

Submission Form

Please use the following pages when making a submission.

You do not have to answer all the questions or provide personal information if you do not want to.

Please return the questions to:

Tanith Robb
Sector Policy
Ministry of Health
PO Box 5013
Wellington

Email: tanith_robbs@moh.govt.nz

If you would like to make an electronic submission download the questions from www.moh.govt.nz, save the Word document to your computer, fill it in and email it to: tanith_robbs@moh.govt.nz

Submissions close on **Friday 11 August 2006**.

This submission was completed by:

Name: Dr Kathryn Woad and Ms Greta Riley on behalf of Cancer Trials New Zealand (CTNZ)

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Organisation: Cancer Trials New Zealand (CTNZ), University of Auckland.....

Position: Research Fellow and Research Manager

Are you submitting this as:

- an individual
- on behalf of a group or organisation
- other (please specify).....

Please indicate which sector(s) your submission represents:

- | | |
|-------------------------------------------------------|------------------------------------------------|
| <input type="checkbox"/> Consumer | <input type="checkbox"/> Family/whānau |
| <input checked="" type="checkbox"/> Academic/research | <input type="checkbox"/> Māori |
| <input type="checkbox"/> Pacific | <input type="checkbox"/> District Health Board |
| <input type="checkbox"/> Education | <input type="checkbox"/> Local government |
| <input type="checkbox"/> Provider | <input type="checkbox"/> Funder |
| <input type="checkbox"/> Non-government organisation | <input type="checkbox"/> Prevention/promotion |
| <input type="checkbox"/> Professional association | |
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Questions

The following questions have been collated from the questions posed in section 3 on 'Ethical Issues'. They are designed to focus your thinking on the proposed guidelines, but please feel free to make comment on any other aspect of this document.

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?

Yes, it is reasonable to allow an individual to give broad consent to research, with the safeguard that whatever future research is conducted will be subject to ethical review and approval.

The donation of tissue for unspecified use would build a highly valuable resource over time. This would enable researchers in the future to address as yet unanticipated questions which evolve from both new knowledge and emerging technologies.

We would support restricting the broad consent to biomedical research, to allay any fears of misappropriation of tissue.

The potential for increased public benefit is considerable, but should be balanced at all times by the need for research to comply with the current regulations on scientific and ethical practices.

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

In the absence of specific project details potential tissue donors should be provided with information regarding the concepts that will govern the collection, handling, use and destruction of the donated tissue and handling of results.

For example,

- Who / what organisation will have governance over the tissue
- That all projects using this tissue will be subject to ethical and scientific review by accredited review boards, i.e. one which conforms to the International Ethical Guidelines for Biomedical Research Involving Human Subjects (Council for International Organizations of Medical Sciences and World Health Organisation)
- Research results arising from use of the donated tissue are unlikely to directly benefit the individual donor. However, it is anticipated that the knowledge gained from this research will positively impact on the community's health care in the future
- That confidentiality of personal information will be maintained, i.e. any published results will not contain identifiable information
- That consent to use donated samples may be withdrawn
- Potential for commercialisation of results from future research, in the context of resulting community benefit

Issues associated with genetic research raise a range of concerns within different sections of the community, which include important cultural differences regarding notions of genetic inheritance. We think it appropriate to inform potential donors of the possibility of this type of research being conducted on their tissue, particularly in the light of the unspecified nature of the research for which the consent is being sought.

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

Potential research participants should be given a range of options for consent, which allows them to exercise their right to direct use of their tissue, and assess their personal risk versus potential benefit.

These should include:

- Option to refuse use in future unspecified research
- Allowing use to be restricted to research into certain conditions / disorders
- Specific consent allowing tissue to be sent overseas (yes / no option)

Participants must be able to refuse future unspecified use.

The option of allowing future use of tissue only when it is anonymised or coded may limit the power of information which could be obtained from the tissue, but may be appropriate for certain studies. If the data / sample is to be used in a study which requires anonymisation, this can be done at the repository before release to researchers, and will therefore not exclude a “linked” tissue sample from anonymised research projects. We also accept that allowing an option of anonymisation might encourage donation by those who might otherwise not consent to the use of their tissue.

We do not support contacting donors to request future use. It is more practicable and potentially more acceptable to ask for broad consent at the time of tissue collection, with the safeguard that the use of tissue will be regulated by accredited review boards.

The issue of commercialisation is complex. Donors might prefer that companies should not make money from the use of their tissue. In many cases however, research benefit will be achieved by collaboration with, or funding by, industry, and donors should be informed of this research reality.

Offering a range of options for consent is reasonable and practicable, since simple database management enables easy categorisation of tissues according to a donor’s wishes, and subsequent use in accordance with these requests.

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

The results generated from research on donor tissue are by their very nature, experimental. Until findings are validated and clinical standard tests / treatments are available, we would suggest that direct feedback to an individual of their own ‘results’ would be inappropriate. We would expect the results of research to be fed back to the community via existing processes of publication, and long term improvements in health care.

We would also suggest that it be a requirement that researchers seek advice from the ethics committee on the best way to disseminate any findings which may have the potential to cause either consequential or dignitary harm. For example, participants will be largely unaware of the specific nature of the research carried out using their tissue, and there needs to be consideration of the potential impact of unexpected results on a donor and /or their community.

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

Whilst tissues may be donated for future unspecified use, each experimental design should be vetted, whether for use by researchers in New Zealand or overseas. This is necessary for scientific rigour, protection of tissue resources and for public trust in the research process. Patient information sheets / consent forms should be required to include a short description of the expected adherence to ethical review.

We support a formal agreement between the researchers and the tissue repository stating compliance with ethical guidelines, ownership and commercialisation requirements, restrictions on secondary release of tissues, and means of return or disposal.

The policy for determining appropriate access to tissue and the requirement for ethical review needs to be further developed. We would envisage that large scale Tissue banks would have their own review boards with representation from researchers, community, ethics and law, thus providing a point of safeguard against tissue misuse. These boards could also provide leadership and advocacy in future debates. There are also likely to be many smaller repositories held by individual researchers. These smaller collections are unlikely to have such formal governance structures. They will however, be subject to the regulations of the host research institution.

6. 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?

Overseas research projects which request access to tissue samples donated for future unspecified research must be subject to scientific and ethical review. Overseas Institutional Review Boards, or their equivalents, must adhere to the International Ethical guidelines for Biomedical Research involving Human subjects, and be appropriately accredited.

We support application for overseas use of New Zealand tissue on a project-by-project basis. Furthermore, we support a formal agreement between the researchers and the tissue repository stating compliance with ethical guidelines, ownership and commercialisation requirements, restrictions on secondary release of tissues, and means of return or disposal.

We understand the risk of a strict regulatory environment excluding New Zealand tissue samples from overseas research. However, we feel that project-by-project application for use allows more control of valuable New Zealand tissue resources, and likely compliance with the wishes of New Zealand donors.

It is not clear from this document what jurisdiction NZ Ethics Committees would have once tissue collected in NZ is released overseas for unspecified research, or what agreements might guide tissue usage. Issues of commercialisation and ownership are also unclear, as is the potential for secondary release of tissues from the original overseas repository.

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?

We would support that the original consent should allow for linking of sample and data. If donated tissue is linked, it then allows for children to withdraw their samples at a later date. If specific studies require anonymised samples, this can be arranged for that specific study before release.

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 tissue?

No. We do not support delegated authority as routine practice for approval. Scientific and ethical review of proposed research is essential to ensure protection of both the resource and the trust of the community. The public perception of biomedical research might not be best served by an awareness of ethical decision making based, at least in part, on timeliness.

In addition we do not support the view of the NBAC (see Appendix: International Guidelines) that where tissues are unidentified, or unlinked, that no ethical review is required at all. Whilst there may be limited consequential harm in this example, there is still the possibility of dignitary harm, whereby the donors religious or cultural beliefs may be harmed, and this may be of particular importance in New Zealand. This difference of opinion also highlights the need for rigorous protection of samples when they are released to researchers outside New Zealand's cultural and ethical environment.

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

We would wish to emphasise that scientific and ethical review of proposed research using tissue donated for future unspecified use is paramount. In addition, we do not feel that the process for application to use tissue collected for future unspecified use has been fully developed in this document. We suggest that there should be a well detailed process for accessing tissue, and clearly defined responsibility for maintaining ethical standards.

For example: What will be the monitoring process and who will be obliged to police ethical use of tissue? Does responsibility for monitoring the ethics of those groups to whom human tissue is released lie with the investigator who releases them? What happens to tissue in the event that a repository is closed down, for example, due to loss of funding?

It should not be assumed that all repositories will be large governed biobanks. In many cases we would expect researchers to hold a small number of samples within their own collections. Does a prospective researcher need to apply to the ethics committee with a letter from the collection curator agreeing to supply subject to ethics approval / signed agreement assuring compliance with intent of donor?

10. Do you have any other comments on the proposed guidelines?