

On approval of the Rules for biological safety research, preservation and transportation of tissues (part of tissue) of a person and (or) organs (part of organ) intended for import and export

Unofficial translation

Order of the Minister of Healthcare of the Republic of Kazakhstan dated December 15, 2020 No. ҚР ДСМ-265/2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on December 20, 2020 No. 21807

Unofficial translation

In accordance with clause 8 of article 217 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On Public Health and Healthcare System" **I HEREBY ORDER:**

1. To approve the Rules for biological safety research, preservation and transportation of tissues (part of tissue) of a person and (or) organs (part of organ) intended for import and export.

2. To recognize as invalid the order of the Minister of Healthcare of the Republic of Kazakhstan dated November 25, 2009 No. 780 "On approval of the Rules for biological safety research, preservation and transportation of tissues and (or) organs (part of organs), blood and its components, intended for import and export" (registered in the Register of State Registration of Regulatory Legal Acts as No. 5944, published in 2010 in the Collection of the acts of central executive and other central state bodies of the Republic of Kazakhstan No. 7).

3. The Department for Organization of Medical Care of the Ministry of Health of the Republic of Kazakhstan, in accordance with the procedure, established by the legislation of the Republic of Kazakhstan, shall ensure:

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

2) placement of this order on the Internet resource of the Ministry of Healthcare of the Republic of Kazakhstan after its official publication;

3) within ten working days after the state registration of this order with the Ministry of Justice of the Republic of Kazakhstan submission to the Legal Department of the Ministry of Healthcare of the Republic of Kazakhstan of information about implementation of measures stipulated by subclauses 1) and 2) of this clause.

4. Control over execution of this order shall be entrusted to the supervising Vice-Minister of Healthcare of the Republic of Kazakhstan.

5. This order shall come into force upon expiry of ten calendar days after the date of its first official publication.

Rules for biological safety research, preservation and transportation of tissues (part of tissue) of a person and (or) organs (part of organ) intended for import and export

Chapter 1. General Provisions

1. These Rules for biological safety research, preservation and transportation of tissues (part of tissue) of a person and (or) organs (part of organ) intended for import and export (hereinafter referred to as the Rules) have been developed in accordance clause 8 of article 217 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On Public Health and Healthcare System" (hereinafter referred to as the Code) and establish the procedure for biological safety research, preservation and transportation of tissues (part of tissue) of a person and (or) organs (part of organ) intended for import and export.

2. In these Rules, the following terms and definitions are used:

- 1) organ – a part of a body, which performs a certain function;
- 2) removal of tissues (part of tissue) of a person and (or) organs (part of organ) – a surgery to remove one or more of the tissues (part of tissue) of a person and (or) organs (part of organ) from a donor for the purposes of transplantation to a recipient;
- 3) preservation of tissues (part of tissue) of a person and (or) organs (part of organ) – a set of measures to ensure the protection of cells of tissues (part of tissue) of a person and (or) organs (part of organ) from internal and external influence, in order to preserve vital activity of tissues (part of tissue) of a person and (or) organs (part of organ);
- 4) transportation of tissues (part of tissue) of a person and (or) organs (part of organ) – a set of measures to deliver tissues (part of tissue) of a person and (or) organs (part of organ) for storage and transportation;
- 5) donor - a person, a human corpse, an animal from which donor blood, its components, other donor material (including sperm, eggs, tissue of reproductive organs, reproductive cells, embryos), as well as the removal of organs (part of an organ) and/or tissues (part of tissue) for transplantation to a recipient;
- 6) recipient - a patient who has undergone a transfusion of donor blood or components and (or) drugs isolated from it, the introduction of male or female donor material (sperm, egg cells, embryos) or organ transplantation (part of organ) and (or) tissues (part of tissue) from a donor, as well as artificial organs (part of organ);
- 7) tissue – a set of cells and intercellular substance that have the same structure, function and origin;

8) transplantation – spare-part surgery of organs (part of an organ) and (or) tissues (part of tissue) to another place in the body or into another organism.

Chapter 2. Procedure for biological safety research of tissues (part of tissue) of a person and (or) organs (part of organ) intended for import and export

3. Biological safety research of tissues (part of tissue) and (or) organs (part of organ), intended for import and export includes compulsory determination of infections in the donor's blood for the human immunodeficiency virus (hereinafter - HIV), syphilis, viral hepatitis B, viral hepatitis C, according if medically required - for types of infections in accordance with clause 1 of article 205 of the Code, and is performed in healthcare organizations carrying out activities in the field of blood service of the Republic of Kazakhstan (hereinafter referred to as the healthcare organizations).

Upon receipt of a primary reactive or questionable result for markers of HIV infection, a donor blood sample must be sent to the laboratory of the republican health organization operating in the field of HIV infection prevention for additional research.

4. To determine the markers of HIV, syphilis, viral hepatitis B, viral hepatitis C in the donor's blood for the purpose of biological safety research of tissues (part of tissue) and (or) organs (part of organ), the following are used:

polymerase chain reaction method (hereinafter - PCR);

methods of enzyme immunoassay (hereinafter - ELISA), immunochemiluminescence analysis (hereinafter - ICLA) or electrochemiluminescence analysis (hereinafter - ECLA).

In healthcare organizations, the donor's blood is tested by ICLA or ECLA or ELISA for HIV, syphilis, viral hepatitis B and hepatitis C and PCR qualitative determination of HIV1 RNA, viral hepatitis C and viral hepatitis B DNA; according to indications - for types of infections in accordance with clause 1 of article 205 of the Code.

5. All blood samples tested for HIV, syphilis, viral hepatitis B and C are archived and stored in the laboratories of health care organizations operating in the field of blood services at temperatures from minus 20 to minus 70 for 12 months from the date of testing.

Chapter 3. Procedure for preservation of tissues (part of tissue) of a person and (or) organs (part of organ) intended for import and export

6. The preservation of tissues (part of tissue) of a person and (or) organs (part of organ) intended for import and export is carried out in public healthcare organizations and is performed by a medical worker who has a professional medical education in accordance with clause 2 of article 209 of the Code.

7. The preservation of tissues (part of tissue) of a person and (or) organs (part of organ) intended for import and export is performed immediately upon their removal and in compliance with all sanitary and epidemiological requirements.

8. The following methods are used for preservation of tissues (part of tissue) of a person and (or) organs (part of organ) intended for import and export:

- 1) hypothermic at temperatures up to plus 4-5 in special preservative solutions;
- 2) low temperature at temperatures from 0 to minus 196 ;
- 3) hypothermic method in a humid chamber.

9. Containers containing tissues (part of tissue) and (or) organs (part of organ), intended for import and export, comply with safety requirements, serviceable, hermetically sealed and made of material that does not affect the physicochemical, microbiological and physiological characteristics tissues (part of tissue) and (or) organs (part of organ).

Containers are not allowed to be used for other purposes.

10. After preservation of tissues (part of tissue) of a person and (or) organs (part of organ) intended for import and export, the health organization issues a Passport of the preserved tissue (part of tissue), organ (part of organ) (hereinafter - Passport) in the form according to the appendix to this order.

11. The passport is drawn up in three copies: the first one is kept in the healthcare organization; the second is provided in a healthcare organization subordinate to an authorized body that coordinates transplantation and high-tech medical services; third - attached to the container subject to import and export.

12. The seized organs (part of the organ) of vision and (or) tissues (parts of tissues) of a person are placed in sterile vials with 2.0 ml of saline. The vials are closed with a lid and marked with the name of the removed organs (part of the organ) of vision and (or) tissues (parts of tissues) of a person, the date of conservation, the number assigned to the donor.

13. Method of preservation of organs (parts of organs) of sight and (or) tissues (parts of tissues) of a person:

- 1) with hypothermic conservation - from plus 2 to plus 4 from 24 to 168 hours;
- 2) with cryothermal conservation - from minus 20 to minus 80 up to 2 years;
- 3) in a humid chamber - from 4 to 48 hours.

Chapter 4. Procedure for transportation of tissues (part of tissue) of a person and (or) organs (part of organ) intended for import and export

14. Transportation of tissues (part of tissue) of a person and (or) organs (part of organ) intended for import and export is carried out in public healthcare organizations and is performed by a medical worker who has a professional medical education in accordance with clause 2 of article 209 of the Code.

15. Transport of tissues (part of tissue) and (or) organs (part of organ) is carried out in special containers in compliance with the principles of the "cold chain".

Transportation of organs (part of organs) of sight and (or) tissues (part of tissues) of a person is carried out in a thermocontainer in compliance with the temperature regime from 0 to plus 4 .

Transportation of organs of the heart, lungs, kidneys and liver of a person is carried out in containers with observance of the temperature regime from 0 to plus 4 .

For long-term transportation of the donor's heart and lungs, special medical equipment is used, which provides an increase in the transportation time from 12 to 18 hours at a temperature of + 34 .

The transportation time in a container of a donor heart from the moment of removal to transplantation is up to 4 hours.

The transportation time in a container of donor lungs from the moment of removal to transplantation is 4 to 6 hours.

The transportation time in the container of donor kidneys and donor liver from the moment of removal to transplantation is up to 24 hours.

16. Transportation of tissues (part of tissue) of a person and (or) organs (part of organ) is carried out by land, water, air transport.

Appendix to the rules

Passport of the preserved tissue (part of tissues) of a person and (or) organ (part of organ)

Date, time of removal of tissues (part of tissue) of a person and (or) organs (part of organ) :

Name, quantity of tissues (part of tissue) of a person and (or) organs (part of organ):

Healthcare organization where the removal of tissues (part of tissue) of a person and (or) organs (part of organ) was performed:

surname, name, patronymic (if any) of the donor, age, sex: _____

blood group, rhesus factor _____

Donor's medical record No.: _____

Reason of the donor's death:

Method of preservation of tissues (part of tissue) of a person and (or) organs (part of organ), name of the preservation solution:

Date of expiration of the preservative solution _____

Date and results of the ELISA and (or) PCR test for:
HIV infection: _____

B hepatitis: _____

C hepatitis: _____

Syphilis: _____

The name of the healthcare organization, full name (if any), the position of persons who carried out the removal and preservation of tissues (part of tissue) of a person and (or) organs (part of organ):

surname, name, patronymic (if any), signature of persons, responsible for preservation:

— Date, time: _____

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