

**On approval of the Standard of organization of the provision of medical services for transplantation of tissues (parts of tissue) and (or) organs (parts of organs) in the Republic of Kazakhstan and other types of medical assistance to donors and recipients and the Rules and conditions for extraction, procurement, storage, preservation, transportation of tissues (parts of tissue) and (or) organs (parts of organs)**

*Invalidated Unofficial translation*

Order of the Minister of Healthcare of the Republic of Kazakhstan dated March 26, 2019 No. RK DSM-13. Registered with the Ministry of Justice of the Republic of Kazakhstan on March 26, 2019 No.18415.

*Unofficial translation*

**Footnote. Expired by Order of the Minister of Health of the Republic of Kazakhstan dated 25.11.2020 No. RK DSM-207/2020 (effective after ten calendar days after the date of its first official publication).**

In accordance with paragraph 1 of Article 1 and subparagraph 6) of paragraph 1 of Article 7, and paragraph 7 of Article 170 of the Code of the Republic of Kazakhstan dated September 18, 2009 "On public health and health care system" I HEREBY ORDER:

1. To approve:

1) The Standard of organization of the provision of medical services for the transplantation of tissues (parts of tissue) and (or) organs (parts of organs) in the Republic of Kazakhstan and other types of medical assistance to donors and recipients in accordance with Annex 1 to this Order;

2) The Rules and conditions for extraction, procurement, storage, preservation, transportation of tissues (parts of tissue) and (or) organs (parts of organs) in accordance with Annex 2 to this Order.

2. To recognize as terminated some of the orders of the Ministry of Healthcare of the Republic of Kazakhstan in accordance with Annex 3 to this Order.

3. To amend Order of the Minister of Healthcare and Social Development of the Republic of Kazakhstan dated June 29, 2015 No. 534 "On approval of the Rules for the formation of a list of health organizations for extraction, procurement, storage, preservation, transportation of tissues (parts of tissue) and (or) organs (parts of organs)" (registered in the Registry of state registration of the Republic of Kazakhstan regulatory acts under No. 11743, and published in Adilet information and legal system on the 24 of June, 2015):

The Rules of formation of the list of health organizations for extraction, procurement, storage, preservation, transportation of tissues (parts of tissue) and (or) organs (parts of organs)" approved by this Order, set out in a new edition according to Annex 4 to this Order.

4. The Department of Organization of Medical Assistance of the Ministry of Health of the Republic of Kazakhstan in the manner prescribed 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) within ten calendar days from the date of state registration of this Order, sending a copy thereof in paper and electronic forms both in the Kazakh and Russian languages to the Republican State Enterprise with the Right of Economic Management “Republican Center of Legal Information” for official publication and inclusion in the Reference Control Bank of Regulatory Legal Acts of the Republic of Kazakhstan;

3) placement of this Order on the Internet resource of the Ministry of Health of the Republic of Kazakhstan after its official publication;

4) within ten working days after the state registration of this Order, submission to the Department of Legal Services of the Ministry of Health of the Republic of Kazakhstan of information on the implementation of measures provided for in subparagraphs 1), 2) and 3) of this paragraph.

5. Control over the execution of this order shall be entrusted to the Vice-Minister of Healthcare of the Republic of Kazakhstan, L.M. Aktayev.

6. This Order shall come into effect ten calendar days after the day of its first official publication.

*Minister of Healthcare of the  
Republic of Kazakhstan*

*E. Birtanov*

Annex 1 to Order of the Minister  
of Healthcare of the  
Republic of Kazakhstan  
dated March 26, 2019  
№ ҚР ДСМ-13

## **The Standard of organization of the provision of medical services for transplantation of tissues (parts of tissue) and (or) organs (parts of organs) in the Republic of Kazakhstan and other types of medical assistance to donors and recipients**

### **Chapter 1. General Provisions**

1. The Standard of organization of the provision of medical services for the transplantation of tissues (parts of tissue) and (or) organs (parts of organs) in the Republic of Kazakhstan and other types of medical assistance to donors and recipients (hereinafter referred to as the Standard) is developed in accordance with subparagraph

6) of paragraph 1 of Article 7 and Chapter 2 “Transplantation of tissues (parts of tissue ) and (or) organs (parts of organs) of the Code of the Republic of Kazakhstan dated September 18, 2009 “On public health and health care system” (hereinafter referred to as the Code).

2. This Standard shall establish the requirements for the organization of the provision of medical services for the transplantation of tissue (parts of tissue) and (or) organs (parts of organs) (hereinafter referred to as the Transplantation services).

3. The following terms and definitions shall be used in this Standard:

1) guaranteed volume of free medical care (hereinafter referred to as the Guaranteed volume of medical care) - the volume of medical care shall be provided at the expense of budget funds according to the list determined by the Government of the Republic of Kazakhstan, citizens of the Republic of Kazakhstan, oralmen, as well as foreigners and stateless persons permanently residing in the Republic of Kazakhstan;

2) donor - a person, a human corpse, an animal from which donor blood, its components, other donor material (including sperm, eggs, reproductive tissue, reproductive cells, embryos) are taken, as well as tissue (parts of the tissue) extraction and (or) organs (parts of organs) and hematopoietic from stem cells for transplantation to the recipient;

3) laboratory of immunological typing (HLA-laboratory) - a structural unit in organizations engaged in activities in the field of blood donation, blood collection, its components and preparations;

4) recipient - a patient who receives transfusion of donated blood or components and (or) preparations extracted from it, introduction of male or female donor material (sperm, egg, embryos) or transplantation of tissue (part of tissue) and (or) organ (parts of an organ) from a donor;

5) register of donors of tissue (part of tissue ) and (or) organs (part of organs) - a database of persons who agree to donate tissue (part of tissue) and (or) organs (part of organs), hematopoietic stem cells typed according to the HLA system;

6) register of recipients of tissue (part of tissue) and (or) organs (part of organs) - a database of persons who need transplantation of tissue (part of tissue) and (or) organ transplant (part of organs), typed according to the HLA system;

7) transplantation services - medical services for transplantation, engraftment of tissues and (or) organs (parts of organs) to another place in the body or to another organism, the types of which are approved by order of the Minister of Healthcare and Social Development of the Republic of Kazakhstan dated December 28, 2016 No. 1112 (registered in the Register of State Registration of Normative Legal Acts No. 14630);

8) the authorized body in the field of health care (hereinafter referred to as the authorized body) is the central executive body that provides leadership and intersectoral coordination in the field of protecting the health of citizens, medical and

pharmaceutical science, medical and pharmaceutical education, sanitary and epidemiological welfare of the population, circulation of medicines and medical products, quality control of medical services.

**Chapter 2. Requirements for donors and recipients and the conditions for receiving medical assistance in connection with the upcoming surgical intervention to extract tissues (part of tissue) and (or) organs (part of organs) and transplantation**

4. A person who wants to act as a living donor (hereinafter referred to as the Potential living donor) shall provide the transplantation services of a health care organization with consent to the extraction of tissues (part of tissue) and (or) organs (part of organs) and their (its) transfer to potential recipient subject to paragraphs 4 and 5 of Article 169 of the Code were notarized.

5. In the cases provided for in paragraph 6 of Article 169 of the Code, written notarized consent shall be provided by legal representatives of minors or legally incapable persons.

6. Transplantation services shall be provided to foreigners and stateless persons legally residing in the Republic of Kazakhstan in accordance with the legislation of the Republic of Kazakhstan in the field of population migration.

The stay of these persons in the territory of the Republic of Kazakhstan shall be confirmed by providing notarized copies of an identity document, a copy of the visa of the Republic of Kazakhstan or a certificate of temporary registration of an immigrant or an insert to the passport on registration of an immigrant or a note in the migration card to the healthcare organization providing transplantation services.

7. Services for the transplantation of tissues (parts of tissue) and (or) organs (parts of organs) from a human corpse (hereinafter referred to as the Cadaveric donor) to foreigners and stateless persons shall not be provided.

8. Transplantation services, as well as medical assistance, including a comprehensive medical examination, shall be provided to citizens of the Republic of Kazakhstan, oralmans , as well as foreigners and stateless persons permanently residing in Kazakhstan within the guaranteed volume of free medical care (GVFMC) in accordance with with paragraph 5 of article 88, with sub paragraph 2) of paragraph 1 and subparagraph 2) of paragraph 2 of article 171 of the Code, on the basis of clinical protocols for transplantation. Transplantation services, as well as medical assistance, including a comprehensive medical examination, shall be provided to foreigners and stateless persons temporarily residing in Kazakhstan in accordance with subparagraph 9) of paragraph 2 of Article 35 of the Code, on the basis of clinical protocols for transplantation.

9. The decision on the extraction of tissues (part of tissue) and (or) organs (part of organs) from a potential living donor and the provision of transplantation services shall be taken on the basis of:

1) the results of a comprehensive medical examination or available tissue compatibility (an immunological property of organic tissues that promotes their engraftment in tissues of another organism) of a potential donor with a potential recipient;

2) documents submitted in accordance with paragraphs 4 and 5 of this Standard;

3) a positive opinion of the council on the possibility of extraction of tissues (part of tissue) and (or) organs (part of organs) in compliance with the requirements provided for in Article 171 of the Code.

10. The procedure and conditions for the extraction, procurement, storage, preservation, transportation of tissues (tissue parts) and (or) organs (parts of organs) shall be carried out in accordance with paragraph 7 of Article 170 of the Code.

11. Health organizations providing transplant services include health organizations included in the list formed in accordance with Order No. 534.

### **Chapter 3. Organization of the provision of transplantation and medical care services to a living donor and recipient, potential living donor and potential recipient, donors, potential recipients and recipients of organs (parts of organs), tissue (parts of tissue)**

12. To determine the immunological compatibility of the tissue (part of the tissue) and (or) the organ (part of the organ) during transplantation, HLA laboratories shall be created that function as a structural unit in organizations operating in the field of blood donation, blood collection, its components and preparations.

13. HLA-laboratory conducting research on histocompatibility of organs and tissues for transplantation.

14. The decision on the predicted histocompatibility of organs and tissues of a living donor and a potential recipient shall be made by a specialist (transplantologist) by analyzing and comparing the results of studies on histocompatibility of organs and tissues.

15. The histocompatibility of the organs (tissues) of the cadaver and the potential recipient shall be determined by the medical information system "Accounting for donors and recipients" (hereinafter referred to as the MISADR) in automatic mode, by comparing the results of studies on the histocompatibility of organs and tissues.

16. The main studies to determine the histocompatibility of organs and tissues in the provision of transplantological care shall be:

1) formulation of the test for compatibility of the potential recipient and the cross-match donor;

2) HLA typing in potential recipients and donors.

17. The results of determining the histocompatibility of organs and tissues shall be transmitted to the health organization that sent the material for research. The transfer of results shall be carried out only to the representative of the above healthcare organization (attending physician or courier with a power of attorney). If it is necessary to urgently transfer the results of the study to the attending physician, an electronic version of the results of the study shall be used in compliance with the confidentiality standards in accordance with the Law of the Republic of Kazakhstan dated May 21, 2013 "On personal data and its protection". The transfer of the results to the donor or potential recipient, as well as their relatives shall be prohibited.

18. Transplant coordination in the territory of the Republic of Kazakhstan shall be carried out by the coordination center.

19. The purpose of transplant coordination shall be to create a national organ donation system in the Republic of Kazakhstan.

20. The main directions of organization of transplant coordination shall be:

1) formation and maintenance of a single waiting list of "recipients and donors", its systematic updating, providing access to specialized specialists;

2) distribution of cadaveric donor organs and tissues in transplant centers;

3) interaction with health organizations that carry out activities in the field of organ and tissue transplantation;

4) interaction with the media, nongovernmental, domestic and foreign medical organizations on issues of promoting organ donation;

5) participation in the development and introduction of proposals for improving regulatory legal acts in the field of transplantology;

6) organization of trips and arrivals of transplantation teams, transportation of biomaterials, cadaveric donor organs and tissues;

7) participation in the development and implementation of international, national and regional programs in the field of transplantology;

8) post-transplant monitoring of the health status of recipients;

9) conducting an analysis of the activities of transplantation centers for compliance with the performance assessment indicators.

21. Distribution of cadaveric donor organs and tissues to transplantation centers shall be based on the selection of the recipient for the cadaveric donor organ, taking into account the criteria defined in MISADR:

1) emergency status;

2) complete match for HLA locus (match for all locus, i.e., donor HLA=recipient HLA);

3) age category (priority for children);

4) long-waiting (> 3 years);

5) the MELD scale (a model for assessing the terminal stage of liver disease, designed to assess the relative severity of the disease and prognosis of life in patients with terminal stage of liver failure);

6) a group of antibodies;

7) compatibility of blood groups;

8) compatibility index (HLA);

9) the number of matches in the split (HLA);

10) coincidence of blood groups;

11) percents antibodies.

22. Transplant coordination shall be carried out in the interaction of transplant coordinators at the following levels:

1) the republican transplant coordinator (provides coordination of the work of regional transplant coordinators);

2) regional transplantation coordinator (provides interdepartmental interaction of medical organizations in the field of donation of cadaveric tissues (tissue parts) and (or) organs (parts of organs) for the supervised administrative - territorial units and shall be subordinated to the republican transplantation coordinator for transplant coordination).

3) a stationary transplant coordinator (ensures the identification of a potential cadaveric donor in donor hospitals and shall be subordinated by the transplant coordination to a regional transplant coordinator).

23. To ensure transplant coordination in transplant centers coordinator shall be assigned in transplant center (the doctor(s) who is (are) staff employee(s) of the organization or structural unit shall be created.

24. The centralized registration of donors and recipients, the formation of a waiting list and statistical data shall be carried out using MISADR in accordance with Order of Minister of Healthcare and Social Development of the Republic of Kazakhstan dated May 29, 2015 No. 422 "On approval of the Rules for the formation and maintenance of registers of tissue (parts of tissue) recipients and (or) organs (part of organs), as well as donors of tissue (part of tissue) and (or) organ (part of organs)" (registered in the Register of State Registration of Normative Legal Acts No. 11477). Hospitalization of a living donor and a potential recipient shall be carried out on a planned or emergency basis (according to medical indications from a potential recipient) to the transplantation center at the conclusion of a consultation.

25. Hospitalization living donor, a potential recipient or recipient in case of emergency shall be carried out within the framework of GVFMC on medical grounds by direction of specialists of primary health care and health care organizations, emergency medical services, self-referral, regardless of place of residence and place of attachment, to the nearest medical organization providing inpatient treatment.

26. Living donor and recipient, the potential living donor and the potential recipient of transplant services and medical assistance shall be provided with assistance of specialized professionals whose qualifications meet the minimum qualification criteria approved by Order of the Minister of Healthcare and Social Development of the Republic of Kazakhstan dated June 29, 2015 № 534 "On approval of Regulations for the formation of the list of health care organizations for the extraction, preparation, storage, preservation, transport tissues (parts of tissues) or organs (parts of organs) and tissue transplantation (parts of tissues) or organs (parts of organs) (registered in the Register of state registration of normative legal acts under No.11743) (hereinafter referred to as the Order No. 534).

27. The list of tissue banks and cells shall be formed in accordance with Order No. 534.

28. If a potential donor is identified, data on the presence of a lifetime refusal of a voluntary donation of organs and tissues after death for transplantation shall be checked.

29. The delivery of a team of specialists to a donor hospital for the extraction, procurement, storage, preservation and transportation of organs and tissues from a cadaveric donor shall be carried out after stating death of brain or cardiac death and deciding on the extraction of donor organs and tissues.

30. In cases of delayed departure of ambulance transport, stationary and regional transplant coordinators shall arrange the delivery of blood samples of a potential donor to the immunological tissue typing laboratory.

31. Specialists from immunological tissue typing laboratories shall conduct a study on the tissue compatibility of a cadaveric donor blood sample with blood samples from potential recipients.

32. The final decision on the extraction of an organ or tissue shall be taken by a consultation of specialists from the transplant center.

33. A team of specialists shall perform the extraction, procurement, storage, preservation of organs and tissues from a cadaveric donor after an intraoperative assessment of the functional suitability of cadaveric donor organs and tissues by performing, if necessary, an express biopsy from the organs and tissues of a cadaveric donor and pathomorphological examination. A pathological examination and rapid biopsy of the organs and tissues of a cadaveric donor shall be provided by the donor hospital.

34. Transportation of donor organs and tissues, as well as transportation of specialists for the collection of donor organs in the Republic of Kazakhstan, shall be carried out in the form of air medical service and land transport in accordance with Order of the Minister of Healthcare of the Republic of Kazakhstan dated July 3, 2017 No. 450 "On approval of the Rules for the provision of ambulance services in the

Republic of Kazakhstan” (registered in the Register of State Registration of Normative Legal Acts No. 15473).

35. Transplantation centers, where cadaveric donor organs are distributed, shall call potential recipients from the waiting list as determined by MISADR, conduct consultations, examination, determine contraindications for transplantation and decide on hospitalization.

36. Hospitalization of a potential recipient in a hospital for transplantation of organs and tissues from a cadaveric donor shall be carried out on an emergency basis at the conclusion of a consultation of the transplantation center.

37. The transplantation of an organ (part of an organ) from a cadaveric donor (cadaver) to a potential recipient shall be carried out in accordance with Order on the waiting list if there is tissue compatibility.

38. The specialist of the transplant center shall provide the patient with full information about possible health complications in connection with the upcoming surgical intervention on extraction and transplant an organ (part of organ).

39. The potential recipients suffering from a mental disorder (disease), recognized by court decision incapable or is a minor, shall be provided with transplant care with written consent of their legal representatives.

40. The consent of the potential recipient and the donor may be withdrawn, except for cases when medical personnel, for health reasons, have already started surgical intervention and its termination is impossible due to a threat to the life and health of the patient.

41. Refusal of transplant care indicating possible consequences shall be documented in medical files and signed by the patient, if he is incapable by his/her legal representatives, as well as by a medical professional, in accordance with paragraph 3 of Article 93 of the Code.

42. When a recipient is discharged after transplantation of a donor organ (part of an organ) to the health (public health) department where the recipient resides, a notice shall be sent to the recipient of the organ (part of the organ) in accordance with Order of the acting Minister of Healthcare of the Republic of Kazakhstan dated November 23, 2010 No. 907 “On approval of the forms of primary medical documentation of healthcare organizations” (registered in the Register of State Registration of Normative Legal Acts No. 6697) (hereinafter referred to as the Order No. 907)). The notice shall be compiled by the attending physician - transplantologist and certified by the seal of the transplant center.

43. When the recipient is discharged after transplantation of tissue (parts of tissue), recommendations shall be given that determine the conditions for re-hospitalization to evaluate the results of therapy.

## **Chapter 4. Specific conditions for the organization of medical**

### **assistance to donors and recipients**

44. Healthcare organizations providing medical assistance to donors and recipients shall include:

1) an organization managed by an authorized body and coordinating transplantation (hereinafter referred to as the Coordination center);

2) blood center (immunological typing laboratories (HLA laboratories));

3) air ambulance center ;

4) healthcare organizations included in the list of organizations for the transplantation of tissue (parts of tissues) or organs (parts of organs) formed in the manner determined by the authorized body in accordance with paragraph 5 of Article 170 of the Code;

45. Medical assistance to a living donor, recipient and potential recipient, including in connection with the upcoming surgical intervention to provide transplantation services (hereinafter referred to as the Potential living donor), shall be provided by a healthcare organization in the following forms:

1) outpatient care in the form of primary health care (hereinafter referred to as the PHC) and consultative and diagnostic care (hereinafter referred to as the CDC);

2) hospital-replacing care;

3) stationary support;

4) ambulance (optional attachment);

5) air ambulance (optional attachment).

46. PHC to a living donor and recipient, potential living donor and potential recipient shall include:

1) examination by a doctor and conducting clinical diagnostic tests in accordance with the clinical protocols of diagnosis and treatment (hereinafter referred to as the CP) ;

2) direction of the patient to provide a CDC with extracts from medical records outpatient shape № 027/y in accordance with Order № 907;

3) referral to planned hospitalization for the provision of specialized medical care and high-tech medical services to transplant centers through the Hospitalization Bureau Portal in accordance with Order of the Minister of Healthcare and Social Development of the Republic of Kazakhstan dated September 29, 2015 No. 761 “On approval of the Rules for the provision of inpatient care” (registered in the Register of State Registration of Normative Legal Acts No. 12204) (hereinafter referred to as Order No. 761);

4) provision of medicinal preparations , including the provision of free medicine in accordance with subparagraph 2) of paragraph 1 of Article 88 of the Code;

5) examination of temporary disability in accordance with Order Minister of Healthcare and Social Development of the Republic of Kazakhstan dated March 31, 2015 No. 183 “On approval of the Rules for the examination of temporary disability, the issuance of a sheet and certificate of temporary disability” (registered in the Register of State Registration of Normative Legal Acts No. 10964);

6) referral for medical and social examination to determine and establish disability in accordance with Order of the Minister of Healthcare and Social Development of the Republic of Kazakhstan dated January 30, 2015 No. 44 “On approval of the Rules for conducting medical and social examination” (registered in the State Registration Register normative legal acts No. 10589);

7) Implementation of registration of the consent or revocation of consent of intravital voluntary donation of organs and tissues after death for transplantation purposes in information system "Register of attached population" in the presence of attachment to the organization of primary health care in accordance with Order of the Minister of Healthcare and Social Development of the Republic of Kazakhstan dated 18 May 360, No. 360, “On the Approval of the Rules for the Intravital, Voluntary Donation of Tissues (Part of Tissue) and (or) Organs (Part of Organs) after Death for Transplantation” (registered in the Register of State Registration of Normative Legal Acts No. 11381);

8) dynamic (dispensary) observation in the postoperative (post-transplant) period.

47. CDC of a living donor and recipient, potential living donor and potential recipient shall be provided in accordance with Order of the Acting Minister of Healthcare and Social Development of the Republic of Kazakhstan dated July 28, 2015 No. 626 “On approval of the Rules for the provision of advisory and diagnostic assistance” (registered in the Register of state registration of regulatory legal acts No. 11958) and includes the implementation of the required volumes of diagnostic and therapeutic measures at the outpatient level.

48. Based on the results of the examination, taking into account the complaints presented and the medical history, studying the data of physical, laboratory and instrumental methods of research, the profile specialist shall draw up a preliminary conclusion with a justification for the diagnosis, estimate the severity of the disease and, if the patient has medical indications for transplantation, send him to a consultation in nearest transplant center.

49. Outpatient care shall be provided to a living donor and recipient, potential living donor and potential recipient in accordance with Order of the Minister of Healthcare and Social Development of the Republic of Kazakhstan dated April 27, 2015 No. 272 “On Approval of Standards of Public Health Services” (registered in the Register state registration of regulatory legal acts No. 11304).

50. Hospital-replacing assistance shall be provided to a living donor and recipient, potential living donor and potential recipient in accordance with Order Minister of Healthcare and Social Development of the Republic of Kazakhstan dated August 17, 2015 No. 669 “On approval of the Rules for the provision of hospital-replacing care” (registered in the Register of State Registration of Regulatory legal acts No. 12106).

51. Inpatient assistance and transplantation services shall be provided to transplantation centers in accordance with Order No. 761 in the form of specialized and (or) high-tech medical care in accordance with Order of the Minister of Healthcare of the Republic of Kazakhstan of 7 to a living donor and recipient, potential living donor and potential recipient. February 12, 2017 No. 12 “On approval of the Rules for the provision of high-tech medical services (registered in the Register of state registration of regulatory legal acts in for No. 14868).

Annex 2 to Order of the Minister  
of Healthcare of the  
Republic of Kazakhstan  
dated March 26, 2019  
№ КР ДСМ-13

## **Terms and conditions of extraction, procurement, storage, preservation, transportation of tissues (parts of tissue) and (or) organs (parts of organs)**

### **Chapter 1. General Provisions**

1. These Rules and conditions for the extraction, procurement, storage, preservation , transportation of tissues (parts of tissue) and (or) organs (parts of organs) (hereinafter referred to as the Rules) are developed in accordance with paragraph 7 of Article 170 of the Code of the Republic of Kazakhstan dated September 18, 2009 years “On the health of the people and the health care system” and determine the procedure and conditions for the extraction, procurement, storage, preservation, transportation of tissues (parts of tissue) and (or) organs (parts of organs).

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

- 1) organ - part of the body that performs a specific function;
- 2) an actual donor - a person with stated biological death and (or) irreversible brain death , with ongoing artificial measures to maintain the vital functions of the organs, the presence of consent and the absence of medical contraindications to the extraction of tissues (part of the tissue), organs (part of organs) for transplantation;
- 3) potential donor - a person with stated biological death or irreversible brain death (brain death);
- 4) potential recipient - a patient who needs transplantation of tissues (parts of tissue ) and (or) organs (parts of organs), registered in the register of donors, recipients and individuals, awaiting transplantation of tissues (parts of tissue) and (or) organs (parts of organs) ;

5) hematopoietic stem cells - a part of the tissue of the internal environment of the body, human bone marrow cells with polypotency, in the process of life located in the bone marrow, peripheral blood (after stimulation) and umbilical cord blood;

6) hemacon - a single-use container used to collect blood and its components in the process of donation and subsequent storage;

7) the authorized body in the field of health care (hereinafter referred to as the Authorized body) is the central executive body responsible for the management and intersectoral coordination in the field of protecting the health of citizens, medical and pharmaceutical science, medical and pharmaceutical education, sanitary and epidemiological welfare of the population, circulation of medicines and medical devices, quality control of medical services;

8) donor hospital - a healthcare organization that carries out a set of measures for conditioning and preparing a cadaveric donor for tissue (part of the tissue) and (or) organs (part of the organs);

9) tissue and cell bank - a healthcare organization, regardless of the form of ownership, engaged in cryogenic storage of tissue and cells in the territory of the Republic of Kazakhstan;

10) cadaveric donor - kadaver, which removed tissue (of the fabric) and (or) organs (parts of organs) for subsequent transplantation;

11) irreversible brain death - a complete loss of the integral function of brain cells, accompanied by the death of all brain matter;

12) HLA typing — an immunological typing system (hereinafter referred to as the HLA system) of antigens located on human leukocytes and determining the tissue compatibility of the donor and recipient during transplantation of tissues (part of the tissue) and (or) organs (part of organs);

13) regional transplantation coordinator - a doctor providing interdepartmental interaction of medical organizations in the field of transplantation of tissues (part of tissue) and (or) organs (part of organs) in regional centers and cities of republican significance, being a staff member of the institution “Republican Coordination Center for Transplantation” Hereinafter referred to as the RCCT);

14) regional center of transplantation - a healthcare organization subordinate to the public health administration of regions and cities of republican significance of the Republic of Kazakhstan, which provides services for the extraction, preparation, storage, preservation, transportation of tissues (part of tissue) and (or) organs (part of organs) and tissue transplantation ( parts of tissue) and (or) organs (parts of organs);

15) republican transplant coordinator - a doctor who ensures coordination of the work of regional transplant coordinators, who is a full-time employee of the RCCT;

16) recipient - a patient who receives transfusion of donated blood or components and (or) preparations extracted from it, introduces male or female donor material (

sperm, egg, embryos) or transplantation of tissue (part of tissue) and (or) organ (part of organ ) from the donor;

17) republican transplant center - a healthcare organization subordinate to the authorized body that provides services for the extraction, procurement, storage, preservation, transportation of tissues (part of the tissue) and (or) organs (part of organs) and transplantation of tissues (part of tissue) and (or) bodies (parts of bodies) on the basis of research institutes and research centers, in cities of republican significance;

18) inpatient transplant coordinator - a doctor who is a full-time employee of the donor hospital and is subordinate to the regional transplant coordinator for coordination of the transplant service in the region;

19) register of donors of tissue (part of tissue) and (or) organs (part of organs) - a database of people who agree to donate tissue (part of tissue) and (or) organs (part of organs) hematopoietic from stem cells typed according to the HLA system;

20) register of recipients of tissue (part of tissue) and (or) organs (part of organs) - a database of persons in need of transplantation of tissue (part of tissue) and (or) organs (part of organs), typed according to the HLA system;

21) extraction of tissues (parts of tissue), organs (parts of organs) - extraction of tissues (parts of tissue), one or more organs (parts of organs) from a donor for the purpose of transplantation to a recipient;

22) preparation of tissues (parts of tissue) and (or) organs (parts of organs) - an operational measure to mobilize tissues (parts of tissue) and (or) organs (parts of organs) for the purpose of subsequent conservation;

23) conditioning of tissues (parts of tissue) and (or) organs (parts of organs) - a set of measures to maintain the hemodynamic parameters of a cadaveric donor in order to protect organs from ischemia;

24) preservation of tissues (parts of tissue) and (or) organs (parts of organs) - a set of measures ensuring the protection of tissue cells (parts of tissue) and (or) organs (parts of organs) from internal and external influences in order to preserve the vital activity of tissues ( parts of tissue) and (or) organs (parts of organs);

25) storage of tissues (parts of tissue) and (or) organs (parts of organs) - a set of measures aimed at maximizing the preservation of viability of tissue cells (parts of tissue) and (or) organs (parts of organs) until transplantation;

26) transportation of tissues (parts of tissue) and (or) organs (parts of organs) - a set of measures for the delivery of tissue (parts of tissue) and (or) organs (parts of organs) for storage and transplantation;

27) tissue - a combination of cells and intercellular substance having the same structure, function and origin;

28) living donor - a person who is in a genetic relationship with the recipient or having tissue compatibility with him (an immunological property of organic tissues that promotes their engraftment in the tissues of another organism);

29) transplant team - a group of doctors who have certificate in the specialty "general surgery" and underwent retraining in the specialty "transplantology", training and (or) retraining in the procurement, extraction, preservation, transportation and storage of tissues (part of tissue) and (or) organs (parts of organs), as well as other specialists whose assistance is necessary for the full implementation of the above measures;

30) a state-owned enterprise under the right of economic management "Republican Center for the Coordination of Transplantation and High-Tech Medical Services" (RCTC) - a medical organization that provides coordination of transplantation services in the republic;

31) transplant center - a republican or regional transplant center;

32) transplantation - transplantation, engraftment of tissues and (or) organs (parts of organs) to another place in the body or to another organism ;

33) fetal cells - cells with high dividing ability, obtained from abortive material at gestational periods of 18-22 weeks.

3. Extraction and preparation of tissues (parts of tissue) and (or) organs (parts of organs) from infected donors shall not performed.

## **Chapter 2. The procedure for the extraction, procurement, storage, preservation, transportation of tissues (parts of the tissue) and (or) organs (parts of organs)**

4. The extraction, procurement, storage, preservation and transportation of tissues (parts of the tissue) and (or) organs (parts of organs) for the purpose of transplantation shall be carried out by the doctors of the transplantation team in accordance with the clinical protocols, Sanitary rules "Sanitary and epidemiological requirements for healthcare facilities" approved by Order of the Minister of Healthcare of the Republic of Kazakhstan dated May 31, 2017 No. 357 (registered in the Register of State Registration of Normative Legal Acts under No. 15760) (hereinafter referred to as the Sanitary Rules).

5. The regional coordinator shall organize the delivery of blood samples of the potential donor to the laboratory to conduct studies typed by the system - HLA and establish tissue compatibility with the potential recipient.

6. HLA - typing for tissue compatibility shall be carried out by healthcare organizations subordinate to the authorized body.

7. Prior to the extraction of tissues (parts of tissue) and organs (parts of organs) for transplantation by specialists of a donor hospital, in accordance with clinical protocols,

conditioning of tissues (parts of tissue) and organs (parts of organs) shall be carried out

8. The preparation of a living donor for the extraction, procurement and preservation of tissues (parts of the tissue) and (or) organs (parts of the organs) shall be carried out by specialized specialists of the Transplantation Centers.

9. The RCTC, in cooperation with the republican state enterprise on the basis of economic management “National Coordination Center for Emergency Medicine”, organizes the arrival of the transplant team to the donor hospital for the extraction, procurement, storage, preservation and transportation of tissues (part of the tissue ) and (or) organs ( parts of organs) no later than 24 hours from the moment of obtaining consent to the extraction of tissues (parts of tissue) and (or) organs (parts of organs) from the actual donor.

10. Before extraction of tissues (part of tissue) and (or) organs (part of organs) for transplantation, the transplantation team conducts a preliminary and intraoperative assessment of functional suitability.

11. Extraction of tissues (parts of tissue) and (or) organs (parts of organs) for transplantation shall be carried out in compliance with a respectful and dignified attitude to the body of a deceased person.

12. The extracted tissues (parts of the tissue) and (or) the organs (parts of the organs) shall be placed in sterile, bioinert, serviceable and hermetically sealed containers with the appropriate labeling and temperature conditions (0-4 ° C) for 6-12 hours from the date of extraction, or in special devices for storing and transporting tissues (parts of tissue) and (or) organs (parts of organs).

13. Containers intended for storage and transportation of tissues (parts of tissue) and (or) organs (parts of organs) shall not be used for other purposes.

14. Solutions for the preservation of tissues (parts of tissue) and (or) organs (parts of organs) are subject to periodic microbiological examination, at least once a month.

15. After the procurement, extraction and preservation of tissues (part of the tissue) and (or) organs (part of the organs) is completed, the doctors of the transplantation team shall fill out the Act on the extraction of organs and tissues from the corpse donor for transplantation in the form No. 018/y (hereinafter referred to as the Act of extraction), approved by Order of the Acting Minister of Healthcare of Republic of Kazakhstan from November 23, 2010 № 907 "On approval of forms of primary medical records of healthcare organizations" (registered in the Register of state registration of normative legal acts under № 6697) (hereinafter referred to as the Order № 907).

16. One copy of the Extraction Act shall be pasted into the inpatient medical record issued by the donor in the form No. 003/y, approved by Order 907 (hereinafter

referred to as the Medical record), and one copy shall be attached to each unit of extracted tissue (part of the tissue) and (or ) organs (parts of organs).

17. When tissue (part of the tissue) and (or) organs (part organ) is removed and procured for transplantation from a living donor, a corresponding entry shall also be made on the medical record issued on it.

18. Tissues (parts of tissue) and (or) organs (parts of organs), after procurement, extraction, preservation, storage and transportation, which are considered unsuitable for transplantation, shall be disposed of in accordance with the Sanitary Rules after pathological studies .

19. Before the collection of umbilical cord blood by obstetric organizations in the first period of labor, the peripheral blood of a female donor shall be taken for testing for transfusion infections, determination of group and Rhesus affiliation.

20. In case of positive results for the presence of transfusion infections, the corresponding samples shall be taken and disposed of.

21. Cord blood sampling shall be carried out after the birth of the baby and its separation from the placenta, by puncture of the vein of the placental segment of the umbilical cord, until the moment of birth of the placenta, subject to the conditions of aseptic and antiseptic, by gravity, into the hemacon with constant stirring of the incoming blood with a preservative solution.

22. The following information shall be indicated on the hemacone label:  
surname, name, patronymic (if any) of the female donor;  
date and time of umbilical cord blood collection.

23. After the umbilical cord blood is drawn into the hemacon, cord blood shall be additionally drawn into the vacutainer with an anticoagulant for immunohematological examination (collection from an already born placenta is possible) with the following information on the label:

- 1) "cord blood";
- 2) surname, name, patronymic (if any) of the female donor; date of birth.

24. Storage and transportation of the prepared cord blood to the stem cell bank shall be carried out in thermally insulating containers at a temperature of + 15 ° C to + 24 ° C for no more than 48 hours from the time of collection.

25. Upon receipt of tissue and umbilical cord blood cells from a hemacone in a bank the following actions shall be carried out:

- 1) a visual assessment of the tightness of the hemacone with umbilical cord blood for the lack of hemolysis, blood clots, assessment of the labeling of each hemacone, the presence and correctness of the accompanying documentation, the temperature regime for the storage and transportation of umbilical cord blood;

- 2) weighing a hemacone with umbilical cord blood, determining the weight of a cord blood sample;

- 3) determination of the number of nucleated cells in cord blood, taking into account the degree of dilution of the sample with an anticoagulant;
- 4) determining the sterility of a cord blood sample.
26. If inconsistencies are detected, the cord blood sample shall be recognized as an fully rejected, written off and disposed.
27. Obtaining hematopoietic stem cells of umbilical cord blood (hereinafter referred to as the HSC) shall be carried out by fractionation method manually or automatically in closed systems. After the fractionation process is completed, samples of residual plasma and HSC are collected for archiving in cryovials, which are stored during the entire period of storage of the corresponding stem cell sample from umbilical cord blood in a tissue and cell bank at a temperature of  $-80^{\circ}\text{C}$  in electric refrigerators.
28. A sample of HSC shall be estimated by the number of CD34 + nucleated cells.
29. Before cryopreservation, HSCs shall be mixed with a substance (cryoprotectant ) that protects cellular elements from the damaging effects of ultralow temperatures when they are frozen.
30. HSCs shall be stored in polymer cryosacks, which are labeled with the concentration and composition of the cryoprotectant, the date of freezing, the name of the tissue and cell bank.
31. For additional protection, the cryosack with HSCs shall be hermetically sealed in a cryoprotective wrapping bag.
32. The container with the HSC sample shall be stored in Dewar vessels at a temperature not exceeding  $-150^{\circ}\text{C}$ , in liquid nitrogen or its vapor for no more than 20 years.
33. The procurement, processing and storage of HSCs in a tissue and cell bank shall be carried out on the basis of a contract for storage of HSCs concluded in accordance with the civil legislation of the Republic of Kazakhstan.
34. Fetal cells shall be extracted in obstetrical organizations by ancillary organizations from abortive material obtained by aborting at a later date (18-22 weeks of fetal development) for social reasons in accordance with the Rules for the operation of artificial abortion, approved by Order of the Minister of Healthcare of the Republic of Kazakhstan of 30 October 6, 2009 No. 626 (registered in the Register of State Registration of Normative Legal Acts under No. 5864).
35. When abortive material is removed, a corresponding entry shall be made in the medical record .
36. The procurement, storage, preservation and transportation of abortive material shall be carried out by biotechnologists, doctors of the transplantation team in compliance with the Sanitary Rules .

37. Upon completion of cell isolation, a cytological study of the obtained material shall be performed to calculate the number of viable cells and the concentration of the procured material.

38. Cellular material shall be placed in test tubes with the addition of a cryoprotectant with further program freezing of fetal cells and with quarantine for the period of examination.

39. The quarantine of fetal cells and the procedure for determining their unsuitability (culling) shall be carried out in accordance with the Sanitary Rules.

40. The obstetric organizations quarterly monitor fetal cells for sterility and viability by conducting cytological and bacteriological studies.

41. After receiving the results of a study of fetal cells for sterility, the cellular material shall be transferred for storage to a sterile refrigerated deep-frozen tanker for further transplantation. Prima, Note: not sterile cell material shall be utilized.

42. Before the introduction of fetal cells, the following tests shall be taken to determine the indications and contraindications for the patient:

- 1) blood test for antibodies to HIV;
- 2) blood test for the Wasserman reaction ;
- 3) blood test for viral hepatitis B, C;
- 4) general blood test;
- 5) general analysis of urine;
- 6) biochemical blood test;
- 7) coagulogram.

43. Fetal cells shall be introduced after preparation of the cellular material, collection of a brief history, measurement of blood pressure, heart rate, body temperature, according to the clinical protocol, intraarticular, intramuscular, lumbar or intravenous in a ward.

44. Upon the extraction of hematopoietic and mesenchimal stem cells of the bone marrow (hereinafter referred to as HMSC BM), medical organizations shall make an appropriate entry in the medical record .

45. After the extraction of the HMSC BM shall be transported to the laboratory for isolation, preservation and storage of cells, which is equipped with sterile containers for transporting biomaterial in accordance with the Sanitary Rules.

46. Procurement, storage, preservation, and transportation of HMSC BM shall be carried out by biotechnologists and doctors of the transplantation team.

47. Upon completion of the isolation of HMSC KM, a cytological study of the obtained material shall be carried out to count viable cells and an analysis of the phenotypic composition, to assess the number of nucleated cells, CD34 +.

48. Cellular material shall be placed in test tubes with the addition of a cryoprotectant with further program freezing of cells and with quarantine for the examination period.

49. The quarantine of the HMSC BM and the determination of unsuitability (culling) shall be carried out in accordance with the Sanitary Rules.

50. After obtaining the results of the HMSC BM study of sterility, the cellular material shall be transferred for cultivation, transplantation to recipients or storage in a sterile deep-frozen refrigerated tanker.

51. On a quarterly basis, medical organizations monitor the HMSC BM for sterility and viability by conducting cytological and bacteriological studies.

52. Before the introduction of the HMSC BM, the following tests shall be taken to determine the indications and contraindications for the recipient:

- 1) blood test for antibodies to HIV;
- 2) blood test for the Wasserman reaction ;
- 3) blood test for viral hepatitis B, C;
- 4) general blood test;
- 5) general analysis of urine;
- 6) biochemical blood test;
- 7) coagulogram.

HMSC BM shall be administered after preparation of cellular material, anamnesis, blood pressure measurement, heart rate, body temperature, according to the clinical protocol, systemically (intravenously) or locally in the operating room.

Annex 4 to Order of the Minister  
of Healthcare of the  
Republic of Kazakhstan  
dated March 26, 2019  
№ КР ДСМ-13

Approved by Order of the Minister  
of Health and Social Development  
of the Republic of Kazakhstan  
dated June 29, 2015 No. 534

**Rules for the formation of a list of healthcare organizations for the extraction, procurement, storage, preservation, transportation of tissues (part of the tissue) or organs (parts of the organs) and transplantation of tissues (parts of the tissues) or organs (parts of the organs)**  
**Chapter 1. General Provisions**

1. These Rules for the formation of a list of health care organizations for the extraction, preparation, storage, preservation, transportation of tissues (parts of the tissue) or organs (parts of the organs) and transplantation of tissues (parts of the tissue) or organs (parts of the organs) (hereinafter referred to as the Rules), determine the order of compiling a list of healthcare organizations providing services for the

extraction, procurement, storage, preservation, transportation of tissues (part of the tissue) or organs (part of organs) and transplantation of tissues (part of tissues) or organs (part of organs) (hereinafter referred to as the List).

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

1) authorized body in the field of healthcare (hereinafter referred to as the Authorized body) is the central executive body responsible for the management and intersectoral coordination in the field of public health , medical and pharmaceutical science, medical and pharmaceutical education, sanitary and epidemiological welfare of the population, circulation of medicines and medical devices, quality control of medical services;

2) donor hospital - a healthcare organization that provides services for preparing a cadavre for multi- organ sampling of organs and/or tissues for transplantation;

3) transplant center - a healthcare organization that provides services for the extraction, procurement, storage, preservation, transportation and transplantation of tissues (parts of tissue) and organs (parts of organs);

4) transplantation team - a group of medical personnel consisting of an operating surgeon who has certificate in the specialty "General Surgery" (transplantology) or " Cardiac Surgery" and assisting surgeons, anesthesiologist, operating nurse, as well as other specialists;

5) tissue and cell bank - a medical organization, a structural unit of a medical organization engaged in the preparation and storage of tissues (parts of tissue) for subsequent transplantation.

6) Republican state enterprise on the right of economic management “Republican Center for the Coordination of Transplantation and High-Tech Medical Services” of the Ministry of Health of the Republic of Kazakhstan (hereinafter referred to as the RCCTHMS) is a healthcare organization that ensures the creation of an effective national organ donation system;

7) recipient survival - a biostatistical indicator reflecting the duration of life in a group of patients after transplantation of an organ (part of an organ).

8) transplantation - transplantation, engraftment of tissues and (or) organs (parts of organs) to another place in the body or to another organism;

9) social health insurance fund (hereinafter referred to as the Fund) is a non-profit organization that accumulates deductions and contributions, as well as procures and pays for the services of health entities that provide medical assistance in the amounts and under the conditions provided for by the contract for the procurement of medical services, and other functions defined by the laws of the Republic of Kazakhstan;

10) high-tech medical services (hereinafter referred to as the HTMS) - services provided by specialized specialists in diseases requiring innovative, resource-intensive and (or) unique diagnostic and treatment methods.

**Chapter 2. The procedure for forming a list of healthcare organizations for the extraction, procurement, storage, preservation, transportation and transplantation of organs parts of organs)**

3. In order to receive and consider documents of a healthcare organization that claims to provide medical services for the extraction, procurement, storage, preservation, transportation and transplantation of organs (parts of organs) and gives recommendations, the Fund shall create an expert council.

4. Healthcare organization applying for the provision of medical services for the extraction, preparation, storage, preservation, transportation and transplantation of organs (parts of organs) (hereinafter referred to as the Transplantation center) corresponds to the following:

1) it shall be located on the basis of a multidisciplinary medical organization having specialized departments (cardiology, pulmonology, nephrology , hepatology and others), in accordance with the transplantology profile, as well as structural units in accordance with Annex 1 to these Rules;

2) it shall have at least 10 beds for the treatment of patients with organ failure;

3) it shall be equipped with additional specialized medical equipment, in accordance with Annex 2 to these Rules;

4) it shall have at least two operating teams for transplantation (2 doctors - transplantologists , 4 doctors - surgeons, 2 doctors an angiosurgeon , 2 operating sisters );

5) specialists of the transplantation center and specialists of a multidisciplinary medical organization shall meet the minimum qualification characteristics in accordance with Annex 3 to these Rules;

6) it shall have an Annex to a medical license in the specialty "transplantology".

5. Healthcare organization, which claims to provide services for the extraction, procurement, storage, preservation, transportation and transplantation of organs (parts of organs), shall send an application with the following list of documents for consideration to the expert council of the fund:

1) a positive opinion of the territorial department of the Public Health Protection Committee of the Ministry of Health of the Republic of Kazakhstan on the assessment of the conformity of personnel and equipment of a health care organization, which claims to provide HTMS with the information specified in the description of the health care organization based on the documentation provided;

2) certificate (copy of certificate) of state registration (re-registration) of a legal entity;

3) a list of specialized equipment in accordance with Annex 4 to these Rules;

- 4) copies of documents on the availability of premises;
  - 5) information about the medical staff (copies of individual employment contracts, copies of work books, copies of orders for employment, copies of certificates of specialists, copies of educational documents, including training);
  - 6) information on the availability of specialized ambulance vehicles for transporting transplant teams and transporting tissue (part of tissue) and organs (part of organs).
6. The application is submitted to the Fund's office with the mark "For the expert council of the Fund" in stitched and numbered form without corrections and blots, the last page being verified by the signature of the head or his authorized representative and sealed with the seal of the healthcare organization (if any).
7. The application shall be rejected:
- 1) in case of delivery of an incomplete package of documents in accordance with paragraph 5 of these Rules;
  - 2) in case of improper execution of a package of documents in accordance with paragraph 6 of these Rules.
8. The expert council of the fund considers a package of documents within ten working days from the date of receipt.
9. The expert council makes a negative opinion in the following cases:
- 1) when establishing the inaccuracy of the submitted documents;
  - 2) non-compliance of the healthcare organization with paragraph 4 of these Rules.
10. In the event of a negative opinion, the expert council of Fund within 3 working days sends a written refusal to the healthcare organization, which claims to provide medical services for the extraction, preparation, storage, preservation, transportation and transplantation of organs (parts of organs).
11. Upon acceptance of a positive recommendation, the expert council of the fund shall forward to the authorized body a protocol of the decision with a recommendation to be included in the List.
12. The structural unit of the authorized body submits documents with the recommendations of the expert council of the fund for consideration by the Medical and Economic Council of the authorized body (hereinafter referred to as the MEC).
13. In case of coordination of the MEC, the organization of health care shall be entered into the list of transplant centers by the order of the authorized body.
14. The list of transplant centers approved by the authorized body is posted on the Internet resource of the authorized body.
15. In the event of a negative conclusion, the authorized body within 5 working days shall send a written refusal to the medical organization that claims to render services for the extraction, procurement, storage, preservation, transportation and transplantation of organs (parts of organs).

**Chapter 3. The procedure for forming a list of healthcare organizations for the preparation of a cadavre for multi- organ harvesting of organs (part of organs) and (or) tissue or (part of tissues) for transplantation**

16. In order to formulate a list of healthcare organizations for preparing a cadavre for multi- organ harvesting of organs (part of organs) and (or) tissue (part of tissue) for the purpose of transplantation, an expert council of the Fund shall be created.

17. The expert council of the fund shall accept and review the documents of a healthcare organization that is for the first time applying for the provision of medical services for preparing a cadavre for multi- organ harvesting of organs (parts of organs) and (or) tissue (parts of tissues) for transplantation.

18. Healthcare organization applying for the provision of medical services for preparing a cadavre for multi- organ harvesting of organs (part of organs) and (or) tissue (part of tissue) for transplantation (hereinafter referred to as the Donor hospital) shall correspond to the following:

1) shall be a multidisciplinary medical organization with specialized departments ( intensive care, intensive care, stroke center, polytrauma);

2) specialized specialists shall be trained and have practical skills in ascertaining brain death.

19. Healthcare organization, for the first time applying for the provision of medical services for preparing a cadavre for multi- organ sampling of organs (parts of organs) and (or) tissue (parts of tissues) for transplantation, shall send an application with the following list of documents for consideration to the expert council of the fund:

1) certificate (copy of certificate) of state registration (re-registration) of a legal entity;

2) a copy of the license to engage in medical activities;

3) the organizational structure approved by the first head and certified by the seal of the organization.

20. The application shall be submitted to the Fund's office with the mark "For the expert council of the Fund" in a stitched and numbered form without corrections and blots, with the last page a being certified by the signature of the head or his authorized representative and sealed with the seal of the healthcare organization (if any).

21. The application shall be rejected:

1) in case of delivery of an incomplete package of documents in accordance with paragraph 19 of these Rules;

2) in case of improper execution of a package of documents in accordance with paragraph 20 of these Rules.

22. The expert council of the fund shall consider a package of documents within ten working days from the date of receipt.

23. The expert council shall make a negative opinion in the following cases:

- 1) when establishing the inaccuracy of the submitted documents;
- 2) non-compliance of the healthcare organization with paragraph 18 of these Rules.

24. In the event of a negative opinion, the expert council of Fund within 3 working days shall send a written refusal to the healthcare organization, which claims to provide medical services for preparing a cadavre for multi- organ procurement of organs (part of organs) and (or) tissue (part of tissue) for transplantation .

25. When accepting a positive opinion, the expert council of the fund shall send a protocol of decision with the recommendation to be included in the List to the authorized body.

26. The structural unit of the authorized body submits documents with the recommendations of the expert council of the fund for consideration by the MEC.

27. In case of coordination of the MEC, the organization of health care by the order of the authorized body is included in the list of centers of donor hospitals.

28. The list of donor hospitals approved by the authorized body shall be posted on the Internet resource of the authorized body.

29. In the case of a negative opinion, the authorized body within 5 working days sends a written refusal to the medical organization that claims to provide medical services for preparing a cadavre for multi- organ sampling of organs (part of the organs ) and (or) tissue (part of tissue) for transplantation.

#### **Chapter 4. The procedure for forming a list of health care organizations for the extraction, procurement, storage, preservation, transportation and transplantation of tissue (part of tissues)**

30. In order to receive and consider documents of a healthcare organization that claims to provide medical services for the extraction, preparation, storage, preservation , transportation and transplantation of tissue (part of tissues), an expert council of the Fund shall be created.

31. Healthcare organization applying for the provision of medical services for the extraction, preparation, storage, preservation, transportation and transplantation of tissue (a part of tissues) (hereinafter referred to as the Tissue and cell bank) shall correspond to the following:

- 1) in the case of storing tissue (part of tissue) in liquid nitrogen , the storage rooms shall be equipped with an independent exhaust ventilation system and emergency ventilation, which is automatically switched on by a signal from a gas analyzer;

- 2) the power supply of the tissue and cell bank shall provide for the availability of a backup source of electrical equipment.

32. Healthcare organization that claims to provide services for the extraction, preparation, storage, preservation, transportation and transplantation of tissue (part of

tissue) shall send an application to the expert council of the Fund for consideration with the following list of documents attached:

- 1) certificate (copy of certificate) of state registration (re-registration) of a legal entity;
- 2) a copy of the annex to the medical license in the specialty "transplantology";
- 3) a list of specialized equipment of the Bank of containers and cages in accordance with Annex 4 to these Rules;
- 4) a copy of documents on the availability of premises;

33. The application shall be submitted to the Fund's office with the mark "For the expert council of the Fund" in a stitched and numbered form without corrections and blots, with the last page being certified by the signature of the head or his authorized representative and sealed with the seal of the healthcare organization (if any).

34. The application shall be rejected:

- 1) in case of delivery of an incomplete package of documents in accordance with paragraph 32 of these Rules;
- 2) in case of incorrect execution of a package of documents in accordance with paragraph 33 of these Rules.

35. The expert council of the fund shall consider a package of documents within ten working days from the date of receipt.

36. The expert council shall make a negative opinion in the following cases:

- 1) when establishing the inaccuracy of the submitted documents;
- 2) non-compliance of the healthcare organization with paragraph 31 of these Rules.

37. In the event of a negative opinion, the Fund's expert council within 3 working days shall send a written refusal to the healthcare organization that claims to provide services for the extraction, preparation, storage, preservation, transportation and transplantation of tissue (part of tissues).

38. When adopting a positive opinion, the Fund's expert council shall send to the authorized body the protocol of the decision with the recommendation to be included in the List.

39. The structural unit of the authorized body submits documents with the recommendations of the expert council of the fund for consideration by the MEC.

40. In case of coordination of the MEC, the organization of health protection by the order of the authorized body is included in the list of tissue and cell banks.

41. The list of tissue and cell banks approved by the authorized body shall be posted on the Internet resource of the authorized body.

42. In the event of a negative opinion, the authorized body within 5 working days shall send a written refusal to the medical organization that claims to provide services for the extraction, preparation, storage, preservation, transportation and transplantation of tissues (part of tissue).

43. Tissue and cell banks shall notify the Fund within one month in the event of liquidation or reorganization.

44. The list shall be approved by the authorized body in accordance with Annex 5 to these Rules and is published on the official website of the authorized body.

45. The Fund's expert council once a year, no later than November 1, shall analyze the activities of transplant centers for compliance with performance indicators in accordance with Annex 6 to these Rules, which are taken into account by the fund and the authorized body when compiling the list of transplant centers for the next year.

46. In case of discrepancy between the performance assessment indicators and the transplantation center, a caution is issued or it is excluded from the list of transplantation centers.

47. The authorized body reserves the right to make a decision on changing the List, taking into account the need for the development of transplantology in the Republic of Kazakhstan.

48. Each case of an unfavorable outcome of the extraction and transplantation of an organ (part of an organ) is subject to state control in accordance with applicable law.

Annex 1  
to the Rules for the formation of a  
list of healthcare  
organizations for  
the procurement,  
extraction, preservation,  
storage, transportation and  
transplantation of tissues (parts of  
tissue) (or) organs  
(parts of organs)

### **The list of structural units of the transplant center**

- 1) consultative and diagnostic department (office);
- 2) reception department;
- 3) clinical diagnostic laboratory;
- 5) microbiological laboratory;
- 6) department of functional diagnostics;
- 7) department of endoscopy;
- 8) department of efferent therapy;
- 9) department of radiation diagnostics;
- 10) department of blood transfusion (blood bank);
- 11) sterilization department;
- 12) department of anesthesiology-resuscitation;
- 13) operating unit;
- 14) infection control cabinet;

15) department of rehabilitation and rehabilitation treatment;

17) a pharmacy;

18) pathologist - anatomical laboratory

Annex 2  
to the Rules for the formation of a  
list of healthcare organizations for  
the procurement,  
extraction, preservation,  
storage, transportation and  
transplantation of tissues  
(parts of tissue) (or) organs  
(parts of organs)

### Equipment list for transplant center

No	Name	Quantity required
for transplantation of heart		
1.	Apparatus for hemodialysis and hemodiafiltration	not less than 2
2.	Apparatus for intra-aortic balloon counterpulsation	2
3.	Centrifuge blood pump	not less than 2
4.	Apparatus for the transportation of donor hearts	1
for transplantation of liver		
5.	Circulatory Bypass Machine	1
6.	Molecular Adsorbing Circulating System	1
for transplantation of lung		
7.	Extracorporeal Membrane Oxygenation Apparatus	1
for transplantation of kidney and pancreas		
8.	Laser lithotripter	1
9.	Pneumatic lithotripter	1
10.	Set for nephroscope with rigid fibroureteroskopom	1
11.	Set for nephroscope with flexible fibroureteroskopom	1
general equipment		
12.	Mass spectrometer	1
13.	4-channel flow cytospectrofluorimeter	1
14.	Amplifier ( thermal cycler ) multichannel	1
15.	Blot Hybridizer	1
16.	Thermocycler multichannel to I real-time PCR	1
17.	Immunoassay analyzer automatic	1
18.	Expert Class Ultrasound Diagnostic Unit with Doppler	not less than 2
19.	Computer tomograph (with calculation of the volume of the liver - volumetry )	1
20.	Magnetic resonance tomograph	1

21.	Angiograph	1
22.	Blood purification and autotransfusion system	2
23.	Apparatus for heating iv blood solutions and blood products	2
24.	Mobile X-ray System	1
25.	Operational coagulator	2
26.	Surgical suction	2
27.	Bedside monitor (with invasive blood pressure detection and gas analyzer)	4
28.	Bedside monitor (with invasive blood pressure detection and gas analyzer)	4
29.	Drug dispenser (FM station)	10
30.	Mobile transport container	not less than 4
31.	Insulated container with cold elements	not less than 5
32.	Transport refrigerator	6
33.	Stationary fridge	not less than 2
34.	Expert-class mobile ultrasound device with doppler	1 (+1)
35.	Acid Base Analyzer	1
36.	Three-channel electrocardiograph with automatic mode	1
37.	Portable ambulance ventilator	2
38.	Sanitary vehicle with a special signal (specially equipped)	not less than 1
39.	Tabletop medical scales	2
40.	Binocular magnifiers (2.5x, 4x, 6x)	5
41.	Microsurgical Instrument Set	2
42.	Vascular instrument kit	2
43.	Cavitation Ultrasonic Surgical Aspirator	1
44.	Anesthesia apparatus for children	2
45.	X-ray apparatus t C-arc	1
46.	Argon plasma coagulator	1
47.	Harmonic ultrasonic scalpel with a set of handles	2
48.	The patient heating system on the operating table for children	2
49.	Stand for endovideo surgical laparoscopic interventions ( organs harvesting from donors - liver, kidneys)	1
50.	Set of surgical instruments - mini - assistant (early expanders)	1
51.	Monitor for monitoring a patient with parameters for tracking blood pressure, electrocardiogram, oxygen saturation	2
52.	Scales for determining the dry weight of the patient	1

Annex 3  
to the Rules for the formation of a  
list of health care organizations for  
the procurement,  
extraction, preservation,  
storage, transportation and  
transplantation of tissues

(tissue parts) (or) organs  
(parts of organs)

### Minimum qualification characteristics of transplant center specialists

No	Transplant Center by Profile	Qualification requirements
1	Liver transplantation	<p>1) certificate of a specialist in the specialty "General Surgery" (coloproctology), advanced training in transplantology, organ harvesting from the cadavre and donor organ transportation, including using specialized equipment for transporting human organs, for liver transplantation ;</p> <p>2) certificate of a specialist in the specialty "Anesthesiology and Intensive Care ( perfusionology, toxicology) (adult)", "Anesthesiology and Intensive Care (perfusionology, toxicology, neonatal resuscitation) (pediatric)";</p> <p>3) certificate of a specialist in the specialty "Gastroenterology (endoscopy according to the profile of the main specialty, ultrasound diagnostics according to the profile of the main specialty) (adult)", "Gastroenterology (endoscopy according to the profile of the main specialty, ultrasound diagnostics according to the profile of the main specialty) (children)";</p> <p>4) certificate of a specialist in the specialty: "Therapy (teenage therapy, dietetics)", "Cardiology (ultrasound diagnostics according to the profile of the main specialty, functional diagnostics according to the profile of the main specialty, interventional cardiology, interventional arrhythmology) (adult)", "Cardiology (ultrasound diagnostics according to the profile of the main specialty, functional diagnostics according to the profile of the main specialty, interventional cardiology, interventional arrhythmology) (pediatric) ", including interventional", "Clinical laboratory diagnostics", "Radiation diagnostics", "Functional diagnostics", "Pathological anatomy (adult, pediatric)".</p> <p>5) certificate of a specialist with an average level of qualification in the specialties of "Nursing" or "Nursing (nurse / nurse brother, nurse / nurse brother of general practice, specialized nurse / brother)".</p>
2	Kidney transplant	<p>1) certificate of a specialist in the specialty "General Surgery" (transplantology), advanced training in transplantology, organ harvesting from the cadavre and donor organ transportation, including using specialized equipment for transporting human organs, for kidney transplantation;</p> <p>2) certificate of a specialist in the specialty "Anesthesiology and Intensive Care ( perfusionology, toxicology) (adult)", "Anesthesiology and Intensive Care (perfusionology, toxicology, neonatal resuscitation) (pediatric)";</p> <p>3) certificate of a specialist in the specialty "Endocrinology (adult)", "Endocrinology ( children's)"; "Therapy (teenage therapy, dietetics)", "Cardiology (ultrasound diagnostics according to the profile of the main specialty, functional diagnostics according to the profile of the main specialty, interventional cardiology, interventional arrhythmology) (adult)", "Cardiology (ultrasound diagnostics according to the profile of the main specialty, functional diagnostics according to the profile of the main specialty, interventional cardiology, interventional arrhythmology) (pediatric) ", including interventional", "Clinical laboratory diagnostics", " Radiation diagnostics", " Functional diagnostics ", " Pathological Anatomy ( adult, children) ", the work experience in the specialty for at least 3 years;</p> <p>4) certificate of a specialist with an average level of qualification in the specialties of "Nursing" or "Nursing (nurse / nurse brother, nurse / nurse brother of general practice, specialized nurse / brother)".</p>
		<p>1) certificate of a specialist in the specialty "Cardiac Surgery", "General Surgery" (thoracic surgery, transplantology), advanced training in transplantology, organ harvesting from the cadaver and donor organ transport, including using specialized equipment for transporting human organs (heart or lung, or complex "heart-lung);</p>

3	Heart transplant	<p>2) certificate of a specialist in the specialty "Anesthesiology and Intensive Care ( perfusionology, toxicology) (adult)", "Anesthesiology and Intensive Care (perfusionology, toxicology, neonatal resuscitation) (pediatric);</p> <p>3) certificate of a specialist in the specialty “Endocrinology (adult)”, “Endocrinology ( pediatric)”, “Therapy (teenage therapy, dietetics)”, “Clinical laboratory diagnostics”, “ Radiation diagnostics”, “Functional diagnostics”, “Pathological anatomy ( adult, children) ”;</p> <p>4) certificate of a specialist with an average level of qualification in the specialties of " Nursing" or "Nursing (nurse / nurse brother, nurse / nurse brother of general practice, specialized nurse / brother)".</p>
4	Heart-lung transplantation	<p>1) certificate of a specialist in the specialty “Cardiac Surgery”, “General Surgery” (thoracic surgery, transplantology), advanced training in transplantology, organ harvesting from the cadaver and donor organ transport, including using specialized equipment for transporting human organs (heart or lung, or complex "heart-lung);</p> <p>2) certificate of a specialist in the specialty "Anesthesiology and Intensive Care ( perfusionology, toxicology) (adult)", "Anesthesiology and Intensive Care (perfusionology, toxicology, neonatal resuscitation) (pediatric)";</p> <p>3) certificate of a specialist in the specialty "Cardiology" (ultrasound diagnostics according to the profile of the main specialty, functional diagnostics according to the profile of the main specialty, interventional cardiology, interventional arrhythmology) (adult and (or) pediatric), "Therapy (teenage therapy, dietetics)", " Clinical laboratory diagnostics ”,“ Radiation diagnostics ”“ Functional diagnostics ”,“ Pathological anatomy (adult, pediatric) ”;</p> <p>4) certificate of a specialist with an average level of qualification in the specialties of " Nursing" or "Nursing (nurse / nurse brother, nurse / nurse brother of general practice, specialized nurse / brother)".</p>
5	Pancreas transplantation	<p>1) certificate of a specialist in the specialty “General Surgery” (transplantology), advanced training in transplantology, organ harvesting from the cadaver and donor organ transportation, including using specialized equipment for transporting human organs, in particular for pancreas transplantation;</p> <p>2) certificate of a specialist in the specialty "Anesthesiology and Intensive Care ( perfusionology, toxicology) (adult)", "Anesthesiology and Intensive Care (perfusionology, toxicology, neonatal resuscitation) (pediatric)";</p> <p>3) certificate of a specialist in the specialty: “Endocrinology (adult)”, “Endocrinology ( children's)”, “Therapy (teenage therapy, dietetics)”, “Clinical laboratory diagnostics”, “ Radiation diagnostics”, “Functional diagnostics”, “Pathological anatomy ( adult, children) ”;</p> <p>4) certificate of a specialist with an average level of qualification in the specialties of " Nursing" or "Nursing (nurse / nurse brother, nurse / nurse brother of general practice, specialized nurse / brother)".</p>
6	Corneal transplantation	<p>1) certificate of a specialist in the specialty “Ophthalmology (adult, pediatric)”, advanced training in the transportation of donor organs (tissues), including using specialized equipment for the transportation of human organs (tissues), trained in corneal transplantation, in particular in transplantation cornea;</p> <p>2) certificate of a specialist in the specialty "Anesthesiology and Intensive Care ( perfusionology, toxicology) (adult)", "Anesthesiology and Intensive Care (perfusionology, toxicology, neonatal resuscitation) (pediatric)";</p> <p>3) certificate of a specialist with an average level of qualification in the specialties of " Nursing" or "Nursing (nurse / nurse brother, nurse / nurse brother of general practice, specialized nurse / brother)".</p>
		<p>1) certificate of a specialist in the specialty “General Surgery” (transplantology, ultrasound diagnostics according to the profile of the main specialty), advanced training in transplantology, cadavre tissue collection and donor tissue transportation, including using specialized equipment for human tissue transportation, transplantation tissue;</p>

7	Tissue transplantation	<p>2) certificate of a specialist in the specialty "Anesthesiology and Intensive Care (perfusionology, toxicology) (adult)", "Anesthesiology and Intensive Care (perfusionology, toxicology, neonatal resuscitation) (pediatric)";</p> <p>3) certificate of a specialist in the specialty "Gastroenterology (endoscopy according to the profile of the main specialty, ultrasound diagnostics according to the profile of the main specialty) (adult)", "Gastroenterology (endoscopy according to the profile of the main specialty, ultrasound diagnostics according to the profile of the main specialty) (children)";</p> <p>4) certificate of a specialist in the specialty "Therapy (teenage therapy, dietetics)", "Cardiology (adult)", "Cardiology (adult)", including interventional ", "Traumatology-orthopedics (orthopedics) (adult, children's) ", "Clinical laboratory diagnostics", "Hematology (adult)", "Radiation diagnostics", "Functional diagnostics", "Pathological anatomy (adult, pediatric)";</p> <p>5) certificate of a specialist with an average level of qualification in the specialties of "Nursing" or "Nursing (nurse / nurse brother, nurse / nurse brother of general practice, specialized nurse / brother)".</p>
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Annex 4  
to the Rules for the formation of a  
list of healthcare organizations for  
the procurement,  
extraction , preservation,  
storage, protractor and  
transplantation of tissues  
(tissue parts) (or) organs  
(part of organs)

### **The list of specialized medical equipment for the Bank of tissue and cells**

No.	Name	Required quantity (pcs)
1.	Dewar cryogenic storage	1
2.	Apparatus for programmed cryogenic freezing	1
3.	Refrigerated Centrifuges	1
4.	Low temperature refrigerated trucks	1
5.	Refrigeration units with automatic temperature monitoring	1
6.	Laminar cabinet with supply and exhaust ventilation	1

Annex 5  
to the Rules for the formation of a  
list of  
healthcare organizations for the procurement  
,  
extraction , preservation,  
storage, transportation and  
transplantation of tissues  
( tissue parts) (or) organs  
(part of organs)

**The list of healthcare organizations for the extraction, procurement, storage, preservation and transportation of tissues (parts of the tissue), or organs (parts of the organs) and transplantation of tissues (parts of the tissues) or organs (parts of the organs)**

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1. Health care organizations authorized for the extraction, procurement, storage, preservation, transportation of organs (parts of organs) and organ transplantation (parts of organs) (transplant centers)

No	Name of medical organization	Transplantation*											
		kidneys				liver				hearts	lung	heart - lung	pancreatic cancer
		adult population		child population		adult population		child population					
		from a living donor	from a cadaveric donor	from a living donor	from a cadaveric donor	from a living donor	from a cadaveric donor	from a living donor	from a cadaveric donor				
1	2	3 *	4*	5*	6 *	7 *	8*	9*	10*	11*	12*	13*	14*

2. Health organizations on the basis of which the extraction and preservation of tissues and (or) organs (parts of organs) from corpses for the purpose of transplantation (donor hospitals) are carried out

No	Name of the medical organization	Certificate of registration (re-registration) of legal entities, certificate of state registration of an individual entrepreneur, (No. of registration and date of issue)	Address, Phone numbers
1	2	3	4 5

2. Health organizations providing services for the extraction, procurement, storage, preservation, transportation and transplantation of tissues (parts of tissue) (tissue and cell banks)

No	Name of medical organization	Certificate of registration (re-registration) of legal entities, certificate of state registration of an individual entrepreneur, ( registration number and date of issue)	Address, ( Phone numbers	Name of tissue (parts of tissue) , cells
1	2	3	4	5

In columns 3-14, the words "allowed", "forbidden" shall be written

Annex 6  
to the Rules for the formation of a  
list of  
healthcare organizations for  
the procurement,  
extraction , preservation,  
storage, transportation and  
transplantation of tissues  
(tissue parts) (or) organs  
(parts of organs)

### Transplantation Center Performance Indicators \*

Transplantation	Quantity estimate		Quality rating	
	Number of transplants performed per year	Evaluation result	Recipient, transplant survival, mortality	Evaluation result
	Less than 10 operations per year	caution	One-year recipient survival of less than 90% One-year transplant survival of less than 80%	caution
			Biennial recipient survival of less than 85%.	

kidneys	Less than 10 operations for the 2nd year in a row	exclusion from the list of Transplant Centers	Two- year transplant survival of less than 75%	exclusion from the List of transplant centers
			mortality due to surgical reasons within 15-30 days after surgery	exclusion from the List of transplant centers
liver	Less than 5 operations per year	exclusion from the list of Transplant Centers	One - year recipient survival of less than 75%	caution
			Biennial recipient survival of less than 65%	exclusion from the List of transplant centers
hearts	Less than 5 operations per year	exclusion from the list of Transplant Centers	One-year survival patients that meet 75%	caution
heart- lung	Lack of operations for 3 years	caution	patient survival <40% in the first year	caution
	Lack of operations for 5 years	exclusion from the list of Transplant Centers,		
lung	Less than 2 operations per year.	caution	One-year recipient survival of less than 50%	caution
	Lack of operations for 3 years			
	Lack of operations for 5 years	exclusion from the list of Transplant Centers	Biennial recipient survival of less than 40%	exclusion from the List of transplant centers
pancreatic cancer	Less than 1 operation per year or no operation for 3 years	caution	One-year recipient survival of less than 85%	caution
	Lack of operations for 5 years	exclusion from the list of Transplant Centers	Biennial recipient survival of less than 75%	exclusion from the List of transplant centers
Personnel training	Each transplant center provides advanced training for at least one transplant specialist in the profile annually for at least 216 hours			

\* These assessment indicators do not apply to medical organizations providing pediatric transplantology services.

Annex 3 to Order of the  
Minister of Healthcare of the  
Republic of Kazakhstan  
dated March 26, 2019  
No. ҚР ДСМ-13

### List of decrees of the Ministry of Health recognized as terminated

1. Order of the Minister of Healthcare of the Republic of Kazakhstan dated October 30, 2009 No. 623 “On approval of the Rules for the withdrawal, procurement, storage,

preservation, transportation, transplantation of tissues (part of tissue) and (or) organs (part of organs) from donor to recipient” (registered in the Register of State Registration of Normative Legal Acts No. 5909);

2. Order of Acting Minister of Healthcare of the Republic of Kazakhstan dated September 12, 2011 No. 615 “On Amendments and Additions to the Order of the Minister of Healthcare of the Republic of Kazakhstan dated October 30, 2009 No. 623 “On Approval of the Rules for the Extraction, Preservation, and Transplantation of Tissues and (or) Organs (Parts of Organs) ) from person to person and from animals to person” (registered in the Register of State Registration of Normative Legal Acts No. 7253);

3. Order of the Minister of Healthcare of the Republic of Kazakhstan dated October 3, 2013 No. 573 "On Amending Order of the Minister of Healthcare of the Republic of Kazakhstan dated October 30, 2009 No. 623" On the approval of the Rules for the extraction, conservation, transplantation of tissues and (or) organs (parts) organs) from person to person and from animals to person” (in the Register of State Registration of Normative Legal Acts No. 8866);

4. Order of the Minister of Healthcare and Social Development of the Republic of Kazakhstan dated May 28, 2015 No. 406 “On Amending Order of the Minister of Healthcare of the Republic of Kazakhstan dated October 30, 2009 No. 623“ On approval of the Rules for the extraction, preservation, and transplantation of tissues and (or ) organs (parts of organs) from person to person and from animals to person ”(Registered in the Register of State Registration of Normative Legal Acts for 11348).