

NB: Unofficial translation, legally binding only in Finnish and Swedish.

Ministry of Justice, Finland

Act on Assisted Fertility Treatments (1237/2006)

In accordance with a decision of Parliament the following is enacted:

Chapter 1

General provisions

Section 1

Scope of application

This Act applies to the provision of assisted fertility treatment in which a human gamete or an embryo is placed in a woman for the purpose of creating a pregnancy. This Act also applies to the donation and storage of gametes and embryos for use in assisted fertility treatment.

The provisions of this Act concerning gametes also apply to the pre-stages of gametes.

For purposes of this Act, the inserting in a woman of the untreated and unstored sperm of man without the professional involvement of a person entitled to practise as a physician or of another outsider against compensation shall not be considered assisted fertility treatment.

Section 2

Definitions

For purposes of this Act

- 1) *couple* means woman and man living together in marriage or in a relationship comparable to marriage;
- 2) *person receiving treatment* means a couple or a woman not living in marriage or in a relationship comparable to marriage
- 3) *donation of gametes* means the donation of one's own sperm or eggs for use in assisted fertility treatment provided to another;
- 4) *donor* means a person who donates his/her gametes;

5) *service provider* means a healthcare unit and physician holding a licence referred to in section 24

6) *healthcare unit* means a health centre as referred to in the National Health Act (66/1972), hospital and separate medical care unit as referred to in the Act on Specialized Medical Care (1062/1989), other entity with responsibility for care as decided by the hospital district joint municipal board and healthcare services provider as referred to in the Act on Private Healthcare (152/1990).

Section 3

Use of gametes and embryos in assisted fertility treatment

Subject to the provisions of this Act, the gametes and embryos of the person receiving treatment as well as gametes and embryos donated in accordance with this Act may be used in assisted fertility treatment.

Imported gametes and embryos may be used in assisted fertility treatment when the requirements laid down in this Act in respect of donor, donation and donated gametes and embryos are met.

Section 4

General restrictions on use of gametes and embryos

The following may not be used in assisted fertility treatment:

- 1) genetically manipulated gametes and embryos,
- 2) cloned embryos, and
- 3) gametes and embryos which have been used in research.

For purposes of this Act, the following are not considered research:

- 1) the observation of gametes and embryos intended for assisted fertility treatment or other procedure on such gametes and embryos whose purpose is to maintain or improve the viability of these if such observation or other procedure does not jeopardise the natural development of the embryos, and
- 2) a procedure which without jeopardising the natural development of a gamete or an embryo allows to verify that they do not carry a certain serious inherited disease or to confirm the embryo's sex for the purpose referred to in section 5.

When the gametes of a donor have provided progeny to five recipients of assisted fertility treatment, the gametes donated by that person may no longer be used in assisted fertility treatment given to others.

Section 5

Influencing the characteristics of the child

The characteristics of the child to be born as a result of assisted fertility treatment may be influenced through selection of gametes or embryos or by other means only in the cases referred to in subsections 2 and 3 hereunder.

The health of the child to be born may be influenced by selecting gametes or embryos that have been verified to be free of serious disease. Determination of the child's sex may be influenced if the gametes used in the assisted fertility treatment are the couple's own and the child born from these gametes would be at substantial risk of serious disease if the child were to be of the other sex.

If donated gametes are used in the assisted fertility treatment, the attending physician shall select gametes whose donor resembles in appearance the respective parent of the child to be born, unless otherwise requested by the person receiving treatment.

Section 6

Disposal of gametes and embryos

Stored gametes and embryos shall be destroyed without delay once the service provider becomes aware of the death of the person whose gametes are concerned or either of the persons whose gametes gave rise to the embryos.

Gametes and embryos stored for treatment of one's own infertility shall be destroyed without delay once the service provider receives a request for such disposal from the person whose gametes are concerned or, in respect of embryos, from either of the persons whose gametes gave rise to the embryos.

Donated gametes or embryos shall be destroyed without delay when it has been observed in a physical inspection or by other means that they cannot be used in assisted fertility treatment or when the donor in the manner referred to in section 16(3) has withdrawn his/her consent to the use of the gametes in assisted fertility treatment. Donated gametes and embryos shall nonetheless be destroyed no later than ten years from the collection of the donation.

A service provider shall notify the National Authority for Medicolegal Affairs if it is aware of the gametes of a given donor not having been used in assisted fertility treatment prior to disposal thereof.

Section 7

Use of gametes and embryos for other purposes

The provisions of section 6 notwithstanding, instead of being destroyed, gametes and embryos may be used for another legal purpose if a consent for such use has been obtained from the person or persons whose gametes are concerned or whose gametes gave rise to the embryos.

Chapter 2

Provision of assisted fertility treatment

Section 8

Prohibition on provision of assisted fertility treatment

Assisted fertility treatment may not be provided if:

- 1) the written consent of the person receiving the treatment has not been obtained,
- 2) either party of the couple receiving treatment is married to a third person,
- 3) pregnancy would pose a substantial risk to the health of the woman or the child due to the age or health of the woman,
- 4) a person consenting to the provision of assisted fertility treatment has withdrawn consent or died,
- 5) it is apparent that the child's balanced development cannot be guaranteed, or
- 6) there is reason to presume that the child will be given up for adoption.

Section 9

Service provider's obligation to provide information

Prior to providing treatment, the service provider shall counsel the person receiving treatment on the legal status of the child to be born as a result of treatment and the legal status of the other parties.

In the event that donated gametes or embryos are used in the assisted fertility treatment, the service provider shall furthermore counsel the person receiving treatment on the potential impact which the biological origin of the child to be born as a result of treatment may have on the relations between family members and on ways to prevent or alleviate any problems that may arise. The service provider shall afford an opportunity for the person receiving treatment to discuss these matters with an expert.

The provisions of the Act on the Status and Rights of Patients (785/1992) concerning the patient's right to obtain information shall furthermore apply to the right of the person receiving treatment to obtain information.

Section 10

Consent document of the person receiving treatment

The consent given to assisted fertility treatment shall be formulated into a document (*consent to treatment*), which shall include the following:

- 1) the name and personal identification number of the person(s) giving consent or, if a person lacks a personal identification number, his/her date of birth (*identification data*),

- 2) the method of treatment to which consent is given,
- 3) any conditions that may attach to the provision of treatment,
- 4) the period of validity of the consent;
- 5) confirmation of receipt of the counselling and services referred to in section 9,
- 6) date and signature of the person(s) giving consent and of the service provider receiving consent.

The person giving consent shall be given a copy of the consent to treatment. One copy shall be kept in the archives of the service provider, where it shall be stored separate from any other patient documents concerning the parties. The giver of consent may withdraw consent by notifying the service provider thereof.

Section 11

Decision on assisted fertility treatment

The decision on providing assisted fertility treatment shall be taken by the attending physician after ensuring that the conditions for providing treatment have been met.

Section 12

Notations and certificate of assisted fertility treatment

The method used in assisted fertility treatment, compliance with any conditions imposed and the date(s) of use of the method as well as confirmation of pregnancy shall be noted on the archived copy of the consent to treatment. The service provider shall furnish the person who has received assisted fertility treatment with this data upon request.

The donor code referred to in section 14 shall also be noted on the consent to treatment if donated gametes or embryos have been used in the assisted fertility treatment.

The service provider providing assisted fertility treatment shall notify the service provider which collected the donation when assisted fertility treatment referred to in section 16(2) has resulted in the birth of a child and the sperm of a donor who gave his consent that he may be confirmed as the father of the child born as a result of the treatment was used in that treatment. The party which collected the donation shall notify the donor thereof without delay and inform him of the donor code assigned to him and the service provider which provided the treatment.

Chapter 3

Donation and transfer of gametes and embryos

Section 13

Donor

Gametes may be donated by persons over the age of 18 who pass a physical examination ensuring that:

- 1) the donation of gametes does not pose a health hazard to them, and
- 2) they do not have any serious inherited disease or any communicable disease that may cause a serious illness to the woman receiving assisted fertility treatment or to the child who may be born as a result of assisted fertility treatment.

Section 14

Donor code

Instead of identification data, donors shall be referred to by code only (*donor code*) after being accepted as donor in the physical examination referred to in section 13. The service provider collecting the donation shall enter the donor code on the archived copy of the donor consent referred to in section 17(2) and on the container in which the donated gametes are stored.

If the donor has given consent to confirmation of paternity as referred to in section 16(2), this shall be indicated in the donor code.

Section 15

Information to be collected about the donor

The provisions concerning the protection of personal data notwithstanding, information describing the colour of the donor's skin, eyes and hair as well as the donor's height and ethnic origin may be collected and recorded for the purpose referred to in section 5(3) in connection with the physical examination on the donor. No other information about the donor besides that referred to herein and in section 17 may be collected.

Section 16

Donor consent to use of gametes

A donor's gametes may be used in assisted fertility treatment only if the donor has given such consent to the service provider collecting the donation. Prior to consent, the donor shall be counselled as to the medical and legal ramifications of the donation of gametes.

The gametes of a donor may be used in the assisted fertility treatment of persons other than couples only by the donor's consent. A sperm donor may furthermore give his consent that he may be confirmed as the father of a child to be born as a result of such

treatment, in which case the provisions of section 12(1) regarding provision of information to the person receiving assisted fertility treatment apply to him.

A donor may withdraw the consent referred to in subsections 1 and 2 above. However, such withdrawal carries no effect inasmuch as the donor's gametes have been used in assisted fertility treatment before the service provider providing the treatment has received notification of the withdrawal. The withdrawal shall be made to the service provider which collected the donation. This service provider shall make a dated notation of withdrawal on the donor consent referred to in section 17, provide the donor with a certificate of receipt of the withdrawal and notify without delay the service provider to which donated gametes have been transferred for use in assisted fertility treatment of the withdrawal of consent.

Should the withdrawal concern the consent to confirmation of paternity referred to in subsection 2, both the service provider taking receipt of the withdrawal and the service provider notified thereof shall ensure that any containers containing unused gametes shall be marked with the new donor code issued by the service provider taking receipt of the withdrawal indicating that the donor has not given consent to confirmation of paternity.

A service provider shall keep a register of the gametes it has transferred to another service provider. The register shall indicate the following:

- 1) the code of the donor whose gametes have been transferred,
- 2) the date of the transfer, and
- 3) the name of the service provider to whom the gametes have been transferred.

Section 17

Donor consent document

A document shall be prepared on the donor's consent to the use of his/her gametes in assisted fertility treatment (*donor consent*). The document shall contain the following:

- 1) the donor's identification data,
- 2) confirmation of performance of physical examination referred to in section 13,
- 3) confirmation of receipt of counselling referred to in section 16(1),
- 4) conditions imposed on the use of gametes, if any,
- 5) consent to the assisted fertility treatment referred to in section 16(2), if any,
- 6) consent to confirmation of paternity referred to in section 16(2), if any,
- 7) period of validity of consent, and
- 8) date and signature of donor and service provider receiving consent.

The donor shall be given a copy of the donor consent. A copy shall be filed in the archives of the service provider which collects the donation, where it shall be kept separate from any other patient documents concerning the donor.

Section 18

Notification of information about donor to donation register

The service provider collecting the donation shall without delay notify the donation register referred to in section 22 of the donor's donor code and identification data and specify whether the donation consisted of sperm, eggs or embryos.

The donation register shall be notified of any consent given by the donor to confirmation of paternity as referred to in section 16(2). Should the donor subsequently withdraw such consent, the donation register shall be notified thereof and of the donor's new donor code.

Section 19

Storage and disposal of documents concerning donor

The information about the donor collected in connection with the physical examination referred to in section 13 shall be kept in the archives of the service provider responsible for keeping the donor's donor consent under section 17(2), separate from any other patient documents concerning the said donor.

The donor's identification data, the personal information collected about the donor in connection with the physical examination, the archived copy of the donor consent and the register data referred to in section 16(5) shall be removed from the service provider's archives and destroyed after two years from the use, disposal or transfer for a purpose referred to in section 7 of the donated gametes or embryos. The service provider to which the gametes or embryos were transferred shall without delay notify the transferring service provider of the above measures taken.

Section 20

Donation and transfer of embryos

A couple may donate extra embryos created for use in their own assisted fertility treatment for use in the assisted fertility treatment of another. The consent of both the woman and the man is required for donation, and both shall be considered donors. The provisions herein concerning the donation and transfer of gametes shall apply to the donation and transfer of such embryos.

Donated embryos other than those referred to in subsection 1 may not be accepted for use or used in assisted fertility treatment.

Section 21

Ban on remuneration

No remuneration may be given or promised for the donation of gametes. However, the donor may be paid a reasonable sum in compensation of expenses, loss of income and other inconvenience arising from the donation as provided for in greater detail in the Decree of the Ministry of Social Affairs and Health. Any agreement concerning other remuneration or payment relating to donation shall be null and void.

Chapter 4

Right of person born from donated gamete or embryo to obtain information

Section 22

Donation register

The National Authority for Medicolegal Affairs keeps a register of the donations of gametes and embryos for assisted fertility treatment purposes (*donation register*). The identification data of each donor and information on the donor code, possible consent concerning confirmation of paternity as referred to in section 16(2) and withdrawal thereof and specification as to whether the donation consisted of sperm, eggs or embryos, as notified by the service provider, shall be recorded in this register.

Section 23

Right to obtain information

Non-disclosure provisions notwithstanding, a person who may have been born from a donated gamete or embryo shall, upon attaining the age of eighteen (18), be entitled to obtain from the service provider a copy of the consent to treatment and the donor code noted thereon and, by providing the donation register with the code, to learn the identity of the donor.

In the event that assisted fertility treatment as referred to in section 16(2) has been provided and the donor of the sperm has given his consent that he may be confirmed as the father of the child born as a result of such treatment, the mother and the child are entitled to learn from the service provider the donor code and, by providing the donation register with the code, the identity of the donor.

Chapter 5

Provisions concerning activities

Section 24

Licence

The storage of gametes and embryos and the provision of assisted fertility treatment are subject to a licence from the National Authority for Medicolegal Affairs. A licence may be granted to a healthcare unit or specialised physician in possession of the specialised expertise and personnel required for the activities as well as appropriate facilities and equipment for the activities and submitting a report on the appropriate organisation of the counselling services referred to in section 9. A licence may also be granted to apply only to a specific method of storage or treatment.

Section 25

Storage fees

A service provider may charge for the storage of gametes and embryos at maximum a fee that covers the costs arising from such activity and reasonable remuneration.

Section 26

Information on activities and audit of activities

A service provider shall provide the relevant authorities with information about its activities referred to in this Act for the purposes of supervision, monitoring and compilation of statistics as is provided in further detail by a Decree of the Ministry of Social Affairs and Health.

The National Authority for Medicolegal Affairs may order an audit of activities.

Section 27

Revocation of licence

The National Authority for Medicolegal Affairs may revoke a licence referred to in section 24 in the event of material breaches of the provisions concerning activities in the storage of gametes or embryos or in the provision of assisted fertility treatment. In the event of deficiencies or defects in activities, the National Authority for Medicolegal Affairs may order the suspension of activities until such deficiencies or defects have been remedied or revoke the licence if deficiencies or defects have not been remedied within the reasonable time provided.

A decision concerning suspension of activities or revocation of licence shall be complied with regardless of appeal.

Section 28

Cessation of activities

When a service provider ceases to operate, the documents relating to its storage of gametes and embryos shall be transferred for safekeeping to a public service provider designated by the National Authority for Medicolegal Affairs or to a private service provider consenting thereto. The remaining inventory of gametes or embryos shall be transferred to the same service provider subject to its consent. If consent is withheld, the inventory shall be destroyed.

When a service provider ceases to operate, the consents to treatment shall be transferred in public healthcare to the archives of the body maintaining the service provider and in private healthcare to the archives of the State Provincial Office in whose territory the services were provided.

The provisions herein concerning the rights and obligations of service provider shall apply to the party which accepted the inventory or related documents.

Chapter 6

Miscellaneous provisions

Section 29

Non-disclosure

The documents referred to herein are patient documents as referred to in the Act on the Status and Rights of Patients. The donor code noted on the consent to treatment and the information obtainable from the donation register on the basis of the donor code may only be disclosed to persons with the right to obtain information as provided in section 23.

Section 30

Safekeeping of information

Information entered in the donation register and consents to treatment on which a donor code has been noted may not be destroyed. However, information concerning a donor whose gametes have not been used and can no longer be used in assisted fertility treatment may be deleted from the donation register.

Section 31

Further provisions

Further provisions will be laid down as necessary by Decree of the Ministry of Social Affairs and Health concerning the following:

- 1) the storage and disposal of gametes and embryos referred to in section 6,
- 2) the physical examination referred to in section 13,

- 3) the donor code and its use,
- 4) the keeping of the register referred to in section 16(5),
- 5) the compensation referred to in section 21,
- 6) the facilities, equipment and personnel as well as other operational conditions referred to in section 24,
- 7) the fees referred to in section 25,
- 8) the provision of information on the activities of service providers referred to in section 26,
- 9) measures relating to the transfer of documents and inventories of gametes and the disposal of inventories referred to in section 28, and
- 10) implementation of this Act.

Chapter 7

Penal provisions

Section 32

Offence of unlawful use of gametes

A person who intentionally or through gross negligence

- 1) uses gametes or embryos in assisted fertility treatment in violation of section 4(1),
- 2) influences or attempts to influence the characteristics of the child in violation of section 5,
- 3) collects, stores or uses in assisted fertility treatment gametes or embryos without donor consent, or
- 4) stores gametes or embryos or provides assisted fertility treatment without a licence referred to in section 24

shall be sentenced to a fine or imprisonment of not more than one year for the *offence of unlawful use of gametes*.

Section 33

Offence of violation of child identity

A person who intentionally or through gross negligence fails to comply with the provisions of sections 12 or 14 concerning donor code, the provisions of section 18 concerning notification of information to the donation register or the provisions of sections 10, 28 or 30 concerning the safekeeping of documents shall be sentenced to a fine or imprisonment of not more than one year for the *offence of violation of child identity*.

Section 34

Assisted fertility treatment offence

A person who-intentionally or through gross negligence provides assisted fertility treatment in violation of section 8 shall be sentenced to a fine or imprisonment of not more than one year for *assisted fertility treatment offence*.

Section 35

Assisted fertility treatment violation

A person who in violation of section 21 intentionally gives or promises any remuneration or compensation of expenses for the donation of gametes or embryos shall be sentenced to a fine for *assisted fertility treatment violation*.

Section 36

Breach of non-disclosure obligation

A sentence for breach of the non-disclosure obligation provided for in section 29 shall be passed in accordance with Chapter 38, section 1 or 2 of the Penal Code (39/1889) unless the act is punishable under Chapter 40, section 5 of the Penal Code or unless more severe punishment is provided for the act elsewhere in law.

Chapter 8

Transitional provisions and entry into force

Section 37

Entry into force

This Act enters into force on 1 September 2007.

Measures necessary for the implementation of this Act may be undertaken prior to the Act's entry into force.

Section 38

Transitional provisions

Gametes or embryos donated prior to this Act's entry into force may only be used in assisted fertility treatment

- 1) if the donor has consented to the child to be born being informed of his/her identity as provided in section 23, or
- 2) for a period of three years from the entry into force of the Act for the purpose of having a biological full sibling to a child born earlier to the person receiving treatment as a result of assisted fertility treatment.

In the event that an application for a licence referred to in section 24 has been submitted prior to this Act's entry into force, the service provider may continue its activities without a licence after this Act's entry into force in compliance with the provisions herein until such time that decision has been rendered on the application. Decision on such an application shall be rendered within six (6) months of this Act's entry into force.

Government Bill HE 3/2006, Grand Committee report 1/2006, Legal Affairs Committee report 12/2006, Reply of Parliament 122/2006