Guidelines on the Use of Human Tissue for Future Unspecified Research Purposes
Discussion document
How to Have Your Say

Your feedback is important in helping to develop the Guidelines on the Use of Human Tissue for Future Unspecified Research Purposes. Please take this opportunity to have your say. A number of questions have been posed throughout the ‘Ethical Issues’ section of the document to help focus your responses.

Please forward your submission to:

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All submissions are due by 5 pm, Friday 11 August 2006.

If you require additional copies of this document, you can print them from the website: www.moh.govt.nz – look under publications.

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The Ministry of Health is interested in any comments you may have on any aspect of the proposed Guidelines. All submissions will be analysed before the draft guidelines are finalised and sent to the Minister of Health for final approval. It would help the analysis of submissions if your comments were referenced either to the specific questions raised throughout the ‘Ethical Issues’ section of the document or to the relevant clause of the proposed guidelines. To assist you in making your submission, the questions raised in the document are gathered together after the proposed guidelines, at the back of this document.

If you are making a submission on behalf of an organisation, please describe the organisation and its interest in relation to the proposed Guidelines on the Use of Human Tissue for Future Unspecified Research Purposes, identify your position within the organisation, and indicate the extent of any consultation or discussion you have undertaken with your organisation. If you are making a submission individually, please indicate the reason for your interest (eg, as a consumer, researcher or health practitioner).

Please note that your submission and all correspondence you have with the Ministry may be the subject of requests under the Official Information Act 1982. If there is any
part of your submission or correspondence that you consider could be properly withheld under the Act, please include comment to this effect along with reasons why you want the information withheld. If you are an individual as opposed to an organisation, the Ministry will omit your personal details from the submission if you include the following statement at the front of your submission and sign it:

‘I do not give permission for my personal details to be released to persons requesting my submission under the Official Information Act 1982.’
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1 Introduction

1.1 The purpose of this document

The purpose of this discussion document is to seek your views on the proposed guidelines on the use of human tissue for future unspecified research purposes. There are currently no specific guidelines covering this area. However, both researchers and ethics committees have highlighted the need for a consistent approach. Once finalised, it is proposed that the guidelines would form part of the Operational Standard for Ethics Committees, and would be used by researchers, and by ethics committees when considering applications for the use of human tissue, and information derived from that tissue, for future unspecified research purposes.

This document provides background to the issue, and explores the kinds of developments in research that are creating the need for tissue collections without a specific research purpose. The document also reviews the current regulatory framework in New Zealand with respect to informed consent for the donation and use of human tissue, outlines some of the current international thinking on the issue, and discusses the ethical issues associated with this type of tissue use.

In response to these complex ethical issues, proposed national guidelines have been developed to inform researchers of New Zealand’s approach to the use of human tissue for future unspecified research purposes, and to ensure consistency in the way these types of research applications are considered by health and disability ethics committees. The guidelines reflect the need to protect individuals’ autonomy and respect the importance of informed consent while allowing participants to consent to use of their tissue in future unspecified research.

1.2 Definition of human tissue

Human tissue is any human cells and any material that includes human cells. However, the guidelines do not cover gametes and embryos, and established cell lines derived from human embryos.¹

1.3 Why is human tissue important for research?

In New Zealand, as in other countries, tissue taken during post-mortem or medical treatment is often retained beyond the period necessary to establish the cause of death or to establish a medical diagnosis. This includes material in pathology archives such as histology slides of various tissues like blood, bone marrow and tumours, and other stored reference collections. Having such tissue available is crucial to many aspects of diagnosis and treatment, population health programmes and illness prevention, and to extending our understanding of the human body and its functions.

¹ Gametes and embryos, and established cell lines derived from human embryos, are covered by the Human Assisted Reproductive Technology Act 2004 and guidelines on the research use of established embryonic stem cell lines (currently being finalised).
Advances in science and technology are now enabling new approaches to research using human tissues in areas such as cancer and the genetic determinants of disease, as well as developments in current clinical treatments and the promise of new therapies. These developments make use of – or are sometimes wholly dependent on – tissues collected for other clinical, diagnostic or research purposes, and they are prompting the creation of new collections of tissues for research in various forms of ‘bio-banks’ around the world.

In New Zealand a number of major research projects rely on stored tissue, such as the Human Brain Bank in Auckland, which uses donated brain tissue to conduct research on neuro-degenerative diseases, and the Otago School of Dentistry, which is studying tissue samples to determine if there is a link between oral cancer and the yeast that causes oral thrush. There is also an interest in establishing a DNA bank to use in research on rare disorders.

In the case of rare diseases, particularly, there is considerable research value in being able to source tissues from different countries, and there can be benefit to both patients and researchers if New Zealand researchers are able to participate in and contribute to international research.

1.4 Consenting to unspecified research

As a result of these developments, several New Zealand research groups wish to bank human tissue for future unspecified research. In particular, researchers involved in international research, including clinical research collaborations, wish to send human tissue to study centres overseas for future unspecified research.

It is increasingly likely that researchers will be interested in accessing tissues samples for research purposes not anticipated at the time of collecting the tissue. It is also likely, especially as new technologies develop, that there will be increasing research interest in accessing tissues held in a number of different collections, and across national boundaries.

These developments raise a number of issues for researchers, patients, research participants and ethics committees, including:

- Is it reasonable or acceptable to ask donors of tissues to give consent to a future unspecified use of their tissues in research?
- If such consent can be given, what information should be provided, and what conditions is it reasonable or acceptable for donors to be able to place on that future unspecified use?
- If such consent can be given, should there be any constraints on, or requirements for, the use of information derived from those tissues?
- If such consent can be given, are there any additional protections for those tissues samples that should be in place with respect to New Zealand researchers accessing them?
• Is it acceptable, and if so under what conditions, for tissue samples sent overseas for diagnosis to be stored and used for future unspecified research? If so, what oversight or protection is it reasonable to require from New Zealand?

• If parents or guardians have given proxy consent to the future unspecified use of children’s tissues, what provisions, if any, should be in place to provide for children to withdraw consent at or after age 16?

These issues are discussed further in the ‘Ethical Issues’ section of the document.
2 Current Regulatory Frameworks and Requirements

A range of Acts, regulations, guidelines and approval procedures already cover the non-therapeutic use of human tissue.

- Human Tissue Act 1964
- Code of Health and Disability Services Consumers’ Rights 1996
- Operational Standard for Ethics Committees
- Guidelines for Health Research with Children
- National Application Form for Ethical Approval of a Research Project
- Hazardous Substances and New Organisms Act 1996

These are discussed in more detail below.

2.1 Human Tissue Act 1964

The Human Tissue Act 1964 governs the collection of tissue from deceased persons (excluding stillborn children) and its use in therapy, medical education, research, post-mortem examination and anatomical examination. It also provides for non-coronial post-mortem examinations, schools of anatomy and inspectors of anatomy.

The following is a summary of the constraints on the use of tissue for non-therapeutic purposes established in the Human Tissue Act.

- If the deceased has requested this use then the use may be authorised by the person lawfully in possession of the body. Any terms specified by the deceased must be honoured.
- If the deceased has objected, then this use cannot be authorised.
- If the deceased has not stated an opinion, then the decision rests with the partner and family.
- If there is no known objection from the deceased or relevant family, then the use may be authorised by the person lawfully in possession of the body.

The Ministry of Health has undertaken a major review of the regulatory framework for human tissue with a view to replacing the current Human Tissue Act with new legislation, and it is expected that new legislation will be introduced in 2006. New legislation will address, among other things, the use of human tissue in research, what requires consent and who can give consent, safety, storage and disposal. The proposed ethical guidelines for future unspecified use of human tissue might need to be reviewed once new human tissue legislation is in place, to ensure consistency with the new legislation.
2.2 Code of Health and Disability Services Consumers’ Rights 1996

The Code of Health and Disability Services Consumers’ Rights is a regulation made under the Health and Disability Commissioner Act 1994. It provides a set of rights for people receiving health and disability support services and the responsibilities of providers, including rights in relation to informed consent. It only applies to living people. The rights that are most relevant to the use of tissue for future unspecified research purposes are described below.

- Services may be provided to a consumer of health and disability services only if that consumer makes an informed choice and gives informed consent. For example, a person’s agreement must be obtained, after being given sufficient information, to give a sample of tissue such as a biopsy or blood test, or to have a surgical procedure such as the amputation of a limb.
- Consumers of health and disability support services must be fully informed of any proposed participation in teaching or research (including being informed about whether the research requires and has received ethical approval). Consent to participate in research as part of a health care procedure must be informed and in writing.
- Every consumer may use an ‘advance directive’ in accordance with the common law. An advance directive is a written or oral instruction whereby a consumer makes a choice about a possible future health care procedure that is intended to be put into effect if the person is unable to make that choice at the time due to incompetence.
- Right 7(10) requires that informed consent be obtained before storing, preserving or using bodily substances or body parts obtained in the course of a health care procedure. There are two exceptions to this general requirement: research that has received the approval of an ethics committee; or for professionally recognised quality assurance programmes, external audit or evaluation activities that are aimed at improving the quality of services (see section 3). In his review of the Health and Disability Commissioner Act and Code, the Commissioner emphasised that ‘informed consent for the use of body parts or bodily substances in research will still be required in the vast majority of cases, and research proposals will need to address the question of consent by participants’ (Health and Disability Commissioner 2004: 42).
- Clause 4 of the Code extends the meaning of ‘consumer’ for the purposes of Right 7(10) to include a person entitled to give consent on that person’s behalf.
- Right 9 extends all the other rights in the Code to occasions when a consumer is participating in, or it is proposed that a consumer participate in, teaching or research.

2 Right 7(1).
3 Right 6(1)(d).
4 Right 7(6).
5 Right 7(5).
These rights mean that consumers of health and disability support services need to agree to the collection of tissue at the time of a health care procedure – whether that tissue is to be used for their health care or is being collected for teaching or research. They do not, however, rule out broad consent to the storage and use of human tissue for future unspecified research purposes.

2.3 Operational Standard for Ethics Committees

The Operational Standard for Ethics Committees (Ministry of Health 2006) guides the operation of health and disability ethics committees and accredited institutional ethics committees.

The primary role of health and disability ethics committee is to provide independent ethical review of proposed health research and innovative practice conducted in New Zealand in order to safeguard the rights, health and wellbeing of consumers and research participants and, in particular, those persons with diminished autonomy. In order to do this, ethics committees are required to:

- foster an awareness of ethical principles and practices in the health and disability sector and research community
- facilitate excellence in health research and innovative practice for the wellbeing of society
- collaborate with researchers to ensure that the interests, rights, dignity, welfare, health, and wellbeing of participants and consumers are protected
- give due consideration to community views
- consistent with section 4 of the New Zealand Public Health and Disability Act 2000 and He Korowai Oranga (Minister of Health and Associate Minister of Health 2002), recognise and respect the principles of the Treaty of Waitangi
- operate in accordance with the Operational Standard for Ethics Committees
- operate in accordance with any guidance issued or approved by the Minister of Health.

All proposed health and disability research investigations that involve human participants must be submitted to an ethics committee for review. In particular, ethics committees are required to review proposals that seek to further scientific or professional knowledge by means of laboratory analysis of the blood, tissues, etc of living people, cadavers or discarded human body tissues.
2.4 Guidelines for Health Research with Children\textsuperscript{6}

These guidelines set out special ethical considerations for research involving children, and form part of the Operational Standard for Ethics Committees. They are based on six principles, which are mostly taken from the Guidelines of the Royal College of Paediatrics and Child Health 1999 and the European Convention for the Protection and Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine 1996.

Summarised, the key principles recognise that:

- research involving children is important for the benefit of all children
- children have their own unique set of interests
- research should only be done with children if comparable research with adults could not answer the same question, and if the purpose is to obtain information relevant to the needs of children
- a research procedure that is not intended to directly benefit the child participant is not necessarily unethical
- all research proposals involving children should be reviewed by an accredited ethics committee
- legally valid consent should be obtained from the child, parent or guardian, as appropriate. When parental consent is obtained, the assent or consent of the children should also be obtained, wherever possible.

These guidelines appear to have legal standing in New Zealand through the Code of Rights. Right 4(2) of the Code provides: ‘Every consumer has the right to have services provided that comply with legal, professional, ethical and other standards’ (Peart et al 2003).

2.5 National Application Form for Ethical Approval of a Research Project

All research applications seeking ethical approval must be submitted on the National Application Form for Ethical Approval of a Research Project. In relation to human tissue, the form requires detailed information about:

- tissue collection – who will undertake the procedure, the type of tissue, and the number and volume of samples
- tissue use – who will have access to tissue samples, whether samples will go out of New Zealand and for what purpose
- tissue storage and disposal – the means of storage and labelling, the length of storage and method of disposal, and whether data or other information will be stored for use in a later study

\textsuperscript{6} This subsection is based on the Operational Standard for Ethics Committees, Ministry of Health 2006, Appendix 1, pp. 52–56.
• genetics issues, including:
  – whether the research involves analyses of DNA or clinical genetics, and if so, how samples are to be collected and stored, whether they will be transported out of New Zealand, and who will have access to them; if samples are to be collected from Māori, a separate analysis of these issues is required for those samples
  – information about the ability for the sample or data to be withdrawn by the participant
  – whether it will be possible to link information from DNA analysis to other health information about the participant, and how privacy is to be assured
  – whether a clinical geneticist will be involved in the study, and if provision has been made for genetic counselling to be available to participants if required.

2.6 Hazardous Substances and New Organisms Act 1996
The Hazardous Substances and New Organisms Act 1996 exists to protect the environment and the health and safety of people and communities by preventing or managing the adverse effects of hazardous substances and new organisms. The Act was amended in October 2003 so that the definition of a ‘new organism’ includes the genetic modification of human cells and tissues, including genetically modified human cells. Where research using human cells involves importing or developing genetically modified cells, the law requires approval from the Environmental Risk Management Authority (ERMA). ERMA approval is additional to approval from a health and disability ethics committee.

2.7 Health Information Privacy Code 1994
The Health Information Privacy Code is established under the Privacy Act 1993 and governs the collection, storage, security, access, correction and retention of health information. It is concerned with protecting the privacy of individuals and the highly personal information relating to identifiable individuals that is required for health care.

In terms of the use of human tissue, the question arising most frequently is whether genetic information, obtainable from human tissue, requires more protection than that currently provided by the Health Information Privacy Code. Requirements regarding consent to the use of information derived from human tissue, including genetic information, will be included in proposed new human tissue legislation.

2.8 Other codes
Health practitioners are also regulated, practise under professional codes and can be subject to disciplinary proceedings. Employers, such as District Health Boards, have codes of confidentiality and good practice as part of their terms of employment.
3 Consent

A major focus of this document is the question of whether and how to allow people to consent to an unspecified use of their (or their child’s) donated tissue. One response might be to say, ‘What’s the issue? Why not just let people consent to what they want to?’ The issue is that at the very heart of protecting the rights of people whose tissue may be used in various ways is the notion of informed consent: someone has to be fully aware of what decision they are making and the alternatives available before we can be sure that the process is fair.

This section looks at informed consent, how it relates to children, the distinction between specific and broad consent, and how linking or de-linking data affects the process.

3.1 Informed consent

Informed consent is a central part of the New Zealand health and disability sector. The importance of informed consent is reflected in the Code of Health and Disability Services Consumers’ Rights and ethics committee processes, and the requirements for informed consent are part of the protection of the welfare and rights of research participants.

Informed consent is the ability to make choices based on sufficient information and consideration, as described in the Operational Standard for Ethics Committees (Ministry of Health 2006). It assumes that:

- adequate information is provided to enable an informed judgment to be made
- information provided is presented in a way that will enable it to be understood by each individual
- the consent is voluntary (participation is free from manipulation, coercion, inducement or any other undue influence) (Ministry of Health 2006: para 28).

Informed consent is based on information, and the Operational Standard specifies a number of dimensions to that information, including (para 30):

- all foreseeable risks, side-effects or potential harm that are material to the research participant, and how significant risks will be monitored and managed
- the right to withdraw from the research or innovative practice at any time, and to withdraw data from any participation until a specified time, without affecting treatment or future health care
- the right of access to health information about that individual, as set out in the Health Information Privacy Code 1994
- how long the data and/or tissue will be kept, how the data and/or tissue will be stored, who will be responsible for the secure storage of the data and/or tissue, and how the data and/or tissue will be destroyed
- the research participant’s access to research findings.
In addition, the Operational Standard specifies that research involving the storage, preservation or use of human tissues or bodily substances cannot proceed without the consent of the person or their legal representative, and that 'consent should be obtained before human tissue or bodily substances may be used for any purpose other than that for which consent was originally given' (para 33).

The Operational Standard also recognises that the Code of Health and Disability Services Rights makes provision (Right 7(10)) for a body part or bodily substance removed or obtained in the course of a health care procedure to be stored preserved or used without informed consent:

b. ... for the purposes of research that has received the approval of an ethics committee;

c. for the purposes of one or more of the following activities, being activities that are each undertaken to assure or improve the quality of services:
   (b) a professionally recognised quality assurance programme:
   (c) an external audit of services:
   (d) an external evaluation of services (para 34).

Further, the Operational Standard states that:

Ethics committees may waive the need for informed consent for storage, preservation or use of human tissue or bodily substances where it is not practicable to get consent, or where the ethics committee is satisfied that the potential public benefit in allowing the research to proceed outweighs the very strong need to protect an individual’s right to consent. In practice, this situation will be uncommon and only occur in limited circumstances ... (para 36).

3.2 Consent for children

There are, of course, situations where an individual is unable to give informed consent; for instance, because of incapacity or injury, or because of their young age. In such situations alternative means of protecting the individual are necessary. Most often that consent is sought from a patient’s or research participant’s legal representative or guardian. In the case of children, their parents or guardians are responsible for them until the age of 18. However, as set out in the Care of Children Act 2004, in New Zealand the legal age of consent for a health care procedure is generally 16 years.

The Operational Standard advises that:

- children and their parents, guardians or caregivers must be fully informed about research in a manner best suited to their needs, and if proxy consent is given, the proxy must also be advised of the child’s right to withdraw from the research at any time (para 262)
- children’s consent or assent must be obtained unless the child is unable to communicate, and care must be taken to ensure that no pressure is placed upon a child to consent in research if the procedures are not intended to be of direct benefit (para 263)
children have the right to withdraw consent to the continued use or retention of personally identifiable health research data once they attain the age of 16 (para 265).

From this it may be inferred that children also have the right to withdraw consent to the continued storage and use of their tissue once they attain the age of 16. Provision needs to be provided by researchers wherever possible for this to occur.

The Operational Standard includes guidelines for research with children (refer section 2.4 of this document). These allow for research with children that is not of direct benefit to the child but is likely to yield generalisable knowledge about the child's disorder or condition where:

- any risk represents a minor increase over minimal risk
- the interventions or procedures present experiences to the child participants which are reasonably commensurate with those inherent in their actual or expected medical, psychological, social or educational situations (para 260).

Where research is not of direct benefit to the child, nor likely to yield generalisable knowledge about the child's disorder or condition, research can only proceed where there is minimal risk, and that risk is commensurate with the importance of the knowledge gained.

The Operational Standard does recognise that informed consent is not the only way in which research participants' rights and interests can be protected, and also that there are some practices (eg, quality assurance) where patient or research participant consent is not required. Where informed consent is not required or practical, there are other means by which the person's rights and interests must be protected, and responsibility for ensuring this lies with ethical review.

3.3 Specific and broad consent

Informed consent from research participants is normally sought for a specific project and is limited to that project ('specific consent').

Under certain conditions, however, participants may give consent to the use of their data and tissue in future research proposals that are an extension of, or closely related to, the original research project, or even future proposals that are in the same general area of research. In some instances, consent may include permission to enter the original data into a database or tissue bank. The usual expectation is that research subjects and health care patients will not have their tissues used in additional and subsequent research without their knowledge, and many would also expect to be able to choose for themselves the uses to which their tissues are put.

The issue under consideration in this document is whether it is ethical for participants to give informed consent for the use of their tissue, or information derived from their tissue, in future unspecified research where participants' comprehension of the nature and extent of the research will inevitably be very limited. This type of consent is commonly called 'broad consent'.

The Nuffield Council on Bioethics (2003) outlines the benefits of broad consent in Pharmacogenetics: Ethical issues:

Allowing broad consent may be of significant benefit to researchers and to society’s interest in the acquisition of knowledge about health and disease. Researchers may not be able to predict at the start of a study whether the information gathered may subsequently be useful in additional research. If this proves to be the case, the practical difficulties of contacting participants and obtaining new consent for the use of their data in a different project, perhaps a number of years later, may be prohibitive.

3.4 Linking data

Whenever tissue samples are accessed for research, there are decisions about whether or not, or in what ways, links can be made between the tissue sample itself, and personal and health information about the donor. There are various reasons why such links are desirable.

- The research may be of direct clinical relevance to the donor of the tissue.
- Research results may be important to informing choices made about clinical care.
- Even when research results are not of direct clinical relevance to the donor, the donor may still have an interest in knowing what use their tissues were put to, and what knowledge was generated.
- There are research situations where it is important to be able to access information about the donors of those tissues – information that includes medical history and treatment, and possibly clinical outcomes following treatment. Some of this information may be subsequent to the donation of the tissues.

There are therefore decisions to be made about whether tissues samples should be available for research in anonymous form (no identification attached or possible), coded form (links can be made in either or both directions between tissue samples and records of the donor), or identifiable form. These decisions need to consider both:

- whether, and in what circumstances, there is or should be an obligation for researchers to provide feedback to tissue donors
- the practices and governance arrangements that provide protection to patient confidentiality and privacy when tissues are made available in coded or identifiable form.

Any discussion of a requirement to re-contact donors, whether for re-consent for research not envisaged at the time of donation of the tissues or to provide information on the results of research using donated tissue, needs to consider issues of practicality, benefit and opportunity cost.
4 Ethical Issues

Developments in technology have opened up fresh possibilities for research, and it is now possible to explore new questions using tissue samples collected for many different purposes and held in a range of tissue repositories both in New Zealand and overseas. There is considerable potential for increased knowledge of disease processes and causes, and for new treatments.

However, these developments raise a number of ethical issues, including:

- whether or not consent for future unspecified research use of tissues is acceptable, and if so under what conditions
- the use of information arising from the use of these tissues
- requirements for protecting tissue samples
- the sending of tissue samples overseas
- provisions for children to later withdraw consent to the use of their samples.

In addition, the issue of expedited ethical review has been raised for situations where consent to future unspecified research use of tissues has been given.

So far we have looked at the regulatory framework governing the use of human tissue, and in particular at the regulations covering informed consent. The following discussion now seeks to tease out the ethical issues, and to provide an interpretation of the current Operational Standard in relation to these issues.

4.1 Consenting to unspecified use

Is it reasonable or acceptable to ask donors of tissues to give consent to a future unspecified use of their tissues in research?

Patients and research participants will have various motives for participating in research. There is the potential for personal benefit (eg, possible access to novel treatments, or increased knowledge about their particular condition), but there are also altruistic reasons, including contributing to medical advances in areas related to their own or a family member’s health conditions, or to the advance of understanding of diseases and the development of treatments for other conditions. Some are simply keen to contribute to the creation of knowledge, whether in medicine or in other areas.

For some of these people, the motivation to contribute to research may be such that they are quite happy, or even highly motivated, for their tissues to be used for future unspecified research. They may not feel any need to know the exact uses of their tissues, and consider any restriction on a person’s right to make such a choice as paternalistic and a denial of their autonomy. They may see the right to donate their tissues in this way as similar to the right to donate their body, after death, to medical research.
However, allowing consent to future unspecified use of tissues is a shift from current requirements for consent, where there has been a clear requirement that consent be informed consent. As we have seen, informed consent from research participants is normally sought for a specific project and is limited to that project (‘specific consent’). The issue under consideration in this document is whether it is ethical for participants to give informed consent for the use of their tissue, or information derived from their tissue, in future unspecified research where participants’ comprehension of the nature and extent of the research will inevitably be very limited (‘broad consent’).

The issue here is to balance the participant’s right to informed consent against the potential for public benefit. There appears to be an implicit assumption that the physical risk to participants is minimal, given that the sample has already been collected. Risks to privacy and confidentiality would still need to be addressed in the same ways that are required when consent is sought and given.

Given that there are times when tissues can already be used in research without specific consent (see section 3), it seems reasonable to permit individuals to make a decision to donate their tissues for future unspecified research. Here the individual, rather than an ethics committee, in a context of low risk, is making the assessment for themselves about how they see the balance between the potential for benefit from the research and their personal need to be fully informed about research conducted on their tissues.

Consent to future unspecified use should, however, be distinct from consent for use in specified research. Potential participants may have a different set of preferences to guide their decisions when considering known research or future unspecified research.

The nature of consent could be anything from broad consent (yes, do what you like with it) to a more nuanced set of choices that could include such considerations as whether tissue samples can be linked (prospectively as well as retrospectively) to clinical or other personal information, how tissue should be disposed of, the range or type of research for which it could be used, or who may have access to the tissues for research purposes.

If it is reasonable for individuals to be able to give consent to future unspecified research use of their tissues, it is also important for there to be some agreement about what range of preferences they should be offered and can express within the consent process.

Q1. Do you think it is reasonable for patients and research participants to be able to consent to future unspecified use of their tissues in research?
4.2 Information and options

If consent to future unspecified research can be given, what information should be provided, and what conditions is it reasonable or acceptable for donors to be able to place on that future unspecified use?

Information

Although it is not possible to describe the use to which tissue is to be put, information can be provided about:

- options for how the tissue will be stored, managed and disposed of
- safeguards for protecting confidentiality and privacy
- provisions for withdrawing consent
- different cultural views of the significance of research using tissues
- who may have access to the samples and under what conditions
- ethical review of any future use.

Many of these information requirements are similar to those already expected for ethical review of research using tissue samples. The Operational Standard requires that at the time of consent, potential donors of tissue samples be informed about how data and tissue are to be stored and disposed of. Researchers can be expected to provide culturally appropriate options that are acceptable to potential donors. They will also be mindful of the requirements of the Operational Standard that they ‘not discriminate in the selection and recruitment, whether by inclusion or exclusion, of actual and future participants except where the exclusion or inclusion of particular groups is essential to the purpose of the research’ (Ministry of Health 2006: para 74). It will be important, therefore, to provide options acceptable to a broad range of potential tissue donors.

Tissue samples hold different cultural significance for people of different cultural traditions, and also within cultural groups. Some individuals may find that their wish to donate tissue to research is at odds with the values of the collective to which they belong. Possibly the potential for this conflict should be included in the information provided to the potential participant.

Where tissue samples may be sent overseas, it is important that potential participants know what provision there is for ethical review of future unspecified research with their samples, and be informed that the cultural values that inform ethical review in New Zealand and the options for disposal of tissues (including return of samples) will not be the same internationally.

The value of tissue collections will be to both private and public sectors, between which there are frequent collaborations. It may be that there will be commercial benefit from the use of tissues, although that benefit (eg, a new drug) is likely to result from knowledge gained from research with many tissues rather than with any particular tissue. However, it is appropriate that potential donors be informed of the commercial intention of the research collection, and who else could be granted access to the samples.
Options for consent

This information can then inform the choices potential participants can make about what uses of their tissues are acceptable to them in relation to the identification and/or linking of samples to clinical information, the range of acceptable research uses, and who else may have access to the samples in addition to the team that is seeking this consent.

Separate consent should be sought to send samples overseas, because some options for disposing of samples will not be available, and samples would no longer be subject to New Zealand ethical review or privacy requirements. Provision for withdrawing consent may also not be available.

Options provided to a potential research participant could include:

• refusing the use of their tissue samples in future unspecified research
• permitting the use of tissue samples in anonymised or coded form, with or without a need to contact them for future research use
• permitting the use of tissue samples for any future use, or for research into specific conditions only
• permitting third party use
• the means of disposal of tissue samples
• permission to send samples overseas
• permission for use in commercial research collaborations.

Q2. What information do you think should be provided to potential research participants?
Q3. Do you think the options for consent are reasonable and practicable? What other options could or should be provided to potential research participants?

4.3 Information derived from human tissue

If consent to future unspecified research can be given, should there be any constraints on, or requirements for, the use of information derived from those tissues?

Participants in research have an interest in the results of that research. The interest may be simply curiosity, or result from a sense of personal investment in the work, or the participant may have a direct clinical interest (what can this research contribute to my clinical care, or that of others with my condition, or others in my family?).
Where research is planned at the time of consent to collect a tissue, it is likely that researchers can be clear about how information from the research will be provided to the participant. When tissue is donated for future unspecified research such clarity may not be possible. The research may happen when contact details are out of date or the donor has died; it may be carried out by research teams other than that for which the sample was originally collected; some research could use tissues in unidentifiable form; or the original clinical or research contact may no longer be available. These factors may make re-contacting donors impracticable, very demanding on resources or even undesirable. If re-contact was required, it could result in contacting tissue donors about research they did not know was happening, they may not be interested in hearing about, or that has the potential to be distressing.

On the other hand, some information arising from the future use of tissues may be of direct clinical relevance to the donor of the tissue. In the case of a rare or severe disease it is likely that samples will be taken in the context of clinical care, and that it is sufficient to rely on information made available to the clinician involved in the research to inform subsequent care. However, there are also tissue banks being developed that are specific to particular conditions or clusters of conditions (e.g., rare genetic diseases, or cancers) where the ongoing clinical care of the research participants is not in the hands of research-active clinicians.

Whether or not there is a responsibility on the tissue bank to retain up-to-date contact details of donors and to ensure information is fed back to them or their clinical teams will depend on an assessment of the benefits or rights of the donor, compared with the costs such a requirement would place on research teams and funding. At times, any such requirement for later contact would be sufficient to exclude New Zealand from international collaborations.

There is already provision for ethics committees to put aside the requirement for informed consent for the use of stored tissues in research, and implied in that, the requirement to re-contact people with results of research arising from the use of their tissues. However, at the time consent is being sought for future unspecified research use, it is important that people be informed about whether or not information arising from the research will be provided to them, and if so through what mechanisms.

Q4. 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?
4.4 Additional protections within New Zealand

If consent to future unspecified research can be given, are there any additional protections for those tissue samples that should be in place with respect to New Zealand researchers accessing those samples?

Tissues donated to tissue banks or other research collections may be of interest to a wide range of researchers in subsequent years, including the research team or institution where the sample was originally collected and from elsewhere.

Tissue collections, and the institutions that care for them, will have their own policies and requirements as to who can access those tissues and for what work. Their own governance arrangements will regulate third party access. Tissue samples will be of limited size, and guardians of the samples may, for instance, only make them available for research directly relevant to the purpose for which they were originally collected, or only to research teams within their own organisation.

Whatever the policy of the particular tissue collection, all New Zealand research involving human tissue samples must be subject to ethical review. Ethical review of research using tissues for which future unspecified consent has been given must have confidence in the governance structures of research institutions to ensure that consent agreements are respected. However, this is true of all research. For this reason, the draft guidelines do not propose that the Operational Standard require any additional safeguards for New Zealand researchers accessing tissues donated for future unspecified use.

Q5. 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?

4.5 Tissue sent overseas

Is it acceptable, and if so under what conditions, for tissue samples sent overseas to be stored and used for future unspecified research? If so, what oversight or protection is it reasonable to require from New Zealand?

The value of tissue collections may also be realised in research projects that cross national boundaries. Collected in one country, the request to use and/or store the tissues may come from another country with different mechanisms and standards for ethical review. Different tissue collections may also be subject to different governance structures that provide differing means of protection and oversight of the tissues.

In addition to providing potential participants with a choice about whether or not their samples are sent overseas (see 4.2 above), ethics committees and research teams need to be confident that the standard of ethical review and governance of tissue collections is adequate to ensure that participants’ wishes are respected.
The current national application form for ethical approval for the use of human tissues already requests information about storage and future use of tissue samples to be used in research, including when samples are to be sent overseas. This information will inform assessments about the protections in place for samples where consent has been given to future unspecified use. The question about ethical safeguards needs to be interpreted in the broad sense that includes the governance arrangements of institutions holding tissue samples, in order for ethics committees to have confidence that the wishes of donors will be respected.

Q6. 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?

4.6 Research use of children's tissue

If parents or guardians have given proxy consent to the future unspecified use of children’s tissues, what provisions, if any, should be in place to provide for children to withdraw consent at or after age 16?

In a number of clinical situations (e.g., childhood cancer, rare genetic diseases) parents can give proxy consent for the use of their child’s tissues for research. Whether for specified or unspecified future research, there is an issue about what provision, if any, should be made to enable children to later withdraw that consent.

The current Operational Standard affirms the right to withdraw consent (para 30), and the Code of Health and Disability Services Consumers’ Rights provides for people to give consent when they are able, and this is usually by the time they are 16. Taken together, this has been interpreted as an expectation that those whose tissues were donated for research purposes should have the right to withdraw that consent when they are of an age to make their own choice.

Provision to withdraw consent would require that:

- tissues not be de-linked until after the child is of an age to give consent, and has done so – or is known to have died
- someone (family or institution) remembers that proxy consent has been given, either so that the child knows their need to approach the institution to give or withdraw consent, or so that the institution can (at a suitable age) approach the child for re-consent. If the institution carries responsibility for re-contacting the child it will be necessary to retain up-to-date contact details.
Such requirements may have a number of consequences.

- Parents would not be able to give consent for anonymised tissue samples to be given for future unspecified research. All tissue samples for this purpose would need to remain linked or identifiable.

- Tissues would not be able to be anonymised or de-linked until after consent is clarified by the now-grown child. This may mean that the tissues may not be included in some studies where researchers only wish to use anonymised or de-linked samples, and hence the contribution of that sample would be less than it might have been.

- If parents/family do not remember or inform the child that their tissues have been donated, or the now-grown child is not aware of the need to clarify consent, the samples will never be anonymised or made available in de-linked form.

- If responsibility to clarify consent with the now-grown child lies with the research institution rather than with the now-grown child, that institution will need to maintain up-to-date contact details for the child. This is unlikely to be an issue where the sample is collected in the context of clinical care (eg, for a childhood cancer), where the clinical team is involved in the research and is likely to remain in contact for some time. However, if the child recovers (or dies) that contact may be lost. There are also likely to be situations where the sample is collected from a child for research and there is no need for ongoing clinical contact, or the child’s clinical team is not directly involved in the research. In these situations it may be very difficult, if not impracticable, to maintain contact details. As with contacting people many years down the line with research results, there is also the potential for contact with tissue donors who did not know their sample was being used, are not interested in hearing about the use to which it is put, or find the information distressing.

- A requirement for the option of future withdrawal of consent may exclude researchers from international collaborations where samples need to be sent overseas, and exclude children from early access to novel or innovative treatments, or from making a contribution to understanding the disease processes from which they suffer.

If, on the other hand, there were no provision for later withdrawal of consent once the child is 16, there would be a different set of possible consequences.

- The proxy consent of the parents on behalf of the child would stand over the long term, with the child only able to withdraw consent if they know of the tissue donation, the sample has not been anonymised or de-linked, and they are able to make contact with the research institution. If all these conditions are met, they may be able to opt out of the research using their tissue.

- Tissues could be anonymised or de-linked, and made available to researchers for a range of possible research.

- The risk of exclusion from international research where anonymised or de-linked samples are used would be avoided, with subsequent potential benefits to the child where the research includes such things as access to innovative treatments, as well as to the researchers and their work.

The Operational Standard already recognises, in the case of the use of tissues in research, that an ethics committee may permit research in the absence of consent.
where it is not practicable to seek consent from an individual, and a potential public good can be weighed against the right of an individual to give consent.

Where parents or guardians have given proxy consent, it would seem reasonable also to permit parents or guardians to consent to future unspecified research use of a child’s tissues (including anonymisation and/or de-linking of samples) without the child needing to re-consent later. Re-consent poses significant practical difficulties, especially when weighed against the potential for public benefit. In addition, an ethics committee later reviewing a request to use such samples will be better informed about the likely wishes of the tissue donor, via the family’s consent, than in some situations where ethics committees may approve tissue use where there is no indication of whether tissue donors would be prepared to have their tissues used for future unspecified research.

Permission from parents to give proxy consent rather than providing for a child to later withdraw consent would apply whether the samples were to be used in research in New Zealand or overseas. If samples are to be sent overseas, however, it is important that parents and guardians are informed of any arrangements for ethical review that are different from those that apply in New Zealand and may be ethically significant to the family, such as the means of disposal of tissues.

Q7. 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?

4.7 Expedited ethical review and anonymised tissues

In a number of jurisdictions (eg, Australia, the USA) provision is being made for research with anonymised tissue samples to be carried out without ethical review. Research institutions are required to provide oversight. This option is not currently possible in New Zealand within the current regulatory environment. The Operational Standard currently requires ethical review of research that:

... seeks to further scientific or professional knowledge ... by means of laboratory analysis of human blood, tissues, etc, of living people, cadavers or discarded body tissues (for example, placenta) (Ministry of Health 2006: para 99).

However, there is provision in the Operational Standard for the chair of an ethics committee to delegate authority to approve (among other categories of research), ‘requests for the use of tissue/body parts that would normally be discarded and where the consumer has given consent’ (para 189). This could be extended to include delegated authority to approve the use of anonymised tissues. Such a provision would facilitate rapid turnaround times for low-risk research.

4.8 Specified areas of future use

There is also an argument that when tissues are donated to bio-banks or tissue banks, and donors consent to their samples being used for future as-yet unspecified research
related to the research for which the sample was originally collected, approval for use of those samples could be delegated to the bank, and not require subsequent ethics committee approval.

As with the above suggestion with respect to anonymised tissue, such a provision would not be feasible within the current regulatory environment. However, such research use could be facilitated if guidance to ethics committees extended the provision for delegated authority to include ‘requests for the use of tissue/body parts where the consumer has given consent to future unspecified forms of research in specified areas’.

Q8. Would participants be adequately protected, and would timely review of low-risk research be 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?

Q9. Are there any additional issues relating 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?
5 Cultural Considerations

New Zealand is a culturally and socially diverse country, and different groups in our society may have different responses to the issues raised by research that seeks to store and use tissue samples.

The use of human tissue in research and the requirements for research activities may be of particular interest to different cultural and religious groups, for whom tissue may have a symbolic significance. It is worth noting, however, that while concerns may be based in a particular cultural or religious belief, they may be shared by the population more generally.

5.1 Māori

Māori may have a particular interest in the use and storage of human tissue for research, particularly where tissue samples are sent to overseas study centres for specified or unspecified future use.

The following issues may arise for some Māori.7

- Informed consent may need to be explicit and identify the purpose for which donated tissue would be used.
- Both individuals and whānau/hapū may need to be recognised in the consent process.
- There may need to be an option for the return of tissue, and if tissue is not returned, for it to be disposed of in a culturally appropriate way.
- In terms of organ donation, a traditional Māori view is that organs and other parts of the body are part of an integrated whole and should not be considered in isolation from the whole.
- Genetic information derived from tissue from Māori is not owned by the individual, but it belongs to the Māori collective and needs to be protected.

5.2 Operational Standard

The Operational Standard provides direction on cultural and social responsibility, reminding researchers and ethics committees of both individual and collective values, particular considerations and responsibilities with respect to Maori, and the cultural diversity within and between communities.

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The Operational Standard emphasises the importance of cultural considerations in ethical review:

Research, innovative practice and the provision of services must be undertaken in a culturally sensitive and appropriate manner in full discussion and partnership with research participants and/or health and disability services consumers (Ministry of Health 2006: para 12).

It points out that:

[In some cultures the rights and autonomy of an individual may be complicated and constrained to a greater or lesser extent by those of related individuals and groups with specific authority over, or cultural ties to, that individual ... Ethics committees should also be aware and respect that in some cultures community values are often emphasised. Members of such societies see value in collective activities well beyond the value of each person's individual share of the benefits. New Zealand’s cultural diversity means that there may be a range of views on the relative weight of individual and collective values (paras 78–79).

In relation to consent, the Operational Standard states:

New Zealand law focuses on the requirement for an ‘individual’ to give their consent. In some communities and cultures, consent is not always considered to be an individual matter, but involves interested parties, such as consultation with extended families or community elders. Consent should be obtained in the most culturally appropriate manner for the participant. Proposals should, where appropriate, outline the processes intended to ensure that appropriate consultation occurs. In such situations, an individual is still free to give or withhold consent (para 40).
6 Proposed Guidelines on the Use of Human Tissue for Future Unspecified Research Purposes

The following guidelines should be read as a supplement to the Operational Standard for Ethics Committees (Ministry of Health 2006), providing an interpretation of the current Standard in relation to consent for future unspecified research use of human tissue.

The guidelines provide for individuals to consent to their tissues being used for future unspecified research, but specify the information and options that individuals should have before making that choice, and the issues that an ethics committee should consider.

In addition, the following amendment is proposed to section 6.8, paragraph 203 of the Operational Standard:

The chairperson may have delegated authority to approve the following:

vi. requests for the use of tissue/body parts that are fully anonymised
vii. requests for the use of tissue/body parts where the consumer has given consent to future unspecified forms of research.

6.1 Proposed guidelines on the use of human tissue for future unspecified research purposes

1. Participants may consent to the use of their tissue in future unspecified research.

2. Consent to the future unspecified use of a person’s tissue samples must be distinct from consent to collect the sample, and distinct from consent for use in specified research.

3. Information provided to an individual prior to seeking their consent for future unspecified use of tissue samples must include:

   3.1 all future unspecified research in New Zealand will be subject to ethical review. When tissue is sent overseas, future research may be considered by an overseas ethics committee without New Zealand representation

   3.2 whether or not, and under what circumstances, information about future unspecified research would be made available to the donor and/or (where relevant) their clinician

   3.3 an indication of the type or nature of the research to be carried out and its implications for the individual, where possible

   3.4 whether there is provision for withdrawal of consent for use of a sample, including for children when they reach 16, including, if relevant, where tissue is sent overseas

   3.5 where tissue will be stored, how it will be disposed of, and whether there is a cultural protocol for its disposal
3.6 whether or not tissue samples could be provided to other researchers and institutions, and whether or not that could include samples being sent overseas

3.7 known possible researchers or institutions that may use the tissues, if possible

3.8 whether or not collected samples will be provided to commercial biomedical companies, or will be used in commercial research collaborations

3.9 what provisions will be made to ensure patient confidentiality

3.10 who will own the tissue samples once they have been collected

3.11 that the participant’s decision regarding the storage of specimens for future research will in no way affect the quality of a participant’s clinical care

3.12 that different cultural views may inform choice about donation of tissue; for example, for some Māori, human tissue contains sacred genetic material that is collectively owned by whānau, hapū and iwi. Others may be concerned that when their genetic material is sent overseas, processes for monitoring and tracking what happens to their genetic material may not be available

3.13 information about the institution holding the tissue, for example, its aims, research procedures and research governance.

4. Consent forms must offer sufficient options to help individuals understand the nature of the choices that are open to them. Options could include:

4.1 refusing use of their tissue in future unspecified research

4.2 permitting only unidentified or de-linked use of their tissue in such research

4.4 permitting coded or identified use of their tissue for one particular study only, with further contact permitted to ask for permission to do further studies

4.5 permitting coded or identified use of their tissue for any study relating to the condition for which the sample was originally collected, with further contact allowed to seek permission for other types of studies

4.6 permitting coded or identified use of their tissue for any kind of future study

4.7 permitting anonymous use of their tissue for any kind of future study

4.8 permitting use of their tissue in commercial research collaborations

4.9 permitting access to medical and personal records, where coded or identified use of samples is permitted

4.10 available means of disposal of tissue (including culturally appropriate options)

4.11 permitting provision of samples to researchers other than those collecting the initial samples (third party use)

4.12 permitting sending of tissue overseas to collaborating researchers.

5. Before granting ethical approval, the ethics committee needs to be confident that:

5.1 donors of tissues will be presented with available information about potential future uses of their tissue, including any options available to them
5.2 there are procedures and processes in place to ensure ongoing protection of patient confidentiality

5.3 there are appropriate procedures and processes in place to re-contact the patient or their clinician where researchers have agreed to provide clinically relevant information that arises from the research

5.4 that the organisation storing the tissue has adequate governance structures, procedures and processes in place to ensure the donor’s choices are respected, such as appropriate storage facilities, control of access to tissue and information, and ongoing funding

5.5 if samples are being sent overseas and will not be subject to review by an ethics committee approved by the New Zealand Health Research Council, that any future use of tissue samples or the information derived from them will have ethical and scientific review by a committee or institutional review board which conforms to the *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (Council for International Organizations of Medical Sciences and World Health Organization 2002).
References


Appendix: International Guidelines

Although guidelines from other jurisdictions have no authority in New Zealand, they provide a context for our discussion in terms of how others have addressed these issues and the decisions they have made.

Council for International Organizations of Medical Sciences and World Health Organization

The International Ethical Guidelines for Biomedical Research Involving Human Subjects, produced by the Council for International Organisations of Medical Sciences and World Health Organization (2002) allows, in the commentary on the guidelines, for some limited waiver of informed consent, when:

... the research design involves no more than minimal risk and a requirement of individual informed consent would make the conduct of the research impracticable (for example, where the research involves only excerpting data from subjects’ records).

In relation to the use of specimens (or medical records) collected in the course of clinical care, these:

... may be used for research without the consent of the patients/subjects only if an ethical review committee has determined that the research poses minimal risk, that the rights or interests of the patients will not be violated, that their privacy and confidentiality or anonymity are assured, and that the research is designed to answer an important question and would be impracticable if the requirement for informed consent were to be imposed. Patients have a right to know that their records or specimens may be used for research. Refusal or reluctance of individuals to agree to participate would not be evidence of impracticability sufficient to warrant waiving informed consent. Records and specimens of individuals who have specifically rejected such uses in the past may be used only in the case of public health emergencies.

Where researchers wish to use biological specimens (or records) collected or used by another investigator, in the same or another country:

This raises the issue of whether the records or specimens contain personal identifiers, or can be linked to such identifiers, and by whom. ... If informed consent or permission was required to authorize the original collection or use of such records or specimens for research purposes, secondary uses are generally constrained by the conditions specified in the original consent. Consequently, it is essential that the original consent process anticipate, to the extent that this is feasible, any foreseeable plans for future use of the records or specimens for research. Thus, in the original process of seeking informed consent a member of the research team should discuss with, and, when indicated, request the permission of, prospective subjects as to: i) whether there will or could be any secondary use and, if so, whether such secondary use will be limited with regard to the type of study that may be performed on such materials; ii) the conditions under which investigators will be required to contact the research subjects for
additional authorisation for secondary use; iii) the investigators’ plans, if any, to destroy or to strip [the records or specimens of personal identifiers]; and iv) the rights of subjects to request destruction or anonymisation of biological specimens or of records or parts of records that they might consider particularly sensitive, such as photographs, videotapes, or audiotapes.

These guidelines clearly permit the collection of tissues for further specified use, and leave open the possibility that there ‘could be’ a secondary use. They also signal the importance of discussing with potential donors any constraints on the types of research that can be carried out on the tissue, when additional authorisation is necessary, what personal data is attached to the sample, and the rights of donors to request the anonymisation or destruction of specimens or records.

National Health and Medical Research Council (Australia)

In Australia, the National Health and Medical Research Council, Australian Research Council and Australian Vice-Chancellors’ Committee Draft of the National Statement on Ethical Conduct in Human Research: Second consultation draft (2006) states:

2.2.13 In many circumstances, consent is limited to the specific project under consideration (‘specific consent’). Under certain conditions, however, consent may extend to the use of data in future research projects which are an extension of, or closely related to, the original research project, or even in future projects which are in the same general area of research, for example, genealogical, ethnographical, epidemiological, chronic illness research, etc (‘extended consent’). In some circumstances this ‘extended consent’ may include permission to enter the original data into a databank. Any restrictions on the use of participants’ data should be recorded and the record kept with the collected data so that it is always accessible to researchers who want to access those data for research.

2.2.14 Participants may give their consent for the use of their data in future unspecified research that may not be related to the original project (‘unspecified consent’). Information about the nature and extent of this research will inevitably be limited. It is important to ensure at the time of agreement that the terms of the unspecified consent are clearly explained and recorded. Research proposals that rely on unspecified consent to the use of data may still require approval from a Human Research Ethics Committee (HREC), except where alternative processes of approval set out in paragraphs 5.1.7–5.1.9 apply to the research. Research proposals should include a record of the unspecified consent given by participants.

2.2.15 Data additional to that covered by the original extended or unspecified consent will sometimes be needed for research. Additional consent for access to such data may need to be sought from potential participants.

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8 These guidelines are still in draft form and are yet to be finalised.
The draft guidelines make provision for institutions to assess low-risk research, and to exempt certain classes of research from ethical review. Research that can be exempted from review (while still requiring institutional decision), includes ‘Research in which the only involvement of subjects is ... (b) the use of existing collections of data or records that contain only non-identifiable data about human beings’ (section 5.1.9).

Medical Research Council (UK)

In the United Kingdom, the Medical Research Council’s Operational and Ethical Guidelines: Human tissue and biological samples for use in research were updated in 2005 following the passage of the Human Tissues Act 2004 (UK). They state:

Although current MRC guidance ... states that it is not acceptable to seek completely unconditional blanket consent, for example using terms such as ‘all biological or medical research’, it is now considered reasonable to request consent for example for ‘future medical research projects which would have to be approved by a properly constituted research ethics committee’. It would be for the research ethics committee subsequently to decide whether each new research project could proceed on the basis of such broad consent. The MRC plans to review the guidance again in light of the Codes of Conduct to be issued by the Human Tissue Authority.

Nuffield Bioethics Council (UK)

The Nuffield Bioethics Council (2003) recommends:

Having obtained broad consent, all future projects must be approved by a competent Local Research Ethics Committee. We consider that it is permissible to request broad consent to the use of samples which are anonymous or anonymised. Where samples collected for a particular study are coded or identified, broad consent to future research may also be permissible, but should be sought separately from consent to the initial study ... An indication of the type or nature of the research likely to be carried out and its implications for the individual should be given where possible.

National Bioethics Advisory Commission (US)

The US National Bioethics Advisory Commission, in its 2001 report Research Involving Human Biological Materials: Ethical issues and policy guidance, stresses the importance of considering anonymous, linked and unlinked samples. It also draws attention to the necessity of distinguishing between historical collections of tissues (collected when standards for informed consent were different) and those collected according to their recommendations for informed consent.

Recommendation 8: When an investigator is conducting research on coded or identified samples obtained prior to the implementation of NBAC’s recommendations, general releases for research given in conjunction with a clinical or surgical procedure must not be presumed to cover all types of research over an indefinite period of time. Investigators and IRBs should review existing consent documents to determine whether the subjects anticipated and agreed to participate in the type of research proposed. If the existing documents are
inadequate and consent cannot be waived, the investigator must obtain informed consent from the subjects for the current research or in appropriate circumstances have the identifiers stripped so that samples are unlinked.

To facilitate future research with tissue samples, the Commission recommends:

... consent forms should be developed to provide potential subjects with a sufficient number of options to help them understand clearly the nature of the decision they are about to make. Such options might include, for example:

a) refusing use of their biological materials in research
b) permitting only unidentified or unlinked use of their biological materials in research
c) permitting coded or identified use of their biological materials for one particular study only, with no further contact permitted to ask for permission to do further studies
d) permitting coded or identified use of their biological materials for one particular study only, with further contact permitted to ask for permission to do further studies
e) permitting coded or identified use of their biological materials for any study relating to the condition for which the sample was originally collected, with further contact allowed to seek permission for other types of studies, or
f) permitting coded use of their biological materials for any kind of future study.

There are situations where the NBAC considers it appropriate to waive consent even where the tissues are coded or identified, when there is little or no risk to the subjects whose consent would be difficult or impossible to obtain. The presumption is that the research is of minimal risk if:

a) the study adequately protects the confidentiality of personally identifiable information obtained in the course of research
b) the study does not involve the inappropriate release of information to third parties, and
c) the study design incorporates an appropriate plan for whether and how to reveal findings to the sources or their physicians should the findings merit such disclosure.

Their report also makes distinctions between linked and unlinked samples in the assessment of need for ethical review at all. Where tissues are unidentified, or unlinked, they do not think ethical review is required at all.

In its recommendations covering the release of samples from a tissue repository the NBAC recommends:

Before releasing coded and/or identified samples from its collection, a repository should require that the investigator requesting the samples either provide documentation from the investigator’s IRB that the research will be conducted in compliance with applicable federal regulations or explain in writing why the research is not subject to those regulations.
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_robb@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_robb@moh.govt.nz

Submissions close on Friday 11 August 2006.

This submission was completed by:

Name: .......................................................................................................................... .......
Address: ............................................................................................................................
Email: ................................................................................................................................
Organisation: ..................................................................................................................
Position: .............................................................................................................................

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:

☐ Consumer
☐ Academic/research
☐ Pacific
☐ Education
☐ Provider
☐ Non-government organisation
☐ Professional association
☐ Other (please specify) .......................................................................................... .......
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?

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

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

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?
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?

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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?

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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?

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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?

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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?

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