some cases also as egg donors. Such a certificate would protect against, for example, loss of clinical records and the proliferation of family secrets in relation to ART.