

CONSENT FOR EGG DONATION

I, _____ (ovum donor) wish to participate in the Oocyte (Egg) Donation Program offered by the California Center for Reproductive Health (CCRH) by donating my oocytes (eggs) in order to allow another woman (female recipient) to become pregnant. Before participating in the Egg Donation Program, it is important to understand the proposed procedures, along with the known material risks, benefits, discomforts, precautions, and social and legal considerations. Accordingly, I hereby acknowledge my understanding of the following:

The egg donation process involves the daily administration of one or more injectable medications over the course of several days for the purpose of stimulating the ovaries to produce multiple eggs (controlled ovarian hyperstimulation). During the stimulation, vaginal ultrasound examinations and blood tests will be performed to monitor the growth of eggs. At the conclusion of ovarian stimulation an egg retrieval procedure (follicle aspiration) is performed under mild sedation, during which eggs are harvested under ultrasound guidance. Harvested eggs are then typically fertilized with sperm, and embryos are conceived. Resulting embryos are typically transferred into a female recipient's uterus for the purpose of establishing pregnancy.

I agree to participate in the Egg Donation Program for the purpose of donating my eggs for use by an infertile woman (female intended parent) or by a male patient lacking a female partner (male intended parent) for the purpose of establishing a pregnancy. Eggs obtained from me will be fertilized with the sperm of a male partner or sperm donor and, if fertilized, resulting embryos will be transferred to a female recipient's uterus (female intended parent or gestational surrogate), cryopreserved (frozen), or discarded. Alternatively, the intended parent(s) may choose to freeze all or any of harvested eggs unfertilized.

I understand that the identity of the recipient/intended parent(s) receiving the donated eggs may not intentionally be revealed to me, and that my identity may not be revealed to the female recipient or her partner/spouse or intended parent(s).

RELINQUISHMENT OF RIGHTS

I understand that by donating my eggs, I relinquish and give up *any and all rights* to the donated eggs, to any resulting embryos (whether cryopreserved or not), and to *any* child or children who may be born as a result of the donation, and I agree that I shall not attempt to assert such rights. This donation is being done voluntarily and irrevocably with knowledge that the donated eggs will be used by intended parent(s) attempting to establish a pregnancy. However, I recognize that intended parent(s) may choose to freeze eggs (fertilized or unfertilized), to have them placed in a recipient's uterus (intended mother or surrogate), to discard them or have them destroyed, to give them up for medical research or to give them up for adoption by another person(s). I acknowledge that I will not be provided with any information about the donated eggs, results of the attempted fertilization, the establishment of any pregnancy or any information of any type concerning the outcome of the uterine implantation/transfer with embryos resulting from the donated eggs.

My initials indicated that I consent to the relinquishment of all my rights to donated eggs/resulting embryos/resulting children:

Initials

PRE-DONATION PROCEDURE/REQUIREMENTS

In order to participate in the Egg Donation Program, I must meet or agree to participate in the following requirements:

1. I must be between the ages of 18-34.
2. I must provide basic information such as height, weight, hair color, eye color, and national origin. I understand that all questions about my medical, mental and psychosocial history must be answered honestly and truthfully.
3. I must have regular menstrual cycles.
4. I must have no medical history which would indicate an unusual risk for anesthesia (i.e. bleeding disorders, heart conditions, etc.)
5. I must use barrier contraception for two menstrual cycles prior to egg retrieval, except in the event of a tubal ligation.
6. I must undergo pre-donation screening and evaluation. This includes a complete medical history, psychosocial evaluation, physical examination and specific laboratory tests, including testing for HIV status. I must have a negative medical history for any genetic (inherited) diseases including but not limited to cancer, sickle cell anemia, cystic fibrosis, or Tay Sachs disease; no evidence of current infection; a negative history for sexually transmitted diseases; no history of significant substance abuse (drugs or alcohol); no significant medication use; and no history of chemotherapy or radiation therapy.
7. I must undergo psychological screening to be a suitable matching donor with recipients.



I will notify the staff at CCRH if the information I have given, which might affect my eligibility to participate in the Egg Donation Program, changes during my screening or participation. If I am found to be a suitable ovum donor, I understand that participation in the Egg Donation Program depends upon the existence of a suitable matched recipient/intended parent(s).

I understand that there may be a risk of passing on sexually transmitted and other diseases through the use of the eggs I donate. I represent that to the best of my knowledge I do not presently have any of the following diseases: HIV/AIDS, HTLV, Hepatitis, Syphilis, Chlamydia, or Gonorrhea. I further submit that I have not had sexual contact with a member of a high risk group for AIDS, i.e. homosexuals, intravenous drug users or hemophiliacs.

My initials indicated that I attest that I am currently free of HIV/AIDS, HTLV, Hepatitis, Syphilis, Chlamydia and Gonorrhea:

Initials

OVUM DONOR PROCEDURE IN DETAIL

Active participation in an egg donation cycle will last for approximately two (2) menstrual cycles. During this time, barrier contraception must be used, unless previously sterilized by tubal ligation. Approximately two weeks after initiation of oral contraceptive pills (OCPs), or on day 21 to 22 of the menstrual cycle, treatment with a daily injection of a medication intended to suppress the ovaries (Lupron) will be initiated (you will self-inject or have a friend inject you). This is called “downregulation” and will last for approximately fourteen (14) days. This medication will place your ovaries in a state of rest. On occasion, downregulation may be achieved with OCPs alone, without the use of Lupron. After confirmation of adequate downregulation with an ultrasound examination using a vaginal ultrasound probe and a blood test, daily injections of gonadotropins (hormones intended to stimulate the ovaries for multiple egg growth) will be administered (you will self-inject or have a friend inject you) in a process called controlled ovarian hyperstimulation (COH). Lupron injections will also continue daily during ovarian hyperstimulation, intended to prevent premature ovulation. If Lupron was not used for downregulation, a different injectable medication will be added during ovarian hyperstimulation to prevent premature ovulation (Ganirelix or Cetorelix). After the first three to five (3-5) days of gonadotropin stimulation, another ultrasound examination and blood sample will be performed to assess your ovarian response to the stimulation medications. This will be repeated every two to three (2-3) days until the egg retrieval procedure. An average of eight to ten (8-10) days of the gonadotropin medication is typically required to achieve maturation of the eggs, as determined by the size of ovarian follicles visualized under ultrasound. Once your ovarian follicles reach a mature size, a final injection (trigger shot) is administered (you will self-inject or have a friend inject you), and approximately 36 hours following trigger shot injection, the egg collection procedure is performed. A separate consent for Controlled Ovarian Hyperstimulation must be signed before ovarian stimulation begins.

My initials indicated that I consent to controlled ovarian hyperstimulation:

Initials

Egg collection will be accomplished by ultrasound guided needle aspiration, done under conscious sedation anesthesia. An anesthesiologist will start an intravenous line and deliver medications which will make you go into a twilight sleep. You will not feel pain during the procedure or remember the procedure upon waking. Once under anesthesia, a transvaginal ultrasound probe with an attached needle guide will be placed vaginally. Under ultrasound guidance, an aspiration needle will be advanced through the vaginal wall and into the ovary, and follicles will be aspirated. You will be awakened immediately upon completion of the egg retrieval procedure. A separate Consent for Follicle Aspiration must be signed before the egg retrieval procedure.

My initials indicated that I consent to the follicle aspiration procedure:

Initials

BENEFITS AND RISKS OF EGG DONATION

One benefit of donating eggs may be the fulfillment of helping another person(s) have a child, who would have otherwise been unable to do so using more conventional fertility treatments or assisted reproductive techniques. Additionally, as part of the screening process to become an egg donor, you may obtain valuable information about your general health and reproductive system. Furthermore, you may receive a monetary compensation for your participation in the Egg Donation Program.



I. Physical Risks

Short Term Risks

The short term risks and side effects of this procedure are related to the physical requirements associated with the egg donation process. You will be required to transport yourself to and from the office for approximately five to seven visits required for ovarian stimulation monitoring. In addition, you will need transportation to and from our office (provided by someone else) on the day of the follicle aspiration. Since you are acting as an independent contractor, the responsibility and liability for the risks associated with this travel are yours.

The risk associated with the daily injection of the medication and with the occasional blood drawing is for the most part limited to temporary mild pain or discomfort at the injection (or phlebotomy) site, and possible formation of a mild hematoma (bruise). Prior to the follicle aspiration procedure, you will have an intravenous (IV) line started, which may make you temporarily uncomfortable. You will be given an injection of narcotics and sedatives in order to make you feel sleepy and make you comfortable for the aspiration.

The follicle aspiration procedure involves the placement of a needle through the vaginal wall and directly into each ovary and aspiration (withdrawal) of the fluid from all the ovarian follicles. In this manner, the eggs are obtained from the ovary. There is a theoretical risk of damage to an internal organ like bowel or the bladder, or of pelvic infection and bleeding associated with this procedure. However, these complications are exceptionally rare as the procedure is done under direct ultrasound guidance and with antibiotic prophylaxis. You will be given a separate consent for the aspiration procedure.

Risks of the Medications

The Medications which you will be using are all of a hormonal nature and are used to prepare your ovaries for the follicle aspiration procedure. Since they are hormones, there may be an emotional response associated with the use of these medications. The response varies from individual to individual but may include depression, euphoria, restlessness, irritability, and sleeplessness. For a full description of the side effects of all of the medications, you are encouraged to ask for the package insert.

One of the side effects that you will be monitored for is ovarian hyperstimulation syndrome (OHSS). When young fertile women are given fertility drugs, the ovary may over respond and produce many follicles and very high levels of estrogen. When this happens, by a mechanism that is not well understood, some women will develop OHSS, which is associated with ovarian swelling above and beyond that seen with normal response, as well as with fluid collection in the abdomen ("ascites"). Patients may become nauseous and feel bloated. In severe cases, patients may experience significant shortness of breath and pain due to fluid accumulation, which may require the evacuation of fluid from the abdominal cavity. In extreme cases admission to the hospital may be required in order to give intravenous fluids and for pain management and observation. The incidence of severe OHSS is approximately 1% and a moderate form is expected in about 5% of cases. Very rarely OHSS has been associated with blood clot formation and death.

Since COH induces the growth of multiple follicles within one or both ovaries, ovaries have a tendency to enlarge beyond their normal size. Rarely, an enlarged ovary may undergo twisting called ovarian torsion. When ovarian torsion occurs, moderate to severe pelvic pain is often experienced on one or both sides of the lower abdomen. As ovaries may remain enlarged and cystic for several weeks even after egg retrieval, the risk of ovarian torsion will persist until ovaries regain their normal size. Therefore, it is important to limit strenuous physical activity like aerobic exercise for a minimum of two weeks following egg retrieval. If ovarian torsion is suspected surgical intervention is often necessary to "untwist" the ovary in order to alleviate pain and other symptoms and to prevent permanent damage to the ovary. The likelihood of ovarian torsion following COH is extremely low (<1%).

Since COH induces the growth of multiple follicles within one or both ovaries, following egg retrieval the persistence of ovarian cysts within one or both ovaries is common. Such cysts may remain for several weeks but almost always resolve spontaneously. On occasion, ovarian cysts may rupture, which may lead to pain and internal bleeding. Very rarely, a ruptured ovarian cyst may require surgical intervention.

Some studies have suggested an association between fertility drugs and ovarian and breast cancer. This association has been challenged by many fertility specialists in the United States and abroad. Most research studies have failed to demonstrate any causation between the use of fertility medications and ovarian or breast cancer. Additionally, ovarian hyperstimulation does not seem to be associated with increased risk of endometrial or cervical cancer.

Long Term Risks

The ultimate long term risks of undergoing ovarian hyperstimulation and follicle aspiration are not known. While many thousands of cycles of ovarian stimulation and follicle aspiration have been performed worldwide, most of these have occurred in infertile women, while a much lower number of cycles have been performed on egg donors. As such, it is not known whether this type of procedure can have an adverse impact on your future fertility. However, there is nothing about the stimulation or the procedure that would reasonably compromise your future fertility, unless a pelvic infection occurs following egg retrieval (which is exceptionally rare).

Ovarian stimulation and follicle aspiration does not remove from your body any eggs that would otherwise remain there. All of these would naturally be lost each month either by ovulation or by a process of degeneration and resorption called atresia, which is the fate of the majority of eggs in your ovaries. As a result, the process of egg donation is not thought to speed up ovarian aging or the depletion of the eggs in your ovaries. However, since the procedure is relatively new, the possibility of ovarian dysfunction in 10 or 20 years time cannot be fully excluded, and as such, you may experience fertility problems in the future. This may happen regardless of whether or not you become an egg donor. However, it is important for you to understand that it is not known with complete certainty that egg donation will not compromise your future fertility.

II. Emotional Side Effects

In addition to the physical effects described above, you may find that the process of donating eggs to another woman may cause you some emotional distress in the future. As mentioned above, the use of hormonal medications may be associated with a variety of emotional swings. You should also understand that certain religious groups (notably Catholics and Orthodox Jews) do not approve of many forms of infertility treatment, including oocyte donation. You may meet with disapproval from individuals who belong to these groups. You should ask yourself what emotional impact you will feel if a child is born as a result of your egg donation. Will you feel a need to seek this child out five or ten years down the line? If you later find that you are unable to have children, will you regret your decision to donate eggs now, or will you rather feel satisfied that at least you had the opportunity to help someone else have a child? These are personal questions that you should answer for yourself. You should understand that donating eggs is not exactly like donating blood, since in egg donation you are donating genetic material for the purpose of reproduction in another person. You may find that you have some long-term emotional feelings about the egg donation process. You will be asked to undergo psychological screening before you become eligible for egg donation.

III. Legal Implications.

The process of egg donation is analogous to sperm donation. However, because it is relatively new, limited case law has been established regarding its use. In the absence of substantial prior judgment being rendered by a court, there is no assurance that any contract which is entered into as regards to egg donation will necessarily be honored in the future.

With respect to sperm donation, courts have basically upheld the anonymity of the donor and the legal parenthood of the recipient couple (if the couple is married and wife conceives as a result of artificial insemination by donor sperm, the husband becomes the legal father of that child at the moment of conception). Nevertheless, when you donate eggs to another couple, you at least theoretically expose yourself to the potential risk of future interaction with the couple or the child.

Initials

Certification of Informed Consent for Egg Donation

Your signature below indicates that you have read the preceding consent, that you have had the opportunity to ask questions, and that your questions have been answered to your satisfaction. Furthermore, in signing this informed consent you agree to hold harmless Eliran Mor, MD, Irene Woo MD, and the California Center for Reproductive Health, its employees affiliates and associates, from any inquiry or untoward events that may occur to you as a result of egg donation.

EGG DONOR NAME (print)

EGG DONOR SIGNATURE

DATE

WITNESS (print)

WITNESS SIGNATURE

DATE