

Unofficial translation  
August 28, 2001

**No. 101/2001**

**Act**

**on the Medical Use of Human Organs and Tissues**

Issued in Helsinki, February 2, 2001

By decision of Parliament, the following is enacted:

Chapter 1

**General provisions**

Section 1

*Scope of application*

This Act lays down provisions on the following:

- 1) removal, storage and use of human organs and tissues for the treatment of human disease or injury;
- 2) retention, storage and use for medical purposes of organs and tissues removed during diagnosis and treatment of human disease;
- 3) use of human embryos for a purpose other than fertility treatment or medical research;
- 4) use of human organs, tissues and tissue samples for a purpose other than that for which they were removed or retained;
- 5) use of a cadaver for medical teaching and research.

Separate provisions will be issued concerning removal during diagnosis, treatment or medical research of organs and tissues needed in order to establish cause of death. The same applies to the retention of blood and the use of gametes for fertility treatment.

## Chapter 2

### **Removal of organs and tissues from living donors for transplantation**

#### Section 2

##### *General preconditions*

Organs and tissues may be removed from donors who have given their consent in order to treat human disease or injury. Removed organs and tissues may be stored for future use.

Organs and tissues may only be removed if this does not cause the donor any major health hazard or serious harm, if there is no treatment available for the recipient as effective as transplantation, and if no suitable organ or tissue from a dead donor is available, or the prognosis is expected to be appreciably better than the prognosis of transplantation from a deceased donor.

Doctors treating recipients may not be involved in decisions concerning the removal of organs or tissues.

#### Section 3

##### *Consent of the donor*

Donors must give informed written consent to the removal of an organ or tissue. They are entitled to withdraw consent at any time before removal of the organ or tissue, without being required to state any reason.

Before giving written consent, donors must be provided with an explanation of the significance of the procedure for themselves and the recipients, and be informed that their consent can be withdrawn at any time before the organ or tissue is removed. The donor's personal

physician contributing to the decision to donate must personally make the explanation to the donor.

If the donor is under-age or, though of age, does not have the capacity to decide on his/her treatment because of disease, mental disorder or some other reason (*incapacitated*), the written consent of his/her legal representative must be obtained before the removal takes place. However, no organ or tissue may be removed if the person concerned objects. The donor's personal physician contributing to the decision to donate must personally make the explanation referred to in paragraph 2 to the donor's legal representative. The physician must also establish the views of an under-age or incapacitated donor in so far as the donor's age and developmental level permit.

#### Section 4

##### *Removal of non-regenerative organs or tissues*

Adult persons able to decide about their treatment may donate non-regenerative organs or tissues only to treat disease or injury in a near relative or other person close to them.

A permit from the National Board of Medicolegal Affairs (TEO) is required for all removals of organs or tissues.

#### Section 5

##### *Under-age or incapacitated donors*

Under-age or incapacitated persons may only donate regenerative tissue or part of a regenerative organ to treat disease or injury threatening the life of a sibling if no suitable tissue or organ is available from a deceased or legally competent donor. If the donor is under-age, but of an age and developmental level that allows him/her to decide about personal treatment, the

recipient can be a near relative or other close person. Cells can also be donated in situations other than the above-mentioned if no suitable cells are available from a deceased or legally competent donor.

A permit from the National Board of Medicolegal Affairs (TEO) is required for the removal of tissue or part of an organ.

## Chapter 3

**Retention of organs and tissues**

## Section 6

*General preconditions and restrictions*

Organs and tissues removed from a patient during diagnosis or treatment can be retained and stored for medical use.

Embryos can only be used for fertility treatment or medical research.

## Section 7

*Patient's consent and other preconditions for retention*

The patient's informed written consent is required for the retention of organs or tissues referred to above in section 6, paragraph 1, and for subsequent storage and use. If patients are incapacitated or unable to understand the significance of the matter because of being under-age, the written consent of their legal representative is required for such retention. Patients or their legal representatives are entitled to withdraw consent at any time before ultimate use of an organ or tissue, without stating any reason.

Before giving consent, patients must be provided with an explanation of the purpose and significance of the removal, and informed that they can withdraw their consent before ultimate use of the organ or tissue. The physician treating the patient must personally give an explanation to the patient or his/her legal representative.

If organs or tissues are retained during termination of pregnancy, a permit from the National Board of Medicolegal Affairs (TEO) is required.

## Chapter 4

### **Removal of organs and tissues from a deceased donor**

#### Section 8

##### *General preconditions*

Organs and tissues may be removed from the deceased, and may be stored for later treatment of another person's disease or injury.

Death must be certified as laid down by Ministry of Social Affairs and Health decree.

Physicians who certify death may not be involved in removing organs and tissues.

#### Section 9

##### *Consent*

Organs and tissues of a deceased person may be removed unless there is reason to assume that the person would have objected while still alive, or that a near relative or other close person would object.

If a person has, while alive, given consent to the removal of organs and tissues for the purpose referred to in section 8, paragraph 1, the measure can be performed despite being forbidden by a near relative or other close person.

#### Section 10

##### *Restrictions on removal*

Organs and tissues may not be removed if this impedes investigation of the cause of death.

No action may be taken to remove organs or tissues if the police have to carry out an investigation to establish the cause of death and object to such removal, or if removal would materially impede forensic investigation of the cause of death.

## Chapter 5

**Medical research and teaching in connection with post-mortem examination**

## Section 11

*Preconditions for research and teaching*

With a permit from the National Board of Medicolegal Affairs (TEO), cadavers can be used during post-mortem examination, and organs and tissues removed, for medical research and teaching other than that related to investigation of the cause of death.

## Section 12

*Restrictions on research and teaching*

A cadaver may not be used, nor organs or tissues removed, for research and teaching purposes if this impedes investigation of the cause of death or removal of organs and tissues as laid down in this Act for treatment of human disease or injury. Research and teaching may not be initiated if the police need to carry out an investigation to establish the cause of death and object to initiation of the said research and teaching.

All research and teaching must be carried out with respect for the deceased and in a way that does not materially change the deceased's appearance. Research and teaching may not be carried out if there is reason to assume that the deceased would have objected while still alive.

## Section 13

*Surrender of cadavers for teaching purposes*

Cadavers may be donated to university departments of anatomy for medical teaching purposes if the deceased

gave written consent for such surrender while still  
alive.

## Chapter 6

**Provisions concerning activities**

## Section 14

*Origin and safety of organs and tissues*

Only human organs and tissues, and products made from them, the safety of which has been tested using appropriate methods, and whose origin can be traced, may be used to treat human disease or injury.

Imported organs and tissues and products made from them may only be used to treat human disease or injury if the preconditions concerning the donor and the donation laid down in this Act are fulfilled.

## Section 15

*Safeguarding the quality of activities*

Health care units or other units engaging in removal, retention or storage as referred to in this Act, or using human organs and tissues removed, retained or stored in accordance with this Act, must have appropriate facilities and equipment, and the necessary personnel.

## Section 16

*Organ and tissue registers*

A register shall be kept in order to supervise the safety and traceability of human organs and tissues removed, retained and stored for the treatment of human disease or injury and the legality of said removal, retention, storage and use. The register shall be kept by a health care unit or other unit storing human organs and tissues for the treatment of human disease or injury and using them for organ and tissue transplants. The Finnish Red

Cross may keep a register of voluntary bone marrow donors.

The register shall contain the following information: the name and social security number or other identification code of the donor and recipient, the necessary contact data, test results on the organ or tissue concerned, information on the donor and recipient related to safe use of organs and tissue, information on the health care units involved in removing, storing and using organs and tissues, information on provision of organs or tissues for a purpose other than that for which they were removed or retained, and data on National Board of Medicolegal Affairs (TEO) permits for removal of organs and tissues, and on the donor's or patient's consent to removal or retention of organs and tissues.

The information in the register shall be kept for 50 years from the death of a donor or, if there is no data on the death, for 100 years from the most recent register entry. If a donor withdraws consent, the register keeper must so inform the unit receiving the organ or tissue. The information on the donor must then be removed from the organ or tissue transplantation register unless there is some other reason under the law to retain it.

#### Section 17

##### *Provision of information from the register*

Information deposited in the register, other information concerning donors and recipients, and documents concerning them, shall be considered confidential.

Notwithstanding the confidentiality provisions, the register keeper shall provide another health care unit or other unit involved in the activities referred to in paragraph 1 with any information in the register needed to ensure safe use of an organ or tissue. On request, the

register keeper shall also provide an authority regulating and supervising the activities referred to in this Act with information from the register. What is provided in the Act on the Openness of Government Activities (621/1999) also applies to the provision of information.

Notwithstanding the confidentiality provisions, the register keeper is entitled to obtain information needed to ensure the safety and traceability of organs and tissues from a health care unit or other unit removing, retaining, storing or using human organs and tissues, or caring for a donor or recipient.

No charge may be made for provision of the information referred to in paragraphs 2 and 3 above.

#### Section 18

##### *Remuneration and prohibition on commercialization*

No donor or assignee of a donor may be promised or paid a fee for the removal and use of an organ or tissue as laid down in this Act, or for the donation of a cadaver.

The donor of an organ or tissue who suffers lack of income for a whole day because of removal of an organ or tissue as referred to in this Act to meet a vital transplantation need or for essential related tests and examinations, and does not get paid or receive corresponding compensation for this period, is entitled to a daily allowance as provided concerning daily allowance in the Sickness Insurance Act (364/1963). The daily allowance will be paid for every weekday notwithstanding section 19 of the said Act.

A health care unit or other unit involved in removing, retaining, storing or using organs and tissue may not pursue financial gain from the activities provided for in

this Act. However, the health care unit or other unit may charge another health care unit for handling and transporting organs and tissues, and for carrying out the tests needed to ensure safety and for providing storage. The charge made may not exceed the total cost of producing the service.

#### Section 19

##### *Change of purpose for which organs and tissue will be used*

An organ or tissue from a living person which is removed, retained or stored, and cannot for some medical reason be used for the purpose originally planned, may be used for some other justifiable medical purpose with the donor's consent. If the organ or tissue has been removed from an under-age or incapacitated person, the consent of his/her legal representative is required.

If the removal or retention of an organ or tissue requires a permit from the National Board of Medicolegal Affairs (TEO), a change of purpose requires not only the consent referred to in paragraph 1 but also a permit from the aforesaid Board.

An organ or tissue removed or retained from a cadaver that cannot, for a medical reason, be used for the purpose for which it was originally removed may be used for some other justifiable medical purpose only with a permit from the National Board of Medicolegal Affairs (TEO).

#### Section 20

##### *Change in purpose for which tissue samples will be used*

Tissue samples taken for therapeutic or diagnostic purposes may be surrendered and used for medical research with the patient's consent. If the person is under-age or

incapacitated, consent must be obtained from his/her legal representative. The National Board of Medicolegal Affairs (TEO) may, however, grant permission for the surrender or use of tissue samples taken for therapeutic or diagnostic purposes or to establish the cause of death in situations in which the person's consent is impossible to obtain because of the large number of samples, the age of the samples or other such reason, or because the person has died.

Tissue samples taken for medical research purposes may be surrendered and used for medical research other than that stated in the consent document only with the consent of the person concerned. If the said person has died, the National Board of Medicolegal Affairs (TEO) may, however, grant permission for such research if justifiable cause exists.

Tissue samples taken for therapeutic or diagnostic purposes, or to establish the cause of death, may be surrendered and used for medical research and teaching purposes with permission from the health care unit or other unit for whose activities the sample was taken as long as no personal data are used in the surrender or use situation.

Tissue samples taken for therapeutic, diagnostic or medical research purposes may be surrendered and used to establish the hereditary character of a disease diagnosed in another person only if the person from whom the sample was taken gives his/her consent. If the person is under-age or incapacitated, consent must be obtained from his/her legal representative. If the person has died or the tissue sample was taken in order to establish the cause of death, the health unit or other unit for whose activities the sample was taken shall decide whether to surrender the tissue sample, unless the deceased specifically prohibited this while alive.

Tissue samples taken for therapeutic or diagnostic purposes, to establish the cause of death, or for medical research can be surrendered in order to establish paternity to a research institution specified by a court of law or some other authority.

Tissue samples taken for therapeutic or diagnostic purposes, or to establish the cause of death, may not be surrendered or used for any purpose other than that for which they were taken if this will hamper their use for the original purpose.

## Chapter 7

**Miscellaneous provisions**

## Section 21

*Definition of death*

A person is considered to be dead when brain function has totally ceased.

## Section 22

*Permits*

The National Board of Medicolegal Affairs (TEO) can grant the permit referred to in section 4, paragraph 2, and section 5, paragraph 2, if the preconditions for removal laid down in this Act have been met and removal of the organ or tissue is justified in terms of the recipient's treatment.

The National Board of Medicolegal Affairs (TEO) can grant the permit referred to in section 7, paragraph 3, section 11, section 19, paragraphs 2 and 3, and section 20, paragraphs 1 and 2, if the activity can be considered medically justified, there are appropriate facilities, equipment and personnel, and a responsible physician has been appointed for the activity. The Board can grant a permit for a fixed or indefinite period, and more detailed conditions concerning how the activity is arranged can be appended to the permit.

## Section 23

*Supervision of activities and withdrawal of permits*

The National Board of Medicolegal Affairs (TEO) can order the activities referred to in section 7, paragraph 3, section 11, section 19, paragraphs 2 and 3, and section 20, paragraph 1, to be suspended, or withdraw a permit

granted for the activities referred to in the above provisions, if current provisions or permit conditions are not being observed in the activities.

If necessary, the National Board of Medicolegal Affairs (TEO) can order performance of an inspection of the facilities and activities of an establishment that has been granted a permit, and of documents needed for supervisory purposes.

A decision to withdraw a permit must be complied with even if it has been appealed.

#### Section 24

##### *More detailed provisions*

More detailed provisions on the preconditions for grant of the permits referred to in this Act and on enforcement of the Act will be issued by Government Decree.

The Ministry of Social Affairs and Health will issue more detailed provisions and instructions as necessary concerning the following:

- 1) the arrangement of removal, retention, storage and use of organs and tissues and tissue samples at health care units and other units;
- 2) compensation for the costs of health care units or other units;
- 3) entries to be made in the organ and tissue transplantation register and patients' medical records.

The Ministry of Social Affairs and Health must approve the content of the necessary forms.

#### Section 25

##### *Penal provision*

Whosoever knowingly

- 1) removes, retains or stores an organ or tissue without the consent or permit laid down in this Act;
  - 2) surrenders a removed, retained or stored organ, such tissue or tissue sample, or uses it without the consent, permit or request laid down in this Act;
  - 3) fails to keep the personal register needed to supervise the traceability and safety of organs, and activities, as laid down in this Act;
  - 4) uses for human treatment organs or tissues or products made of them whose origin is unknown or whose safety has not been established;
  - 5) imports into Finland organs or tissues that have been removed or retained contrary to the preconditions on donors laid down in this Act, or imports into Finland organs or tissues from states whose legislation does not meet the preconditions laid down in this Act regarding the removal and traceability of organs; or
  - 6) promises or pays an organ donor or his/her assignee a fee for removal of organs or tissues,
- shall be sentenced to a fine *for violation of the provisions on medical use of human organs and tissues*, unless more severe punishment is provided for the act elsewhere in the law. The act referred to in subparagraph 3 above is also punishable if it occurred through gross negligence.

## Section 26

### *Appeal*

A National Board of Medicolegal Affairs (TEO) decision can be appealed as provided in the Administrative Judicial Procedure Act (586/1996).

A National Board of Medicolegal Affairs (TEO) decision as referred to in sections 4 and 5 of this Act cannot be appealed.

## Chapter 8

**Entry into force**

## Section 27

*Implementing and transitional provisions*

This Act comes into force on September 1, 2001.

This Act repeals the Act of April 26, 1985, on the removal of human organs and tissues for medical purposes (355/1985), and all later amendments.

The operating permits required in this Act must be applied for within one year of the Act's entry into force.

Measures necessary for the implementation of this Act can be undertaken before its entry into force.

Helsinki, February 2, 2001

**President of the Republic**

**TARJA HALONEN**

Minister of Health and Social Services *Osmo Soininvaara*