

Information about the Genome Database of the Latvian population

Dear Sir or Madam!

We invite you to participate in the project of the development of the Genome Database of Latvian population in collaboration with Latvian Biomedical Research and Study centre. We kindly ask you read the following information carefully before signing the consent form.

The aim of the project:

Scientists have discovered that almost all disease development is facilitated by the interaction between heredity and harmful environmental factors. The aim of the project is to collect information about the heredity and genes of the population of Latvia, and environmental factor which might affect disease development, and store this information in a united database. These genetic studies would allow us to obtain new information about disease development and make steps for prophylaxis to attain or prevent these diseases. During the development of the Genome Database of Latvian population several scientific groups are participating to study gene influence on disease development. These researches will receive anonymized samples of your biological material and information about your health status from the Genome Database of Latvian population.

Description of enrolment procedures:

A certified medical specialist will draw a sample of your venous blood. Afterwards, a trained interviewer will help you to fill in the health and hereditary questionnaire, in which you will be asked to answer questions about you and your relatives regarding hereditary and environmental factors, which might affect disease development. Your health and hereditary information, and blood samples will be coded to ensure confidentiality.

Coded blood samples will be transported to Latvian Biomedical Research and Study centre and processed, to make sure your genetic information could be suitable for genetic analysis and long term storage in specifically designed restricted authorization area. Only project participants and persons with specific permissions will be allowed to use this coded information for scientific research only. Your personal data and other information that is acquired during enrolment and research process will not be accessible, with exclusion of cases provided in the legal regulation of the Republic of Latvia, these examples are described further in this form.

The informed consent, sample and data identification code will be stored at State Genome Registry.

Duration of the project:

Genome Database of Latvian population is developed and maintained at Latvian Biomedical Research and Study centre for an unlimited period of time. Your consent form will be stored at State Genome Registry for 75 years after the last revisions made.

Potential risks:

The participation in genome research will not harm your health. You will be required to provide a blood sample the same way as in case of a regular blood test. In rare cases a local hemorrhage or in very rare cases local skin inflammation can develop at the site of venipuncture.

Data confidentiality and the rights of the project participant:

Confidentiality of your personal data, health and hereditary information, genetic research results are ensured by “Human Genome Research Law” and “Personal Data Protection Law” of the Republic of Latvia. This information will be stored in a restricted access area and will not be provided to your relatives, insurance companies, or employers. Obtained data and tissue materials will not be used for commercial purposes and will not be illegally given to third parties.

The data collected about you in Genome Database of Latvian population will be given to the requesting parties only in cases that are provided to State Genome Registry, in cases described in “Human Genome Research Law”, and to you personally based on a submitted written application. Information about your health and results of genetic research (not your personal information!) will be accessible to researchers, who’s projects are approved by the Genome Research council and the Central Medical Ethics committee. With your written consent (with exclusion of emergency medical help) your health information will be accessible for your doctor in case of reasonably grounded request.

You have rights to access your data that are stored at Genome Database of Latvian population and supplement new data. You also have rights to prohibit supplementation, renewal and control of your data stored at Genome Database of Latvian population or limit the extent of your genome research. You have rights at any moment to withdraw your participation in the genome research project, in this case your tissue material, health status and hereditary information will be destroyed in Genome Database of Latvian population and in State Genome Registry.

Voluntary participation:

Your participation is voluntary. Your refusal to participate in this project will not harm you by any means.

Potential benefits:

Participation in this project will not give you any immediate benefit, but will serve for the generation of novel knowledge about diseases and heritability, that in future might help you, your relatives or the general society. In accordance with “Human Genome Research Law” you do not have the rights to demand charge for your biomaterial, health and hereditary information, as well as for the use of the genetic research results.

Contact person:

If you have additional questions please contact Prof. Janis Klovins at Latvian Biomedical Research and Study centre, Ratsupites str. 1-1, Riga, LV – 1067, Latvia.

Consent document of the gene donor*
(in relation to Genome Database of Latvian population)

I. (filled in by gene donor or his/her legal guardian)

1. I have received and carefully studied the written information about the aim of the genetic research project, content, duration and potential risks. All my questions were answered promptly and understandably. I had enough time to consider my decision to become a gene donor.

2. I am informed that I have rights to access the data regarding genetic research of my biological sample. I understand that I do not have the right to demand any charge for my samples, my health or genealogy research, as well as the use of the research results.

3. Supplementation, renewal and control of my health status in the genome database is:

- allowed
- prohibited

4. Research of my genome is:

- not limited
- limited to a certain extent (provide limitations)

5. Abroad shipment of my biologic material and health status information for genetic research is:

- allowed
- prohibited

6. If during the research of my genome any information about potential threats to my health or the health of my relatives will be discovered, I:

- agree that this information is communicated to me
- agree, that this information is communicated to me in cases if the risk for the health is preventable
- do not want this information to be communicated to me

7. I agree to be a gene donor in the genome research project voluntary, without any charge. I agree that for the purposes of the genetic research my tissue samples will be taken and health status and (or) genealogy can be recorded. I understand that at any time I have the right to withdraw my participation without providing any explanations. In this case my tissue sample, health status and any personal information will be destroyed.

| Gene donor | |
|--|--|
| Name and Surname (in block letters) | |
| Personal ID No. | |
| Address | |
| Date (day, month, year) | |
| Signature | |

II

| Gene researcher/Doctor of the gene donor | |
|---|--|
| Name and Surname (in block letters) | |
| Employment | |
| Signature | |
| Date (day, month, year) | |
| Place of consent completion | |

*“gene donor” – term used in “Human Genome Research Law” of the Republic of Latvia to describe a participant consenting to the research of his/her genetic material. Therefore, “gene donor” is a historical term, however, overtime biobank has evolved having much broader sense of patient recruitment and biosample application.