

Part B: Non-Therapeutic Use of Tissue

This Part of the discussion document is concerned with the use of human tissue for non-therapeutic purposes. These purposes and the current regulatory framework are described, and the key problems are identified. Sections B4 to B10 then discuss issues to be covered by a new regulatory framework.

B1 Non-therapeutic uses of human tissue

Human tissue has a number of non-therapeutic uses. It is crucial to many aspects of diagnosis and treatment, population health programmes, illness prevention, and extending our understanding of the human body and its functions.

The main non-therapeutic uses of tissue are as follows.

B1.1 Diagnosis and other uses as part of health care

Tissue is used as part of the care of individual health care consumers, or may result from such care. For example, a small tissue sample (a biopsy) may be taken for testing to assist a health practitioner with diagnosis; or tissue, such as placenta or an appendix, may result from childbirth or a surgical procedure. The proposals in this document are not generally concerned with tissue obtained during a health care procedure except where this tissue may be used for another non-therapeutic purpose (eg, tissue resulting from surgery that is donated and subsequently used in research or education). This situation is discussed in later sections.

B1.2 Anatomical examination

Whole bodies of deceased persons that have been bequeathed with consent are dissected and examined by health practitioners during their education (eg, medical students or physiotherapy students). This allows a detailed examination of the structure of the human body and how the components relate to each other.

B1.3 Education and training

Tissue from living or deceased persons is used for education and teaching. For example, health practitioners may study preserved specimens before undertaking a complex procedure on a patient, or may study microscope slides of tissue as part of in-service training within hospitals (particularly in teaching diagnosis skills). Tissue samples may also be used as part of other teaching programmes or courses to enhance the quality of care for New Zealanders.

B1.4 Research

Our understanding of the human body, its ailments and potential treatments is expanding rapidly, and human tissue is vital for such research. The research uses for human tissue are many and varied. For example, the Human Brain Bank in Auckland uses donated tissue to research the causes and potential ways of treating neuro-degenerative diseases of the brain (eg, Alzheimer's, Parkinson's and Huntington's disease), and the Otago School of Dentistry is studying tissue samples to determine if there is a link between oral cancer and the yeast that causes oral thrush. Research over the years using human tissue has also vastly increased our understanding of, and ability to treat or minimise the impact of, heart disease, cancer, HIV/AIDS and many other diseases.

B1.5 Determining the cause of death, or gathering more information about an illness, through a post-mortem examination

The majority of post-mortem examinations are now undertaken under the authority of the coroner when required under the Coroners Act 1988, such as when the cause of death is otherwise unable to be ascertained (coronial post-mortems and the Coroners Act are under review by the Ministry of Justice). However, a non-coronial or hospital post-mortem may be requested by the family of the deceased or by the physician to provide further information about the cause of death of a person.

B1.6 Clinical audit

A clinical audit for quality assurance purposes may include examination of preserved tissue, such as specimens stored on microscope slides. This type of audit would usually be undertaken on existing tissue collections (such as those used for clinical purposes, described above).

Note that the above categories of non-therapeutic tissue use do not stand alone. Tissue collected for anatomical examination may be preserved and used subsequently for education or research. Tissue collected for clinical purposes may be valuable for researchers, and a post-mortem examination provides a practical time to collect tissue, with consent, for other purposes.

B2 Current regulation of tissue for non-therapeutic use

The regulation of non-therapeutic tissue use spans a range of acts and regulations. These are listed below and then described. Much of the current regulatory framework is currently being amended or reviewed.

- Human Tissue Act 1964 – governs the collection of tissue from deceased persons for anatomical examination, education, and research. It also provides for non-coronial post-mortem examinations, schools of anatomy and inspectors of anatomy.
- Code of Health and Disability Services Consumers' Rights 1996 – sets out the rights of consumers of health and disability support services and the responsibilities of providers.
- Operational Standard for Ethics Committees 2002– provides the operating procedures for health and disability ethics committees.
- Hazardous Substances and New Organisms Act 1996 – amended in October 2003 to include the genetic modification of human cells and tissues.
- Supplementary Order Paper to the Human Assisted Reproductive Technology Bill 1996 – proposes a framework for the regulation of assisted human reproductive procedures and research. Certain unacceptable activities will be prohibited, and all applications to undertake human reproductive research and non-established procedures will require ethical approval.
- Health (National Cervical Screening Programme) Amendment Act 2004 that has recently amended the Health Act 1956 to give effect to some of the recommendations of the Gisborne Cervical Screening Inquiry.
- Health Information Privacy Code 1994 – provides protection for health information relating to identifiable individuals.

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

B2.1 Human Tissue Act 1964

The Human Tissue Act is contained in Appendix 2. The Act is concerned with the bodies of deceased persons (excluding stillborn children) and their use in medical education, research, post-mortem examination and anatomical examination.⁵ The Act is particularly focused on anatomical examination and schools of anatomy.

⁵ The Act also provides the legislative base for the collection of tissue from deceased persons for therapeutic uses; namely, organ and tissue donation. Issues relevant to organ and tissue donation are discussed in Part C of this document.

For all uses of tissue covered by the Act, the Act requires decency to be observed. This requires any person performing an examination or removing any part of a body under the Act to do so in a way that avoids unnecessary mutilation of the body and in an orderly, quiet and decent manner.⁶

B2.1.1 Requirements for tissue collection and use

The Act sets out the requirements to be met before:

- tissue can be removed from the body of a deceased person for medical education or research
- a hospital may conduct a post-mortem examination
- the body of a deceased person may be released to a school of anatomy.

With regard to obtaining consent, or, as it is phrased in the Human Tissue Act, establishing a 'lack of objection', the Act distinguishes between when the wishes of the deceased person are known and when they are not known. Table B1 provides a summary of the consent provisions in the Act. In each of these cases, the person lawfully in possession of the body of the deceased must be sure that an inquest or coronial post-mortem is not required before the body can be used for any of the purposes in the Act.

The person lawfully in possession of the body may be:

- the person in charge of the hospital where the deceased person is lying (a hospital is defined in the Health and Disability Services [Safety] Act 2001 and the Mental Health [Compulsory Assessment and Treatment] Act 1992)
- the superintendent of any penal institution where the deceased inmate is lying.⁷

In ascertaining the views of the persons listed in Table B1, the person lawfully in possession of the body is required to make 'such reasonable inquiry as may be practicable' to inform their decisions. In guidance issued in 1987, this phrase is described by the Department of Health (1987a) as requiring (in the context of organ donation), in most instances, that the matter be discussed with any one relative who has been in close contact with the deceased person. The relative should be asked their views, the views of the deceased and also if there is any reason to believe that any other relative would be likely to object.

The guidance further notes that there is no need to establish a lack of objection from all relatives or to make inquiries that are unreasonable or impractical. For example, if a donor's relatives were found to be young children, inaccessible or seriously ill, it would be impractical to ask them (Department of Health 1987a).

Section B2.1.3 describes the Human Tissue Act in practice.

⁶ See section 11 Human Tissue Act 1964.

⁷ Superintendents have been replaced with chief executives or general managers in most institutions.

Table B1: Decision authority over the use of tissue for anatomical examination, education, research and non-coronial post mortem under the Human Tissue Act 1964

	Anatomical examination	Education or research	Non-coronial post-mortem
Person lawfully in possession of the body	May allow this use provided there is no known objection from the deceased, surviving partner, or any surviving relative.	May allow this use provided there is no known objection from the deceased, surviving partner, or any surviving relative.	May allow this use provided there is no known objection from the deceased, surviving partner or any surviving relative.
Deceased person (the wishes of the deceased may be written, or oral and witnessed by two people)	May request or object to the use.	May request or object to the use. In requesting this use, the person may specify the terms of the request (eg, body parts to be used and for what purpose).	May object to this use.
Surviving partner	<ul style="list-style-type: none"> • Must agree with the request of the deceased. • May object to a request by the person lawfully in possession to use the body for this purpose. 	May object to a request by the person lawfully in possession to use the body for this purpose.	May object to this use.
Surviving near relative	If there is no surviving partner, must agree to a request of the deceased that their body be used for this purpose.	Not mentioned in relation to education.	Not mentioned in relation to post-mortem.
Any surviving relative	The same right as a surviving partner to object to a request by the person lawfully in possession to use the body for this purpose.	The same right as a surviving partner to object to a request by the person lawfully in possession to use the body for this purpose.	May object to this use.

	Anatomical examination	Education or research	Non-coronial post-mortem
Summary	<ul style="list-style-type: none"> • If the deceased has requested this use then the partner must agree before this use can be authorised by the person lawfully in possession. • If the deceased has objected then this use cannot be authorised. • If the deceased hasn't 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. 	<ul style="list-style-type: none"> • If the deceased has requested this use then the use may be authorised by the person lawfully in possession. Any terms specified by the deceased must be honoured. • If the deceased has objected, then this use cannot be authorised. • If the deceased hasn't 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. 	<ul style="list-style-type: none"> • The deceased, partner and family can all object to the use. • If there is any objection the use cannot proceed. • 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.

B2.1.2 Tissue management, monitoring and oversight

The Act sets some requirements for the management of tissue and provides some coverage of monitoring and oversight matters. These requirements are focused on tissue that has been donated for anatomical examination and schools of anatomy. In particular the Act provides that:

- schools of anatomy may be established on the authority of the Governor-General by order in council
- anatomical examination may only take place at a school of anatomy by a medical practitioner licensed by the Minister of Health, unless permission is given by an inspector of anatomy and school authorities for a body, or body parts, to be moved to another place for the purpose of teaching anatomy
- schools of anatomy must keep specific records about the bodies of deceased persons that have been bequeathed to the school
- inspectors of anatomy are appointed to oversee the practices of schools of anatomy
- inspectors of anatomy are to provide regular reports about bodies of deceased persons that have been bequeathed to the school
- inspectors of anatomy may give permission for any part of a body donated for anatomical examination to be retained indefinitely for further study
- all human remains resulting from anatomical examination are to be buried or cremated in accordance with the written instructions of an inspector, who will take into consideration any wishes that the deceased or their relatives have expressed.

B2.1.3 The Human Tissue Act in practice

There are a number of points to note concerning the operation of the Human Tissue Act in practice.

- Schools of anatomy do not accept bodies of deceased persons for anatomical examination without the consent of both the deceased and their family. Box B1 following describes the process used by schools for accepting bequeathed bodies.
- The ability, under the Act, for unclaimed bodies to be released for anatomical examination, education or research is not used in current practice in New Zealand. These provisions reflect historical circumstances when the bodies of persons that died without known relatives or sufficient resources for burial could be released for anatomical study. Unclaimed bodies have not been used in New Zealand since the 1950s.⁸
- Schools of anatomy are very appreciative of the donations of tissue they receive and currently receive sufficient bequests to fulfil teaching requirements.
- Schools of anatomy and inspectors of anatomy have developed good working relationships and report that the current provisions for managing and overseeing the processes regarding anatomical examination are working well.

Box B1: Bequests to schools of anatomy

The schools of anatomy at the universities of Auckland and Otago accept 30 to 45 bodies each annually and they both have similar processes for accepting bequests. The schools provide information about the process to individuals, family, solicitors, health practitioners, hospital staff, and organisations such as the Public Trust. After considering the information, those wishing to make a bequest are asked for a letter or completed form confirming their wish. Schools encourage people to discuss their wishes with close relatives and ascertain whether anyone is likely to object to their wish.

Public support for the bequest of bodies is good and the schools are able to meet their need for tissue from the geographic region around the school. Those wishing to bequeath their body are asked to inform their family and friends of the arrangements they would like if a school is unable to accept their bequest.

After the person's death, the family, health practitioner or undertaker informs the school. The licensed anatomist then checks the school's records. If the school does not have a record of the bequest, there are two options:

- i) an open discussion is held with the family to confirm that it was the wish of the deceased to bequest their body and to ensure that the family are all in agreement that the bequest should proceed; or
- ii) it is automatically declined – it is very important that a body is only accepted with the collective agreement of the whole family. A bequest will not be accepted if it is likely to cause any disharmony within a family.

⁸ For a fuller discussion of this history, see Jones 1994.

Following further discussion with family to ensure that everyone is comfortable with the process and understands what will happen, the body is moved to the school and embalmed. The school then writes to the family expressing their appreciation and gratitude for the bequest.

Bodies bequeathed to the schools are used for a variety of teaching and research purposes by medical and dental students, allied health science students, and academic staff. Most are used for anatomical examination. They may also be prepared by members of the technical staff as prosections. With the permission of the inspector, some tissue is preserved and kept using a technique known as plastination. Plastinated tissue keeps almost indefinitely and is extremely valuable for both teaching and research purposes.

Once the examination is complete, the school requests the permission of the inspector of anatomy to cremate the remains. If a family wishes, the person's ashes will be returned to them – under these circumstances no tissue is retained (excluding microscopic samples and tissue for which explicit consent has been gained from the family). Some families do not wish to have the ashes returned to them. If this is the case, the school ensures that the person's ashes are disposed of in a dignified manner – usually they are scattered in the memorial rose gardens at the crematorium. In Auckland an annual service of thanksgiving is held in the University's chapel.

The schools meet all the costs associated with the process, including the return of the ashes to the relatives where this has been requested.

B2.2 Code of Health and Disability Services Consumers' Rights 1996

The Code of Health and Disability Services Consumers' Rights (the Code) is contained in Appendix 3.

The Code is in regulations made under the Health and Disability Commissioner Act 1994. It provides a set of rights for people receiving health and disability support services and only applies to living people. The rights that are most relevant to tissue used for non-therapeutic purposes are described below.

- Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent.⁹ For example, a person must agree, 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).¹⁰ Consent to participate in research as part of a health care procedure must be informed and in writing.¹¹

⁹ Right 7(1).

¹⁰ Right 6(1)(d).

¹¹ Right 7(6).

- Every consumer may use an ‘advance directive’ in accordance with the common law.¹² An advance directive is a written or oral instruction where 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 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.
- Any body parts or bodily substances removed or obtained in the course of a health care procedure may be stored, preserved or utilised only with the informed consent of the consumer.¹³ This right is currently subject to some amendment (see section B2.2.1 for further discussion).

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. The Code also gives consumers the right to decide if any tissue that results from a health care procedure can be used for other purposes; for example, a person who has had surgery to amputate a leg can give informed consent for the amputated leg to be used for research into varicose vein formation. The Code also requires consumers to be given sufficient information to make an informed decision.

B2.2.1 Amendment to Right 7(10)

Right 7(10) of the Code provides that ‘any body parts or bodily substances removed or obtained in the course of a health care procedure may be stored, preserved or utilised only with the informed consent of the consumer’. That is, consent needs to be gained for the initial collection of tissue for health care purposes and for the subsequent storage and use of the tissue. Separate from this Review, the Government has decided to amend Right 7(10) as there are times when it is in the greater public interest to allow certain research and audit activities to be undertaken without specific informed consent. However, safeguards *must* be in place to ensure that this ability is only used when appropriate.

In 1999 the then Health and Disability Commissioner undertook a review of the Code, which included extensive consultation with consumers and the health and disability sector.¹⁴ As part of the Commissioner’s review, some researchers, pathologists and ethics committees proposed that Right 7(10) be amended to allow ethics committees to review specific research proposals to see whether the public interest should allow exceptions from compliance with the informed consent requirements in the Code. The current Health and Disability Commissioner accepted this proposal.

¹² Right 7(5).

¹³ Right 7(10).

¹⁴ Section 21 of the Health and Disability Commissioner Act 1994 requires reviews of the Code by the Commissioner.

The underlying concern is that it is not always reasonably practical to fulfil the consent requirements of Right 7(10), and in some cases this may hinder valuable public health research and audit activities for quality improvement processes. For example, a researcher may propose to use specific body parts or bodily substances for a purpose that was not envisaged, or indeed possible to envisage, at the time the samples were collected from the consumers, and it may not be practicable, or possible, to locate the consumers to seek new consent, particularly given the highly mobile nature of the New Zealand population, the number of samples that may be involved, and the time that may have elapsed since consent was initially obtained.

A similar exception is contained in Rule 11(2)(c)(iii) of the Health Information Privacy Code, which enables information to be disclosed without an individual's authorisation, where it is not desirable or not practicable to obtain individual authorisation, and the information is to be used for research purposes (which have been approved by an ethics committee), and the information will not be published in an identifiable form.

Right 7(10) of the Code is to be changed to the following:

Any bodily substances or body parts removed or obtained in the course of a health care procedure may not be stored, preserved or used other than:

- (a) with the informed consent of the consumer; or
- (b) for the purpose of research that has received the approval of an ethics committee; or
- (c) for the purpose of a professionally recognised quality assurance programme or an external audit or evaluation of services that is undertaken to assure or improve the quality of services.

For each research proposal reviewed, ethics committees will need to weigh up the public interest in allowing for an exception from the informed consent provisions of the Code against the very strong ethical principle of protecting individual autonomy. This is a strong protection for health and disability consumers.

It is expected that this change will be contained in the Code by mid-2004.

B2.3 Operational Standard for Ethics Committees

Ethics committees have an important role in governing the use of tissue from both live and deceased persons. They have two key roles:

- scrutinising health and disability support research proposals
- scrutinising proposals for innovative practice (an innovative practice involves the provision of a clinical intervention that is untested, unproven or not in common use).

They are an important check to ensure that the expansion of scientific knowledge and the development of new treatment and technologies take place in a safe and ethical manner.

The Operational Standard for Ethics Committees (Ministry of Health 2002) guides the operation of Health and Disability Services Ethics Committees and accredited Institutional Ethics Committees. It also recognises the role and functions of the National Advisory Committee on Health and Disability Support Services Ethics (NEAC), the National Ethics Committee on Assisted Human Reproduction (NECAHR),¹⁵ and the Health Research Council Ethics Committee (HRCEC). A description of the different ethics committees and their roles is contained in Appendix 4.

The objectives of ethics committees covered by the Operational Standard are to:

- safeguard the rights and interests of participants in research and innovative practice, and consumers of health and disability services
- protect Māori cultural interests, promote the wellbeing of Māori and ensure mechanisms for Māori participation in ethical review
- foster awareness of ethical principles and practices within service providers, researchers and the wider community
- consider any ethical matters relevant to health and disability services
- promote excellence in research for the wellbeing of society
- give due consideration to both local and national community views and perspectives in ethical review
- assure the public that the above are being done.

In reviewing a research or innovative practice proposal, an ethics committee uses the principles given in Table B2, many of which are underpinned by legal provisions such as the New Zealand Bill of Rights Act 1990, the Code, the Mental Health (Compulsory Assessment and Treatment) Act 1992 and the Protection of Personal and Property Rights Act 1988.

Table B2: Principles of ethical review

Main principles	Additional issues for Māori
Respect for persons Informed consent Privacy and confidentiality Validity of research proposal Minimisation of harm	Respect for Māori collectives – whānau, hapū, and iwi Gaining consent of collectives Collective ownership of information Kaupapa Māori and Māori-focused methodologies Minimising harm to te taha whānau (family and community), te taha hinengaro (emotional wellbeing and state of mind), te taha wairua (spirit), te taha tinana (the body or physical self)
Justice Cultural and social responsibility Compensation for research participants	Cultural diversity Koha

¹⁵ If the legislative proposals in section B2.5 are passed, NECAHR will be replaced by a ministerial advisory committee on assisted reproductive procedures and human reproductive research, and a designated ethics committee. These committees will consider policy matters and individual applications, respectively.

All proposed health and disability research investigations that involve human participants must be submitted to an ethics committee for review.¹⁶ In particular, ethics committees are required to review proposals that seek to further scientific or professional knowledge by means of laboratory analysis of human blood, tissues, etc of living people, cadavers or discarded body tissues.

Currently, the Operational Standard for Ethics Committees states that ‘Research involving research participants or the use of human tissue or bodily substances or innovative practice may not proceed without first obtaining consent from the individual or the individual’s legal representative’. It continues: ‘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.’ These provisions will need to be updated and further guidance developed in light of the proposed amendment to Right 7(10) of the Code described in section B2.2.1.

B2.3.1 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. The HRCEC develops this form and reviews it periodically. In terms of 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
- 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.

¹⁶ Proposals for innovative practice are also required to be submitted for review by an ethics committee. However, these proposals fall outside the scope of the non-therapeutic use of human tissue. Innovative practice is defined in the Operational Standard as practice that involves the provision of a clinical intervention (diagnostic, therapeutic or prophylactic), be it a therapeutic drug, medical device or clinical procedure, that is untested, unproven or not in common use and therefore poses its own unique set of characteristics and issues.

B2.3.2 Current work on the systems for ethical review in New Zealand

The systems for ethical review in New Zealand are currently being examined by the National Ethics Advisory Committee (NEAC). NEAC is established under section 16 of the New Zealand Public Health and Disability Act 2000. Its statutory functions are to:

- provide advice to the Minister of Health on ethical issues of national significance in respect of any health and disability matters (including research and health services)
- determine nationally consistent ethical standards across the health and disability sector and provide scrutiny for national health research and health services.

As a first priority, the Minister of Health has asked NEAC to provide advice on four matters arising from the Ministerial Inquiry into the Under-Reporting of Cervical Smear Abnormalities in the Gisborne Region. These matters are to:

- develop guidelines on conducting observational studies in an ethical manner and establish parameters for the ethical review of observational studies (including guidance regarding weighing up the harms and benefits of this type of health research)
- consider the application of second opinion and appeals processes and recommend their appropriate use for ethics committees
- review the current processes for the ethical review of national and multi-centre research
- review the operation of ethics committees and the impact their decisions are having on independently funded evaluation exercises and on medical research generally in New Zealand.

These four matters combine to form a broad review of the current processes for ethical review of health and disability research in New Zealand. NEAC provided advice on these matters to the Minister of Health in December 2003, and NEAC's advice is under consideration by the Minister.

B2.4 Hazardous Substances and New Organisms Act 1996

The Hazardous Substances and New Organisms Act is primarily concerned with protecting the environment and the health and safety of people and communities. This Act has recently been amended so that the genetic modification of human cells and tissues has been brought within its coverage.

Human cells are defined as:

'Human cells' –

- (a) means human cells, human cell lines, or human tissues that are being grown or maintained outside the human body; and
- (b) includes human reproductive cells or human embryonic cells that are being grown or maintained outside the human body.

The effect of this change is that any proposal to genetically modify human cells and tissues, or import genetically modified human cells and tissues, will require approval under the Hazardous Substances and New Organisms Act. This will include a risk assessment process that will assess the potential for adverse environmental, health and economic effects.

It is important to note that the Hazardous Substances and New Organisms Act applies to the genetic modification of human cells outside the human body (ie, in test tubes). If these cells were then to be used for other purposes (eg, clinical trials in humans), additional processes will apply. In the case of clinical trials, the approval processes under the Medicines Act 1981 will apply.¹⁷

B2.5 Supplementary Order Paper to the Human Assisted Reproductive Technology Bill

The Health Select Committee is currently considering a Supplementary Order Paper to the Human Assisted Reproductive Technology Bill 1996 (HART SOP). The Committee is due to report back on the Bill in April 2004. It is important to note that the proposals in the HART SOP may be subject to change as a result of the select committee process.

The objectives of the proposals in the HART SOP are to:

- prohibit unacceptable assisted reproductive procedures (eg, human cloning for reproductive purposes), commercial surrogacy and the commercial supply of embryos or human gametes; this includes making unlawful the importation of reproductive tissues, or embryos that have been subject to an unacceptable practice
- provide a framework for regulating and guiding the performance of assisted reproductive procedures and the conduct of human reproductive research
- ensure that the performance of non-established assisted reproductive procedures and all human reproductive research can only be conducted with the continuing approval of an ethics committee
- establish a comprehensive information-keeping regime to enable people conceived using donated gametes to access information about their genetic origins and to enable donors and offspring to access information about each other.

The main interaction between this proposed legislation and a new human tissue regulatory framework is the use of embryos for the collection of stem cells, and the subsequent use of embryonic stem cells and cell lines. Embryonic stem cells have the potential to be valuable in research and health treatments, although some people have ethical concerns about the collection of embryonic stem cells because the collection means that the embryo is prevented from developing into a human being.

¹⁷ Work is under way to replace the Medicines Act to implement the joint therapeutic products regulatory scheme and to regulate New Zealand-specific aspects of medicines. The process for the approval of clinical trials will be carried into the new regulatory environment for therapeutic products.

Under the proposals in the HART SOP, a ministerial advisory committee would be established. This committee would be required to consider and undertake public consultation and develop advice on the creation and use of embryos for research purposes, which is likely to require consideration of whether the destruction of embryos to collect embryonic stem cells is acceptable in New Zealand. This is a very complex issue that needs careful consideration.

If it is decided that embryonic stem cells can be collected in New Zealand, individual applications to use or create embryos for this purpose will require ethical approval under the HART legislation.

If the embryonic stem cells and cell lines are to be used:

- for reproductive research, the approval processes under the proposed HART legislation would apply
- for any process that involved genetic modification of the cells outside the human body, the Hazardous Substances and New Organisms Act described in section B2.4 will apply
- for therapeutic purposes in humans (including clinical trials), the processes in the Medicines Act will apply¹⁸
- for other research purposes, this document seeks your views about whether additional requirements are required (stem cells and cell lines are discussed further in section B8.2).

B2.6 Health (National Cervical Screening Programme) Amendment Act 2004

The Health (National Cervical Screening Programme) Amendment Act has recently been passed and responds to some of the recommendations of the Gisborne cervical screening. The Act amends the Health Act 1956.

Most relevant to this Review is the amendment to the regulation-making powers in section 121A of the Health Act 1956. The amendment allows the regulations made under the Health Act that require health information to be kept, to be extended to specimens. Currently, the Health (Retention of Health Information) Regulations 1996 only apply to traditional types of health information, such as doctors' notes. The Regulations set out the minimum periods for which health information must be retained, the safeguards to be taken by holders of health information, and the procedures to be followed before health information may be destroyed. The amendment to the Health Act allows these regulation-making powers to be extended to specimens collected as part of the delivery of health care.

¹⁸ Work is under way to replace the Medicines Act, to implement the joint therapeutic products regulatory scheme and to regulate New Zealand-specific aspects of medicines regulation. The approval process for clinical trials will be carried into the new regulatory environment for therapeutic products.

Now that the Health (National Cervical Screening Programme) Amendment Act is passed regulations can be made to require specimens taken from an individual as part of clinical care to be retained in the same way that other health information is retained, thus providing a complete record of a person's health history.

Giving effect to this regulation-making power is discussed further in section B10.

B2.7 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 that is required for health care.

In terms of the review of human tissue, the question arising more frequently is whether genetic information, obtainable from human tissue, requires more protection than that currently provided by the Health Information Privacy Code.

Privacy and genetic information issues are discussed further in Section B9.

B2.8 Coroners Act 1988

Following a report by the Law Commission (2000), the Ministry of Justice is undertaking a review of the Coroners Act 1988. The review is centred on both the structure of the coronial system and the processes used within that system. The review of processes has aimed to strike a balance between the cultural and spiritual needs of families and the public good associated with understanding the causes and circumstances of death in an accurate and timely way. Some of the issues raised in the review of the Coroners Act are pertinent to the review of human tissue and are raised in later sections of this document.

B3 What are the issues, gaps and problems?

The central concern is that currently New Zealand lacks an overall framework for dealing with tissue for non-therapeutic uses. The legislation described in the previous section provides a patchwork of coverage, but it is not comprehensive, consistent, or organised in an easily understandable way. Aspects of the legislation are also out of date and need to reflect modern practices and structures.

Particular problems are:

- the place of informed consent – informed consent is a central part of the health and disability sector in New Zealand, but currently the legislation is unclear about informed consent in a number of areas, including:
 - the test of 'lack of objection' instead of 'informed consent' for the use of tissue from deceased persons

- the need for informed consent for the collection of tissue at a post-mortem examination
- the role of family members in giving consent for tissue use after a person has died
- inconsistent requirements for tissue management and monitoring depending on the use of the tissue and the donor of the tissue
- whether current provisions provide the protection of genetic information that New Zealanders expect
- the lack of coverage of some types of tissue (eg, stillborn children)
- out-of-date terminology and definitions.

The current legislation and regulations also fail to provide recognition of Māori and other cultural perspectives.

The next section proposes a new approach to non-therapeutic tissue regulation, which recognises the special nature of tissue, is aligned with current good practice, and as far as possible streamlines regulation across the different non-therapeutic uses of tissue. It is proposed that informed consent be the guiding principle for use of tissue for non-therapeutic purposes, while recognising that there may be times when the benefits from tissue use may outweigh this principle. Your views on the proposed approach are sought throughout the section.

There are also gaps in the current framework regarding the acceptability of the sale and purchase of human tissue, the import and export of human tissue, and how new and challenging uses of tissue can be formally addressed on an ongoing basis. These issues are covered in 'Part D: Common concerns for all uses of tissue', because they relate to both therapeutic and non-therapeutic uses of tissue.

The central issues that will need to be included in a new framework for regulating the non-therapeutic uses of human tissue are:

- informed consent
- tissue management, oversight and monitoring
- definitions
- special types of tissue
- privacy and genetic information
- amending the regulations made under the Health Act 1956.

Before moving to these issues in detail, section B4 discusses post-mortem examinations. Post-mortem examinations, both in New Zealand and overseas, have been the subject of some controversy, and the sad events where tissue from post-mortem examinations has been retained without consent (such as at Greenlane Hospital) have illustrated the need for a clear legislative framework in this area.

B4 A note about non-coronial post-mortem examinations

A non-coronial, or hospital, post-mortem examination is conducted to provide further information about the cause of death of a person. Obtaining this information can benefit the family of the deceased person and the public, and can provide an overall improvement in health care delivery.

The number of hospital post-mortems being undertaken has been declining steadily for some time. This trend is of concern to many health practitioners and policy makers focused on quality improvement and clinical audit, as evidence suggests that the causes of death recorded without the benefit of a post-mortem are subject to error (Royal College of Pathologists of Australasia 2002, Rutty et al 2001).

The Royal College of Pathologists (2002) identifies the following benefits of conducting a non-coronial post-mortem examination:

- identifying the presence or absence of pathologies and providing family with the best information about the cause of death
- identifying diseases with genetic components, enabling accurate health care information to be given to family
- providing information about the cause of death and pathology for clinical audit (ensuring that the illness is being correctly diagnosed and treated)
- contributing to the knowledge about poorly understood diseases
- contributing to the evaluation of medical therapies and surgical techniques
- providing an accurate cause of death, which contributes to improved mortality statistics that inform public policy
- contributing to medical research and education.

In order to achieve these types of benefits, the value of a post-mortem examination needs to be recognised and the public must be confident that such an examination will be undertaken with the utmost sense of decency and respect.

The Human Tissue Act governs agreement to a non-coronial post-mortem examination being conducted. That Act is silent, however, on the process or any requirements to be met before tissue may be collected and retained from the post-mortem examination. In the past, consent to a non-coronial post-mortem was assumed to also be consent to the collection and retention of tissue. This assumption is clearly at odds with the expectations New Zealanders have of the health and disability sector.

Section B5 discusses consent and agreement to a post-mortem being conducted. This section (B4) discusses the collection and retention of tissue once consent to undertake a post-mortem examination has been addressed.

B4.1 Why is it necessary to retain tissue from a post-mortem examination?

It may be desirable to retain tissue from a hospital post-mortem examination for two reasons:

- to undertake more detailed examination about the death as part of the post-mortem examination
- to undertake other research or education.

Determining the cause of death through the pathological study of the tissue of the deceased person can be a complex process, which requires tissue to be retained after the body of the deceased person has been released to the family, whānau or funeral director.

Common reasons for needing to retain tissue, particularly organs, are that the:

- organ is small and all of it is required for examination
- tissue shows signs of a complex abnormality and a more comprehensive examination is required – possibly by another specialist doctor
- tissue needs to be prepared in a special manner before certain types of examination and testing can be undertaken, and this takes time.

These reasons for retaining tissue relate to the conduct of the post-mortem and obtaining a full picture of the causes of death.

Tissue may also be desired to be retained at post-mortem for other reasons – usually to further education or research into the condition from which the person has died.

B4.2 New provisions for tissue retention at non-coronial post-mortem examinations

The Ministry considers that the two reasons for collecting and retaining tissue from a hospital post-mortem examination should be treated differently in the new regulatory framework for human tissue. It is proposed that the new regulatory framework should make it clear that:

- consent to conduct a non-coronial post-mortem examination explicitly includes consent to retain tissue, *where that tissue is to be retained for the purposes of the post-mortem examination only*; in this situation, the person giving consent for the post-mortem examination should be given information about the tissue to be retained, the reason for its retention and the length of time it will be retained for
- if it is proposed that tissue be retained for any reason other than for the purposes of the post-mortem (such as ongoing research or education), separate and specific consent is required.

These proposals are consistent with the approach to tissue retention proposed as part of the review of the Coroners Act.

We are seeking your views

2. Do you agree that the new regulatory framework should make it clear that:
 - a) consent to conduct a non-coronial post-mortem examination explicitly includes consent to retain tissue, *where that tissue is to be retained for the purposes of the post-mortem only*; and that the person giving consent for the post-mortem examination should be given information about the tissue to be retained, the reason for its retention and the length of time for which it will be retained?
 - b) if it is proposed that tissue be retained for any reason other than for the purposes of the post-mortem (such as ongoing research or education), that separate and specific consent is required for this purpose?

Please explain any changes you would make and why.

B5 Informed consent

Informed consent is a central part of the New Zealand health and disability sector. Seeking informed consent is an important way in which the people interacting with the health and disability support sector are shown respect and dignity. It is based on the principle of self-determination, such that mature people should be able to decide how their life unfolds (van Diest and Savulescu 2002). The principle of informed consent is very important to the use of human tissue for non-therapeutic purposes, but also creates particular challenges when dealing with tissue from deceased persons, and when there are other situations where it seems it is not desirable or practical always to obtain informed consent.

Box B2: What is informed consent?

Informed consent is the ability to make choices about one's life based on sufficient information and consideration. It consists of the following components.

- Adequate information is provided to enable an informed judgement to be made.
- The information provided is presented in a way that will enable it to be understood.
- The consent is voluntary (ie, it is free from manipulation, coercion, inducement or any other undue influence) (Ministry of Health 2002).

B5.1 General principles: striking the right balance

New Zealand has developed a strong culture of informed consent, and this is reflected in the Health and Disability Services Consumers' Code of Rights and ethics committee processes (described in sections B2.2 and B2.3). While the test of 'lack of objection' is used in the Act, in practice the Human Tissue Act also uses informed consent for the collection and use of tissue for non-therapeutic purposes, in recognition of the fact that there are significant gaps in the Human Tissue Act regarding post-mortem examinations.

New Zealanders also recognise that there may be specific circumstances where important public health research would be prevented because obtaining informed consent is not practicable (eg, problems of sample bias, or donors cannot be traced).

The amendment to Right 7(10) of the Code (discussed in section B2.2.1) illustrates the protection for consumers that can be put in place through ethics committees providing rigorous scrutiny of research applications that do not propose seeking informed consent. When ethics committees look at these types of applications they will be considering very carefully whether:

- the proposed outcome of the research justifies not seeking informed consent
- the type of research to be conducted means it is better not to seek informed consent.

For example, a study that links pathological diagnoses of cancer made many years ago with the Cancer Registry and mortality data could be conducted to improve our understanding of the spread of cancer and how it can be prevented. The specimens in this type of study would need to be linked to identifying information so that the pathological diagnoses could be checked with current diagnostic criteria, the Cancer Registry and mortality data. It may not be practical to obtain informed consent to use such specimens – many years may have passed since the samples were taken and lots of these people will have moved, and some will have passed away. It would also be very expensive to try to locate everybody. But there is real benefit to the health of New Zealanders from knowing more about the spread of cancer and ways to prevent it.

In the above example, an ethics committee would examine the proposal and consider both the practicality of obtaining informed consent (can it realistically be done) and the desirability of doing so (cancer is a sensitive issue). The committee would also consider whether using the specimens could cause any harm and whether there are particular cultural considerations that need to be taken into account. The researchers would also be bound by the Health Information Privacy Code, which protects information about identifiable individuals.

After weighing up all these factors an ethics committee would then decide if the research project should be allowed to go ahead or not. Ethics committees would consider all such applications on a case-by-case basis.

The need to strike this balance arises in other contexts, and the Ministry proposes that an approach similar to that used in the amended Right 7(10) should be taken. That is, the principle of informed consent should be foremost in the new legislative framework, but, as a secondary principle, the framework should allow the public good associated with the use of tissue to outweigh informed consent in some situations. In these situations, individuals and their families should be protected by some type of safeguard (such as ethics committees in the example above).

We are seeking your views

3. Do you think the new legislative framework should have informed consent as its foremost principle?
4. If so, should a secondary principle recognise that in certain circumstances, the public good associated with the use of tissue will outweigh informed consent *provided that* safeguards are in place?

Please explain your reasons for agreeing or disagreeing.

One specific situation where the Ministry considers that it may not be necessary to seek specific informed consent is when tissue or human samples (eg, blood or urine) are used in laboratory quality control procedures. For example, a small sample of tissue may be used to check that particular dyes that show the presence or absence of micro-organisms are working properly. This is an important part of maintaining the quality of health care services.

A safeguard that could be applied in this situation is that people are informed, before a tissue sample is taken, that this use could be made of the sample, and that it would be anonymised before it was used for this purpose. This would mean that the person testing or calibrating equipment would not know who the tissue sample belonged to. It is also useful to note that health practitioners and other employees of health care institutions are required to abide by confidentiality agreements as part of their terms of employment or other professional codes.

We are seeking your views

5. Do you agree that it is acceptable for tissue samples to be used for the purposes of laboratory quality control, so long as the person giving the sample is told beforehand that their tissue may be used for this purpose and the sample is made anonymous? If you disagree, please explain why.

B5.2 Seeking consent in different circumstances

This section discusses seeking consent to tissue collection and use in a range of circumstances. The proposals aim to apply the principle that informed consent should be the foremost consideration while recognising that there are certain circumstances where the public good associated with the use of tissue will outweigh the need for informed consent. In these situations safeguards need to be in place.

The proposals in this section raise two issues that are discussed in later sections:

- From whom should consent be sought (see section D2)?
- How should consent be recorded (see section B5.4)?

B5.2.1 Consent: living people

The Code applies to living people and clearly sets out the rights of consumers of health and disability support services to make an informed choice and give informed consent. Under the Code, the person using health and disability support services, or a person entitled to give consent on behalf of that individual, gives consent.

A person may give consent through, for example, a power of attorney or an advance directive.

The Code also provides for situations where a consumer is not competent to make an informed choice and give informed consent, and there is no one else entitled to make this decision. In terms of the collection of tissue for non-therapeutic purposes, including health care, teaching and research, Right 7(4) and Right 9 interact to mean that if a person is not competent to make a decision:

- a) the provider may collect and use tissue where it is in the best interests of the consumer; and
- b) reasonable steps have been taken to ascertain the views of the consumer; and
- c) if the consumers views have been ascertained the provider must assess if the provision of services is consistent with the informed choice the consumer would make if they were competent; or
- d) if it is not possible to ascertain the views of the consumer, the provider must take into account the views of other suitable persons who are interested in the welfare of the consumer and who are available to provide such advice.

In practice, it is unlikely that these provisions would allow for the collection and use of tissue for education or research unless this was explicitly recorded by the individual when they were competent.

The Ministry and the Health and Disability Commissioner consider that these provisions are working well and no changes are proposed.

B5.2.2 Consent: deceased persons

The provisions presently in the Human Tissue Act for the collection of tissue from deceased persons for non-therapeutic purposes are lacking in a number of respects and do not reflect current practice. This section considers how a new system for consent with regard to deceased persons could be designed.

Any new regulatory provisions will need to cover:

- deceased people whose wishes are unknown
- deceased people whose wishes are known.

This section also considers whether different levels of consent should be required for different uses of tissue from deceased persons.

Firstly, it is useful to address definitional issues.

‘Lack of objection’ or ‘informed consent’

The Human Tissue Act requires the person lawfully in possession of the body to establish that there is no objection to the use of tissue from a deceased person. The Ministry considers that the test of ‘lack of objection’ should be updated to reflect ‘informed consent’, as described in Box B2.

We are seeking your views

6. Do you agree that the concept of ‘informed consent’ is preferable to ‘lack of objection’ and that this should be included in the new regulatory framework? If not, please explain your reasons.

When the wishes of the deceased are unknown

If a person dies without indicating what their wishes are regarding a hospital post-mortem examination, anatomical examination, education or research being undertaken using tissue from their body, the Human Tissue Act allows the person lawfully in possession of their body to authorise these uses of tissue provided their partner or family do not object.

In updating the regulatory framework there are a number of issues that need considering, including:

- whether the current ability for unclaimed bodies of deceased persons to be used for non-therapeutic purposes should be retained
- in what circumstances it is acceptable for appropriate people to give consent for tissue from a deceased person whose wishes are unknown to be used for non-therapeutic purposes
- what should happen when tissue collected during the life of a person is proposed to be used after that person’s death for a different purpose.

These issues are addressed in turn.

While not used in practice, the Human Tissue Act allows for unclaimed bodies of deceased persons to be used for anatomical examination, education or research under the authority of the person in lawful possession of the body. These provisions reflect the time before the mid-1900s when the bodies of those who had died without known relatives or money for burial were the primary source of tissue for anatomical examination. These people usually died in hospital, the poorhouse or mental health institutions.¹⁹

The Ministry considers that the new legislation should remove this provision, making the new legislation consistent with current practice by schools of anatomy and the principle of informed consent.

¹⁹ For a fuller discussion of this history, see Jones (1994).

We are seeking your views

7. Are there any reasons why the provision in the Human Tissue Act allowing the use of unclaimed bodies for non-therapeutic purposes should be retained?
8. If the provision were removed, do you foresee any problems being created for the practice of anatomical examination, education or research? If so, do you have suggestions for how these could be addressed?

The next issue to consider is, whether, and in what circumstances, it is acceptable for consent to be given for tissue from a deceased person whose wishes are unknown to be used for non-therapeutic purposes. The Ministry considers it to be useful to distinguish anatomical examination from other non-therapeutic uses.

- Anatomical examination – for reasons previously explained, schools of anatomy do not accept bequests of bodies if the wishes of the deceased person are unknown. The Ministry supports this approach and proposes that the new regulatory framework reflect this practice as a requirement.
- Other non-therapeutic purposes – depending on the reasons for a person’s death, and any illnesses they had, there can be real benefit to families, health professionals, researchers and the health and disability system as a whole in knowing more about the tissue of the deceased person (see, for example, the reasons for undertaking a post-mortem examination listed in section B4). Further knowledge may be gained as part of a detailed post-mortem examination or other research or education activities.

The Ministry considers that it is appropriate for tissue from deceased persons whose wishes are unknown to be used for non-therapeutic purposes (excluding anatomical examination) provided that appropriate consent has been obtained from a person able to give consent on behalf of the deceased person. The persons who may be able to give such consent are discussed in section D2. There are two reasons for the Ministry holding this view.

- As compared with anatomical examination, the use of tissue for other non-therapeutic purposes may not have been considered by an individual before their death. It is likely, therefore, that their wishes will be unknown.
- Following public concern about the retention of tissue at post-mortem without consent, it was revealed that many people would have given consent for the tissue of their loved ones to be retained and used for research and education if they had been asked, and that some people may have desired that this benefit was derived from the sad death of their loved one.

We are seeking your views

9. Do you agree that it is not appropriate for the body of a deceased person to be used for anatomical examination if the views of the deceased person about this use are not known? Please explain any comments.
10. Do you agree that the new legislative framework should allow tissue from deceased persons to be used for non-therapeutic purposes (other than anatomical examination) with appropriate informed consent? If not, please explain your reasons.

The third issue in this area is what should happen when tissue is collected during the life of a person (when the provisions of the Code would apply), but it is proposed to be used after that person has died and specific consent for this use has not been obtained. Examples of potential uses are to assist with the genetic testing of a relative, or to undertake a research project that was not anticipated at the time the tissue was collected.

This is an area where it is not possible to obtain informed consent and the secondary principle could apply. That is, the use of the tissue could be permitted provided that appropriate safeguards are in place.

These situations could be managed by requiring another form of approval. Possible mechanisms are as follows.

- If the proposed use is a one-off event for clinical purposes, consent could be sought from another family member.
- If the proposed use is a research project, or audit, the provisions should be consistent with the recent amendment to Right 7(10) of the Code. This approach would mean that tissue could not be used unless the research had been approved by an ethics committee, or the tissue was to be used for a professionally recognised quality assurance programme (an external audit or evaluation of services undertaken to assure or improve the quality of services).

We are seeking your views

11. When tissue has been collected during the life of a person and is wanted for uses after that person's death for a reason where the wishes of the deceased person are not known, should the new legislation allow these uses with appropriate safeguards? If so, are the following suggested safeguards appropriate.
 - a) If the proposed use is a one-off event for clinical purposes, consent could be sought from another family member.
 - b) If the proposed use is a research project, or audit, the tissue could not be used unless the research had been approved by an ethics committee, or the tissue was to be used for a professionally recognised quality assurance programme, an external audit or evaluation of services that was undertaken to assure or improve the quality of services.

Please describe any other ideas you have.

When the wishes of the deceased person are known

Some people have clearly recorded or discussed their preferences about any use of their body, or body parts after their death. There are three situations that can arise when a person has clearly recorded or expressed their wishes.

- They have recorded an objection to their body being used after their death for non-therapeutic purposes: in this situation, the person's wishes are easily, and appropriately, followed. This is the current law in the Human Tissue Act and the Ministry supports continuing this position.
- They have recorded a desire that their body be used after their death and their family is aware of and in agreement with their wishes: in this situation it is also relatively straightforward to follow through with the deceased person's wishes.
- They have recorded a desire that their body be used after their death and their family is in disagreement with their wishes. This third situation is somewhat more complex; that is, what should happen when it is known that a person wished for their body to be used for non-therapeutic purposes, but at the time of their death their family does not want this to happen. This situation does not occur frequently as most people want to follow through with the wishes of their loved one, but it does arise at times.

Schools of anatomy can not accept bequeathed bodies from deceased persons if a family member objects. While it would be possible to design the law to *require* that the wishes of the deceased to donate their body for non-therapeutic purposes be followed, the Ministry considers that it is preferable to allow flexibility for a deceased person's family and the relevant health professionals to resolve these issues. Currently schools of anatomy and researchers work carefully and sensitively with families to resolve these issues at a very difficult time. Sometimes it is decided to follow the wishes of the deceased, and sometimes it is decided that this is too distressing for the family and the wishes are not followed. This case-by-case approach seems to work well.

We are seeking your views

12. Do you agree that, where a person is known to object to their body being used after their death for non-therapeutic purposes, this objection should be respected and their body should not be able to be used for these purposes, as is currently in the Human Tissue Act 1964? If you disagree please explain your reasons.
13. Do you think that the new legislation should allow families to have the final say over the donation of tissue from their deceased loved one for non-therapeutic purposes? If not, please explain why you think the wishes of the deceased should be *required* to be followed and if there should be any exceptions to this requirement.

B5.3 Consent for children

Guidance on obtaining consent for health care procedures for children is provided in the document *Consent in Child and Youth Health: Information for practitioners* (Ministry of Health 1998). The key concern for the Review is consent for the non-therapeutic use of tissue from children who have died.

Much of the concern in New Zealand and overseas about the retention of tissue without consent from a post-mortem examination has related to tissue from children who had died. Many parents were understandably very upset that consent had not been sought, and many noted that if consent had been sought it would have been given.

It is important that the new legislative framework is clear about the need to obtain consent for the use of tissue from children for non-therapeutic purposes.

Until a child is 18 years old their parents or guardians are responsible for them. However, the legal age of consent in New Zealand is 16 years. This raises a question as to what should happen for a child aged between 16 and 18 years. To address this difficulty the Care of Children Bill proposes that competence as opposed to chronological age be used as a guide to the decisions children and young people are able to make. The Ministry supports this policy and proposes that:

- consent to obtain tissue from a deceased child should be obtained from the parents or persons responsible for the day-to-day care of the child (it would be preferable to obtain consent from both parents, although precisely who is involved will depend on the nature of the family relationships)
- if a child or young person is legally competent,²⁰ and their wishes in relation to the non-therapeutic uses of their tissue are known, then the same procedures as with adults should apply (as described in section B5.2.2).

In some cases it may be argued that the mother has a greater need than the father to know the cause of death of a newly born child, a stillbirth or miscarriage. In these types of situations the information to be gained from a post-mortem examination may allow the mother to assess the risk to herself of future pregnancies. The Ministry is seeking your views about whether, in this situation, the wishes of the mother should prevail.

We are seeking your views

14. Do you agree that consent from the parents or guardians should always be gained for tissue from a deceased child to be used for non-therapeutic purposes? If you don't agree, please explain why.
15. If a child or young person is legally competent, and their wishes in relation to the non-therapeutic uses of their tissue are known, then should the same procedures as with adults apply? If you don't agree, please explain why.
16. Should both parents have an equal say in what happens to the body of their deceased child, or are there circumstances where the mother's wishes should prevail?

²⁰ Children under 16 with sufficient understanding of the issues may be able to give consent under the principle of *Gillick* competence established in *Gillick v West Norfolk Area and Wisbech Area Health Authority* [1985] 3 All ER 402.

B5.4 Recording consent

Currently the provisions for recording consent vary.

- In the Code (which applies to living people), consent may be oral for any procedure, except those that involve participation in research, participation in an experimental procedure, a general anaesthetic, or a significant risk of adverse effects. In these circumstances consent must be given in writing.
- Under the Human Tissue Act (which relates to deceased persons), people may have expressed their wishes in writing or orally. If a person has expressed their wishes orally, it must have been in the presence of at least two witnesses.

While written consent to any procedure makes it clearer what an individual wants, the Code recognises that this is not practical for every situation and that oral consent for more routine procedures is sufficient.

When dealing with consent issues for deceased persons it can be argued that consent should always be in writing. This may not be practical, however, as a person with the capacity to give consent may only be contactable by telephone or email. The person may be unwilling to travel, or physically unable to give consent in writing. In these types of situations the views of the person able to give consent may be clearly understood, but risk being disregarded because they are not recorded in writing.

We are seeking your views

17. Are there situations in which consent for non-therapeutic uses of human tissue may be given other than in writing? If so, should any safeguards or special procedures apply? Are there alternative forms of consent that may be acceptable?

B6 Tissue management, oversight and monitoring

The current regulatory framework does not provide comprehensive coverage of tissue management requirements, or oversight and monitoring issues. Section B2.1.2 describes the coverage of these issues in the Human Tissue Act for tissue used for anatomical examination. While the provisions for anatomical examination are working well, they do not extend to tissue that has been obtained for other purposes, and there are gaps in the coverage (eg, tissue transport). Simply extending the provisions to other tissue use, or collections outside schools of anatomy, may not work well.

B6.1 A framework for tissue management

Tissue is held in different places, including universities, District Health Boards and some private hospitals. In thinking about designing a new framework for tissue management, consideration needs to be given to these different settings. Consideration also needs to be given to the level at which different issues are addressed: some may be best covered by legislation (such as informed consent for collection, as previously discussed) and others may be best addressed by codes of practice or standards. Legislation may require a code or standard to be developed.

Issues that may be suitable for coverage in a tissue management framework that is not included in legislation include, among others:

- protocols for managing tissue that are consistent with cultural practices
- the types of records that should be kept about tissue (this will include some of the matters currently covered by the Human Tissue Act, such as recording the names of deceased persons, the time their body was transferred to the school of anatomy, and any parts that have been retained for further study; record keeping requirements will also need to contain processes for unlinking and anonymising samples)
- safety procedures to ensure that people handling tissue for non-therapeutic purposes are protected from pathogens that may be present in the tissue
- those persons who should be allowed to undertake certain procedures (eg, currently only a licensed anatomist may practise anatomy)
- identification of a nominated 'person responsible' for a tissue collection
- the status and management of historical tissue collections, where it is unknown whether consent has been obtained for the tissue to be retained
- appropriate ways to transport tissue
- appropriate ways to store tissue
- appropriate processes for the return or respectful disposal of tissue, including recognising that at times not all tissue will be able to be returned as some may be destroyed as part of testing processes, or may represent a health hazard if it is infectious
- communication with families at difficult times
- consent requirements and (potentially) standard consent forms.

Agencies in the health and disability sector already have a lot of information on these types of issues, which could be used to inform an overall tissue management framework, including:

- detailed guidelines developed by the Auckland District Health Board Body Parts, Tissues and Substances Review Panel (Auckland District Health Board 2002)
- the Auckland District Health Board's *Tikanga: Recommended best practice policy* (Auckland District Health Board undated)
- guidance on ethical processes for human specimen collection, storage, use and disposal developed for the Department of Health (Human Specimen Ethical Guidelines Committee 1992)
- guidance, developed by Te Puni Kōkiri (1999a, 1999b), for both service providers and Māori for the removal, retention, return and disposal of body parts and organs
- Health Research Council (2002) ethical guidelines for researchers using human tissue
- best practice models for anatomical examination developed by schools of anatomy.

Some of these documents are becoming dated, however, and others may be affected by the new regulatory regime currently being designed. Given these factors and the fact that the status of existing material is not always clear, there is merit in considering developing a single framework that provides a consistent and comprehensive approach to tissue management across the different non-therapeutic uses.

A consistent approach to tissue management would not necessarily take the form of a single standard for all agencies. There may be issues that are better considered separately, and there may be aspects of such a standard that would not apply to some agencies or some types of tissue – the coverage of microscopic samples would need to be considered, for example. The level of detail that such a framework prescribed also needs consideration.

The development of an overarching framework for the management of tissue for non-therapeutic use involves a significant amount of work, and the Ministry is interested in your views on this proposal.

We are seeking your views

18. Do you think that an overarching standard or code for tissue management that can be applied flexibly to different agencies is appropriate? Please explain why or why not.
19. Please tell us your suggestions for what should, or should not, be covered by such a framework and why.
20. Please tell us if you think there are agencies for which, or specific occasions when, there should be exemptions from the requirements of such a framework.

B6.2 Oversight and monitoring

Currently the formal oversight and monitoring of non-therapeutic tissue in the Human Tissue Act is confined to the inspectorate regime for schools of anatomy (see section B2.1.2). The Code also provides for complaints to be made to the Health and Disability Commissioner if a consumer considers that their rights under the Code have been breached. While many health practitioners, researchers and professional bodies are actively addressing the appropriate use of tissue, some form of ongoing oversight and monitoring may be necessary to align public policy with public concerns.

An important consideration in any oversight and monitoring regime is to ensure that the regime is commensurate with the risks posed and does not place unnecessary costs or burdens on to agencies managing tissue, or on to the health and disability sector in general. On the other hand, any regime must be robust and meet the expectations of New Zealanders that tissue-related matters are well managed.

One potential way to provide oversight and monitoring is through a system of standard setting, audit and certification. This system is used to ensure the safety and quality of health and disability support services under the Health and Disability Services (Safety) Act and may provide a model for the non-therapeutic tissue area.

The Health and Disability Services (Safety) Act works as shown in Table B3.

Table B3: Framework for services safety under the Health and Disability Services (Safety) Act 2001

	Process	Requirements to be met	Sign-off
↓	Service to be covered (eg, hospital, rest homes)	A service not yet anticipated by the Act may be added so long as acceptable standards have been developed or will be developed within 12 months and providers have at least 12 months to comply with the standard.	Governor-General
	Standard (has the status of regulation)	This must be independently developed in consultation with the sector, ²¹ and consultation must have been considered, and be in the public interest in terms of safety and compliance costs.	Minister of Health
	Audit and certification	Designated audit agencies must be independent and approved.	Director-General of Health

If this type of model were considered appropriate, one question that needs to be resolved is whether the Police should continue to be involved in monitoring and audit processes. Currently the two inspectors of anatomy are senior members of the New Zealand Police and have developed good working relationships with the schools of anatomy. The Police are independent of the health and disability sector and have a standing in the community that can provide the public with reassurance that the schools of anatomy are following good processes. However, if the proposals in this document were carried forward, the scope of monitoring and audit to be undertaken would be wider than the current ambit of the inspectors and is likely to require more specialist knowledge.

We are seeking your views

21. Please share your ideas on possible approaches to monitoring tissue management practices that allow for robust monitoring to take place without imposing unnecessary compliance costs on the health and disability support sector.
22. Do you think that a system based on standards, audit and certification could work in New Zealand? Please tell us why or why not, and share any other ideas you have.
23. Do you think that the New Zealand Police should continue to be involved in the monitoring and audit of non-therapeutic tissue use? What type of role should the Police fulfil?

So far this document has considered two fundamental aspects of a new legislative framework for the non-therapeutic use of human tissue: informed consent for tissue use and tissue management practices. We now consider a number of other matters that need to be addressed as part of the new framework.

²¹ Consultation is required with consumers, representatives of affected providers and a number of providers, funders and consumers.

B7 Definitions

As part of the overall improvement of the framework for human tissue use, the Ministry believes there are particular terms that need to be considered and updated to reflect contemporary structures and practices. This section covers the following terms:

- ‘body’
- ‘lawful possession of a body’.

B7.1 Body

A body is defined in the Human Tissue Act as ‘a dead human body, but does not include the body of a stillborn child’. The legislative coverage of stillborn children and fetuses is discussed in section B8.1.

The Ministry considers that the definition of a body in legislation could be more respectfully worded, and suggests the following terms may be preferable:

- ‘tūpāpaku, or body of a deceased person’
- ‘tūpāpaku, or deceased human being’.

We are seeking your views

24. Please share any suggestions you have for terms that respectfully describe a ‘body’. Are either of the following terms acceptable:
- a) tūpāpaku, or body of a deceased person?
 - b) tūpāpaku, or deceased human being?

B7.2 Lawful possession of a body for non-therapeutic purposes

It has long been considered as a matter of common law²² that there is no property in the body of a deceased person. That is, no one is able to ‘own’ the body of a deceased person, and determining what happens to a human body after death cannot be decided on the basis of anyone owning the dead body.

The Human Tissue Act recognises, however, that there are times when it is helpful for some people to have limited rights to the possession of a body for particular purposes. The Human Tissue Act recognises the person in charge of a hospital or the superintendent of a penal institution as the ‘person lawfully in possession of a body’ for the purposes of the Act. That is, the person is able to be in possession of those bodies that are to be used for research, anatomical examination or education – not all the people that may die in the institution.

²² The common law is the body of law that has been built up through the decisions of the Courts.

Having this type of central point of authority is intended to ensure that institutions, such as hospitals, can maintain overall control of the collection and retention of tissue occurring under their auspices. Recent revelations both in New Zealand and overseas have demonstrated what can happen when tissue is collected and retained by individual clinicians or departments without such a system of centralised control.

There are two issues to consider.

- Can the phrase ‘lawful possession’ be improved to reflect the fact that there is no property in a human body, but that at times people have control over the bodies of others, need to provide care for others and have guardianship responsibilities. For example, it is important to many Māori that the tūpāpaku is not left alone and is cared for appropriately.

Alternative terms that may be appropriate are:

- the person with lawful control over the body
 - the person with lawful responsibility for the body
 - the person with custody or care or control of the body.
- Is it appropriate to assign a single person as being in possession of a body simply on the basis of that person being the ‘person in charge’ of an institution.

The management structure of most modern hospitals can include, for example, the board of the District Health Board, the chief executive, the hospital manager and the clinical director. Under such a structure it is unclear who would be ‘the person in charge’ for the purposes of the Act.

There are three options for resolving this ambiguity.

- a) Legislation could prescribe a particular position within a hospital as the person lawfully in possession (eg, the institution’s chief executive or medical director). Prescribing a particular position could help to remove the ambiguity of the ‘person in charge’, although some District Health Board chief executives are responsible for more than one hospital.
- b) Legislation could require institutions to appoint, or nominate for appointment, a particular person from time to time.
- c) A third alternative is for legislation to prescribe a particular person, to be the person in possession, with the ability for this responsibility to be delegated as appropriate. For example, the chief executive of a District Health Board could be prescribed as the person in possession, and the chief executive may then delegate this responsibility to the hospital manager, clinical director or other person, as appropriate. Under the New Zealand Public Health and Disability Act, this delegation would need to be included in a District Health Board’s Delegation Policy, which is approved by the Minister of Health.²³

²³ New Zealand Public Health and Disability Act 2000, schedule 3, clause 39.

We are seeking your views

25. Please tell us your ideas for a phrase that may be preferable to 'the person lawfully in possession of the body'. Are the phrases 'the person with lawful control of the body', 'the person with lawful responsibility for the body' or 'the person with custody or care or control of the body' appropriate?
26. Please tell us your ideas for removing the ambiguity created by the term 'the person in charge (of an institution)'. In the case of hospitals, which of the following three options do you prefer for the new legislation:
 - a) a particular position within a hospital designated as the person lawfully in possession (eg, the institution's chief executive or medical director)?
 - b) a requirement that institutions appoint or nominate for appointment a particular person from time to time?
 - c) a particular position within the District Health Board, likely to be the chief executive, with the ability for this responsibility to be delegated as appropriate?

Please share any other suggestions you have.

B8 Special types of tissue

This section discusses and seeks your views about some specific types of tissue that may need special provisions in the new legislative framework:

- stillborn children and foetal tissue
- stem cells (excluding haematopoietic stem cells covered by the Health Act (see Appendix 5).

B8.1 Stillborn children and foetal tissue

The use of tissue from stillborn children or foetuses raises particular issues. In part this is due to the distress and sensitivity that usually surrounds the premature loss of a child, or the decision to terminate a pregnancy. Because of the sensitive and personal nature of tissue from stillborn children and foetuses it is important that the legislative framework provides clear guidance.

Currently, stillborn children and foetuses are excluded from the Human Tissue Act through the definition in the Act of a 'body'. The Code may cover stillborn children and foetuses through the mother, but this is not clear.²⁴ Ethics committee guidance also makes reference to the use of foetal tissue in research.

²⁴ Application of the Code of Rights to the removal and retention of body parts from abortuses and stillborns. Unpublished correspondence to the Health and Disability Commissioner.

The use of tissue from a stillborn child, or foetus following the termination of a pregnancy, is objectionable to some people. Other people consider that the benefits to be gained from education or research outweigh other considerations, provided that consent is gained for the tissue use.

The Ministry considers that it would be wise to include stillborn children and foetuses in the new regulatory regime. This would make it clear that requirements to use tissue from stillborn children and foetuses, such as the need to obtain consent, apply.

B8.1.1 Ethical concerns

The use of foetal tissue for non-therapeutic purposes, predominantly research, raises particular ethical concerns, such as ensuring there is no inducement provided to the mother to have an abortion.

Overseas jurisdictions have specific information to guide ethical decision-making in this area. For example, the United Kingdom draws on the Polkinghorne Guidelines (Polkinghorne 1989). New Zealand ethics committees do not have detailed New Zealand-specific guidance to draw upon. The Operational Standard and advice from the Health Research Council (2002), however, steer their decision-making, and approval of a research application would be dependent on factors such as:

- obtaining informed consent from the mother
- recognition and management of cultural issues
- a clear separation between the decision to terminate a pregnancy and the decision to allow the use of foetal tissue for research – in particular the decision to terminate a pregnancy should be taken before consent is sought to use foetal tissue
- no inducement such as payment, koha, gifts or otherwise being offered to the mother, or those who may influence her decision, to either terminate a pregnancy or allow the use of foetal tissue
- ethics committee guidelines are clear that it is unacceptable to provide payment, koha or gifts that are an undue inducement to participate in research.

Other non-therapeutic uses of tissue from stillborn children and foetuses (beyond research) could be managed through the consent processes already described and the tissue management standard suggested in section B6.

We are seeking your views

27. Do you think that stillborn children and foetuses should be brought within the coverage of the new regulatory framework? If not, please explain why.
28. Currently, New Zealand does not have separate guidance for ethics committees and researchers to follow when dealing with research using stillborn children and foetal tissue. Do you think guidance in addition to the general guidelines detailed above is needed? Please explain your response.

B8.2 Stem cells and cell lines

B8.2.1 Tissues and cells in research

This section is concerned with the use of cells and tissue (particularly stem cells) for research purposes. This research, including that on stem cells, is likely to include the development of cell lines. Table B4 sets out the current controls on the collection and use of cells and tissues for research. The controls cover ethical, environmental (genetic modification) and health safety issues.

The question for this Review is whether the current regulation of the collection and use of cells and tissue for research is sufficient, or if additional controls are required for particular cells or tissues. If additional controls are desired, then the purpose of those controls and the types of cells or tissues to which they should apply need to be clearly described.

Stem cells are cells that have the ability to continuously divide and develop into different kinds of tissues. Because of this property they are of great interest to researchers and have considerable potential for future health treatments. It is anticipated that researchers will be able to trigger stem cells to transform into specific cells types – blood, skin and neural cells, for example. These cells could then be used to repair diseased or damaged tissue and may be able to treat diseases such as cancers, spinal cord injury, heart disease and neurological disease. Research using stem cells is a relatively new area.

Stem cells can be obtained from a number of different sources, including:

- early embryos (around five to six days old), eg embryos created for IVF treatment but not required for that purpose could be used with the informed consent of the relevant parties.
- fetuses (from pregnancy terminations – see also the discussion in section B8.1)
- umbilical cord blood
- other tissues from humans (often called adult stem cells).

Currently in New Zealand, Auckland University is undertaking research that uses stem cells obtained from adults (with informed consent). There is no research in New Zealand that uses embryonic stem cells.

Cell lines are cells grown in culture and have been derived from tissue that has been processed to extract a certain type of cell. This cell is then grown in the laboratory to form an ongoing cell line. Many types of cell lines are in existence and this technique allows for the ongoing study of both healthy and diseased tissues. Cell lines can be established from many types of cells, including stem cells.

Embryonic stem cells

As described above, stem cells are found in embryos and the special properties of embryonic stem cells mean that these cells may offer considerable opportunities for health treatments. The use of embryonic stem cells is a controversial issue, however, as the collection of stem cells from embryos means that the embryo is not able to develop into a human being.

The collection of embryonic stem cells is a complex and challenging issue internationally for policy makers, researchers and ethicists. In New Zealand it is proposed, under the Supplementary Order Paper to the Human Assisted Reproductive Technology Bill (see section B2.5), that a ministerial advisory committee be established to consider and consult on a number of issues, including the use of gametes and embryos for research purposes. This will undoubtedly include consideration of issues related to embryonic stem cell collection in New Zealand. If the decision is made to allow for the collection of embryonic stem cells, guidelines and/or regulations will be developed for this purpose. In addition, any research application that involves the collection of embryonic stem cells would require the approval of an ethics committee established under the Human Assisted Reproductive Technology legislation, as well as being subject to the controls in Table B4.

There is also the potential to use imported embryonic stem cell lines, in which case the matters raised in section D5 regarding the import and export of tissue will be important.

Table B4: Framework governing the collection and use of tissues and cells for research in New Zealand²⁵

Body/mechanism	Role	Responsibility
Regional ethics committees (not established in legislation, but the requirements to submit proposals for ethical review are derived from a variety of sources ²⁶)	Decide on individual research applications to obtain and use cells and tissues.	Must follow the Operational Standard for Ethics Committees, and ensure the health and safety of any human participants in research or clinical trials.
Code of Health and Disability Services Consumers' Rights 1996	Provides a set of rights for people receiving health and disability support services, including when it is proposed that the consumer participate in teaching or research.	Health practitioners who are likely to be responsible for tissue collection must, among other things, ensure that the consumer has given informed consent and received sufficient information to guide their decisions (see section B2.2 for a fuller discussion).
Mechanisms under the Hazardous Substances and New Organisms Act 1996	To assess the potential for adverse environmental, health and economic effects of genetic modification of human cells and tissues.	A research proposal to genetically modify human cells would need to be approved under the Hazardous Substances and New Organisms Act 1996 before it could proceed.
Health Research Council committees: Standing Committee on Therapeutic Trials (SCOTT) and the Gene Technology Advisory Committee (GTAC) (committees of the Health Research Council to fulfil the requirements of the Medicines Act 1981 ²⁷)	Under s30 of the Medicines Act, the Director-General of Health may permit the use of medicines that have not received marketing consent, to be used in clinical trials for the purpose of obtaining clinical and scientific information on advice from a health research committee.	Under proposals in this discussion paper, the use of human cells or cells lines as a therapeutic product would first have to go through clinical trials. Applications to undertake clinical trials would be scrutinised by SCOTT and/or GTAC. Based on this advice and ethical considerations, trials may be approved by the Director-General of Health.

²⁵ Appendix 4 contains a description of the ethics committees referred to in this table, and section B2.3 describes ethical review processes.

²⁶ Sources include the Code of Health and Disability Services Consumers' Rights, international declarations such as the Declaration of Helsinki, approval requirements of funding organisations, and the Injury Prevention, Rehabilitation and Compensation Act 2001. (See B2.3).

²⁷ Work is under way to replace the Medicines Act, to implement the joint therapeutic products regulatory scheme and to regulate New Zealand specific aspects of medicines regulation. The approval processes for clinical trials will be carried forward into this new environment for therapeutic products regulation.

We are seeking your views

29. Are the current processes outlined in Table B4 for reviewing the ethical and safety dimensions of research applications using cells and tissues (specifically stem cells) sufficient, or should such research be subject to any additional review processes before it can proceed? If so, please explain your reasons.
30. What should the main purpose of any additional processes be?

B8.2.2 Established cell lines (including stem cell lines)

Cell lines are lines of single cells that have been grown in the laboratory from human tissue samples. They have been processed and reproduced in a culture medium. Most human tissues can be grown in this way, and this allows ongoing research of both healthy and diseased tissues to be undertaken.

These cell-line cultures can survive for many years – potentially well after the death of the original donor. They are important tools for both medical diagnosis and research. The cell lines are almost always unable to be linked to the original donor of the tissue.

There are thousands of cell lines in existence, and many are sold by providers of laboratory supplies²⁸ and imported. Some lines are also established in New Zealand. The use of established cell lines, predominantly for research, is currently not regulated and is generally not subject to ethics committee review. The question for this review is whether there are any circumstances when these cell lines should be subject to ethical review, and if so what the purpose of such a review would be.

In considering this question it is important to note that:

- the collection of the original human tissue sample will be subject to consent requirements (see sections B4 and B5 for a discussion of informed consent requirements)
- ethical review processes are concerned with protecting human participants (see section B2.3 for a discussion of ethical review issues)
- cell lines are almost always anonymous
- reviewing projects that propose to use cell lines would consume a considerable amount of ethics committee resource
- a code of practice for importing human tissue is proposed in section D5.

On balance, the Ministry does not consider that ethical review of projects using established cell lines is warranted as routine, but is interested in your views.

²⁸ These types of sales are different from those discussed in section D4, as the remuneration relates to the process of work and skill that has allowed the cell line to develop and be maintained – it does not relate to the donation of the original tissue.

We are seeking your views

31. Do you think there are any circumstances in which established cell lines should be subject to ethical review, and if so what would the purpose of such a review be?

B9 Privacy and genetic information

This section discusses genetic information, which is obtainable from human tissue, and the current protections for genetic information under the Health Information Privacy Code 1994. The question that has arisen in this Review is whether this coverage is sufficient, or whether changes to the Health Information Privacy Code should be investigated.

B9.1 Why is genetic information different?

Genetic testing is increasingly being used in the provision of health care to obtain genetic information for the purposes of:

- improving the diagnosis of diseases
- providing individuals with information about whether they have a higher risk of developing certain diseases
- contributing to the development of new therapeutic interventions to treat genetic disorders.

The United Kingdom Human Genetics Commission identified the following reasons for distinguishing between genetic information and other types of health information (Human Genetics Commission 2000).

- 1) Genetic information is uniquely identifying information. Only an identical twin will have exactly the same genotype as someone else.
- 2) Genetic information can be obtained from a very small amount of material and does not require lengthy observation or history-taking. It may also be possible to obtain a sample without the knowledge or consent of the person affected – such as from a sample obtained in the past for another purpose, or from cells shed unknowingly (eg, hair follicles).
- 3) Genetic information may be used to predict some rare inherited disorders that develop later in life and to predict what may be passed by a parent to children. This prediction may be made even before the birth of the person in question.

- 4) The predictive possibilities may be of interest to people other than the owner of the tissue sample tested (eg, insurance companies or employers, who might wish to take them into account in their dealings with the subject). In many (though not all) cases, genetic information is not only information about the individual person, but about his or her biological relations. Genetic information about one family member may have significant implications for other members of the family, including information about susceptibility to disease and issues of family genetic relationships. (In other cases, of course, genetic information may have no implications for other family members. This will be the case where a mutation has occurred in an individual's cells leading to disease such as cancer.)
- 5) Genetic information has a potential commercial value and methods of obtaining it may be the subject of patents. In addition, there are complex issues as to ownership interests in human DNA.
- 6) Collections of genetic information combined with individual medical and life-style information provide an important research resource for understanding individual susceptibilities to disease and its treatment. Increasingly, drug treatments may be targeted to sub-sets of the population identified, in part, by genetic information.
- 7) Genetic information may be collected for a variety of very different purposes (disease prediction, determining family relationships, etc). However, once this information is collected, it can be used for a quite different purpose from that for which the provider of the information originally gave consent.

B9.2 Protections for genetic information

Although the majority of the human genetic structure is identical from one individual to another, it is the variations in our genetic structure that give rise to each individual's particular physical characteristics. We may also have shared family characteristics that are passed from one generation to the next. Such characteristics range from the colour of our hair or eyes, to our susceptibility or resistance to different diseases. Information about the more or less unique genetic variations that contribute to making us who we are is very personal.

There are many advantages to knowing each person's genetic structure and how those characteristics are shared within families. Knowing that members of a particular family are more likely to suffer from a particular medical condition can help people take precautions with regard to their own health. Knowledge of a person's particular genetic makeup may enable medicines to be specifically tailored to that individual in the future. This would enable more effective medication with reduced or eliminated side-effects.

Genetic information can be obtained from a variety of sources. Such information can range from general information gathered through the study of a family's medical history, to the observation of a person's external physical characteristics, to the analysis of blood and tissue samples containing DNA.

Concerns have been raised about the possibility of uncontrolled access to and use of genetic information, given the relative ease with which genetic material can be obtained. A commonly acknowledged concern is that access to such information could potentially lead to discrimination by insurance companies and employers. It is also of concern to some people that parts of their unique genetic makeup may be used for purposes other than that for which the original consent was given, without their knowledge or consent. Māori and Pacific peoples may have specific concerns about genetic information and implications for whakapapa or genealogy.

B9.2.1 The Health Information Privacy Code

The Health Information Privacy Code (HIPC) is established under the Privacy Act. The principles in the Privacy Act apply to all 'personal information' collected or held by agencies. Personal information is information about identifiable living persons. The HIPC applies to 'health information', which is a subset of personal information. The HIPC also applies to health information about deceased persons that was obtained after 1993/94, but only with respect to the disclosure of that information.

The HIPC defines health information as information about an identifiable individual, which includes information:

- about the health of that individual, including his or her medical history
- about any disabilities that individual has, or has had
- about any health services or disability services that are being provided, or have been provided, to that individual
- provided by an individual in connection with the donation of any body part or any bodily substance of that individual, or derived from the testing or examination of any body part or any bodily substance of that individual
- about that individual which is collected before or in the course of, and incidental to, the provision of any health service or disability service to the individual.

The HIPC applies specific rules to agencies in the health sector which hold the types of information described above to ensure the protection of individual privacy. The HIPC also recognises that there is public benefit in allowing access to some information for particular purposes, and allows the use of anonymised health information with appropriate safeguards.

In terms of tissue, the HIPC covers any information given in association with body parts or bodily substances, or derived from them.

Potential gaps in the HIPC in relation to genetic information may therefore be:

- coverage for the actual tissue sample from which genetic information may be gathered
- whether it is appropriate, or even possible, for genetic information to be anonymised and used for other purposes.

If the HIPC were to be amended to specifically address genetic information, some of the issues that will need to be addressed are:

- whether it is possible to anonymise genetic information and how this should be done
- whether a distinction should be made between a portion of genetic information about a person, and the complete set of genetic information about a person
- how consent to collect, access, use and/or dispose of genetic information should be obtained and recorded
- whether there are times when consent would not be needed to use genetic information, and if so, what safeguards would be needed for this to happen
- whether individuals should be able to own genetic information derived from the analysis of their tissue
- whether there are any circumstances in which genetic information should be disclosed to other family members
- whether family members, or any individual who has not authorised the genetic testing of their tissue, should have the right not to know the outcome of such testing, and whether there are any circumstances in which this right could be breached. For example if a general consent to the use of tissue in research had been given and subsequent analysis shows the likelihood of a genetic condition that may be treatable.

We are seeking your views

32. The implications of access to genetic information are complex and affect people beyond the individual who is the source of the information. We are seeking your thoughts on whether the coverage of the Health Information Privacy Code should be extended to specifically address genetic issues. If so, please tell us your views on any or all of the issues listed above.

B10 Retention of specimens as health information under the Health Act 1956

As part of the Government's response to the recommendations of the Gisborne Cervical Screening Inquiry (Duffy et al 2001), the Health (National Cervical Screening Programme) Amendment Act has recently been passed by Parliament. The Act makes a number of changes to the legislative provisions for screening programmes. Most relevant to this review are the changes to the regulation-making powers in the Health Act 1956.

Section 121A of the Health Act allows regulations to be made to govern the retention of health information. The Act extends this regulation-making power to cover specimens, as well as more traditional types of health information such as doctors' notes.

The Act allows changes to be made to the Health (Retention of Health Information) Regulations 1996 to ensure the appropriate coverage of specimens.

The change was made in response to the Gisborne Cervical Screening Inquiry, which considered that cervical screening slides and blocks should be retained to allow robust quality assurance and audit programmes to be conducted. The regulation-making power is broader than just cervical screening specimens and recognises that there is broader benefit in a full health record being retained.

This discussion document is seeking your initial views on the matters to be resolved in extending the Health (Retention of Health Information) Regulations to include specimens.

B10.1 Health (Retention of Health Information) Regulations 1996

Currently the Health (Retention of Health Information) Regulations 1996 (the Retention Regulations) require providers of health or disability services to retain health information about identifiable individuals for a minimum period of 10 years from the last time the person received a health or disability service. Information must be retained whether or not:

- the provider holding the information is the person that most recently provided a service
- the information existed before 1996, when the Retention Regulations came into effect
- the information includes material that existed before the beginning of the 10-year period.

Health information may be transferred between providers (eg, if a person moves and wants their new general practitioner to have their previous record), or may be given to the individual concerned.

It is useful to note that the Health Information Privacy Code and the Code of Health and Disability Services Consumers' Rights cover issues of access to health information and privacy.

B10.1.1 Issues for the retention of specimens

The Retention Regulations can now be extended to require the retention of specimens. The Ministry has identified the following issues as needing to be resolved before the regulations are extended.

The definition of a ‘specimen’ to be covered by the regulations

The proposed amendment to the Health Act defines a specimen as ‘a bodily sample or tissue sample taken from a person’, but for the purposes of the Retention Regulations this broad definition may need to be refined. For example, cervical smear slides would need to be retained, but all blood samples, or urine samples taken during a person’s lifetime, may not need to be retained. Neither may the tissue from which a specimen for a microscope slide has been obtained. Consideration will also need to be given to specimens that are held in specialist databases, such as the Guthrie Card samples held at the National Testing Centre.²⁹

The key consideration in defining the specimens to be retained is the purpose for which the specimens are to be retained. The main purpose is ensuring that a full health record is kept to facilitate clinical management, and quality assurance.

The minimum period or periods for which specimens should be retained

The retention period could be variable depending on the type of specimen involved. This involves examining the minimum 10-year period for other health information and whether this is appropriate for specimens, or whether a different length of time is more appropriate.

Any particular storage conditions that may be required for specimens

For example, there may need to be special facilities that ensure the specimen is able to be used again if required (including whether different arrangements are needed for different types of specimens). There are also likely to be practical space issues to be considered.

Return of specimens

There are implications for specimens of health information being able to be returned to the individual concerned, and whether special requirements will be needed.

Ways that the regulations can be designed to anticipate future developments in technology

For example, in the future it is feasible that records of specimens may be kept electronically (similar to X-rays), meaning that the physical specimen may not need to be retained.

The Ministry is also aware that currently there is a gap in the coverage of the Retention Regulations regarding the management of health information held by a provider that ceases to practice. It would be wise to make changes to the Retention Regulations to cover this circumstance when other changes are being made. This would cover the situation, for example, where a general practitioner resigns, or a laboratory holding specimens goes out of business.

²⁹ The Privacy Commissioner has recently recommended, among other things, that clear guidance on the retention of Guthrie Card specimens be developed. See Privacy Commissioner 2003.

We are seeking your views

33. Following the passage of the Health (National Cervical Screening Programme) Amendment Act, changes are able to be made to the Health (Retention of Health Information) Regulations 1996 to cover the retention of specimens as well as other health information.

The Ministry is proposing that the following changes be made to the regulations:

- a) the definition of a 'specimen', beyond 'a bodily sample or tissue sample taken from a person', should be covered by the regulations (ie, the sorts of specimens the regulations should apply to)
- b) the purposes for which different sorts of specimens should be retained
- c) the minimum period or periods for which specimens should be retained and any particular period for which particular specimens should be retained
- d) particular storage conditions that may be required for specimens (including whether different arrangements are needed for different types of specimens), and the practical issues that arise from any storage requirements
- e) the implications for specimens of health information being able to be returned to the individual concerned
- f) ways the regulations can be designed to anticipate future developments in technology
- g) the management of health information (including specimens) when a provider ceases to practise or be in business.

Are there matters in addition to those listed above that you think need to be considered when changes are made to the regulations? Please explain your suggestions and share your initial thoughts about what should be covered by the regulations in relation to these issues.