|  |  |
| --- | --- |
| 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, 43 |

**Terms and conditions for storage of pseudonymised tissue samples, descriptions of DNA and descriptions of health condition of gene donors**

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

Adopted on 17 December 2001, No. 127  
[RTL 2002, 1, 8](https://www.riigiteataja.ee/akt/86998)  
entry into force 6 January 2002

The Regulation is established on the basis of subsection 18 (2) of the [Human Genes Research Act](https://www.riigiteataja.ee/akt/dyn=112032019043&id=12803316!pr18lg2).

**§ 1.****Scope of application**

 (1) The requirements to be established with this Regulation are binding on the controllers of the Gene Bank and the processors of the Gene Bank who apply for or have received the right from a controller of the Gene Bank to store 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]

 (2) Storage of tissue samples, descriptions of DNA or descriptions of health condition includes the establishment of storage conditions in compliance with this Regulation, the preparation of pseudonymised tissue samples, descriptions of DNA or descriptions of health condition for storage and the protection of the stored tissue samples, descriptions of DNA or descriptions of health condition from destruction, theft, unauthorised copying and tampering.

**§ 2.****General requirements**

 (1) Pseudonymised tissue samples, descriptions of DNA and descriptions of health condition are stored by the controller. The controller is responsible for such storage. The controller may transfer pseudonymised tissue samples, descriptions of DNA and descriptions of health condition to a processor for storage in order to reduce the risk of destruction and tampering and also at the request of the processor if this would facilitate the subsequent processing of the tissue samples, descriptions of DNA or descriptions of health condition at the place of their storage and compliance with the agreement entered into with the controller of the Gene Bank.

 (2) The processor who has received a pseudonymised tissue sample, description of DNA and description of health condition issued by the controller is responsible for such tissue sample, description of DNA and description of health condition.

 (3) For storage of tissue samples, descriptions of DNA or descriptions of health condition, it is necessary to have the storage premises and storage equipment that ensure the protection of the stored tissue samples, descriptions of DNA or descriptions of health condition from destruction, theft, unauthorised copying and tampering.

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

**§ 3.****Requirements of storage premises**

 (1) Pseudonymised tissue samples, descriptions of DNA and descriptions of health condition are stored in specially built or adapted premises whose structure and location in the building makes it impossible for unauthorised persons to access the premises and ensures that the tissue samples, descriptions of DNA and descriptions of health condition are indefinitely usable for performing genetic research.

 (2) The minimum fire resistance class of the storage premises is A120. Smoking and use of open fire or flammable substances in the storage premises is forbidden. The amount of wooden, textile and synthetic materials used in fitting out the premises must be kept to minimum. The storage premises must be equipped with a fire detection and fire alarm system and a sufficient number of suitable portable fire extinguishers.

 (3) The storage premises must be safe from water damage and floods.

 (4) The storage premises must be burglar-proof and have no windows. The storage premises must be equipped with an automatic surveillance and alarm system.

 (5) The storage premises must ensure that the tissue samples, descriptions of DNA and descriptions of health condition are preserved in the case of general power failure.

 (6) The heating and ventilation system of the storage premises must ensure that the required temperature and humidity is maintained in the storage premises.

 (7) In the storage premises, there must be no chemically active substances, radiation, magnetic or electric fields that may damage the tissue samples, descriptions of DNA and descriptions of health condition.

**§ 4.****Requirements of preparation for storage**

  Before receiving the tissue samples, descriptions of DNA and descriptions of health condition for storage, the processor must ensure that:  
 1) The tissue samples, descriptions of DNA and descriptions of health condition are pseudonymised;  
 2) The pseudonymised tissue sample has not reached its expiration date for gene research.

**§ 5.****Requirements of storage**

 (1) Pseudonymised tissue samples are stored with a clear label.

 (2) Pseudonymised descriptions of DNA and descriptions of health condition are stored in an information system located in the storage premises.

 (3) The information system containing the pseudonymised descriptions of DNA and descriptions of health condition must be protected against the deletion, amendment, copying, reading or other processing of data by unauthorised persons.

 (4) The information system containing the pseudonymised descriptions of DNA and descriptions of health condition must allow for verifiable identification of the time and date of processing the data and the person who actually processed the data.

**§ 6.****Safety plan**

 (1) The person storing the pseudonymised tissue samples, descriptions of DNA and descriptions of health condition must establish a safety plan to prevent damage to and destruction of the tissue samples, descriptions of DNA or descriptions of health condition being stored.

 (2) The safety plan must provide for measures for protecting and saving the tissue samples, descriptions of DNA and descriptions of health condition in the case of potential emergency.

 (3) The processors must obtain the approval of the controller of the Gene Bank regarding the safety plan.