

**On approval of the Rules for inclusion of the citizens of the Republic of Kazakhstan with artificial organs (part of organ) and (or) tissues (part of tissue) in the register of potential recipients of organs (part of organ) and (or) tissues (part of tissue)**

***Unofficial translation***

Order of the Minister of Healthcare of the Republic of Kazakhstan dated December 11, 2020 No. ҚР ДСМ-256/2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on December 15, 2020 No. 21786

      Unofficial translation

      In accordance with clause 3 of article 216 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On Public Health and Healthcare System" **I HEREBY ORDER:**

      1. To approve the Rules for inclusion of the citizens of the Republic of Kazakhstan with artificial organs (part of organ) and (or) tissues (part of tissue) in the register of potential recipients of organs (part of organ) and (or) tissues (part of tissue) according to the Appendix to this order.

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

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

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

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

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

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

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| *Minister of Healthcare* *of the Republic of Kazakhstan* | *A. Tsoy* |

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|  | Appendix  to the order of the  Minister of Healthcare of the  Republic of Kazakhstan dated December 11, 2020 No. ҚР ДСМ-256/2020 |

**Rules for inclusion of the citizens of the Republic of Kazakhstan with artificial organs (part of organ) and (or) tissues (part of tissue) in the register of potential recipients of organs (part of organ) and (or) tissues (part of tissue)**

**Chapter 1. General Provisions**

      1. These Rules for inclusion of the citizens of the Republic of Kazakhstan with artificial organs (part of organ) and (or) tissues (part of tissue) in the register of potential recipients of organs (part of organ) and (or) tissues (part of tissue) (hereinafter referred to as the Rules) have been developed in accordance with clause 3 of article 216 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On Public Health and Healthcare System" and shall determine the procedure for inclusion of the citizens of the Republic of Kazakhstan with artificial organs (part of organ) and (or) tissues (part of tissue) in the register of potential recipients of organs (part of organ) and (or) tissues (part of tissue).

      2. The following basic concepts are used in these Rules:

      1) register of potential recipients of organs (part of organ) and (or) tissues (part of tissue) – a database of potential recipients of organs (part of organ) and (or) tissues (part of tissue);

      2) an authorized body in the field of healthcare (hereinafter referred to as the authorized body) – a central executive body, carrying out management and cross-sectoral coordination in the field of public health protection, medical and pharmaceutical science, medical and pharmaceutical education, sanitary and epidemiological well-being of the population, circulation of medicines and medical devices, quality control of medical services;

      3) MISKRDR – medical information system for keeping records of donors and recipients;

      4) artificial organs — devices designed to temporarily or permanently replace the functions of the recipient's own organs (part of an organ);

      5) multidisciplinary group (hereinafter referred toa s the MDG) - a group of different specialists, formed depending on the nature of the violation of the functions and structures of the patient's body, the severity of his clinical condition;

      6) regional transplantation center – a healthcare organization subordinate to local public healthcare bodies of regions, cities of republican significance and the capital, which provides services for the removal, procurement, storage, conservation, transportation and transplantation of organs (parts of an organ) and (or) tissues (part of tissue);

      7) regional transplantation coordinator – a doctor who ensures interdepartmental interaction of medical organizations in the field of organ transplantation (part of an organ) and (or) tissues (part of tissue) in regional centers, cities of republican significance and the capital, who is a full-time employee of the Coordination Center;

      8) republican transplantation center – a healthcare organization subordinate to the authorized body, which provides services for the removal, procurement, storage, conservation, 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 significance and the capital;

      9) republican transplantation coordinator – a doctor who coordinates the work of regional transplantation coordinators and effective interdepartmental interaction of medical organizations on transplantation services in the Republic of Kazakhstan, who is a full-time employee of the Coordination Center for Transplantation;

      10) recipient – a patient who has undergone a transfusion of donor blood or components and (or) drugs isolated from it, the introduction of a male or female donor material (sperm, ovum, embryos) or organ transplantation (part of an organ) and (or) tissues (part of tissue) from a donor, as well as artificial organs (parts of organs);

      11) Coordination Center for Transplantation (hereinafter referred to as the Coordination Center) - a healthcare organization engaged in the coordination and support of organ transplantation (part of an organ) and (or) tissues (part of tissue), the regulation of which is approved by the authorized body;

      12) transplantation center – republican or regional transplantation center;

      13) potential recipient – a patient who needs transplantation of tissues (part of tissue) and (or) organs (part of an organ).

      3. Citizens of the Republic of Kazakhstan with artificial organs (parts of an organ) and (or) tissues (part of tissue), if necessary, are included in the register of potential recipients for transplantation of donor organs (parts of an organ) and (or) tissues (part of tissue).

      4. The formation of information about citizens with artificial organs (parts of an organ) and (or) tissues (part of tissue) for inclusion in the register of potential recipients shall be carried out on the basis of the recipient's written consent to the collection and processing of personal data according to Appendix 1 to these Rules.

      5. Collection, processing and updating of personal data shall be carried out in accordance with the current legislation of the Republic of Kazakhstan.

**Chapter 2. Procedure for inclusion of the citizens of the Republic of Kazakhstan with artificial organs (part of organ) and (or) tissues (part of tissue) in the register of potential recipients of organs (part of organ) and (or) tissues (part of tissue)**

      5. MDG of transplantation centers makes a decision on the need to include citizens with artificial organs (parts of an organ) and (or) tissues (part of tissue) in the register for transplantation of donor organs (parts of an organ) and (or) tissues (part of tissue).

      6. The formation and maintenance of the register shall be carried out by the Coordination Center. The basis for inclusion in the register of potential recipients is:

      1) conclusion of the MDG of the transplantation center;

      2) consent of the patient for collection and processing of personal data according to Appendix 1 to these Rules;

      3) information about the patient according to Appendix 2 to these Rules.

      7. The Transplantation center, within five working days after the decision is made by the MDG, shall send to the regional transplantation coordinator in electronic form the documents specified in subclauses 1) - 3) of clause 6 of these Rules.

      8. The regional transplantation coordinator, within five working days from the date of receipt of the documents specified in subclauses 1) - 3) of clause 6 of these Rules, shall form an electronic application to MISKRDR for the inclusion of citizens with artificial organs (parts of an organ) and (or) tissues (part of tissue) to the register.

      9. The Republican transplantation coordinator shall consider the application for the inclusion of citizens with artificial organs (parts of the organ) and (or) tissues (part of tissue) in the register of potential recipients within one working day from the moment of receipt. Based on the results of consideration, the application shall be accepted or rejected.

      10. The application for the inclusion of citizens with artificial organs (parts of an organ) and (or) tissues (part of tissue) in the register of potential recipients shall be rejected in cases of:

      1) failure to provide documents, specified in subclauses 1) - 3) of clause 6 of these Rules;

      2) the date of the MDG decision exceeds three months;

      3) the absence of necessary information for inclusion to the register of potential recipients according to Appendix 2 to these Rules.

      11. The Coordination Center, within five working days after the inclusion of citizens with artificial organs (parts of an organ) and (or) tissues (part of tissue) in the register of potential recipients, shall send to the patient and to the transplantation center a notification of inclusion in the register in the form according to Appendix 3 to these Rules.

      12. If the application is rejected, the regional transplantation coordinator takes measures to eliminate the identified comments within five working days and re-forms the application to MISKRDR for the patient to be included in the registry.

      13. In the case of inclusion of citizens with artificial organs (parts of an organ) and (or) tissues (part of tissue) in the register, a specialist of the tissue typing laboratory, within five working days, includes a potential recipient in the schedule for taking blood samples and informs the state health organization operating in the sphere of blood service at the place of residence of a potential recipient. Heads of public health organizations operating in the blood service ensure the delivery of blood samples to the tissue matching laboratory.

      14. A tissue typing laboratory specialist conducts immunological typing of a potential recipient, the results of which are entered into the register of potential recipients within ten working days.

      15. Information about persons, who are in the register, becomes irrelevant in the following cases:

      1) at the request of the potential recipient;

      2) in case of the death of the potential recipient;

      3) after transplantation of an organ (part of organ);

      4) when identifying contraindications for transplantation;

      5) when departing the Republic of Kazakhstan for permanent residence.

      16. In accordance with the Law of the Republic of Kazakhstan dated May 21, 2013 "On personal data and their protection", information entered and received from registers is confidential information and is not transferred to third parties, except for cases of their provision to:

      1) authorized body for the purpose of monitoring and coordinating the timely maintenance of registers;

      2) state healthcare organizations and healthcare organizations with state participation, carrying out activities in the specialty "transplantology" in accordance with the license;

      3) other bodies and organizations in accordance with the legislation of the Republic of Kazakhstan.

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|  | Appendix 1  to the Rules for inclusion  of the citizens of the  Republic of Kazakhstan with  artificial organs (part of organ) and  (or) tissues (part of tissue) in the  register of potential recipients of  organs (part of organ) and (or)  tissues (part of tissue) |
|  | Form |

**Patient's consent for collection and processing or personal data**

      I am a patient, (legal representative) (underline):

      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      (surname, name, patronymic (if any) of the recipient, (legal representative)

      being in \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      (name of medical organization)

      give my consent to the entry, collection, processing and storage of my personal data necessary for inclusion in the register of potential recipient organs (parts of an organ) and (or) tissues (part of tissue)

      Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      (patient or legal representative)

      Date of completion: \_\_\_\_\_\_/\_\_\_\_\_\_/20\_\_

      Doctor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      (surname, name, patronymic (if any)) Signature: \_\_\_\_\_\_\_\_\_\_\_

      Note:

      In accordance with the Law of the Republic of Kazakhstan dated May 21, 2013 "On personal data and their protection", information entered and received from registers is confidential information and is not transferred to third parties, except for cases of their provision to:

      1) authorized body for the purpose of monitoring and coordinating the timely maintenance of registers;

      2) state healthcare organizations and healthcare organizations with state participation, carrying out activities in the specialty "transplantology" in accordance with the license;

      3) other bodies and organizations in accordance with the legislation of the Republic of Kazakhstan.

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|  | Appendix 2  to the Rules for inclusion  of the citizens of the  Republic of Kazakhstan with  artificial organs (part of organ) and  (or) tissues (part of tissue) in the  register of potential recipients of  organs (part of organ) and (or)  tissues (part of tissue) |
|  | Form |

**Information about the patient**

      Patient

      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      (surname, name, patronymic (if any))

      Date of birth "\_\_\_" \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_ sex \_\_\_\_\_\_

      Individual Identification Number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |
| --- | --- |
| Place of residence |  |
| Contact information about the patient, including his phone numbers (mobile, home), e-mail address, phone numbers of the spouse, close relatives |  |
| Main diagnosis |  |
| Anthropometric parameters (height and weight) |  |
| Blood group and Rh factor |  |

      Doctor of the transplantation center \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      (full surname, name, patronymic (if any))

      or Secretary of the multidisciplinary group at the local government health authority of the region, city of republican status or the capital

      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      (full surname, name, patronymic (if any))

      Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_ "\_\_\_\_\_" \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 20\_\_\_\_\_

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|  | Appendix 3  to the Rules for  inclusion of the citizens of the  Republic of Kazakhstan with  artificial organs (part of organ) and  (or) tissues (part of tissue) in the  register of potential recipients of  organs (part of organ) and (or)  tissues (part of tissue) |
|  | Form |

**Notification about inclusion of the patient in the register of potential recipients of organs (part of organ) and (or) tissues (part of tissue)**

      The citizen \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      (surname, name, patronymic (if any) полностью)

      Place of residence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      E-mail\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      (name of Coordination Center for Transplantation)

      hereby informs that on "\_\_\_" \_\_\_\_\_\_\_\_\_\_ 20\_\_ on the basis of decision of the multidisciplinary group (under the local executive body in the field of healthcare or transplantation center – underline as necessary).

      You have been included in the register of potential recipients of organs (part of organ) and (or) tissues (part of tissue) for transplantation\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

                              (indicate the organ (part of organ( and (or) tissue (part of tissue)).

      Director \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

                              (full surname, name, patronymic (if any))

      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      (signature)

      "\_\_" \_\_\_\_\_\_\_\_\_\_\_\_\_ 20\_\_.

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