



MINISTRY OF HEALTH OF UKRAINE

ORDER

09.09.2013 № 787

Registered in the Ministry
of Justice of Ukraine
October 2, 2013
under № 1697/24229

About the statement of the Order of application of assisted reproductive technologies in Ukraine

{ With changes made in accordance with the Order of the Ministry of Health № 165 dated March 6, 2014 }

In accordance with part seven of Article 281 of the Civil Code of Ukraine, Article 123 of the Family Code of Ukraine, subparagraph 6.21 of subparagraph 6 of paragraph 4 of the Regulation of the Ministry of Health of Ukraine, approved by Decree of the President of Ukraine of April 13, 2011 № 467, treatment of infertility with the use of assisted reproductive technologies I ORDER :

1. To approve the attached Procedure for the use of assisted reproductive technologies in Ukraine.
2. The Minister of Health of the Autonomous Republic of Crimea, heads of structural subdivisions on health care of region, Kyiv and Sevastopol city state administrations should bring this order to the attention of subordinate health care institutions and to control its implementation.
3. The order of the Ministry of Health of Ukraine of December 23, 2008 № 771 "On approval of the Instruction on the procedure for the use of assisted reproductive technologies", registered in the Ministry of Justice of Ukraine on March 20, 2009 under № 263/16279, is repealed.
4. The Department of Reforms and Development of Medical Care (M. Hobzey) to ensure the submission of this order for state registration to the Ministry of Justice of Ukraine in the manner prescribed by law.
5. This order comes into force from the date of its official publication.
6. The control over the implementation of this order is assigned to Vice- Minister A. Tolstanov.

Minister
AGREED:

R. Bogatiryova

First Deputy Chairman
of the General representative body
of Employers at national level
Executive Director of the
Social insurance fund of
accidents at work and occupational diseases
of Ukraine

O. Miroshnichenko

First Deputy Chairman of the
General representative body of
all-Ukrainian trade unions
and trade union associations

V.G. Akopian

Head's assistant of the
executive directorate of the
Social Insurance Fund
on temporary disability

G.V. Osovyi

President of the National Academy
of Medical Sciences of Ukraine

T.G. Gaiduk

A.M. Serduk

APPROVED
Order of the Ministry of

health care of Ukraine


09.09.2013 № 787

Registered in the Ministry of

Justice of Ukraine

October 2, 2013

under № 1697/24229



ORDER
OF THE APPLICATION OF ASSISTED REPRODUCTIVE TECHNOLOGIES IN UKRAINE

1. GENERAL PROVISIONS

1.1. This Order regulates the relationship between patients (women, men) and health care facilities that ensure the use of assisted reproductive technologies (hereinafter - HCF), and determines the mechanism and conditions of application of assisted reproductive technologies.

1.2. In this Order, the terms are used in the following meanings:

assisted reproductive technologies (hereinafter - ART) - methods of infertility treatment, in which the manipulation of reproductive cells, some or all stages of preparation of reproductive cells, fertilization and development of embryos before their transfer to the patient's uterus are carried out in vitro;

in vitro - a technique for performing an experiment or other manipulations in special laboratory glassware or in a controlled environment outside a living organism.

1.3. Other terms are used in the meanings given in the Fundamentals of the legislation of Ukraine on health care and regulations in the field of health care.

1.4. Assisted reproductive technologies must be used in health care facilities that have a license to implement economic activities in medical practice, appropriate equipment and facilities in accordance with Annex 1 to this Order.

Accreditation certificates are also required for healthcare facilities that have been operating in medical practice for more than two years.

{ Paragraph 1.4 of Section I as amended by the Order of the Ministry of Health № 165 of March 6, 2014 }

1.5. Patients have the right to choose a HCF for ART.

1.6. ART procedures are performed in HCFs that have medical staff in accordance with the staff list approved by the HCF.

1.7. Adult women and / or men are eligible for medical treatment for ART.

1.8. The question of application of ART methods is resolved after the patient / patients application for the use of assisted reproductive technologies in the form given in Annex 2 to this order (hereinafter - the patient's application for the use of assisted reproductive technologies), medical examination and screening.

1.9. Data of medical examination and screening of patients are entered in the form of primary recording documentation № 025 / o "Medical card of an outpatient № ", approved by the order of the Ministry of Health of Ukraine dated February 14, 2012 № 110, registered in the Ministry of Justice of Ukraine on April 28, 2012 under № 661/20974.

1.10. In the absence of contraindications to ART treatment programs, patients are referred for treatment to the HCF in the presence of examination results. Patients can apply for ART treatment directly, without referral.

1.11. After ART, working patients are issued a certificate of incapacity for work in accordance with the Instruction on the procedure for issuing documents certifying temporary incapacity for work, approved by the order of the Ministry of Health of Ukraine dated November 13, 2001 № 455, registered in the Ministry of Justice of Ukraine on December 4, 2001 under № 1005 / 6196.

- 1.12. The outpatient supervision of the patient after ART is carried out in accordance with the Order of the Ministry of Health of Ukraine of July 15, 2011 417 «On the organization of outpatient obstetric and gynaecological care in Ukraine».
- 1.13. Execution of each ART treatment program is carried out with mandatory clinical monitoring and control of the general condition of the patient. In case of violation of the treatment regime by patients, further medical care according to ART methods is terminated by a reasoned decision of the doctor.
- 1.14. Medical care according to ART methods is provided in conditions of confidentiality in accordance with Article 40 of the Fundamentals of the legislation of Ukraine on health care.
- 1.15. Medical staff who provide medical care to patients using ART methods inform them about the possible ineffectiveness of ART attempts (non-achievement of pregnancy) and the possible occurrence of complications in the manner prescribed by sections III, IV of this order.
- 1.16. Collection and processing of personal data is carried out in compliance with the requirements of the Law of Ukraine "On information" and the Law of Ukraine "On personal data protection".

2. SCOPE OF EXAMINATION OF PERSONS FOR WHOM ART PROGRAMS ARE CARRIED OUT

2.1. The scope of the woman's examination:

1) mandatory:

- the therapist's opinion on the state of somatic health and the absence of contraindications for pregnancy;
- determination of blood group and rhesus factor (when entered in a woman's passport valid for life);
- clinical blood test;
- coagulogram;
- blood tests for syphilis, HIV, hepatitis B and C (valid for 3 months);
- blood tests (IgM, IgG) for toxoplasmosis, chlamydia, cytomegalovirus and rubella;
- bacterioscopic analysis of secretions from three points (vagina, urethra and cervical canal);
- cytological examination of smears from the cervix;
- general gynecological examination;
- ultrasound examination of the pelvic organs;
- blood test for antimullerian hormone (AMG), prolactin (PRL), follitropin (FSH), lutropin (LH), progesterone (P), estradiol (E2);

2) according to the indications (additional):

- examination of the uterus and fallopian tubes (hysterosalpingography, sonosalpingoscopy, laparoscopy, hysteroscopy);
- colposcopy;
- endometrial biopsy;
- bacteriological examination of material from the urethra and cervical canal;
- blood test for testosterone (T), cortisol (K), thyroxine (T3), triiodothyronine (T4), thyrotropin (TSH), somatotropin (STG);
- determination of blood glucose levels;
- examination for the presence of antisperm and antiphospholipid antibodies;
- examination for the presence of antibodies to thyroglobulin and antibodies to thyroperoxidase,

- antimicrosomal antibodies;
- examination for signs of antiphospholipid syndrome and other disorders of the immune system;
- examination for urogenital and TORCH infections;
- conclusions of other specialists according to the indications (determined by the doctor);
- karyotyping, medical and genetic counseling, other molecular genetic research;
- fluorography;
- ultrasound of internal organs, thyroid gland;
- breast ultrasound for women not older than 40 years and mammography for women older than 40 years;
- biochemical blood test: kidney tests, liver tests, total bilirubin, protein fractions, glucose.

At detection of diseases in the presence of indications to ART treatment of the revealed pathology is carried out.

2.2. The scope of the man's examination:

1) mandatory:

- determination of blood group and rhesus factor (when entered in the man's passport valid for life);
- blood tests for syphilis, HIV, hepatitis B and C (valid for 3 months);
- spermogram;
- fluorography of the lungs;


2) according to the indications:

- andrologist consultation;
- karyotyping, medical and genetic counseling and other molecular genetic research;
- examination for TORCH-complex infections;
- blood test for follitropin (FSH), lutropin (LH), testosterone (T), prolactin (PRL), thyroxine (T3), triiodothyronine (T4), thyrotropin (TSH);
- DNA fragmentation;
- MAR test.

3. METHODS OF TREATMENT OF ART

3.1. Indications for in vitro fertilization (hereinafter - IVF):

1) female infertility:

- absence of fallopian tubes;
 - obstruction of the fallopian tubes;
 - pronounced adhesions of the pelvic organs;
 - impaired follicle growth and ovulation;
 - follicle luteinization syndrome;
 - endometriosis;
 - repeated unsuccessful attempts of intrauterine insemination;
 - repeated unsuccessful attempts to stimulate folliculogenesis;
 - infertility associated with age (after 36 years) and premature ovarian failure;
 - infertility that cannot be treated by other methods;
- 

2) male infertility:

- infertility of unknown origin;
- diseases that require preimplantation genetic diagnosis (hereinafter - PGD) to exclude the possibility of giving birth to a child with hereditary pathology;
- obstructive azoospermia;
- asthenozoospermia;
- oligozoospermia;
- oligoastenoteratozoospermia;
- erectile dysfunction;
- anejaculation;
- retrograde ejaculation;
- anatomical defects of the penis (hypospadias, epispadias);
- immunological factors (autoantibodies and sperm agglutination).


3.2. Contraindications for IVF:

- somatic and mental illnesses that are contraindications for pregnancy and childbirth;
- body length of the uterus is less than 35 mm;
- acute inflammatory diseases of any localization at the beginning of the ART treatment program; процети;
- congenital malformations or acquired deformities of the uterine cavity, which do not allow implantation of the embryo (s) and pregnancy;
- benign uterine tumors that deform the uterine cavity and (or) require surgical treatment;
- malignant tumors of any localization (it is allowed to obtain gametes in order to preserve the reproductive potential).

3.3. Stages of IVF:

- selection and examination of patients;
- controlled ovarian stimulation (induction of superovulation);
- monitoring of folliculogenesis and endometrial development;
- transvaginal aspiration of ovarian follicles, search for oocytes;
- sperm preparation;
- oocyte insemination and embryo cultivation in vitro;
- embryo transfer - transfer of embryos into the uterine cavity;
- support of the luteal phase of the stimulated menstrual cycle;
- diagnosis of pregnancy.

IVF is also possible in the natural menstrual cycle without the use of ovulation inducers.



3.4. Controlled ovarian stimulation (hereinafter - COS):

- 1) the IVF procedure can be performed with the use of COS. Only medicinal products registered on the territory of Ukraine in accordance with the procedure established by law may be used for COS. The choice of the scheme of stimulation, medicines, correction of their doses is carried out by the doctor taking into account the instruction on use of medicines, individual differences of the patient, results of clinical and ultrasonic examination, monitoring;
- 2) groups of medicines that can be used within the protocols of COS: gonadotropins (menopausal human gonadotropin - MGH, follicle-stimulating hormone - FSH, recombinant FSH - rFSH; gonadotropin-releasing hormone (hereinafter - GnRH), gonadotropin-releasing hormone antagonists (hereinafter - GnRH-ant), selective estrogen receptor modulators (hereinafter - SERM) - clomiphene citrate, non-steroidal aromatase inhibitors(Letrozole).

3.5. Transvaginal aspiration of follicles to obtain oocytes:

- 1) transvaginal aspiration of ovarian follicles and aspiration of follicular fluid to obtain oocytes are performed after 35-36 hours from the time of introduction of the ovulation trigger;
- 2) the procedure is performed on an outpatient basis in aseptic conditions of a specialized manipulation room or small operating room under ultrasound control with the help of special puncture needles;
- 3) if it is impossible to perform transvaginal aspiration (atypical location of the ovaries), oocytes can be obtained laparoscopically. After the procedure, the patient remains under the supervision of medical staff for at least two hours to monitor general health.

3.6. Obtaining and registering sperm for IVF:

- semen of a man or donor prepared according to the appropriate technology is used for IVF;
- in case of using a husband's semen before giving it, it is recommended that he abstain from sexual activity for 3-5 days;
- sterile container for collecting ejaculate is marked;
- sperm delivery is carried out in a separate room;
- the obtained sperm of the patient is used for IVF with a note about its indicators in the protocol of cultivation of embryos according to the form given in annex 3 to this order.

3.7. Insemination of oocytes and cultivation of embryos in vitro:

- follicular fluid obtained by puncturing the follicles is transferred to a Petri dish. In the case of obtaining immature oocytes can be performed method of maturation of oocytes in vitro (hereinafter - MIV);
- the aspirate is examined under a stereomicroscope with 10-50 times magnification, oocytes are found and transferred to special nutrient media. A Petri dish with oocytes in a nutrient medium is transferred for cultivation to an incubator with a temperature of 37 ° C and 5-6% concentration of carbon dioxide in a gaseous medium; it is possible to carry out cultivation using a three-gas system (oxygen, nitrogen, carbon dioxide);
- both native and cryopreserved sperm are washed from seminal plasma before use and the fraction of morphologically normal and actively motile sperm is separated. You can use the techniques of centrifugation-flotation or centrifugation in a density gradient;

- insemination of oocytes is performed after 2-6 hours of preincubation, and the presence of fertilization of oocytes is usually assessed using an inverted microscope after 16-18 hours, when clearly visualized male and female pronucleus;
- zygotes are transferred to a fresh culture medium, where the initial development of embryos takes place, or cryopreserved.

3.8. Embryo transfer(ET):

- transfer of embryos to the uterine cavity can be carried out at different stages, starting from the zygote stage and ending with the blastocyst stage, which is formed in humans on the 5-6th day after fertilization;
- it is recommended to transfer no more than 1-2 embryos to the uterine cavity. However, with the predicted reduced probability of implantation, it is possible to transfer a larger number of embryos - 3 (with clinical justification and with the consent of the patient). There may be ET of one selective embryo (with the consent of the patient) and cryopreservation of the remaining embryos for use in subsequent cycles;
- special elastic catheters are used for ET, which are inserted into the uterine cavity through the cervical canal;
- it is possible to perform ET under the control of ultrasound scanning.


3.9. Support of the luteal phase of the stimulated menstrual cycle:


- support of the luteal phase of the stimulated menstrual cycle is carried out by the medicine progesterone or its analogues, the medicine a-GnRH;
- in the absence of risk of ovarian hyperstimulation syndrome (hereinafter - OHSS) support of the luteal phase of the cycle may also include the introduction of medicine HCG, which are prescribed on the day of embryo transfer, and then 2-4 times with an interval of 2-4 days;
- doses and frequency of the introduction of medicine are determined by the doctor taking into account the individual characteristics of a particular patient.

3.10. Diagnosis of early pregnancy:

- diagnosis of pregnancy by the level of beta-HCG in the blood or urine is carried out in 10-16 days from the date of embryo transfer;
- ultrasound diagnosis of pregnancy is performed no earlier than 21 days after embryo transfer.

3.11. Possible complications during IVF:

- ovarian hyperstimulation syndrome (OHSS);
 - allergic reactions associated with the introduction of medicines for controlled superovulation and support of the luteal phase of the stimulated menstrual cycle;
 - bleeding;
 - acute inflammation or aggravation of chronic inflammation of the female genitals;
 - ectopic pregnancy;
 - multiple uterine and heterotopic pregnancy;
 - torsion of the ovary;
 - ovarian apoplexy;
 - trauma of adjacent organs.
- 

- 3.12. After the end of the fertilization cycle, in the presence of a rest of unused oocytes / embryos, the patient may decide to use these oocytes / embryos for the treatment programs of other patients.
- 3.13. Data on the rest of oocytes or embryos and their use are recorded in the register of storage and use of cryopreserved oocytes, the form of which is given in Annex 4 to this order, or the register of storage and use of cryopreserved embryos, the form of which is given in Annex 5 to this order.
- 3.14. Intracytoplasmic sperm injection (hereinafter - ICSI) into the cytoplasm of the oocyte is performed using an inverted microscope equipped with micromanipulators, using special microinstruments and nutrient media.
- 3.15. Indications to intracytoplasmic sperm injection:
- oligozoospermia;
 - asthenozoospermia;
 - teratozoospermia in accordance with the current standards of ejaculate assessment;
 - inability to secrete a sufficient number of sperm (50-100 thousand actively motile sperm per oocyte);
 - use of sperm obtained from the testicle or its appendage;
 - use of cryopreserved sperm;
 - use of cryopreserved oocytes;
 - fertilization of oocytes of women of older reproductive age;
 - absence of fertilization in previous IVF programs;
 - low frequency of fertilization in previous IVF programs;
 - abnormal fertilization in previous IVF programs;
 - no fertilization in the current cycle of IVF, re-insemination of oocytes on the second day;
 - carrying out the technique of maturation of eggs in vitro;
 - the need for preimplantation genetic diagnosis;
 - clinically significant presence of antisperm antibodies in the ejaculate;
 - idiopathic infertility;
 - morphological abnormalities of oocytes (including thickening of the zona pellucida);
 - carrying out the technique of intracytoplasmic injection of morphologically selected sperm;
 - ejaculatory disorders, including retrograde ejaculation, anejaculation with spinal cord injury, etc.;
 - high level of DNA fragmentation.
- 3.16. Contraindications for intracytoplasmic sperm injection are determined in accordance with paragraph 3.2 of this section.
- 3.17. Methods of intracytoplasmic sperm injection consists of the following stages:
- preparation of oocytes;
 - deprivation of sperm movement by violating the integrity of the tail membrane;
 - violation of the integrity of the outer cytoplasmic membrane of the oocyte;
 - introduction of sperm into the cytoplasm of the oocyte with a glass microneedle;
 - cultivation and other stages, as in IVF.
- 

3.18. Preparation of oocytes:

- before performing the technique of intracytoplasmic sperm injection, denudation (removal of radial coronal cells) of oocytes is performed;
- micromanipulation is performed only on mature oocytes.


3.19. Sperm collecting:

- sperm for intracytoplasmic injection of sperm can be obtained from ejaculate or using manipulation methods;
- the choice of the optimal method of obtaining of sperm is made by a doctor;
- the method of preparation of sperm from ejaculate or aspirate obtained from the testicle or its appendage is chosen by the embryologist individually depending on the quantity and quality of sperm. Sperm for injection into the egg can be obtained from the ejaculate in pathospermia;
- in azoospermia and pathospermia, the following manipulation methods can be used: microsurgical aspiration of sperm from the epididymis; percutaneous aspiration of sperm from the epididymis; aspiration of sperm from testicular tissue; extraction of sperm from testicular tissue;
- manipulation is performed on the day of transvaginal follicle aspiration and oocyte collection in women. If it is necessary to carry out the procedure of fertilization with sperm from the epididymis, the manipulation can be carried out 12-24 hours before receiving oocytes, testicular - for 48-72 hours;
- in the case of using cryopreserved sperm from testicular aspirate or epididymis, the procedure of obtaining sperm is carried out in advance, regardless of the day of puncture of the ovarian follicles;
- indications for manipulation to obtain sperm are obstructive azoospermia, testicular failure and inability to ejaculate;
- contraindications for manipulation to obtain sperm are the presence of acute infectious diseases of any localization, coagulation disorders (hypocoagulation);
- complications: local pain, hematoma of the scrotum, edema, atrophic changes.

The scope of examination of a man before the procedure for obtaining sperm is carried out in accordance with paragraph 2.2 of section II of this order.

4. INTRAUTERINE INSEMINATION

- 4.1. Intrauterine insemination (hereinafter - IUI) with husband sperm or donor sperm is one of the forms of infertility treatment and can be performed by introducing prepared (capacitated) sperm into the uterine cavity during ovulation.
- 4.2. The decision to use IUI with semen of a husband or a donor is made by the patient on the recommendation of a doctor depending on the quantitative and qualitative characteristics of ejaculate and the patient's application for the use of assisted reproductive technologies. 4.3.
- 4.3. The IUI procedure is entered in the register of intrauterine insemination with husband's sperm (annex 6) or in the register of intrauterine insemination with donor's sperm (annex 7).
- 4.4. The procedure of IUI is carried out in the conditions of a natural menstrual cycle or with use of ovulation inductors.

- 4.5. Native or cryopreserved capacitive sperm is used when carrying out IUI with a husband's sperm.
- 4.6. Cryopreserved semen is used during IUI with donor's sperm. Defrosted capacitive donor's sperm is used after repeated negative test results for HIV, syphilis and hepatitis B, C (6 months after receiving donor's sperm).
- 4.7. For the patient, the donor must be anonymous (except for relative or non-anonymous donors).
- 4.8. Indications for carrying out IUI by husband's sperm:
- 1) the husband:
 - subfertile sperm;
 - ejaculatory and sexual disorders;
 - retrograde ejaculation (if it is possible to get enough sperm for IUI);
 - hypospadias;
 - hypospermia (small volume of ejaculate);
 - high viscosity of seminal plasma;
 - antisperm antibodies;
 - use of cryopreserved sperm;
 - use of cryopreserved sperm for delayed reproduction;
 - 2) the wife:
 - infertility of unknown origin;
 - cervical infertility factor;
 - the presence of antisperm antibodies;
 - ovulatory dysfunction that can be treated;
 - allergy to sperm;
 - vaginismus.
- 4.9. Indications for carrying out IUI by donor's sperm:
- 1) the husband:
 - severe oligoastenoteratozoospermia, azoospermia;
 - ejaculatory and sexual disorders;
 - unfavorable medical and genetic prognosis;
 - 2) the wife:
 - medical and social indications (at the request of the woman).
- 4.10. Contraindications for IUI are determined in accordance with paragraph 3.2 of section III of this order.
- 4.11. Conditions for conducting IUI:
- 1) the husband:
 - two spermograms confirming the presence of more than 10 million motile sperm in the ejaculate;
 - 2) the wife:
 - confirmed patency of at least one fallopian tube;
 - ovulatory cycle (spontaneous or induced).
- 

4.12. The scope of additional examination of patients before IUI is carried out in accordance with Section II of this order.

4.13. The order of carrying out IUI:

- the decision to use husband's sperm or donor's sperm is made by patients on the advice of a doctor and depends on the quantitative and qualitative characteristics of ejaculate;
- IUI can be used both in the natural menstrual cycle and with the use of ovulation inductors;
- the introduction of sperm is carried out in the periovulatory period. Only capacitive sperm can be used for IUI;
- the frequency of procedures and the intervals between them is determined by the doctor individually;
- possible use of native or cryopreserved husband's sperm, as well as cryopreserved donor's sperm;
- the number of IUI attempts is determined by the doctor.

4.14. Possible complications during IUI:

- allergic and other reactions associated with the introduction of medicines to stimulate ovulation, provided by their manufacturer;
- shock-like reaction with the introduction of capacitive sperm into the uterine cavity;
 - ovarian hyperstimulation syndrome;
 - acute or aggravation of chronic inflammation of the female genitals;
 - occurrence of multiple or ectopic pregnancy.

5. DONATION OF GAMETS AND EMBRYOS


5.1. Gamete and embryo donation is a procedure by which donors, with written voluntary consent, provide their sexcells- gametes (sperm, oocytes) or embryos for use by other persons in the treatment of infertility.

The use of embryo donation is carried out on medical grounds, subject to the written informed voluntary consent of patients, ensuring the anonymity of the donor and maintenance of medical confidentiality.

5.2. Gamete and embryo donation is carried out in the presence of relevant documentation: informed voluntary consent for sperm donation (annex 8), patient / patient application for the use of donor oocytes (annex 9), informed voluntary consent for oocyte donation (annex 10), informed voluntary consent for embryo donation (annex 11).

5.3. In case of complications of COS, provided for in paragraph 3.4 of Section III of this order, of the egg donor during the gamete donation procedure (in the COS cycle) within 30 days after aspiration of oocytes, the HCF provides medical care to patients.

5.4. Oocyte donors can be:

- women;
 - close relatives;
 - anonymous voluntary donors;
 - patients in IVF programs who, with the written voluntary consent, provide the recipient with a portion of their oocytes.
- 

5.5. Requirements for oocyte donors:

- a woman aged from 18 to 36;
- the presence of a healthy child born;
- absence of negative phenotypic signs;
- satisfactory physical health;
- absence of contraindications for participation in the oocyte donation program;
- absence of hereditary diseases;
- absence of bad habits: drug addiction, alcoholism, substance abuse.

5.6. Indications for IVF using donor oocytes:

- absence of oocytes acquired or congenital, due to natural menopause;
- risk of transmission of hereditary diseases;
- unsuccessful repeated attempts of IVF with low quality of embryos and unsatisfactory response of the ovaries to controlled stimulation and repeated production of oocytes and embryos of low quality.

5.7. Contraindications for ART using donor oocytes are determined in accordance with paragraph 3.2 of Section III of this order.

5.8. The scope of examination of oocyte donors and patients (recipients) is the same as during the IVF procedure (Section II of this order).

5.9. List of necessary documents for oocyte donation (hereinafter - OD):

- informed voluntary consent for oocyte donation;
- oocyte donor questionnaire (annex 12);
- personal card of the oocyte donor (annex 13).

The oocyte donor questionnaire is filled and coded by a physician. The coding scheme is determined by the health care institution. The work with donors is conducted by a doctor who conducts a medical examination of the donor before each attempt of IVF, monitors the timely conduct and results of laboratory tests in accordance with the schedule of the examination.


5.10. Algorithm for implementing the oocyte donation program:

- synchronization of menstrual cycles or controlled stimulation of the ovaries in the previous cycle with subsequent fertilization with the sperm of the patient's husband or donor and freezing of embryos;
- preparation of the recipient for the transfer of cryoembryos for embryo transfer in the planned menstrual cycle;
- IVF techniques, intracytoplasmic sperm injection (according to the indications);
- observation of the oocyte donor by a doctor before the start of the next menstruation (about 2 weeks), expected for the cycle of OD;
- donor oocytes can be frozen for further use.

In order to preserve the reproductive health of the female oocyte donor, it is recommended to perform no more than 8 COS attempts in total, a second COS attempt is performed no earlier than 2 months after the previous one.

5.11. A sperm donor can be a man aged from 20 to 40 years having a healthy child born from him.

5.12. The sperm donor must have no negative phenotypic signs.

- 5.13. Sperm donation is allowed in the absence of somatic and hereditary diseases that may adversely affect the health of the unborn child, deviations from normal morphometric and phenotypic features, as well as other contraindications.
 - 5.14. Sperm donation is not allowed under the condition of use of narcotic, psychotropic and toxic substances, abuse of alcoholic beverages.
 - 5.15. The personal card of the sperm donor shall be filled in for the sperm donor according to the form given in annex 14 to this order.
 - 5.16. Data on the use of donor sperm shall be entered in the register of storage and use of donor sperm according to the form given in Annex 15 to this order.
 - 5.17. The ART specialist performs a medical examination of the sperm donor, control the results of laboratory tests in accordance with the examination schedule.
 - 5.18. Requirements for donor sperm: normozoospermia.
 - 5.19. The choice of a sperm donor is made by the spouse or patient voluntarily on the basis of the phenotypic characteristics of the anonymous donor.
 - 5.20. Only pre-frozen and thawed donor sperm may be used before ART. The use of thawed sperm is allowed after repeated negative results of tests for HIV, syphilis, hepatitis B and C and not earlier than 6 months after cryopreservation. The use of cryopreserved donor sperm prevents direct contact between donor and recipient
 - 5.21. Embryo donors can be patients of the IVF program, who have unused cryopreserved embryos remaining in the cryobank after the birth of a child. In the case of fertilization of donor oocytes with donor sperm, they may be transferred to the uterine cavity of the recipient or cryopreserved (with subsequent transfer in subsequent cycles).
 - 5.22. With the voluntary, informed, written consent of donor patients, these embryos can be used to donate to an infertile patient / married recipient, as well as to female recipients who are not married.
 - 5.23. Data on the use of cryopreserved embryos shall be entered in the register, storage and use of cryopreserved embryos.
 - 5.24. The use of donor gametes and embryos is carried out upon the application of the patient / patients for the use of assisted reproductive technologies with donor gametes / embryos in the form given in Annex 16 to this order, the patient's application for the use of donor oocytes informed by voluntary consent.
 - 5.25. Recipients (at their request) may be provided with a phenotypic portrait of gamete and embryo donors.
 - 5.26. Contraindications for ART using donor embryos are determined in accordance with paragraph 3.2 of section III of this order.
 - 5.27. Examination of recipients of embryos, donor oocytes and sperm is performed in the same way as in the procedure of IVF.
 - 5.28. Examination of sperm donors and donor oocytes is performed in the same way as in the procedure of IVF.
- 

6. SURROGATE MOTHERHOOD

6.1. Necessary conditions for surrogate motherhood (hereinafter - SM) are:

- medical evidences for SM, provided for in paragraph 6.2 of this section;
- documents required for conducting the SM, provided for in paragraphs 6.10, 6.11 of this section;
- spouses (or one of the future parents) in whose interests the SM is performed must have a genetic link with the child;
- a surrogate mother should not have a direct genetic link to the child. It is allowed to bear pregnancy by close relatives of future parents (mother, sister, cousin, etc.).

6.2. Indications for SM are:

- absence of the uterus (congenital or acquired);
- deformation of the cavity or cervix in congenital malformations or due to surgery, benign tumors, in which pregnancy is impossible;
- structural-morphological or anatomical changes of the endometrium that lead to loss of receptivity, synechia of the uterine cavity, which are not treatable;
- severe somatic diseases, in which pregnancy threatens the further health or life of the recipient, but which do not affect the health of the future child;
- unsuccessful repeated attempts of ART (4 or more times) with repeated receipt of high quality embryos, the transfer of which did not lead to pregnancy.

6.3. Examination of the surrogate mother is carried out on the general grounds for the treatment of ART.

6.4. A surrogate mother may be a healthy adult woman having her own healthy child, a voluntary written application of the surrogate mother in the form given in annex 17 to this order, as well as the absence of medical contraindications.

6.5. Contraindications for ART by surrogacy and the scope of examination of patients are determined in accordance with Section II and paragraph 3.2 of Section III of this order.

6.6. Algorithm for the implementation of ART by surrogacy:

- choice of surrogate mother;
- synchronization of menstrual cycles of the recipient and surrogate mother, preparation of embryos / cryoembryos;
- procedure of transferring the embryo to the uterus of the surrogate mother;
- cryopreservation of unused embryos;
- diagnosis of pregnancy;
- monitoring the course of pregnancy in the SM in accordance with paragraph 1.13 of section I of this order;
- determination together with the doctor who observes the pregnant woman, the method of childbirth, place of birth, method of feeding the newborn;
- childbirth can be a partnership between the recipients and the surrogate mother.

6.7. Information on a child born by a surrogate mother on the day of discharge from the maternity hospital / department by telephone is provided to the children's clinic (at the child's place of residence).

6.8. If the parents of a child born by a surrogate mother are foreigners, they shall notify the temporary place of residence until the documents are registered and they leave the country for patronage by specialists in pediatrics and supervision.

6.9. In the case of the birth of a child by a woman to whom a human embryo conceived by the spouses as a result of ART has been transferred, the state registration of the birth of a child is carried out at the request of the spouses who gave consent to such transfer.


In this case, simultaneously with the document confirming the fact of birth of the child by this woman, an application for her consent to the registration of the spouses by the child's parents is submitted, the authenticity of the signature on which must be notarized, as well as a certificate of genetic link of the parents (mother or father) with the fetus (annex 18)

Thus in the column "For marks" of the registration act of birth the following record is made: "Mother of the child according to the medical certificate of birth is the citizen (a surname, a first name, a patronymic)", and also names of establishment (institution) are noted, who issued the certificate, date of issue and number, notary data (surname and initials, notary district or state notary office), date and registration number of the woman's signature on the application for her consent to the registration of the spouses by the child's parents, respectively to paragraph 11 of Chapter 1 of Section III of the Rules of state registration of Acts of civil status in Ukraine, approved by the order of the Ministry of Justice of Ukraine of October 18, 2000 № 52/5 (as amended by the order of the Ministry of Justice of Ukraine of December 24, 2010 № 3307/5), registered in the Ministry of Justice of Ukraine on October 18, 2000 under № 719/4940.

6.10. List of documents required for the SM, for the surrogate mother:

- application of surrogate mother;
- copy of the surrogate mother's passport;
- copy of the marriage or divorce certificate of the surrogate mother (except single women);
- copy of the child's birth certificate (children's);
- consent of the surrogate mother's husband to her participation in the surrogacy program in the form given in annex 19 to this order (except single women).

6.11. The list of documents required for the SM, by the spouse in whose interests the SM is carried out:

- application of the patient / patients regarding the use of ART;
 - copies of passports;
 - copy of the marriage certificate;
 - notarized copy of a written joint agreement between the surrogate mother and the woman (husband) or spouses.
- 

7. CRYOPRESERVATION OF SPERM, OOCYTES, EMBRYOS AND BIOLOGICAL MATERIAL OBTAINED FROM THE TESTICLE OR ITS APPENDAGE, OVARIAN TISSUE.

7.1. Cryopreservation of sperm, oocytes, embryos and biological material obtained from the testicle or its appendage, ovarian tissue and their storage are carried out on application for cryopreservation of sperm, oocytes, ovarian tissue or biological material obtained from the testicle or its appendage, (annex 20), and application for embryos cryopreservation (annex 21)

The data are entered in the register of storage and use of sperm of patients, biological material obtained from the testicle or its appendage, exposed to cryopreservation (annex 22), the register of storage and use of cryopreserved oocytes, register of storage and use of cryopreserved ovarian tissue (annex 23), the register of storage and use of cryopreserved embryos.

7.2. Заклад охорони здоров'я забезпечує необхідний режим зберігання та використання біоматеріалу на основі рекомендованих і апробованих протоколів виробників живильних середовищ. Процедура заморожування та розморожування проводиться ембріологом на підставі заяви на розморожування сперми, ооцитів, оваріальної тканини чи біологічного матеріалу, отриманого з яєчка або його придатка, за формою, наведеною у додатку 24 до цього Порядку, та заяви на розморожування і перенесення ембріонів за формою, наведеною у додатку 25 до цього Порядку.

8. EMBRYO REDUCTION

8.1. In order to prevent obstetric and prenatal complications associated with multiple births, manipulation can be performed to reduce the number of developing embryos - embryo reduction.

8.2. Embryo reduction is carried out only on the conclusion of the council of doctors on the need for its implementation, which involves at least three doctors.

8.3. The number of embryos to be reduced is determined by the patient on the recommendation of a doctor and a written application for embryo reduction according to the form given in annex 26 to this order.

8.4. Indications for embryo reduction are the presence of 2 or more fetuses after the use of ART in the presence of an application for embryo reduction.

8.5. Contraindications for embryo reduction:

- risk of interruption of pregnancy at the time of the procedure;
- acute inflammatory diseases of any localization at the time of the procedure.

8.6. Examination of the patient for embryo reduction is carried out in accordance with section II of this order.

8.7. The selection of embryos that remain and are to be reduced should be made taking into account the data of ultrasound examination, which characterize their condition for up to 12 weeks of pregnancy.

8.8. Access to embryos (transvaginal, transcervical, transabdominal) and the method of suspending their development are determined in each case by a doctor.

8.9. For the prevention of multiple births, the method of embryo transfer of one selected embryo is introduced. The remaining embryos are cryopreserved for use in subsequent cycles.

8.10. Possible complications of embryo reduction:

- bleeding;
- infectious and septic diseases;
- allergic reactions to medicines introduced;
- thromboembolic complications;
- stopping of the development of the remaining embryo (embryos).

9. CUTTING THE ZONA PELLUCIDA OF THE EMBRYO

9.1. Cutting the zona pellucida of the embryo (auxiliary hatching) before embryo transfer (transfer of embryos to the uterine cavity) can be performed in patients of the older age group (35 years and older) or in unsuccessful previous attempts at implantation in treatment cycles, at defects of a zona pellucida, after thawing of cryopreserved embryos.

9.2. This manipulation is performed in order to increase the frequency of implantation by facilitating the hatching of blastocysts.

10. PREIMPLANTATION MEDICAL GENETIC DIAGNOSIS

10.1. Preimplantation medical genetic diagnosis (hereinafter - PGD) of monogenic and chromosomal defects in oocytes and embryos at the stage before embryo transfer, as well as determination of the sex of the embryo to prevent hereditary diseases associated with sex, developed for women who have a high risk of giving birth to children with hereditary pathology. The main advantage of PGD is a reduction in the risk of hereditary diseases and an increase in the frequency of pregnancy (in some cases), the ability to avoid invasive interventions on the ovum and abortion in case of pathology. Research can be performed on polar bodies of oocytes, individual blastomeres of the embryo, trophoectoderm cells.

10.2. Indications for PGD are the risk of giving birth to children with a mutation of any isolated gene or with chromosomal abnormalities detected as a result of medical and genetic examination (clinical and genetic examination, karyotyping).

10.3. PGD may be performed at the patient's own will together with an application for preimplantation genetic testing in the form given in annex 27 to this order.


10.4. PGD is performed using in situ fluorescent hybridization, polymerase chain reaction (PCR) methods, etc.

10.5. In case of pregnancy after PGD, prenatal diagnosis is recommended.

11. TRANSPORTATION OF CRYOCORSERVED EMBRYOS / OOCYTES / SPERM / OVARIAN TISSUES / TESTICULAR TISSUES OR ITS APPENDAGE WITHIN UKRAINE AND ABROAD

11.1. Patients' gametes (sperm or oocytes), testicular tissue or its appendages, ovarian tissue and embryos are the biological material of the patient / patients, and the HCF provides their storage.

11.2. Donor gametes (sperm or eggs) are stored in the HCF.



11.3. At the request of the patient / patients their biological material can be transported to another HCF both on the territory of Ukraine and abroad. The written application of patients in this case is accompanied by an act on the transport of cryopreserved embryos / oocytes / sperm / ovarian / testicular tissue or its appendage in the form given in annex 28 to this order..

12. PROCEDURE FOR APPLICATION OF ART IN ORDER TO PRESERVE FERTILITY

12.1. Before treatment of oncological diseases (C00-C97; malignant neoplasms of all localizations, including lymphatic and hematopoietic tissues), hematological, autoimmune diseases at the request of the woman and at the written application of the patient / patients on the use of assisted reproductive technologies, the ART program for cryopreservation of oocytes, embryos is conducted.

12.2. The conclusion on the possibility of controlled ovarian stimulation is prepared by a specialist in reproductive medicine on the basis of a consultation with an oncologist; in the case of non-oncological diseases - rheumatologist, hematologist.

12.3. The following fertility schemes are recommended:

- IVF program in a natural cycle with cryopreservation of oocytes, embryos;
- IVF program with the use of medicines from the group of aromatase inhibitors, antiestrogenic medicines with cryopreservation of oocytes, embryos;
- if it is impossible to carry out the IVF program, cryopreservation of ovarian tissue is recommended, specified in Section VII of this order.

12.4. If there is an anamnesis of malignant neoplasms, the ART program may be performed after consultation with an oncologist or if there is a document confirming that the woman has undergone treatment and deregistered from the cancer register.

Acting Director of the Department of Health care
reform and development

E.Moroz