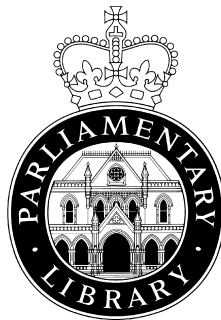


# BILLS DIGEST

**HUMAN TISSUE BILL 2006**

**Date of Introduction: 07 November 2006**

**Bills Digest No. 1447**



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**HUMAN TISSUE BILL 2006**

Date of introduction:	07 November 2006
Portfolio:	Health
Select Committee:	As at 14 November, 1 <sup>st</sup> reading not held

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**PURPOSE**

“This Bill replaces the Human Tissue Act 1964 (the 1964 Act), and regulates collection and use of tissue from dead human bodies. It also regulates trading in tissue, export and import of tissue, and use of tissue for non-therapeutic purposes (for example, audit, research, education, and anatomical examination). Further, while collection and use of tissue from living people is largely covered by existing legislation and common law, the Bill also requires informed consent for:

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

The Bill also gives examples of lawful collection and use of human tissue”<sup>1</sup>.

**BACKGROUND****Key elements of the Bill**

“Key elements of the Bill include:

- establishing a consent framework for the collection and use (for both therapeutic and non-therapeutic uses, and including retention and disposal) of human tissue from bodies;
- a requirement, subject to some exceptions, for informed consent for analysis of tissue taken from living people where the Code of Health and Disability Services Consumers’ Rights 1996 does not apply, and the analysis is for the purpose of obtaining genetic or other information about a particular actual or potential condition, or trait, of the donor;
- a requirement, subject to some exceptions, for informed consent for use for a secondary purpose, after the donor's death, of tissue taken from a living person;

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<sup>1</sup> Human Tissue Bill, 2006 No 82-1, Explanatory Note, General policy statement, p. 1.

- repealing Part 3A of the Health Act 1956, which regulates trading in blood and controlled human substances, and replacing it with similar but extended provisions covering, for example, trading in all human tissue;
- power to make regulations prescribing or approving standards for collection or use of human tissue for audit, education, research, or other non-therapeutic purposes;
- power to make regulations controlling export and import of human tissue<sup>2</sup>; and the
- creation of a consent framework for collection and use of human tissue.

## MAIN PROVISIONS

### What is human tissue?

The Bill provides that human tissue is material that:

- is, or is derived from, material collected from a living individual or from a body<sup>3</sup>; and
- is or includes human cells; and
- is not excluded, for the purposes of some or all of the provisions of this Bill because it is an “in vitro<sup>4</sup> human embryo” or an “in vitro human gamete” or human cell lines.

The Bill provides that an “in vitro human embryo” or an “in vitro human gamete” is not human tissue for the purposes of any provision of the Act, and that human cell lines are human tissue only for the purposes of Clauses 48 and 76 (standards for collection and use of human tissue for non-therapeutic purposes) and Clauses 63 and 77 (standards for export and import of human tissue) (*Part 1, Clause 6*).

### Appropriate consent and informed consent

The Bill defines “appropriate consent” as the informed consent (if any) that the Bill requires for the relevant collection or use of human tissue. Informed consent, in relation to any collection, or use, of human tissue, means consent:

- to that kind of collection or use of the tissue (and so does not include agreement in general terms, given by an applicant for, or holder of, a driver licence, to be an organ donor); and

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<sup>2</sup> Human Tissue Bill, 2006 No 82-1, Explanatory Note, General policy statement, p. 2.

<sup>3</sup> A “body” is a “dead human body” or “the body of a still-born or other dead foetus” (*Part 1 of the Bill, Clause 5, definition of “body”*).

<sup>4</sup> “in vitro”, in relation to an embryo or gamete, means an embryo or gamete that is outside a living organism (*Part 1 of the Bill, Clause 5, definition of “in vitro”*).

- given by an individual (a decision-maker) that the Bill recognises as a (or the) individual who is entitled to consent to that kind of collection or use of the tissue; and
- given by the decision-maker freely, and after he or she has received all information that a reasonable person, in the decision-maker's circumstances, needs in order to give informed consent (both of which matters are presumed, in the absence of evidence to the contrary, under Clause 44 (see below)); and
- given, and not later revoked, in accordance with the Bill (*Part 1, Clause 7*).

### **Who is the “responsible person” in relation to a body?**

The Bill defines the responsible person, in relation to a body, as “the person lawfully in possession of the body” and specifies the persons lawfully in possession of bodies of specified kinds (e.g. a prison manager is the person lawfully in possession of a body that is the body of a prisoner and which is “lying in the prison”; the person for the time being in charge of a “hospital care institution” is the person lawfully in possession of “a body lying in that institution”) (*Part 2, Clause 8; Schedule 1 of the Bill*).

### **Tissue collected from living people by health practitioners**

The Bill provides that the collection or use of human tissue is lawful if done by or on behalf of a health practitioner for the purpose of the practice of his or her profession and that tissue is:

- collected from a health consumer or disability services consumer, or used after being so collected, and collected or used in accordance with the Code of Health and Disability Services Consumers' Rights prescribed by regulations made under Section 74(1) of the Health and Disability Commissioner Act 1994; or
- non-consumer human tissue collected or used with appropriate consent (as defined in Clause 7 of the Bill (see above)); or
- collected lawfully from a living individual for a lawful purpose and used, for a secondary purpose and after the donor's death, with appropriate consent (as so defined (see above)) (*Part 2, Subpart 1, Clause 11*).

### **Tissue collected by medical practitioner performing post-mortem**

The Bill provides that collection or use of human tissue is lawful if done by, or in accordance with the instructions of, a medical practitioner for the purposes of a lawful post-mortem of a body and that tissue is:

- collected from the body; and
- collected or used with appropriate consent (as defined in clause 7 (see above)) (*Part 2, Subpart 1, Clause 12*).

**Tissue from bodies for therapeutic purposes, medical education, or research**

The Bill provides that collection or use of human tissue is lawful if done for therapeutic purposes or for medical education or research and that tissue is:

- collected from a body by a qualified person (in accordance with Clause 50 (see below)); and
- collected or used with appropriate consent (as defined in Clause 7 (see above)) (*Part 2, Subpart 1, Clause 13*).

**Other collections lawful**

The Bill provides that the following are lawful:

- collection or use by or on behalf of a school of anatomy, for the purposes of the study and practice, in accordance with the Bill, of the science of anatomy, of tissue that is, or is collected from, a body and that is collected or used with appropriate consent (as defined in Clause 7 (see above)) (*Part 2, Subpart 1, Clause 14*);
- collection or use by or on behalf of the responsible person for the purposes of the burial, cremation, or other lawful disposal of tissue that is, or is collected from, a body (*Part 2, Subpart 1, Clause 15*);
- use of existing holdings of human tissue of educational, historical, or other cultural significance and, in particular, the use of human tissue if done by or on behalf of a museum, educational or research institution, or similar organisation and it is done for preservation, education, research, testing (including donor analysis), and public display, or for any of those purposes, pending lawful disposition or lawful disposal and, on the repeal of the 1964 Act, that tissue had been collected from living people or from bodies, and was being used for all or any of those purposes by the organisation concerned<sup>5</sup> (*Part 2, Subpart 1, Clause 16(1)*);
- use of human tissue done for a purpose that is lawful in New Zealand if that tissue was collected outside New Zealand and imported in accordance with Clause 63 of the Bill (standards, etc, for export and import of human tissue) (*Part 2, Subpart 1, Clause 17*).

**No collection without consent**

The Bill prohibits the collection or use of human tissue from bodies for a purpose that is not a secondary purpose without appropriate consent. However, such consent is not required for certain purposes (for example, no consent is required for collection or use of human tissue from bodies for the purposes of the prevention, detection, investigation, prosecution, or punishment of offences or for the purposes of

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<sup>5</sup> Clause 16(2) gives examples of tissue of that kind. Such human tissue includes ancient human remains, ancient tattooed dried human heads (toi moko or moko mokai), ancient artefacts, (for example, flutes) made from human bone, and human tissue on or in military uniforms, or military equipment, of historical interest.

performing a post-mortem ordered by certain officers such as a coroner or by the High Court). The Bill also prohibits the use of human tissue from a body for a secondary purpose without appropriate consent. However such consent is not required in certain circumstances such as for testing or disposal of tissue if that testing or disposal is necessary to avoid endangering the health or safety of members of the public (*Part 2, Subpart 2, Clauses 20 - 23*).

### **Consent required for donor analysis of all non-consumer human tissue**

The Bill prohibits the collection of non-consumer human tissue for donor analysis, carrying out donor analysis of non-consumer human tissue, or both, without appropriate consent<sup>6</sup>. However, certain kinds of collection of non-consumer human tissue for donor analysis, carrying out of donor analysis of non-consumer human tissue, or both, are exempt from this provision. (*Part 2, Subpart 3, Clauses 24 and 25*).

### **Consent for collection from living person for secondary purpose after death**

The Bill prohibits the use of tissue from a living individual for a secondary purpose after the donor's death without appropriate consent. However certain kinds of use for a secondary purpose, after the donor's death, of human tissue from a living individual are exempt from this provision (*Part 2, Subpart 4, Clauses 26 and 27*).

### **Consent to the collection, use, and secondary use of human tissue from bodies**

The Bill specifies who may give consent to the collection, use, and secondary use of human tissue from bodies. The person or persons entitled to give informed consent differ depending on the purpose of the collection and use of the tissue. For collection or use of human tissue from a body for a purpose or secondary purpose that is not anatomical examination, public display, or both, the informed consent required is informed consent given

- by the individual concerned, before his or her death; or
- if no consent can be given in that way, by that individual's nominee or nominees; or

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<sup>6</sup> The term “non-consumer human tissue” “... means human tissue that is, or is derived from, human tissue that is collected from a living individual, but is neither:

- collected from a consumer in the course of a health care procedure; nor
- derived from human tissue collected in that way (*Part 1, Clause 5, definition of non-consumer human tissue*”).

The term “consumer” “... means a health consumer or disability services consumers, as those terms are defined in section 2(1) of the Health and Disability Commissioner Act 1994” (*Part 1, Clause 5, definition of “consumer”*”).

The term “donor analysis” in relation to human tissue “... means analysis for the purpose of providing information (including genetic information) about an actual or potential condition or trait of the individual from whom, or from whose body, the tissue was collected (*Part 1, Clause 5, definition of “donor analysis”*”).

- if no consent can be given in either of those ways, by that individual's "immediate family"<sup>7</sup>;
- if no consent can be given in either of those ways and if that individual's immediate family declines to give consent, by a "senior available next of kin" of that individual (*Part 2, Subpart 5, Clause 28; Clause 34(2) and Schedule 2 of the Bill (governing the determination of senior available next of kin of dead individual)*).

### **Person entitled to give consent for donor analysis of non-consumer human tissue**

The Bill provides that, for the collection of non-consumer human tissue for donor analysis, carrying out of donor analysis of non-consumer human tissue, or both, the informed consent required is informed consent given by the individual from whom the tissue concerned was collected or derived. His or her death does not affect the validity of the consent (*Part 2, Subpart 6, Clause 30*).

### **Other matters**

The Bill makes comprehensive provision for:

- the giving or making, and recording, of consents, nominations, and other matters (*Part 2, Subpart 5, Clauses 32 – 41*);
- ascertaining whether appropriate consent exists and may be acted on (*Part 2, Subpart 5, Clauses 42 – 47*);
- the collection and use of tissue for non-therapeutic purposes (*Part 2, Subpart 6, Clause 48*);
- post-mortems (*Part 2, Subpart 6, Clause 49*);
- the collection of tissue from bodies for use for therapeutic purposes or for medical education or research (*Part 2, Subpart 6, Clause 50*);
- anatomical examinations (*Part 2, Subpart 6, Clauses 51 and 52*);
- rules for the observance of decency ("A person who performs a post-mortem or anatomical examination, or collects tissue from a body ... must ... do so in

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<sup>7</sup> The term "immediate family", in relation to a dead individual, " ... means members of the individual's family, whanau, or other culturally recognised family group, who ... were in a close relationship with the individual ... or ... 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 ... to avoid doubt, includes a person whose relationship to the dead individual was, or was through, 1 or more relationships that are, that or those of:

- spouse, civil union partner, or de facto partner of the individual;
- child, parent, guardian, grandparent, brother, or sister of the individual;
- stepchild, step-parent, stepbrother, or stepsister of the individual (*Part 1, Clause 5, definition of "immediate family"*).

a manner that avoids unnecessary mutilation of the body that is being examined, or from which the collection is being effected ... and ... conduct the examination or collection in an orderly, quiet, and decent manner”) (*Part 2, Subpart 6, Clause 53*);

- rules for the trading of human tissue (*Part 2, Subpart 6, Clauses 54 – 62*);
- technical and miscellaneous provisions (including enforcement provisions, offences and penalties, the making of regulations and Orders in Council, the appointment, functions and powers of inspectors of schools of anatomy) (*Part 3, Clauses 64 – 95; Schedule 5 (governing the incorporation of standards in regulations made under Clauses 76 and 77 by reference)*).