ACART Consultation on Informed Consent.
Submission by John Forman.

Hello Martin and Stella,

Further to recent discussions, here is my submission on this consultation. It does not follow your questions in order, but it addresses a number of them generally and some more specifically.

I'd like an opportunity to meet with ACART, or its working group on this topic, to discuss the detail of this proposal. I think the consultation has captured some points well and generally heads in the right direction, but it has some gaps that need to be addressed, and some inconsistencies as well.

As you may know, I was on ACART for 6 years to 2011. Informed consent was always one of my "hot topics" in its deliberations. When we started work on the informed consent advice towards the end of my term, there was some consensus in the committee that our previous work could have been better and less challenging if we had in fact dealt with the informed consent issues first, rather than deal with aspects of consent guideline by guideline. As a result, the consent provisions remain a bit piecemeal. This consultation brings some good momentum towards filling the gaps but there is still an unfinished jigsaw implicit in what you propose.

In addition to my ACART experience, I was the executive director of NZORD, the NZ Organisation for Rare Disorders from 2001 until leaving in June this year. NZORD took a very close interest in all ART policy even before the HART Act. So my interest is also well informed by that role and experience, but essentially this submission needs to be considered a personal one.

In summary, the things I'd like to discuss with ACART include:

- Agreement in principle that there should be regulations regarding informed consent for ART procedures. They exist for all other areas of health and disability services and procedures, including research, plus human tissue collection, use and disposal. ART procedures are at least as important as these other related areas and should not rely on any lesser level of rules or guidance to regulate them.
- In particular, that the regulations should be principles-based and avoid being driven by current practice which may simply have evolved without adequate debate and clarity.
- My concern that the proposed regulations seem to be directed mostly at gametes, with limited reference to consent issues about embryos, and an implicit assumption that existing guidelines and practice would deal with consent regarding embryos. I think that is not a satisfactory situation, and is not consistent with my first point about the level of regulation there should be.
- Additional concern that the interpretation in the consultation document regarding one aspect of consent for embryos, appears to be based on clinic practice regarding embryos from donated egg and donated sperm. This is the "point of no return" of fertilisation which seems to me to be inconsistent with the intent of the wording in the guidelines that were put in place, and in my view also inconsistent with the principles in the HDC code about the right to change or withdraw consent.
- This interpretation also imports a very unfortunate concept of "property" into the HART framework, to the extent that at that point, for those embryos but not others, the control over the use of the embryo would transfer to others. Nowhere else in ART

procedures does this occur in such a way as to deny the chance of a donor to vary or withdraw consent. Nor does any similar change of "status" occur in any other part of HDC code-governed procedures or research, or elsewhere in blood or human tissue regulation.

- The interpretation regarding embryos mentioned above also seems to contradict the notes in your paragraph 152 regarding the intent of the HART Act provision – "In particular, it makes this provision in cases where one party from whom the embryo has been formed withdraws their consent." I believe the provisions regarding consent and withdrawing consent should be the same when the embryo is formed from donated egg and donated sperm, as when the embryo is a surplus embryo a couple intend to donate. It is clear from the guidelines for the latter case that implantation is the point of no return. As mentioned earlier I believe that was also the intent of the guideline wording for embryos from donated egg and donated sperm.
- Though the guideline on donation of egg or sperm between certain family members is silent on the issue, I believe that the right to withdraw consent should remain active in those cases until the point of implantation, to remain consistent with the intent of the code, the HART act provision mentioned in your paragraph 152, and with the principles I have outlined above.

The specific reason for wishing to discuss this in person with ACART is the complicated nature of the issues and principles and the realisation that conversation about them is the best way to achieve clarity about the arguments that are advanced, and to hear and debate counterarguments, to the benefit of all involved.

Despite the tricky aspects of these issues, I believe it is possible to achieve a clear set of principles to inform good regulation to guide practice, and avoid some of the unfortunately imported ideas and principles that confuse things from time to time.

Regards, John

John Forman