# CONSULTATION ON INFORMED CONSENT

## THE VIEWS OF A SAMPLE OF SPERM DONORS

### A REPORT BY PROFESSOR KEN DANIELS,

### UNDERTAKEN ON BEHALF OF THE

### ADVISORY COMMITTEE ON ASSISTED HUMAN REPRODUCTION (ACART)

PROFESSOR (ADJUNCT) KEN DANIELS ONZM

AHR PROFESSIONAL SERVICES

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# DESCRIPTION OF SERVICES REQUESTED (as per contract)

Professor Daniels will contact his network of fertility donors and explain the purpose of this consultation. He will talk to them about the importance of people making informed decisions and, based on the questions in the consultation document, ask for their comments on their experience with fertility treatment. Specifically he will ask them to explain whether they fully understood the procedures they were involved in and what the lasting effects of their decisions would be, including the possibility that in future they might have further contact with any offspring they are a genetic parent of. He will ask what information the fertility services provided and how they provided it.

Professor Daniels will analyse the views of the participants and prepare a report for ACART, explaining if and how the participants were informed by the service providers and whether they consider they were fully informed.

Professor Daniels will identify any processes or information the service provider's use that might need to be changed to ensure consent is fully informed. He will, if applicable, recommend options for making improvements. Professor Daniels will submit his written report, with anonymised data, to ACART.

Participants will be people who have donated gametes for use in fertility treatment.

There will be a minimum of 6 participants, identified by Professor Daniels.

Professor Daniels may talk to the participants individually or in groups, or both, as he chooses. Discussion can be in person or by "Skype".

# PARTICIPANTS

As per the contract, six previous sperm donors were contacted and asked to participate. They were each provided with the attached information sheet ( Appendix 1 ) which included the invitation to take part in the consultation. All agreed but for one the participation was limited due to other personal circumstances at the time.

Three were interviewed via telephone while the remaining three provided their own written comments.

All six donors were recruited some years ago, so there is no input from donors recruited over the last 5 years.

All donors except one were recruited by clinics on the understanding they would remain anonymous with no future contact from offspring. All six are willing to have contact with “their” offspring and for four of them contact has taken place. Three have met the offspring and for one there is continuing written communication without any meeting having yet taken place. For the remaining two donors there has been no initiative/contact from offspring probably because they do not know of the family building history.

# RESPONSES FROM PARTICIPANTS

## Question 1: Access to information that must be disclosed to patients and donors prior to consent

A. All said yes.

B. All but one said yes.

Meeting with staff focused too much on technical and procedural.

There was nothing on counselling or implications.

I did not think about the consequences and no one guided me in to this area.

"As with other health informed consent processes, the prospective patients and donors ought to receive a patient information sheet (PIS) consisting of a summary of the key points of the Standard, together with a full copy of the Standard and any other information relevant to the consent decision-making process."

## Question 2: Form of consent

A. All said yes

B. Need to have audit trial for donors and recipients

Electronic recording should be used to avoid loss of papers

"It should be given in permanent and authorised form, which can be electronic rather than in writing and this helps with disability access issues as .eg for those unable to write easily and/or sign."

"Strictly speaking the choice of undergoing ART is a decision by the person directly involved, and as such it only requires their consent in writing."

## Question 3: Donor consent to use gametes or embryos for training purposes

A. All but one said no. Person saying yes said that donors should be making all decisions relevant to them

B. ”When I was a donor nearly 35 years ago, the very act of making a donation seemed to be considered as a consent in itself for the gametes to be used for the procreation of children. No documentation passed between me and the service provider. This was of no concern to me nor, presumably was it to the many other donors. It certainly passed through my mind that some part of my donation might be used, without my knowledge, for research purposes or for verifying the adequacy of the provider’s freeze/thaw methodology. The possibilities of such other uses did not concern me. So I do not now see consent needs to be sought for personnel training purposes. I assume that only eggs/sperm from each donor in excess of what is required for ART would be used for training/research.”

“A list of possible uses from which the donors can choose those that apply, would make this clearest”

## Question 4: Placing conditions on donor consent

A. 5 said Yes and 1 No

B. “The only conditions should be what is currently permitted by law”

“A gift is a gift and it is normal social practice that the giver does not have any say as to how the gift is used. Perhaps if they want to express a wish as to how the gift was used or not used, then that would be possibly acceptable, but to place absolute restrictions, I find, is unacceptable. If they do want to place restrictions on the use of the gift then they should not give the gift. I realise that this would exclude some potential gamete

providers but I would be certain that it would only be a few. If potential donors want to discriminate against certain groups of people who cannot have a child for whatever reason, then they should not be given the opportunity to express their discriminatory nature and should be eliminated as possible donors."

"Donors ought to have control over how their donations are used, but what limits are placed on these conditions is difficult (sex-selection is given as an existing prohibition). Limits on time and number are relatively straightforward, those on the nature of recipients could be more controversial, while those on the nature of the resulting offspring seem the most difficult of all. Examples of recipient restrictions list the relationship of the recipient (hetero, gay, or none), but could a donor restrict by ethnicity, religion, disability status etc? Regarding the offspring, it would seem reasonable at this stage that apart from number, the donor cannot impose conditions on characteristics such as gender, physical traits, how they're raised etc."

C. Limits should be kept to a minimum.

Need to take account of others rights and well-being.

## Question 5: Ongoing information for donors on the use of their gametes

A. 4 Yes and 1 No

B. 4 yes and 1 No

C. "Once a gift is given, the donor should not expect more than is currently provided."

"The donor ought to be offered at the time of donation options for ongoing information, along with stressing an obligation on both parties to keep each other informed of any changes in contact details. As long as the clinic has sent information to the last received address, then it

should be seen as fulfilling its obligation (email etc obviously makes this less of a problem than physical address). Given the donor has the right to vary their consent at any time, informing a donor prior to use, would also mean informing the potential recipient/s that consent might be withdrawn, up to the time of conception. Also, if a donor had supplied a change of address and a clinic didn't process it, conflict could arise if the donor checks later to find that the clinic had been sending information to the wrong address, which the donor would have acted upon! Donors should have the right to any information that does not violate the privacy of recipients & offspring."

"I certainly feel that there should be some restriction on the number of "families" who can use the gametes from one donor. But I do not feel that the donor is the authority that determines this issue. As a donor I was told verbally that generally gametes from one donor were used for just two recipients. My suspicions that this regime did not apply to me meant that I was not too surprised to find out 35 years later that there were six recipients. This was of interest but no concern to me as it did not seem an excessive number."

"Because of my own attitude at the time, I think that donors should be given the option of receiving ongoing information as to the use that has been made of their donation. This assumes that complete anonymity is maintained. In fact the extent of the details of information provided should be defined. [I assume that the detailed information is somehow excluded from access through the Official Information Act.] The option should not be one off, so if a donor has previously opted not to be informed, then they can at any time reverse this option. I only found out details about the use of my gametes some 30 years later when two offspring requested contact with me."

Anything that encourages openness by parents should be included. Parents should know what donors are expecting.

## Question 6: Withdrawal or variation of consent by donors

A. 4 yes and 1 No

B. “ART has a single goal for women who for whatever reason other than their own biological ability, are unable to maintain a foetus within their uterus to full term. It offers them the possibility of pregnancy without recourse to the natural process of insemination. The final stage in the process is the presence within the female recipient of a healthy, fertilised embryo through means provided by ART. Once the embryo is *in vivo*, barring natural abortion, unsatisfactory gestation or parturition, a child will be born. Deliberate abortion, other than for clinical reasons, is not an option. So once the embryo is *in vivo* any choices in terms of amending or withdrawing consent are no longer available.

However for purely practical reasons it would seem reasonable to bring the cut off time for the amendment or withdrawal of consent to a time before the practical side of ART begins, otherwise valuable resources could be wasted. Obviously consent forms need to be signed before any practical processes begin. However because of the very personal nature of the issues allowance has to be made for any of the signatories to have a change of mind. I think that a signatory who expresses reservations about their decision should be allowed three month period post signing. This would give plenty of time for a signatory to think more deeply about the consequences of their approval and/or consult others about their decision. After the three months a signatory should be given two choices, one to withdraw consent or to request further, and final three month period. Any longer than this six month period would be an untenable burden on the parties directly involved.”

“I would not agree to a donor, for example, withdrawing consent after one child is born thereby preventing the mother from creating full sibling.”

"Per Q4, donors ought to have control over how their donations are used, which includes the right to change or withdraw consent prior to fertilisation, e..g in response to changes in their life circumstances, such as a medical finding or a new partner who isn't happy with the donation, whose views they wish to respect. As stated in Q5 however, this means that prospective recipients would need to be advised that consent might be withdrawn prior to fertilisation, and also that in the event of a clinic not processing a change of contact details, it might find itself having completed a fertilisation which it discovers later, the donor would not have allowed to proceed, had they been advised at the time (unless the default for the clinic is to regain consent, rather than assume it)."

## Question 7: Consent of a partner, family or whānau to donation or use of donor gametes

A. 4 Yes ( Partner consent should not be required) 1 No

B. B 4 yes and 1 No

Partner needs to be involved and issues talked through by both. This is because there are implications for both donor and partner.

There is a potential conflict between the individualistic approach of western society and what said previously about the donor being the person making the decision and not his partner but when one thinks about the cultural then the communitarian position comes in to focus (Maori).

"I see no need at all for approval or even consent to be sought from family."

"In my era, I am very sure that it was verbally suggested that I seek approval from my then wife. This I did as a very brief exchange during which we did not discuss any aspects of the proposal. Without thinking

about it she gave her immediate verbal approval. There was subsequently one extremely brief passing reference to it between us, but never again. Were I to remind her now I am very sure that she would no recollection.

Partners need to be informed (preferably via an information and Q and A session for both), not least as it has a bearing on the potential half-siblings for any current or future offspring of the partnership, but they should not be required to give consent. Informing of family/whanau should be up to the donor—consent not required."

"Despite that, I am most concerned that the suggestion that consent of the donor's/recipient's partner should not be necessary. I feel that this is giving the opportunity and officially sanction to, possible deception on the part of the donor/recipient, even though that hopefully only applies to a small proportion of them. I think that it is a must that the donor's partner knows that his/her partner is facilitating a birth of a child outside their relationship. Rather than requiring consent from the partner I would suggest that the consent form must be countersigned by the partner in a section that says that they have read and understood the consent form. Though this would not assure approval nor consent it would ensure the partner was fully aware of what was happening. There should be a compulsory session of both the donor/recipient and their partner with a counsellor who would outline all the many and varied sequelae, many of which the participant would not probably have even considered."

## Question 8: Couple disputes about the future use of embryos

A. All answered Yes

B. All answered Yes

Again a potential conflict between an individual making decisions and here a couple so not individual, so partnership recognised in one area

but not other. For one partner to have the say may potentially impact on child—not wanted by other partner

"Clearly it's not appropriate for an individual to lose control over their gametes in embryo form, and for these to be seen by another as their property, given the right to withdraw consent at any time before the point of no return. Nonetheless, a cooling off period of 12 months is likely to lead to better accepted long-term outcomes than a decision in the heat of the moment. Any deliberate or accidental illegal use of the embryos during this 12 month period would lead to some tricky legal issues!"

## Question 9: Form of requirements for informed consent

A. All favour regulations being promulgated to cover this area.

Need for this area to be standardised and formulated.

Given that clinics are making this a business ACART needs to seek to manage this in a patient and child focused way.

Regulations need to be able to be adapted as developments occur.

## Question 10: Comments or suggestions

A. "One of the issues that arises with informed consent is how much information to provide and in many cases a defensive approach of providing (dumping!) "everything" is used, yet is likely to mean less not more informed consent. A carefully developed summary of the key matters should be provided. A donor should choose an appropriate level of detail and thus exercise informed consent."

B. "The document raises some potential legal issues arising in an ongoing consent process and also where consent is withdrawn in the case of future embryo use. It will be important to consider the potential

“gone wrong” situations, in formulating appropriate rules, procedures and safeguards.”

“As a donor I knew that I was making and absolute gift with no expectations. A donor who seeks more information and a right of veto is not donating for the right reasons”

Birth certificates should be annotated in some way to let offspring know that gamete donation was used.

Need to see ART as multidisciplinary as many of issues are psychosocial and not just medical.

# EXTRA QUESTIONS AS PER CONTRACT

## Comments on experience with fertility providers in relation to informed consent discussion including what information the fertility provider supplied.

"Having given consent 24 years ago, I can't recall the details, but I believe I was happy with the process at the time or I wouldn't have gone ahead. At the same time, our understanding of the implications of donor conception has grown with experience, and there are more possibilities eg types of recipients, so I would expect a more thorough process today, than that of the early 1990's."

## Did donors fully understand the procedure they were involved in and the lasting effects of their decisions. including the possibility that in future they might have further contact with any offspring they are a genetic parent to.

"I agreed that I could be contacted, unmediated by a third party (although contact to date has taken place via the clinic), but I don't think as a 29-year old I had the same appreciation of what being a donor entailed as I do now. In the end there's only so much that can be done to ameliorate this, but the trend to older donors, some of whom already have families, I expect assists in closing this gap."

"I've also been reflecting on other issues that might come within the gambit of informed consent here, and which I may include in the feedback, viz:

- Requirement for donors to investigate and disclose medical/genetic information
- Requirement for recipients to inform offspring of the nature of their conception
- Obligations on donors to provide descriptive, identifying and contact information

- Rights of children prior to reaching 18 to request information / have contact (with parental & donor consent)

- Rights of donors to descriptive, non-identifying information pre-18, and right to request identifying/contact information 18+ (with DCP consent)

- Gender-equity right of single men via surrogacy (a tricky issue in itself) to have donor conceived offspring

- Providing donor at the time of meeting offspring with the information they gave at the time of donation (some 20+ years prior)”

All respondents said that the implications of donating had not been fully discussed with them and in particular the implications of future contact with offspring and their needs were not covered.

# ANALYSIS OF RESPONSES FROM PREVIOUS SPERM DONORS

## Question 1.

It was clear that all previous donors felt there was no or insufficient discussions with them concerning the future implications of their decision to donate. There was a feeling that the donor was seen as “a means to an end” and that the focus was on the technical and procedural elements of donating. There was a desire for full information to be presented in writing.

## Question 2.

Consent is clearly felt to be necessary and for this to be in writing as it provides for accountability and audit.

## Question 3.

A clear list of how sperm might be used (including for training purposes.) should be provided to prospective donors. There did not seem to be any objection to sperm being used for training purposes, but this possibility should be stated as an option that donors consent to.

## Question 4.

Most participants wanted the opportunity to place restrictions on use but there was concern about how this might be implemented and whether the choices made might be discriminatory. This was not seen as a simple yes/no issue.

## Question 5.

The majority view is that donors have the right to ongoing information but this should be an option presented to donors for them to choose. An interesting suggestion is that it could be considered that it may be important to recipients to know what the expectations of donors were before choosing a particular donor.

## Question 6.

Underlying many of the responses from participants was a view that they wished they had been treated with more respect—not treated as a means to an end. This is evident in this response. One way of looking at this is for clinics to see the donor as a ”partner” in the treatment. It is also clear that there is a wish for provision to be made for donors to change their minds.

## Question 7.

While there is strong support for the notion of partners being involved in the decision making it is not seen as necessary to extend this to them signing a consent form.

## Question 8.

It is clear that all participants agreed with the suggestion of a 12 month “cooling off” period in the case of disputes about the use of a couple’s embryos.

## Question 9.

There is strong support for regulations to be established as this would lead to standardisation. Regulations also need to be amenable to development in the light of new knowledge.

## Question 10.

One of the participants is a lawyer and emphasised throughout the need to ensure that all information and decision making in relation to informed consent needed to be consistent with the law.

## Extra questions as per contract.

In summary all respondents said that the implications of donating had not been fully discussed with them and in particular the implications of future contact with offspring and their needs were not covered. They acknowledged that changes had taken place since they donated and were pleased that this was the case. They appreciated that the current review of informed consent provisions was part of this and welcomed the opportunity to contribute from their experiences.

# SUMMARY

The participants were all previous sperm donors, some of whom donated many years ago. All but one had been recruited on the basis of their donation being anonymous, although all were now open to contact with “their” offspring and four of the six had had contact and in three of these face to face meetings had taken place. Their engagement with clinics at the time of donating was described as unsatisfactory as insufficient attention was given to explaining/discussing the implications of their donating and in particular the needs of the offspring. They were pleased that changes had now taken place and welcomed the more “open” and family approach to gamete donation. They felt there was a need for prospective donors to meet with counsellors who could assist them in their preparation for becoming a donor. They viewed informed consent as very important and supported the notion that regulations should be formulated to cover this area.

Given that it appears that counselling for prospective donors is provided by clinics in New Zealand (ACART may wish to ascertain this is the case) one of the major concerns of this group of donors is now being met. The allocated time did not allow for detailed contact with service providers and it would be my suggestion that ACART ask providers to supply their documentation relating to informed consent as part of this consultation.

If the decision is made to formulate regulations I am sure that two and possibly three of these donors would be more than willing to provide feedback.

# APPENDIX 1

## INVITATION TO PARTICIPATE IN CONSULTATION ON INFORMED CONSENT — ADVISORY COMMITTEE ON ASSISTED HUMAN REPRODUCTION (ACART)

## INTRODUCTION

The Government Advisory Committee (ACART) is considering whether to make changes to the ways in which fertility service providers (clinics) engage with clients to ensure that those clients make fully informed decisions when they decide to have treatment or to make donations. The Committee needs to confirm the need for any changes and exactly what those changes should be. It will make recommendations to the Minister of Health.

ACART has contracted with me to access gamete donors who are known to me so that their views can be presented to the Committee. It is recognised that many, if not most, donors will not necessarily want to be identified as making a submission and therefore having their name recorded in the report. My engagement with you is undertaken on a completely confidential basis, in other words your name or any identifying information will not be presented to ACART as part of my report. It is also recognised by ACART that donors may not know about or respond to the general call for submissions and this would mean input from donors would be missing.

## PROCESS

The consultation document will be sent to you. The document gives important background information and then addresses a number of questions. For each of these questions again background information is presented.

While ACART is very interested in answers to these questions it is also keen for me to gather additional information from you about your experiences with fertility providers. With this in mind the following options seem appropriate.

1. You can respond to the questions in the document and send these to me by post or electronically. I would then have a telephone conversation or skype session to cover some of the additional points which ACART has asked me to ascertain views on.
2. As for 1 above but we could have a discussion about the questions before you complete the answers yourself
3. I can telephone or skype with you after you have read the document and you can share your views with me and I can record them. I would therefore complete the written exercise on your behalf. You would receive a copy of what I had written and be asked to confirm they are your views!
4. Any other option which seems suitable to you.

I am to submit a final report to ACART on September 18th. Once accepted by ACART I will be more than happy to send you a copy as this will give you and overview of yours and other donor's views.

## THANKS

Thank you very much for being willing to take part in this consultation. ACART and I really appreciate it. From my research and counselling I know so many parents have appreciated what you have done for them in terms of assisting them to build their family.

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