INFORMED CONSENT FOR IVF-ICSI

Definitions

IVF: In Vitro Fertilization.
ICSI: Intra-cytoplasmatic sperm injection into an egg.
ET (intrauterine Embryo Transfer): placement of embryos in the uterus for their implantation in the endometrium.
Gamete: Male or female reproductive cells (egg or sperm)
Embryo: product resulting from the fertilization between an egg and a sperm.
Gamete bank: cells and tissue bank that obtains, stores and/or provides human sperm and oocytes (eggs) to be used in assisted reproductive technologies (ARTs). Male donors must be above legal age and under 40 years old while female donors must be above legal age and under 34 years old. Both male and female donors are selected through clinical, psychological, infectious diseases and genetic evaluation under specific quality and biosafety standards.
Health center: health center performing medically assisted reproductive procedures and technologies in accordance with Resolution 1305/2015 of the National Ministry of Health.

Indication

With own gametes: This procedure is indicated for patients who have damaged Fallopian tubes, other anatomic alterations, endometriosis, poor egg quality or quantity and/or failure of previous treatment cycles.
With donated gametes: This procedure is indicated for:

- Women who have absence of ovarian activity (menopause); absence of ovaries (oophorectomy); alterations in egg number or quality; multiple failures in assisted reproductive technologies; possibility of transmitting genetic disorders; recurring pregnancy losses attributed to female causes, advanced age; other causes.
- Men with azoospermia, alterations in sperm count, quality or shape, multiple failures in assisted reproductive technologies probably due to male causes, presence of hereditary diseases genetically transmitted by the father, recurring pregnancy losses that can be attributed to male causes
- Same-sex couples.
- Women without partner.

Treatment steps

Previous medical evaluations:
Women: blood hormonal evaluations, general laboratory checkup, blood evaluations for infectious diseases, karyotype, transvaginal ultrasound, vaginal discharge culture, uterus and Fallopian tubes evaluation (hysterosalpingography), gynecological exam up to date and cardiologic evaluation. Up to date vaccination. Pre-conception counselling.
Men: infectious disease evaluation in blood, karyotype, complete semen analysis (including fertilizing capacity– Kruger and Sperm DNA Fragmentation Test according to the case). Pre-conception counselling.
Pre-conception folic acid intake will be indicated to the woman who will undergo pregnancy.
Ovarian stimulation (only for the patient providing the eggs): In order to achieve a higher number of eggs and increase chances of pregnancy, ovaries are stimulated through the administration of medication and oral and/or injectable hormones, in a dose that will be determined by previous medical evaluation and ultrasound monitoring.
Egg retrieval (only for the patient providing the eggs): It is performed through ultrasound-guided ovarian puncture (needle aspiration). This is an ambulatory procedure that requires anesthesia. Progesterone supplement will be indicated after the procedure.
Providing the sperm sample:

a) Gametes of the women's partner: Deliver of a simple during the morning of the procedure.
b) Bank gametes: The bank providing the gametes will deliver the sample in the morning of the procedure. (separate consent form to be signed)

Egg Insemination/injection and embryo culture: fresh or previously cryopreserved eggs can be used. Eggs need to be mature in order to be used. Semen is processed by means of the appropriate technique according to the sample's characteristics. Eggs are fertilized through IVF or ICSI depending on the characteristics of the semen sample. Fertilization is evidenced on the following day. From then on, embryo development will be evaluated periodically.
Embryo Transfer: Between 48 and 120 hours or in a subsequent cycle if necessary, the resulting embryos will be transferred to the uterus using a cannula through the cervix, under ultrasound control and without anesthesia. This is an ambulatory procedure that does not require hospitalization. The embryo transfer is performed to the person who consented to the embryo reception. If the person who consented to the reception is not the same person providing the eggs, whether fresh or cryopreserved and thawed, the endometrium of the woman who will carry on the pregnancy needs to be prepared by means of hormone administration so that it is in receptive conditions.

Embryo cryopreservation: Excess embryos that were not transferred are cryopreserved, if the patient/s decide/s on it and after signing the corresponding consent form. If there is no such consent, only the necessary amount of eggs will be inseminated/injected in order to avoid having embryos in excess of those that will be transferred.
Post Embryo Transfer: Hormone administration continues until new medical indication.

Risks
Related to ovarian stimulation: abdominal pain, headache, bloating, ovarian torsion, mild ovarian hyper-stimulation syndrome (the severe form occurs in 2 to 5% of all cases).
Related to medication (side effects): from none to all of the following symptoms can occur: redness and pain in the application site, mild weight loss or gain, fluid retention, changes in appetite, increase of breast tenderness, vaginal bleeding, vaginal yeast infections, increase of vaginal discharge, hot flashes, general discomfort, menstrual cramps, fatigue, skin rash, headaches, mood swings, sleeping disorders, nausea and vomiting.
Related to endometrium preparation: cancellation due to inadequate endometrium condition, uterine bleeding, others.
Related to follicle aspiration: cancellation due to insufficient response to stimulation, intra-abdominal infection or hemorrhage that may require ambulatory treatment with antibiotics or hospitalization with or without the need of laparoscopy or laparotomy.
Related to egg thawing: it is possible that some or all of the thawed eggs do not survive the thawing process.
Related to Embryo Transfer: cancellation due to lack of gametes, complete fertilization failure, obtaining non-viable embryos, other causes leading to embryo cryopreservation and a deferred embryo transfer.
Congenital anomalies and genetic disorders: Probabilities of occurrence with the use of these reproductive techniques are deemed to be similar to those of the general population. All human beings have multiple mutations associated with autosomal recessive disorders as carriers, which does not mean that we will develop the disorder, but there is a chance of transmitting it to our children. These disorders are expressed when the two gametes used in the treatment, male and female, present a mutation for the same disease. In these conditions, there is a 25% risk of having a child with such disease. In order to reduce that risk, Cegyr recommends performing genomic platform analyses to those who provide gametes. Cegyr evaluates donors (male and female) by means of the use of genomic platforms.
Rh Isoimmunization: If the patient who will carry the possible pregnancy is Rh-negative and one of the gametes comes from an Rh-positive person, there is a risk of Rh incompatibility. This probability can be reduced through the administration of gamma-globulin, if indicated by the obstetrician.
Related to pregnancy: The embryo transfer to the uterus does not guarantee that pregnancy will occur. In addition, in case of pregnancy, miscarriage is a possibility (risk similar to general population), ectopic pregnancy (4%) or any other complication that could be present during a spontaneous pregnancy. Even the transfer of only one embryo implies the minimal risk of having a multiple pregnancy. In case of transferring two embryos, this risk amounts to 20% of pregnancies. The risks of multiple gestations include preterm labor and its neonatal complications, hypertension and maternal diabetes, among others.
Psychological aspects: There can be alterations in interpersonal relationships (with your partner, with the baby o with the couple's social circle). In every assisted reproductive technology, we suggest holding interviews with psychological teams specialized in reproduction.

Outcome / Success rates
Although the outcome of each particular case depends on individual characteristics of patients, the probability of achieving a clinical pregnancy with the patient's own eggs is approximately 25% per cycle, varying from nearly 40% in patients under 35, approximately 15% in patients between 40 and 42 and less than 1% for women over 43 years old. In the case of women receiving donated eggs, the pregnancy rate is not age-related, varying from 30% to 50% per embryo transfer cycle. It is clear from these numbers that treatment does not guarantee getting pregnant.

Information provided
I/we have read and understand the information above in relation to the procedure I/we will undergo.

I/we were able to ask questions to the physician in charge and clear all doubts about the procedure, its risks, benefits and eventual complications related to the procedure I/we will undergo. The explanations I/we have received have been provided in a clear and simple language.

I/we have been informed that all medical data related to this procedure are confidential, including my/our medical record, diagnostic tests and/or images according to article 2 sub-section d) of Law No. 26,529 on Patient's rights in relation to health professionals and health institutions, modified by Law No. 26,742, Regulatory Decree No. 1089/2012 and articles 8 and 10 of Law No. 25,326 on Personal Data Protection. Disclosure of such information (whether total or partial) will

only take place in exceptional situations under legal requirement, relieving Cegyr from the physician-patient privilege or in extraordinary circumstances based on Cegyr's founded criteria.

I/We have been informed about and provide consent to the use of non-identifying data about the outcome of this treatment to be reported to several national and international databases for statistical and/or scientific purposes, according to the laws regulating the matter.

I/We have been informed that I/we can obtain, at any time, a copy of my/our medical record, according to the provisions of Law No. 26,529 of Patient's rights in relation to health professionals and health institutions (arts. 12 and following) modified by Law No. 26,742, Regulatory Decree No. 1089/2012 and Law No. 25,326 on Personal Data Protection.

I/We have been informed and understand that the embryo/s resulting from the assisted reproductive technologies will be transferred to ……..……[1] who will carry on the pregnancy within the frame of an individual or joint parenting project with……...……[2]

I/We have been informed and understand that the filial legal tie with the person/s born through this technique is determined by the will to conceive documented in this informed consent within the frame of an individual or joint parenting project, according to article 562 of the National Civil and Commercial Code.

I/We have been informed and understand that that the action to challenge the filiation of children born from the treatment herein consented is not admissible according to article 577 of the National Civil and Commercial Code.

I/We have been informed and understand that in order to register the birth of the person/s born through the use of this human assisted reproductive technology, at the corresponding Registry of Civil Status and Capacity of Persons, this informed consent needs to be filed, previously legalized by Notary Public or certified by the local health authority, according to article 561 of the National Civil and Commercial Code, and I/we understand it is my/our sole responsibility to obtain the notarization or certification by health authority and pay for its cost as an effect of the filiation determination of the children born as a result of the use of this type of medical procedures.

I/We have been informed and understand that the number of embryos to be transferred (one -1- or two –2-) is a decision made by the medical team/health center and it is their responsibility, as appropriate in each case in order to accomplish pregnancy, with the purpose of reducing the risks of multiple gestation and protecting the patient's health. I/We understand that if I/we do not previously consent to embryo cryopreservation, only the necessary amount of eggs will be inseminated/injected in order to avoid excess embryos.

I/We have been informed and understand the importance of staying in permanent communication with Cegyr's medical staff during the entire treatment period.

I/We have been informed and understand that this consent is valid only for obtaining these embryos and for its/their immediate transfer. In case of excess embryos and acceptance of embryo cryopreservation and after signing the corresponding consent, another consent authorizing the thaw and transfer of frozen embryos will need to be signed and delivered before carrying out the procedure. A similar consent must be renewed for each ART procedure, according to article 560 of the National Civil and Commercial Code, being only the new updated consent the one needed to register the birth at the Registry of Civil Status and Capacity of Persons, after notarization or certification according to the provisions of article 561 of the National Civil and Commercial Code.

I/We have been informed and understand that I/we can withdraw this consent jointly or individually at any time before the embryo transfer, according to article 7 of Law No. 26,862 de Integral Access to Assisted Reproductive Technologies' Procedures and Techniques and its Regulatory Decree No. 956/2013 (article 7) and the provisions of article 561 of the National Civil and Commercial Code. Consent withdrawal must be notified irrefutably and in writing to the health center providing the services, expressly stating their will to withdraw this consent and discontinuing the IVF/ICSI procedure. I/We understand that in case we had embryos at the time the consent is withdrawn, I/we will be legally responsible for them and their maintenance costs.

I/We have been informed and understand I/we could be denied admission based on a duly founded decision made by the Institution, without this being construed as an act of discrimination of any kind.

I/We have been informed and understand that the eggs and sperm that by medical decision were not used in my/our procedure, eggs that fail to fertilize or did not fertilize normally and arrested embryos, not fit for being transferred, could be analyzed with the purpose of evaluating some cellular and/or molecular mechanisms that could help us understand potential problems.

Section for donated gametes

I/We have been informed and understand that donated gametes come from anonymous donors, that is to say, I/we understand that we will not know the identity of the donor, as well as the donor will not have any information about the recipient/s, or the result of fertilization, if the procedure resulted in pregnancy or not and if a child was born or not. However, I/we understand that in case of risk to the health of the person/s born through this technique with donated gametes, the medical information about the donor could be revealed, but not his/her identity, except in cases of judicial authorization according to article 564 of the National Civil and Commercial Code.

I/We have been informed and understand that although Cegyr will try to perform a phenotype match with donors, it cannot be guaranteed that the donor will have similar features to those of the recipient nor any results regarding I the phenotype of the potential newborns.

I/We have been informed and understand that the recognition by the donor or the filing of a filiation legal action or any related legal claim are not admissible in relation to the newborn, according to article 577 of the National Civil and Commercial Code.

I/We have been informed and understand that the person/s born as a result of this procedure do/does not have any legal bond with the donor, except to the effects of marriage hindrances according to article 575 of the National Civil and Commercial Code.

I/We have been informed and understand that the donation is voluntary, altruistic and free, reason why the recipient/s will not have any economic obligation towards the donor.

I/We have been informed and understand that the eggs obtained from a female donor can be used for more than one recipient, as well as different samples from a same male donor can be used for more than one recipient.

I/We have been informed and understand the importance of letting my/our son/daughter know that she/he has been born as a result of an assisted reproductive technology procedure with donated gametes, by virtue of his/her identity right, according to articles 563 and 564 of the National Civil and Commercial Code.

I/We have been informed and understand that Cegyr's gamete donation program offers psychological and genetic counselling in order to reduce the risks mentioned before. Not using these services is under my/our own full responsibility.

CONSENT

By signing this document I/we **express my/our will,** fully conscious and freely, to undergo the IVF/ICSI treatment FOR WHICH THE FEMALE GAMETES ARE PROVIDED BY ……[3], THE MALE GAMETES ARE PROVIDED BY ……...……...[3], and the resulting EMBRYO TRANSFER WILL BE PERFORMED ON……...……..[1] and **AUTHORIZE** the medical professionals of the health center to apply the treatment and or techniques to me/us that they consider necessary for that purpose.

In case of legal conflicts in the interpretation of this document, we agree to submit ourselves to the jurisdiction of the Civil Courts of the City of Buenos Aires.

It is the responsibility of the patients to inform the health center during the entire cryopreservation period of any changes to the indicated address. Otherwise, the following address will be the valid one for the purposes of this consent.

[1] Please state name and last name
[2] Please state name and last name or cross out the line
[3] Please state name and last name or add the word "Donor"

PATIENT 1

Last name and names:……...……Identity card number/Passport:…….Age:……

Address:……PC/ZC:…….....

City:…….State.:……..……..Country:…….

Phone number:……...…..Mobile phone number:……..E-Mail:……

……
Signature, printed name and date

PATIENT 2

Last name and names:……...……Identity card number/Passport:…….Age:……

Address:……PC/ZC:…….....

City:…….State.:……..……..Country:…….

Phone number:……...…..Mobile phone number:……..E-Mail:……

……
Signature, printed name and date

TREATING PHYSICIAN

……
Signature, printed name and date

I/We have been informed and understand the information included in the section "*Congenital anomalies and genetic disorders"* about Genomic Platform and autosomal recessive disorders. By signing this document **express my/our will,** fully conscious and freely, on how to proceed in relation to this test that is recommended by Cegyr's program.

Treatment with the couple's own gametes

We,……..[1] and ……..[1], ……[2] accept the performance of the genomic platform analysis to both of us, since we are the ones providing our gametes and we are aware of the risk of the potential consequences to our future children that this decision may have.

Treatment with donated female gametes

We,……..[1] and ……..[1], who accept the use of eggs from a female donor evaluated through genomic platform analysis, ……[2] accept the performance of the genomic platform analysis to …….[1] who is providing the male gametes and we are awareof the risk of the potential consequences to our future children that this decision may have.

Treatment with donated male gametes

I/we,…….[1] and ……..……[3], ……[2] accept the performance of the genomic platform analysis to …….[1] who is providing the female gametes and we are aware of the risk of the potential consequences to our future children that this decision may have.

Treatment with both male and female donated gametes

I/we,…….[1] and ……..……[3], who accept the use of eggs from a donor who has been evaluated by means of genomic platform analysis, ……[2] accept the use of a semen sample from a donor evaluated through genomic platform analysis and we are aware of the risk of the potential consequences to our future children that this decision may have.

[1] Please state name and last name
[2] Please state YES or NO
[3] Please state name and last name or cross out the line

PATIENT 1
Last name and names:……

……
Signature, printed name and date

PATIENT 2
Last name and names:……...

……
Signature, printed name and date

TREATING PHYSICIAN

……
Signature, printed name and date

Three (3) copies of this consent are signed in this act. Two of the copies of this consent will be delivered to the patient/s (one for herself or themselves and the other one to proceed with the registration at the Registry of Civil Status and Capacity of Persons of the child born through this assisted reproduction technology, after notarization or certification by competent health authority) and the remaining copy will be filed at the Health Center.