ACART Consultation on Informed Consent.
Submission by Debra Wilson.

Feedback form

Please provide your contact details below.

Name:	Dr Debra Wilson
If this feedback is on behalf of an organisation, please name the organisation:	
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. Senior Lecturer in Law, University of Canterbury

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We will acknowledge all feedback.

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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?

Yes [X] No [ ]

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

Yes [X] No [ ]

Please give reasons for your views.

a) The Fertility Services Standard (88 pages) can only be purchased ($61-68) or viewed on site. One would imagine that its language is not something able to be easily skimmed or understood by the average person seeking IVF. Some form of lay person's guide should be available to be read at a location of the person's choosing- one that is a less stressful environment than a clinic. This is arguably required under the requirements in the Code of 'effective communication'.

b) Rights of other parties. It should be made very clear that others can withdraw consent. Learning from overseas cases, the main issues that arise are:

- Where both parties agree in writing that even after a relationship breakdown one party can still use the frozen embryos. Then, one changes their mind. The other party may be unaware that the agreement is not binding or enforceable (Evans, also an anecdotal NZ case I was asked to advise on)
- Where one party states that even if they die, they wish the embryos to be used by the other party (or, to be implanted in a surrogate). It should be made clear whether this is sufficient to allow the use of the embryos as directed. This scenario has arisen recently in both New Zealand and the United Kingdom (source=newspaper reports)
- Whether parents or whanau have any rights over the frozen embryos. This has been an issue recently in China, where the only child died, and the parents wished to implant the frozen embryos in a surrogate, to continue the family line.)

Question 2: Form of consent

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

ACART Consultation on Informed Consent.
Submission by Debra Wilson.

Yes [ ] No [ ]

(b) Do you have any other comments?

Yes [X] No [ ]

(a) I agree that it is good business practice for consent to be in writing. Whether it should be required, however, is unclear. The Proposed Advice mentions the Code requirement of written consent in certain situations (Right 7.6). Another comparison might be Right 7.5, which doesn't require Advanced Directives to be in writing. This is a pretty major omission from the list in Right 7.6, and might reflect the general hesitation of courts (particularly in the UK and US) to enforce advanced directives, even when in writing. If consent is to be in writing, one must be careful to ensure that this does not result in simply a 'checklist' with a signature at the end. These checklists have been considered to not necessarily equate to informed consent in the context of advanced directives, and also in relation to the 'donor' consent on drivers licenses. The written consent should be obtained in such a way as to make it clear that the signatories actually understand, and are not just ticking boxes. Again, proposed advanced directive forms might show how this might work. Instead of simple checklists, some are phrased as a series of questions for example "what do you want to happen in this scenario? " this would demonstrate the understanding required for informed consent to be established.

(b) The comments at para 59 might be overstating the benefits of written consent. "a clear requirement for written consent may give peace of mind to recipients who are feeling anxious about the outcome of an assisted reproductive procedure." If this peace of mind is not founded on a legal basis, however, this could cause more harm than good. Again, the Evans case provides an example. Evans was about to undergo chemotherapy, which would render her infertile. As she wanted children, her choices were to freeze embryos at the relevant clinic (fertilised with her egg and her partner's sperm) or to freeze her eggs at a different clinic (the current clinic didn't offer that facility). Based on promises from the partner that even if the relationship broke down, she could still use the embryos, she chose the first option. If she had been aware that, despite this promise (even if in writing), the partner could still withdraw consent, she would have chosen the second option (which was more difficult, both in chances of the de-frosted eggs being fertile and in finding a clinic that would freeze eggs).

Further, "a written record may also provide assurance to donors that the conditions placed on their consent will be implemented by the service provider". Is this an artificial peace of mind? Presumably this written record will not be enforceable. As an example, imagine a sperm donor who states that he only wants his sperm used by a married couple due to religious beliefs, and this is recorded in writing. If the clinic then uses the sperm to assist a non-married couple or a single person, is there anything that the donor can do? demand the pregnancy terminated?

It should also be considered that requiring written consent for the storage and use of embryos, in which various scenarios are addressed (which must surely be required for informed consent) may start to resemble a contract- particularly in light of my comments above about the donor imposing conditions. What are the implications of this for understanding the legal status of an embryo? There are numerous cases in which courts have been asked to decide whether embryos are person, property, or something in between (deserving of respect as future life, but not currently life). In some of these cases written agreements have been involved, complicating the situation. with numerous differing beliefs as to when life begins (from religious, cultural, ethical/moral perspectives or just gut feelings), could a requirement of consent in writing unintentionally hint at the adoption of one of these beliefs? If the clinics are requiring written consent anyway, without a written requirement in legislation, is it better to leave a written requirement out of discussions so as to not unintentionally reignite debates on the beginning of life?

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 ☐ No ☐

(b) Do you have any other comments?

Yes [ ] No [X]

Please give reasons for your views.

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?

Yes [X] No [ ]

(c) Do you have any other comments?

Yes [ ] No [ ]

Please give reasons for your views.

ACART Consultation on Informed Consent.
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I personally feel very uncomfortable about allowing conditions- I feel that unless the donor has chosen to donate to a specific person, the donations should go to the most compatible or next person on the waiting list. My level of discomfort may arise because in trying to imagine what conditions would be imposed, the only ones I can come up with (marital status, religion, sexual orientation) are grounds for discrimination under the Human Rights Act. Having said that, the arguments in the proposed advice are persuasive.

Two reasons stand out in support of allowing conditional donations:

i) The position of the gamete donor is different and more complex than the position of an organ donor. While these donors are specifically not parents under the HART Act, the Act also requires donors to supply information so donor offspring can access this and understand their genetic/cultural background.

ii) There is a shortage of donors. A May 2015 article in NZ Herald commented on the increase of single women wanting fertility treatment (80 in 2012 to 156 in 2014) resulting in a backlog of 150 donors. This shortage of donors is an international trend following legislative reforms in recent years removing the anonymity of sperm donors (for reasons specified under (a)). One response to this has been to import sperm from Norway (which still allows anonymous donation) but this has created additional issues, including that of safety. If conditional donations will increase the potential number of donations, this may justify its consideration. [as a comparator, the uncomfortable idea of a commercial market in organ donation is being considered in many countries. This idea is gaining support on the basis that it might increase available organs, benefitting both those who can afford to pay, and those who can't. Similarly here, conditional gamete donations might increase the pool of available gametes. While these can be allocated to those meeting the condition, it will leave available the non-conditional donations for the other hopeful parents]

(b) One would hope that if there are no limitations placed on the types of conditions that can be imposed, the clinics would exercise appropriate judgment and refuse conditions that society would consider unacceptable or immoral. External oversight of recorded conditions might help satisfy society that any conditions did not fall into the 'unacceptable' category.

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?

Yes [X] No [ ]

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

Yes [X] No [ ]

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

Yes [X] No [ ]

Please give reasons for your views.

a) The stated ability to withdraw or vary consent is greatly reduced or impaired if the donor is not given this information. As the Proposed Advice has stated previously, the position of gamete donors is different to that of organ donors. The donor's biological (although not legal) connection to any future children is an important one, and information should be provided in order to respect this. I agree that donors should be offered the opportunity to be provided information in relation to (i) and (ii) (my assumption here is that 'outcome(s) includes both pregnancy achieved and successful delivery. In my opinion both pieces of information should be provided). The onus should be on the donor to keep contact details up to date. In addition, I would add (iii) if any condition imposed by the donor is complied with.

b) It should be made clear that this is information only. Withdrawing and varying of consent is discussed in the next question, but the rights and abilities of the donor at this point should be made clear. As an example, the donor should not be able to request additional information on the intended recipient parent(s) to judge whether the particular individuals are 'deserving' or 'suitable' (with the exception of ensuring that any prior conditions imposed have been satisfied.
This might be an opportunity to enable the donor to update any information recorded on social/medical backgrounds as required under the HART Act (for example if new medical or family information has become available). The donor might feel more inspired to add to the information previously provided if made aware of a successful pregnancy. This can only be of benefit to the future child(ren).

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.

Withdrawal of consent

(a). I agree with the arguments in paragraphs 114-116. I feel this represents an appropriate balancing of interests.

As indicated in my answer to Question 5, the ability to withdraw or vary consent is only meaningful if the donors are a) informed of the use, and b) given a reasonable amount of time to withdraw consent.

Variation of consent

(a) I am more hesitant with this. At this stage, consent would only be varied by adding additional conditions (it couldn't involve removing conditions, because informing the donor that his gametes were about to be used contrary to conditions would make the ability to impose conditions redundant). If this was permitted, would this go beyond merely informing the donor of the use, to being more like asking the donor's permission to use the gametes for a particular individual/couple? If that was the case, the donor would be able to request personal information about the recipients in order to determine whether he wished to vary his conditions. To phrase it another way, 'withdrawal of consent' is non-personal: the donor decides for whatever reason that he doesn't want anyone to use his gametes. 'variation of consent' has the potential to become personal: the donor doesn't want these particular people to use his gametes, since he doesn't see them as suitable.

I would feel more morally comfortable with the idea that the donor's response to being advised of the use of his gametes as either acceptance (by silence) or rejection (by withdrawal of consent). I don't think a middle ground of imposing additional conditions is appropriate at this stage.

(b) I would prefer the 'point of no return' for variation to be before the donor is advised of potential use. How that would work in practice, I don't know. I feel that wishing to vary conditions should be donor-triggered and initiated, not triggered by the clinic informing the donor of intended use.

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?

Yes [ ] No [X]

(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?

Yes [ ] No [ ]

Please give reasons for your views.

(a) The autonomy (whether this is correctly defined as reproductive autonomy, or simply autonomy) of the individual should be respected in this situation. This would be consistent with the approach of the Status of Children Act Rules about Parentage in ss18-22, that when a woman becomes pregnant as a result of an AHR procedure, her (non-donor_ partner is not a parent unless he consented. If the partner has no rights in relation to the child, it may reasonably follow that the partner's consent is not necessary.

(b) This seems difficult to accept in light of my answer to (a), but I do not have sufficient knowledge in this area to feel comfortable commenting. If it is thought that the family or whanau's consent is required, then this would provide a stronger case for (a) to be reconsidered.
Any answer to (b) should apply to all people, regardless of cultural background, otherwise issues of fairness or even applicability might apply (in relation to applicability, I'm thinking of the Takamore burial case, where he whanau and the partner disagreed as to whether cultural beliefs were relevant since the deceased did not appear to regard these as important).

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?

Yes [ ] No [X]

(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 [ ] No [ ]

Please give reasons for your views.

I assume that the idea of a cooling off period is part of the proposed advice to prevent emotional reactions during a relationship break-up. Is 12 months too long, though? While this time period might allow emotions to cool, it also might equally contribute to stress, particularly where one party is desperate for children and this is the only chance (for example the Evans v Amicus Healthcare example where Evans had undergone chemotherapy for cancer and was subsequently rendered infertile) or if one party feels very strongly that children should not be raised outside of a marital home, and the parties are divorcing. This might result in 12 months of one party trying to convince the other to consent, when the other party has made a decision and simply wants to move on. It might also result in the question of use of embryos becoming a bargaining chip in relationship property disputes.
Another issue is whether this 12 month delay might prevent the woman being eligible for public funding due to age.

The idea of mediation is interesting, though. Instead of just giving a 'cooling off period' and hoping that the two people will use this time to discuss their differing views, perhaps there could be a requirement that where one party is withdrawing consent the clinic can require (or strongly suggest) that counselling/discussion occurs first. Having the clinic initiate this might result in a stronger likelihood that it might occur (as opposed to a situation where one party suggests this and the other rejects it simply due to a bad breakup). If it is clear that there is no chance of a meeting of the minds (for example if the male believes strongly that children should only be created in the course of marriage) then there is little point requiring a 12 month cooling off period- and indeed, this might cause further stress to the parties.

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Question 9: Form of requirements for informed consent

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

Yes [ ] No [ ]

(b) Do you have any other comments?

Yes [ ] No [X]

Please give reasons for your views.

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?

No.