



On approval of the rules for removal and preservation of visual organs from cadavers for transplantation in pathologic anatomy and forensic medical examination organizations

Unofficial translation

Order of the Minister of Health of the Republic of Kazakhstan dated December 21, 2020 No. ҚР DSM-307/2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on December 22, 2020 No. 21850

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In accordance with paragraph 4 of Article 212 of the Code of the Republic of Kazakhstan dated July 7, 2020 On Public Health and Health Care System, **I hereby ORDER:**

1. Approve the rules for removal and preservation of visual organs from cadavers for transplantation in pathologic anatomy and forensic medical examination organizations in accordance with the appendix to this order.

2. The Department for organization of medical aid of the Ministry of Healthcare of the Republic of Kazakhstan, in accordance with the procedure established by the legislation of the Republic of Kazakhstan, shall:

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

2) post 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, report to the Legal Department of the Ministry of Healthcare of the Republic of Kazakhstan on execution of the actions provided for in subparagraphs 1) and 2) of this paragraph.

3. Control over the execution of this order shall be assigned to the supervising Vice Minister of Healthcare of the Republic of Kazakhstan.

4. This order shall be enforced upon expiry of ten calendar days after the date of its first official publication.

*Minister of Healthcare
of the Republic of Kazakhstan*

A. Tsoi

"AGREED"

Ministry of Justice
of the Republic of Kazakhstan

Appendix
to Order No. KR DSM-307/2020
of the Minister of Healthcare
of the Republic of Kazakhstan
as of December 21, 2020

Rules for removal and preservation of visual organs from cadavers for transplantation in in pathologic anatomy and forensic medical examination organizations

Chapter 1. General Provisions

1. These rules for removal and preservation of visual organs from cadavers for transplantation in pathologic anatomy and forensic medical examination organizations (hereinafter -the Rules) have been developed in accordance with paragraph 4 of Article 212 of the Code of the Republic of Kazakhstan dated July 7, 2020 On Public Health and Health Care System and define the procedure for the removal and preservation of visual organs from cadavers for transplantation in pathologic anatomy and forensic medical examination organizations

2. The following terms and definitions shall be used in these Rules:

1) organ - a part of the body that performs a specific function;

2) the register of citizens who have availed of the right to posthumous donation of organs (parts of an organ) and (or) tissues (parts of tissue) (hereinafter - the Register) - a database of adults and capable persons willing to exercise their right to refusal or consent in the lifetime to a posthumous donation of organs (part of an organ) and (or) tissues (part of tissue) for transplantation, created as a module in the state information system "Register of attached population";

3) the authorized health care body (hereinafter -the authorized body) - the central executive body performing management and cross-sectoral coordination in the health protection of citizens of the Republic of Kazakhstan, medical and pharmaceutical science, medical and pharmaceutical education, sanitary -epidemiological well-being of the population , circulation of medicines and medical devices, medical services (assistance) quality:

4) a potential posthumous donor of organs (parts of an organ) and (or) tissues (parts of tissue) of vision (hereinafter - a potential donor) - a dead body of a person aged eighteen years and older, with biological death, ascertained no later than 48 hours, that is kept in state pathological anatomy and forensic medical examination organizations, licensed to provide the services in transplantation of organs (part of an organ) and (or) tissues (part of tissue) in keeping with the medical activity profile;

5) procurement of organs (parts of an organ) and (or) tissues (parts of tissue) of vision - an operational measure to mobilize organs (parts of an organ) and (or) tissues (parts of tissue) of vision for subsequent conservation purpose;

6) removal of organs (parts of an organ) and (or) tissues (parts of tissue) of vision - removal of organs (parts of an organ) and (or) tissues (parts of tissue) of vision from cadavers for transplantation purpose;

7) conservation of organs (parts of an organ) and (or) tissues (parts of tissue) of vision - a set of measures to ensure protection of the cells of the organs (parts of an organ) and (or)

tissues (parts of tissue) of vision against internal and external influences, in order to preserve vital activity of the organs (parts of an organ) and (or) tissues (parts of tissue) of vision;

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

9) transportation of organs (part of an organ) and (or) tissues (part of tissue) of vision - a set of measures for the delivery of organs (part of an organ) and (or) tissues (part of tissue) of vision for storage and transplantation;

10) transplant center - a healthcare organization subordinate to the authorized body that provides services in the removal, procurement, storage, banking, transportation and transplantation of organs (part of an organ) and (or) tissues (part of tissue) on the basis of research institutes and research centers, in cities of republican status and the capital;

11) transplantation - transplanting organs (part of an organ) and (or) tissues (part of tissue) to another place in the body or into another organism;

12) Transplantation Coordination Center (hereinafter - Coordination Center) - a healthcare organization in charge of coordination and maintenance of transplantation of organs (part of an organ) and (or) tissues (part of tissue);

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

3. Retrieval and conservation of organs (parts of an organ) and (or) tissues (parts of tissue) of vision from cadavers for the transplantation purpose shall be performed in state pathologic anatomy and forensic medical examination organizations, with a license for providing medical services in transplantation of organs (part of an organ) and (or) tissues (part of tissue) in keeping with the medical activity profile, in accordance with paragraph 4 of Article 212 of the Code.

4. Retrieval of organs (part of an organ) and (or) tissues (part of tissue) of vision for the purpose of transplantation in ophthalmology shall be carried out in the presence of a conclusion on the occurrence of biological death, absence of medical contraindications and in the cases provided for in paragraph 11 of these Rules.

5. The object for the removal of organs (parts of an organ) and (or) tissues (parts of tissue) of vision shall be cadavers subject to pathological examination (diagnostics) or forensic medical examination.

6. Medical contraindications for the removal of organs (part of an organ) and (or) tissues (part of tissue) of vision for the transplantation purpose shall be:

1) infectious diseases;

2) contamination with poisons that can cause blood hemolysis (with the exception of poisoning by substances that act fast on vital centers, causing cardiac arrest);

3) drowning;

4) damage to organs (parts of an organ) and (or) tissues (parts of tissue) of vision.

Chapter 2. Procedure for removal and preservation of organs (parts of an organ) and (or) tissues (parts of tissue) of vision from cadavers for the purpose of transplantation in ophthalmology

7. The heads of state pathological anatomy and forensic medical examination organizations shall daily (including on weekends and holidays) provide information to the Coordination Center on the presence of potential donors, from whom the removal of organs (parts of an organ) and (or) tissues (parts tissue) of vision does not interfere with pathological diagnostics or forensic medical examination.

8. Within 2 hours from receiving information on a potential donor, the Coordination Center shall check the information in the Register for a citizen's lifetime expression of will on organ (part of an organ) and (or) tissue (part of tissue) donation after death for the purpose of transplantation. The results of the check shall be reported to the transplant center and to the state pathologic anatomy and forensic medical examination organization within 2 hours after the check.

9. In case of lifetime consent, the transplant center shall immediately notify the spouse and (or) one of the close relatives (legal representatives) of the lifetime expression of the will of the deceased on posthumous donation of organs (part of an organ) and (or) tissues (part of tissue) of vision upon receipt of the information from the Coordination Center.

10. Removal of organs (parts of an organ) and (or) tissues (parts of tissue) of vision for transplantation from a cadaver shall not be carried out:

1) if the medical organization was notified by the time of retrieval that this person declared during his lifetime his disagreement to the removal of his organs (part of an organ) and (or) tissues (part of tissue), including by registering the disagreement in the Register;

2) if the medical organization was notified by the time of retrieval that after the death of the deceased person, the spouse, and in his (her) absence, one of the close relatives, declared their disagreement with the removal of his/her organs (part of the organ) and (or) tissues (parts of tissue) (including in the presence of the lifetime consent of the deceased);

3) in the case when the lifetime will of the deceased person is unknown:

in the presence of a written disagreement of the spouse to the removal of his/her organs (part of the organ) and (or) tissues (part of the tissue), and in his (her) absence - one of the close relatives (including with the consent from other close relatives of the deceased);

in the absence of the will of the spouse to remove his/her organs (part of the organ) and (or) tissues (part of the tissue), and in his (her) absence – of one of the close relatives declared within 24 hours from the moment of notification;

4) in the event that the removal of organs (parts of an organ) of vision and (or) tissues (parts of tissue) interferes with a forensic medical examination or pathologic anatomical diagnostics.

11. Removal of organs (part of an organ) and (or) tissues (part of tissue) of vision for transplantation from a deceased person shall be carried out:

1) in the case of a lifetime consent of this person to the removal of his or her organs (part of an organ) and (or) tissues (part of tissue) for the purpose of transplantation, in the absence of the declared written disagreement of the spouse, and in his (her) absence - consent one of the close relatives of the deceased;

2) when the lifetime expression of the will of a person is unknown:

with the written consent of the spouse;

in the absence of a spouse - with the written consent of one of the close relatives, declared within 24 hours from the moment of notification on a potential donor's death. In this event, with the simultaneous presence of disagreement (disagreements) from other close relatives of the deceased, the removal of organs (part of an organ) and (or) tissues (part of tissue) shall not be carried out;

3) if the removal of organs (part of an organ) of vision and (or) tissues (part of tissue) does not interfere with a forensic medical examination or pathologic anatomical diagnostics.

12. The absence of a spouse in these Rules means the civil status of a person at the time of death, in which he was not married (matrimonial state).

13. The removal of organs (parts of an organ) and (or) tissues (parts of tissue) of vision shall be carried out within 24 hours after the pronounced biological death, provided that the dead body had been kept under low-temperature conditions - within 48 hours.

14. Removal of organs (part of an organ) and (or) tissues (part of tissue) of vision for the purpose of transplantation shall be carried out with due respect for the body of a deceased person.

15. After removal of organs (part of an organ) and (or) tissues (part of tissue) of vision, the appearance and shape of the eye socket area shall be subject to cosmetic restoration through the use of prostheses, as well as stitching and fixation of the eyelids.

16. The removed organs (parts of an organ) and (or) tissues (parts of tissue) of vision shall be placed in sterile vials, filled with 2.0 milliliters of saline. The vials shall be closed with a lid and marked with the name of the removed organs (part of the organ) and (or) tissues (part of the tissue) of vision, the date of conservation and the number assigned to the donor.

17. A labeled vial with an eyeball shall be placed in a refrigerator and stored at a temperature from +2 degrees Celsius to +4 degrees Celsius.

18. Upon completion of procurement, removal and conservation of organs (part of an organ) and (or) tissues (parts of tissue) of vision, the specialists who carried out the removal shall fill out an act in the form approved in accordance with subparagraph 31) of Article 7 of the Code.

19. One copy of the act of removal shall be pasted into the medical record of an inpatient issued for the donor, approved in the form in accordance with subparagraph 31) of Article 7

of the Code, and one copy shall be attached to each removed organ (part of the organ) and (or) tissues (parts of tissue) of vision.

20. Organs (parts of an organ) and (or) tissue (parts of tissue) of vision after procurement, removal, conservation, storage and transportation that are pronounced as unsuitable for transplantation after pathological examination (diagnosis), shall be disposed of in accordance with the established regulatory legal acts in the field of sanitary - epidemiological well-being.