|  |  |
| --- | --- |
| Issuer: | Minister of Social Affairs |
| Type of act: | Regulation |
| Type of text: | Full text |
| In force from: | 15 March 2019 |
| In force until: | In force |
| Publication reference: | RT I, 12.03.2019, 45 |

**Procedure for issuing tissue samples, descriptions of DNA and descriptions of health condition of gene donors**

Adopted on 17 December 2001, No. 126
[RTL 2002, 1, 7](https://www.riigiteataja.ee/akt/86997)
entry into force 6 January 2002

The Regulation is established on the basis of subsection 20 (4) of the [Human Genes Research Act](https://www.riigiteataja.ee/akt/dyn%3D112032019045%26id%3D12803316%21pr20lg4).

**Chapter 1
GENERAL PROVISIONS**

**§ 1.****Scope of application**

 (1) The Regulation establishes the procedure for issuing tissue samples, including DNA, descriptions of DNA and descriptions of health condition from the Gene Bank, including the form of the record of issue and the procedure for the completion and preservation thereof.

 (2) The requirements to be established with this Regulation are binding on the controllers of the Gene Bank, the processors of the Gene Bank and any third parties who accept pseudonymised tissue samples, descriptions of DNA or descriptions of health condition.
[[RT I, 12.03.2019, 41](https://www.riigiteataja.ee/akt/112032019041) - entry into force 15 March 2019]

**Chapter 2
ISSUING OF PSEUDONYMISED TISSUE SAMPLES, DESCRIPTIONS OF DNA AND DESCRIPTIONS OF HEALTH CONDITION**
[[RT I, 12.03.2019, 41](https://www.riigiteataja.ee/akt/112032019041) - entry into force 15 March 2019]

**§ 2.****Right to issue pseudonymised tissue samples, descriptions of DNA and descriptions of health condition**
[[RT I, 12.03.2019, 41](https://www.riigiteataja.ee/akt/112032019041) - entry into force 15 March 2019]

 (1) Pseudonymised tissue samples, descriptions of DNA and descriptions of health condition may be issued from the Gene Bank only by the controller of the Gene Bank. The controller may not assign the right to issue pseudonymised tissue samples, descriptions of DNA and descriptions of health condition to a processor of the Gene Bank.
[[RT I, 12.03.2019, 41](https://www.riigiteataja.ee/akt/112032019041) - entry into force 15 March 2019]

 (2) The controller of the Gene Bank may, in turn, issue pseudonymised tissue samples, descriptions of DNA and descriptions of health condition that have been issued from the Gene Bank only in accordance with legislation if such right arises from the agreement concluded between the controller and the processor of the Gene Bank.
[[RT I, 12.03.2019, 41](https://www.riigiteataja.ee/akt/112032019041) - entry into force 15 March 2019]

 (3) The controller or the processor of the Gene Bank who has issued pseudonymised tissue samples, descriptions of DNA and descriptions of health condition must ensure by imposing contractual obligations that the person who has accepted the tissue samples, descriptions of DNA or descriptions of health condition prepares records of issue when passing on a tissue sample, a description of DNA or a description of health condition.
[[RT I, 12.03.2019, 41](https://www.riigiteataja.ee/akt/112032019041) - entry into force 15 March 2019]

**§ 3.****Paid nature of issue of tissue samples, descriptions of DNA and descriptions of health condition**

 (1) The controller of the Gene Bank issues tissue samples, descriptions of DNA and descriptions of health condition for a fee, if such practice is agreed on in the agreement entered into between the controller of the Gene Bank and the person accepting tissue samples, descriptions of DNA and descriptions of health condition.

 (2) In an agreement entered into between a legal person governed by public law or a state authority of the Republic of Estonia and the controller of the Gene Bank, it may be agreed that only the direct data issuance related costs of issuing descriptions of DNA or a part thereof are covered.

**§ 4.****Term of issue of tissue samples, descriptions of DNA and descriptions of health condition**

 (1) The controller of the Gene Bank issues tissue samples, descriptions of DNA and descriptions of health condition within a reasonable term agreed on in the agreement entered into between the controller of the Gene Bank and the person accepting tissue samples, descriptions of DNA and descriptions of health condition.

 (2) The agreement entered into between the controller of the Gene Bank and the person accepting tissue samples, descriptions of DNA and descriptions of health condition may contain stipulations regarding a fine for delay in case of delays in issue. The controller of the Gene Bank bears no responsibility for any damage that the person applying for tissue samples, descriptions of DNA and descriptions of health condition may suffer.

**§ 5.****Agreement on issuing tissue samples, descriptions of DNA and descriptions of health condition**

 (1) The controller of the Gene Bank must enter into an agreement with the person accepting tissue samples, descriptions of DNA and descriptions of health condition before issuing any tissue samples, descriptions of DNA and descriptions of health condition.

 (2) The agreement specified in subsection 1 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) In order to fulfil their obligations, the controller of the Gene Bank may require that the person accepting tissue samples, descriptions of DNA and descriptions of health condition provide information regarding the purpose and circumstances of the use of the tissue samples, descriptions of DNA and descriptions of health condition and the identity or personnel of the user. The controller of the Gene Bank refuses to enter into an agreement on issue of tissue samples, descriptions of DNA and descriptions of health condition or carry it out if the issue of tissue samples, descriptions of DNA and descriptions of health condition is in conflict with the Human Genes Research Act or if the protection of personal data and rights of gene donors is not ensured.

 (4) The controller of the Gene Bank has the obligation to notify the data protection supervision authority of any circumstances related to violations or suspected violations of data protection legislation by the person accepting tissue samples, descriptions of DNA and descriptions of health condition.

**§ 6.****Preparation of tissue samples, descriptions of DNA and descriptions of health condition for issue**

 (1) Before issuing tissue samples, descriptions of DNA and descriptions of health condition, the controller or a processor of the Gene Bank must examine the compliance of the tissue samples, descriptions of DNA and descriptions of health condition to be issued with the terms and conditions of the agreement specified in subsection 5 (1) of the Regulation and the application for issue.

 (2) The controller or a processor of the Gene Bank completes and signs the records of issue to be issued along with the tissue samples, descriptions of DNA and descriptions of health condition.

**Chapter 3
ISSUING OF DE-PSEUDONYMISED DESCRIPTIONS OF DNA AND DESCRIPTIONS OF HEALTH CONDITION**
[[RT I, 12.03.2019, 41](https://www.riigiteataja.ee/akt/112032019041) - entry into force 15 March 2019]

**§ 7.****Right to issue and receive de-pseudonymised descriptions of DNA and descriptions of health condition**
[[RT I, 12.03.2019, 41](https://www.riigiteataja.ee/akt/112032019041) - entry into force 15 March 2019]

 (1) Only the controller of the Gene Bank has the right to issue de-pseudonymised descriptions of DNA and descriptions of health condition.
[[RT I, 12.03.2019, 41](https://www.riigiteataja.ee/akt/112032019041) - entry into force 15 March 2019]

 (2) Only a gene donor and the doctor of a gene donor has the right to receive the de-pseudonymised description of DNA and description of health condition in the instances provided for in subsections 11 (2), 16 (1) and 16 (2) of the Human Genes Research Act.
[[RT I, 12.03.2019, 41](https://www.riigiteataja.ee/akt/112032019041) - entry into force 15 March 2019]

 (3) A gene donor and the doctor of a gene donor has the right to receive the de-pseudonymised description of DNA and description of health condition free of charge. The gene donor and the doctor of the gene donor have no right to use the de-pseudonymised description of DNA and description of health condition of the gene donor for commercial purposes or disclose the data to third parties who intend to use the data for commercial purposes.
[[RT I, 12.03.2019, 41](https://www.riigiteataja.ee/akt/112032019041) - entry into force 15 March 2019]

**§ 8.****Procedure for issuing de-pseudonymised descriptions of DNA and descriptions of health condition**
[[RT I, 12.03.2019, 41](https://www.riigiteataja.ee/akt/112032019041) - entry into force 15 March 2019]

 (1) Before accepting the application to issue de-pseudonymised descriptions of DNA and descriptions of health condition, the controller of the Gene Bank verifies that the gene donor/a third party has the right to receive data from the Gene Bank.

 (2) The gene donor who wants to receive their de-pseudonymised description of DNA and description of health condition must submit an application to receive data to the controller in such a way that it is possible to clearly identify the person; the gene donor must specify which data should be issued and to whom. If the data is not issued to the gene donor in person, the confidentiality of the data during transfer must be secured by encryption or other relevant methods.

 (3) The controller documents the date of issuing the de-pseudonymised description of DNA and description of health condition and information on the person to whom the data was issued.
[[RT I, 12.03.2019, 41](https://www.riigiteataja.ee/akt/112032019041) - entry into force 15 March 2019]

**Chapter 4
RECORDS OF ISSUE**

**§ 9.****Data to be entered in records of issue and form of records of issue**

 (1) The records of issue must include the following information:
 1) information identifying and characterising the records
 2) information identifying the persons or the representatives of the persons issuing and receiving the tissue samples, descriptions of DNA and descriptions of health condition
 3) information identifying and characterising the tissue samples, descriptions of DNA and descriptions of health condition being issued
 4) information identifying the method of issue
 5) terms and conditions of further use and preservation of the tissue samples, descriptions of DNA and descriptions of health condition being issued
 6) any statements of the issuer and the recipient
 7) a statement that the records may not be copied without the written consent of the controller of the Gene Bank
 8) the method of sending the records of issue to the controller of the Gene Bank
 9) other important information

 (2) [Invalid - [RT I, 12.03.2019, 41](https://www.riigiteataja.ee/akt/112032019041) - entry into force 15 March 2019]

 (3) The code issued for the tissue sample, description of DNA or description of health condition by the controller may not be amended or deleted.

**§ 10.****Preparation of records of issue**

 (1) Records of issue are prepared by the issuer in at least two copies so that one copy is kept by the controller, one copy by the person issuing or transferring the tissue sample or data and one copy by the recipient.

 (2) Records of issue must not be amended after they have been completed and signed.

 (3) Records of issue must be prepared and completed in a way that ensures the identifiability of any subsequent changes to the data entered in the records.

**§ 11.****Signing records of issue**

 1) The person issuing tissue samples, descriptions of DNA and descriptions of health condition signs the records of issue when the preparations for issue have been completed.

 (2) The person receiving tissue samples, descriptions of DNA and descriptions of health condition signs the records of issue after verifying the veracity of the information entered in the records of issue and sends one copy of the records of issue to the controller of the Gene Bank using a courier service or other method specified by the controller of the Gene Bank and communicated to the recipient. The person issuing tissue samples, descriptions of DNA and descriptions of health condition is responsible for the proper completion of the records of issue and the forwarding thereof to the controller.

 (3) If the recipient of the tissue samples, descriptions of DNA and descriptions of health condition establishes inaccuracies in the information specified in the records of issue, they must promptly notify the issuer of the tissue samples, descriptions of DNA and descriptions of health condition thereof and refuse to sign records of issue and to receive the tissue samples, descriptions of DNA and descriptions of health condition while ensuring that the tissue samples, descriptions of DNA and descriptions of health condition are preserved and the rights and the confidentiality of the gene donor are protected.

**§ 12.****Preservation of records of issue**

 (1) Records of issue are preserved by the controller of the Gene Bank permanently and in accordance with the requirements established for the preservation of pseudonymised tissue samples, descriptions of DNA and descriptions of health condition in a regulation of the Minister of Social Affairs based on subsection 18 (2) of the Human Genes Research Act.
[[RT I, 12.03.2019, 41](https://www.riigiteataja.ee/akt/112032019041) - entry into force 15 March 2019]

 (2) The controller and the person who received tissue samples, descriptions of DNA or descriptions of health condition must preserve the records of issue while the tissue samples, descriptions of DNA or descriptions of health condition specified in the records of issue are in their possession.

Appendix

Records of issue
[Invalid - [RT I, 12.03.2019, 41](https://www.riigiteataja.ee/akt/112032019041) - entry into force 15 March 2019]