Text consolidated by Valsts valodas centrs (State Language Centre) with amending laws of:

12 June 2003 [shall come into force on 15 July 2003];

24 February 2005 [shall come into force on 23 March 2005];

18 May 2006 [shall come into force on 20 June 2006];

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If a whole or part of a section has been amended, the date of the amending law appears in square brackets at the end of the section. If a whole section, paragraph or clause has been deleted, the date of the deletion appears in square brackets beside the deleted section, paragraph or clause.

The *Saeima* 1 has adopted

the President has proclaimed the following law:

**Human Genome Research Law**

**Chapter I**

**General Provisions**

**Section 1. Terms Used in the Law**

Terms used in the Law:

1) **decoding** – the personal identification of a gene donor by using the unique code which has been assigned to a tissue sample, a description of DNA, a description of the state of health or genealogy, or the identification of a tissue sample, description of DNA, description of the state of health or genealogy on the basis of the identity of the gene donor;

2) **tissue sample** – cells, the DNA thereof, intercellular substances and body fluids taken from a human for the performance of genetic research;

3) **DNA** – the molecule of deoxyribonucleic acid that contains genetic information;

4) **description of DNA** – the digital model of DNA created as a result of the genetic research;

5) **genome** – the aggregate of the genes of an organism containing genetic information regarding the structure of the organism, life-processes therein and the response of the organism to the environment;

6) **gene** – the part of the DNA molecule which contains genetic information regarding the synthesis of an organism’s protein or performs regulating functions by determining the structure of some individual component of the organism or the stage of the life process;

7) **gene donor** – a natural person who transfers a tissue sample for genetic research;

8) **genome database** – a set of data containing coded descriptions of the DNA, coded descriptions of the state of health, coded genealogical and genetic data, as well as coded DNA samples and coded tissue samples to be used for genetic research;

9) **database of gene donors** – data that allows the identification of a gene donor and genealogy in the genome database;

10) **gene researcher** – a natural person or a legal person who performs genetic research;

11) **genealogy** – information regarding ascendants and descendants of a gene donor: given name, surname, date of birth and blood relationship;

12) **genetic research** - scientific research of DNA and the other components of tissues for the purpose of determining the connection between genes, gene products and hereditary characteristics;

13) **genetic testing** – the genetic analysis of a person, which is performed for the purpose of his or her identification or the diagnosis of diseases, as well as for the selection of preventive or treatment measures;

14) **genetic data** – the data related to genes, gene products and hereditary characteristics, also the description of the DNA or the part thereof, which has been drawn up as a result of the genetic research;

15) **coding** – replacement of the personal data of a gene donor with the unique code which allows the identification of the gene donor by the tissue sample, description of the DNA and description of the state of health or genealogy; and

16) **description of the state of health** – the data which is collected for the performance of genetic research and which provide the information regarding the state of health, the diseases from which the gene donor has suffered, his or her lifestyle, physical and social environment and hereditary characteristics.

[*12 June 2003*]

**Section 2. Purpose and Operation of the Law**

(1) The purpose of the Law is to regulate the establishment and operation of the single genome database of the State population (hereinafter – the genome database) and genetic research, to ensure the voluntary nature and confidentiality of the gene donation in respect of the identity of gene donors, and also to protect persons from the misuse of genetic data and the discrimination related to the genetic data.

(2) The Law regulates:

1) the provisions for the tissue sample processing, preparation of the description of the DNA, description of the state of health and genealogy in relation to the genome database;

2) the genetic research regulations in relation to the genome database and organisation of the supervision of such research;

3) the rights and obligations of gene donors, activity of the chief processor, authorised processor of the genome database and gene researchers;

4) the restrictions in relation to the use of tissue samples, the use of descriptions of the DNA compiled in the genome database, descriptions of the state of health and genealogy;

5) coding and decoding provisions.

[*12 June 2003*]

**Section 3. General Principles of Human Genome Research**

(1) In genetic research the interests, rights and protection of a gene donor shall be set higher than the interests of society and science.

(2) The gene donor shall participate voluntarily in the genetic research.

(3) It is prohibited to discriminate against a person in relation to his or her genetic origin and any other data acquired as a result of the genetic research, and also on the basis of the fact that the person is or is not a gene donor.

(4) The human genome research is permitted only for the purpose of acquiring scientifically justified information that may be utilised for the improvement of the health of the person and the whole of society.

(5) The human genome research shall be scientifically justified, and such research shall be performed, taking into account the professional criteria and guarantees of the relevant sector.

(6) Genome research of a deceased person may not be performed if this is against his or her expressed will while alive. If such a will was not expressed, it is prohibited to perform the genome research of the deceased person.

[*12 June 2003*]

**Section 4. Chief Processor of the Genome Database**

(1) The chief processor of the genome database (hereinafter – the chief processor) is the State scientific authority authorised by the Cabinet to establish and regularly supplement the genome database. The Cabinet shall determine the requirements to be met by the chief processor and procedures by which the conformity of the State scientific authorities with the referred to requirements is evaluated.

(2) The tasks of the chief processor shall be the following:

1) to organise the taking and keeping of tissue samples, the preparation, storage and destruction of descriptions of the state of health and genealogies;

2) to perform the coding;

3) to perform the genetic research and to collect, store, destroy or issue the genetic data;

4) to provide the State Population Genome Register with the genetic data acquired as the result of the genetic research related to a particular gene donor;

5) to promote the development of genetic research in Latvia;

6) to promote the utilisation of the results of the genetic research for the improvement of health of the person and the whole of society.

(3) The chief processor shall provide the Ministry of Health and the Ministry of Education and Science with an annual report regarding the use of the State budget resources for the implementation of a genetic research programme financed from the State budget.

[*12 June 2003; 24 February 2005*]

**Section 5. Genome Research Board**

(1) The Genome Research Board (hereinafter – the Board) operates in accordance with the by-laws approved by the Cabinet and the main tasks of it shall be the following:

1) to examine projects and concepts related to genetic research, to provide opinions on such projects and concepts and to coordinate the implementation thereof;

2) to facilitate the provision of the public with information regarding the purposes and procedures of the genetic research;

3) to represent the interests of the public in the field of genetic research.

(2) Staff of the Board shall be approved by the Cabinet upon recommendation from the Minister for Welfare.

[*2 November 2017*]

**Section 6. Authorised Processor of the Genome Database**

The authorised processor of the genome database (hereinafter – the authorised processor) is an authorised natural person or a legal person of the chief processor who performs the individual activities related to the genome database, except for the coding and decoding. The Cabinet shall determine the requirements to be met by the authorised processor.

**Section 7. State Population Genome Register**

(1) The Cabinet shall determine the procedures for the establishment, supplementing and maintaining of the State Population Genome Register.

[*24 February 2005*]

**Section 8. Genetic Research and Genetic Testing**

(1) Genetic research is permitted for the purpose of studying and describing the mutual connection between genes, the human state of health, lifestyle and physical and social environment, in order to discover, on the basis of such research, disease diagnostic and treatment methods that will help to assess the health risks of the individuals and to prevent the causes of diseases.

(2) Genetic research shall be performed in accordance with the procedures determined by the Cabinet.

(3) If the genetic research is performed irrespective of the genome database, the information regarding the state of health of the person, tissue samples and descriptions of the DNA shall be included in the genome database only upon a written consent of the gene donor. In such case, a gene researcher has the right to work with the tissue samples which he or she has collected and stored in the genome database within the scope of their powers as prescribed by the Law.

(4) Tissue samples taken from humans for genetic testing and the results of the relevant research shall not be included in the genome database.

(5) The genetic testing shall be performed in accordance with the medical technology approved in accordance with the procedures specified by the Cabinet.

[*12 June 2003; 24 February 2005*]

**Section 9. Provisions for Processing of Personal Data**

The Personal Data Protection Law shall govern the provisions for the processing of the personal data included in the genetic research, genome database and the database of gene donors, insofar as this Law does not prescribe otherwise.

[*12 June 2003*]

**Chapter II**

**Consent to Become a Gene Donor and Rights of Gene Donors**

**Section 10. Consent to Become a Gene Donor**

(1) Before a person participates in the genetic research, a doctor shall issue to the person written information regarding:

1) the purpose, content and duration of the genome research project;

2) potential risks;

3) the right to freely express his or her consent and to revoke it at any time;

4) a possibility to perform genetic research outside of Latvia;

(2) The consent of a person to take tissue samples from him or her, to prepare and supplement the description of the state of health or the genealogy, to include such description in the genome database and use it in the genetic research and for the purpose of statistics, to bring it out of Latvia, and also to use the genetic data shall be provided in writing. The consent document of a gene donor shall be prepared in two copies, the document shall be signed and dated by the gene donor or the lawful representative of a minor, and the chief processor or the authorised processor. One copy of the consent document shall be kept in the State Population Genome Register, the other copy shall be issued to the gene donor or the lawful representative of a minor.

(3) The State Population Genome Register shall keep the consent document of a gene donor for 75 years after the last entry characterising the tissue samples, the description of the state of health and the description of the DNA.

(4) The Cabinet shall determine the standard form of the consent document and the procedures for the completion and keeping thereof.

(5) If genetic research is performed independently of the genome database, the consent document shall be signed and dated by the gene researcher and the gene donor or the lawful representative of a minor. One copy of the consent document shall be issued to the gene donor or the lawful representative of a minor, the other – to the gene researcher.

[*12 June 2003; 2 November 2017*]

**Section 11. Rights of the Gene Donor**

(1) A gene donor has the following rights:

1) to become acquainted or refuse to become acquainted with the data stored in the genome database regarding the gene donor;

2) to prohibit the supplementation, renewal or verification of the description of his or her state of health in the genome database;

3) to revoke his or her consent to being a gene donor at any time. In such a case the tissue samples, the description of the state of health of the gene donor and any information related to the identification of a person shall be destroyed;

4) to restrict the scope of research of his or her genome.

(2) The gene donor has no rights to request payment for the transfer of tissue samples, for the preparation or research of the description of his or her state of health or genealogy, and also for the use of research results.

[*12 June 2003*]

**Section 12. Genome Research of a Person with Restricted Capacity to Act and a Minor**

(1) The genome research of a person with restricted capacity to act is permitted only in the case where such research provides direct benefit for the health of the person and the risk allowed for in the research is commensurate with the gained benefit.

(2) The genome research of a person with restricted capacity to act shall be performed only with a written consent of the gene donor and the Central Medical Ethics Committee.

(3) The genome research of a minor shall be performed only with a written consent of the lawful representative of a minor.

[*2 November 2017*]

**Chapter III**

**Operations with Tissue Samples, Descriptions of the State of Health, Genealogies, DNA Descriptions and Personal Data of the Gene Donor**

[*12 June 2003*]

**Section 13. Taking of Tissue Samples and Preparation of Descriptions of the State of Health**

(1) The chief processor or the authorised processor shall take tissue samples and prepare the descriptions of the state of health.

(2) The chief processor or the authorised processor shall prepare and supplement the description of the state of health based on the information provided by the gene donor and the information received from the medical treatment institutions regarding the gene donor.

(3) The doctor shall submit to the chief processor a completed form the standard form of which the Minister for Welfare has approved and which shall include the following information:

1) the given name, surname and personal identity number, sex and place of residence of the gene donor;

2) the medical treatment institution (name) in which tissue samples were taken;

3) information regarding the tissue sample and the method how such tissue sample was obtained.

(4) The chief processor or the authorised processor may prepare the genealogy of a gene donor based on the data provided by the gene donor or the results of the genetic research.

(5) In taking the tissue samples for preparation of the description of the state of health, confidentiality regarding the identity of a gene donor, and also his or her tissue samples, the description of the state of health and genealogy shall be observed.

[*11 June 2003; 18 May 2006*]

**Section 14. Use of Genealogies**

(1) Within the scope of the genome database, it is only permitted to use genealogies for the preparation of tissue samples, descriptions of the DNA and descriptions of the state of health on the basis of blood relationship.

(2) The chief processor may provide the gene researcher with the information regarding the mutual connection between the coded tissue samples, coded DNA samples and coded descriptions of the state of health on the basis of blood relationship in accordance with Section 17, Paragraph two of this Law.

**Section 15. Storage and Bringing out of Latvia of Tissue Samples, Descriptions of DNA and Descriptions of the State of Health**

(1) The chief processor shall store the coded tissue samples, coded descriptions of the DNA and coded descriptions of the state of health in the genome database in Latvia in accordance with the procedures specified by the Cabinet.

(2) The Board may, on the basis of a submission of the chief processor, authorised processor or gene researcher, issue a permit for bringing the parts of coded tissue samples (aliquots) and copies of the coded descriptions of the state of health out of Latvia upon the written consent of a gene donor only in the following cases:

1) for the performance of genetic research within the scope of international medical, genetic and bio-pharmaceutics scientific projects;

2) for the establishment of the internationally acknowledged genetic database for medical and ethnogenetic research, if the relevant agreement regarding the establishment of the genetic database in Latvia has been entered into.

(3) The Cabinet shall determine the procedures by which the permits for bringing the parts of coded tissue samples (aliquots) and copies of coded descriptions of the state of health out of Latvia are issued, and also the procedures for the control of the use of tissue samples.

[*12 June 2003*]

**Section 16. Other Rights Related to Genetic Research**

(1) It is only permitted to use the genome database for scientific research, research and treatment of the diseases of a gene donor, research of the health of society and for statistical purposes. It is prohibited to use the genome database for any other purpose.

(2) The chief processor, authorised processor and gene researcher are entitled to handle the coded tissue samples, coded descriptions of the state of health and coded genealogies within the scope of powers prescribed in the Law.

(3) The doctor of a gene donor has the right to receive a decoded description of the state of health of the gene donor included in the genome database if it is necessary for the treatment of the gene donor and a written consent of the gene donor has been received.

[*12 June 2003*]

**Section 17. Issuance of Tissue Samples, Descriptions of DNA, Descriptions of the State of Health and Genealogies**

(1) The Cabinet shall determine the procedures for the issuance of coded tissue samples, coded descriptions of DNA, coded descriptions of the state of health and coded genealogies, and also the sample of the issuance statement form and procedures for the completion and storage thereof.

(2) With the consent of the Board, the chief processor may issue the coded tissue samples, coded descriptions of the state of health and coded genealogies included in the genome database or parts thereof as the set of data for such genetic research in Latvia which is not related to the genome database on the condition that such set of data includes tissue samples, descriptions of DNA and descriptions of the state of health of at least five gene donors and that the provisions of Section 8 of this Law are complied with. In such case a payment may be requested for the use of coded tissue samples, coded descriptions of the DNA, coded descriptions of the state of health and coded genealogies, however, it may not exceed the costs related to the acquisition, preparation and storage of the relevant samples in the genome database; moreover, the chief processor may not profit as a result of such use. This requirement shall not apply to the issuance of data to the gene donor or the doctor of the gene donor.

(3) [12 June 2003]

[*12 June 2003*]

**Section 18. Destruction of Personal Data, Tissue Samples, Descriptions of DNA and Descriptions of the State of Health of the Gene Donor**

The Cabinet shall determine procedures for the destruction of personal data, tissue samples, descriptions of the DNA and descriptions of the state of health of a gene donor, and also the standard from of the destruction statement and procedures for the completion and storage thereof.

[*12 June 2003*]

**Chapter IV**

**Coding and Decoding**

**Section 19. Coding**

(1) Immediately after receipt of the consent document and the relevant tissue samples, descriptions of DNA, descriptions of the state of health and genealogies in the genome database, the chief processor shall assign a unique code consisting of 16 different symbols to each tissue sample, description of DNA, description of the state of health and genealogy. The chief processor shall receive a permit from the State Data Inspectorate for the use of the selected code assigning method.

(2) The chief processor shall replace with a code all personal data in respect of tissue samples, descriptions of the DNA, descriptions of the state of health, the given name, surname, personal code, and place of residence of the gene donor, thus providing the possibility to again identify a gene donor.

(3) The chief processor shall indicate the code assigned to a tissue sample, description of the DNA, description of the state of health or genealogy on the consent document of a gene donor. Within a week after the coding, the chief processor shall transfer the consent document with the code indicated therein to the State Population Genome Register, and this code shall be the only possible decoding key.

(4) The chief processor, authorised processor, and gene researchers are allowed to mark tissue samples, descriptions of DNA, descriptions of the state of health and genealogies only with such codes which the chief processor assigned to such tissue samples, descriptions of DNA, descriptions of the state of health and genealogies.

[*2 November 2017*]

**Section 20. Decoding**

The State Population Genome Register is permitted to decode data only for the following purposes:

1) to destroy tissue samples, descriptions of DNA and descriptions of the state of health;

2) to provide access to the data of a gene donor included in the genome database, except for the genealogy, upon his or her request in writing;

3) to renew, supplement or verify the description of the state of health of a gene donor, except for the case where the gene donor has prohibited in writing to supplement, renew or verify the description of his or her state of health;

4) to take a new DNA sample with the written consent of the gene donor if the tissue sample has been destroyed or does not contain sufficient genetic information;

5) to make changes in the genealogy of a gene donor if the results of the genetic research are in contradiction with the genealogy previously prepared or to provide new information on such genealogy;

6) to issue the description of the state of health of a gene donor to the doctor of the gene donor upon his or her written request in which the necessity to acquire information has been justified, and with a written consent of the gene donor.

[*12 June 2003*]

**Chapter V**

**Supervision and Procedures for the Examination of Complaints**

**Section 21. Data Protection Supervisory Authority**

The State Data Inspectorate shall perform the supervision of the collection of the descriptions of the state of health and genealogical data, coding and decoding of tissue samples, descriptions of DNA, descriptions of the state of health and genealogical data, and also the processing of tissue samples, descriptions of DNA, descriptions of the state of health and genealogical data.

**Section 22. Compliance with Principles of Ethics**

The Central Medical Ethics Committee shall evaluate the compliance with principles of ethics in the genetic research and the establishment and operation of the genome database.

**Section 23 Examination of Complaints**

(1) A person may submit a complaint regarding violations of this Law to the State Data Inspectorate.

(2) Decisions by the State Data Inspectorate may be appealed in the court.

The Law shall come into force on 1 January 2004.

[*12 June 2003*]

The Law has been adopted by the *Saeima* on 13 June 2002.

President V. Vīķe-Freiberga

Rīga, 3 July 2002