

Fertility Center, LLC
and
Embryo Services, LLC

INFORMED CONSENT: ANONYMOUS DONOR OOCYTE (EGG)
Oocyte Recipient Form

We, _____ (wife) and _____ (husband), have voluntarily engaged the services of the physicians of the Assisted Reproduction Technologies (ART) program of the Fertility Center, LLC and/or Embryo Services, LLC, herein after referred to as THE CENTER, to perform in vitro fertilization using oocytes (or eggs) obtained from the ovaries of an anonymous donor and fertilized with the recipient husband's sperm. The egg donor was recruited by THE CENTER. We understand that this consent extends from the initial period of participation in the program until the cycle has been completed, or our physician makes a determination that this treatment will result in a very small chance for pregnancy or no chance at all, or until we decide to discontinue participation in the program. We also realize that within thirty days prior to the transfer date, the egg donor must undergo the FDA-mandated tests to confirm she continues to test negative for a number of sexually-transmitted diseases as well as for HIV. Should she test positive, we realize the cycle must be cancelled. We understand the FDA does not give any exceptions to the requirement to cancel a cycle due to a final positive testing.

An anonymous egg donor cycle includes the following steps or procedures:

1. Ovulation induction of donor
2. Preparation of recipient wife's uterus
3. Retrieval of eggs from donor
4. Collection of recipient husband's sperm
5. In vitro fertilization of eggs
6. Transfer of embryo(s) into the recipient wife's uterus
7. Support of early pregnancy

In other words, eggs removed from the donor's ovaries and body are mixed with the recipient husband's sperm to achieve fertilization, allowed to grow in the laboratory for a few days, and transferred into the recipient wife's uterus. The recipient may not become pregnant from this treatment, or one or more embryos may grow into a full-term baby or babies.

This program follows the guidelines of the American Society for Reproductive Medicine. If the recipient wife is age 40 or older, it is recommended that she consult with a perinatologist (high-risk pregnancy specialist) to understand any potential risks that a pregnancy may pose to her health. It is strongly recommended that the recipient couple also consult with a psychologist to assess and explore the emotional issues surrounding this non-traditional method of family building. The recipient couple will be required to undergo IVF Profile Labs to screen for blood types, Rh factors and infectious diseases (HIV, Syphilis and Hepatitis B and C) in accordance with guidelines established by the ASRM. The recipient woman also will be screened for Rubella, Cystic Fibrosis Carrier and Cytomegalovirus Titer and must undergo an evaluation of the uterine cavity to ensure a normal environment for implantation and allow for measurements in preparation for an embryo transfer. Additional blood work may be ordered based on physicians' recommendations. Donors are screened for all the infectious diseases mentioned above in addition to Chlamydia and Gonorrhea as well as nicotine and other drugs.

Patient Initial _____ Partner Initial _____ Date _____

Step 1: Ovulation Induction

Agents to promote the simultaneous maturation of a number of eggs in the donor's ovaries will be administered to her daily at dosages according to her particular needs. In general, the purpose of using these agents is to improve the efficiency of obtaining numerous, fertilizable eggs. The agents may include Lupron, Follistim and/or Gonal F. Some reactions that have been reported are allergic sensitivity, pain, rashes, ectopic pregnancy, headaches, fluid retention, weight gain, irritability, depression, fatigue and visual disturbances.

Occasionally, these medications can overstimulate the ovaries resulting in Ovarian Hyperstimulation Syndrome involving ovarian enlargement which may be accompanied by abdominal distention and abdominal pain. In rare cases, the syndrome may become severe, causing accumulation of fluid in the abdomen and sometimes around the lungs which may cause breathing difficulties. Even more rarely, the ovaries can bleed or undergo twisting which may require surgery. The fluid shifting can affect blood clotting and, in very rare cases, can be life threatening. Treatment consists of hospitalization, blood work, bed rest and aspiration of the fluid. Careful monitoring is critical to help prevent this condition.

The donor will undergo serial blood tests and vaginal ultrasound scans of her ovaries to assess hormone levels as well as the size and growth of the developing follicles, which are the fluid-filled sacs surrounding the eggs. Unfortunately, bruises are common with repeated blood sampling. Ultrasound waves are not harmful to the body in general or the ovaries in particular. The waves are sent and their echo is received by a probe placed just inside the vagina, which causes minimal discomfort if any at all.

When the size of the follicles is optimal, an injection of human chorionic gonadotropin (hCG) such as Novarel, Pregnyl, Profasi or Ovidrel will be given to trigger the final maturation of the eggs and the rupture of the follicles. The eggs must be retrieved when they have reached the final stage of maturity, but before rupture occurs.

NOTE: Currently 1 out of every 424 women in the United States will develop ovarian cancer in her lifetime. Recent studies have suggested an association between fertility drugs and the development of ovarian cancer; however, the risk of ovarian cancer is increased in women who do not become pregnant and deliver. Some of those women will have taken fertility drugs, but it is still unclear whether it is the infertility itself or the fertility drugs which are responsible for this association. If there is an increased risk of developing ovarian cancer as a result of taking fertility medications, that risk is very low provided the medication use was short term. Further research is needed to determine if a direct association exists between the use of fertility drugs and the development of ovarian cancer.

Step 2: Uterus Preparation

Birth control pills will be prescribed to help synchronize the recipient's cycle with the donor's cycle. In addition, the recipient's uterus will be prepared for placement of the fertilized egg(s). Treatment with estrogen and progesterone is necessary to substitute for ovarian production. The risks of taking these hormones are similar to the risks involved in taking the birth control pills. No unusual side effects have been reported. Frequent blood tests and an ultrasound study of the uterine lining will be administered to the recipient during this protocol.

Step 3: Egg Retrieval

In most cases, the eggs will be retrieved from the donor by ultrasound-guided transvaginal aspiration. A needle guide is placed alongside the ultrasound probe and inserted into the vagina. A special needle is then inserted through the needle guide, penetrating the vaginal wall and directed into the ovaries. This procedure generally requires only mild sedation and not general anesthesia. Rare risks of this procedure include injury to other abdominal structures (such as the bowel or blood vessels), infection or excessive bleeding.

On very rare occasions, the egg(s) may need to be retrieved by laparoscopy for various reasons. If this is the case, a small incision will be made in the area of the umbilicus to allow placement of a specialized telescope (laparoscope) to visualize the ovaries. Other small incisions will be made near the pubic hairline for placement of a probe and an instrument to grasp the ovaries. A needle will be inserted through the lower abdominal wall into the pelvis for aspiration under direct visualization with laparoscope. Rare risks of this procedure include injury to other abdominal structures (such as the bowel or blood vessels), infection or excessive bleeding. Should one of these rare complications occur, there is a chance that the donor's own fertility could be compromised.

During egg retrieval (as with any invasive procedure), complications may occur that may require a larger operation (either laparoscopy or laparotomy) to take care of the complications.

With either the ultrasound approach or the laparoscopic approach, physicians may fail to retrieve eggs either because the donor's ovaries did not respond to the stimulation or because they could not be collected due to technical problems. If a large number of eggs are collected from the donor, the recipients may choose to donate eggs to other couples or to cryopreserve excess embryos for future potential use. These issues need to be decided in advance before the cycle begins to allow for proper scheduling and coordination. These alternatives are offered on a voluntary basis. No penalties will be assessed nor will care be denied should a recipient couple refuse to donate excess eggs.

Following retrieval, the donor's participation in the cycle ends.

Step 4: Sperm Collection

Semen will be obtained from the recipient's husband by masturbation in close proximity to the laboratory. Alternatively, the semen may be collected at home or at another site provided that the specimen can be in the laboratory within 45 minutes of ejaculation. If the semen is collected at a site other than at the laboratory, it will be necessary to sign an affidavit testifying that this is the semen of the recipient's husband.

The specimen will be processed by the laboratory and used to fertilize the eggs which are incubated in a suitable culture medium. If for some reason a specimen cannot be produced or if a "male factor" condition exists or if an unexpected poor specimen is produced, donor sperm can be used. This issue must be discussed with physicians before the cycle begins, and separate blood tests and donor matching must be accomplished well in advance of the egg retrieval.

Step 5: In Vitro Fertilization

After processing, the sperm will be added to the incubated eggs for fertilization. Subsequently, an embryo or embryos will be allowed to develop over several days into a pronuclear stage (4 to 8 cells) for transfer. This may or may not occur depending on the quality and maturity of the eggs and sperm collected as well as other factors not yet identified.

Step 6: Embryo Transfer

Following several cell divisions, replacement of a viable embryo(s) will be made into the recipient's uterus by means of a small plastic tube inserted through the vagina and cervix into the uterus. The risks of this procedure include a very small chance of infection and fever as well as allergic reactions.

As the chances of multiple pregnancy increase significantly without further improvement in pregnancy rates when three or more embryos are transferred into the uterus, THE CENTER's policy is to transfer no more than three embryos at one time until a woman reaches the age of 39. The remaining embryos can be cryopreserved to be used for subsequent cycles, discarded, offered for donation to another couple, or used for research projects by THE CENTER as allowed by government rules and regulations. These options all require separate consent forms that must be signed and notarized before the cycle begins.

Step 7: Pregnancy Support

Should a positive pregnancy test occur following the embryo transfer, progesterone therapy will be continued until the twelfth week of pregnancy to provide hormonal support for the early pregnancy and help decrease miscarriage rates. Blood tests and ultrasounds will be administered during the first trimester to assess normal growth and to document number of fetuses and fetal heartbeats.

IMPORTANT POINTS TO REMEMBER

1. The donor's ovaries may not respond to the ovulation induction protocol resulting in insufficient eggs for retrieval. If this happens, the cycle may have to be canceled.
2. The donor's ovaries may over stimulate in response to this protocol, producing too many follicles and estradiol levels that are too high as determined by the physician for the health and safety of the donor. If this happens, the cycle may have to be canceled.
3. Only a single follicle may develop as a result of ovulation induction. If this happens, the cycle may have to be canceled.
4. An attempt to retrieve eggs from the donor may be unsuccessful.
5. The husband may fail to produce a semen sample for fertilization of the eggs.
6. Fertilization may not occur, or there may be very poor fertilization. This is most likely when "male factor" infertility issues are involved and could eliminate or decrease the chance for pregnancy.
7. The embryo(s) may not cleave and divide after fertilization.
8. The embryo(s) may not implant after transfer.
9. The embryo(s) may not develop normally, resulting in a very early miscarriage (biochemical pregnancy) or a clinically-evident miscarriage.
10. An ectopic pregnancy (tubal pregnancy) may occur.
11. Although great care is taken with all specimens, a laboratory accident may result in loss of or damage to the eggs, sperm or embryos.
12. A pregnancy may result in the birth of a baby or babies with congenital anomalies, although the odds for such an outcome are no greater with assisted reproduction. A genetic amniocentesis or chorionic villus sampling may be done when appropriate.
13. As more than one embryo is transferred into the uterus, multiple pregnancies (twins, triplets, etc.) with subsequent risks may occur.
14. Egg donors are at risk to develop Ovarian Hyperstimulation Syndrome. This rare condition occurs in only one percent of women that are stimulated for ovulation induction using gonadotropins. The symptoms begin after egg retrieval and usually occur with pregnancy, typically of multiples. Because donors are instructed to use barrier contraception during egg donation cycles, donor pregnancies and associated risks for ovarian hyperstimulation are very low. However, when a donor's ovaries stimulate excessively, hCG injections may need to be avoided. As a result, the cycle may have to be canceled.
15. While efforts are made to match the general physical characteristics of the anonymous egg donor with the recipient couple's own physical characteristics, no guarantees can be made. In addition, the reliability of the health and medical history of the donor (including familial genetic diseases, illegal drug use, contagious diseases, etc.) cannot be guaranteed.
16. No one can guarantee the physical or mental characteristics of any children resulting from these procedures. The recipient couple as well as their successors, offspring and assigns release and agree to hold harmless from liability the physicians, associates and staff of THE CENTER for complications resulting from pregnancy or childbirth following assisted reproduction procedures; from liability for any mental, emotional and physical problems; and from liability for physical or mental disabilities of any children produced following these procedures.
17. Although egg donors are carefully screened for infectious diseases as recommended by the ASRM, no test is 100 percent accurate. The ASRM suggests an alternate option involving HIV testing prior to the beginning of a cycle in which all embryos resulting from retrieved donor eggs are frozen to be thawed and transferred to the recipient's uterus six months later after the donor has retested negative for HIV. While nearly eliminating any chance for the virus to be transferred from donor to recipient, this option also decreases the rate of success since not all cryogenically preserved embryos survive the thawing process or implant after transfer.
18. While egg donors are counseled to abstain from sexual activity during a cycle, abstinence cannot be guaranteed.
19. The recipient couple indicates by signing this consent form their agreement to release the anonymous donor from any legal or financial responsibilities from an established pregnancy or medical costs related to that pregnancy and delivery. The couple and their heirs will release the anonymous donor from any financial and legal responsibility for the children from conception forward and also release the physicians, their associates, and the staff at THE CENTER from any financial responsibilities for the children from conception forward.
20. The recipient couple is financially responsible for all costs incurred before and on the day of retrieval, including complications involving a more involved surgery (in case of uncontrolled bleeding), immediate hospitalization for recovery of the more involved surgery, and any medications needed for all procedures. The recipient couple will not be financially responsible for medical expenses incurred after the day of egg retrieval except for expenses involved in recovery from a more involved procedure occurring on the day of egg retrieval.

Patient Initial _____ Partner Initial _____ Date _____

21. There is little information available regarding overall pregnancy rates in this specific type of procedure. The success rate may be similar to that achieved with other types of in vitro fertilization procedures, but THE CENTER does not guarantee that the success rate with donor eggs will be similar to that of other programs.
22. As insurance coverage for any or all procedures in the ART program may not be available, the recipient couple is personally responsible, individually and collectively, for all medical and hospital expenses incurred by or for wife, husband and anonymous egg donor in connection with procedures. Efforts have been made in good faith to project all costs related to this treatment on the financial disclosure given by THE CENTER. However, some costs may be unavailable for disclosure due to the inability to always accurately predict the extent and nature of needed procedures and potential complications as well as the fact that all costs are subject to change without notice.
23. The recipient couple is free to discontinue participation in the ART program at any time, either verbally or in writing. Their decision to discontinue participation will in no way prejudice other treatment that may be received from THE CENTER. If there is a decision to discontinue participation in the program, the recipient couple will be personally responsible for all the expenses incurred prior to such discontinuation and related to anonymous egg donor screening and/or treatment in the program.
24. The results of treatment or any aspect of treatment may be published in medical literature. If publication of data occurs, all reasonable precautions will be taken to protect the anonymity of all parties. Participants in the ART program grant permission for related statistics to be published, provided names are not used.
25. Anonymity is required for the egg donor as well as the recipients. The donor has signed a consent agreeing not to try under any circumstances to contact the recipients and is aware that absolutely no information will be given to her from this program concerning either the recipient wife or husband. The donor has agreed to relinquish any rights to responsibility or claims to any children or embryos resulting from her donation of eggs.
26. The anonymous donor has been counseled that once an IVF cycle has begun, she is ethically responsible to complete that cycle to the best of her ability. If the donor is unable to fulfill this obligation and complete retrieval for any personal reason other than as is medically indicated by one of our physicians, or if the donor does not follow our instructions, no participation reimbursement will be made. If cancellation of the cycle is required for a medical reason as indicated by one of our physicians, including poor ovulation induction, a partial participation reimbursement of \$400 will be made to the donor by the recipient couple.
27. The physicians, their associates and the staff at THE CENTER have not undertaken hereby or in any other document or oral communication to advise the recipient couple of their legal rights, now existing or hereafter arising, and specifically disclaim any responsibility to do so. It is recommended that the recipient couple consult legal counsel so as to be fully informed of their legal rights and obligations and the legal rights and obligations of others involved in this procedure. If the recipient couple elects not to do so, such elections are hereby acknowledged to have been determined without reliance upon statements, oral or written, of the physicians, their associates or the staff at THE CENTER.
28. The recipient couple releases the physicians, their associates and the staff at THE CENTER from any responsibilities or legal liabilities related to the recruiting of the anonymous donors from the surrounding communities.
29. The recipient wife and husband must be at least 18 years old.
30. Egg donors must be between the ages of 21 and 33.

IT IS OUR INTENTION THAT ANY EMBRYOS NOT USED IN THE INITIAL FRESH EMBRYO TRANSFER SHALL BE ONE OF THE FOLLOWING:

That the embryos be frozen for later use by us. **** requires additional consents ****

YES _____ (initial please)

NO _____

That the embryos be discarded immediately after the embryo transfer.

YES _____ (initial please)

NO _____

That the embryos be donated for use by other infertile couples, if otherwise permitted by applicable law. We waive any and all claims to the right of any children that may result from these embryos. Any children from this process are the legal children of the recipient couples. In the case of donation, both donor and recipient remain anonymous to each other. This alternative is offered on a purely voluntary basis and couples are never denied care should they refuse to donate embryos. **** requires additional consents ****

YES _____ (initial please)

NO _____

That the embryos be used in research projects permitted by current ART program policies and applicable legal requirements. **** requires additional consents ****

YES _____ (initial please)

NO _____

If we do not wish to discard, to cryopreserve or to donate supernumerary embryos to couples or research, we understand we have the right to only expose a limited number of eggs to sperm. We understand that if we limit the number of eggs inseminated, we may end up with no fertilized eggs and consequently no embryos for transfer or a lesser number of eggs fertilized than originally inseminated, which may decrease the chances of successful pregnancy. We indicate here our wish for _____ (all or number) eggs to be inseminated.

_____ (initials)

If pregnancy occurs following these procedures, the risk of multiple births is approximately 24% (twins 20%, triplets 4%, quadruplets less than 0.4%). After discussion of the chances of multiple pregnancy and its attendant risks, we have decided to have _____ (range) fertilized embryos transferred.

_____ (initials)

We understand that thousands of babies have been born around the world through IVF since 1978, and that there is no indication of any increase in the rate of abnormalities in children born as a result of IVF. The incidence of abnormalities appears to be no greater than that for babies born as a result of natural conception, which is about three percent. Any abnormality in babies born as a result of IVF is our sole responsibility and we will not hold THE CENTER liable.

_____ (initials)

WE HAVE READ AND UNDERSTAND THIS INFORMED CONSENT AND ACKNOWLEDGE RECEIPT OF A COPY. ALL QUESTIONS THAT WE HAVE ASKED HAVE BEEN ANSWERED IN A SATISFACTORY MANNER.

WE RELEASE THE CENTER'S PHYSICIANS, ASSOCIATES AND STAFF THEREOF FROM ALL RISKS INCLUDING ANY MEDICAL AND EMOTIONAL AS WELL AS SUBSEQUENT LOSSES RELATED TO VOLUNTARY PARTICIPATION IN THIS PROGRAM.

Wife's signature

Date

Husband's signature

Date

Notary's signature

Date

Commission Expires On

Date

I have thoroughly reviewed the information contained in this consent with the above named persons and believe they have made an informed decision regarding assisted reproductive treatment.

Staff Signature

Date

Revised July 1, 2008

Patient Initial _____

Partner Initial _____

Date _____