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Submission to the Ministry of Health on Guidelines on the Use of Human Tissue for Future Unspecified Research Purposes

The National Council of Women of New Zealand (NCWNZ) is an umbrella organization representing 38 nationally organized societies and a number of individual women. NCWNZ has 31 branches to which women from 150 societies are affiliated. The Council's function is to serve women, families and the community through research, study, consultation and action.

The number of respondents to the Guidelines on the Use of Human Tissue for Future Unspecified Research Purposes was approximately 60 people from Branch, NGO and individual level, including the Interchurch Bioethics Council. This response is based partly on the responses of these people and partly on relevant general policy developed by NCWNZ over many years. In 2004 NCWNZ made a submission on the Review of the Regulation of Human Tissues and Tissue-based Therapies. In that submission NCWNZ argued that some flexibility to allow for new technologies and advances in science was valuable for the country, but that appropriate education and fully informed consent of participants was imperative. In 2006 NCWNZ responded to the Human Tissue (Organ Donation) Amendment Bill supporting the use of human tissue and donor organs provided that donors opted on to the donor register and that all participants were fully informed. Some of the issues raised in those submissions and the submission on Guidelines for the Practice of Embryo Donation for Reproductive Purposes covered the question of the ethics of using human tissue and those policies inform the responses to the questions in this Discussion Document.

This response does not include reference to the human tissue that is composed of gametes and embryos, and established cell lines derived from human embryos. The human tissue which is the subject of this response is all other human tissue from material such as adult stem cells, brain tissue, blood, bone marrow, tumours and so on which are essential for clinical, diagnostic and research purposes.

Ministry of Health Guidelines on the Use of Human Tissue for Future Unspecified Research Purposes: Discussion Document Questions pp 34 – 36.

1. **Do you think it is reasonable to ask patients and research participants to give some form of consent to future unspecified use of their tissues in research?**

The majority of the respondents replied in the affirmative but noting that it is vital that consent is as fully informed as possible. Donors must understand that it is not possible to know at the consent stage what research will be done in the future. There must be honesty and openness and transparency between researcher and donor. One respondent who was personally involved in the Greenlane research on babies stressed the importance of this.

One form of consent could include allowing storage of tissues in a linked form with the donor being asked at the relevant time to approve research and this would include contacting children when they were old enough.

A smaller number of respondents, two individuals and two Branches, were totally opposed to unspecified research and thus the need to gain consent. The main reason for this point of view was a lack of trust in the integrity of researchers in future and especially of foreign-based research organizations.

2. What information do you think should be provided to potential research participants?

At the time of donation, donors should be able to specify the range of purposes for which they are willing or not willing to allow their tissues to be used. This is essential because of the boundless nature of possible work and in order to give donors some measure of control. The exclusions or limits to consent must to be made at the time of the initial consent and an opportunity to withdraw within some specified timeframe must be provided.

The donor needs to have information as to what will happen to tissues if the donor dies or is not contactable. It may be necessary to obtain legal advice on this matter. The family does not have legal rights to override the wishes of the donor but the cultural nature of the question must be kept in mind. For Maori the use of human tissue is a question of deep spirituality. Tissues are not just a collection of cells, but have deep meaning for the potential donor.

Under information, it may be important to explain everything to whanau in addition to the individual (but only at donor's request). For consent to be fully informed there has to be the opportunity to consult with family/whanau/supporters etc., as with consent issues in other research.

Donors need to fully understand the options of linked or unlinked storage of tissues and the implications of the decision made. In particular, they need to realise that if the tissue is unlinked, the decision to do this is irreversible and may prevent data obtained being of direct benefit to them. It also removes the possibility of withdrawal of consent in the future.

In the case of children, the competence of a child to make a decision must be considered in terms of the Gillick competence concept. While adults may decide to opt for unlinked storage of tissues for themselves, the rights of children must be respected. Parents are advised not to de-link information for children in order to give children the right to decide for themselves in the future, including the right to withdraw their tissue if they so wish. Children should have their future choices preserved as much as possible.

The question of consent is about treating all people as intelligent rational human beings each with his or her own intrinsic worth. It is also important to maintain confidentiality and protect donors from the misuse of their data by others. This is however a requirement for all health information and should not be regarded as a justification for de-linking information from tissues, and thereby losing choices for the future.

Again with regard to de-linking, donors need to understand that in some types of research e.g. genetic research into familial patterns of disease, the de-linking of tissues from personal information would make it impossible for that particular donor's tissue to be involved in the research or for that donor or donor's family to benefit from such research.

3. Do you think the options for consent are reasonable and practicable? What other options could or should be provided to potential research participants?

The options were agreed to by those who supported the thrust of the Discussion Document but the following options also need to be available:

i) Options should include the donor being able to state that there are certain areas of research for which they give permission and for which new permission need not be requested e.g. research into the particular area of disease from which the donor suffers.

ii) Options should also include the right to exclude future research on certain topics, e.g. for cultural or religious reasons a donor may wish to exclude research into contraception, abortion, creation of interspecies hybrids, xenotransplantation.

iii) Donors who do not wish to approve of unspecified future research may wish to state that their tissues may be stored and a request made in the future for research on a yet-unknown topic. This is implied in 4.4 but there would be a requirement for approval to be given for linked storage of tissues.

Those who were opposed to the storage of human tissue for future unspecified research were in favour of the full disclosure of research possibilities – in other words continuing the dialogue especially where the dialogue concerned cultural sensitivity.

4. Do you think there should be any requirements on the use of information derived from tissues that are donated for future unspecified research that are additional to or distinct from those already required in relation to other research with human tissue?

As is already required with respect to other health information, confidentiality and protection of donors' rights are of paramount importance. Likewise, the particular requirements regarding linking and de-linking of personal information and tissue, and the timeframe for which information and tissues are kept are of particular significance regarding future unspecified research.

One respondent expressed concern that information derived from the tissues might lead to interspecies research. Parents of blastocytes might have an abhorrence of any interspecies use even if it is to do with, for example, viral research.

5. Do you agree that there is no need for ethics committees to require any additional safeguards of participants' interests with respect to NZ researchers accessing samples donated for future unspecified research? If you do not agree, what safeguards would you propose?

Samples should be linked (unless donors specifically request that they be de-linked) and access to samples should take into account:

i. special requirements as under 3 above
ii. accessing for research will require ethics committee approval, whose requirements will include whether or not donors need to be asked to give approval for specific research, depending on the limits of consent made at the time of donation of tissue.

Such was the abhorrence of human cloning among those who responded that perhaps human cloning should be specifically excluded as an avenue of future research. Additional safeguards should include review of consent every two years over the life of the tissue because research aims and knowledge can change rapidly and may lead to fields of research which are not supported by the donor.

5. What would constitute a reasonable level of assurance to ethics committees that samples sent overseas will be subject to appropriate governance and ethical review? Is

any additional assurance required over and above that currently sought when consent is given for tissues to be sent overseas for specified research?

For approval for tissues to be sent from New Zealand to other countries, ethics committee approval would be required and for most respondents the requirement in point 5.5 of the proposed guidelines would be adequate. Donors should be assured of rigorous Ethics Committees approval and that adherence to these guidelines would be required. However many respondents were opposed because of the difficulty of monitoring and supervision. Examples were provided of foreign factory practices and the ease with which monitors can be hoodwinked to argue the difficulty of keeping track of human tissue samples in research.

This does raise another important question. What guidelines will be in place re the importation of tissues for research into New Zealand? We need to be aware that we are part of a worldwide community and have an obligation to respect and care for the empowerment and protection of others as for ourselves. New Zealand therefore should not import into our health system tissues which have not been collected, stored and treated in a way that would satisfy ethical standards in New Zealand.

7. **Do you think it is reasonable to permit tissue samples from children to be de-linked or anonymised on the basis of parental proxy consent, even though this will foreclose any possibility of children later withdrawing consent to the use of their tissue for future unspecified research?**

A decision to anonymise tissue samples should only be done in special circumstances and should be an active decision by the donor. Therefore while adults are entitled to make this decision for themselves, they should not make this decision for their children. When they reach an age of competence children may make this decision for themselves, if they wish to do so. It is also important that they can make the decision to withdraw their tissue from availability for research. The ability to make such decisions will be removed from children if their tissue samples are de-linked from personal information. One respondent also pointed out that if in future, diseases unknown today, appeared in some of the tissue samples stored, it would be impossible to identify them if the original tissues had been de-linked.

8. **Would participants be adequately protected, and timely review of low-risk research enhanced, if provision were made for delegated authority to the chair of an ethics committee to include:**
   - *use of anonymised tissue and*
   - *use of tissues where the participant has given consent for future unspecified research use of their tissues?*

This proposal was vigorously opposed. It was thought that such a provision would not adequately protect participants of research with tissue samples. Firstly, there is no definition of 'low risk', and it should be noted that while this question refers to low risk research, there is no mention of low risk in the relevant paragraph 4, points (i) and (ii) of the proposed guidelines.
As the research in question is to be done in the future and will presumably follow on from other earlier research it seems unlikely that there will be unexpected urgency for approval. It is hoped that application for approval will enable review by the Ethics Committee to take place in a timely fashion.

Any expedited review should be carried out by two or three people rather than solely by the chairperson. Delegating authority to a chair could lead to abuse especially when the research was being carried out off-shore where supervision is less easily done by the country of origin.

9. Are there any additional issues related to consent for future unspecified research use of tissue that need to be considered in any guidelines for research? If so, what are they, and what consideration would you want to emphasise?

Approval for research by an Ethics Committee is generally for a specified timeframe and extension of approval may be dependent on an interim report on the research. Research for unspecified research in the future is a different concept. Consideration should be given to whether permission to store tissue or to use tissue for research will be for a specific time frame and whether the researcher will have to re-apply for ethics committee approval. Ethics parameters and community beliefs and standards change over a period of time and it seems unwise for approval for research to be for an indefinite period of time.

10. Any other comments on the proposed guidelines?

Terminology should be clearer and more consistent. The terms "consumer", "donor" and "participant" are used. "Donor" is the preferable term as in "tissue donor", since "participant" applies to research in which the participant has a more active role.

There needs to be electronic protection of information regarding tissue. There also needs to be rigorous interviewing regimes with donors, using a spread of weeks and a variety of interviewers to ensure that the donor is both well informed and unpressurised. It is usual in approving research proposals to state that the participant may withdraw consent within a certain timeframe, or until research is at a certain stage. It is suggested that consideration be given to requiring a certain time lapse after a donor gives consent during which a donor may reconsider and withdraw consent. Obviously this could only be applicable with linked research. This is to compensate for the situation in which, because of the unspecified nature of the research and the timeframe, there cannot be a time in which donors may withdraw consent. This is based on the principles of virtue ethics in which the nature of the researcher is a factor.

The Interchurch Ethics Council stated that the de-linking of information and tissues is not good practice. The Council noted that in considering the reporting of information from research, there could be an additional option for samples to be unlinked from the participant's identification details, but results could be made available to stakeholders such as groups which represent a particular cohort e.g. Rare Diseases Association, if research is relevant to this group of people. This would enhance the possibility that members of that group would benefit from research, and is a not an unusual part of an information sheet and consent form for a research proposal. While it is pointed out that the de-linking of a donor's contact details or identification details would mean that they would not benefit from research outcomes, it is common for participants in research proposals to be made aware that the research will not benefit them but will benefit the particular cohort of those with a particular disease and whether this is the case would have to be made clear in the information given to donors, whether they are to be linked or de-linked. In considering confidentiality and storage issues, consideration could be given to the concept of Maori guardianship (kaitiaki) as is practiced in such situations as guardianship of blood banks.

This is a complex issue but NCWNZ appreciates the opportunity to comment.

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