17 September 2015

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Alison Douglass
Chair
Advisory Committee on Assisted Reproductive Technology (ACART)
PO Box 5013
WELLINGTON

Dear Ms Douglass

Informed Consent and Assisted Reproductive Technology: Proposed advice to the Minister of Health

Thank you for the opportunity to comment on the Advisory Committee on Assisted Reproductive Technology's (ACART) consultation document on ACART's proposed advice to the Minister of Health (the Minister), *Informed Consent and Assisted Reproductive Technology* (the consultation document).

As you are no doubt aware, as Health and Disability Commissioner, I am charged with promoting and protecting the rights of health and disability services consumers, as set out in the Code of Health and Disability Services Consumers' Rights (the Code). One of my functions under the Health and Disability Commissioner Act 1994 is to make public statements in relation to any matter affecting the rights of health or disability services consumers.

The consultation document asks ten questions in respect of informed consent in relation to Assisted Reproductive Technology (ART), and requests feedback on those questions. While the questions raise a number of wider considerations, and I acknowledge the time and thought that has gone into these, I have limited my response to those issues that are directly relevant to the Code.

Application of the Code to ART
Section 2.2 of the consultation document sets out the current requirements for informed consent to ART in New Zealand. Paragraphs 33 and 34 state:

> 33. The Health and Disability Commissioner has indicated that the removal, retention, use or return of gametes is covered by the Code. Accordingly, gamete donors are entitled to receive information and make an informed decision as to how the gametes are to be used or stored, and what will happen to them (including whether or not they are to be exported).

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34 While the Code does not address all matters of informed consent in relation to assisted reproduction, any regulations or guidelines must be consistent with the Code.

The description of the application of the Code to ART and the removal, use and retention of gametes would, in my view, benefit from further clarification. The starting point for my jurisdiction in relation to health services is set out in section 2 of the Health and Disability Commissioner Act 1994 (the Act). "Health services" is specifically defined to include "fertility services" and, accordingly, the rights in the Code apply to persons undergoing assisted reproductive procedures. For the purposes of the consultation document, this means that every person undergoing an assisted reproductive procedure has the right to effective communication, full information, and to make an informed choice and to give informed consent to that procedure.

Right 6(1) of the Code provides that every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive. In my view, a reasonable consumer undergoing an assisted reproductive procedure, where the purpose of that procedure is to remove gametes for future use, would expect to know what will happen to those gametes, including any embryos created from them. In most circumstances, the disclosure of such information would, in fact, be required in order for that consumer to be able to give informed consent, in accordance with Right 7 of the Code.

As I have previously noted, "... it is my view that, at the time gametes are extracted for fertility treatment, each gamete donor should be fully informed and asked about their wishes for the future use of any surplus embryos, and any future use of those surplus embryos should be in accordance with the stated wishes of the gamete donors...". I remain of that view and support the general strengthening of these requirements.

In addition, Rights 7(9) and 7(10) of the Code contain requirements in relation to the use, return, and disposal of body parts and bodily substances removed or obtained in the course of a health care procedure. There is no definition in either the Act or Code of "body part" or "bodily substance"; however sperm and eggs would be considered "bodily substances". As such, Rights 7(9) and 7(10) afford additional specific protections in relation to the use, return, and disposal of gametes removed or obtained in the course of a health care procedure. I note, however, that embryos do not come within these definitions, and so Rights 7(9) and 7(10) do not apply to the use, return or disposal of embryos.

I suggest that any advice to the Minister of Health further clarify the application of the Act and Code to informed consent requirements in relation to assisted reproduction. This is particularly relevant when considering the completeness of the conclusion in paragraph 154 that there is a "lack of a detailed regulatory framework for informed consent in regard to assisted human reproduction".

Written consent

At paragraph 54 of the consultation document it is stated that "Right 6 of the Code requires informed consent to a health care procedure to be in writing in certain situations; for example, where there is a significant risk of adverse effects on the consumer." I note that it is, in fact, Right 7(6) that requires this.

Furthermore, while you have correctly noted that the requirement for written consent does not extend to all situations that may arise in provision of ART, I have often noted the importance

of maintaining full and accurate documentation, including documentation of consent discussions, and support any proposal that encourages this practice.

The use of gametes and embryos for training purposes
At paragraph 68 of the consultation document it is stated that Right 6 of the Code applies to the issue of donor consent to the use of gametes or embryos for training purposes. I note that Right 6 relates to the provision of information, rather than the giving of consent per se, and thus does not embody all of the requirements of informed consent. While Right 6 applies to the provision of information in relation to health services, Rights 5 and 7 of the Code are also important. Right 5 of the Code sets out the right of health and disability services consumers to effective communication from providers. Right 7 provides that, as a general rule, services may be provided only if a consumer chooses and gives informed consent to those services.

Right 9 of the Code extends all of the rights of the Code to those occasions when a consumer is participating in, or it is proposed that a consumer participate in, teaching or research. This also covers situations involving "training".

Donors of gametes have a right pursuant to the Code to consent to any proposal to use their gametes for teaching/training purposes, other than as provided for in Rights 7(10)(b) and (c). As noted above, the general information and consent requirements of Rights 6 and 7 can be interpreted to mean a similar right exists in respect of embryos (although noting that Rights 7(9) and 7(10) do not apply to embryos).

Paragraph 76 of the consultation document states that ACART is of the opinion that it would be desirable for consent requirements to be regulated as to the potential use of a donor's gametes and embryos for training purposes. As set out above, consent requirements are already covered by the Code.

Ongoing information provided to gamete donors about the use of their gametes
It is stated that HDC previously expressed the opinion that, consistent with the Code, gamete donors should have the option of making an informed decision *at* multiple points of the process. I note that the opinion expressed was, in fact, that gamete donors should make a decision *about* multiple points of the process (i.e. how their gametes will be used, stored, and what will happen to them after treatment is completed), and that any future use of the gametes should only be in accordance with the choice the consumer made. Discussion and consent as to the storage, preservation and use of any embryos created should also occur.

When this consent occurs is not specifically addressed by the Code. In my view, full disclosure about the matters above, and related consent, should occur at the point of initial donation of gametes. However, I note that it is well established that informed consent is a process, and as noted in the consultation document at page 4, the process "includes the right to refuse consent, and also the right to change one's mind by withdrawing or varying consent". Therefore, I consider that, where appropriate, gamete donors should also be given this opportunity when their gametes are to be used in the future, and I agree with the proposal in paragraph 107 of the consultation document.

Requirements for informed consent to be set out in regulations
As noted above, at paragraph 153 it is stated that there is a "lack of a detailed regulatory framework for informed consent in regard to assisted human reproduction", and, at paragraph 155 that "The Code provides guidance on informed consent, but ... does not specifically

address assisted reproduction." I do not agree with that analysis. As discussed above, assisted reproductive procedures are covered by the Code.

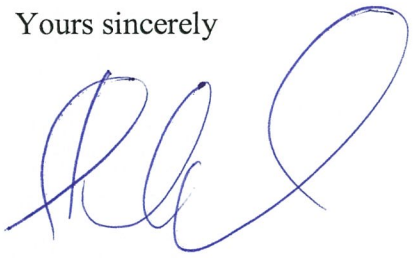
For this reason, I do not support the creation of another set of regulations on informed consent, where the procedures in question are already regulated by the Code. Rather, in my view, the more appropriate solution would be to continue to develop guidelines or standards that outline how the Code applies specifically to ART, and what that means in terms of informed consent requirements. I note that Right 4(2) of the Code requires providers to comply with legal, professional, ethical, and other relevant standards. Similarly and more specifically, Right 6(1)(e) states that every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including any other information required by legal, professional, and other relevant standards. By virtue of these two rights, any standards set by ACART in relation to informed consent and ART would effectively be imported into the Code, itself a regulation.

Conclusion

I trust that you find these comments of assistance. Please do not hesitate to contact Associate Commissioner, Legal and Strategic Relations, Dr Katie Elkin on (04) 494 7919 or by email at katie.elkin@hdc.org.nz if you have any questions about this submission.

As discussed with Ministry of Health Senior Policy Analyst, Martin Kennedy, Dr Elkin and I would be interested in meeting with you in relation to this submission. Please contact Kerry Norman on (04) 494 7917 in order to arrange a suitable time.

Yours sincerely



Anthony Hill
Health and Disability Commissioner