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as at 28 October 2021



## Human Tissue Act 2008

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Date of assent    18 April 2008  
Commencement    see section 2

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#### Note

The Parliamentary Counsel Office has made editorial and format changes to this version using the powers under subpart 2 of Part 3 of the Legislation Act 2019.

Note 4 at the end of this version provides a list of the amendments included in it.

**This Act is administered by the Ministry of Health.**

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**The Parliament of New Zealand enacts as follows:**

**1 Title**

This Act is the Human Tissue Act 2008.

**2 Commencement**

- (1) Sections 1, 2, and 89 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 89.
- (3) The rest of this Act comes into force on a date to be appointed by the Governor-General by Order in Council.
- (4) An order under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

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**Legislation Act 2019 requirements for secondary legislation made under this section**

<b>Publication</b>	PCO must publish it on the legislation website and notify it in the <i>Gazette</i>	LA19 s 69(1)(c)
<b>Presentation</b>	The Minister must present it to the House of Representatives	LA19 s 114, Sch 1 cl 32(1)(a)
<b>Disallowance</b>	It may be disallowed by the House of Representatives	LA19 ss 115, 116

*This note is not part of the Act.*

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Section 2(3): Human Tissue Act 2008 (except sections 1, 2, 87, 88, 89, and the heading above section 87) brought into force, on 1 November 2008, by clause 2 of the Human Tissue Act 2008 Commencement Order 2008 (SR 2008/311).

Section 2(4): inserted, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

## Part 1 General provisions

### 3 Purpose of this Act

The purpose of this Act is to help to ensure that collection or use of human tissue—

- (a) occurs only with proper recognition of, and respect for,—
  - (i) the autonomy and dignity of the individual whose tissue is, before or after his or her death, collected or used; and
  - (ii) the cultural and spiritual needs, values, and beliefs of the immediate family of that individual; and
  - (iii) the cultural, ethical, and spiritual implications of the collection or use of human tissue; and
  - (iv) the public good associated with collection or use of human tissue (whether for health practitioner education, the investigation of offences, research, transplantation or other therapeutic purposes, or for other lawful purposes); and
- (b) does not endanger the health and safety of members of the public; and
- (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

- (1) To help to achieve its purpose, this Act—
  - (a) requires, unless they are done for a purpose specified in section 20, 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;
    - (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
- (b) makes it an offence to collect or use tissue if the informed consent required has not been given; and
- (c) imposes other requirements for and restrictions on collection or use of human tissue; and
- (d) provides for related matters; and
- (e) repeals and replaces (with modified provisions)—
  - (i) the Human Tissue Act 1964; and
  - (ii) Part 3A (trading in human blood and controlled human substance) of the Health Act 1956.
- (2) This section is intended as a guide only.

## 5 **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 1.
- (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 2.
- (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 3.
- (4) The diagrams are intended as a guide only.

## 6 **Interpretation**

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

**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

**body** means a dead human body

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

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

**close available relative** has the meaning given to it by section 10



**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

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

**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

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

**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:

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

**Director-General** means the chief executive under the Public Service Act 2020 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 whose tissue was collected

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

**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 5(1) of the Customs and Excise Act 2018

**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

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

**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 7

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

- (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
- (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:
  - (i) spouse, civil union partner, or de facto partner of the individual;
  - (ii) child, parent, guardian, grandparent, brother, or sister of the individual;
  - (iii) stepchild, step-parent, stepbrother, or stepsister of the individual

**importation** has the same meaning as in section 5(1) of the Customs and Excise Act 2018

**informed consent** has the meaning given to it by section 9

**informed objection** has the meaning given to it by section 9

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

**marae** includes the area of land on which all buildings such as the whareniui (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

**medicine** means a medicine within the meaning of the Medicines Act 1981

**Minister** means the Minister of Health

**national organ and tissue donor register** means any register established or recognised by regulations under section 78

**nomination** means a nomination under section 39

**nominee** means a person nominated under section 39

**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—

- (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 health practitioner education or any kind of research; and
- (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, or has objected in general terms, to that applicant or holder being an organ donor

**overriding objection** has the meaning given to it by section 9

**post-mortem** means a post-mortem examination

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

**responsible person** has the meaning given to it by section 12

**school of anatomy** means a school of anatomy whose establishment is authorised by an order made under section 77

**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

**use**, in relation to any human tissue,—

- (a) includes—
  - (i) the performance of a post-mortem involving that tissue; and
  - (ii) research using that tissue; and
  - (iii) anatomical examination and public display of that tissue; and
  - (iv) testing (including donor analysis) of that tissue; and
  - (v) storage of that tissue; and
  - (vi) disposal of that tissue; and
- (b) in particular, includes use of that tissue in the development, making or preparation, and testing of controlled drugs, medicines, or both; and

- (c) includes, whether or not that tissue is non-health-care tissue, and except as provided in paragraph (e), the use of that tissue (for example, the administration or transplantation of that tissue) in the carrying out of a health-care procedure; and
- (d) includes, except as provided in paragraphs (e) and (f), use of that tissue for a secondary purpose; but
- (e) does not include use of that tissue in so far as it is, or is part of, a controlled drug, a medicine, or both; and
- (f) does not include the importation or the exportation of that tissue.

Section 6 **Director-General**: amended, on 7 August 2020, by section 135 of the Public Service Act 2020 (2020 No 40).

Section 6 **exportation**: amended, on 1 October 2018, by section 443(3) of the Customs and Excise Act 2018 (2018 No 4).

Section 6 **importation**: amended, on 1 October 2018, by section 443(3) of the Customs and Excise Act 2018 (2018 No 4).

Section 6 **Registrar**: amended, on 1 March 2017, by section 261 of the District Court Act 2016 (2016 No 49).

## 7 Human tissue defined and illustrated

- (1) **Human tissue or tissue** means material that—
  - (a) is, or is derived from, a body, or material collected from a living individual or from a body; and
  - (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) A human embryo or human gamete is not human tissue for the purposes of any provision of this Act.
- (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 47 and 74 (which relate to standards for collection or use of human tissue for non-therapeutic purposes):
  - (b) sections 66 and 75 (which relate to standards, etc, for export and import of human tissue).
- (4) Examples of human tissue therefore include the following:
  - (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):
  - (d) human blood:

- (e) human bone marrow:
- (f) human eyes:
- (g) human hair, nails, and skin:
- (h) human lung washouts:
- (i) human mucus, sputum, or urine.

## **8 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
- (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.

## **9 Informed consent, informed objection, and overriding objection defined**

(1) **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 that applicant or holder being an organ donor); and
- (b) given by a person who is entitled to give it under subpart 3; and
- (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
- (e) not later revoked in accordance with the requirements of subparts 4 and 5.

(2) **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
- (b) raised by a person who is entitled to raise it under subpart 3; and

- (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
  - (e) not later revoked in accordance with the requirements of subparts 4 and 5.
- (3) **Overriding objection**, in relation to any kind of collection or use of tissue to which a close available relative has given informed consent, means an objection—
- (a) to that kind of collection or use of the tissue; and
  - (b) raised under section 41 by a person referred to in the paragraph of section 10(1) or (2) that refers to the close available relative; and
  - (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
  - (e) not later revoked in accordance with the requirements of subparts 4 and 5.

#### 10 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,—
- (a) a person who was a spouse, civil union partner, or de facto partner of the individual immediately before his or her death; or
  - (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—
    - (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—
    - (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,—
- (a) a parent of the individual; or

- (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.

## 11 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.

## 12 Responsible person defined

- (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.
- (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—
    - (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—
    - (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—
    - (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—
    - (i) received and possessed by the school for anatomical examination; and
    - (ii) lying in the school.

- (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.
- (4) **Possession** includes the exercise of a right to custody.  
Compare: 1964 No 19 ss 2(2), 3(6)

### **13 Act binds the Crown**

This Act binds the Crown.

## **Part 2 Human tissue**

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

#### *Preliminary provisions on collection or use of tissue*

### **14 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.

### **15 Responsible person must help if consulted**

The responsible person must, if consulted under section 14(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 14(1).

### **16 Act does not require collection or use**

Nothing in this Act requires any person to collect or use human tissue.



**17 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.

**18 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 or used.

*When informed consent required and not required*

**19 Collection or use for which informed consent required**

- (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.
- (2) Subsection (1) does not apply to collection or use—
  - (a) for a purpose specified in section 20; or
  - (b) for a purpose that is an offence against, or prohibited by, any law (other than sections 22, 23, and 24).
- (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.

**20 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:
  - (i) the maintenance of the law, including the prevention, detection, investigation, prosecution, or punishment of offences; or
  - (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:
- (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—
  - (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
  - (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:
  - (i) a coroner acting under section 31 of the Coroners Act 2006; and
  - (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:
- (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):
- (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:
  - (i) a professionally recognised quality assurance programme:
  - (ii) an external audit of services:
  - (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
  - (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:

- (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.

*How subpart relates to other laws, etc*

## **21 Other laws, and lawfulness of use, etc, not affected**

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 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
- (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**

*Tissue that is, or is collected from, bodies*

## **22 Collection or use without informed consent**

- (1) A person commits an offence, and is liable on 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
  - (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,—
  - (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.

Section 22(1): amended, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).

*Non-health-care tissue***23 Donor analysis, etc, without informed consent**

A person commits an offence, and is liable on conviction to imprisonment for a term not exceeding 1 year or a fine not exceeding \$50,000, if—

- (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.

Section 23: amended, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).

*Tissue from living individuals***24 Use for secondary purpose after donors' deaths without informed consent**

A person commits an offence, and is liable on 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.

Section 24: amended, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).

*Affirmative defence and assumptions***25 Affirmative defence for informed consent offences**

It is a defence in a prosecution for an offence against section 22, 23, or 24 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
- (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.

**26 Person 16 years old or older assumed to be capable**

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)

**27 Consent or objection assumed to be free and informed**

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 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.

**28 Person assumed to have taken into account immediate family's cultural and spiritual needs, values, and beliefs**

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 42.

**29 When consent or objection on behalf of immediate family may be assumed to comply with section 40**

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 40 only if the person is satisfied, based on all information available to the person in the circumstances, that—

- (a) the member has taken the steps to consult required by section 40(a); and
- (b) the member has formed the belief, and that belief is based on the reasonable grounds, required by section 40(c).

**30 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.

**Subpart 3—Who is entitled to give informed consent**

*Tissue that is, or is collected from, bodies*

**31 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.
- (2) Informed consent to which this section applies may only 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:
- (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
  - (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—
  - (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—
  - (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)

### **32 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.
- (2) Informed consent to which this section applies—
  - (a) may only be given under subsections (3) and (4); and
  - (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:
  - (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
    - (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:

- (b) a close available relative of that individual after his or her death, if—
  - (i) no consent has been given under paragraph (a); 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)

*Non-health-care tissue*

**33 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.
- (2) Informed consent to which this section applies may only be given by the individual from whom the tissue concerned was collected or derived.
- (3) This section does not limit section 34.

*Tissue from living individuals*

**34 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.
- (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:
  - (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
    - (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*

**35 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 31 and 32, 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—

- (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
- (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.

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

**36 Immediate family: procedure when it is not practicable to ascertain whether decision made on its behalf**

Informed consent or an informed objection must, for the purposes of sections 31, 32, and 34, 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 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.

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

*Capacity and consent or objections on behalf of another*

**37 Capacity to give or raise or make, etc, consent, objection, or nomination, etc**

- (1) An individual who is not capable cannot give, raise, make, amend, revoke, revoke and replace, or accept or disagree with informed consent, an informed objection, an overriding objection, or a nomination.
- (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
  - (b) cannot give, raise, make, 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.

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

**38 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 31, 32, 33, or 34 to give informed consent, or to raise an informed objection or overriding objection, to collection or use of certain human tissue.



- (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.
- (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
  - (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.

#### Subpart 4—Further provisions on consent or objections by, or on behalf of, nominees, immediate family, and close available relatives

### **39 Nominations and consent or objections by nominees**

- (1) An individual may, for the purposes of this Act, nominate 1 or more nominees if the individual is, under section 31(2)(a) or 32(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.
- (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.
- (3) Section 38(3) gives examples of persons who may be authorised, under a law other than this Act, to give consent on that individual's behalf.
- (4) 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) 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
  - (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.

**40 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 subpart 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
- (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.

**41 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
  - (b) any use for a secondary purpose of tissue that is from a living individual.
- (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 10(1) or (2) that refers to the close available relative.
- (3) For the purposes of sections 14, 22, 24, and 25, an objection raised under this section overrides the informed consent given by the close available relative.

**Subpart 5—Process for, and form, amendment, and recording of,  
consent, objections, and nominations**

**42 Duty to take into account immediate family's cultural and spiritual needs, values, and beliefs**

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.

**43 Form of consent, objection, or nomination**

- (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—
  - (a) in writing (with or without witnesses); or
  - (b) orally and in the presence of 2 or more witnesses present at the same time.
- (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.
- (3) For the purposes of this section,—
  - (a) **will** has the same meaning as in the Wills Act 2007; and
  - (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)

**44 Written consent or objection on behalf of immediate family may include details of consultation, etc**

Informed consent or an informed objection given or raised in writing, in accordance with section 43(1)(a), and given or raised by a member, and on behalf, of the immediate family of a dead individual, under section 40, may include details of either or both of the following:

- (a) the steps taken to consult required by section 40(a);
- (b) the grounds for the belief required by section 40(c).

**45 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.
- (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.

**46 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 43) from being recorded in the national organ and tissue donor register.
- (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.

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

### *Collection or use of tissue for non-therapeutic purposes*

#### **47 Standards for collection or use of human tissue for non-therapeutic purposes**

- (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 74.
- (2) This section applies even if the collection or use of the tissue is required, permitted, or otherwise controlled by law.
- (3) A person commits an offence, and is liable on 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 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).

Section 47(3): amended, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).

### *Post-mortems, official inquiries, etc*

#### **48 Restriction on collecting or using tissue if official post-mortem or inquiry directed or opened**

- (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 knows, or ought reasonably to know,—
  - (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 20(d) has directed or ordered a post-mortem of a body, or may do so; or
  - (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.
- (3) A person commits an offence, and is liable on 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 that is, or is from, a body, and the person knows, or ought reasonably to know, what is specified in subsection (1)(a), (b), or (c); and

(b) that act contravenes subsection (2).

Compare: 1964 No 19 s 3(5)

Section 48(3): amended, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).

**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.
- (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
  - (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.
- (3) A person commits an offence, and is liable on 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).

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

Section 49(3): amended, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).

*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.
- (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 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:
  - (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:

- (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:
  - (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.
- (4) A person commits an offence, and is liable on 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
  - (b) that act contravenes subsection (1) or (2).

Compare: 1964 No 19 s 3(4)

Section 50(4): amended, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).

### *Anatomical examinations and public display*

#### **51 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.
- (2) A person commits an offence, and is liable on 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).
- (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.

Section 51(2): amended, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).

#### **52 Anatomical examinations must usually be performed at schools of anatomy**

- (1) A person must not, unless authorised by section 53 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.
- (2) A person commits an offence, and is liable on 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).

Compare: 1964 No 19 ss 7(2), 12(b), (c)

Section 52(2): amended, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).

### **53 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—
  - (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
  - (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.
- (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*

### **54 Duty 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 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 or examined, or from which the collection is being effected; and
- (b) conduct the examination or collection in an orderly, quiet, and decent manner.

Compare: 1964 No 19 s 11

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

### **55 Interpretation**

- (1) In sections 57 to 65, unless the context otherwise requires,—
  - appointed entity** means an entity appointed under section 63
  - 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:
  - (iii) a constituent of an organ, bone marrow, or tissue described in subparagraph (ii):
  - (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:
- (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:
  - (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 (*see* subsection (2)) declares not to be blood for the purposes of sections 57 to 65

**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
  - (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 (*see* subsection (2)) declares to be included in this definition; but
- (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 (*see* subsection (2)) declares not to be a controlled human substance for the purposes of sections 57 to 65.
- (2) An order under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

Compare: 1956 No 65 s 92A



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**Legislation Act 2019 requirements for secondary legislation made under this section**

<b>Publication</b>	PCO must publish it on the legislation website and notify it in the <i>Gazette</i>	LA19 s 69(1)(c)
<b>Presentation</b>	The Minister must present it to the House of Representatives	LA19 s 114, Sch 1 cl 32(1)(a)
<b>Disallowance</b>	It may be disallowed by the House of Representatives	LA19 ss 115, 116

*This note is not part of the Act.*

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Section 55(1) **blood** paragraph (b)(ii): amended, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

Section 55(1) **controlled human substance** paragraph (a)(iii): amended, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

Section 55(1) **controlled human substance** paragraph (b)(ii): amended, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

Section 55(2): inserted, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

## 56 Trading in human tissue generally prohibited

- (1) No person may, except under an exemption under section 60, require or accept, or offer or provide, financial or other consideration for human tissue.
- (2) A person commits an offence, and is liable on 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).
- (3) Subsection (1) does not apply to the following:
  - (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;
  - (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).
- (4) **Consideration for human tissue** in subsection (1) does not include consideration for the collection or use of the tissue.
- (5) Consideration referred to in subsection (4) may be required or accepted, or offered or provided, from or by 1 or more persons, or on 1 or more occasions, or both.
- (6) **Use**, in this section, includes import and export.
- (7) This section does not limit or affect section 59.

Compare: 1956 No 65 s 92B

Section 56(2): amended, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).

### **57 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.
- (2) A person commits an offence, and is liable on 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).
- (3) 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.
- (4) For the purposes of subsection (3), 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.
- (5) Every appointed entity described in subsection (3)(a) and every employee or agent described in subsection (3)(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.

Compare: 1956 No 65 s 92C

Section 57(2): amended, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).

### **58 Consideration not generally to be provided for collection of blood or controlled human substance for administration to another person**

- (1) No person may, except under an exemption under section 60, 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.
- (2) A person commits an offence, and is liable on 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).

- (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.

Compare: 1956 No 65 s 92B(2)

Section 58(2): amended, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).

### **59 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 60, require or accept from the person to whom that blood or that substance is administered financial or other consideration for collecting or using it.
- (2) A person commits an offence, and is liable on 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).
- (3) This section does not limit or affect section 56.

Compare: 1956 No 65 s 92D

Section 59(2): amended, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).

### **60 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—
- (a) section 56 (trading in human tissue generally prohibited);
  - (b) section 58 (consideration not generally to be provided for collection of blood or controlled human substance for administration to another person);
  - (c) section 59 (person administering blood or controlled human substance not to charge recipient for its collection or use);
  - (d) section 61 (advertising prohibited).
- (2) The Minister may in the same manner vary or revoke an exemption under subsection (1).
- (3) A notice made under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements), unless it applies only to 1 or more named persons.

- (4) After giving a notice under this section that is not secondary legislation, the Minister must—
- (a) publish a copy in the *Gazette* as soon as practicable; and
  - (b) present a copy to the House of Representatives no later than the 16th sitting day after the day on which the notice is given.

Compare: 1956 No 65 s 92E

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**Legislation Act 2019 requirements for secondary legislation made under this section**

<b>Publication</b>	The maker must publish it in the <i>Gazette</i>	LA19 ss 73, 74(1)(a), Sch 1 cl 14
<b>Presentation</b>	The Minister must present it to the House of Representatives	LA19 s 114, Sch 1 cl 32(1)(a)
<b>Disallowance</b>	It may be disallowed by the House of Representatives	LA19 ss 115, 116

*This note is not part of the Act.*

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Section 60(3): replaced, on 28 October 2021, by regulation 77 of the Legislation Act (Amendments to Legislation) Regulations 2021 (LI 2021/247).

Section 60(3)(a): amended, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

Section 60(4): replaced, on 28 October 2021, by regulation 77 of the Legislation Act (Amendments to Legislation) Regulations 2021 (LI 2021/247).

Section 60(4): inserted, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

## 61 Advertising prohibited

- (1) No person may, except under an exemption under section 60, distribute an advertisement relating to the purchase or sale in New Zealand of human tissue.
- (2) A person commits an offence, and is liable on 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).
- (3) Subsection (1) does not apply to distribution of an advertisement relating to the purchase or sale in New Zealand of the following:
  - (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:
  - (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).
- (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
- (b) to exhibit to public view in any premises or place; or
- (c) to deposit in any area, yard, garden, or enclosure comprising part of or appurtenant to any premises.

Compare: 1956 No 65 s 92F

Section 61(2): amended, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).

## 62 Liability of employers, principals, and directors

- (1) This section applies to an offence against section 56(2), 57(2), 58(2), 59(2), or 61(2) and involving a contravention of section 56(1), 57(1), 58(1), 59(1), or 61(1) (which relate to unlawful or prohibited trading in, or actions involving, human tissue, blood, and controlled human substances).
- (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—
  - (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—
  - (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.
- (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
  - (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.

Compare: 1956 No 65 s 92G

**63 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.
- (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:
  - (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).
- (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.
- (7) After giving a notice under subsection (1), (3), 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.

Compare: 1956 No 65 s 92H

**64 Exemption from Part 2 of Commerce Act 1986**

- (1) 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
    - (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.

- (2) An order under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

Compare: 1956 No 65 s 92I

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**Legislation Act 2019 requirements for secondary legislation made under this section**

<b>Publication</b>	PCO must publish it on the legislation website and notify it in the <i>Gazette</i>	LA19 s 69(1)(c)
<b>Presentation</b>	The Minister must present it to the House of Representatives, unless it relates exclusively to an individual (in which case a transitional exemption applies under Schedule 1 of the Legislation Act 2019)	LA19 s 114, Sch 1 cl 32(1)(a)
<b>Disallowance</b>	It may be disallowed by the House of Representatives	LA19 ss 115, 116

*This note is not part of the Act.*

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Section 64(2): inserted, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

## 65 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 63 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.
- (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 63 of this Act must be treated as a provision of the Health Act 1956.

Compare: 1956 No 65 s 92J

### *Exportation and importation of human tissue*

## 66 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 75.
- (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 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, or omits to do, an act; and
  - (b) that act or omission contravenes subsection (1).

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

Section 66(3): amended, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).

## Part 3

### Technical and miscellaneous provisions

#### *Enforcement provisions*

#### **67 Matters to be ascertained by authorised persons**

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 68 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
- (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

#### **68 Powers of authorised persons**

- (1) The powers referred to in section 67, 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:
    - (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:
  - (c) *[Repealed]*
  - (d) search for and seize—
    - (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 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.
  - (f) *[Repealed]*
  - (g) *[Repealed]*
  - (h) *[Repealed]*



- (2) The provisions of Part 4 of the Search and Surveillance Act 2012 (except subpart 3 and sections 118 and 119) apply with any necessary modifications.
- (3) *[Repealed]*  
Compare: 2004 No 92 s 68  
Section 68(1)(c): repealed, on 1 October 2012, by section 258(2) of the Search and Surveillance Act 2012 (2012 No 24).  
Section 68(1)(f): repealed, on 1 October 2012, by section 258(2) of the Search and Surveillance Act 2012 (2012 No 24).  
Section 68(1)(g): repealed, on 1 October 2012, by section 258(2) of the Search and Surveillance Act 2012 (2012 No 24).  
Section 68(1)(h): repealed, on 1 October 2012, by section 258(2) of the Search and Surveillance Act 2012 (2012 No 24).  
Section 68(2): replaced, on 1 October 2012, by section 258(3) of the Search and Surveillance Act 2012 (2012 No 24).  
Section 68(3): repealed, on 1 October 2012, by section 258(3) of the Search and Surveillance Act 2012 (2012 No 24).

## **69 Entry of dwellinghouses and marae**

- (1) An authorised person must not enter a dwellinghouse or marae under section 68(1)(a), except—
- (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).
- (2) An issuing officer (within the meaning of section 3 of the Search and Surveillance Act 2012) may, on an application made by an authorised person in the manner provided for an application for a search warrant in subpart 3 of Part 4 of that Act, issue a search warrant in respect of a dwellinghouse or marae if satisfied that there are reasonable grounds to believe that in that house or marae—
- (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.
- (3) *[Repealed]*
- (4) 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 68, and the provisions of that section apply to the execution of the warrant.
- (5) Subject to subsection (6) and section 72, the provisions of Part 4 of the Search and Surveillance Act 2012 (except sections 118 and 119) apply.
- (6) 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.

Compare: 2004 No 92 s 69

Section 69(2): amended, on 1 October 2012, by section 258(4) of the Search and Surveillance Act 2012 (2012 No 24).

Section 69(3): repealed, on 1 October 2012, by section 258(5) of the Search and Surveillance Act 2012 (2012 No 24).

Section 69(5): replaced, on 1 October 2012, by section 258(6) of the Search and Surveillance Act 2012 (2012 No 24).

## **70 Identification of authorised person**

*[Repealed]*

Section 70: repealed, on 1 October 2012, by section 258(7) of the Search and Surveillance Act 2012 (2012 No 24).

## **71 Notice requirements when place entered**

*[Repealed]*

Section 71: repealed, on 1 October 2012, by section 258(7) of the Search and Surveillance Act 2012 (2012 No 24).

## **72 Disposal of property seized**

Subpart 6 of Part 4 of the Search and Surveillance Act 2012 applies to any property seized by an authorised person under section 68(1)(d), subject to the following provisions:

- (a) *[Repealed]*
- (b) *[Repealed]*
- (c) *[Repealed]*
- (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.

Compare: 2004 No 92 s 72

Section 72: amended, on 1 October 2012, by section 258(8)(a) of the Search and Surveillance Act 2012 (2012 No 24).

Section 72(a): repealed, on 1 October 2012, by section 258(8)(b) of the Search and Surveillance Act 2012 (2012 No 24).

Section 72(b): repealed, on 1 October 2012, by section 258(8)(b) of the Search and Surveillance Act 2012 (2012 No 24).

Section 72(c): repealed, on 1 October 2012, by section 258(8)(b) of the Search and Surveillance Act 2012 (2012 No 24).

## **73 Obstructing inspections, etc, by authorised persons**

Every person commits an offence, and is liable on 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:

- (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:
- (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

Section 73: amended, on 1 July 2013, by section 413 of the Criminal Procedure Act 2011 (2011 No 81).

### *Regulations and Orders in Council*

#### **74 Regulations prescribing or approving quality, safety, and other standards for collection or use of human tissue for non-therapeutic purposes**

- (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.
- (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.
- (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.
- (6) Regulations under this section are secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

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#### **Legislation Act 2019 requirements for secondary legislation made under this section**

<b>Publication</b>	PCO must publish it on the legislation website and notify it in the <i>Gazette</i>	LA19 s 69(1)(c)
<b>Presentation</b>	The Minister must present it to the House of Representatives	LA19 s 114, Sch 1 cl 32(1)(a)
<b>Disallowance</b>	It may be disallowed by the House of Representatives	LA19 ss 115, 116

*This note is not part of the Act.*

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Section 74(6): inserted, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

#### **75 Regulations prescribing or approving requirements and quality, safety, and other standards for export and import of human tissue**

- (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:
  - (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.
  - (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).
  - (5) Regulations under this section are secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

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**Legislation Act 2019 requirements for secondary legislation made under this section**

<b>Publication</b>	PCO must publish it on the legislation website and notify it in the <i>Gazette</i>	LA19 s 69(1)(c)
<b>Presentation</b>	The Minister must present it to the House of Representatives	LA19 s 114, Sch 1 cl 32(1)(a)
<b>Disallowance</b>	It may be disallowed by the House of Representatives	LA19 ss 115, 116

*This note is not part of the Act.*

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Section 75(5): inserted, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

## 76 Regulations may incorporate standards by reference

Regulations under section 74 or 75 may incorporate standards by reference, in accordance with Schedule 5.

## 77 Orders authorising establishment of schools of anatomy

- (1) 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
  - (b) at the place or places, and on the conditions (if any), specified in the order.
- (2) An order under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

Compare: 1964 No 19 s 7(1)

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**Legislation Act 2019 requirements for secondary legislation made under this section**

<b>Publication</b>	PCO must publish it on the legislation website and notify it in the <i>Gazette</i>	LA19 s 69(1)(c)
<b>Presentation</b>	The Minister must present it to the House of Representatives	LA19 s 114, Sch 1 cl 32(1)(a)
<b>Disallowance</b>	It may be disallowed by the House of Representatives	LA19 ss 115, 116

*This note is not part of the Act.*

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Section 77(2): inserted, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

**78 Regulations establishing or recognising national organ and tissue donor register**

- (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:
  - (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
  - (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).
- (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 2020 to the collection, use, and disclosure of personal information by and for the purposes of the register.
- (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
  - (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).
- (7) Regulations under this section are secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

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**Legislation Act 2019 requirements for secondary legislation made under this section**

<b>Publication</b>	PCO must publish it on the legislation website and notify it in the <i>Gazette</i>	LA19 s 69(1)(c)
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<b>Presentation</b>	The Minister must present it to the House of Representatives	LA19 s 114, Sch 1 cl 32(1)(a)
<b>Disallowance</b>	It may be disallowed by the House of Representatives	LA19 ss 115, 116

*This note is not part of the Act.*

Section 78(4): amended, on 1 December 2020, by section 217 of the Privacy Act 2020 (2020 No 31).

Section 78(7): inserted, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

## 79 Regulations prescribing form of search warrant

*[Repealed]*

Section 79: repealed, on 1 October 2012, by section 258(9) of the Search and Surveillance Act 2012 (2012 No 24).

### *Inspectors of schools of anatomy*

## 80 Appointment

- (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
  - (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.

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—

- (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
- (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).
- (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:
    - (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.
  - (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.
- 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—
    - (a) to the school for anatomical examination; or
    - (b) from the school to another place, under section 53.
  - (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.
  - (3) Inspectors of the same school of anatomy may combine their reports, or report together jointly, under this section.
- 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.

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**

- (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
  - (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—
    - (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
    - (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—
- (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.

*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.
- (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 2008, until the licence is renewed or replaced under Part 12 of the Land Transport (Driver Licensing) Rule 1999.

- (2) This section does not limit or affect section 199(9) to (11).
- (4) Section 199(2)(q) is repealed.
- (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 inserting the following subsections after subsection (8):
  - (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 2008, while that information continues to be shown on the relevant driver licence in accordance with section 28B.
  - (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 6 of the Human Tissue Act 2008), organ donor information that was, or may have been, formerly shown—
    - (a) on the relevant driver licence, under section 28B; and
    - (b) by the national register, under subsection (9).
- (11) Subsection (10) overrides subsection (9).

Section 87(6): amended, on 10 May 2011, by section 100(3) of the Land Transport (Road Safety and Other Matters) Amendment Act 2011 (2011 No 13).

## **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.

## **89 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.
- (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.
- (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(3).
- (5) Dates appointed under section 2(3) or subsection (1) or (2) of this section may be appointed by the same order or different orders.
- (6) An order under this section is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

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**Legislation Act 2019 requirements for secondary legislation made under this section**

<b>Publication</b>	PCO must publish it on the legislation website and notify it in the <i>Gazette</i>	LA19 s 69(1)(c)
<b>Presentation</b>	The Minister must present it to the House of Representatives	LA19 s 114, Sch 1 cl 32(1)(a)
<b>Disallowance</b>	It may be disallowed by the House of Representatives	LA19 ss 115, 116

*This note is not part of the Act.*

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Section 89(6): inserted, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

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

**90 Interpretation**

- (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:

- (a) transplantation, or another therapeutic purpose, for the benefit of 1 or more persons other than A:
- (b) educational purposes or research purposes

*Amendment to Human Assisted Reproductive Technology Act 2004 and relating to gametes and embryos*

**91 Regulations**

- (1) This section amends the Human Assisted Reproductive Technology Act 2004.
- (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 2008) for informed consent for collection of gametes, embryos, or both—

- (a) from dead individuals; and
  - (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.
- (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.

*Consequential amendments and repeals*

**92 Consequential amendments**

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

**93 Repeals**

- (1) The Human Tissue Act 1964 (1964 No 19) is repealed.
- (2) Part 3A (trading in human blood and controlled human substance) of the Health Act 1956 is repealed.

*Savings and transitional provisions*

**94 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.
- (2) On and after that repeal, those notices must be treated as if they were given under section 60 (exemptions), and may be revoked, varied, or added to, under that section accordingly.

**95 Entities appointed under Health Act 1956 to collect and distribute blood and controlled human substances**

- (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 63 (appointed entities to collect and distribute blood and controlled human substances), and may be revoked, varied, or added to, under that section accordingly.

**96 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 77, and may be amended, revoked, or revoked and replaced under that section accordingly.
- (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:
  - (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:
  - (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:
  - (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.

**97 Existing holdings of human tissue**

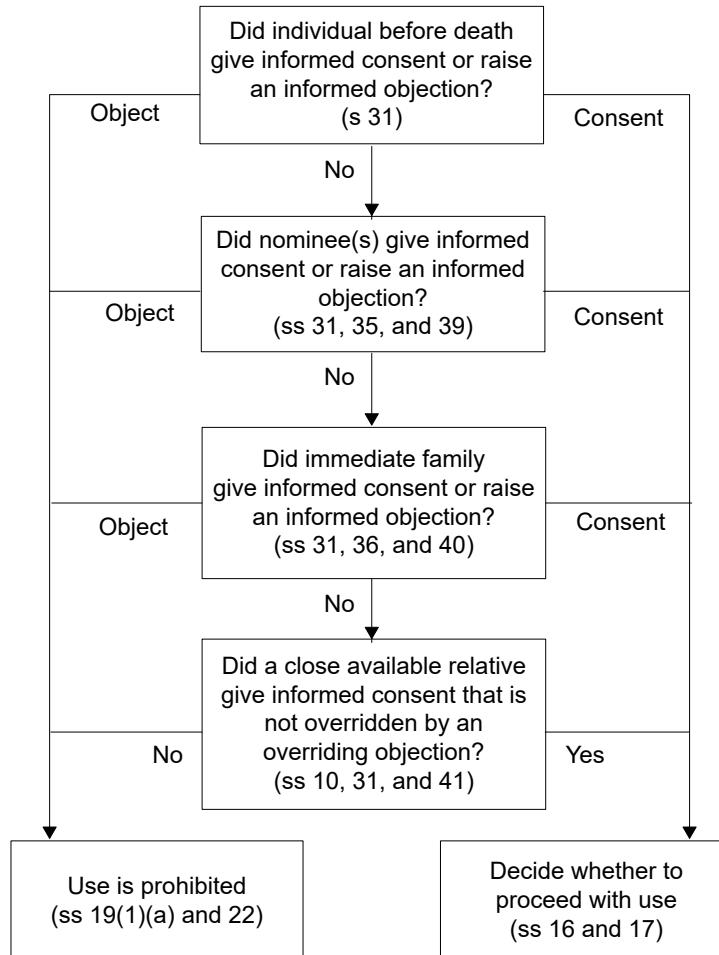
- (1) This section applies to human tissue that, immediately before the repeal of the Human Tissue Act 1964, had been collected, or was being used (**existing holdings**).
- (2) Collection, use, exportation, and importation of existing holdings must comply with all relevant requirements and quality, safety, and other standards prescribed or approved by regulations under section 74 or 75.
- (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.

- (4) To avoid doubt **requirements**, in subsection (3), includes requirements that are, or are part of, offences or prohibitions.

## Schedule 1

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

s 5(1)

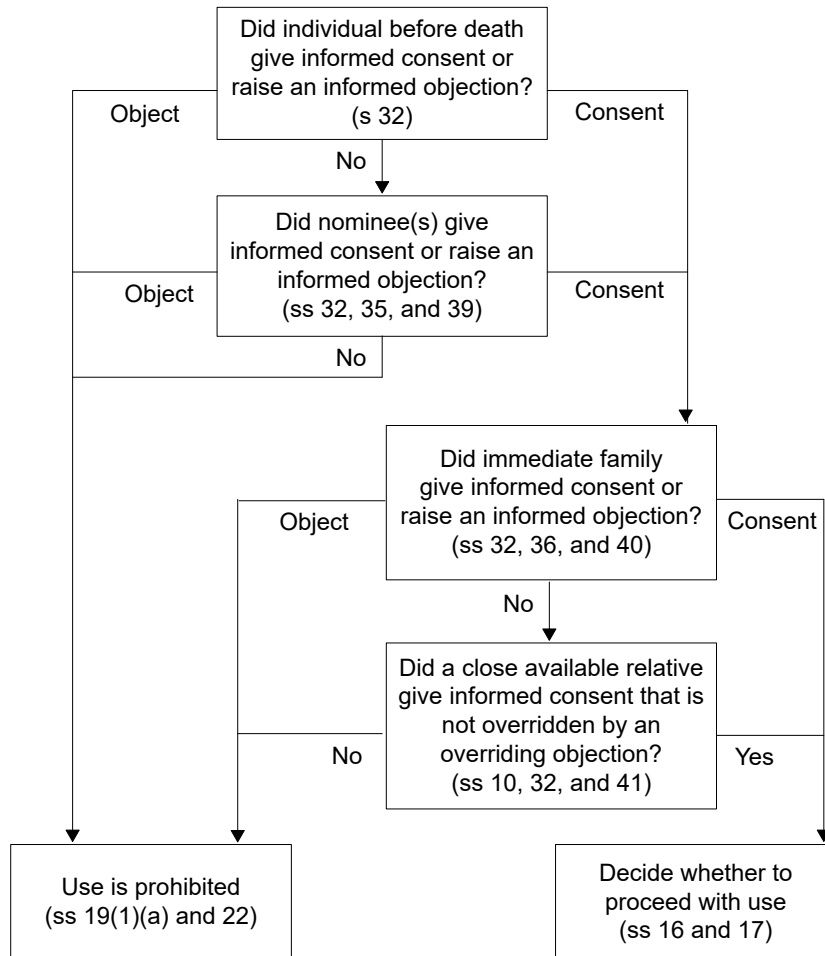


- Persons proposing to collect or use tissue must comply with s 14.
- In determining whether consent or an objection is informed consent, an informed objection, or an overriding objection, see in particular ss 9, 26-30, 37, 38, and 43.

## Schedule 2

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

s 5(2)

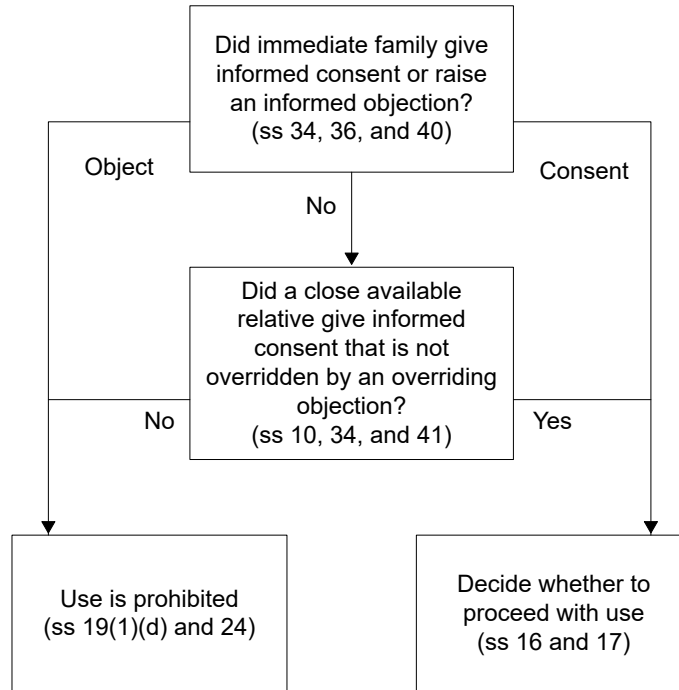


- Persons proposing to collect or use tissue must comply with s 14.
- In determining whether consent or an objection is informed consent, an informed objection, or an overriding objection, see in particular ss 9, 26-30, 37, 38, and 43.
- Examination and some display of bodies of individuals under 16 years is prohibited: s 51.

### Schedule 3

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

s 5(3)



- Persons proposing to collect or use tissue must comply with s 14.
- In determining whether consent or an objection is informed consent, an informed objection, or an overriding objection, see in particular ss 9, 26-30, 37, 38, and 43.



**Schedule 4**  
**Form of search warrant**

s 69

*Warrant under section 69(2) of Human Tissue Act 2008 to enter dwellinghouse  
or marae*

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

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 2008 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 the Human Tissue Act 2008,—

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 68 of that Act.

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

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

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

## Schedule 5

### Incorporation of standards in regulations by reference

s 76

#### 1 Regulations may incorporate standards by reference

- (1) Regulations under section 74 or 75 that approve standards (for example, New Zealand standards) may incorporate those standards by reference.
- (2) Standards may be incorporated by reference in the regulations—
  - (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 74 or 75 have legal effect as part of those regulations.

Compare: 1956 No 65 s 112ZG

#### 2 Effect of amendments to, or replacement of, standards incorporated by reference in regulations

An amendment to, or replacement of, standards incorporated by reference in regulations under section 74 or 75 (the **initial regulations**) has legal effect as part of the initial regulations only if—

- (a) the amendment or replacement material is made by the person or organisation originating the incorporated material; and
- (b) the amendment or replacement material is of the same general character as the material amended or replaced; and
- (c) regulations made under section 74 or 75 after the making of the initial regulations state that the particular amendment or replacement has that effect.

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—
  - (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.

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 74 or 75 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.

Compare: 1956 No 65 s 112ZJ

## 5 Requirement to consult

- (1) This clause applies to regulations made under section 74 or 75 that—
  - (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) 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
  - (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
  - (c) make copies of the proposed standards available for purchase at a reasonable price; and
  - (d) give notice in the *Gazette* stating that—
    - (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
    - (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
  - (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

- (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.
- (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—
  - (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
  - (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
  - (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
    - (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
    - (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.
- (2) The standards are—
  - (a) standards incorporated by reference in regulations under section 74 or 75;
  - (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.
- (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**

*[Repealed]*

Schedule 5 clause 7: repealed, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

**8 Application of Regulations (Disallowance) Act 1989 to standards incorporated by reference**

*[Repealed]*

Schedule 5 clause 8: repealed, on 28 October 2021, by section 3 of the Secondary Legislation Act 2021 (2021 No 7).

**9 Application of Standards and Accreditation Act 2015 not affected**

Clauses 1 to 8 do not affect the application of sections 29 to 32 of the Standards and Accreditation Act 2015.

Schedule 5 clause 9: replaced, on 1 March 2016, by section 45(1) of the Standards and Accreditation Act 2015 (2015 No 91).

## Schedule 6

### Consequential amendments

s 92

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

Section 39(c)(ii): omit “Human Tissue Act 1964” and substitute “Human Tissue Act 2008”.

Section 40(1)(b) and (4): omit “Human Tissue Act 1964” and substitute in each case “Human Tissue Act 2008”.

Section 42(2)(b): omit “Human Tissue Act 1964” and substitute “Human Tissue Act 2008”.

Section 51(2)(b) and (3)(c): omit “Human Tissue Act 1964” and substitute in each case “Human Tissue Act 2008”.

#### **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.

#### **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).

#### **Health Act 1956 (1956 No 65)**

Section 22E: omit “section 92H” and substitute “section 63 of the Human Tissue Act 2008”.

#### **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 2008”.

Section 100(2)(vii): omit “Human Tissue Act 1964” and substitute “Human Tissue Act 2008”.

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

Section 55(1)(b): omit “section 92A of the Health Act 1956” and substitute “section 55 of the Human Tissue Act 2008”.

Section 55(1)(b): omit “section 92H” and substitute “section 63”.

Section 55(3): omit “Part 3A of the Health Act 1956” and substitute “section 55 of the Human Tissue Act 2008”.

Section 65(4)(b): omit “within the meaning of Part 3A of the Health Act 1956” and substitute “as defined in section 55 of the Human Tissue Act 2008”.

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

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

## Notes

### **1** *General*

This is a consolidation of the Human Tissue Act 2008 that incorporates the amendments made to the legislation so that it shows the law as at its stated date.

### **2** *Legal status*

A consolidation is taken to correctly state, as at its stated date, the law enacted or made by the legislation consolidated and by the amendments. This presumption applies unless the contrary is shown.

Section 78 of the Legislation Act 2019 provides that this consolidation, published as an electronic version, is an official version. A printed version of legislation that is produced directly from this official electronic version is also an official version.

### **3** *Editorial and format changes*

The Parliamentary Counsel Office makes editorial and format changes to consolidations using the powers under subpart 2 of Part 3 of the Legislation Act 2019. See also PCO editorial conventions for consolidations.

### **4** *Amendments incorporated in this consolidation*

Legislation Act (Amendments to Legislation) Regulations 2021 (LI 2021/247): regulation 77

Secondary Legislation Act 2021 (2021 No 7): section 3

Public Service Act 2020 (2020 No 40): section 135

Privacy Act 2020 (2020 No 31): section 217

Customs and Excise Act 2018 (2018 No 4): section 443(3)

District Court Act 2016 (2016 No 49): section 261

Standards and Accreditation Act 2015 (2015 No 91): section 45(1)

Search and Surveillance Act 2012 (2012 No 24): section 258

Criminal Procedure Act 2011 (2011 No 81): section 413

Land Transport (Road Safety and Other Matters) Amendment Act 2011 (2011 No 13): section 100(3)

Human Tissue Act 2008 Commencement Order 2008 (SR 2008/311)