

Egg Donation Informed Consent

This document explains the treatment, major risks, and responsibilities of the egg donor. Egg donation involves in vitro fertilization (IVF), a treatment involving four main steps: (1) administration of medications to develop additional eggs in the egg donor's ovaries, (2) removing the eggs from her ovaries, (3) placing eggs and sperm together to allow fertilization; and (4) transferring the fertilized eggs (embryos) to a recipient's uterus to attempt pregnancy.

Pre-Treatment Requirements, Screening, and Testing

Egg donors must be in good health and avoid any activity, behavior, or medication during treatment that would reduce the chances of conceiving a healthy child or increase risks to an unborn child:

- Take a daily prenatal vitamin containing folic acid to reduce the chance of congenital defects (e.g. spina bifida).
- Do not smoke or take recreational drugs for at least 3 months before and during treatment.
- Do not use alcohol or take aspirin or aspirin-like products once you have started your stimulation medication (e.g. Motrin, Advil, Naprosyn, Aleve, etc.). Tylenol is a suitable alternative.
- Discuss prescription and over-the-counter medications with a physician before beginning.

Donors undergo counseling, education, screening, and testing to demonstrate eligibility as a potential egg donor. They are also screened and tested for communicable disease, according to Food and Drug Administration (FDA) regulations.

In Vitro Fertilization (IVF)

Ovulation Induction: Injectable medications are used to stimulate development of multiple ovarian follicles (containing eggs). Blood tests and ultrasounds are performed to monitor progress.

Egg Retrieval: When the eggs are mature, they are removed from the ovaries.

Fertilization: Sperm is used to fertilize the eggs outside of the body and are incubated to create embryos.

Embryo Transfer: One or more embryos are transferred into the uterus of the recipient female.

Embryo Freezing (Cryopreservation): Following embryo transfer, most recipients cryopreserve (freeze) remaining embryos for future use. If embryos remain after the desired number of embryo transfers, the recipient may donate them to another recipient for embryo transfer; donate them to science; or discard them. The Fertility Center will not destroy embryos, but recipients may do so.

Ovulation Induction

During a woman's normal menstrual cycle, one ovarian follicle (containing an egg) develops and matures within the ovary, resulting in the release of a single egg. Ovarian follicle growth is influenced by hormones, including follicle stimulating hormone (FSH) and luteinizing hormone (LH). FSH is the main hormone that stimulates follicles to grow and produce a hormone called estradiol. Estradiol testing can be used to assess follicle growth. When the follicle matures, additional LH is released by the pituitary gland. This "LH surge" helps mature the egg and causes ovulation 36-40 hours later.

Fertility Medications

Self-administered injectable medications are used to increase the number of follicles. This allows for multiple eggs to be collected at egg retrieval, so the recipient has the option to create several embryos for future pregnancy attempts. It is recommended that donors avoid pregnancy the month before and during use of these medications. There are several injectable medications used for this phase of treatment:

Follicle Stimulating Hormone: (usually Gonal F or Follistim). Increases egg production and quality.
Menopur Increases egg production and quality.
Leuprolide acetate (Lupron), Cetrotide, or Ganirelix. Prevents luteinizing hormone (LH) surge.
Human Chorionic Gonadotropin (hCG) or Lupron. Used to mature eggs and/or trigger ovulation.

During treatment, follicular development is measured with vaginal ultrasound exams and estradiol blood hormone tests. Frequent monitoring helps determine appropriate medication dosing and procedure timing, which helps avoid side effects and risks to the donor.

Side Effects may include nausea, vomiting, hot flashes, headaches, mood swings, insomnia, and fatigue. Allergic reactions, although rare, are possible. Additional serious side effects are also possible:

Ovarian Hyperstimulation: After egg retrieval, follicles refill with fluid to form cysts. Symptoms generally occur 4-10 days after ovulation induction or egg retrieval and usually resolve within 2 weeks without intervention. Symptoms include ovarian enlargement with abdominal discomfort, distention, and weight gain; fluid in the abdomen or chest cavity; nausea and vomiting; shortness of breath. Women with severe hyperstimulation (approximately 1% of patients) may be admitted to the hospital for observation and treatment. Rare, but serious consequences can occur and may include formation of blood clots leading to medical complications such as stroke, kidney damage, or death.

Ovarian Torsion: In less than 1% of cases, the ovary may twist, decreasing its blood supply and resulting in severe lower abdominal pain, necessitating surgery to untwist or remove the ovary. *While taking stimulation medication, patients are advised not to engage in bouncing, jumping, running, jogging, horseback riding, jet skiing, or any activity which will jostle or twist the abdominal region.*

Egg Retrieval

Egg retrieval is an outpatient procedure performed by ultrasound guided needle aspiration. An antibiotic is taken prior to egg retrieval to reduce chances of infection. The donor receives conscious intravenous (IV) sedation to reduce pain and anxiety. Complications of anesthesia may include nausea, vomiting, drowsiness, or allergic reaction. An ultrasound probe is placed in the vagina to visualize the ovarian follicles, while a needle is introduced through the vaginal wall into each follicle. Follicle fluid is removed and examined by the embryologist for eggs. This process is repeated with each follicle in both ovaries, and is usually completed within twenty minutes. The patient rests in recovery for one hour afterwards. Because the medications may cause drowsiness, the donor cannot drive to or from the egg retrieval. A responsible party must be available for all donor transportation.

Egg retrieval complications occur in less than 1% of cases and may include injury to blood vessels, intestines, or bladder, resulting in hemorrhage or infection. Complications could result in hospitalization and, possibly, additional medical or surgical treatments which could impair chances of achieving future pregnancy. In rare instances, it may be necessary to remove an ovary or perform a hysterectomy.

Anonymous Egg Donation

Egg donations at The Fertility Center are anonymous, unless a recipient arranges to obtain a donor independently. In anonymous cases, women volunteer to donate their eggs with the understanding that The Fertility Center will not disclose the identity of the recipient(s), nor will the recipient(s) be given the identity of the egg donor. Egg donor information shared with a recipient includes a history profile completed by the egg donor, with an office generated patient ID number, but does not include donor name or other identifiable information. Hard copies of egg donor medical records are not shared with recipients; however, the egg donor understands that information from her medical records, including blood testing and screening results may be provided. Early childhood photos are provided to the recipient, but adult photos are not. This limited information is provided to help recipients choose an appropriate egg donor for their needs, without disclosing donor identity.

Informed Consent for Egg Donation

I voluntarily choose to be an egg donor at The Fertility Center. I agree to undergo psychological and medical screening and testing to determine my eligibility. I understand I will need to self-administer injectable medications to increase the number of eggs I produce in a monthly cycle. These eggs will be retrieved from my ovaries for donation to a recipient.

I understand that my donated eggs may be used in the following ways:

- (1) The eggs will be fertilized with sperm to create embryos. The embryos will be used to attempt pregnancy. I am aware that these embryos may be frozen for an embryo transfer at a later date. Unused embryos can be donated by the recipient to other recipients to attempt pregnancy, discarded by the recipient, or sent for scientific research.
- (2) The eggs will be vitrified (frozen) for future use. When a recipient is ready to use them, the eggs will be thawed and fertilized with sperm to create embryos. The embryos will be used to attempt pregnancy. I am aware that these embryos may be frozen for an embryo transfer at a later date. Unused embryos can be donated by the recipient to other recipients to attempt pregnancy, discarded by the recipient, or sent for scientific research.

I give my permission for detailed laboratory testing of my blood, including but not limited to, testing for HIV (the AIDS virus), hepatitis, syphilis, gonorrhea, West Nile Virus and Chlamydia. I authorize the disclosure of my results to anyone physically exposed to my blood or tissues. I understand that my records may be reviewed by regulatory agencies. I understand that by law certain positive tests must be reported to public health authorities and it is possible my sexual contacts could be notified of potential exposure to communicable disease. Some testing results may be reported as ambiguous or indeterminate—results which are unclear may still render me ineligible as a donor, and may require follow up with my primary physician. I understand that if any of the screening or testing renders me ineligible as a donor by the FDA or The Fertility Center, I will not receive any payment for any portion of my appointments and I will not be eligible to donate.

I understand I should use a barrier form of contraception or abstain from intercourse before and during ovarian stimulation. Because multiple follicles (containing eggs) are stimulated, it is possible that I could become pregnant if I do not use appropriate contraception during or after my IVF cycle. I release The Fertility Center from any responsibility if I become pregnant during this procedure.

I understand that my retrieved eggs may be allocated to more than one recipient as determined by The Fertility Center and my reimbursement remains the same for either scenario. I agree that once the eggs are removed from my body, I completely waive and relinquish any and all parental rights and responsibilities that I might have to any child(ren) born from these eggs. I understand that the law and the recipient(s) of my eggs will regard the donated eggs and any resulting embryos as those of the recipient(s). Any child(ren) born from the eggs shall be regarded as the child(ren) of the recipient(s) to whom the embryos are transferred. In the State of Michigan, as with many states, the female that delivers a child is the legal parent, even if it is not genetically her child.

I understand that the recipient(s) of the eggs has released me from liability for any and all problems occurring during pregnancy and for any mental or physical disabilities, financial support, care, custody, health or welfare of a child(ren) born from my egg donation.

I understand that The Fertility Center will not disclose my identity to any of the recipients, unless I am donating to a known couple or if disclosure is required by law, now or in the future. I will not be provided with information regarding the egg recipient(s); however, I may inquire about the outcome of

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my egg donation for evaluation of my own fertility. I have the option of knowing if there is a birth or births, including the month and year of birth, and that it is up to me to request that information.

I understand with advancements of genetic testing, it is possible for my identity to be revealed to a recipient or offspring if anyone genetically related to me participates with a program that does genetic testing. I understand The Fertility Center cannot be held liable for such disclosure. Examples of this, but not limited too, are: 23andMe, Ancestry.com, etc.

In the unlikely event that I become ill or am injured as a direct result of my participation as an egg donor, I will notify The Fertility Center immediately. For anonymous donors, a supplemental medical insurance policy is purchased by the recipient, which is *only valid for medical expenses related to egg donation complications*. I understand my current medical insurance will be billed first to cover these expenses. The supplemental policy will then cover any expenses not paid by my own medical insurance. If I do not currently have medical insurance, the supplemental policy will be billed first. I acknowledge and agree that my acceptance into treatment and my continued participation is at the sole discretion of The Fertility Center. My cycle may be cancelled without monetary reimbursement by The Fertility Center at any time. I understand that my ability to participate in future treatment cycles is at the sole discretion of The Fertility Center.

I agree to report to The Fertility Center any newly diagnosed and/or discovered genetic disorder(s) or major medical conditions that affect me or any family members, so that recipients can be notified when appropriate. I understand that in the future I may be contacted with questions about my family history and/or to be notified if a child born from my eggs has any genetic or other defects that may be of relevance to me. I agree to inform The Fertility Center if I engage or have engaged in any activities that put me at risk for communicable disease (e.g. sharing injection needles or exposure to communicable disease). I have reviewed all egg donor requirements of The Fertility Center and affirm, to the best of my knowledge, I am fully eligible to participate as an egg donor at The Fertility Center.

I understand that medical information concerning my treatment may be analyzed and used in publication. In addition, in accordance with federal law, non-identifying information and information concerning my treatment will be submitted to a national data registry that publishes statistics on treatment outcomes.

By participating as an egg donor, I accept all stated responsibilities and risks. I consent to the process and procedures as described in this document and explained to me by Fertility Center staff. After having read this document and spoken with Fertility Center staff, I understand the risks involved in egg donation; have had all questions concerning this process fully answered to my satisfaction; and consent to being an egg donor at The Fertility Center. In so doing, I affirm that I understand, assume and accept all risks of my participation.

Egg donor's signature: _____ Date: _____

Staff witness or notary signature: _____ Date: _____