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[**See the digital seal**](https://www.riigiteataja.ee/akt_digitemplid.html?id=112032019027)

**Requirements for processor of Gene Bank**

Adopted on 8 March 2019, No. 22

The regulation is established on the basis of section 5 of the [Human Genes Research Act](https://www.riigiteataja.ee/akt/dyn%3D112032019027%26id%3D114032014030%21pr5lg1).

**§ 1.****Scope of application**

  The regulation establishes the requirements for natural or legal persons and the Estonian state or local government authorities who wish to obtain the right to process the Gene Bank from the controller of the Gene Bank.

**§ 2.****General requirement**

  A prospective processor must be able to fulfil the agreement concluded with the controller of the Gene Bank, comply with the laws and regulations on the processing of the Gene Bank and ensure the protection of the personal data and rights of the gene donors.

**§ 3.****Requirements for processors**

 (1) A processor must have the necessary knowledge, sufficient experience and financial resources for processing the Gene Bank.

 (2) A processor must have a thorough knowledge of the Human Genes Research Act and the legislation enacted on the basis thereof as well as other legislation, good scientific practice and ethical standards regulating the maintenance of the Gene Bank and compliance with its obligations.

 (3) In order to process the Gene Bank, the processor must have the following at their disposal:
 1) appropriately qualified and trained personnel
 2) appropriate and sufficiently large premises
 3) appropriate equipment, helpdesk and resources
 4) necessary materials, packaging and labels
 5) SOPs and work regulations approved by the management board of the controller
 6) appropriate conditions for storage and transport
 7) the required intellectual property rights
 8) the organisational and technical means, knowledge and experience necessary for ensuring that data protection requirements are met

 (4) The processor must have performed any and all obligations arising from tax laws in a timely manner and no bankruptcy proceedings must have been initiated against them.

**§ 4.****Agreement to be concluded with the processor**

 (1) The controller may conclude an agreement with a prospective processor who complies with the requirements stipulated in the Human Genes Research Act and this regulation.

 (2) The agreement specified in subsection 1 of this section establishes the conditions necessary for fulfilling the obligations of the controller of the Gene Bank, ensuring that the personal data and rights of gene donors are protected and complying with law.

 (3) The agreement specified in subsection 1 of this section must contain, *inter alia*, the following stipulations:
 1) The extent of the rights and obligations of the processor when processing the Gene Bank.
 2) The security and safety measures to be applied by the processor.
 3) Other requirements of the work organisation of the processor.
 4) The arrangements for training the processor and their employees.
 5) The remuneration procedure of the processor.
 6) The procedure for provision of materials and equipment to the person taking tissue samples and the person preparing descriptions of health condition.
 7) Liability of parties and the procedure for resolution of disputes.

**§ 5.****Special requirements to the monitor**

 (1) For the purposes of this Regulation, a monitor is a person who examines whether the processor meets their obligations properly and if the data and tissue samples to be submitted to the controller of the Gene Bank comply with the requirements.

 (2) The monitor must have adequate training in the fields of medicine and science in order to perform their duties.

**§ 6.****Other special requirements**

 (1) The processor must comply with the conditions for the preservation requirements of pseudonymised DNA samples, descriptions of DNA and descriptions of health condition established pursuant to subsection 18 (2) of the Human Genes Research Act.

 (2) The processor who has a tissue sample or biological residues of the extracted DNA or the tissue sample in their possession must be able to destroy the tissue samples and the biological residues resulting from their treatment using an autoclave.

**§ 7.****Entry into force of regulation**

  This regulation enters into force on 15 March 2019.

Riina Sikkut
Minister of Health and Labour

Marika Priske
Secretary General