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The Genetic Integrity Act (2006:351)

Swedish Code of Statutes no 2006:351

Ministry/Agency: Ministry of Health and Social Affairs

Title: The Genetic Integrity Act (2006:351)

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Chapter 1. Introductory provisions

Purpose and scope of the Act

Section 1

This Act sets out provisions on restrictions on the use of certain biotechnology developed for medical purposes and on certain legal effects of such use.

The purpose of the Act is to safeguard the integrity of the individual.

Section 2

The Act applies to

- the use of genetic investigations and genetic information and gene therapy,
- genetic investigation in general medical screening,
- prenatal and preimplantation genetic diagnosis,
- measures for purposes of research or treatment using human eggs,
- insemination, and
- fertilisation outside the body.

The Act also contains provisions on criminal liability for trade in human biological material.

Other associated legislation

Section 3

The Health and Medical Services Act (1982:763) sets out basic provisions on patients' self-determination and on respect for the equal dignity of all human beings within health and medical services, and the Health and Medical Services (Professional Activities) Act (1998:531) sets out provisions on the obligations of healthcare professionals.

The Biobanks in Medical Care Act (2002:297) regulates how human biological material may be collected, stored and used for certain purposes, with respect to the integrity of the individual.

As regards protecting the individual and respecting human dignity in research there are provisions in the Act concerning the Ethical Review of Research involving Humans (2003:460).

Relationship to the Personal Data Act

Section 4

Unless otherwise provided by this Act or regulations issued under this Act, the Personal Data Act (1998:204) is applicable to the processing of personal data.

Definitions

Section 5

In this Act the following terms have the meaning set out in this section:

genetic investigation: an investigation in health and medical care or medical research for the purpose of providing data concerning the genome of a human being through molecular genetic, microbiological, immunological, biochemical, cytogenetic or comparable method of analysis or through collecting data on his or her biological relatives,

genetic information: information concerning the result of a genetic investigation, though not to the extent the information only includes data on the current state of health of the person investigated,

prenatal diagnosis: medical investigation of a pregnant woman and the foetus she is carrying,

prenatal genetic diagnosis: genetic investigation of a foetus or pregnant woman to obtain information about diseases, pre-disposition to diseases and malformation of the foetus, through amniocentesis, chorionic villus sampling or blood testing,

preimplantation genetic diagnosis: genetic investigation of a fertilised egg before it is implanted in a woman's uterus,

gene therapy: a treatment that involves introducing, with the use of a carrier (vector), a healthy gene into the cells of an individual with a genetic disease,

insemination: introducing sperm into a woman artificially, and

somatic cell nucleus transfer: replacing the cell nucleus of an egg with the nucleus from a body cell.

Chapter 2. Genetic investigation and information and gene therapy

Prohibition against using genetic investigation and information

Section 1

Unless by virtue of provisions laid down by law, no party may stipulate as terms of an agreement that the other party must undergo a genetic investigation or provide genetic information about himself or herself.

Unless by virtue of provisions laid down by law, no party may inquire into or use genetic information about the other party in connection with an agreement. No person may effect access to genetic information about another person without authority.

The first paragraph and the second paragraph, first sentence, do not apply in the area of family law.

The use of genetic information in insurance

Section 2

With regard to risk-rated personal insurance, notwithstanding the provisions of Section 1, second paragraph, first sentence, an insurance company may inquire into or use genetic information in connection with entering into, amendment or renewal of an agreement, provided that

1. the person insured is over the age of 18 years and the amount insured that becomes payable in the event of an insurance loss is a lump sum in excess of 30 price base amounts as defined by the National Insurance Act (1962:381), or
2. the person insured is over the age of 18 years and the amount insured that becomes payable in the event of an insurance loss is a periodic indemnity in excess of four price base amounts per year.

Gene therapy

Section 3

Experiments for the purposes of research or treatment that entail genetic changes that can be inherited in humans may not be carried out.

Section 4

Treatment methods that are intended to bring about genetic changes that can be inherited in humans may not be used.

Chapter 3. Genetic investigation in general medical screening

Requirement for permission

Section 1

A genetic investigation that constitutes or is part of general medical screening may be carried out only with the permission of the National Board of Health and Welfare.

Such an investigation may not include any other than the person who has consented in writing.

There are special provisions concerning the investigation of foetuses in Chapter 4.

Conditions for permission

Section 2

Permission as referred to in Section 1 may only be granted if the genetic investigation is directed at seeking knowledge of serious illness or is otherwise of particular importance to health and medical care.

Consideration of the issue of permission shall take special account of

1. if the planned investigation is intended to indicate or exclude a disease risk which can be prevented or if the disease in question is treatable,
2. if the investigation can be assumed to indicate evidently heightened risks of the disease in question, and

3. if those in charge of and carrying out the investigation have the competence necessary and if the protection of integrity of the data concerning the genetic conditions of the participants in the investigation can be assumed to be satisfactory.

Section 3

Permission as referred to in Section 1 may be subject to the conditions necessary to restrict the investigation or control it.

Permission may be revoked if the associated conditions are disregarded or if there are other special grounds. Permission may be revoked until further notice pending final settlement of the matter.

Chapter 4 Prenatal diagnosis, prenatal genetic diagnosis and preimplantation genetic diagnosis

Conditions for prenatal diagnosis

Section 1

All pregnant women shall be offered general information on prenatal diagnosis. A pregnant woman who has a medically established increased risk of giving birth to an impaired child shall be offered further information on prenatal genetic diagnosis.

After receiving the information the woman will decide, in consultation with her doctor, whether she is to undergo prenatal diagnosis or prenatal genetic diagnosis.

The pregnant woman shall receive all the information concerning the health status of the foetus that is obtained from prenatal diagnosis. Data on the foetus that does not concern its health status shall only be disclosed if the woman so requests.

Conditions for preimplantation genetic diagnosis,

Section 2

Preimplantation genetic diagnosis may only be used if the man or woman has a predisposition towards a serious monogenetic or chromosomal hereditary disease, which entails a high risk of having a child with a genetic disease or impairment.

The treatment may not be used to choose characteristics, but only be aimed at preventing the child from inheriting the predisposition towards the disease or impairment in question.

Preimplantation genetic diagnosis may not be used without the permission of the National Board of Health and Welfare to try to have a child with a set of genes that enables the child to become a donor of blood stem cells to a severely ill sibling. Permission may only be given if there are exceptional grounds for allowing such use.

Chapter 5. Measures for purposes of research or treatment using human eggs

Section 1

Measures under the provisions of this chapter using human eggs that have been fertilised or subjected to somatic nuclear transfer assume that the donors of eggs, sperm or somatic cell have been informed of the purpose of the measure and thereafter given their consent.

If fertilisation has taken place as described in Chapter 7, it is also required that the woman or man who is not the donor of egg or sperm in the couple being treated has been informed of the purpose of the measure and thereafter given her or his consent.

Section 2

As regards research subject to review under the Act concerning the Ethical Review of Research involving Humans (2003:460), instead of Section 1 of this Chapter, the provisions on information and consent in Sections 16, 17 and 19 of that Act shall be applicable.

If fertilisation has taken place as referred to in the provisions of Chapter 7 of this Act, a research subject shall be equated with the woman or man in the couple being treated who is not the donor of egg or sperm.

Section 3

Experiments for the purpose of research or treatment on fertilised eggs and eggs used for somatic cell nuclear transfer may be carried out no longer than up to and including the fourteenth day after fertilisation or cell nuclear transfer respectively.

If a fertilised egg or an egg used for somatic cell nuclear transfer has been used for such an experiment, it shall be destroyed without delay when the measure has been accomplished.

Provisions on gene therapy are set out in Chapter 2, Sections 3 and 4 of this Act.

Section 4

A fertilised egg or an egg used for somatic cell nuclear transfer may be stored in a frozen state for a maximum of five years or a longer period determined by the National Board of Health and Welfare under Section 6.

The period during which the egg has been frozen is not included in the period during which experiments may be carried out under Section 3.

Section 5

If a fertilised egg has been used for an experiment for purposes of research or treatment, the egg may not be introduced into a woman's body. The same applies if the egg, before fertilisation, or the sperm used for fertilisation have been used for such an experiment or if the egg has been subject to somatic nuclear transfer.

Section 6

If there are exceptional grounds, for special cases the National Board of Health and Welfare may consent to an extension of the period specified in Section 4 for storage in a frozen state.

If consent is given the National Board of Health and Welfare shall determine the further period during which storage may take place.

Consent may be subject to conditions. It may be revoked if the conditions are disregarded or if there are other grounds for revocation.

Chapter 6. Insemination

Conditions for treatment

Section 1

Insemination may be carried out only if the woman is married or cohabiting. Written consent for insemination is required from the spouse or cohabitee.

Under the provisions of the Registered Partnership Act (1994:1117) it follows that references in this chapter to spouses also apply to registered partners.

Where treatment may be carried out

Section 2

Without the permission of the National Board of Health and Welfare, insemination with sperm from a man to whom the woman is not married or with whom the woman does not cohabit may not be carried out other than at publicly financed hospitals. Such insemination shall be carried out under the supervision of a doctor specialising in gynaecology and obstetrics.

Special review

Section 3

For insemination referred to in Section 2 the doctor shall review whether, considering the medical, psychological and social circumstances of the spouses or cohabittees, it is appropriate for insemination to take place. The insemination may only be carried out if it can be assumed that the prospective child will grow up under good conditions.

If insemination is refused, the spouses or cohabittees may request that the National Board of Health and Welfare review the matter.

Choice of sperm donor

Section 4

For insemination referred to in Section 2 the doctor shall select a suitable sperm donor. Sperm from a deceased donor may not be used for insemination. Data concerning the donor shall be recorded in a special journal. This shall be retained for at least 70 years.

Right to information

Section 5

A person conceived through insemination with sperm from a man to whom the woman is not married or with whom the woman does not cohabit has the right to access the data on the donor recorded in the hospital's special journal, if he or she has reached sufficient maturity.

If a person has reason to assume that he or she was conceived through such insemination, the social welfare committee is obliged, on request, to help this person find out if there are any data recorded in a special journal.

Duty to provide information to a court

Section 6

If, in a case concerning paternity or parenthood, as defined in Chapter 1, Section 9 of the Children and Parents Code, it is necessary to obtain existing data on an insemination, the person responsible for the insemination or another person with access to the data is obliged to disclose this information at the request of a court.

Import of sperm

Section 7

Frozen sperm may not be imported into the country without the permission of the National Board of Health and Welfare.

Chapter 7. Fertilisation outside the body

Introductory provision

Section 1

This chapter contains provisions on

1. fertilisation of a woman's egg outside her body, and
2. introduction of a fertilised egg into a woman's body.

Under the provisions of the Registered Partnership Act (1994:1117) it follows that references in this chapter to spouses also apply to registered partners.

Conditions for treatment

Section 2

A donor of an egg or sperm shall be of age. The donor shall provide written consent for the egg to be fertilised or for the sperm to be used for fertilisation. The donor may revoke his or her consent up to the time of fertilisation.

Section 3

A fertilised egg may be introduced into a woman's body only if the woman is married or cohabiting and the spouse or cohabitee gives written consent to this. If the egg is not the woman's own, the egg shall have been fertilised using the husband's or cohabitee's sperm.

Where treatment may be carried out

Section 4

Without the permission of the National Board of Health and Welfare, fertilisation of an egg from a woman into whose body the egg is to be introduced, using sperm from the woman's husband or cohabitee, may not take place other than at publicly financed hospitals. What has been stated also applies to the introduction of the egg into a woman's body.

If the egg is not from the woman or if the sperm is not from the woman's husband or cohabitee, fertilisation and introduction of the egg may only take place at hospitals which have set up units for training doctors under an agreement between the universities conducting medical training programmes and the county councils concerned.

Special review

Section 5

If fertilisation outside the body is to take place with an egg other than the woman's own or with sperm from a man who is not the woman's husband or cohabitee, a doctor shall review whether, considering the medical, psychological and social circumstances of the spouses or cohabitees, it is appropriate for fertilisation outside the body to be carried out. Fertilisation outside the body may only be carried out if it can be assumed that the prospective child will grow up under good conditions.

If fertilisation outside the body is refused, the spouses or cohabitees may request that the National Board of Health and Welfare review the matter.

Choice of donor

Section 6

For fertilisation outside the body a doctor shall select egg or sperm from a suitable donor.

Eggs or sperm from a donor who is deceased may not be used for fertilisation.

Data concerning the donor shall be recorded in a special journal. This shall be retained for at least 70 years.

Right to information

Section 7

A person conceived through fertilisation outside the body using an egg other than the woman's own or sperm from a man who is not the woman's spouse or with whom the woman does not cohabit has the right to access the data on the donor recorded in the hospital's special journal, if he or she has reached sufficient maturity.

If a person has reason to assume that he or she was conceived through such fertilisation, the social welfare committee is obliged, on request, to help this person find out if there are any data recorded in a special journal.

Duty to provide information to a court

Section 8

If, in a case concerning paternity, maternity as defined in Chapter 1, Section 7 of the Children and Parents Code or parenthood as defined in Chapter 1, Section 9 of the Children and Parents Code, it is necessary to obtain existing data on a fertilisation outside the body, the person responsible for the fertilisation or another person with access to the data is obliged to disclose this data at the request of a court.

Chapter 8. Other provisions

Appeal

Section 1

The decisions of the National Board of Health and Welfare pursuant to Chapter 3, Section 1 or 3, Chapter 5, Section 6, Chapter 6, Section 3 and Chapter 7, Section 5 may be appealed to a general administrative court.

Leave to appeal is required for an appeal to the administrative court of appeal.

Other decisions by the National Board of Health and Welfare pursuant to this Act are not open to appeal.

Provisions on liability etc.

Section 2

A person who violates Chapter 2, Section 1, first paragraph, Section 3 or Section 4, shall be sentenced to a fine or imprisonment for up to six months, unless the act is punishable by a more severe penalty under the Swedish Penal Code.

Section 3

A person who violates Chapter 5, Section 3, 4 or 5, shall be sentenced to a fine or imprisonment for up to one year. Minor violations of Chapter 5, Section 4 shall not be penalised.

Public prosecution for violations mentioned in the first paragraph may only be instituted with the consent of the National Board of Health and Welfare.

Section 4

A person who carries out insemination habitually or for profit in contravention of the provisions of Chapter 6 or under the circumstances stated provides sperm for such insemination shall be sentenced to a fine or imprisonment for up to six months.

Section 5

A person who violates Chapter 7, Section 3 or 4 , habitually or for profit, shall be sentenced to a fine or imprisonment for up to six months.

Section 6

A person who for profit takes, hands over, receives or procures biological material from a living or deceased person or tissue from an aborted foetus shall be sentenced to a fine or imprisonment for up to two years. The same penalty shall be imposed on a person who uses or takes advantage of such material for transplantation or for other purposes despite the knowledge that the material has been taken, handed over, received or procured for profit. Cases of minor violation shall not be penalised.

Biological material also refers to material from human eggs and from cells and cell lines from such eggs.

The prohibition against trade in biological material does not apply to blood, hair, breast milk and teeth. Nor does it apply to deidentified cell lines from fertilised eggs or from eggs used for somatic cell nuclear transfer.

Section 7

Biological material used for an offence under Section 6 shall be declared forfeit, unless this is manifestly unreasonable. The same applies to proceeds from such an offence.

Authorisations

Section 8

The Government or the authority designated by the Government may, to protect life and health, issue further regulations on

1. genetic investigations in health and medical care,
2. prenatal diagnosis and preimplantation genetic diagnosis, and
3. fertilisation outside the body and introduction of eggs into a woman's body.

The Government or the authority designated by the Government may issue regulations concerning exceptions from the requirement for permission laid down in Chapter 3, Section 1.

Enforcement regulations

Section 9

Regulations on the enforcement of this Act will be issued by the Government or the authority designated by the Government.

Transitional provisions

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1. This Act shall enter into force on 1 July 2006.
2. The provisions of Chapter 2, Section 1, first paragraph and the second paragraph, first sentence and Section 2 shall apply to the area of insurance only from 1 January 2007.
3. This Act supersedes the Act on the Use of Certain Genetic Technology in Medical Screening (1991:114), the Insemination Act (1984:1140), the Act on Measures for Purposes of Research or Treatment using Fertilized Human Ova (1991:115) and the Act on Fertilisation Outside the Body (1988:711).
4. The provision in Chapter 6, Section 5 does not apply in cases when the sperm donor has donated sperm before 1 March 1985.