

Human Tissue Bill

Government Bill

As reported from the Health Committee

Commentary

Recommendation

The Health Committee has examined the Human Tissue Bill and recommends that it be passed with the amendments shown.

Introduction

The bill replaces the Human Tissue Act 1964. It regulates the collection and use of tissue from dead human bodies and sets up a framework for informed consent for human tissue use. The bill also regulates trading in tissue, the exporting and importing of tissue, and the use of tissue for non-therapeutic purposes (for example audit, research, education, and anatomical examination). Further, although the collection and use of tissue from living people is largely covered by existing legislation and common law, the bill also requires informed consent for—

- donor analysis of tissue collected from living people otherwise than in the course of a health care procedure, and
- the use for a secondary purpose, after the donor's death, of human tissue from a living person.

Most of the submissions we received supported the intent of the bill to regulate the collection and use of human tissue. The issues that attracted particular concern were—

- organ donation and how to increase the rate of donation, with a particular focus on the effect of having an organ and tissue donor register
- the consent framework and its appropriateness
- how the bill might affect research
- provisions concerning the sale, purchase, and importation of human tissue
- the collection and use of gametes and embryos, and foetal tissue.

We found that the many issues we needed to understand and consider in relation to the bill were complex.

Organ and tissue donor register

We were informed that there is as yet no compelling evidence that an organ and tissue donor register increases the overall rate of organ and tissue donation. Nevertheless, some of us feel that a register would be useful as a focus for informing and educating the public and thus promoting organ and tissue donation. Others feel that the cost of establishing a register could be better used to fund a direct information campaign. The majority of us do not recommend establishing a register at present, but recommend including a clause that permits the establishment of an opt-on register by regulation at a later date. The majority of us consider that this provision makes the mandatory establishment of a register as provided for in the Human Tissue (Organ Donation) Amendment Bill unnecessary.

We have taken up issues of delegated legislation with the Regulations Review Committee and have considered their advice. Because the enabling provisions of this bill provide only for an opt-on register, we do not consider that human rights issues or issues of an especially controversial nature are raised here. Those were the two principles that the Regulations Review Committee drew to our attention.

Right for decision makers to raise an informed objection

The bill provides a hierarchy of decision makers who may consent to the collection or use of a dead individual's tissue. In the bill as introduced, this hierarchy does not refer specifically to the right of decision makers to object. The decision maker chooses between giving or not giving consent. If the decision is to not give informed

consent, the decision may pass to the next member of the hierarchy. We do not think it is reasonable for someone to make a decision if a higher-ranked decision-maker has objected. Therefore, we recommend that the bill be amended to provide equally for raising an informed objection or giving informed consent. Either consent or objection would have legal standing and would prevent lower-ranked decision-makers from consenting or objecting.

Cultural context of informed consent

We recommend that a person giving informed consent or raising an informed objection to the collection or use of a dead individual's tissue should be required to take into account, and to decide what weight to give to, the cultural and spiritual needs, values, and beliefs of the immediate family of the individual whose tissue is, or is not, to be collected. We also recommend that a person proposing to collect or use tissue should, unless aware of evidence to the contrary, be entitled to assume that this relevant cultural context has been taken into account. Some of us further recommend that a person proposing to collect or use tissue should also be required to take into account the relevant cultural context of the person whose tissue is being collected.

Authority to not act on informed consent

The proposed consent framework in the bill gives primacy to any informed consent given or objection raised by the individual whose tissue might be collected or used. However, we understand the difficulty of enforcing the wishes of the deceased individual if those wishes conflict with the wishes of the individual's family. Most of us consider it necessary that anyone proposing to collect or use human tissue, such as organ donation co-ordinators or transplant surgeons, be able to decide not to proceed with collection or use of tissue where families strongly oppose it. We consider that the bill should provide informed consent requirements that must be met before tissue collection or use; it should not require that collection or use must happen if these informed consent requirements are met. We therefore recommend making it explicit that nothing in the bill requires that—

- collection or use of human tissue proceed
- informed consent for the collection or use of tissue be acted on.

Consent or objection on behalf of immediate family

Subpart 5 of the bill specifies a hierarchy of those who can give informed consent or raise an objection to the collection or use of human tissue. Flowcharts from page 10 of this commentary illustrate the consent hierarchy. If the wishes of the dead person are unknown, and he or she has not nominated another person to consent or object on his or her behalf, the right to consent or object passes to the immediate family of the individual, who must decide on a majority basis. We consider that specifying that a majority of family members must consent or object is inappropriate, and that it would be better to allow a family to reach general agreement. We recommend that the bill specify that the family should convey its decision after the required steps to consult have been taken, and once it is clear that all capable family members accept, or would if consulted accept, the decision.

Research issues

We emphasise that the amendments recommended in response to the following concerns among researchers would not make lawful any activity that is currently prohibited.

Inclusion of established human cell lines

The inclusion of established human cell lines within the definition of human tissue under clause 6 of the bill led to the concern that further ethical approval or proof of consent for the use of established human cell lines would then be required. Submitters on the bill argued that gaining consent for the initial tissue collection is sufficient because human cell lines grow continuously, and there is no need for further interaction with the donor.

Although we are cautious about the use of human tissue in research, we agree that research using some established cell lines (but not, for example, human embryonic stem cell lines) should not require further ethical approval for such use of tissue. For many cell lines the original donor is deceased, unknown, or untraceable and retrospective consent would be very difficult, if not impossible, to obtain. We also agree that it should not be necessary to obtain further ethical approval for research using existing pathology samples on slides. We recommend that these concerns be addressed by amending clause 76, a regulation-making clause, to indicate that the standards or regulations can provide for exceptions to the requirement for ethical approval.

Prohibitions on the sale, purchase, and advertising of human tissue

A number of submitters were concerned with the wide definition of human tissue provided in clause 6. Researchers were concerned that tissue arrays and other forms of scientific and research material that included human tissue, which are currently traded, could not then be purchased and sold.

Researchers were also concerned by the prohibition on advertising human tissue for purchase or sale in New Zealand. We were informed that tissue arrays and other research material containing human tissue are commonly advertised in international scientific catalogues and journals. There was concern that the bill would prohibit such advertising within New Zealand and would hamper the research community in its work.

We consider that the researchers' concerns are best addressed by including exemptions in clause 55 (relating to the sale and purchase of human tissue) and clause 59 (relating to the advertising for sale and purchase of human tissue). The exemptions would apply only to products derived from human tissue or processed human tissue samples that are intended for use in research, quality control, or diagnosis. With these amendments researchers would be able to purchase tissue arrays and other material for research purposes.

Trading in human tissue generally prohibited

Under clause 55 of the bill as introduced a person cannot sell their own tissue or tissue from a body they are the responsible person for. However, if a person obtains possession of tissue that was lawfully collected from another person it can be sold. We recommend that this section be amended so that offering, providing, requiring, or accepting financial or other consideration for human tissue is prohibited, in order to recognise the gift status of human tissue. The current Government policy of providing income support for live donors of kidney or liver tissue would not be affected by this provision. The current charging practice of organisations such as the New Zealand Blood Service and Cordbank Ltd to recover the reasonable costs of collecting or using human tissue would be able to continue.

We also recommend new clause 56A, which reinforces the gift status of blood by generally preventing consideration being provided for its collection for administration to another person. This clause ensures section 92B(2) of the Health Act 1956 is re-enacted,

but also ensures persons collecting blood may provide donors with consideration reasonably related to their costs in donating blood.

Foetal tissue

We consider it would be helpful to clarify in the bill the consent process for the use of human tissue from stillborn children and foetuses. We recommend the addition of a section to clarify that—

- consent requirements relating to foetal tissue collected in the course of a health care procedure are covered by the Code of Health and Disability Services Consumers' Rights
- a dead foetus that has not issued completely from the mother before she died is to be treated as tissue from the body of the mother (so consent requirements are those that apply to the dead mother)
- a dead foetus that has issued completely from the mother (whether or not she is dead) is to be treated as tissue from the body of an individual, separate from the mother (consent requirements would then be the same as those for a dead child).

The Human Assisted Reproductive Technology Act 2004

The collection and use of gametes and embryos is regulated under the Human Assisted Reproductive Technology Act 2004 (the HART Act) and does not come under the purview of this bill. Collection of human embryonic stem cells falls under the HART Act; once those stem cells have been collected their use falls under the regulations in this bill. Importation and exportation of stem cells are also covered by this bill.

Gametes and embryos excluded from definition of human tissue

As the bill is not intended to regulate the collection or use of gametes and embryos, clause 6(2) excludes from the definition of human tissue gametes and embryos that are in vitro (that is, outside a living organism). However, it is not entirely clear whether the bill covers the collection and use of gametes and embryos from dead persons, which it was not intended to do. We therefore recommend that the exclusion in clause 6(2) apply to all gametes and embryos.

Regulations for informed consent to collect or use gametes and embryos

The HART Act regulates the use of gametes and embryos. Regulations may be made under section 76(1)(a) of that Act governing the performance of assisted reproductive procedures and the conduct of human reproductive research. Those regulations may require informed consent for the performance of the procedures or conduct of the research.

However, the HART Act does not provide for regulations requiring informed consent for the collection of gametes and embryos generally, or from dead persons specifically. We therefore recommend inserting into the bill new clause 89A, which would amend section 76 of the HART Act to provide for regulations requiring informed consent for collection of gametes and embryos from dead persons specifically, and more generally in connection with assisted reproductive procedures or human reproductive research. At this stage we are not making any recommendations about the specific form or content of such regulations, which will reflect the outcome of the consultation process being led by the Advisory Committee on Assisted Reproductive Technology.

Furthermore, we recommend extending this power to make regulations requiring informed consent to include “any other lawful use or uses”. This would provide an additional safeguard by ensuring that if lawful uses should arise that are not currently captured by the definitions of human reproductive research or reproductive procedures, informed consent requirements can be placed on them. This change would not make anything lawful that is currently unlawful under the HART Act or any other enactment. We consider that the provision for an expanded requirement for informed consent is an appropriate precautionary approach to adopt in this bill.

Flowcharts

The consent process required for the collection and use of human tissue under the bill is complex. We recommend the inclusion of flowchart diagrams in the schedules of the bill to clarify the hierarchies of consent for some particular uses of human tissue. The flowcharts are reproduced in the succeeding pages of this commentary.

New Zealand National minority view

New Zealand National fully supports the fundamental premise of the bill that the informed consent of an individual has primacy. New Zealand National supports a voluntary, opt-on, informed consent organ and tissue donor register. An organ and tissue donor register will provide an informed consent process, which is fundamental to this bill, as well as being part of an overall strategy to increase organ donation in New Zealand. We are concerned that the focus and the 'call to action' of a public information campaign to raise awareness about organ and tissue donation will be diluted if an informed consent mechanism of recording an individual's wishes is not readily accessible or available.

Māori Party minority view

The Māori Party cannot support this bill in its current form. As was highlighted in the consultation with Māori, the use of human tissue requires the recognition of both individuals and collectives in the consent process. We are disappointed that this issue has not been addressed. Allowing individuals to be the sole decision-makers of whakapapa material does not allow for the collective involvement of whanau. Although the bill does give some consideration to the wishes of the immediate family, the provisions remain insufficient to give whanau the ability to make an overriding objection. It is the view of the Māori Party that the failure of this bill to recognise important cultural values and beliefs outside of a Western framework of individual rights will mean the imposition of this cultural framework over all others, including that held by Māori. The result is not only racist legislation but legislation that is in breach of the Treaty of Waitangi.

Appendix

Committee process

The Human Tissue Bill was referred to the committee on 14 November 2006. The closing date for submissions was 16 February 2007. We received 31 submissions from interested groups and individuals and heard evidence from 19 of them. We received advice from the Ministry of Health and Parliamentary Counsel. The Regulations Review Committee reported to the committee on the powers contained in clause 77(2) and new clauses 79A and 89A.

Committee membership

Sue Kedgley (Chairperson)

Maryan Street (Deputy Chairperson)

Dr Jackie Blue

Dr Jonathan Coleman

Jo Goodhew

Ann Hartley

Sue Moroney

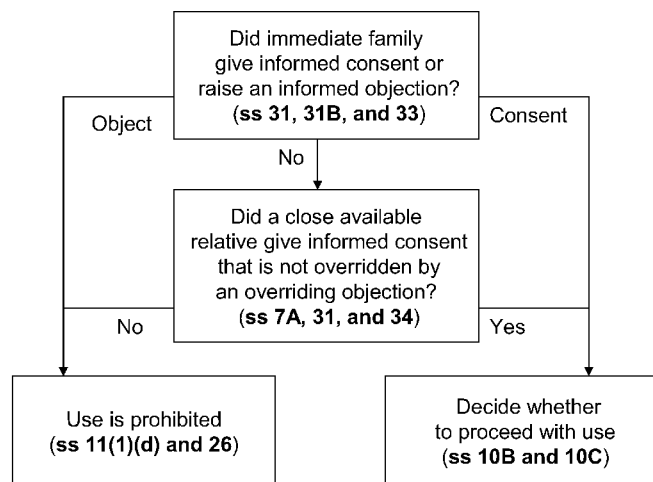
Hon Tony Ryall

Lesley Soper

Barbara Stewart

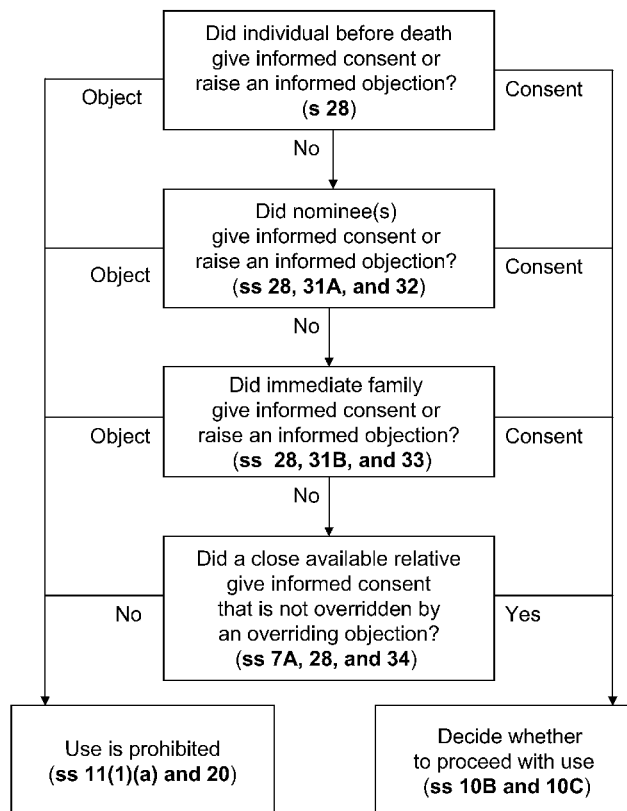
Tariana Turia

Use for secondary purposes after donor's death of tissue from living individual



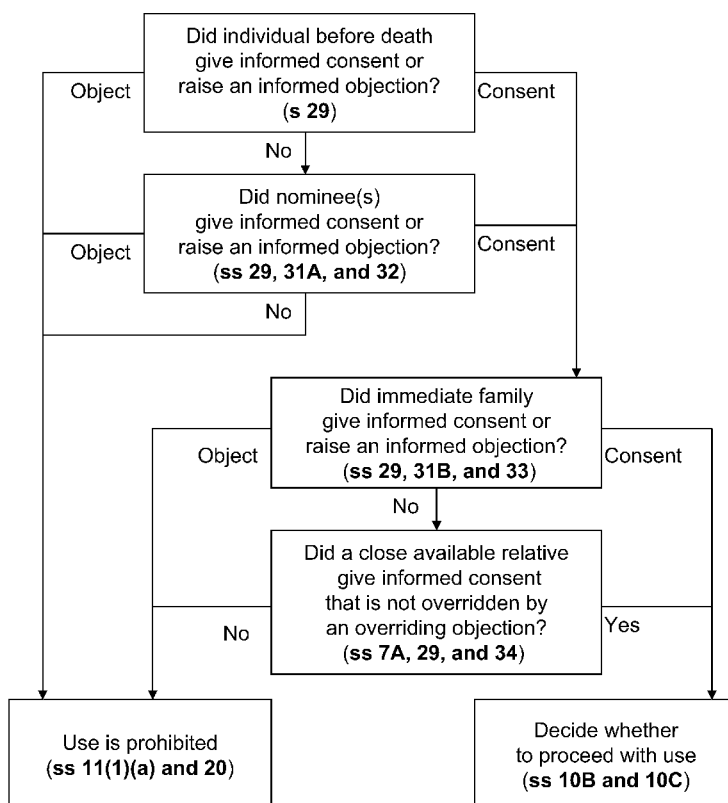
- Persons proposing to collect or use tissue must comply with s 10.
- In determining whether consent or an objection is informed consent, an informed objection, or an overriding objection, see in particular ss 7, 27A–27E, 31C, 31D, and 38.

Use for general purposes of tissue that is or is from bodies



- Persons proposing to collect or use tissue must comply with s 10.
- In determining whether consent or an objection is informed consent, an informed objection, or an overriding objection, see in particular ss 7, 27A–27E, 31C, 31D, and 38.

Use for anatomical examination or public display of tissue that is or is from bodies



- Persons proposing to collect or use tissue must comply with **s 10**.
- In determining whether consent or an objection is informed consent, an informed objection, or an overriding objection, see in particular **ss 7, 27A–27E, 31C, 31D, and 38**.
- Examination and some display of bodies of individuals under 16 years is prohibited: **s 51A**.

Key to symbols used in reprinted bill

As reported from a select committee

Struck out (unanimous)

Subject to this Act,

Text struck out unanimously

New (majority)

Subject to this Act,

Text inserted by a majority

New (unanimous)

Subject to this Act,

Text inserted unanimously

(Subject to this Act,)

Words struck out unanimously

Subject to this Act,

Words inserted unanimously

Hon Pete Hodgson

Human Tissue Bill

Government Bill

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The Parliament of New Zealand enacts as follows:

1 Title

This Act is the Human Tissue Act **2006**.

2 Commencement

Struck out (unanimous)

- | | | |
|-----|---|----|
| (1) | Sections 87(1) and (5) (which repeal a provision under which medical practitioners are entitled, without payment of a fee, to organ donor information from the National Register of Driver Licences) come into force on a date to be appointed by the Governor-General by Order in Council. | 5 |
| (2) | Sections 87(2) to (4) and (6) and 88 and the heading above section 87 (which repeal organ donor provisions in driver licensing legislation) come into force on a date to be appointed by the Governor-General by Order in Council. | 10 |
| (3) | The date appointed under subsection (2) may be the same as, or later than, the date appointed under subsection (1) , and it may be appointed by the order that appoints the date appointed under subsection (1) , or by another later order (for example, one appointing a date under subsection (4)). | 15 |

New (unanimous)

- | | | |
|-----|---|----|
| (1) | Sections 1, 2, and 88A come into force on the day after the date on which this Act receives the Royal assent. | |
| (2) | Sections 87 and 88 , and the heading above section 87 , come into force as provided by section 88A . | 20 |
| (4) | The rest of this Act comes into force on a date to be appointed by the Governor-General by Order in Council. | |

Part 1 General provisions

3 Purpose of this Act

- The purpose of this Act is to help to ensure that collection *(and)* or use of human tissue— 5
- (a) occurs only with proper recognition of, and respect for,—
- (i) the autonomy and dignity of the individual *(from whom, or from whose body, the)* whose tissue is, before or after his or her death, collected or used; 10
and
- (ii) the cultural and spiritual needs, values, and beliefs of the immediate family of, *(and of others who were in a close relationship to, an)* that individual *(who has died)*; and 15
- (iii) the cultural, ethical, and spiritual implications of the collection *(and)* or use of human tissue; and
- (iv) the public good associated with collection *(and)* or use of human tissue (whether for *(medical)* health practitioner education, the investigation of offences, (or) research, (or) transplantation or other therapeutic purposes, or for other lawful purposes); and 20
- (b) does not endanger the health and safety of members of the public; and 25
- (c) generally does not involve the requirement or acceptance, or the offering or provision, of financial or other consideration for the tissue.

4 Overview of this Act

To help to achieve its purpose, this Act— 30

Struck out (unanimous)

- (a) prohibits collection and use (including for secondary purposes) of human tissue from, bodies without appropriate consent (as defined in **section 7**); and
- (b) prohibits collection of non-consumer human tissue for donor analysis, carrying out donor analysis of non-consumer human tissue, or both, without appropriate consent (as so defined); and 35

New (unanimous)

- | | | |
|-----|--|----|
| (a) | requires, unless they are done for a purpose specified in section 12 , informed consent for the following: | |
| | (i) collection or use of human tissue that is, or is collected from, a body: | |
| | (ii) collection of non-health-care tissue for donor analysis: | 5 |
| | (iii) donor analysis of non-health-care tissue: | |
| | (iv) use for a secondary purpose, after the donor's death, of human tissue collected from a living individual; and | 10 |
| (b) | makes it an offence to collect or use tissue if the informed consent required has not been given; and | |

Struck out (unanimous)

- | | | |
|-----|---|----|
| (c) | prohibits use for a secondary purpose, after the donor's death, and without appropriate consent (as so defined), of human tissue from a living person; and | 15 |
| (d) | imposes (<i>certain prohibitions</i>) <u>other requirements for</u> and restrictions on collection (<i>and</i>) <u>or</u> use of (<i>all</i>) human tissue; and | |
| (e) | provides for related matters; and | |
| (f) | repeals and replaces (with modified provisions)— | 20 |
| | (i) the Human Tissue Act 1964; and | |
| | (ii) Part 3A (trading in human blood and controlled human substance) of the Health Act 1956. | |

New (unanimous)

- | | | |
|-----------|--|----|
| 4A | Overviews of use for certain purposes of certain tissue | |
| (1) | A diagrammatic overview of use for general purposes of tissue that is or is from bodies is set out in Schedule 1A . | 25 |
| (2) | A diagrammatic overview of use for anatomical examination or public display of tissue that is or is from bodies is set out in Schedule 1B . | |

New (unanimous)

- (3) A diagrammatic overview of use for secondary purposes after the donor's death of tissue from a living individual is set out in **Schedule 1C**.
- (4) The diagrams are intended as a guide only.

5 Interpretation

5

In this Act, unless the context otherwise requires,—

anatomical examination means examination of a body, or any part of a body, for the purpose of the study and practice of the science of anatomy

Struck out (unanimous)

appropriate consent has the meaning given to it by **section 7**

10

authorised person means a person who is not the Director-General but is authorised in writing by the Director-General to enter and inspect premises for the purposes of this Act

Struck out (unanimous)

body means—

- (a) a dead human body; or
- (b) the body of a still-born child or other dead foetus

15

New (unanimous)

body means a dead human body

capable, in relation to an individual and a decision whether to give, make, ~~raise~~, amend, *(or)* ~~revoke, revoke and replace, or accept or disagree with informed consent, an informed objection, an overriding objection,~~ or a nomination *(for the purposes of this Act)*, means that the individual has the capacity to—

20

- (a) understand the nature, and foresee the consequences, of the decision; and
- (b) communicate the decision

25

New (unanimous)

close available relative has the meaning given to it by **section 7A**

Code means the Code of Health and Disability Services Consumers' Rights prescribed by regulations made under section 74(1) of the Health and Disability Commissioner Act 1994

5

collect, in relation to human tissue, means to remove or take that tissue from a living individual, as a body, or from a body

Struck out (unanimous)

collection and use includes either collection or use

collection or use includes both collection and use

consumer means a health consumer or a disability services consumer, as those terms are defined in section 2(1) of the Health and Disability Commissioner Act 1994

10

New (unanimous)

controlled drug means a controlled drug within the meaning of the Misuse of Drugs Act 1975

Struck out (unanimous)

dead foetus has the meaning given to it by section 2 of the Births, Deaths, and Marriages Registration Act 1995

15

New (unanimous)

dead foetus means a foetus that does not breathe or show any other sign of life (such as beating of the heart, pulsation of the umbilical cord, or definite movement of the voluntary muscles), whether or not all or any of the following apply:

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- (a) the umbilical cord has been severed:
- (b) the placenta has detached:
- (c) the foetus has issued completely from its mother

Struck out (unanimous)**Director-General—**

- (a) means the chief executive under the State Sector Act 1988 of the Ministry of Health; and
- (b) in relation to a power or function delegated by that chief executive, includes a person to whom that chief executive has delegated that power or function

5

New (unanimous)

Director-General means the chief executive under the State Sector Act 1988 of the Ministry of Health

donor analysis, in relation to human tissue, means analysis for the purpose of providing information (including genetic information) about an actual or potential condition or trait of the individual (*from whom, or from whose body, the*) whose tissue was collected

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embryo includes a zygote, and a cell or group of cells that has the capacity to develop into an individual

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ethics committee means an ethics committee—

- (a) established by, or appointed under, an enactment; or
- (b) approved by the Director-General

exportation has the same meaning as in section 2(1) of the Customs and Excise Act 1996

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gamete means—

- (a) an egg or a sperm, whether mature or not; or
- (b) any other cell (whether naturally occurring or artificially formed or modified) that—
 - (i) contains only 1 copy of all or most chromosomes; and
 - (ii) is capable of being used for reproductive purposes

25

head, in relation to a school of anatomy, means the person who is, or who is authorised to represent the (*body*) group of people or the organisation that is, responsible for the operation of the school

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health care procedure has the meaning given to it by section 2(1) of the Health and Disability Commissioner Act 1994

health practitioner has the meaning given to it by section 5(1) of the Health Practitioners Competence Assurance Act 2003

human tissue or **tissue** has the meaning given to it by **section 6**

immediate family, in relation to a dead individual,— 5

- (a) means members of the individual's family, whānau, or other culturally recognised family group, who—
 - (i) were in a close relationship with the individual; or
 - (ii) had, in accordance with customs or traditions of the community of which the individual was part, responsibility for the individual's welfare and best interests; and 10
- (b) to avoid doubt, includes a person whose relationship to the dead individual was, or was a relationship that is established through, 1 or more of the following relationships (*that are, that or those of*): 15
 - (i) spouse, civil union partner, or de facto partner of the individual:
 - (ii) child, parent, guardian, grandparent, brother, or sister of the individual: 20
 - (iii) stepchild, step-parent, stepbrother, or stepsister of the individual

importation has the same meaning as in section 2(1) of the Customs and Excise Act 1996 25

Struck out (unanimous)

in vitro, in relation to an embryo or gamete, means an embryo or gamete that is outside a living organism

informed consent has the meaning given to it by **section 7**

New (unanimous)

informed objection has the meaning given to it by **section 7**

inspector, in relation to a school of anatomy, means a person appointed under **section 80** to be an inspector of that school of anatomy 30

New (unanimous)

marae includes the area of land on which all buildings such as the wharehenui (meeting house), the wharekai (dining room), ablution blocks, and any other associated buildings are situated

medical practitioner means a health practitioner who is, or is deemed to be, registered with the Medical Council of New Zealand continued by section 114(1)(a) of the Health Practitioners Competence Assurance Act 2003

5

New (unanimous)

medicine means a medicine with the meaning of the Medicines Act 1981

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Minister means the Minister of Health

Struck out (unanimous)

national organ and tissue donor register means any register maintained in any medium by or on behalf of the Crown for recording the following:

- (a) consents or nominations given or made for the purposes of this Act; and
- (b) amendments to, or revocations of, those consents or nominations; and
- (c) other donor information

15

New (unanimous)

national organ and tissue donor register means any register established or recognised by regulations under **section 79A**

20

nomination means a nomination under **section 32**

nominee means a person nominated under **section 32**

(non-consumer human) non-health-care tissue means human tissue that is, or is derived from, human tissue that is collected from a living individual, but is neither—

25

- (a) collected from a consumer in the course of a health care procedure; nor
- (b) derived from human tissue collected in that way
- other donor information** includes—
- (a) a request by a person that his or her body or any specified part of his or her body be used after his or her death for therapeutic purposes or for purposes of *(medical) health practitioner* education or any kind of research; and 5
- (b) information (referred to in the Land Transport Act 1998 as organ donor information) indicating that an applicant for, or holder of, a driver licence has agreed in general terms (*to be*), or has objected in general terms, to that applicant or holder being an organ donor 10

New (unanimous)

overriding objection has the meaning given to it by **section 7** 15

post-mortem means a post-mortem examination

New (unanimous)

Registrar means any Registrar or Deputy-Registrar of the High Court or of a District Court

responsible person has the meaning given to it by **section 8**

school of anatomy means a school of anatomy whose establishment is authorised by an order (*that is, or must be treated as if it were,*) made under **section 79** 20

Struck out (unanimous)

secondary purpose, in relation to collection or use of human tissue, means that the collection or use is for a purpose not covered by consent given, and not later revoked, in accordance with this Act 25

New (unanimous)

secondary purpose, in relation to any collection or use of human tissue collected from a living individual or that is, or is collected from, a body, means that the collection or use is for a purpose that is not covered by informed consent—

- (a) to the collection or use, by any person, and for identified purposes, of tissue collected from that living individual or tissue that is, or is collected from, the body; and
- (b) given, and not later revoked, in accordance with the requirements of this Act

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Struck out (unanimous)

senior available next of kin has the meaning given to it by section 34

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still-born child has the meaning given to it by section 2 of the Births, Deaths, and Marriages Registration Act 1995

therapeutic product includes—

- (a) a medicine or related product as those terms are defined in section 2(1) of the Medicines Act 1981; and
- (b) a controlled drug as defined in section 2(1) of the Misuse of Drugs Act 1975

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use, in relation to any human tissue,—

- (a) includes the performance of a post-mortem involving that tissue, research using that tissue, anatomical examination and public (or other) display, testing (including donor analysis), storage, and disposal, of that tissue; and
- (b) in particular, includes use of that tissue in the development, making or preparation, and testing of (therapeutic products) controlled drugs, medicines, or both; and
- (c) includes, (if) whether or not that tissue is (non-consumer human) non-health-care tissue, and except as provided in **paragraph (d)**, the use of that tissue (for example, the administration or transplantation of that tissue) in the carrying out of a health care procedure; (but) and

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New (unanimous)

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|----------|--|----|
| | (ca) includes, except as provided in paragraphs (d) and (e) , use of that tissue for a secondary purpose; but | |
| | (d) does not include use of that tissue in so far as it is, or is part of, a <i>(therapeutic product)</i> <u>controlled drug, a medicine, or both</u> ; and | 5 |
| | (e) does not include the importation or the exportation of that tissue. | |
| 6 | Human tissue defined and illustrated | |
| (1) | Human tissue or tissue means material that— | |
| | (a) is, or is derived from, <u>a body, or material</u> collected from a living individual or from a body; and | 10 |
| | (b) is or includes human cells; and | |
| | (c) is not excluded, for the purposes of some or all of the provisions of this Act, by subsection (2) or (3) . | |
| (2) | <i>(An in vitro)</i> <u>A</u> human embryo or <i>(in vitro)</i> human gamete is not human tissue for the purposes of any provision of this Act. | 15 |
| (3) | Cell lines derived from human cells are human tissue for the purposes of the following sections, but not for the purposes of any other provisions of this Act: | |
| | (a) sections 48 and 76 (which relate to standards for collection <i>(and)</i> <u>or</u> use of human tissue for non-therapeutic purposes): | 20 |
| | (b) sections 63 and 77 (which relate to standards, etc, for export and import of human tissue). | |
| (4) | Examples of human tissue therefore include the following: | 25 |
| | (a) all or any part of a body: | |
| | (b) whole human organs (for example, hearts, kidneys, livers, and lungs) or parts of them (for example, heart valves): | |
| | (c) human stem cells or other human cells (for example, stem cells obtained from human embryos): | 30 |
| | (d) human blood: | |
| | (e) human bone marrow: | |
| | (f) human eyes: | |
| | (g) human hair, nails, and skin: | 35 |
| | (h) human lung washouts: | |
| | (i) human mucus, sputum, or urine. | |

New (unanimous)**6A How Act applies to foetal tissue not subject to Code**

Human tissue that is, or is part of, a dead foetus and is not collected from a consumer in the course of a health care procedure must, for the purposes of this Act, be treated,—

- (a) if the dead foetus did not issue completely from its mother before she died (because of its miscarriage or for any other reason), as tissue that is, or is collected from, the body of the mother of the dead foetus; and 5
- (b) if the dead foetus issued completely from its mother (whether or not she died because of its having issued), as tissue that is, or is from, the body of an individual who is not the mother and did not, before death, give, or nominate any person to give on his or her behalf, informed consent to use of tissue that is, or is collected from, his or her body. 10 15

7 (*Appropriate consent and*) Informed consent, informed objection, and overriding objection defined**Struck out (unanimous)**

- (1) **Appropriate consent**, in relation to any collection or use of human tissue, means the informed consent (if any) required by this Act for that collection or use of tissue. 20

- (2) **Informed consent**, in relation to any kind of collection or use of human tissue, means consent—
 - (a) to that kind of collection or use of the tissue (and so does not include agreement in general terms, given by an applicant for, or holder of, a driver licence, to *(be)* that applicant or holder being an organ donor); and 25

Struck out (unanimous)

- (b) given by an individual (a **decision-maker**) that this Act recognises as an (or the) individual who is entitled to consent to that kind of collection or use of the tissue; and 30

Struck out (unanimous)

- (c) given by the decision-maker freely, and after he or she has received all information that a reasonable person, in the decision-maker's circumstances, needs in order to give informed consent (both of which matters are presumed, in the absence of evidence to the contrary, under **section 44**); and 5
- (d) given, and not later revoked, in accordance with this Act.

New (unanimous)

- (b) given by a person who is entitled to give it under **subpart 3**; and 10
 - (c) given freely, and in the light of all information that a reasonable person, in that person's circumstances, needed in order to give informed consent; and
 - (d) given in accordance with the requirements of **subparts 4 and 5**; and 15
 - (e) not later revoked in accordance with the requirements of **subparts 4 and 5**.
- (3) **Informed objection**, in relation to any kind of collection or use of human tissue, means an objection—
- (a) to that kind of collection or use of the tissue (and so does not include any objection in general terms, raised by an applicant for, or holder of, a driver licence, to that applicant or holder being an organ donor); and 20
 - (b) raised by a person who is entitled to raise it under **subpart 3**; and 25
 - (c) raised freely, and in the light of all information that a reasonable person, in that person's circumstances, needed in order to raise an informed objection; and
 - (d) raised in accordance with the requirements of **subparts 4 and 5**; and 30
 - (e) not later revoked in accordance with the requirements of **subparts 4 and 5**.
- (4) **Overriding objection**, in relation to any collection or use of tissue that is, or is from, the body of a dead individual, and to

New (unanimous)

- which a close available relative has given informed consent, means an objection—
- (a) to that collection or use of the tissue; and
 - (b) raised under **section 34** by a person referred to in the paragraph of **section 7A(1) or (2)** that refers to the close available relative; and 5
 - (c) raised freely, and in the light of all information that a reasonable person, in that person's circumstances, needed in order to raise an overriding objection; and
 - (d) raised in accordance with the requirements of **subparts 4 and 5**; and 10
 - (e) not later revoked in accordance with the requirements of **subparts 4 and 5**.
- 7A Close available relative defined**
- (1) A **close available relative** means, in relation to an individual who was 16 years old or older at the time when he or she died,— 15
 - (a) a person who was a spouse, civil union partner, or de facto partner of the individual immediately before his or her death; or 20
 - (b) if the individual, immediately before his or her death, had no spouse, civil union partner, or de facto partner, or if no person who was then the individual's spouse, civil union partner, or de facto partner is available, a son or daughter— 25
 - (i) of the individual; and
 - (ii) who is 16 years old or older; or
 - (c) if no person referred to in **paragraph (a) or (b)** is available, a parent of the individual; or
 - (d) if no person referred to in **paragraphs (a) to (c)** is available, a brother or sister— 30
 - (i) of the individual; and
 - (ii) who is 16 years old or older.
 - (2) A **close available relative** means, in relation to an individual who was under 16 years of age at the time when he or she died,— 35
 - (a) a parent of the individual; or

New (unanimous)

- (b) if a parent of the individual is not available, a person who was a guardian of the individual immediately before his or her death; or
- (c) if no person referred to in **paragraph (a) or (b)** is available, a brother or sister—
- (i) of the individual; and
- (ii) who is 16 years old or older.

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7B When people not available for purposes of Act

A person who is dead, unknown, or missing, or not capable, must be treated for the purposes of this Act as not available.

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8 Responsible person defined (and illustrated)

- (1) **Responsible person**, in relation to a body, means the person lawfully in possession of the body; but does not include a person entrusted with the body for the purpose only of its burial, cremation, or other lawful disposal.

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Struck out (unanimous)

- (2) For the purposes of **subsection (1)**, the person specified in column 1 of the table in **Schedule 1** is the person lawfully in possession of a body of the kind specified, opposite the reference to that person, in column 2 of that table.

New (unanimous)

- (2) The person specified in a paragraph of this subsection is, for the purposes of **subsection (1)**, the person lawfully in possession of a body of the kind specified in that paragraph:
- (a) the person for the time being in charge of a hospital care institution as defined in section 58(4) of the Health and Disability Services (Safety) Act 2001—a body lying in that institution:
- (b) the person for the time being in charge of a hospital as defined in section 2(1) of the Mental Health (Compulsory Assessment and Treatment) Act 1992—a body that is—

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New (unanimous)

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|---|------------------------------|
| <ul style="list-style-type: none"> (i) the body of a patient (as so defined); and (ii) lying in the hospital: (c) the person for the time being in charge of a secure facility as defined in section 5(1) of the Intellectual Disability (Compulsory Care and Rehabilitation) Act 2003—a body that is— <ul style="list-style-type: none"> (i) the body of a person who was required to stay in the facility; and (ii) lying in the facility: (d) the prison manager of a prison (as those terms are defined in section 3(1) of the Corrections Act 2004)—a body that is— <ul style="list-style-type: none"> (i) the body of a prisoner (as so defined); and (ii) lying in the prison: (e) the head of a school of anatomy—a body that is— <ul style="list-style-type: none"> (i) received and possessed by the school for anatomical examination; and (ii) lying in the school. | <p>5</p> <p>10</p> <p>15</p> |
| <p>(3) Subsection (2) does not limit the rights, powers, or duties of any person entitled under any rule of law to the possession of a body.</p> <p>(4) Possession includes the exercise of a right to custody.</p> <p style="margin-left: 20px;">Compare: 1964 No 19 ss 2(2), <u>3(6)</u></p> | <p>20</p> |
| <p>9 Act binds the Crown
This Act binds the Crown.</p> | <p>25</p> |

Part 2 Human tissue

Struck out (unanimous)

Subpart 1—Lawful collection and use of all human tissue

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|-----------|---|----|
| 10 | Purpose of this subpart | 5 |
| | The purpose of this subpart is to give examples, in sections 11 to 17 , of lawful collection and use of human tissue, and to help to explain— | |
| | (a) requirements, in this Act and other enactments, for lawful collection and use of human tissue; and | 10 |
| | (b) how this Act relates to those other enactments. | |
| | Compare: 1964 No 19 ss 3(3), (7), 7(2) | |
| 11 | Tissue collected from living people by or on behalf of health practitioners practising their professions | 15 |
| | Collection or use of human tissue is lawful if done by or on behalf of a health practitioner for the purposes of the practice of his or her profession (whether in a hospital or other clinical setting, or in an educational, investigative, or research setting) and that tissue is— | |
| | (a) collected from a health consumer or disability services consumer, or used after being so collected, and collected or used in accordance with the Code of Health and Disability Services Consumers' Rights prescribed by regulations made under section 74(1) of the Health and Disability Commissioner Act 1994; or | 25 |
| | (b) non-consumer human tissue collected or used with appropriate consent (as defined in section 7); or | |
| | (c) collected lawfully from a living individual for a lawful purpose and used, for a secondary purpose and after the donor's death, with appropriate consent (as so defined). | 30 |
| 12 | Tissue collected from bodies by or on behalf of medical practitioners performing post-mortems of those bodies | |
| (1) | Collection or use of human tissue is lawful if done by, or in accordance with the instructions of, a medical practitioner for | |

Struck out (unanimous)

- the purposes of a lawful post-mortem of a body and that tissue is—
- (a) collected from the body; and
 - (b) collected or used with appropriate consent (as defined in **section 7**). 5
- (2) A lawful post-mortem of a body is one—
- (a) performed in accordance with **section 49**; and
 - (b) whose performance is authorised or required by law.
- (3) Post-mortems of the kind referred to in **subsection (2)(b)** also include those that one of the following competent legal authorities has, under one of the following enactments, directed or ordered be performed: 10
- (a) a coroner acting under section 7 of the Coroners Act 1988; and
 - (b) the High Court acting under section 39 of the Coroners Act 1988; and 15
 - (c) the Director-General of Health acting under section 78 of the Health Act 1956.
- 13 Tissue collected from bodies for therapeutic purposes or for medical education or research** 20
- Collection or use of human tissue is lawful if done for therapeutic purposes or for medical education or research and that tissue is—
- (a) collected from a body by a qualified person (in accordance with **section 50**); and 25
 - (b) collected or used with appropriate consent (as defined in **section 7**).
- 14 Use of bodies, etc, for study and practice of anatomy**
- Collection or use of human tissue is lawful if done by or on behalf of a school of anatomy for the purposes of the study and practice, in accordance with this Act, of the science of anatomy and that tissue is— 30
- (a) a body, or tissue collected from a body; and
 - (b) collected or used with appropriate consent (as defined in **section 7**). 35

Struck out (unanimous)

- | | | |
|-----------|---|--------------|
| 15 | Lawful disposal of body, etc, by responsible person
Collection or use of human tissue is lawful if done by or on behalf of the responsible person for the purposes of the burial, cremation, or other lawful disposal of the tissue concerned and that tissue is, or is collected from, a body. | 5 |
| 16 | Use of existing holdings of tissue of educational, historical, or other cultural significance | |
| (1) | Use of human tissue is lawful if— | |
| (a) | done by or on behalf of a museum, educational or research institution, or similar organisation; and | 10 |
| (b) | done for preservation, education, research, testing (including donor analysis), and public display, or for any of those purposes, pending lawful disposition or lawful disposal; and | |
| (c) | on the repeal of the Human Tissue Act 1964, that tissue had been collected from living people or from bodies, and was being used for all or any of those purposes by the organisation concerned. | 15 |
| (2) | Examples of tissue of that kind include ancient human remains, ancient tattooed dried human heads (toi moko or moko mokai), ancient artefacts (for example, flutes) made from human bone, and human tissue on or in military uniforms, or military equipment, of historical interest. | 20 |
| 17 | Use of tissue collected outside New Zealand
Use of human tissue is lawful if done for a purpose that is lawful under, or apart from, this Act, and that tissue was— | 25 |
| (a) | collected outside New Zealand; and | |
| (b) | imported in accordance with section 63 (standards, etc, for export and import of human tissue). | |
| 18 | Collection or use for non-therapeutic purposes must comply with prescribed or approved standards
Sections 11 to 17 are subject to section 48 (under which collection or use of human tissue for non-therapeutic purposes must comply with prescribed or approved quality, safety, and other standards). | 30

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Struck out (unanimous)

- 19 Other lawful collection or use not affected by subpart Sections 11 to 17 do not—**
- (a) limit or affect any other rule of law permitting, requiring, or controlling collection or use of human tissue; or
 - (b) make unlawful any collection or use of human tissue if that collection or use is lawful apart from this Act (for example, the taking, analysis, retention, or disposal of a bodily sample under the Criminal Investigations (Bodily Samples) Act 1995).
- Compare: 1964 No 19 ss 3(3), (7), 7(2)
- Subpart 2—Consent required for collection and use (including for secondary purposes) of human tissue from bodies
- 20 Collection and use of human tissue from bodies without appropriate consent prohibited**
- (1) No person may collect or use human tissue from bodies for a purpose that is not a secondary purpose without appropriate consent.
 - (2) This section is subject to **section 21**.
- 21 Exceptions to section 20**
- Section 20** does not apply to collection or use of human tissue from bodies—
- (a) for the purposes of the prevention, detection, investigation, prosecution, or punishment of offences; or
 - (b) for the purposes of a post-mortem of a body that one of the following competent legal authorities has, under one of the following enactments, directed or ordered be performed:
 - (i) a coroner acting under section 7 of the Coroners Act 1988; and
 - (ii) the High Court acting under section 39 of the Coroners Act 1988; and
 - (iii) the Director-General of Health acting under section 78 of the Health Act 1956; or
 - (c) if that collection or use is, or is for the purposes of, the testing or disposal of the tissue because—

Struck out (unanimous)

	(iii) an external evaluation of services; or	
(e)	if that use is, or is for the purposes of, the testing or disposal of the tissue because—	
	(i) that testing or disposal is necessary to avoid endangering the health or safety of members of the public; or	5
	(ii) all reasonable attempts have been made, but have failed, to return the tissue to a family member or other person to whom the tissue would otherwise be returned for disposal.	10
Subpart 3—Consent required for donor analysis, etc, of all non-consumer human tissue		
24	Donor analysis of non-consumer human tissue, etc, without appropriate consent prohibited	
(1)	No person may collect non-consumer human tissue for donor analysis, carry out donor analysis of non-consumer human tissue, or both, without appropriate consent.	15
(2)	This section is subject to section 25 .	
25	Exceptions to section 24	
	Section 24 does not apply to collection of non-consumer human tissue for donor analysis, carrying out of donor analysis of non-consumer human tissue, or both,—	20
(a)	for the purposes of the prevention, detection, investigation, prosecution, or punishment of offences; or	
(b)	for the purposes of implementing a direction or order of a court or tribunal; or	25
(c)	for the purposes of providing, for the medical benefit of another person or a child conceived but not born, information about the individual from whom the tissue was collected or derived, if—	30
	(i) it is not reasonably practicable to find him or her or, if he or she has died, a personal representative or family member of that individual; and	
	(ii) all reasonable efforts have been made to ascertain whether that individual objected to the tissue	35

Struck out (unanimous)

	being used for those purposes, and he or she appears not to have done so; or	
(d)	for the purposes of research that has received the approval of an ethics committee (even though the ethics committee knew that informed consent had not been, and would not be, obtained for the research); or	5
(e)	for the purposes of 1 or more of the following activities, being activities that are each undertaken to assure or improve the quality of services:	
	(i) a professionally recognised quality assurance programme:	10
	(ii) an external audit of services:	
	(iii) an external evaluation of services; or	
(f)	if that use is, or is for the purposes of, the testing or disposal of the tissue because—	15
	(i) that testing or disposal is necessary to avoid endangering the health or safety of members of the public; or	
	(ii) all reasonable attempts have been made, but have failed, to return the tissue to the person or persons to whom the tissue would otherwise be returned for disposal.	20
	 Subpart 4—Consent required for use of human tissue from living individuals for secondary purposes after donors' deaths	 25
26	Use of tissue from living individual for secondary purpose after donor's death without appropriate consent prohibited	
(1)	No person may use for a secondary purpose, after the donor's death, and without appropriate consent, human tissue from a living individual.	30
(2)	This section is subject to section 27 .	
27	Exceptions to section 26	
	Section 26 does not apply to use for a secondary purpose, after the donor's death, of human tissue from a living individual—	35

Struck out (unanimous)

- | | | |
|-----|--|----|
| (a) | for the purposes of the prevention, detection, investigation, prosecution, or punishment of offences; or | |
| (b) | for the purposes of a post-mortem examination of a body that one of the following competent legal authorities has, under one of the following enactments, directed or ordered be performed: | 5 |
| | (i) a coroner acting under section 7 of the Coroners Act 1988; and | |
| | (ii) the High Court acting under section 39 of the Coroners Act 1988; and | 10 |
| | (iii) the Director-General of Health acting under section 78 of the Health Act 1956; or | |
| (c) | for the purposes of research that has received the approval of an ethics committee (even though the ethics committee knew that informed consent had not been, and would not be, obtained for the research); or | 15 |
| (d) | for the purposes of 1 or more of the following activities, being activities that are each undertaken to assure or improve the quality of services: | |
| | (i) a professionally recognised quality assurance programme: | 20 |
| | (ii) an external audit of services: | |
| | (iii) an external evaluation of services: | |
| (e) | if that use is, or is for the purposes of, the testing or disposal of the tissue because— | 25 |
| | (i) that testing or disposal is necessary to avoid endangering the health or safety of members of the public; or | |
| | (ii) all reasonable attempts have been made, but have failed, to return the tissue to the person or persons to whom the tissue would otherwise be returned for disposal. | 30 |

Struck out (unanimous)**Subpart 5—Informed consent required by this Act**

Persons entitled to give informed consent for collection, use, and secondary use of human tissue from bodies

- 28 Who may consent to collection, use, and secondary use for general purposes** 5
- For collection or use of human tissue from a body for a purpose or secondary purpose that is not anatomical examination, public display, or both, the informed consent required is informed consent given—
- (a) by the individual from whose body the tissue concerned is collected, before his or her death; or 10
 - (b) if no consent can be given under **paragraph (a)**, by that individual's nominee or nominees, in accordance with **section 32**; or
 - (c) if no consent can be given under **paragraphs (a) and (b)**, by that individual's immediate family, in accordance with **section 33**; or 15
 - (d) if no consent can be given under **paragraphs (a) and (b)** and if that individual's immediate family declines to give consent, by a senior available next of kin of that individual, in accordance with **section 34**. 20
- Compare: Human Tissue Act 1983 (New South Wales) s 23; Human Tissue Act 2004 (UK) ss 2, 3, 54(9); Transplantation and Anatomy Act 1978 (Australian Capital Territory) ss 27, 28
- 29 Who may consent to collection, use, and secondary use for anatomical examination, public display, or both** 25
- For collection or use of human tissue from a body for a purpose or secondary purpose that is anatomical examination, public display, or both, the informed consent required is informed consent given both— 30
- (a) by the individual from whose body the tissue concerned is collected, before his or her death or, if no consent of that kind can be given, by that individual's nominee or nominees, in accordance with **section 32**; and
 - (b) by that individual's immediate family, in accordance with **section 33** or, if that immediate family declines to 35

Struck out (unanimous)

give consent, by a senior available next of kin of that individual, in accordance with **section 34**.

Compare: Human Tissue Act 1983 (New South Wales) s 23; Human Tissue Act 2004 (UK) ss 2, 3, 54(9); Transplantation and Anatomy Act 1978 (Australian Capital Territory) ss 27, 28

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Person entitled to give consent for donor analysis of non-consumer human tissue, etc

30 Individual concerned may consent

- (1) For collection of non-consumer human tissue for donor analysis, carrying out of donor analysis of non-consumer human tissue, or both, the informed consent required is informed consent given by the individual from whom the tissue concerned was collected or derived.
- (2) His or her death does not affect the validity of the consent.

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Persons entitled to give consent for secondary use after donor's death of tissue from living individual

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31 Who may consent to secondary use

For use for a secondary purpose, after the donor's death, of human tissue from a living individual, the informed consent required is informed consent given—

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- (a) by that individual's immediate family, in accordance with **section 33**; or
- (b) if that individual's immediate family declines to give consent, by a senior available next of kin of that individual, in accordance with **section 34**.

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Giving or making, and recording, of consents, nominations, etc

32 Making of nominations, and consent by nominees

- (1) An individual may for the purposes of **section 28(b) or 29(a)** nominate a person as the nominee, or as one of the nominees, who may (alone or with others), on that individual's behalf, after his or her death, and in accordance with this Act, give consent to collection and use of human tissue from that individual's body.

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Struck out (unanimous)

- (2) A nomination of 2 or more nominees, or that results in 2 or more nominees, must be treated as requiring consent from all nominees unless the nomination clearly authorises some only of those nominees to give, independently from the other or the rest of them, consent on behalf of the individual concerned. 5
- (3) A nomination must be disregarded for the purposes of this Act if no one is able to give consent under it.
- (4) A nominee must be treated as declining to give consent if it is not practicable, within the time available before any consent given must be acted on, to ascertain whether he or she gives that consent. 10

Compare: Human Tissue Act 2004 (UK) ss 3(4), (6), (7)

33 Consent by immediate family

- (1) The immediate family of a dead individual must be treated for the purposes of this Act as declining to give informed consent to collection and use of human tissue collected from that individual while living or from his or her body unless a majority of members of that immediate family agrees with that collection and use. 15
- (2) A majority of members of that immediate family must be treated for the purposes of this Act as agreeing with that collection and use if a member of that immediate family— 20
- (a) has taken all reasonably practicable steps to consult, with a view to achieving general agreement on the matter, members of that immediate family who represent all of the different interests (if any) of that immediate family; and 25
- (b) as a result of taking those steps, believes on reasonable grounds that, if all members of that immediate family were consulted personally, a majority of members of that immediate family would agree with, and give their informed consent to, that collection and use; and therefore 30
- (c) gives informed consent of that kind on behalf of that immediate family in the form required by **section 38**. 35

Struck out (unanimous)

- 34 Consent by senior available next of kin**
- (1) If the immediate family of an individual, after his or her death and the expiry of a period within which it is reasonable for that consent to be given in accordance with **section 33**, declines to give consent to collection and use of human tissue collected from that individual while living or from his or her body, a senior available next of kin of the individual may, on that individual's behalf, and in accordance with this Act, give consent of that kind. 5
- (2) A **senior available next of kin** of a dead individual means a person specified in— 10
- (a) **Part 1 of Schedule 2**, if the individual was 16 years old or older when he or she died; and
- (b) **Part 2 of Schedule 2**, if the individual was under 16 years of age when he or she died. 15
- 35 Amendment or revocation of consent, nomination, etc**
- Consent or a nomination given or made for the purposes of this Act may be amended, revoked, or revoked and replaced in the same way as it may be given or made.
- 36 Consent, nomination, etc, on behalf of another** 20
- (1) This section applies to an individual who is, or who would be if he or she were capable, recognised by this Act as a (or the) person who is entitled to give consent to collection and use of certain human tissue.
- (2) Consent for the purposes of this Act in respect of an individual to whom this section applies may be given, amended, or revoked by any person who is, under the general law, entitled to consent on that individual's behalf. 25
- (3) A nomination in respect of an individual may be made, amended, or revoked by any person who is, under the general law, entitled to consent on that individual's behalf. 30
- 37 Capacity to give or make consent, nomination, etc**
- (1) An individual who is not capable (as defined in **section 5**) cannot give, make, amend, or revoke consent or a nomination for the purposes of this Act. 35

Struck out (unanimous)

- (2) An individual who is under 16 years of age—
- (a) may, subject to **subsection (1)**, give consent for collection of non-consumer human tissue for donor analysis, carrying out of donor analysis of non-consumer human tissue, or both; but 5
 - (b) cannot give, make, amend, or revoke any other consent or a nomination for the purposes of this Act.
- Compare: 1988 No 4 s 5; SR 1996/78 r 2, Schedule, right 7(2)
- 38 Form of consent, nomination, etc** 10
- Consent under this Act, an amendment or revocation of consent under this Act, a nomination, or an amendment or revocation of a nomination must be given or made either—
- (a) in writing (with or without witnesses); or
 - (b) orally and in the presence of 2 or more witnesses present at the same time. 15
- 39 Written consent, etc, may be in will**
- (1) The writing referred to in **section 38(a)** may be contained in a person's will if the relevant consent or nomination, or amendment or revocation of a consent or nomination, relates to tissue that is, or is from, that person's body. 20
 - (2) For the purposes of this section, **will** has the same meaning as in, and it does not matter whether a will complies with section 9 of, the Wills Act 1837 (7 Will 4 and I Vict, c 26).
- Compare: Human Tissue Act 2004 (UK) s 3(5)(c)
- 40 Written consent on behalf of immediate family may include details of consultation within that family** 25
- Consent given in writing, under **section 38(a)**, may, if it is consent by a member of an immediate family on behalf of that family under **section 33(2)(c)**, include details of the steps taken to consult required by **section 33(2)(a)**, or the grounds for the belief required by **section 33(2)(b)**, or both. 30

Struck out (unanimous)

- 41 Consents, nominations, etc, may be recorded in national organ and tissue donor register**
 Nothing in this Act prevents a consent, nomination, amendment, or revocation given or made in accordance with **section 38**, or other donor information, from being recorded in the national organ and tissue donor register. 5
- Ascertaining whether appropriate consent exists and may be acted on*
- 42 Person proposing to collect or use tissue must ascertain whether appropriate consent exists and may be acted on** 10
- (1) A person who proposes to collect or use human tissue must, before collecting or using the tissue, take all reasonably practicable steps to ascertain—
- (a) what consent (if any) is required by this Act for the proposed collection or use of that tissue; and 15
- (b) whether any appropriate consent (as defined in **section 7**) exists and may be acted on.
- (2) If the tissue proposed to be collected or used is tissue from a body, the steps required by **subsection (1)** include, if and so far as they are reasonably practicable,— 20
- (a) consulting the responsible person; and
- (b) ascertaining whether appropriate consent is recorded in the national organ and tissue donor register.
- (3) If consulted under **subsection (2)(a)**, the responsible person must take all reasonably practicable steps to help a person who proposes to collect or use human tissue to comply with **subsection (1)**. 25
- 43 Persons 16 years old or older presumed to be capable**
 An individual who is 16 years old or older must be presumed to be capable (as defined in **section 5**) of giving, making, amending, or revoking consent or a nomination for the purposes of this Act, unless there are reasonable grounds for believing otherwise. 30

Compare: 1988 No 4 s 5; SR 1996/78 r 2, Schedule, right 7(2)

Struck out (unanimous)

44	Consent given presumed to be free and informed	
(1)	This section applies to consent given by an individual (a decision-maker) that this Act recognises as a (or the) individual who is entitled to consent to a kind of collection or use of human tissue.	5
(2)	The consent is presumed, in the absence of evidence to the contrary, to have been given by the decision-maker freely, and after he or she has received all information that a reasonable person, in the decision-maker's circumstances, needs in order to give informed consent.	10
45	Authority to act on appropriate consent	
(1)	Appropriate consent (as defined in section 7) given other than under section 33 or 34 may be acted on with no further authority than this subsection.	
(2)	In particular, appropriate consent (as so defined) given by an individual, nominee, or nominees, in accordance with section 28(a) or (b) , is valid, and may be acted on, even if it is disagreed with by the responsible person, or all or any members of that individual's immediate family, or both.	15
(3)	Appropriate consent (as so defined) given under section 33 or 34 may be acted on with no further authority than this subsection only if the following requirements (if applicable) have been satisfied:	20
(a)	the requirement to comply with section 46 before acting on consent given under section 33 on behalf of the immediate family:	25
(b)	the requirement to comply with section 47 before acting on consent given under section 34 by a senior available next of kin.	
46	Restriction on acting on consent given under section 33 on behalf of immediate family	30
	A person must not act on a consent (to collection and use of tissue from the individual's body) given by a member of the immediate family of a dead individual in accordance with section 33(2)(c) unless, after all reasonably practicable inquiries	35

Struck out (unanimous)

in relation to the individual have been made, it appears to the person that—

- (a) the member has taken the steps to consult required by **section 33(2)(a)**; and
- (b) the member has formed the belief, and that belief is based on the reasonable grounds, required by **section 33(2)(b)**.

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47 Restriction on acting on consent given under section 34 by senior available next of kin

- (1) A person must not act on a consent (to collection and use of tissue from the individual's body) given by a senior available next of kin of a dead individual in accordance with **section 34** unless, after all reasonably practicable inquiries in relation to the individual have been made, it appears to the person that there is no overriding objection.
- (2) An **overriding objection** is an objection, to that collection or use of the tissue, made by a person of the same class as, or of a higher order of class than, the class in **Part 1 or Part 2 of Schedule 2** of the senior available next of kin.
- (3) This section does not limit the duties under **section 42** of a person who proposes to collect or use human tissue.

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Subpart 6—Requirements, etc, for collection and use of all human tissue

*Collection and use of tissue for non-therapeutic purposes***48 Standards for collection and use of human tissue for non-therapeutic purposes**

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- (1) A person collecting or using human tissue for non-therapeutic purposes must comply with all relevant quality, safety, and other standards prescribed or approved by regulations under **section 76**.
- (2) This section applies even if the collection or use of the tissue is required, permitted, or otherwise controlled by law.

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Struck out (unanimous)*Post-mortems*

- 49 Post-mortems must be performed by, or in accordance with instructions of, medical practitioners**
- (1) Every post-mortem must be performed by, or in accordance with the instructions of, a medical practitioner. 5
- (2) A medical practitioner does not contravene **subsection (1)** merely by acting under a direction or order of—
- (a) a coroner acting under section 7 of the Coroners Act 1988; or
- (b) the High Court acting under section 39 of the Coroners Act 1988; or 10
- (c) the Director-General of Health acting under section 78 of the Health Act 1956.

Compare: 1964 No 19 s 4(2)

Collection of tissue from bodies for use for therapeutic purposes or for medical education or research 15

- 50 Collection only by qualified person after examination**
- (1) A person who is not a qualified person must not collect human tissue from a body for use for therapeutic purposes or for medical education or research. 20
- (2) A qualified person must not collect human tissue from a body for use for all or any of those purposes unless satisfied, by personal examination of the body, that life is extinct.
- (3) **Qualified person**, in relation to the collection of human tissue from a body for use for therapeutic purposes or for medical education or research, means a person who is 1 or more of the following: 25
- (a) a person who is, or is acting under the supervision of, a medical practitioner collecting the tissue for the purposes of the practice of his or her profession: 30
- (b) a person authorised in writing by or on behalf of the New Zealand Blood Service, the New Zealand National Eye Bank, or a body that is a successor to that Service or Bank, as suitably qualified to collect tissue of that kind for the purposes of that Service, Bank, or successor body: 35

Struck out (unanimous)

- (c) a person who the Director-General has, by notice in the *Gazette*, authorised as suitably qualified to collect tissue of that kind for 1 or more specified purposes.

Compare: 1964 No 19 s 3(4)

Anatomical examinations

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51 Anatomical examinations must usually be performed at schools of anatomy

- (1) A person must not perform an anatomical examination, or receive, possess, store, or otherwise use a body for anatomical examination, at a place that is not a school of anatomy.

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- (2) This section is subject to **section 52**.

Compare: 1964 No 19 s 7(2)

52 Anatomical examinations outside schools of anatomy

- (1) All or a part of a body may be removed by or on behalf of a person to a place outside a school of anatomy for the purpose of practising anatomy, and the body or part may be received, possessed, stored, and otherwise used at that place for that purpose by or on behalf of the person—

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- (a) is authorised by a school of anatomy to practise anatomy at that school; and

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- (b) has an inspector's written permission, and written permission from the school's head, to do so; and

- (c) takes all reasonable steps to ensure compliance with all terms and conditions (if any) that the inspector, and the school's head, thought fit to impose in giving their written permission for that purpose.

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- (2) **Practise anatomy** means to teach the science of anatomy by performing an anatomical examination.

Compare: 1964 No 19 s 7(3)

Decency to be observed, etc

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53 Duties of those performing post-mortems or anatomical examinations, or collecting tissue from bodies

A person who performs a post-mortem or anatomical examination, or collects tissue from a body, under this Act, must—

Struck out (unanimous)

- (a) do so in a manner that avoids unnecessary mutilation of the body that is being examined, or from which the collection is being effected; and
- (b) conduct the examination or collection in an orderly, quiet, and decent manner.

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Compare: 1964 No 19 s 11

*Trading in blood, controlled human substances, or other human tissue***54 Interpretation**In **sections 55 to 62**, unless the context otherwise requires,— 10**appointed entity** means an entity appointed under **section 60****blood** means human blood; and—

- (a) includes the following:
 - (i) a substance derived from blood:
 - (ii) a human organ, or human bone marrow, or human tissue, including the placenta, of a kind that is suitable as a source from which to derive a constituent of blood that may be used therapeutically or in the preparation of a substance for therapeutic use: 15
 - (iii) a constituent of an organ, bone marrow, or tissue described in **subparagraph (ii)**: 20
 - (iv) human haematopoietic stem cells, or a constituent of human haematopoietic stem cells, that may be used therapeutically or in the preparation of a substance for therapeutic use; but 25
- (b) does not include the following:
 - (i) any substance derived from blood, a human organ, human bone marrow, human tissue, or human haematopoietic stem cells that is intended for use in quality control or as a diagnostic product: 30
 - (ii) any substance containing a fraction of blood, a human organ, human bone marrow, human tissue, or human haematopoietic stem cells that the Governor-General by Order in Council declares not to be blood for the purposes of **sections 55 to 62** 35

Struck out (unanimous)**controlled human substance—**

- (a) means—
- (i) human bone marrow (other than human bone marrow referred to in **paragraph (a)(ii)** of the definition of the term “blood” in this section) that may be used therapeutically or in the preparation of a substance for therapeutic use; or 5
 - (ii) a constituent of human bone marrow described in **subparagraph (i)**; or
 - (iii) any other substance of the human body that may be used therapeutically or in the preparation of a substance for therapeutic use and that the Governor-General by Order in Council declares to be included in this definition; but 10
- (b) does not include— 15
- (i) a product derived from any controlled human substance that is intended for use in quality control or as a diagnostic product; or
 - (ii) a substance containing a fraction of any controlled human substance that the Governor-General by Order in Council declares not to be a controlled human substance for the purposes of **sections 55 to 62**. 20

Compare: 1956 No 65 s 92A

55 Trading in human tissue generally prohibited 25

- (1) No person may, except under an exemption under **section 58**, require or accept financial or other consideration for—
- (a) human tissue (for example, blood, or a controlled human substance) of that person; or
 - (b) human tissue from a body in relation to which that person is the responsible person. 30
- (2) No person may, except under an exemption under **section 58**, provide financial or other consideration for collection or use of—
- (a) human tissue of that person; or 35
 - (b) human tissue from a body in relation to which that person is the responsible person.

Compare: 1956 No 65 s 92B(1), (2)

Struck out (unanimous)**56 Collection of blood or controlled human substance**

- (1) No person may collect blood or any controlled human substance from a person, or from the body of a person, for the purpose of obtaining that blood or that substance for administration to another person. 5
- (2) **Subsection (1)** does not apply to—
- (a) an appointed entity that is authorised to collect blood and controlled human substances from persons; or
 - (b) an employee or agent of an appointed entity who is authorised by the entity to collect blood or controlled human substances on behalf of the entity, if the entity has the power to authorise employees or agents to do so. 10
- (3) For the purposes of **subsection (2)**, an appointed entity is authorised to collect blood and controlled human substances, and has the power to authorise employees and agents of the entity to do so, unless the notice by which the entity is appointed provides otherwise. 15
- (4) Every appointed entity described in **subsection (2)(a)** and every employee or agent described in **subsection (2)(b)** who collects blood or any controlled human substance must give due recognition to the fact that the blood or controlled human substance has been donated. 20
- (5) Every appointed entity described in **subsection (2)(a)** who collects blood or any controlled human substance may require or accept in respect of that blood or that substance financial consideration whose value does not exceed the reasonable costs to the entity of all or any of collecting, analysing, and processing that blood or that substance. 25
- (6) Those costs may include transport costs, compliance or regulatory costs, and other administration costs. 30
- (7) **Subsection (5)** is subject to **section 57**.

Compare: 1956 No 65 s 92C(1), (3)–(5)

57 Charging for administered blood or controlled human substance

A person (**A**) who administers blood or any controlled human substance to another person (**B**) must not, except under an exemption under **section 58**, require or accept financial or other 35

Struck out (unanimous)

consideration from or on behalf of B for that blood or that substance.

Compare: 1956 No 65 s 92D(1)

58 Exemptions

- (1) The Minister may, in his or her discretion, on any terms and conditions he or she thinks fit, and by notice in writing, exempt a person or persons or a class of persons from compliance with any or all of the provisions of— 5
- (a) **section 55** (trading in human tissue generally prohibited): 10
- (b) **section 57** (charging for administered blood or controlled human substance).
- (2) The Minister may in the same manner vary or revoke an exemption of that kind.
- (3) After giving a notice under this section, the Minister must— 15
- (a) publish a copy in the *Gazette* as soon as practicable; and
- (b) present a copy to the House of Representatives no later than its 16th sitting day after the day on which the notice was given.

Compare: 1956 No 65 s 92E

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59 Advertising prohibited

- (1) No person may distribute an advertisement relating to the purchase or sale in New Zealand of human tissue (for example, of blood or a controlled human substance).
- (2) For the purposes of **subsection (1)**, **distribute** means— 25
- (a) to publish or otherwise disseminate, by newspaper, magazine, periodical, book, billboard, radio, television, cinematograph film, or any other means whatever (for example, by the Internet); or
- (b) to exhibit to public view in any premises or place; or 30
- (c) to deposit in any area, yard, garden, or enclosure comprising part of or appurtenant to any premises.

Compare: 1956 No 65 s 92F(1), (2)

Struck out (unanimous)

- 60 Appointed entities to collect and distribute blood and controlled human substances**
- (1) The Minister may from time to time, by notice in writing, appoint 1 or more entities to be responsible for the performance of any functions in relation to blood and controlled human substances specified in the notice. 5
- (2) An appointment under **subsection (1)** may be subject to terms and conditions specified in the notice appointing the appointee.
- (3) The Minister may from time to time, by notice in writing, revoke, vary, or add to any of the following: 10
- (a) the functions for which an appointee is responsible:
- (b) the terms or conditions of the appointment.
- (4) The Minister may, at any time, by notice in writing, revoke an appointment under **subsection (1)**. 15
- (5) A notice given under this section takes effect on the date specified for the purpose in the notice or, if no date is specified for that purpose, on the day after the date on which it is issued.
- (6) An appointed entity that performs, in accordance with a notice given under this section, a function in relation to blood or a controlled human substance, is entitled to do anything, or refrain from doing anything, that is necessary or desirable for the purpose of performing that function, unless a notice given under this section provides otherwise. 20
- (7) After giving a notice under any of **subsections (1), (3)(a), or (4)**, the Minister must, as soon as practicable, publish in the *Gazette*, and present to the House of Representatives, a copy of that notice. 25
- Compare: 1956 No 65 s 92H
- 61 Exemption from Part 2 of Commerce Act 1986** 30
- Nothing in Part 2 of the Commerce Act 1986 applies to—
- (a) a contract, arrangement, understanding, or covenant in relation to blood or controlled human substances that—
- (i) at the time it is entered into is, or is of a class that is, approved for the purposes of this section by the Governor-General by Order in Council; or 35

Struck out (unanimous)

- (ii) is entered into by a person who (at the time it is entered into) is, or is of a class that is, approved for the purposes of this section by the Governor-General by Order in Council; or
- (b) an act done to give effect to a provision of a contract, arrangement, understanding, or covenant to which **paragraph (a)** applies. 5

Compare: 1956 No 65 s 92I

62 Protection of appointed entities

- (1) Section 129 of the Health Act 1956 applies to any appointed entity, and to any employee or agent of an appointed entity, who, in pursuance or intended pursuance of a provision in a notice given under **section 60** (appointed entities to collect and distribute blood and controlled human substances), does an act, or fails or refuses to do an act, in relation to blood or a controlled human substance. 10
15
- (2) For the purpose of applying section 129 of the Health Act 1956 in accordance with **subsection (1)**, a provision in a notice given under **section 60** (appointed entities to collect and distribute blood and controlled human substances) must be treated as a provision of the Health Act 1956. 20

Compare: 1956 No 65 s 92J

Exportation and importation of human tissue

- 63 Standards, etc, for export and import of human tissue**
A person exporting or importing human tissue must comply with all relevant requirements and quality, safety, and other standards prescribed or approved by regulations under **section 77**. 25

New (unanimous)

Subpart 1—Requirements for informed consent for
certain kinds of collection or use of human tissue

Preliminary provisions on collection or use of tissue

- 10 Duty of person proposing to collect or use tissue**
- (1) A person who proposes to collect or use human tissue must, before collecting or using the tissue, take all reasonably practicable steps to ascertain—
- (a) what informed consent (if any) is required by this Act for the proposed collection or use of that tissue; and
 - (b) whether informed consent required by this Act for that collection or use of the tissue has been given; and
 - (c) if informed consent of that kind has been given, whether it is overridden by an overriding objection to that collection or use of the tissue.
- (2) If the tissue proposed to be collected or used is tissue that is, or is collected from, a body, the steps required by **subsection (1)** include, if and so far as they are reasonably practicable,—
- (a) consulting the responsible person; and
 - (b) ascertaining whether the national organ and tissue donor register includes any relevant informed consent or informed objection.
- 10A Responsible person must help if consulted**
The responsible person must, if consulted under **section 10(2)(a)** by a person who proposes to collect or use human tissue, take all reasonably practicable steps to help that person to comply with **section 10(1)**.
- 10B Act does not require collection or use**
Nothing in this Act requires any person to collect or use human tissue.
-

New (unanimous)**10C Person justified in deciding not to collect or use tissue**

A person who proposes to collect or use human tissue is justified in deciding not to do so if satisfied, based on all information available to the person in the circumstances, that any informed consent for the collection or use of that tissue should for any reason not be acted on.

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New (majority)**10D Person collecting or using tissue must take into account cultural and spiritual needs, values, and beliefs**

A person collecting or using human tissue must take into account, so far as they are known to the person based on information available to the person in the circumstances, the cultural and spiritual needs, values, and beliefs of the immediate family of the individual whose tissue is collected.

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New (unanimous)*When informed consent required and not required***11 Collection or use for which informed consent required**

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(1) The following, if done, must be done with informed consent:

- (a) collection or use of human tissue that is, or is collected from, a body:
- (b) collection of non-health-care tissue for donor analysis:
- (c) donor analysis of non-health-care tissue:
- (d) use for a secondary purpose, after the donor's death, of human tissue collected from a living individual.

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(2) **Subsection (1)** does not apply to collection or use—

- (a) for a purpose specified in **section 12**; or
- (b) for a purpose that is an offence against, or prohibited by, any law (other than **sections 20, 24, and 26**).

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(3) An example of collection or use of the kind referred to in **subsection (2)(b)** is any collection or use that is an improper or indecent interference with, or offering of an indignity to, any dead human body or human remains, whether buried or not, contrary to section 150(b) of the Crimes Act 1961.

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New (unanimous)

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|-----------|--|----|
| 12 | Informed consent not required for collection or use for specified purposes | |
| | Informed consent is not required for collection or use of human tissue for any of the following purposes: | |
| | (a) the exercise by a person of that person's powers under any law to collect or use tissue without consent, including (without limitation) powers of that kind exercised for either of the following purposes: | 5 |
| | (i) the maintenance of the law, including the prevention, detection, investigation, prosecution, or punishment of offences; or | 10 |
| | (ii) the protection of the health or safety of members of the public: | |
| | (b) the implementation, by using non-health-care tissue for donor analysis, of a direction or order of a court or tribunal: | 15 |
| | (c) the provision, for the medical benefit of another person or a child conceived but not born, and by using non-health-care tissue for donor analysis, of information about the individual from whom the non-health-care tissue was collected or derived, if— | 20 |
| | (i) it is not reasonably practicable to find that individual or, if he or she has died, a personal representative or family member of that individual; and | 25 |
| | (ii) all reasonable efforts have been made to ascertain whether that individual objected to the tissue being used for those purposes, and he or she appears not to have done so: | |
| | (d) the performance of a post-mortem of a body that one of the following competent legal authorities has, under one of the following enactments, directed or ordered to be performed: | 30 |
| | (i) a coroner acting under section 31 of the Coroners Act 2006; and | 35 |
| | (ii) the High Court acting under section 41 of the Coroners Act 2006; and | |
| | (iii) the Director-General of Health acting under section 78 of the Health Act 1956: | |

New (unanimous)

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|-----|--|----|
| (e) | the carrying out, by using for a secondary purpose tissue that is a body or is collected from a living individual or a body, or by using non-health-care tissue for donor analysis, of research that has received the approval of an ethics committee (even though the ethics committee knew that informed consent had not been, and would not be, obtained for the research): | 5 |
| (f) | the carrying out, to assure or improve the quality of services, and by using for a secondary purpose tissue that is a body or is collected from a living individual or a body, or by using non-health-care tissue for donor analysis, of all or any of the following activities: | 10 |
| | (i) a professionally recognised quality assurance programme: | |
| | (ii) an external audit of services: | 15 |
| | (iii) an external evaluation of services: | |
| (g) | the testing or disposal of tissue that is a body or is collected from a living individual or a body, because— | |
| | (i) that testing or disposal is or may be necessary to avoid endangering the health or safety of members of the public; or | 20 |
| | (ii) that disposal is necessary or desirable because all reasonable attempts have been made, but have failed, to return the tissue to a family member or other person to whom the tissue would otherwise be returned for disposal: | 25 |
| (h) | display by or on behalf of the responsible person and to enable people to pay their final respects to, or that is incidental to the funeral of, the dead individual: | |
| (i) | burial, cremation, or other lawful disposal, by or on behalf of the responsible person, of the tissue concerned. | 30 |

How subpart relates to other laws, etc

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|-----------|--|----|
| 13 | Other laws, and lawfulness of use, etc, not affected | 35 |
| | Nothing in this subpart— | |
| | (a) limits or affects any provision of subpart 6 or Part 3 , or any other enactment or other law (including, without | |

New (unanimous)

	limitation, the Code) permitting, requiring, or controlling collection or use of human tissue; or	
	(b) makes unlawful collection or use of human tissue for a particular purpose if collection or use of tissue for that purpose is lawful apart from this subpart; or	5
	(c) makes lawful collection or use of human tissue for a particular purpose if collection or use of tissue for that purpose is unlawful apart from this subpart.	
	Compare: 1964 No 19 ss 3(3), (7), 7(2)	
	Subpart 2—Offences relating to informed consent	10
	<i>Tissue that is, or is collected from, bodies</i>	
20	Collection or use without informed consent	
(1)	A person commits an offence, and is liable on summary conviction to the penalty specified in subsection (2) , if—	
	(a) the person collects or uses human tissue that is, or is collected from, a body; and	15
	(b) informed consent is required by subpart 1 for that collection or use, and either was not given or was given but was overridden by an overriding objection.	
(2)	The penalty referred to in subsection (1) is,—	20
	(a) if that collection or use is for a secondary purpose, imprisonment for a term not exceeding 3 months or a fine not exceeding \$20,000; and	
	(b) in every other case, imprisonment for a term not exceeding 1 year or a fine not exceeding \$50,000.	25
	<i>Non-health-care tissue</i>	
24	Donor analysis, etc, without informed consent	
	A person commits an offence, and is liable on summary conviction to imprisonment for a term not exceeding 1 year or a fine not exceeding \$50,000, if—	30
	(a) the person collects non-health-care tissue for donor analysis or carries out donor analysis of non-health-care tissue; and	
	(b) informed consent is required by subpart 1 for that collection or use, but was not given.	35

New (unanimous)*Tissue from living individuals*

- 26 Use for secondary purpose after donors' deaths without informed consent** 5
- A person commits an offence, and is liable on summary conviction to imprisonment for a term not exceeding 3 months or a fine not exceeding \$20,000, if—
- (a) the person uses for a secondary purpose, after the donor's death, human tissue from a living individual; and
 - (b) informed consent is required by **subpart 1** for that use, and either was not given or was given but was overridden by an overriding objection. 10

Affirmative defence and assumptions

- 27 Affirmative defence for informed consent offences** 15
- It is a defence in a prosecution for an offence against **section 20, 24, or 26** if the defendant proves, on the balance of probabilities, that he, she, or it believed on reasonable grounds that—
- (a) informed consent was not required by **subpart 1** for the collection or, as the case may be, the use of the tissue; or 20
 - (b) informed consent was required by **subpart 1** for the collection or, as the case may be, the use of the tissue, and was given and was not overridden by an overriding objection.

- 27A Person 16 years old or older assumed to be capable** 25
- A person who proposes to collect or use human tissue is, unless that person is aware of evidence to the contrary, entitled to assume that a person who is 16 years old or older is capable.

Compare: 1988 No 4 s 5; SR 1996/78 r 2, Schedule, right 7(2) 30

- 27B Consent or objection assumed to be free and informed** 35
- A person who proposes to collect or use human tissue is, unless that person is aware of evidence to the contrary, entitled to assume that consent or an objection given or raised by a person has been given or raised by that person freely, and in

New (unanimous)

the light of all information that a reasonable person, in that person's circumstances, needed in order to give informed consent or to raise an informed objection or overriding objection.

- 27C Person assumed to have taken into account immediate family's cultural and spiritual needs, values, and beliefs** 5
 A person who proposes to collect or use human tissue is, unless that person is aware of evidence to the contrary, entitled to assume that a person giving informed consent or raising an informed objection or overriding objection has complied with **section 37A**. 10
- 27D When consent or objection on behalf of immediate family may be assumed to comply with section 33**
 A person who proposes to collect or use human tissue is entitled to assume that informed consent given, or an informed objection raised, to the collection or use, by a member of an immediate family, and on its behalf, has been given or raised in accordance with **section 33** only if the person is satisfied, based on all information available to the person in the circumstances, that— 15
- (a) the member has taken the steps to consult required by **section 33(a)**; and
 - (b) the member has formed the belief, and that belief is based on the reasonable grounds, required by **section 33(c)**. 20 25
- 27E Death does not affect consent, objection, or nomination**
 The death of a person does not affect the validity of any informed consent given, informed objection or overriding objection raised, or nomination made, by that person.

New (unanimous)

Subpart 3—Who is entitled to give informed consent

Tissue that is, or is collected from, bodies

- 28 Who is entitled to give informed consent to collection or use for general purposes**
- (1) This section applies to informed consent to collection or use, for any purpose that is not anatomical examination, public display, or both, of human tissue that is, or is collected from, a body. 5
- (2) Informed consent to which this section applies may only be given by the following people in the following circumstances: 10
- (a) the individual whose body is the tissue, or from whose body the tissue concerned is collected, and before his or her death:
- (b) that individual's nominee or nominees, on behalf of that individual and after his or her death, if— 15
- (i) no consent has been given under **paragraph (a)**; and
- (ii) no informed objection has been raised by that individual:
- (c) a member of that individual's immediate family and on its behalf after that individual's death, if— 20
- (i) no consent has been given under **paragraph (b)**; and
- (ii) no informed objection has been raised by that individual's nominee or nominees:
- (d) a close available relative of that individual after his or her death, if— 25
- (i) no consent has been given under **paragraph (c)**; and
- (ii) no informed objection has been raised on behalf of that individual's immediate family.
- Compare: Human Tissue Act 1983 s 23 (NSW); Human Tissue Act 2004 ss 2, 3, 54(9) (UK); Transplantation and Anatomy Act 1978 ss 27, 28 (ACT) 30
- 29 Who is entitled to give informed consent to collection or use for anatomical examination or public display**
- (1) This section applies to informed consent to collection or use for anatomical examination, public display, or both, of human tissue that is, or is collected from, a body. 35
- (2) Informed consent to which this section applies—
- (a) may only be given under **subsections (3) and (4)**; and

New (unanimous)

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| (b) | is, if given under 1 of those subsections, invalid unless consent has also been given under the other. | |
| (3) | Informed consent to which this section applies may be given by the following people in the following circumstances: | |
| (a) | the individual whose body is the tissue, or from whose body the tissue concerned is collected, and before his or her death: | 5 |
| (b) | that individual's nominee or nominees on behalf of that individual and after his or her death, if— | |
| (i) | no consent has been given under paragraph (a) ; and | 10 |
| (ii) | no informed objection has been raised by that individual. | |
| (4) | Informed consent to which this section applies may be given by the following people in the following circumstances: | |
| (a) | a member of the immediate family of the individual referred to in subsection (3)(a) and on its behalf after that individual's death, if no informed objection has been raised by that individual: | 15 |
| (b) | a close available relative of that individual after his or her death, if— | 20 |
| (i) | no informed consent has been given by that immediate family; and | |
| (ii) | no informed objection has been raised by that immediate family. | |
| | Compare: Human Tissue Act 1983 s 23 (NSW); Human Tissue Act 2004 ss 2, 3, 54(9) (UK); Transplantation and Anatomy Act 1978 ss 27, 28 (ACT) | 25 |

Non-health-care tissue

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| 30 | Who is entitled to give informed consent to collection or use for donor analysis | |
| (1) | This section applies to informed consent to collection of non-health-care tissue for donor analysis, carrying out of donor analysis of non-health-care tissue, or both. | 30 |
| (2) | Informed consent to which this section applies may only be given by the individual from whom the tissue concerned was collected or derived. | 35 |
| (3) | This section does not limit section 31 . | |

New (unanimous)*Tissue from living individuals*

- 31 Who is entitled to give informed consent to use for secondary purpose after donor's death**
- (1) This section applies to informed consent to use for a secondary purpose, after the donor's death, of human tissue from a living individual. 5
- (2) Informed consent to which this section applies may only be given by the following people in the following circumstances:
- (a) a member of the immediate family of the individual referred to in **subsection (1)** and on its behalf after that individual's death, if no informed objection has been raised by that individual: 10
- (b) a close available relative of that individual after his or her death, if—
- (i) no informed consent has been given under **paragraph (a)**; and 15
- (ii) no informed objection has been raised on behalf of that individual's immediate family.

When consent or objection treated as not given or raised for purposes of this subpart 20

- 31A Nominees do not exist or are not available, or it is not practicable to ascertain whether decision made**
- Informed consent or an informed objection must, for the purposes of **sections 28 and 29**, be treated as not having been given or raised by nominees of the individual if the person who proposes to collect or use the tissue is satisfied, based on all information available to that person in the circumstances, that— 25
- (a) there are no nominees of the individual, or no nominees of the individual will be available before the latest time that the tissue can be collected or used; or 30
- (b) it is not practicable, before the latest time that the tissue can be collected or used, to ascertain whether the nominee or nominees of the individual have given informed consent or raised an informed objection to the collection or use proposed. 35

Compare: Human Tissue Act 2004 ss 3(7), (8) (UK)

New (unanimous)

31B Immediate family is not available, or it is not practicable to ascertain whether decision made

Informed consent or an informed objection must, for the purposes of **sections 28, 29, and 31**, be treated as not having been given or raised on behalf of the immediate family of the individual if the person who proposes to collect or use the tissue is satisfied, based on all information available to that person in the circumstances, that—

- (a) members of that immediate family who represent some of the different interests of that immediate family will not be available before the latest time that the tissue can be collected or used; or 10
- (b) it is not practicable, before the latest time that the tissue can be collected or used, to ascertain whether informed consent or an informed objection has been given or raised, on behalf of that immediate family, to the collection or use proposed. 15

Compare: Human Tissue Act 2004 ss 3(7), (8) (UK)

*Capacity and consent or objections on behalf of another***31C Capacity to give or make or raise, etc, consent, objection, or nomination, etc** 20

- (1) An individual who is not capable cannot give, make, raise, amend, revoke, revoke and replace, or accept or disagree with informed consent, an informed objection, an overriding objection, or a nomination. 25
- (2) An individual who is under 16 years of age—
 - (a) may, if capable, give, amend, revoke, or revoke and replace informed consent for collection of non-health-care tissue for donor analysis, carrying out of donor analysis of non-health-care tissue, or both; but 30
 - (b) cannot give, make, raise, amend, revoke, revoke and replace, or accept or disagree with any other kind of informed consent, or an informed objection, an overriding objection, or a nomination. 35

Compare: 1988 No 4 s 5; SR 1996/78 r 2, Schedule, right 7(2)

New (unanimous)

31D	Consent or objection given or raised or made, etc, on behalf of another	
(1)	This section applies to an individual who is entitled under section 28, 29, 30, or 31 to give informed consent, or to raise an informed objection or overriding objection, to collection or use of certain human tissue.	5
(2)	Informed consent or an informed objection or overriding objection in respect of an individual to whom this section applies may, whether or not that individual is capable, be given or raised, amended, revoked, or revoked and replaced by any person who is, under a law other than this Act, entitled to give consent on that individual's behalf.	10
(3)	Persons who may be authorised, under a law other than this Act, to give consent on that individual's behalf include—	
	(a) a parent or legal guardian of that individual; and	15
	(b) a welfare guardian of that individual appointed under the Protection of Personal and Property Rights Act 1988; and	
	(c) an attorney appointed by that individual under a power of attorney described in section 95 of the Protection of Personal and Property Rights Act 1988.	20
	Subpart 4—Further provisions on consent or objections by, or on behalf of, nominees, immediate family, and close available relatives	
32	Nominations and consent or objections by nominees	25
(1)	An individual may, for the purposes of this Act, nominate 1 or more nominees if the individual is, under section 28(2)(a) or 29(3)(a) , entitled to give informed consent, or to raise an informed objection, to collection or use of human tissue that is, or is from, his or her body.	30
(2)	A nomination in respect of an individual to whom subsection (1) applies may, whether or not that individual is capable, be made, amended, revoked, or revoked and replaced by any person who is, under a law other than this Act, entitled to give consent on that individual's behalf.	35

New (unanimous)

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| (2A) Section 31D(3) gives examples of persons who may be authorised, under a law other than this Act, to give consent on that individual's behalf. | |
| (3) A nomination must be made with the nominee's written consent, and can be ended at any time by the nominee giving written notice to that effect to the individual. | 5 |
| (4) A nomination of 2 or more nominees, or that results in 2 or more nominees, must, unless the nomination provides otherwise, be treated as requiring— | |
| (a) any informed consent to be given by all of the 2 or more nominees who are available and willing to decide whether to give informed consent; and | 10 |
| (b) any informed objection to be raised by any or all of the 2 or more nominees who are available and willing to decide whether to raise an informed objection. | 15 |
| 33 Consent or objection on behalf of immediate family | |
| A member of an individual's immediate family may only give informed consent, or raise an informed objection, under sub-part 3 , to collection or use of tissue if that member— | |
| (a) takes all reasonably practicable steps to consult members of that immediate family who represent all of the different interests (if any) of that immediate family; and | 20 |
| (b) takes those steps with a view to achieving general agreement on the matter; and | |
| (c) after taking those steps, believes on reasonable grounds that all capable members of that immediate family accept, or would, if consulted personally, accept, that member's giving informed consent or raising an informed objection to that collection or use on behalf of that immediate family. | 25
30 |
| 34 Close available relative may raise overriding objection | |
| (1) This section applies if a close available relative has given informed consent to— | |
| (a) any collection or use of tissue that is, or is from, the body of a dead individual; or | 35 |

New (unanimous)

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| <p>(b) any use for a secondary purpose of tissue that is from a living individual.</p> <p>(2) An objection to that collection or use, or to that use for a secondary purpose, of that tissue, may be raised by a person referred to in the paragraph of section 7A(1) or (2) that refers to the close available relative.</p> <p>(3) For the purposes of sections 10, 20, 26, and 27, an objection raised under this section overrides the informed consent given by the close available relative.</p> | <p>5</p> <p>5</p> |
| <p>Subpart 5—Process for, and form, amendment, and recording of, consent, objections, and nominations</p> | |
| <p>37A Duty to take into account immediate family’s cultural and spiritual needs, values, and beliefs</p> | |
| <p>A person giving informed consent or raising an informed objection or overriding objection must take into account, so far as they are known to the person based on information available to the person in the circumstances, and decide what weight the person wishes to give to, the cultural and spiritual needs, values, and beliefs of the immediate family of the individual whose tissue is, or is not, to be collected.</p> | <p>15</p> <p>20</p> |
| <p>38 Form of consent, objection, or nomination</p> | |
| <p>(1) Any informed consent, informed objection, overriding objection or nomination given or raised or made for the purposes of this Act must be given or raised or made either—</p> <p>(a) in writing (with or without witnesses); or</p> <p>(b) orally and in the presence of 2 or more witnesses present at the same time.</p> <p>(2) Without limiting subsection (1), any informed consent, informed objection, or nomination may be contained in a person’s will if that consent, objection, or nomination relates to tissue that is, or is from, the person’s body.</p> <p>(3) For the purposes of this section,—</p> <p>(a) will has the same meaning as in the Wills Act 2007; and</p> | <p>25</p> <p>30</p> |

New (unanimous)

- (b) it does not matter whether a will is valid (as defined in section 7 of that Act).

Compare: Human Tissue Act 2004 s 3(5)(c) (UK)

- 40 Written consent or objection on behalf of immediate family may include details of consultation, etc** 5
- Informed consent or an informed objection given or raised in writing, in accordance with **section 38(1)(a)**, and given or raised by a member, and on behalf, of the immediate family of a dead individual, under **section 33**, may include details of either or both of the following: 10
- (a) the steps taken to consult required by **section 33(a)**;
 (b) the grounds for the belief required by **section 33(c)**.
- 40A Amendment, etc, of consent, objection, or nomination**
- (1) Informed consent or an informed objection, overriding objection, or nomination given, raised, or made under this Act may be amended, revoked, or revoked and replaced in the same way as it may be given, raised, or made. 15
- (2) Informed consent given by an individual to collection or use of tissue must be treated as revoked if that individual, without revoking the informed consent, later raises an informed objection to that collection or use. 20
- 41 Consent, objections, nominations, etc, may be recorded in national organ and tissue donor register**
- (1) Nothing in this Act prevents informed consent or an informed objection or nomination (whether or not it is given, raised, or made in the form required by **section 38**) from being recorded in the national organ and tissue donor register. 25
- (2) Informed consent or an informed objection or nomination is not in any way invalid or without effect just because it is not recorded in the national organ and tissue donor register. 30

New (unanimous)

Subpart 6—Other requirements for and restrictions on collection or use of human tissue

Collection or use of tissue for non-therapeutic purposes

- 48 Standards for collection or use of human tissue for non-therapeutic purposes** 5
- (1) A person collecting or using human tissue for non-therapeutic purposes must comply with all relevant quality, safety, and other standards prescribed or approved by regulations under **section 76**.
- (2) This section applies even if the collection or use of the tissue is required, permitted, or otherwise controlled by law. 10
- (3) A person commits an offence, and is liable on summary conviction to imprisonment for a term not exceeding 3 months or a fine not exceeding \$20,000, if— 15
- (a) the person intentionally or knowingly collects or uses human tissue for a purpose (whether or not the person knows the purpose is a non-therapeutic purpose); and
- (b) that act or omission contravenes **subsection (1)**.

Post-mortems, official inquiries, etc

- 48A Restriction on collecting or using tissue if official post-mortem or inquiry directed or opened** 20
- (1) This section applies to a person and a body if the person proposes to collect or use tissue that is, or is from, the body, and the person believes on reasonable grounds— 25
- (a) that a coroner has directed a pathologist to perform a post-mortem of the body, opened an inquiry into the death concerned, or both, or may do either or both; or
- (b) that another competent legal authority specified in **section 12(d)** has directed or ordered a post-mortem of a body, or may do so; or 30
- (c) that both **paragraphs (a) and (b)** apply.
- (2) The person may collect or use, in accordance with any informed consent required by this Act, tissue that is, or is from, the body, only with the approval of the coroner or other competent legal authority concerned. 35

New (unanimous)

- (3) A person commits an offence, and is liable on summary conviction to imprisonment for a term not exceeding 3 months or a fine not exceeding \$20,000, if—
- (a) the person intentionally or knowingly collects or uses tissue (whether or not the person knows the tissue is, or is from, a body to which this section applies); and 5
 - (b) that act contravenes **subsection (2)**.

Compare: 1964 No 19 s 3(5)

49 Post-mortems must be performed by, or in accordance with instructions of, medical practitioners 10

- (1) Every post-mortem must be performed by, or in accordance with the instructions of, a medical practitioner.
- (2) A medical practitioner does not contravene **subsection (1)** merely by acting under a direction or order of—
- (a) a coroner acting under section 31 of the Coroners Act 2006; or 15
 - (b) the High Court acting under section 41 of the Coroners Act 2006; or
 - (c) the Director-General of Health acting under section 78 of the Health Act 1956. 20

- (3) A person commits an offence, and is liable on summary conviction to imprisonment for a term not exceeding 3 months or a fine not exceeding \$20,000, if—
- (a) the person intentionally or knowingly does an act; and
 - (b) that act contravenes **subsection (1)**. 25

Compare: 1964 No 19 ss 4(2), 12(a)

Collection of tissue from bodies for therapeutic purposes, health practitioner education, or research

- 50 Collection only by qualified person after examination**
- (1) A person who is not a qualified person must not collect human tissue that is, or is collected from, a body if that tissue is collected for use for therapeutic purposes or for health practitioner education or any kind of research. 30
- (2) A qualified person must not collect human tissue that is, or is collected from, a body if that tissue is collected for use for all 35

New (unanimous)

or any of those purposes unless the qualified person is satisfied, by personal examination of the body, that the individual concerned is dead.

- (3) **Qualified person**, in relation to the collection of human tissue that is, or is collected from, a body if that tissue is collected for use for therapeutic purposes or for health practitioner education or any kind of research, means a person who is 1 or more of the following: 5
- (a) a person who is, or is acting under the supervision of, a medical practitioner collecting the tissue for the purposes of the practice of his or her profession: 10
- (b) a person authorised in writing by or on behalf of the New Zealand Blood Service, the New Zealand National Eye Bank, or a body that is a successor to that Service or Bank, as suitably qualified to collect tissue of that kind for the purposes of that Service, Bank, or successor body: 15
- (c) a person who the Director-General has, by notice in the *Gazette*, authorised as suitably qualified to collect tissue of that kind for 1 or more specified purposes. 20
- (4) A person commits an offence, and is liable on summary conviction to imprisonment for a term not exceeding 1 year or a fine not exceeding \$50,000, if—
- (a) the person intentionally or knowingly collects human tissue that the person knows is tissue that is, or is collected from, a body (whether or not the person knows that the tissue is collected for all or any of the purposes specified in **subsection (1)**); and 25
- (b) that act contravenes **subsection (1) or (2)**. 30
- Compare: 1964 No 19 s 3(4) 30

*Anatomical examinations and public display***51A Anatomical examination and certain public display of body of person under 16 years prohibited**

- (1) No person may collect or use for anatomical examination, public display, or both, tissue that is, or is collected from, the body of an individual who, at the time he or she died, was under 16 years of age. 35

New (unanimous)

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| (2) | A person commits an offence, and is liable on summary conviction to imprisonment for a term not exceeding 1 year or a fine not exceeding \$50,000, if— | |
| | (a) the person intentionally or knowingly does an act; and | |
| | (b) that act contravenes subsection (1) . | 5 |
| (3) | Subsection (1) does not apply to public display by or on behalf of the responsible person and to enable people to pay their final respects to, or that is incidental to the funeral of, the dead individual. | |
| 51 | Anatomical examinations must usually be performed at schools of anatomy | 10 |
| (1) | A person must not, unless authorised by section 52 to do so, perform an anatomical examination, or receive, possess, store, or otherwise use all or a part of a body for anatomical examination, at a place that is not a school of anatomy. | 15 |
| (2) | A person commits an offence, and is liable on summary conviction to imprisonment for a term not exceeding 3 months or a fine not exceeding \$20,000, if— | |
| | (a) the person intentionally or knowingly does an act; and | |
| | (b) that act contravenes subsection (1) . | 20 |
| | Compare: 1964 No 19 ss 7(2), 12(b), (c) | |
| 52 | Anatomical examinations outside schools of anatomy | |
| (1) | All or a part of a body may be removed by or on behalf of a person to a place outside a school of anatomy for the purpose of practising anatomy, and the body or part may be received, possessed, stored, and otherwise used at that place for that purpose by or on behalf of the person, if the person— | 25 |
| | (a) is authorised by a school of anatomy to practise anatomy at that school; and | |
| | (b) has written permission from the school's head to do so; and | 30 |
| | (c) takes all reasonable steps to ensure compliance with all terms and conditions (if any) that the school's head thought fit to impose in giving his or her written permission for that purpose. | 35 |

New (unanimous)

- (2) **Practise anatomy** means to teach the science of anatomy by performing an anatomical examination.

Compare: 1964 No 19 s 7(3)

Decency to be observed, etc

- 53 Duty of those performing post-mortems or anatomical examinations, or collecting tissue from bodies** 5

A person who performs a post-mortem or anatomical examination, or collects tissue that is, or is collected from, a body, under this Act, must—

- (a) do so in a manner that avoids unnecessary mutilation of the body that is being collected and examined, or from which the collection is being effected; and 10
- (b) conduct the examination or collection in an orderly, quiet, and decent manner.

Compare: 1964 No 19 s 11

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Trading in blood, controlled human substances, or other human tissue

- 54 Interpretation**

In **sections 56 to 62**, unless the context otherwise requires,—

appointed entity means an entity appointed under **section 60** 20

blood means human blood; and—

- (a) includes the following:
- (i) a substance derived from blood:
- (ii) a human organ, or human bone marrow, or human tissue, including the placenta, of a kind that is suitable as a source from which to derive a constituent of blood that may be used therapeutically or in the preparation of a substance for therapeutic use: 25
- (iii) a constituent of an organ, bone marrow, or tissue described in **subparagraph (ii)**: 30
- (iv) human haematopoietic stem cells, or a constituent of human haematopoietic stem cells, that may be used therapeutically or in the preparation of a substance for therapeutic use: 35

New (unanimous)

- (b) does not include the following:
- (i) any substance derived from blood, a human organ, human bone marrow, human tissue, or human haematopoietic stem cells that is intended for use in quality control or as a diagnostic product: 5
 - (ii) any substance containing a fraction of blood, a human organ, human bone marrow, human tissue, or human haematopoietic stem cells that the Governor-General by Order in Council declares not to be blood for the purposes of **sections 56 to 62** 10

controlled human substance—

- (a) means—
- (i) human bone marrow (other than human bone marrow referred to in **paragraph (a)(ii)** of the definition of blood in this section) that may be used therapeutically or in the preparation of a substance for therapeutic use; or 15
 - (ii) a constituent of human bone marrow described in **subparagraph (i)**; or 20
 - (iii) any other substance of the human body that may be used therapeutically or in the preparation of a substance for therapeutic use and that the Governor-General by Order in Council declares to be included in this definition; but 25
- (b) does not include—
- (i) a product derived from any controlled human substance that is intended for use in quality control or as a diagnostic product; or
 - (ii) a substance containing a fraction of any controlled human substance that the Governor-General by Order in Council declares not to be a controlled human substance for the purposes of **sections 56 to 62.** 30

Compare: 1956 No 65 s 92A 35

New (unanimous)

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| 55 | Trading in human tissue generally prohibited | |
| (1) | No person may, except under an exemption under section 58 , require or accept, or offer or provide, financial or other consideration for human tissue. | |
| (2) | A person commits an offence, and is liable on summary conviction to imprisonment for a term not exceeding 1 year or a fine not exceeding \$50,000, if— | 5 |
| | (a) the person intentionally or knowingly does an act; and | |
| | (b) that act contravenes subsection (1) . | |
| (2A) | Subsection (1) does not apply to the following: | 10 |
| | (a) a product derived from human tissue and intended for use in research, in quality control, or as a diagnostic product: | |
| | (b) processed human tissue samples (for example, tissue arrays) intended for use in research, in quality control, or as a diagnostic product: | 15 |
| | (c) human hair collected from living people and that is, is part of, or is for use in, wigs or other hair-pieces: | |
| | (d) human tissue that is, or is part of, a controlled drug or a medicine (other than a medicine that is a blood clotting factor, blood corpuscles, or whole blood). | 20 |
| (3) | Consideration for human tissue in subsection (1) does not include consideration for the collection or use of the tissue. | |
| (4) | Consideration referred to in subsection (3) may be required or accepted, or offered or provided, from or by 1 or more persons, or on 1 or more occasions, or both. | 25 |
| (5) | Use , in this section, includes import and export. | |
| (6) | This section does not limit or affect section 57 . | |
| | Compare: 1956 No 65 s 92B | |
| 56 | Collection of blood or controlled human substance | 30 |
| (1) | No person may collect blood or any controlled human substance from a person, or from the body of a person, for the purpose of obtaining that blood or that substance for administration to another person. | |

New (unanimous)

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|------------|--|----|
| (1A) | A person commits an offence, and is liable on summary conviction to imprisonment for a term not exceeding 6 months or a fine not exceeding \$20,000, if— | |
| | (a) the person intentionally or knowingly does an act; and | |
| | (b) that act contravenes subsection (1) . | 5 |
| (2) | Subsection (1) does not apply to— | |
| | (a) an appointed entity that is authorised to collect blood and controlled human substances from persons or bodies or both; or | |
| | (b) an employee or agent of an appointed entity who is authorised by the entity to collect blood or controlled human substances on behalf of the entity, if the entity has the power to authorise employees or agents to do so. | 10 |
| (3) | For the purposes of subsection (2) , an appointed entity is authorised to collect blood and controlled human substances, and has the power to authorise employees and agents of the entity to do so, unless the notice by which the entity is appointed provides otherwise. | 15 |
| (4) | Every appointed entity described in subsection (2)(a) and every employee or agent described in subsection (2)(b) who collects blood or any controlled human substance must give due recognition to the fact that the blood or controlled human substance has been donated. | 20 |
| | Compare: 1956 No 65 s 92C | |
| 56A | Consideration not generally to be provided for collection of blood or controlled human substance for administration to another person | 25 |
| (1) | No person may, except under an exemption under section 58 , provide financial or other consideration for the collection of blood or a controlled human substance from a person, or from the body of a person, for administration to another person. | 30 |
| (2) | A person commits an offence, and is liable on summary conviction to imprisonment for a term not exceeding 1 year or a fine not exceeding \$50,000, if— | |
| | (a) the person intentionally or knowingly does an act; and | |
| | (b) that act contravenes subsection (1) . | 35 |

New (unanimous)

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|-----------|---|----|
| (3) | Subsection (1) does not prevent a person who collects blood or a controlled human substance from providing to, or for the benefit of, the person from whom the blood or controlled human substance is collected consideration that is reasonably related to, or that does not exceed, the actual and reasonable costs incurred by that person in connection with its collection. | 5 |
| | Compare: 1956 No 65 s 92B(2) | |
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 | | |
| 57 | Person administering blood or controlled human substance not to charge recipient for its collection or use | |
| (1) | No person who administers blood or any controlled human substance to another person may, except under an exemption under section 58 , require or accept from the person to whom that blood or that substance is administered financial or other consideration for collecting or using it. | 10 |
| (2) | A person commits an offence, and is liable on summary conviction to imprisonment for a term not exceeding 1 year or a fine not exceeding \$50,000, if— | 15 |
| | (a) the person intentionally or knowingly does an act; and | |
| | (b) that act contravenes subsection (1) . | |
| (3) | This section does not limit or affect section 55 . | 20 |
| | Compare: 1956 No 65 s 92D | |
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 | | |
| 58 | Exemptions | |
| (1) | The Minister may, in his or her discretion, on any terms and conditions he or she thinks fit, and by notice in writing, exempt a person or persons or a class of persons from compliance with any or all of the provisions of— | 25 |
| | (a) section 55 (trading in human tissue generally prohibited): | |
| | (ab) section 56A (consideration not generally to be provided for collection of blood or controlled human substance for administration to another person): | 30 |
| | (b) section 57 (person administering blood or controlled human substance not to charge recipient for its collection or use): | |
| | (c) section 59 (advertising prohibited). | 35 |

New (unanimous)

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|------|--|----|
| (2) | The Minister may in the same manner vary or revoke an exemption under subsection (1) . | |
| (3) | After giving a notice under this section, the Minister must— | |
| | (a) publish a copy in the <i>Gazette</i> as soon as practicable; and | |
| | (b) present a copy to the House of Representatives no later than its 16th sitting day after the day on which the notice was given. | 5 |
| | Compare: 1956 No 65 s 92E | |
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 | | |
| | 59 Advertising prohibited | |
| (1) | No person may, except under an exemption under section 58 , distribute an advertisement relating to the purchase or sale in New Zealand of human tissue. | 10 |
| (2) | A person commits an offence, and is liable on summary conviction to imprisonment for a term not exceeding 3 months or a fine not exceeding \$20,000, if— | 15 |
| | (a) the person intentionally or knowingly does an act; and | |
| | (b) that act contravenes subsection (1) . | |
| (3) | Subsection (1) does not apply to distribution of an advertisement relating to the purchase or sale in New Zealand of the following: | 20 |
| | (a) a product derived from human tissue and intended for use in research, in quality control, or as a diagnostic product: | |
| | (b) processed human tissue samples (for example, tissue arrays) intended for use in research, in quality control, or as a diagnostic product: | 25 |
| | (c) human hair collected from living people and that is, is part of, or is for use in, wigs or other hair-pieces: | |
| | (d) human tissue that is, or is part of, a controlled drug or a medicine (other than a medicine that is a blood clotting factor, blood corpuscles, or whole blood). | 30 |
| (4) | Distribute , for the purposes of this section, means— | |
| | (a) to publish or otherwise disseminate, by newspaper, magazine, periodical, book, billboard, radio, television, cinematograph film, or any other means (for example, by the Internet); or | 35 |
| | (b) to exhibit to public view in any premises or place; or | |

New (unanimous)

- (c) to deposit in any area, yard, garden, or enclosure comprising part of or appurtenant to any premises.

Compare: 1956 No 65 s 92F

59A Liability of employers, principals, and directors

- (1) This section applies to an offence against **section 55(2), 56(1A), 56A(2), 57(2), or 59(2)** and involving a contravention of **section 55(1), 56(1), 56A(1), 57(1), or 59(1)** (which relate to unlawful or prohibited trading in, or actions involving, human tissue, blood, and controlled human substances). 5
- (2) An act done by a person as the employee (the **employee**) of another person (the **employer**) is, for the purposes of an offence to which this section applies, to be treated as done by the employer as well as by the employee, if— 10
- (a) the employer approved of the act; or
- (b) the employer knew that the act was to be done or was being done and failed to take all reasonable steps to prevent it. 15
- (3) An act done by a person as the agent (the **agent**) of another person (the **principal**) is, for the purposes of an offence to which this section applies, to be treated as done by the principal as well as by the agent, if— 20
- (a) the principal approved of the act; or
- (b) the principal knew that the act was to be done or was being done and failed to take all reasonable steps to prevent it. 25
- (4) If a body corporate is convicted of an offence to which this section applies, a director of the body corporate is to be treated as having committed the same offence, if— 30
- (a) the director approved of the act that constituted the offence; or
- (b) the director knew the offence was to be or was being committed and failed to take all reasonable steps to prevent it.
- (5) **Director**, in **subsection (4)**, includes a person who is concerned in the management of a body corporate. 35

Compare: 1956 No 65 s 92G

New (unanimous)

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|-----------|--|----|
| 60 | Appointed entities to collect and distribute blood and controlled human substances | |
| (1) | The Minister may from time to time, by notice in writing, appoint 1 or more entities to be responsible for the performance of any functions in relation to blood and controlled human substances specified in the notice. | 5 |
| (2) | An appointment under subsection (1) may be subject to terms and conditions specified in the notice appointing the appointee. | |
| (3) | The Minister may from time to time, by notice in writing, revoke, vary, or add to any of the following: | 10 |
| | (a) the functions for which an appointee is responsible: | |
| | (b) the terms or conditions of the appointment. | |
| (4) | The Minister may, at any time, by notice in writing, revoke an appointment under subsection (1) . | 15 |
| (5) | A notice given under this section takes effect on the date specified for the purpose in the notice, or, if no date is so specified, on the day after the date on which it is issued. | |
| (6) | An appointed entity that performs, in accordance with a notice given under this section, a function in relation to blood or a controlled human substance, is entitled to do anything, or refrain from doing anything, that is necessary or desirable for the purpose of performing that function, unless a notice given under this section provides otherwise. | 20 |
| (7) | After giving a notice under subsection (1), (3), or (4) , the Minister must, as soon as practicable, publish in the <i>Gazette</i> , and present to the House of Representatives, a copy of that notice. | 25 |
| | Compare: 1956 No 65 s 92H | |
| 61 | Exemption from Part 2 of Commerce Act 1986 | |
| | Nothing in Part 2 of the Commerce Act 1986 applies to— | 30 |
| | (a) a contract, arrangement, understanding, or covenant in relation to blood or controlled human substances that— | |
| | (i) at the time it is entered into is, or is of a class that is, approved for the purposes of this section by the Governor-General by Order in Council; or | 35 |
| | (ii) is entered into by a person who (at the time it is entered into) is, or is of a class that is, approved | |

New (unanimous)

for the purposes of this section by the Governor-General by Order in Council; or

- (b) an act done to give effect to a provision of a contract, arrangement, understanding, or covenant to which **paragraph (a)** applies.

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Compare: 1956 No 65 s 92I

62 Protection of appointed entities

- (1) Section 129 of the Health Act 1956 applies to any appointed entity, and to any employee or agent of an appointed entity, who, in pursuance or intended pursuance of a provision in a notice given under **section 60** of this Act (which relates to entities to collect and distribute blood and controlled human substances), does an act, or fails or refuses to do an act, in relation to blood or a controlled human substance.

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- (2) For the purpose of applying section 129 of the Health Act 1956 in accordance with **subsection (1)**, a provision in a notice given under **section 60** of this Act must be treated as a provision of the Health Act 1956.

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Compare: 1956 No 65 s 92J

Exportation and importation of human tissue

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63 Standards, etc, for export and import of human tissue

- (1) A person exporting or importing human tissue must comply with all relevant requirements and quality, safety, and other standards prescribed or approved by regulations under **section 77**.

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- (2) This section applies even if the exportation or importation of the tissue is required, permitted, or otherwise controlled by law.

- (3) A person commits an offence, and is liable on summary conviction to imprisonment for a term not exceeding 3 months or a fine not exceeding \$20,000, if—

30

- (a) the person intentionally or knowingly does, or omits to do, an act; and
- (b) that act or omission contravenes **subsection (1)**.

Compare: 2004 No 92 s 9(2)(a), (5)

35

Part 3

Technical and miscellaneous provisions

Enforcement provisions

- 64 Matters to be ascertained by authorised persons** 5
- An authorised person who believes on reasonable grounds that there is a place (the **place**) in which human tissue is collected or used may, at any reasonable time, exercise any of the powers in **section 65** reasonably necessary to ascertain whether—
- (a) collection or use of human tissue at the place involves a contravention of a section of this Act; or 10
 - (b) there is located at the place any thing that is or may be evidence of a contravention of that kind.
- Compare: 2004 No 92 s 67
- 65 Powers of authorised persons** 15
- (1) The powers referred to in **section 64**, in relation to any place, are the powers to—
- (a) enter the place:
 - (b) inspect—
 - (i) any equipment or device believed on reasonable grounds to be used in the place in relation to collection or use of human tissue: 20
 - (ii) any document or record (whether in electronic or other form) in the place and that is believed on reasonable grounds to relate to any collection or use of human tissue: 25
 - (c) take or make copies of, or copies of extracts from, any document or record inspected and, for that purpose,—
 - (i) take possession of and remove the document or record from the place for any reasonable period: 30
 - (ii) in the case of a document or information stored otherwise than on paper, take any reasonable steps to reproduce, in usable form, any or all of the information in it:
 - (d) search for and seize— 35
 - (i) any equipment or device referred to in **paragraph (b)(i)**:
 - (ii) any human tissue:
 - (iii) any document or record (whether in electronic or other form) in the place and that is believed on 40

reasonable grounds to relate to any collection or use of human tissue:

- (e) use any force for gaining entry to the place and for breaking open any article or thing that is in the place, being force that is reasonable in the circumstances and applied in a manner that is calculated to avoid adverse effects on any human tissue: 5
- (f) take photographs, and make drawings, or other representations, of any item that may be seized under **paragraph (d)**: 10
- (g) mark or identify, by any appropriate means, any item that may be seized under **paragraph (d)**:
- (h) require any person appearing to be in charge of the place concerned (or any part of it) to ensure that any item that may be seized under **paragraph (d)** is not removed or interfered with. 15

Struck out (unanimous)

- (i) require any person appearing to be in charge of the place concerned (or any part of it) to answer any question the authorised person may reasonably ask for the purpose of exercising the powers of the authorised person. 20
- (2) An authorised person who enters a place under this section must produce evidence of his or her authorisation—
 - (a) on first entering the place:
 - (b) whenever subsequently reasonably required to do so by a person appearing to be in charge of the place or any part of the place. 25
- (3) An authorised person who enters a place under this section may be accompanied by any number of persons (including any member of the police) reasonably necessary to assist him or her with the exercise of his or her powers under this section. 30
- (4) A person who accompanies an authorised person under **subsection (3)** may, under the direction of the authorised person, exercise each of the powers described in **subsection (1)(a) to (g)**.

Struck out (unanimous)

- (5) This section does not limit the privilege against self-incrimination.

Compare: 2004 No 92 s 68

66 Entry of dwellinghouses and marae

- (1) An authorised person must not enter a dwellinghouse or marae under **section 65(1)(a)**, except— 5
- (a) with the consent of an occupier of the dwellinghouse or marae; or
- (b) with the authority of a search warrant issued under **subsection (2)**. 10
- (2) A District Court Judge, a Community Magistrate, a Justice, or a (*Court*) Registrar who is not a member of the police may, on a written application made on oath by an authorised person, issue a search warrant in the form set out in **Schedule 3** in respect of a dwellinghouse or marae if satisfied that there are reasonable grounds to believe that in that house or marae— 15
- (a) an offence against this Act has been or is being committed; or
- (b) there is any thing that is or may be evidence of the commission of an offence against this Act. 20
- (3) The search warrant authorises the authorised person to whom it is directed to exercise in respect of the dwellinghouse or marae all or any of the powers described in **section 65**, and the provisions of that section apply to the execution of the warrant. 25
- (4) The Judge, Community Magistrate, Justice, or (*Court*) Registrar may issue the warrant unconditionally or subject to any conditions that he or she thinks fit.
- (5) The authorised person to whom the search warrant is directed may execute it on 1 occasion on, or within 14 days after, the date of its issue. 30

Compare: 2004 No 92 s 69

67 Identification of authorised person

- (1) An authorised person exercising powers under **section 65** in respect of any place,— 35

- (a) if a person appearing to be in charge of the place is present on first entering the place, must identify himself or herself to that person; and
 - (b) if (*asked*) reasonably required by the person appearing to be in charge of the place or any part of the place to do so, must produce evidence of his or her identity and evidence of his or her appointment as an authorised person. 5
- (2) If the authorised person executes a search warrant issued under **section 66**, the authorised person must produce the warrant,— 10
- (a) on first entering the place specified in the warrant, to the person appearing to be in charge of the place; and
 - (b) whenever (*subsequently*) later reasonably required to do so by any person appearing to be in charge of the place or any part of that place. 15

Compare: 2004 No 92 s 70

68 Notice requirements when place entered

- (1) If the occupier of the place is not present when an authorised person enters a place under **section 65(1)(a)**, the authorised person must leave in a prominent location at the place a written statement of the time and date of the entry, the name of the person, and the address of the office of the Ministry of Health to which inquiries should be made. 20
- (2) If anything is seized under **section 65(1)(d)**, the authorised person concerned must leave in a prominent location at the place, or deliver or send to the occupier within 10 working days after the search, a written inventory of all things seized. 25

Compare: 2004 No 92 s 71

69 Disposal of property seized 30

Section 199 of the Summary Proceedings Act 1957 applies to any property seized by an authorised person under **section 65(1)(d)**, subject to the following provisions:

- (a) an item seized by an authorised person may be retained by the authorised person or by or on behalf of the Commissioner of Police pending the trial of the person for the offence in respect of which the item was seized; and 35

- (b) any item retained under **paragraph (a)** that is any kind of human tissue must receive the expert treatment that is required to preserve it; and
- (c) the item in question must be returned to the person from whom it was seized,— 5
- (i) if no proceedings are taken in respect of an offence to which the item relates, within 6 months after its seizure; or
- (ii) if proceedings are completed in respect of the offence and no order of forfeiture is made in respect of the item; and 10
- (d) if any person is convicted of an offence to which the item relates, the Court may, if it thinks fit, order that the item be forfeited to the Crown or disposed of as the Court directs at the expense of the convicted person, and may order that the person pay any reasonable costs incurred by the authorised person or the Commissioner of Police in retaining the item. 15

Compare: 2004 No 92 s 72

(Offences and penalties) 20

Struck out (unanimous)

70 Contravening sections specified in Schedule 4

Every person who, with the mental element (if any) required, does an act that contravenes a section specified in column 1 of the table in **Schedule 4** commits an offence and is liable to 1, but not both, of the following: 25

- (a) imprisonment for a term not exceeding the period specified opposite to that section in column 3 of that table:
- (b) a fine not exceeding the amount so specified.

Compare: 1956 No 65 ss 92B(3), (4), 92C(2), 92D(2), 92F(3), 137; 1964 No 19 s 12; 2004 No 92 ss 9(5), 75 30

71 Mental element required for offences against section 70

- (1) For an offence against **section 70** involving a contravention of **section 20, 22, 24, or 26**, no mental element is required, so in proceedings for the offence the prosecution must prove only that the defendant did the act. 35

Struck out (unanimous)

- (2) For an offence against **section 70** involving a contravention of a section other than **section 20, 22, 24, or 26**, the mental element required is intention or knowledge, so in proceedings for the offence the prosecution must prove that the defendant did the act intentionally or knowingly. 5
- (3) **Subsection (2)** does not require the prosecution to prove that the defendant intended to contravene, or knowingly contravened, the section other than **section 20, 22, 24, or 26**.
- 72 Defence for certain offences against section 70** 10
It is a defence in a prosecution for an offence against **section 70** involving a contravention of **section 20, 22, 24, or 26** if the defendant proves that he, she, or it believed on reasonable grounds that appropriate consent (as defined in **section 7**) had been given for the relevant collection and use of the tissue.
- 73 Liability of employers, principals, and directors for certain offences** 15
- (1) This section applies to an offence against **section 70** involving a contravention of any of **sections 55, 56(1), 57, and 59(1)** (which relate to unlawful or prohibited trading in, or actions involving, human tissue, blood, and controlled human substances). 20
- (2) An act done by a person as the employee (the **employee**) of another person (the **employer**) is for the purposes of an offence to which this section applies to be treated as done by the employer as well as by the employee, if— 25
- (a) the employer approved of the act; or
- (b) the employer knew that the act was to be done or was being done and failed to take all reasonable steps to prevent it.
- (3) An act done by a person as the agent (the **agent**) of another person (the **principal**) is for the purposes of an offence to which this section applies to be treated as done by the principal as well as by the agent, if— 30
- (a) the principal approved of the act; or
- (b) the principal knew that the act was to be done or was being done and failed to take all reasonable steps to prevent it. 35

Struck out (unanimous)

- (4) If a body corporate is convicted of an offence to which this section applies, a director of the body corporate is to be treated as having committed the same offence, if—
- (a) the director approved of the act that constituted the offence; or 5
 - (b) the director knew the offence was to be or was being committed and failed to take all reasonable steps to prevent it.
- (5) In **subsection (4), director** includes a person who is concerned in the management of a body corporate. 10
- Compare: 1956 No 65 s 92G

- 74 Obstructing inspections, etc, by authorised persons**
- Every person commits an offence, and is liable on summary conviction to imprisonment for a term not exceeding 3 months, or a fine not exceeding \$20,000, who intentionally does all or any of the following: 15
- (a) obstructs, hinders, or resists an authorised person, or any person lawfully assisting an authorised person, in the exercise of the authorised person's powers under this Act: 20
 - (b) refuses or fails to comply with any lawful requirements of an authorised person under this Act.

Compare: 2004 No 90 s 79; 2004 No 92 s 75

Struck out (unanimous)

- 75 Offences punishable on summary conviction**
- Every offence against a section of this Act is punishable on summary conviction. 25
- Compare: 1956 No 65 s 137; 2004 No 92 s 9(5)

Regulations and Orders in Council

- 76 Regulations prescribing or approving quality, safety, and other standards for collection (and) or use of human tissue for non-therapeutic purposes** 30
- (1) The Governor-General may, by Order in Council, make regulations prescribing or approving standards for collection or

use of human tissue for education, research, or other non-therapeutic purposes.

- (2) The standards may be to ensure minimum levels of quality, safety, or both, or may be for other purposes.
- (3) The standards must include requirements for ethical approval of all research using human tissue. 5

New (unanimous)

- (4) The requirements for ethical approval must not be inconsistent with requirements under the Human Assisted Reproductive Technology Act 2004 for ethical approval for human reproductive research. 10
- (5) However, the standards or the regulations may identify research, or classes or kinds of research, using human tissue to which some or all of the requirements for ethical approval do not apply, or apply subject to conditions or modifications.

77 Regulations prescribing or approving requirements and quality, safety, and other standards for export and import of human tissue 15

- (1) The Governor-General may, by Order in Council, make regulations for either or both of the following purposes:
 - (a) prescribing requirements for exportation of human tissue, importation of human tissue, or both: 20
 - (b) prescribing or approving standards for exportation of human tissue, importation of human tissue, or both.
- (2) Requirements prescribed for importation of human tissue may relate to informed consent having been given and, if so, they may differ from similar requirements in this Act. 25
- (3) The standards may be to ensure minimum levels of quality, safety, or both, or may be for other purposes.
- (4) **Subsections (2) and (3) do not limit subsection (1).**

78 Regulations may incorporate standards by reference 30
Regulations under **section 76 or 77** may incorporate standards by reference, in accordance with **Schedule 5**.

79 Orders authorising establishment of schools of anatomy

The Governor-General may, by Order in Council, authorise the establishment of a school of anatomy where the study and practice of the science of anatomy may be carried on—

- (a) in connection with a university, or a school of medicine, specified in the order; and 5
- (b) at the place or places, and on the conditions (if any), specified in the order.

Compare: 1964 No 19 s 7(1)

New (unanimous)**79A Regulations establishing or recognising national organ and tissue donor register** 10

- (1) The Governor-General may, by Order in Council, make regulations establishing or recognising a register, maintained in any medium by or on behalf of the Crown and called the national organ and tissue donor register, for recording information that is or includes the following: 15
 - (a) informed consent, informed objections, or nominations given, raised, or made for the purposes of this Act; and
 - (b) amendments to, or revocations of, informed consent, informed objections, or nominations given, raised, or made for those purposes; and 20
 - (c) other donor information.
- (2) The regulations may require the register to be maintained by or on behalf of the Crown in 1 or more specified media (whether or not it is maintained in other media). 25
- (3) The regulations may also require the register to be capable of, and to be maintained for, recording 1 or more specified classes, descriptions, or kinds of other donor information.
- (4) The regulations do not affect the application of the Privacy Act 1993 to the collection, use, and disclosure of personal information by and for the purposes of the register. 30
- (5) In particular, the regulations cannot authorise or require the recording in the register of personal information—
 - (a) without authorisation or consent from the individual concerned; and 35

New (unanimous)

- (b) until he or she cancels, or otherwise opts out of, the recording in the register of that information.
- (6) **Subsection (5)** does not limit **subsection (4)**.

Inspectors of schools of anatomy

- 80 Appointment** 5
- (1) The Director-General may from time to time appoint 1 or more persons as an inspector or inspectors of a school of anatomy.
- (2) The persons must be either—
- (a) members of the police appointed with the concurrence of the Commissioner of Police; or 10
- (b) persons who are not members of the police but are persons who wish to be appointed, and who the Director-General considers are suitable for appointment, as inspectors of the school of anatomy. 15
- Compare: 1964 No 19 s 8(1)
- 81 Term of office**
- An inspector continues in office until some other person is appointed in his or her place, unless the inspector ceases to hold that office earlier because he or she— 20
- (a) resigns from it with the consent of the Director-General; or
- (b) was appointed to it under **section 80(1) and (2)(a)** and ceases to be a member of the police; or
- (c) dies; or 25
- (d) is removed from it under **section 82**.
- Compare: 1964 No 19 s 8(2)
- 82 Removal of inspectors who are not members of police**
- (1) If satisfied that 1 or more of the grounds for removal exist in relation to the inspector, the Director-General may at any time, by notice to the inspector, remove from office an inspector appointed under **section 80(1) and (2)(b)**. 30
- (2) The grounds for removal are incapacity affecting performance of duty, neglect of duty, and misconduct.

- (3) Before removing an inspector from office, the Director-General must give the inspector a reasonable opportunity to make submissions, or be heard, or both, on the proposed removal.
- (4) The removal takes effect at the later of the following times: 5
- (a) when the removal notice is received by the inspector:
 - (b) a later time specified for the purpose in that notice.
- Compare: 1993 No 82 s 20G(d)
- 83 Directions to inspectors**
- (1) The Director-General may give inspectors written directions relating to how they must perform the duties of their office. 10
- (2) The inspectors must comply with those directions.
- (3) The Director-General may, by written notice given to the inspectors concerned, amend, revoke, or revoke and replace a written direction under this section. 15
- Compare: 1964 No 19 s 8(1)
- 84 Inspectors must report irregularities**
- (1) An inspector of a school of anatomy must, as soon as is reasonably practicable, report in writing to the Director-General every irregularity (if any) that appears to that inspector to have occurred in respect of the receipt, possession, storage, or other use of a body removed— 20
- (a) to the school for anatomical examination; or
 - (b) from the school to another place, under **section 52**.
- (2) The report must give details of every irregularity concerned and, as far as they are known to the inspector, identifying details of the individual whose body was concerned. 25
- (3) Inspectors of the same school of anatomy may combine their reports, or report together jointly, under this section. 30
- Compare: 1964 No 19 s 8(3)
- 85 Inspectors may visit and inspect school**
- An inspector may, at any reasonable time, visit and inspect the school of anatomy for which he or she is appointed as an inspector. 35
- Compare: 1964 No 19 s 8(4)

*Disclosure of health information to facilitate consideration
of use of tissue for transplantation or
other therapeutic purposes*

- 86 Disclosure to ascertain medical suitability and whether consent required for use has been, or may be, given** 5
- (1) A health agency that holds health information about an individual who has died need not obtain from the individual's representative authorisation for disclosure of the information if—
- (a) the agency believes on reasonable grounds that it is not desirable or not practicable to obtain authorisation of that kind; and 10
- (b) the disclosure is by a person authorised by the agency to a person authorised by an authorised tissue bank; and
- (c) the disclosure of the information is for the purposes of helping the authorised tissue bank, or its agents or employees, to ascertain— 15
- (i) whether tissue of the individual, collected before death or from his or her body, is or may be suitable for use for transplantation or other therapeutic purposes; and 20
- (ii) whether any consent required by law for use for those purposes of tissue of that kind has been, or may be, given.
- (2) The health information about the individual may include— 25
- (a) the fact that the individual has died; and
- (b) identifying details of the individual; and
- (c) identifying details and contact details of members of the individual's family.
- (3) **Authorised tissue bank** means a tissue bank the Director-General has by notice in the *Gazette* authorised for the purposes of this section, and **health agency**, **health information**, and **representative** have the meanings given to them by clause 3 of the Health Information Privacy Code 1994 issued under section 46 of the Privacy Act 1993. 35

*Repeal of organ donor provisions
in driver licensing legislation*

- 87 Land Transport Act 1998 amended**
- (1) This section amends the Land Transport Act 1998.
- (2) Section 28(1)(i) is repealed. 40

- (3) The following section is inserted after section 28A:
- “28B Transitional provision for driver licences showing organ donor information about holders, etc**
- “(1) Organ donor information (if applicable) about the holder continues to be shown on a driver licence, despite the repeals and revocations effected by **sections 87 and 88 of the Human Tissue Act 2006**, until the licence is renewed or replaced under Part 12 of the Land Transport (Driver Licensing) Rule 1999. 5
- “(2) This section does not limit or affect **section 199(9) to (11)**.”
- (4) Section 199(2)(q) is repealed. 10
- (5) Section 199(5) is repealed; and section 199(7) and (8) are consequentially amended by omitting “any of subsections (4) to (6)” and substituting in each case “subsection (4) or (6)”.
- (6) Section 199 is amended by adding the following subsections:
- “(9) The national register may, but need not, continue to show organ donor information, despite the repeals and revocations effected by **sections 87 and 88 of the Human Tissue Act 2006**, while that information continues to be shown on the relevant driver licence in accordance with **section 28B**. 15
- “(10) The Authority may retain for initial disclosure, and may disclose (initially, and again on 1 or more later occasions during the period specified in this subsection), and may for 5 years (or a shorter period considered appropriate by the Authority) after initial disclosure under this subsection retain to disclose again under this subsection, to the national organ and tissue donor register (as defined in **section 5 of the Human Tissue Act 2006**), organ donor information that was, or may have been, formerly shown— 20
- “(a) on the relevant driver licence, under **section 28B**; and 25
- “(b) by the national register, under **subsection (9)**. 30
- “(11) **Subsection (10)** overrides **subsection (9)**.”
- 88 Land Transport (Driver Licensing) Rule 1999 amended**
- (1) This section amends the Land Transport (Driver Licensing) Rule 1999.
- (2) Rules 9(h) and 63(1)(k) are revoked. 35

New (unanimous)

- 88A Commencement of sections 87 and 88**
- (1) **Subsections (1) and (5) of section 87** (which repeal a provision under which medical practitioners are entitled, without payment of a fee, to organ donor information from the national register of all driver licences) come into force on a date to be appointed by the Governor-General by Order in Council. 5
- (2) **Sections 87(2) to (4) and (6) and 88** and the heading above **section 87** (which repeal organ donor provisions in driver licensing legislation) come into force on a date to be appointed by the Governor-General by Order in Council. 10
- (3) The date appointed under **subsection (2)** must be the same as, or after, the date appointed under **subsection (1)**.
- (4) A date appointed under **subsection (1) or (2)** must be the same as, or after, the date appointed under **section 2(4)**.
- (5) Dates appointed under **section 2(4)** or **subsection (1) or (2)** of this section may be appointed by the same order or different orders. 15

Amendment ensuring taking of tissue from live donor for transplantation, etc, is health treatment

- 89 Interpretation** 20
- (1) This section amends the Health and Disability Commissioner Act 1994.
- (2) Section 2(1) is amended by inserting the following definition in its appropriate alphabetical order:
- “**health treatment**, to avoid doubt, includes treatment of a person (A) that is, or is related to, the taking of human tissue from A for all or any of the following purposes: 25
- “(a) transplantation, or another therapeutic purpose, for the benefit of 1 or more persons other than A:
- “(b) educational purposes or research purposes”. 30

New (unanimous)*Amendment to Human Assisted Reproductive Technology Act 2004 and relating to gametes and embryos***89A Regulations**

- (1) This section amends the Human Assisted Reproductive Technology Act 2004. 5
- (2) Section 76 is amended by inserting the following subsections after subsection (1):
- “(1A) Regulations under subsection (1)(a)(i) may prescribe requirements (not inconsistent with this Act, the Health and Disability Commissioner (Code of Health and Disability Services Consumers’ Rights) Regulations 1996, or the Human Tissue Act **2006**) for informed consent for collection of gametes, embryos, or both—
- “(a) from dead individuals; and 10
- “(b) in connection with, or for the purposes of, the performance of assisted reproductive procedures, the conduct of human reproductive research, or any other lawful use or uses of the gametes, embryos, or both. 15
- “(1B) **Subsection (1A)** does not limit subsection (1)(a)(i) or the power under section 6 to declare procedures or treatments not to be established procedures if they involve the use of gametes or embryos collected from a person, who has since died, who did not consent to the specific use of the gametes or embryos before that person’s death.” 20

Consequential amendments and repeals 25**90 Consequential amendments**

The Acts listed in **Schedule 6** are amended in the manner indicated in that schedule.

91 Repeals

- (1) The Human Tissue Act 1964 is repealed. 30
- (2) Part 3A (trading in human blood and controlled human substance) of the Health Act 1956 is repealed.

Savings and transitional provisions

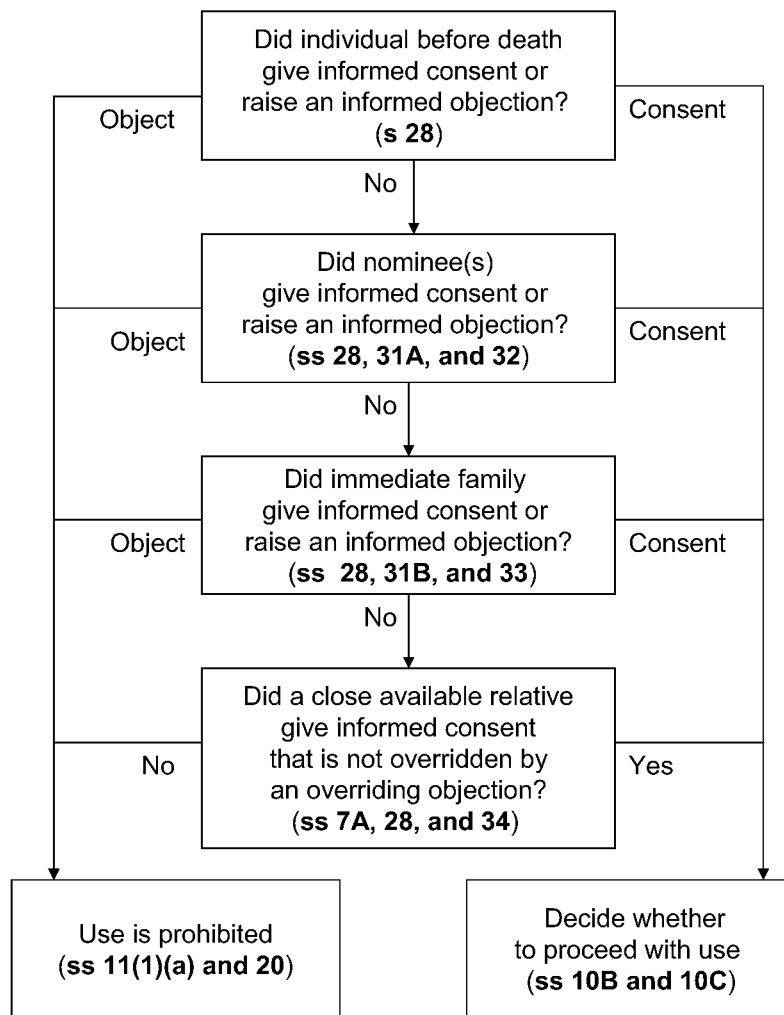
- 92 Exemptions under section 92E(1) of Health Act 1956**
- (1) This section applies to notices given under section 92E(1) of the Health Act 1956 if those notices were in force immediately before the repeal of Part 3A of that Act. 5
- (2) On and after that repeal, those notices must be treated as if they were given under **section 58** (exemptions), and may be revoked, varied, or added to, under that section accordingly.
- 93 Entities appointed under Health Act 1956 to collect and distribute blood and controlled human substances** 10
- (1) This section applies to appointments under section 92H of the Health Act 1956 if those appointments were in force immediately before the repeal of Part 3A of that Act.
- (2) On and after that repeal, those appointments must be treated as if they were made under **section 60** (appointed entities to collect and distribute blood and controlled human substances), and may be revoked, varied, or added to, under that section accordingly. 15
- 94 Schools of anatomy and inspectors of them**
- (1) Orders authorising the establishment of schools of anatomy and in force on the repeal of the Human Tissue Act 1964 must after that repeal be treated as orders under **section 79**, and may be amended, revoked, or revoked and replaced under that section accordingly. 20
- (2) **Orders authorising the establishment of schools of anatomy** means the following orders under section 3 of the Anatomy Act 1875 or section 7 of the Human Tissue Act 1964: 25
- (a) Order in Council Authorising the Establishment of a School of Anatomy in connection with the University of Otago, 15 June 1876 *New Zealand Gazette* No 34 page 407: 30
- (b) Order in Council Authorising the Establishment of a School of Anatomy in connection with Auckland University College, 5 March 1888 *New Zealand Gazette* No 14 page 298: 35
- (c) University of Otago School of Anatomy Order 1969 (SR 1969/278) (Wellington Hospital):
- (d) University of Otago School of Anatomy Order 1988 (SR 1988/206) (Christchurch Hospital).

- (3) Every inspector of a school of anatomy who was in office immediately before the repeal of the Human Tissue Act 1964 continues in office after that repeal as if appointed by the Director-General—
- (a) under **section 80(1) and (2)(a)**, if the inspector is a member of the police; and
 - (b) under **section 80(1) and (2)(b)**, in every other case.
- (4) Every direction by the Minister to an inspector of a school of anatomy under section 8(1) of the Human Tissue Act 1964 and in force on the repeal of that Act must after that repeal be treated as a direction by the Director-General under **section 83**, and may be amended, revoked, or revoked and replaced under that section accordingly.
- 95 Existing holdings of human tissue**
- (1) This section applies to human tissue that, immediately before the repeal of the Human Tissue Act 1964, had been collected, or was being used (**existing holdings**).
- (2) Collection, use, exportation, and importation of existing holdings must comply with all relevant requirements and quality, safety, and other standards prescribed or approved by regulations under **section 76 or 77**.
- (3) However, no other requirements in this Act apply to existing holdings, and the Human Tissue Act 1964 continues to apply to existing holdings as if that Act had not been repealed.
- New (unanimous)**
- (4) To avoid doubt **requirements**, in **subsection (3)**, includes requirements that are, or are part of, offences or prohibitions.

New (unanimous)

Schedule 1A
Use for general purposes of
tissue that is or is from bodies

s4A(1)



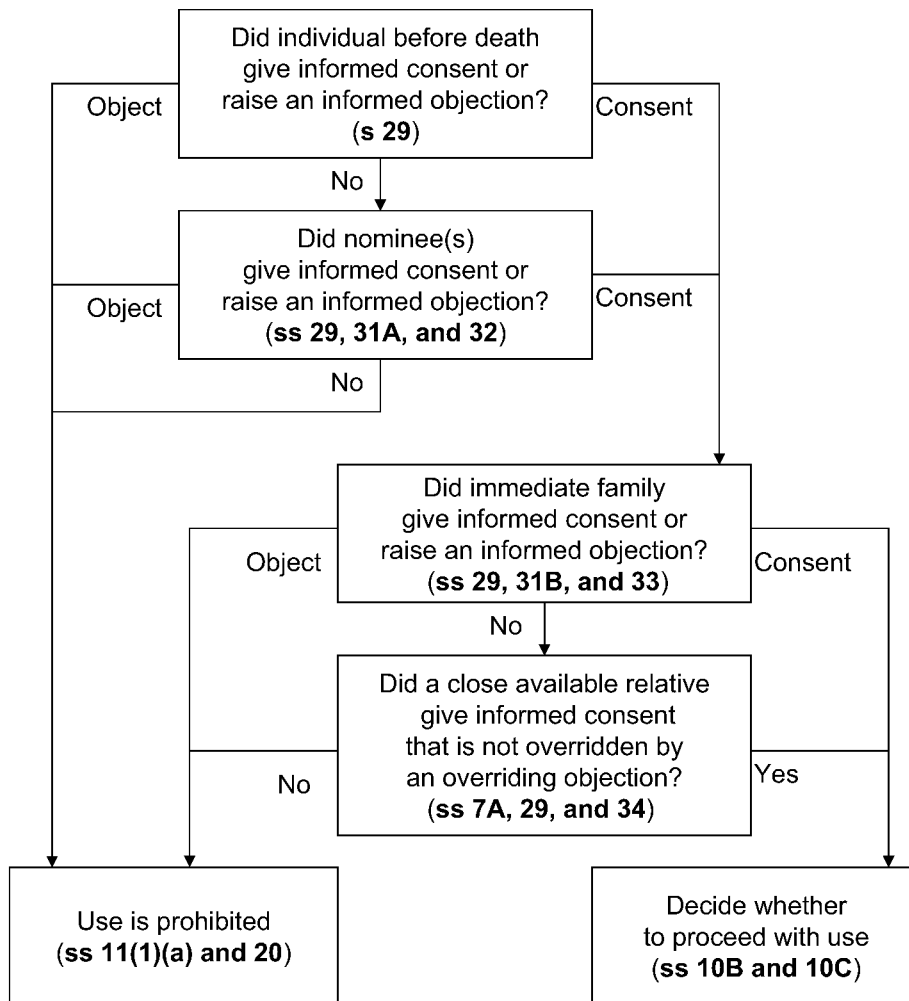
- Persons proposing to collect or use tissue must comply with s 10.
- In determining whether consent or an objection is informed consent, an informed objection, or an overriding objection, see in particular ss 7, 27A–27E, 31C, 31D, and 38.

New (unanimous)

s 4A(2)

Schedule 1B

Use for anatomical examination or public display of tissue that is or is from bodies

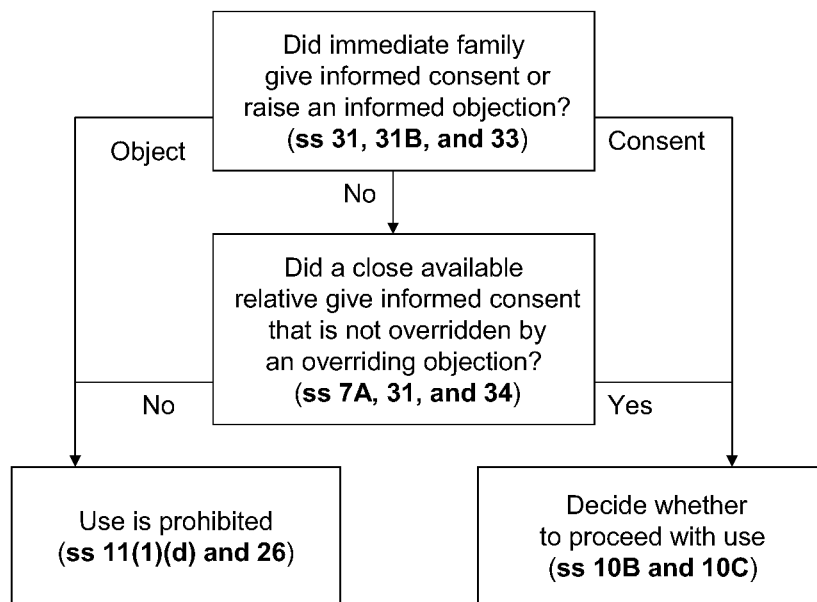


- Persons proposing to collect or use tissue must comply with s 10.
- In determining whether consent or an objection is informed consent, an informed objection, or an overriding objection, see in particular ss 7, 27A–27E, 31C, 31D, and 38.
- Examination and some display of bodies of individuals under 16 years is prohibited: s 51A.

New (unanimous)

s 4A(3)

Schedule 1C
**Use for secondary purposes after donor's death of
tissue from living individual**



- Persons proposing to collect or use tissue must comply with s 10.
- In determining whether consent or an objection is informed consent, an informed objection, or an overriding objection, see in particular ss 7, 27A–27E, 31C, 31D, and 38.

Struck out (unanimous)

s 8(2)

Schedule 1
Person lawfully in possession of certain kinds of body

Column 1	Column 2	
Person	Kind of body	
The person for the time being in charge of a hospital care institution as defined in section 58(4) of the Health and Disability Services (Safety) Act 2001	A body lying in that institution	5
The person for the time being in charge of a hospital as defined in section 2(1) of the Mental Health (Compulsory Assessment and Treatment) Act 1992	A body that is— (a) the body of a patient (as so defined); and (b) lying in the hospital	10
The person for the time being in charge of a secure facility as defined in section 5(1) of the Intellectual Disability (Compulsory Care and Rehabilitation) Act 2003	A body that is— (a) the body of a person who was required to stay in the facility; and (b) lying in the facility	15
The prison manager of a prison (as those terms are defined in section 3(1) of the Corrections Act 2004)	A body that is— (a) the body of a prisoner (as so defined); and (b) lying in the prison	20
The head of a school of anatomy	A body that is— (a) received and possessed by the school, with appropriate consent (as defined in section 7), for anatomical examination; and (b) lying in the school	25
		30

Struck out (unanimous)

Schedule 2 s 34(2)
Senior available next of kin of dead individual

Part 1**Individual 16 years old or older at time of death**

- | | | |
|---|---|----|
| 1 | A person who was a spouse, civil union partner, or de facto partner of the individual immediately before his or her death. | 5 |
| 2 | If the individual, immediately before his or her death, had no spouse, civil union partner, or de facto partner, or if the individual had a spouse, civil union partner, or de facto partner, but a person who was then the individual's spouse or civil union partner, or a de facto partner of the individual, is not available—a son or daughter—
(a) of the individual; and
(b) who is 16 years old or older. | 10 |
| 3 | If no person referred to in clause 1 or 2 is available—a parent of the individual. | 15 |
| 4 | If no person referred to in clause 1, 2, or 3 is available—a brother or sister—
(a) of the individual; and
(b) who is 16 years old or older. | 20 |

Part 2**Individual under 16 years of age at time of death**

- | | | |
|---|---|----|
| 1 | A parent of the individual. | |
| 2 | If a parent of the individual is not available—a person who was a guardian of the individual immediately before his or her death. | 25 |
| 3 | If no person referred to in clause 1 or 2 is available—a brother or sister—
(a) of the individual; and | |

Struck out (unanimous)

Part 2—*continued*

(b) who is 16 years old or older.

Schedule 3

s 66

Form of search warrant

Warrant under section 66(2) of Human Tissue Act 2006 to enter dwellinghouse or marae

To [*state name of authorised person*]. 5

Being satisfied on written application made on oath by an authorised person that there are reasonable grounds to believe that in the dwellinghouse or marae located at [*state address or other description of location*]—

(a) an offence against the Human Tissue Act **2006** has been or is being committed; or 10

(b) there is any thing that is or may be evidence of the commission of an offence against the Human Tissue Act **2006**,—

by this warrant I authorise you, on 1 occasion on, or within 14 days after, the date of the issue of this warrant, to enter that dwellinghouse or marae and exercise the powers conferred by **section 65** of that Act. 15

Dated at [*state place and date of issue*].

Conditions (if any) subject to which warrant issued: [*state conditions*].

..... 20
District Court Judge (*or* Community Magistrate *or* Justice *or* **(Court)** Registrar (not being a member of the police))

Struck out (unanimous)

s 70

Schedule 4
Maximum penalties for contravening specified sections

Column 1 Section	Column 2 General nature of contravention	Column 3 Maximum penalty	
20	Collection and use of human tissue from bodies without appropriate consent	1 year \$50,000	5
22	Use of human tissue from bodies for secondary purpose without appropriate consent	3 months \$20,000	10
24	Collection of non-consumer human tissue for donor analysis, carrying out of donor analysis of non-consumer human tissue, or both, without appropriate consent	1 year \$50,000	15
26	Use of human tissue from living individual for secondary purpose after donor's death without appropriate consent	3 months \$20,000	20
48	Non-compliance with standards for collection and use of human tissue	3 months \$20,000	
49	Performance of post-mortem by person who is not, and is not acting under instructions of, medical practitioner	3 months \$20,000	25
50	Unlawful removal of tissue for use for therapeutic purposes or medical education or research	1 year \$50,000	
51	Unlawful performance of anatomical examination, or receipt, possession, or storage of body for that purpose	3 months \$20,000	30
55(1)	Unlawful trading in human tissue: requiring or accepting financial or other consideration	1 year \$50,000	35
55(2)	Unlawful trading in human tissue: providing financial or other consideration	1 year \$50,000	
56(1)	Unlawful collection of blood or controlled human substance	6 months \$20,000	40

Struck out (unanimous)

Column 1 Section	Column 2 General nature of contravention	Column 3 Maximum penalty	
57	Charging for administered blood or controlled human substance	1 year \$50,000	
59(1)	Prohibited advertising	3 months \$20,000	5
63	Non-compliance with standards, etc, for export or import of human tissue	3 months \$20,000	

s 78

Schedule 5
Incorporation of standards in regulations
by reference

- 1 Regulations may incorporate standards by reference**
- (1) Regulations under **section 76 or 77** that approve standards (for example, New Zealand standards) may incorporate those standards by reference. 5
- (2) Standards may be incorporated by reference in the regulations— 10
- (a) in whole or in part; and
- (b) with modifications, additions, or variations specified in the regulations.
- (3) Standards incorporated by reference in regulations under **section 76 or 77** have legal effect as part of those regulations. 15
- Compare: 1956 No 65 s 112ZG

Struck out (unanimous)

- 2 Effect of amendments to, or replacement of, standards incorporated by reference in regulations** 20
- An amendment to, or replacement of, standards incorporated by reference in regulations under **section 76 or 77** (the **initial regulations**) has legal effect as part of the initial regulations only if regulations made under that section after the making of the initial regulations state that the particular amendment or replacement has that effect.

New (unanimous)

- 2 Effect of amendments to, or replacement of, standards incorporated by reference in regulations** 25
- An amendment to, or replacement of, standards incorporated by reference in regulations under **section 76 or 77** (the **initial regulations**) has legal effect as part of the initial regulations only if— 30
- (a) the amendment or replacement material is made by the person or organisation originating the incorporated material; and

New (unanimous)

- | | | |
|-----|--|---|
| (b) | the amendment or replacement material is of the same general character as the material amended or replaced; and | |
| (c) | regulations made under section 76 or 77 after the making of the initial regulations state that the particular amendment or replacement has that effect. | 5 |

Compare: 1956 No 65 s 112ZH

3 Proof of standards incorporated by reference

- | | | |
|-----|--|----|
| (1) | A copy of standards incorporated by reference in regulations, including any amendment to, or replacement of, the standards, (the standards) must be— | 10 |
| (a) | certified as a correct copy of the standards by the Director-General; and | |
| (b) | retained by the Director-General. | |

- | | | |
|-----|--|----|
| (2) | The production in proceedings of a certified copy of the standards is, in the absence of evidence to the contrary, sufficient evidence of the incorporation in the regulations of the standards. | 15 |
|-----|--|----|

Compare: 1956 No 65 s 112ZI

4 Effect of expiry or revocation of standards incorporated by reference

- | | |
|--|----|
| Standards incorporated by reference in regulations under section 76 or 77 that expire or that are revoked or that cease to have effect cease to have legal effect as part of those regulations only if regulations made under that section state that the standards cease to have legal effect. | 20 |
| | 25 |

Compare: 1956 No 65 s 112ZJ

5 Requirement to consult

- | | | |
|-----|---|----|
| (1) | This clause applies to regulations made under section 76 or 77 that— | 30 |
| (a) | incorporate standards by reference; or | |
| (b) | state that an amendment to, or replacement of, standards incorporated by reference in regulations of that kind has legal effect as part of the regulations. | |

- (2) Before regulations to which this clause applies are made, the Director-General must—
- (a) *(prepare)* identify the standards proposed to be incorporated by reference or the proposed amendment to, or replacement of, standards incorporated by reference (the **proposed standards**) in consultation with persons or organisations whom the Director-General considers appropriate, including persons who are able to represent the views of health practitioners, health researchers, or both, or of classes of health practitioner, health researchers, or both, who will be directly affected by the proposed standards; and 5
 - (b) make copies of the proposed standards available for inspection during working hours for a reasonable period, free of charge, at the head office of the Ministry of Health and at any other places that the Director-General determines are appropriate; and 15
 - (c) make copies of the proposed standards available for purchase at a reasonable price; and
 - (d) give notice in the *Gazette* stating that— 20
 - (i) the proposed standards are available for inspection during working hours free of charge, the place or places at which they can be inspected, and the period during which they can be inspected; and 25
 - (ii) copies of the proposed standards can be purchased and the place or places at which they can be purchased; and
 - (e) allow a reasonable opportunity for persons to comment on the proposal to incorporate the proposed standards by reference; and 30
 - (f) consider any comments they make.
- (3) Before regulations to which this clause applies are made, the Director-General—
- (a) may make copies of the proposed standards available in any other way that he or she considers appropriate in the circumstances (for example, on an internet website); and 35
 - (b) must, if **paragraph (a)** applies, give notice in the *Gazette* stating that the proposed standards are available in other ways and details of where or how they can be accessed or obtained. 40

- (4) A failure to comply with this clause does not invalidate regulations that incorporate standards by reference.

Compare: 1956 No 65 s 112ZK

6 Access to standards incorporated by reference

- (1) The Director-General— 5
- (a) must make the standards referred to in **subclause (2)** (the **standards**) available for inspection during working hours, free of charge, at the head office of the Ministry of Health and at any other places that the Director-General determines are appropriate; and 10
- (b) must make copies of the standards available for purchase at a reasonable price; and
- (c) may make copies of the standards available in any other way that the Director-General considers appropriate in the circumstances (for example, on an internet website); and 15
- (d) must give notice in the *Gazette* stating that—
- (i) the standards are incorporated in the regulations and the date on which the regulations were made; and 20
- (ii) the standards are available for inspection during working hours, free of charge, and the location of the place or places at which they can be inspected; and
- (iii) copies of the standards can be purchased and the location of the place or places at which they can be purchased; and 25
- (iv) if copies of the standards are made available under **paragraph (c)**, the standards are available in other ways and details of where or how they can be accessed or obtained. 30
- (2) The standards are—
- (a) standards incorporated by reference in regulations under **section 76 or 77**;
- (b) any amendment to, or replacement of, those standards that is incorporated in the regulations or the standards referred to in **paragraph (a)** with the amendments or replacement standards incorporated. 35

- (3) A failure to comply with this clause does not invalidate regulations that incorporate standards by reference.
Compare: 1956 No 65 s 112ZL
- 7 Acts and Regulations Publication Act 1989 not applicable to standards incorporated by reference** 5
The Acts and Regulations Publication Act 1989 does not apply to—
(a) standards incorporated by reference in regulations under **section 76 or 77**; or
(b) an amendment to, or replacement of, those standards. 10
Compare: 1956 No 65 s 112ZM
- 8 Application of Regulations (Disallowance) Act 1989 to standards incorporated by reference**
(1) Nothing in section 4 of the Regulations (Disallowance) Act 1989 requires standards that are incorporated by reference in regulations to be laid before the House of Representatives. 15
(2) The Regulations (Disallowance) Act 1989, apart from the modification to the application of section 4 of that Act made by **subclause (1)** of this clause, applies to regulations under **section 76 or 77** that incorporate standards by reference. 20
Compare: 1956 No 65 s 112ZN
- 9 Application of Standards Act 1988 not affected**
Clauses 1 to 8 do not affect the application of sections 22 to 25 of the Standards Act 1988. 25
Compare: 1956 No 65 s 112ZO
-

Schedule 6 Consequential amendments

s 90

Births, Deaths, and Marriages Registration Act 1995 (1995 No 16)

Section 39(c)(ii): omit “Human Tissue Act 1964” and substitute “**Human Tissue Act 2006**”. 5

Section 40(1)(b) and (4): omit “Human Tissue Act 1964” and substitute in each case “**Human Tissue Act 2006**”.

Section 42(2)(b): omit “Human Tissue Act 1964” and substitute “**Human Tissue Act 2006**”. 10

Section 51(2)(b) and (3)(c): omit “Human Tissue Act 1964” and substitute in each case “**Human Tissue Act 2006**”.

New (unanimous)

Coroners Act 2006 (2006 No 38)

Schedule 5: repeal so much as relates to the Human Tissue Act 1964.

Corrections Act 2004 (2004 No 50))

Schedule 2: repeal so much as relates to the Human Tissue Act 1964. 15

Electronic Transactions Act 2002 (2002 No 35)

Part 2 of the Schedule: omit the item relating to section 3 of the Human Tissue Act 1964 (1964 No 19).

New (unanimous)

Health Act 1956 (1956 No 65)

Section 22E: omit “section 92H” and substitute “**section 60** of the Human Tissue Act **2006**”. 20

Health and Disability Services (Safety) Act 2001 (2001 No 93)

Schedule 2: repeal so much as relates to the Human Tissue Act 1964.

Health Practitioners Competence Assurance Act 2003 (2003 No 48)

Section 67(b)(vii): omit “Human Tissue Act 1964” and substitute “**Human Tissue Act 2006**”. 25

Section 100(2)(vii): omit “Human Tissue Act 1964” and substitute “**Human Tissue Act 2006**”. 30

Schedule 4: repeal so much as relates to the Human Tissue Act 1964.

Health Sector (Transfers) Act 1993 (1993 No 23)

Schedule 4: repeal so much as relates to the Human Tissue Act 1964.

Human Rights Amendment Act 2001 (2001 No 96)

Sections 53 and 54 and heading above section 53: repeal.

New (unanimous)**New Zealand Public Health and Disability Act 2000
(2000 No 91)**

5

Section 55(1)(b): omit “section 92A of the Health Act 1956” and substitute “**section 54** of the Human Tissue Act **2006**”.

Section 55(1)(b): omit “section 92H” and substitute “**section 60**”.

Section 55(3): omit “Part 3A of the Health Act 1956” and substitute “**section 54** of the Human Tissue Act **2006**”.

10

Section 65(4)(b): omit “within the meaning of Part 3A of the Health Act 1956” and substitute “as defined in **section 54** of the Human Tissue Act **2006**”.

Relationships (Statutory References) Act 2005 (2005 No 3)

15

Schedule 1: repeal so much as relates to the Human Tissue Act 1964.

Legislative history

7 November 2007
14 November 2007

Introduction (Bill 82–1)
First reading and referral to Health Committee