



**On approval of the Regulation on the Ethics Commission for establishing a genetic link between a potential recipient and an intravital donor for transplantation**

*Unofficial translation*

Order of the Minister of Healthcare of the Republic of Kazakhstan dated December 23, 2020 No. KR HM-318/2020. Registered in the Ministry of Justice of the Republic of Kazakhstan on December 24, 2020 No. 21892

Unofficial translation

In accordance with paragraph 4 of Article 210 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 Regulation on the Ethics Commission for establishing a genetic link between a potential recipient and an intravital donor for transplantation in accordance with Appendix to this order.

2. The Department of organization Medical Aid of the Ministry of Healthcare of the Republic of Kazakhstan, in the manner established by the legislation of the Republic of Kazakhstan, shall ensure:

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

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

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

*Minister of Healthcare of the  
Republic of Kazakhstan*

*A. Tsoy*

Appendix  
to the order  
Minister of Healthcare  
of the Republic of Kazakhstan  
dated December 23, 2020  
No. KR HM-318/2020

**Regulation on the Ethics Commission for establishing a genetic link between a potential recipient and an intravital donor for transplantation**

## Chapter 1. General provisions

1. This Regulation on the Ethics Commission for establishing a genetic link between a potential recipient and an intravital donor for transplantation (hereinafter - the Regulation) was developed in accordance with paragraph 4 of Article 210 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On Public Health and Healthcare system" (hereinafter - the Code) and shall determine the composition and position of the Ethics Commission for establishing a genetic link between a potential recipient and an intravital donor for transplantation (hereinafter - the Ethics Commission).

2. Basic concepts used in this Regulation:

- 1) an organ - a part of the body that performs a specific function;
- 2) a tissue - a set of cells and intercellular substance that have the same structure, function and origin;
- 3) a potential recipient - a patient who needs transplantation of an organ (part of an organ) and (or) tissue (part of a tissue);
- 4) an intravital donor - a person aged eighteen years and older, capable, being in a genetic relationship with a recipient and (or) having tissue compatibility with him/her, expressing a written notarized consent to the removal of an organ (part of an organ) or tissue (part of tissue ) for further transplantation;
- 5) multidisciplinary group (hereinafter - MDG) - a group of different specialists, formed depending on the nature of violation of the functions and structures of a patient's body, the severity of his/her clinical condition;
- 6) transplantation - transplantation of organs (part of an organ) and (or) tissues (part of tissue) to another place in the body or into another organism;
- 8) regional transplantation centre - a healthcare organization subordinate to the local body of state healthcare department of a region, a city of republican significance or the capital of the Republic of Kazakhstan (hereinafter- the Healthcare department), which provides services for the removal, procurement, storage, conservation, transportation and transplantation of organs (part of an organ ) and (or) tissues (part of tissue);
- 9) republican transplantation centre - a healthcare organization subordinate to the authorized body in the field of healthcare, 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 scientific-research institutes and research centres, in the cities of republican significance and the capital;
- 10) transplantation centre - republican or regional transplantation centre.

3. Composition of the Ethics Commission shall be approved by the head of the Healthcare department and consists of at least 7 people.

The Ethics Commission includes the head of the department of treatment and prophylactic activities of the Healthcare department, the chief freelance surgeon of the Healthcare

department, a transplant doctor (remotely (if necessary), representatives of state bodies (by agreement) and public and (or) non-governmental organizations (by agreement).

A meeting of the Ethics Commission shall be considered competent with the participation of two-thirds of the total number of its members. From among the members of the Ethics Commission, the Chairman of the Ethics Commission and the Deputy Chairman of the Ethics Commission shall be elected.

4. Under the genetic link in this Regulation the relationship of persons having common ancestors to great-grandmother and great-grandfather, established on the basis of supporting documents indicating the relationship between a potential recipient and an intravital donor is understood.

5. The Commission in its activities shall be guided by the Constitution of the Republic of Kazakhstan, the Code, this Regulation and other regulatory legal acts of the Republic of Kazakhstan.

## **Chapter 2. Status and powers of the Ethics Commission**

6. The Ethics Commission is a permanent collegial body, created by order of the Healthcare Department to establish a genetic link between a potential recipient and an intravital donor for transplantation. Ethics commissions shall be created in all regions, cities of republican significance and the capital.

7. The powers of the Ethics Commission is to establish a genetic link between a potential recipient and an intravital donor.

## **Chapter 3. Procedure of the Ethics Commission**

8. The transplantation centre, in order to establish a genetic link between a potential recipient and an intravital donor for the purpose of further transplantation of an organ (part of an organ) and (or) tissues (a part of tissue), shall submit an application to the Healthcare Department at the place of residence of a potential recipient for consideration by the Ethics Commission with attachment of copies of:

1) an application of an intravital donor on establishment of a genetic link with a potential recipient for the purpose of further transplantation;

2) an application of a potential recipient on establishment of a genetic link with an intravital donor for the purpose of further transplantation;

3) documents proving the identity of a potential recipient and an intravital donor;

4) a notarized consent of an intravital donor for the removal of an organ (part of an organ) or tissues (part of a tissue) for further transplantation;

5) conclusion of the MDG transplantation centre on the absence of medical contraindications in the intravital donor for the removal of an organ (part of an organ) or tissues (part of a tissue) for further transplantation;

6) copies of an extract from the medical card of a potential recipient indicating the results of laboratory-instrumental, functional, radiation examination and treatment;

7) conclusion of the MDG transplantation centre on the need to transplant an organ (part of an organ) or tissues (part of a tissue) to a potential recipient;

8) documents confirming the relationship between a potential recipient and an intravital donor.

9) an informed consent of an intravital donor and a potential recipient for removal and transplantation in the form approved according to subparagraph 31) of Article 7 of the Code.

9. The Ethics Commission shall reject an application of the transplantation centre in the absence of documents specified in subparagraphs 1) - 9) of paragraph 8 of this Regulation within 3 working days from the date of receipt by the Ethics Commission.

10. The period for consideration of the documents specified in paragraph 8 of this Regulation by the Ethics Commission and adoption of a decision shall be 7 (seven) working days from the date of their receipt for consideration by the Ethics Commission.

11. When questions arise, the Ethics Commission shall engage applicants, specialized specialists and (or) independent experts.

12. Based on the results of consideration of the documents, the Ethics Commission shall make a decision on the presence or absence of a genetic link between a potential recipient and an intravital donor for transplantation, which shall be drawn up in a minutes in the form, according to Appendix to this Regulation.

13. The head of the department of treatment and prophylactic activities of the Healthcare Department shall notify the members of the Ethics Commission about the day, venue of the meeting, its agenda, provide them with relevant materials for review within two working days after the documents are received by the Ethics Commission.

14. Consideration of applications from potential recipients and intravital donors at the Ethics Commission in the cases specified in paragraph 11 of this Regulation shall be carried out with participation of applicants (an applicant). If the presence of applicants (an applicant) is necessary, they shall be notified in a proper manner using the means of communication that ensure the fixation of notification or call.

15. The decision of the Ethics Commission shall be made by a majority vote of the total number of those participating in the meeting of the Ethics Commission.

In case of equality of votes, the decision shall be considered adopted if the Chairman of the Ethics Commission voted for it, and in his/her absence - the Deputy Chairman of the Ethics Commission.

16. The minutes of the Ethics Commission shall be signed by all members of the Ethics Commission, and drawn up in 3 copies, one copy shall be given under signature to the applicants, the second one remains at the Healthcare Department, and the third one shall be transferred to the transplantation centre.

17. The decision of the Ethics Commission shall be appealed in accordance with the legislation of the Republic of Kazakhstan.

Appendix  
to the Regulation  
on the Ethics Commission  
for establishing a genetic link  
between a potential recipient and  
an intravital donor for  
transplantation  
Form

**Minutes of the meeting of the Ethics Commission on establishing a genetic link  
between a potential recipient and an intravital donor for transplantation**

Date \_\_\_\_\_ city \_\_\_\_\_  
Transplantation centre \_\_\_\_\_

\_\_\_\_\_ Full name (patronymic- if any) \_\_\_\_\_

\_\_\_\_\_ Date of birth of an intravital donor \_\_\_\_\_  
Full name (patronymic- if any) \_\_\_\_\_

\_\_\_\_\_ Date of birth of a potential recipient \_\_\_\_\_  
Conclusion of the transplantation center \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

a notarized consent of an intravital donor for removal of an organ (part of an organ) or tissues (part of a tissue) for further transplantation) is attached (yes / no) \_\_\_\_\_  
Documents confirming the genetic link are attached (yes / no) \_\_\_\_\_  
Genetic link is established (yes / no) \_\_\_\_\_

**DECISION**

After a comprehensive consideration of applications and submitted documents of an intravital donor and a potential recipient, the Ethics Commission shall confirm

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— a genetic link between a potential recipient

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— (Full name (patronymic - if any))  
and an intravital donor \_\_\_\_\_

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— (Full name (patronymic - if any))  
Chairman \_\_\_\_\_

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— Signature (full name (patronymic - if any))  
Vice-chairman

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— Signature (full name (patronymic - if any))  
Commission members

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— Signature (full name (patronymic - if any))