**On approval of the rules and conditions for the donation of germ cells, tissues of reproductive organs**

*Unofficial translation*

Order № KR DSM-236/2020 of the Minister of Healthcare of the Republic of Kazakhstan as of December 8, 2020. It is registered with the Ministry of Justice of the Republic of Kazakhstan on December 11, 2020 under № 21760

*Unofficial translation*

In accordance with paragraph 3 of Article 148 of the Code of the Republic of Kazakhstan "On Public Health and the Healthcare System" as of July 7, 2020, I hereby **ORDER**:

1. To approve the appended rules and conditions for the donation of germ cells, tissues of reproductive organs in accordance with the appendix to this order.

2. To invalidate Order № 624 of the Acting Minister of Healthcare of the Republic of Kazakhstan as of October 30, 2009 "On approval of the Rules for the donation and storage of germ cells" (registered in the State Registration Register of Regulatory Legal Acts under № 5903, published in Collected Acts № 2 of central executive and other central state bodies of the Republic of Kazakhstan, 2010).

3. In the manner prescribed by the legislation of the Republic of Kazakhstan, the Medical Aid Department of the Ministry of Healthcare of the Republic of Kazakhstan shall ensure:

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

2) the posting of this order on the website of the Ministry of Healthcare of the Republic of Kazakhstan after its official publication;

3) the submission of information on the 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 of the state registration of this order with the Ministry of Justice of the Republic of Kazakhstan.

4. Control over the execution of this order shall be entrusted to the supervising deputy minister of healthcare of the Republic of Kazakhstan.

5. This order comes into effect ten calendar days of its first official publication.

*Minister of Healthcare of the Republic of Kazakhstan* — *A.Tsoi*

Appendix to Order
№ KR DSM-236/2020
of the Minister of Healthcare
of the Republic of Kazakhstan
as of December 8, 2020

**Rules**
**and conditions for the donation of germ cells, tissues of reproductive organs**
**Chapter 1. General provisions**

1. These rules and conditions for the donation of germ cells, tissues of reproductive organs in the Republic of Kazakhstan (hereinafter referred to as the Rules and Conditions) have been developed in accordance with paragraph 3 of Article 148 of the Code of the Republic of Kazakhstan "On Public Health and the Healthcare System" as of July 7, 2020 ( hereinafter – the Code) and establish the procedure and conditions for the donation of germ cells, tissues of reproductive organs in the Republic of Kazakhstan.

2. Donors of germ cells provide their germ cells (sperm, oocytes) to others to overcome infertility and do not take on parental responsibilities in relation to the unborn child.

3. The birth of 10 (ten) children from one donor is the basis for the termination of the use of this donor for recipients.

4. Donation of germ cells, tissues of reproductive organs is carried out on a voluntary basis.

5. Donation is carried out for a fee and free of charge, anonymously and non-anonymously.

6. Donation of germ cells, tissues of reproductive organs by a married person (people) is carried out with the written consent of both spouses.

7. The use of germ cells, tissues of reproductive organs by a recipient who is married is carried out with the written consent of both spouses.

8. When a man and a woman, both married and unmarried, apply together, the man's sperm is not cryopreserved.

9. When carrying out the procurement of donor germ cells, a written agreement is concluded between the donor and the medical facility that procure the germ cells, in compliance with the requirements of the civil legislation of the Republic of Kazakhstan.

10. Donation of germ cells, tissues of reproductive organs from a donor is carried out under the following conditions:

1) the donor freely and consciously gives written informed consent to the donation of germ cells, tissues of reproductive organs;

2) the oocyte donor is informed in writing about complications for her health in connection with the forthcoming surgical intervention;

3) the donor undergoes a medical and genetic examination and there shall be an opinion of a reproductive doctor or uroandrologist about the possibility of donating germ cells, tissues of reproductive organs.

**Chapter 2. Donation of oocytes**

11. Oocyte donation is carried out with the written informed consent of the donor for the induction of superovulation or in the natural cycle.

12. Requirements for donors of germ cells, tissues of reproductive organs are established by paragraph 1 of Article 148 of the Code.

13. Oocyte donors undergo medical and genetic examinations in accordance with Appendix 1 to these Rules and Conditions.

14. In vitro fertilization (hereinafter - IVF) using donor oocytes is carried out according to indications, in accordance with Appendix 2 to these Rules and Conditions.

15. IVF using donor oocytes is not performed in case of contraindications, in accordance with Appendix 3 to these Rules and Conditions.

16. Examination of men and women (recipients), both married and unmarried, is carried out in accordance with Appendix 4 to these Rules and Conditions.

17. The work with donors is carried out by an obstetrician-gynecologist (reproductologist) who conducts a medical examination of the donor before each donor material collection procedure, monitors the timeliness and results of laboratory tests in accordance with the examination schedule.

18. Oocyte donation is carried out according to the following algorithm:

1) selection of an oocyte donor (according to individual selection criteria and the preferences of the recipient);

2) examination of the donor and recipient;

3) synchronization of the menstrual cycles in the donor and recipient with the help of medications in the case of embryos transfer into the recipient's uterine cavity in a stimulated donor cycle;

4) in the procedure for the transfer of cryopreserved embryos, cycle synchronization is not carried out;

5) a procedure for collecting oocytes for use by recipients or cryopreservation for a germ cell bank.

19. All documents on oocyte donation are kept in a safe as documents for official use.

## Chapter 3. Donation of sperm

20. Donor sperm is used for assisted reproductive methods and technologies (hereinafter referred to as ART).

21. Before donating sperm, sexual abstinence is required for 3-5 days. Sperm is obtained by masturbation. The ejaculate is collected in a special sterile, pre-labeled container. This procedure is carried out in a special room with a separate entrance, corresponding interior, sanitary unit with a washbasin.

22. In the absence of donor sperm in a medical facility, or at the request of the patient, donor sperm from other facilities having a donor sperm bank is used.

23. Only cryopreserved donor sperm is used after receiving repeated (6 months after cryopreservation) negative test results for HIV, syphilis and hepatitis B and C.

24. The use of cryopreserved (thawed) sperm ensures:

1) measures to prevent the transmission of HIV, syphilis, hepatitis and other sexually transmitted infections;

2) exclusion of the possibility of a meeting of the donor and the recipient.

25. Requirements for donor sperm:

1) the volume of ejaculate is more than 1.5 milliliters (hereinafter - ml);

2) the concentration of spermatozoa in 1 ml of ejaculate is 15 million or more; the total number of spermatozoa in the entire ejaculate is 22.5 million or more;

3) the proportion of progressively mobile forms (A + B) is 32% or more;

4) the proportion of morphologically normal forms is 4% or more (according to strict Kruger criteria, 14% or more);

5) cryotolerance;

6) a test that determines the immunocompetent bodies of the surface of the spermatoid ( MAP test) - according to indications.

26. Sperm donors undergo medical examinations in accordance with Appendix 5 to these Rules and Conditions.

27. IVF using donor sperm is carried out according to indications, in accordance with Appendix 6 to these Rules and Conditions.

28. The individual donor card is filled in and coded by the doctor. The coding scheme is free. The donor’s application and his individual card are kept in the safe as documents for official use.

29. A doctor-uroandrologist and a doctor-embryologist work with donors. The doctor organizes medical examinations of the donor, monitors the timeliness and results of laboratory tests in accordance with the examination schedule.

30. The embryologist performs cryopreservation and thawing of sperm, assesses the quality of sperm before and after cryopreservation, selects the necessary storage mode for sperm, keeps records of the material.

31. Donor sperm is registered in the register of donor sperm receipt and in the card of the donor sperm receipt and consumption.

## Chapter 4. Donation of embryos

32. Embryo donors are IVF patients who have unused cryopreserved embryos in the bank. By free decision and written informed consent of patients, these embryos are disposed of, or donated to a medical facility. Embryos transferred to a medical facility are used for gratuitous donation to infertile couples, unmarried women (recipients).

33. Embryos for donation are also obtained by fertilizing donor oocytes with donor sperm.

34. Patients are informed that the effectiveness of the procedure using the remaining cryopreserved embryos of IVF patients is lower than when using embryos obtained from donor germ cells. The recipients are provided with a phenotypic portrait of the donors.

35. IVF using donor embryos is carried out according to indications, in accordance with Appendix 7 to these Rules and Conditions.

Appendix 1
to the rules and conditions
of donation of germ cells,
tissues of reproductive organs

**Medical genetic testing for oocyte donors**

1. Determination of blood group and Rh factor (once).

2. Consultation of a therapist and an opinion on the state of health and the absence of contraindications to surgery (before each procedure).

3. Consultation of a psychiatrist, narcologist (once a year).

4. Consultation of a geneticist, medical and genetic examination (clinical and genealogical study, cytogenetic study) of peripheral blood cells (karyotype) (once).

5. Molecular genetic analysis for mutations in the genes of the most common hereditary diseases (determination of PAH gene mutations in phenylketonuria into deoxyribonucleic acids (hereinafter referred to as DNA) using the molecular genetic method, determination of cystic fibrosis gene mutations in DNA using the molecular genetic method) (according to indications).

6. General clinical urine analysis (general urine analysis) (before each procedure).

7. Electrocardiographic study with reading (before each procedure).

8. Diagnostic fluorography (1 projection) (validity period - 12 months).

9. General blood analysis on an analyzer with differentiation of 5 classes of cells and measurement of the erythrocyte sedimentation rate (ESR) in the blood by the Westergren method (before each procedure);

10. Determination of antibodies to HBsAg of hepatitis B virus in blood serum by enzyme immunoassay (hereinafter - EIA method) (validity period - 3 months).

11. Determination of total antibodies to hepatitis C virus in blood serum by EIA method ( validity period - 3 months).

12. The Wasserman reaction in blood serum (validity period - 3 months).

13. Determination of total antibodies to HIV-1,2 and p24 antigen in blood serum by EIA method (validity period - 3 months).

14. Determination of the degree of purity of the gynecological smear (before each procedure).

15. Biochemical blood test (determination of alanine aminotransferase (ALaT) in blood serum, determination of aspartate aminotransferase (ASaT) in blood serum, determination of total bilirubin in blood serum, determination of glucose in blood serum, determination of total

protein in blood serum, determination of creatinine in blood serum, determination of urea in blood serum (validity period - 1 month).

16. Determination of coagulogram (determination of prothrombin time (PT) with subsequent calculation of prothrombin index (PTI) and international normalized ratio (INR) in blood plasma (PT-PTI-INR), determination of activated partial thromboplastin time (APTT ) in blood plasma, determination of fibrinogen in blood plasma (validity period - 1 month).

17. Cytological examination of a smear from the cervix PAP test (validity period - 12 months).

18. Detection of Chlamydiatrachomatis in biological material by polymerase chain reaction (hereinafter - PCR) (validity period - 3 months).

19. Detection of Neisseria gonorrhea in biological material by PCR, detection of herpes simplex virus types 1 and 2 in biological material by PCR qualitative, detection of cytomegalovirus (HSV-V) in biological material by PCR qualitative (validity -3 months).

20. Determination of IgG, M to the causative agent of rubella in the blood serum by the EIA method (once in the absence of confirming data on vaccination or previous diseases) ( validity period -12 months).

Appendix 2
to the rules and conditions
of donation of germ cells,
tissues of reproductive organs

**Indications for in vitro fertilization using donor oocytes**

1. Lack of oocytes due to natural menopause.

2. Premature ovarian failure syndrome, resistant ovarian syndrome, condition after oophorectomy, radiotherapy or chemotherapy.

3. Abnormal development of genitals, lack of ovaries.

4. Functional inferiority of oocytes in women with sex-linked hereditary diseases.

5. Unsuccessful repeated attempts of in vitro fertilization with insufficient response of the ovaries to the induction of superovulation, repeated obtaining of low quality embryos, the transfer of which did not lead to pregnancy.

6. Rhesus incompatibility of a man and a woman.

7. Anomalies in a woman’s karyotype.

8. Closely related (consanguineous) marriages with the birth of children with developmental defects.

9. Somatic diseases in which ovarian stimulation is contraindicated.

Appendix 3
to the rules and conditions
of donation of germ cells,
tissues of reproductive organs

**Contraindications for in vitro fertilization using donor oocytes**

1. Somatic and mental illnesses, which are contraindications for pregnancy and childbirth.

2. Congenital malformations or acquired deformities of the uterine cavity, in which implantation of embryos or pregnancy is impossible.

3. Tumors of the ovaries.

4. Benign tumors of the uterus requiring surgical treatment.

5. Acute inflammatory diseases of any localization.

6. Malignant neoplasms of any localization.

Appendix 4
to the rules and conditions
of donation of germ cells, tissues
of reproductive organs

**The scope of examinations of men and women (recipients), both married and unmarried**

1. Determination of blood group and Rh factor (once).

2. Consultation of a therapist and an opinion on the state of health and the absence of contraindications to surgery (once a year).

3. Consultation of a psychiatrist, consultation of a narcologist (according to indications).

4. Consultation of a geneticist, medical and genetic examination (clinical and genealogical study, cytogenetic study) of peripheral blood cells (karyotype) (once, according to indications ).

5. Molecular genetic analysis for mutations in the genes of the most common hereditary diseases (determination of PAH gene mutations in phenylketonuria into deoxyribonucleic acids (hereinafter referred to as DNA) using the molecular genetic method, determination of cystic fibrosis gene mutations in DNA using the molecular genetic method) - according to indications.

6. Determination of the degree of purity of the gynecological smear (before each procedure).

7. General clinical urine analysis (general urine analysis) (before each procedure).

8. Electrocardiographic study with reading (validity period – 3 months).

9. Diagnostic fluorography (1 projection) (validity period - 12 months).

10. Biochemical blood test (determination of alanine aminotransferase (ALaT) in blood serum, determination of aspartate aminotransferase (ASaT) in blood serum, determination of total bilirubin in blood serum, determination of glucose in blood serum, determination of total protein in blood serum, determination of creatinine in blood serum, determination of urea in blood serum (validity period - 3 months).

11. Determination of coagulogram (determination of prothrombin time (PT) with subsequent calculation of prothrombin index (PTI) and international normalized ratio (INR) in blood plasma (PT-PTI-INR), determination of activated partial thromboplastin time (APTT ) in blood plasma, determination of fibrinogen in blood plasma (validity period - 3 months).

12. Determination of antibodies to HBsAg of hepatitis B virus in blood serum by enzyme immunoassay (hereinafter - EIA method) (validity period - 3 months).

13. Determination of total antibodies to hepatitis C virus in blood serum by EIA method ( validity period - 3 months).

14. The Wasserman reaction in blood serum (validity period - 3 months).

15. Determination of total antibodies to HIV-1,2 and p24 antigen in blood serum by EIA method (validity period - 3 months).

16. Cytological examination of a smear from the cervix PAP test (validity period - 12 months).

17. Detection of Chlamydiatrachomatis in biological material by polymerase chain reaction (hereinafter - PCR) (validity period - 3 months).

18. Detection of Neisseria gonorrhea in biological material by PCR, detection of herpes simplex virus types 1 and 2 in biological material by PCR qualitative, detection of cytomegalovirus (HSV-V) in biological material by PCR qualitative (validity -3 months).

19. Determination of IgG, M to the causative agent of rubella in the blood serum by the EIA method (once in the absence of confirming data on vaccination or previous diseases) ( validity period -12 months).

20. General blood analysis on an analyzer with differentiation of 5 classes of cells and measurement of the erythrocyte sedimentation rate (ESR) in the blood by the Westergren method (before each procedure).

Appendix 5
to the rules and conditions
of donation of germ cells, tissues
of reproductive organs

**The scope of examinations of sperm donors**

1. Determination of blood group and Rh factor (once).

2. Consultation of a therapist (once a year).

3. Consultation of a urologist-andrologist (once every 6 months).

4. Consultation of a psychiatrist (once a year).

5. Consultation of a geneticist, medical and genetic examination (clinical and genealogical study, cytogenetic study) of peripheral blood cells (karyotype) (once).

6. Molecular genetic analysis for mutations in the genes of the most common hereditary diseases (determination of PAH gene mutations in phenylketonuria into deoxyribonucleic acids (hereinafter referred to as DNA) using the molecular genetic method, determination of cystic fibrosis gene mutations in DNA using the molecular genetic method) - according to indications.

7. Determination of antibodies to HBsAg of hepatitis B virus in blood serum by enzyme immunoassay (hereinafter - EIA method), determination of total antibodies to hepatitis C virus in blood serum by EIA method, the Wasserman reaction in blood serum, determination

of total antibodies to HIV-1,2 and p24 antigen in blood serum by EIA method (before cryopreservation and 3 and 6 months after cryopreservation).

8. Detection of Chlamydiatrachomatis in biological material by polymerase chain reaction (hereinafter - PCR) (validity period - 3 months).

9. Detection of Neisseria gonorrhea in biological material by PCR, detection of herpes simplex virus types 1 and 2 in biological material by PCR qualitative, detection of cytomegalovirus (HSV-V) in biological material by PCR qualitative (validity -3 months).

10. General clinical examination of the urogenital smear (before each procedure).

11. Consultation of a narcologist (once a year).

Appendix 6
to the rules and conditions
of donation of germ cells,
tissues of reproductive organs

**Indications for in vitro fertilization using donor sperm**

1. Azoospermia, severe oligoasthenozoospermia, necrospermia, akinozoospermia, globulozoospermia.

2. Condition after radiotherapy or chemotherapy.

3. Abnormal development of the reproductive system.

4. Absence or functional inferiority of spermatozoa in men with hereditary sex-linked diseases.

5. Unsuccessful repeated attempts of in vitro fertilization with a high index of DNA fragmentation (deoxyribonucleic acid) of spermatozoa and repeated obtaining of low quality embryos, the transfer of which did not lead to pregnancy.

6. Rhesus incompatibility of a man and a woman.

7. Anomalies in the male karyotype.

Appendix 7
to the rules and conditions
of donation of germ cells,
tissues of reproductive organs

**Indications for in vitro fertilization using donor embryos**

1. Absence of oocytes.

2. Unfavorable medical and genetic prognosis.

3. Repeated receipt (more than three times) of low quality embryos, the transfer of which did not lead to pregnancy.

4. The impossibility of obtaining or using sperm from married persons.

Appendix 8
to the rules and conditions
of donation of germ cells,
tissues of reproductive organs

**Contraindications for in vitro fertilization using donor embryos**

1. Somatic and mental illnesses, which are contraindications for pregnancy and childbirth.
2. Congenital malformations or acquired deformities of the uterine cavity, in which implantation of embryos or pregnancy is impossible.
3. Tumors of the ovaries.
4. Benign tumors of the uterus requiring surgical treatment.
5. Acute inflammatory diseases of any localization.
6. Malignant neoplasms of any localization at the time of the procedure.