

On approval of the rules for the operation of the tissue bank

Unofficial translation

Order № KR DSM-251/2020 of the Minister of Healthcare of the Republic of Kazakhstan as of December 11, 2020. It is registered with the Ministry of Justice of the Republic of Kazakhstan on December 14, 2020 under № 21770.

Unofficial translation

In accordance with paragraph 4 of Article 211 of the Code of the Republic of Kazakhstan “On Public Health and the Healthcare System” as of July 7, 2020, I hereby **ORDER**:

1. To approve the rules for the operation of the tissue bank in accordance with the appendix to this order.

2. In the manner prescribed by the legislation of the Republic of Kazakhstan, the Medical Aid Department of the Ministry of Healthcare of the Republic of Kazakhstan shall ensure:

1) the state registration of this order with the Ministry of Justice of the Republic of Kazakhstan;

2) the posting of this order on the website of the Ministry of Healthcare of the Republic of Kazakhstan after its official publication;

3) the submission of information on the implementation of the measures provided for in subparagraphs 1) and 2) of this paragraph to the Legal Department of the Ministry of Healthcare of the Republic of Kazakhstan within ten working days of the state registration of this order with the Ministry of Justice of the Republic of Kazakhstan.

3. Control over the execution of this order shall be entrusted to the supervising deputy minister of healthcare of the Republic of Kazakhstan.

4. This order comes into effect ten calendar days of its first official publication.

*Minister of Healthcare of
the Republic of Kazakhstan*

A. Tsoi

Appendix to Order
№ KR DSM-251/2020
of the Minister of Healthcare
of the Republic of Kazakhstan
as of December 11, 2020

Rules for the operation of the tissue bank

Chapter 1. General provisions

1. These rules for the operation of the tissue bank (hereinafter referred to as the Rules) have been developed in accordance with paragraph 4 of Article 211 of the Code of the

Republic of Kazakhstan “On Public Health and the Healthcare System” as of July 7, 2020 (hereinafter referred to as the Code) and establish the procedure for the operation of the tissue bank.

2. B The following terms and definitions are used in these Rules:

1) storage of organs (part of an organ) and (or) tissues (part of tissue) - a set of measures aimed at maximizing the preservation of the viability of cells of organs (part of an organ) and (or) tissues (part of tissue) until the moment of transplantation;

2) donor - a person, a cadaver, an animal from which donor blood, its components, other donor material (including sperm, oocytes, tissue of reproductive organs, germ cells, embryos) are collected, and also organs (parts of an organ) and (or) tissues (parts of tissue) are removed for transplantation to a recipient;

3) tissue - a set of cells and intercellular substance that have the same structure, function and origin;

4) tissue bank - a state medical facility, medical organization, one hundred percent of the voting shares (stakes in the authorized capital) of which are owned by the state, as well as "Nazarbayev University" medical organizations, that carry out removal, procurement, conservation, transportation, storage of tissues (tissue parts) for subsequent transplantation provided that it has a license for medical activities on the provision of services for the transplantation of organs (organ part) and (or) tissues (parts of tissue) according to the profile of medical activity.

Footnote. Paragraph 2 as amended by the order of the Acting Minister of Healthcare of the Republic of Kazakhstan dated 30.07.2021 No. ҚР ДСМ-71 (shall be enforced upon expiry of ten calendar days after the date of its first official publication).

3. The activity of tissue banks is aimed at the formation of stocks of biological materials and their provision to healthcare entities carrying out transplantation.

4. The power supply to the tissue bank requires the presence of a backup power supply unit.

5. The tissue bank prepares and stores the following tissues (parts of tissue):

- 1) skin;
- 2) bones;
- 3) cartilages;
- 4) tendons;
- 5) dura mater;
- 6) vessels;
- 7) heart valves;
- 8) amniotic membrane;
- 9) animal tissues (skin, bones, peritoneum, pericardium, bones).

Chapter 2. Procedure for the operation of the tissue bank

6. The actions of the tissue bank are aimed at preserving the identity and quality characteristics of tissues (parts of tissue) and compliance with the conditions for their storage.

7. Tissue banks shall provide special rooms (areas) for processing and storing tissue (tissue parts), which are designed and operated to prevent contamination, cross-contamination, mislabeling and deterioration of tissue (tissue parts).

8. Containers for each category of tissue (part of tissue) are identified by a label indicating the nature of the contained tissue (part of tissue) and a barcode of the tissue (part of tissue) or a donor ID label, if necessary.

9. Premises (zones), used for storing tissues (parts of tissue) shall comply with sanitary rules, hygienic standards approved, approved by the Order of the Minister of Healthcare of the Republic of Kazakhstan dated August 11, 2020 No. ҚР ДСМ -96/2020 "On approval of the Sanitary Rules "Sanitary and epidemiological requirements for healthcare facilities" (registered in the Register of State Registration of Normative Legal Acts under No. 21080.

Footnote. Paragraph 9 - as amended by the order of the Acting Minister of Healthcare of the Republic of Kazakhstan dated 30.07.2021 № ҚР ДСМ-71 (shall be enforced upon expiry of ten calendar days after the date of its first official publication).

10. The area of the premises (zones) used for storing tissues (parts of tissue) is divided into zones designed to perform the following functions:

- 1) acceptance of tissues (parts of tissue);
- 2) processing of tissues (parts of tissue);
- 3) main storage of tissues (parts of tissue);
- 4) storage of tissues (parts of tissue) requiring special conditions;
- 5) quarantine storage of tissues (tissue parts).

11. The tissue bank provides storage conditions for tissues (parts of tissue) allowing to preserve the biological properties of tissues (parts of tissue) and prevent their infection and contamination, by creating, in the premises (zones), the required for their storage:

- 1) temperature and humidity conditions;
- 2) sanitary and hygienic regime;
- 3) light mode.

12. The tissue bank storage shall have refrigeration and other necessary equipment.

13. Tissues (parts of tissue) placed in the tissue bank are marked with identification numbers, which are retained until samples are issued from the tissue bank.

14. In case of the storage of tissue (part of tissue) in liquid nitrogen, the storage rooms (zones) are equipped with independent exhaust ventilation system and emergency ventilation, which turns on automatically upon a signal from the gas analyzer.

15. Racks (cabinets), refrigerators and freezers for storing tissues (parts of tissue) are marked to ensure the identification of tissues (parts of tissue) in accordance with the recording system used in the tissue bank.

16. Tissues (parts of tissue), in respect of which a decision on further use has not been made, the use of which has been suspended, which are subject to return, as well as tissues (parts of tissue), in respect of which a decision has been made to suspend or stop their use, are isolated and placed in a specially designated room (zone) having the electronic data processing system that ensures their separation.

17. The equipment used for storing tissues (parts of tissue) in a tissue bank complies with the technical and operational documentation of the producer (manufacturer), with a valid verification mark and (or) a verification certificate if this equipment belongs to measuring instruments.

18. Equipment affecting the storage of tissues (parts of tissue) is designed, placed and maintained in accordance with the documentation for its use (operation).

19. Repair, maintenance, verification and (or) calibration of equipment in the tissue bank is carried out in accordance with the approved schedule so that the quality of the tissue (part of tissue) is not negatively affected.