

# Gene donor consent form information sheet

This leaflet explains in detail the consent form to become a gene donor and getting acquainted with it will help to better understand the Estonian Genome Centre (EGC). Becoming a gene donor is voluntary.

## Estonian Genome Centre of the University of Tartu

The aim of the Estonian Genome Centre of the University of Tartu is to create a database containing health, family tree and genetic data of the Estonian population - a gene repository. The data collected in the biobank allow genetic and health research to find genes that affect the development of diseases. EGC is established and controlled by the Republic of Estonia.

## the Human Genes Research Act

The establishment and maintenance of a biobank is regulated by the Human Genes Research Act. The law regulates the rights and obligations of a gene donor, data protection requirements and other guarantees for the protection of the rights of a gene donor.

## Definitions

- Gene donor - a person who provides his or her own tissue sample in accordance with Human Gene Research Act and for whom a description of the state of health and a family tree are prepared.
- Tissue sample - cells, intercellular material and body fluids taken from a person for genetic research.
- DNA - a molecule of deoxyribonucleic acid in which human heredity information is stored.
- Genetic data - information obtained from genetic research on human genes, gene products or hereditary traits, including a description of DNA or of its part.
- Description of health status - data collected for use in genetic research, which reflects the health status of the gene donor, the diseases suffered and their treatment, lifestyle, living environment and hereditary characteristics.
- Family tree - information in the gene bank about the names, dates of birth and kinship of ascending and descending relatives of the gene donor.
- Genetic research - the scientific research, description and identification of links between DNA, other components of a tissue sample, health descriptions and genealogies, with a view to obtaining data on human genes, gene products and hereditary characteristics.
- Biobank - a collection of tissue samples, DNA profiles, health descriptions, family trees, genetic data and gene donor identification data created and maintained by the controller.

## What's the biobank for?

By analysing the health-, genealogy- and gene data collected in the biobank, genes associated with one or another disease can be found. The database to be created will enable more accurate diagnosis of diseases, more efficient treatment and determination of disease risks in the future.

Creating a biobank is a long-term process. The above opportunities require research and scientific discovery, development and application of new technologies.

## Creating the biobank

The database of the gene bank is formed on the basis of the data of gene donors (description of the state of health and tissue sample). The tissue sample shall be taken by a medical professional who is authorized and qualified to do so. The description of the state of health is prepared by the gene donor her/himself by filling in an electronic questionnaire, which is made available to him/her after signing the consent form. In order to make the information on the gene donor as accurate as possible, the description of the health status of the gene donor is compared and supplemented with data from other databases. EGC can obtain data from state registers and databases containing health information, such as the Cancer Register, the Myocardial Infarction Register, the Register of Causes of Death, as well as from the databases of two regional hospitals - the North-Estonian Regional Hospital and the Tartu University Hospital. In the future, the number of databases from which data can be obtained may increase. Receiving of data from other databases is governed by relevant agreements and the highest possible security measures are applied to the processing of the data. The possibility of data leakage has been minimized through the use of mandatory measures. All tissue samples received in the EGC are processed and stored. Health descriptions and DNA isolated from tissue samples are stored in the biobank in a pseudonymous or coded form.

Based on DNA and health descriptions, genetic studies are performed to obtain gene data from gene donors. Based on the questionnaire filled in by the gene donor, data from other databases and gene research, the genealogy of the gene donor is compiled.

## What is pseudonymisation?

Pseudonymisation or coding is the replacement of data (name and personal identification code) that allow direct identification of a gene donor with a code. The code is 16 digits and is generated by the computer using random numbers and letters. The code is stored securely with the consent form. Pseudonymisation is one of the security measures for data protection. Compliance with all data protection requirements is monitored by the Data Protection Inspectorate.

## Who gets data from the biobank?

Biobank data on a specific gene donor can only be obtained by the gene donor her/himself and his/her family physician with the consent of the gene donor. Researchers only receive pseudonymized data. Pseudonymized data from a biobank can also be given abroad for research. The biobank data is not available to the police, the prosecutor's office, the court, the health insurance fund or insurance companies. Data are also not released to family members or relatives of the gene donor.

## How is the data released?

Descriptions of health status and genetic data are issued in a pseudonymized form from the biobank. Data enabling the direct identification of a gene donor will not be released. In order to prevent the indirect identification of a gene donor, pseudonymized data from at least five gene donors shall be issued at the same time.

## What is done with the data?

Biobank data, including those from other databases, are used for research in the fields of public health and genetics. In research the data is used in a pseudonymized form, which means that the researchers cannot identify whose data they are processing. The aim of the research is to find genes that influence

the development and course of diseases. Biobank data may not be used to identify persons and paternity or to investigate a crime.

### How is discrimination ruled out?

The law explicitly prohibits discrimination and foresees a punishment. Pursuant to the Penal Code, the unlawful restriction of a person's rights or the granting of giving illegal benefits to a person on the basis of his or her heredity is punishable by a fine, detention or imprisonment for up to one year. There are no restrictions on the gene donor, nor are there any benefits for the gene donor. Being a gene donor is a secret that EGC must not disclose. Insurance companies and employers are prohibited from collecting genetic personal data about policyholders and employees. Complaints arising from labour and insurance relations are resolved by the Labour Inspectorate and the Financial Supervision and Resolution Authority.

### What is depseudonymisation?

Depseudonymisation is the identification of a gene donor. Depseudonymisation makes it possible to link the personal data, health status and genetic data of a specific gene donor. Depseudonymisation may only be performed in EGC and only in cases permitted by law.

Depseudonymisation can be done:

- to release data to a gene donor;
- to issue data to the gene donor's family physician;
- to update, supplement and verify the data;
- to request new data from the gene donor with the consent of the ethics committee;
- to take a new tissue sample with the consent of the gene donor;
- to supplement the family tree;
- to destroy data entered in the biobank.

### Who owns the biobank?

The right to use the description of the state of health, the family tree and the written consent of the gene donor and the right to process the personal data contained therein arises for the University of Tartu as the chief processor of the biobank at the time of their preparation. Tissue samples are owned by the University of Tartu from the moment they are taken and are not transferable (sold, donated, etc.). Upon termination of the activities of the chief processor, the right of ownership and data processing of tissue samples shall be transferred to the Republic of Estonia.

### Financing of the biobank

EGC is financed by the Republic of Estonia. A gene donor does not receive money for providing a tissue sample, describing a health condition, or compiling a family tree, researching, and using research results. Gene donor data is stored in the biobank free of charge. The gene donor can access his data free of charge.

### What are the rights of a gene donor?

- A gene donor has the right to receive data about himself or herself from the biobank, except for family tree data. With the consent of the gene donor, the biobank can be accessed by his/her family physician.

- A gene donor has the right to be consulted upon access to the data held about him or her in the biobank. Genetic research data on hereditary traits and hereditary risk may be unpleasant for the gene donor.
- The gene donor has the right not to know his data.
- A gene donor has the right to disclose the fact of being or not being a gene donor.
- The gene donor has the right to submit additional information about himself / herself to the EGC.
- A gene donor has the right to prohibit the supplementation, updating and verification of the description of the state of health maintained in the biobank. Until then, the EGC can obtain data on the health status of the gene donor from other databases.
- The gene donor has the right at any time to request the destruction of data enabling depseudonymisation, after which it is no longer possible to identify the gene donor. Neither the gene donor nor his family physician will ever receive genetic data about the gene donor again. Thus, it is not possible to know what data about a particular gene donor is stored in the biobank.
- If the identity of a gene donor is unlawfully disclosed, the gene donor may demand the destruction of all data collected on him or her in the biobank and of the tissue sample. Other persons who have data from the biobank also have an obligation to destroy the data.
- The gene donor has the right to withdraw the consent until the tissue sample or the description of the health data is pseudonymised. In this case, the data will not reach the biobank. After pseudonymisation, the gene donor has the right to demand the destruction of data enabling depseudonymisation.

## Gene donor consent

People interested in becoming a gene donor can get acquainted with the conditions for becoming a gene donor and get information about blood collection points from the website [geenidoonor.ee](http://geenidoonor.ee). At the same place it is possible to digitally sign the consent form. The security of digital signature issuance in the Republic of Estonia is ensured by the Certification Centre. It is possible to sign a paper consent form at the blood collection site. If you have any questions about becoming a gene donor and signing the consent form, you can call the biobank information line, send an e-mail or contact the EGC office in Tartu, Riia 23b. Information about the contacts of the biobank can be found on the website [geenidoonor.ee](http://geenidoonor.ee). The gene donor consent form is stored in a separate archive in the EGC.

After signing the consent form, a blood sample can be donated at a suitable blood collection point. The locations of the blood collection points are given on the website [geenidoonor.ee](http://geenidoonor.ee). You can fill in the health questionnaire on the same website.

The protection of the rights and ethical standards of gene donors related to the establishment of a biobank is monitored by an independent ethics committee. The Data Protection Inspectorate supervises the collection, storage and coding of gene donor data and tissue samples.