

Fertility Center, LLC
And
Embryo Services, LLC

INFORMED CONSENT: ANONYMOUS DONOR OOCYTE
Anonymous Egg Donor Form

NAME: _____ (herein after referred to as “the donor”)

I am voluntarily agreeing to participate in the Assisted Reproductive Technology Program at the Fertility Center, LLC and/or Embryo Services, LLC hereafter referred to as The Center in order to undergo ovarian stimulation with medication prescribed to produce oocyte(s) solely for the purpose of donating **all** of the oocytes to a recipient who will remain anonymous to me. I understand that this consent extends from the initial period of participation in the IVF program until the donor cycle is completed, or the physician makes a determination that based on previous cycle response(s) this is a treatment that will not result in an ovulation induction process adequate to produce oocytes for recipients use or until I decide to discontinue participation in the ART/Donor program. I realize that within thirty days prior to the transfer date I must undergo the FDA mandated tests to confirm that I continue to test negative for a number of STDs as well as for HIV. Should I test positive I realize the cycle must be cancelled without any payment to me at all. I understand the FDA does not give any exceptions to the requirement to cancel a cycle due to final positive testing results.

An anonymous donor oocyte cycle of IVF (In Vitro Fertilization) includes the following steps or procedures:

1. Ovulation induction for the donor
2. Retrieval of oocytes (eggs)
3. Collection of recipient’s husband sperm
4. In Vitro Fertilization of the oocytes
5. Transfer of the embryo(s) into the recipient’s uterus [the term recipient is used in this document/consent form to refer to the female who receives the embryo and who seeks to become pregnant.]

In other words, oocyte(s) removed from the donor’s ovaries are taken outside the body, mixed with recipient’s husband sperm, or in some cases donor sperm, to allow for fertilization, allowed to grow in the laboratory for a few days and transferred back into the recipient’s uterus. This program follows the guidelines of the American Society for Reproductive Medicine for Anonymous Oocyte Donation Programs. The donor will not be told if a pregnancy occurs as a result of her donation.

Step 1: Ovulation Induction of the Anonymous Donor

Agents to promote the simultaneous maturation of a number of oocytes 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 fertilizable oocytes. The agents may include:

Leuprolide acetate (LUPRON): This is a hormone synthetically made in a laboratory. It is very similar to a substance called GnRH which is naturally produced in the brain. Lupron will be injected daily to suppress some hormonal output from my pituitary gland. I understand that the long-term effects of this medication on me or the effects on the developing embryo(s) are not known. However, information available within the scientific medical community at this time suggests no significant long-term effects on the donor or on the developing oocytes.

In order to harvest more than one egg per treatment cycle, I will be given fertility medications called Follistim, Repronex, or Gonal-F daily by injection. These medications cause the ovaries to develop

multiple eggs, which grow into fluid-filled sacs called follicles. Occasionally, these medications can over-stimulate the ovaries resulting in Ovarian Hyperstimulation Syndrome. This consists of ovarian enlargement which in some cases may be accompanied by abdominal distention and abdominal pain. In rare cases, the syndrome may become severe. Severe hyperstimulation causes accumulation of fluid in the abdomen and sometimes around the lungs which may cause breathing difficulties. Even more rarely, the ovary 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 with ultrasound and blood tests is very important to the prevention of this problem.

Ovulation-Inducing Medications and Development of Ovarian Cancer

Currently 1 out of 424 women in the United States will develop ovarian cancer in their lifetime. Some recent studies have suggested an association between fertility drugs and the development of ovarian cancer. However, it has been known for some time that 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 is responsible for this association. The most recent data available suggests that if there is an increased risk of developing ovarian cancer as a result of taking fertility medications, that risk is very low provided that the use is not of long-term duration. Further research is needed to determine if a direct association exists between the use of fertility drugs and the development of ovarian cancer.

Other adverse reactions that have been reported are: allergic sensitivity, pain, rash, ectopic pregnancy, headaches, fluid retention, weight gain, irritability, depression, fatigue, and visual disturbances. Any of these side effects should be reported to your physician immediately.

I will undergo serial blood tests and ultrasound scans of my ovary(ies) to assess growth of the developing follicles. When the size of the follicles are optimal, an injection of human chorionic gonadotropin (hCG-Novarel, Pregnyl, Profasi or Lupron) will be given to trigger mechanisms that result in final maturation of the oocyte(s) and the rupture of the follicles. The oocytes must be harvested when they have reached the final stage of maturity, but before rupture occurs.

During the process of ovulation induction, there will be frequent blood samples from a vein in the patient's forearm obtained over a period of 7 to 14 days. Each sample requires a maximum of 10ml (2-3 teaspoons) of blood. Unfortunately, with repeated sampling, bruises are not uncommon. At appropriate times, the donor will undergo pelvic sonograms (ultrasound) to determine the size of the follicles. This technique involves the use of sound waves inaudible to the human ear. These are not harmful to the body in general or the ovaries in particular. The waves are sent and their echo is received by a long narrow device (probe) that is gently placed in the vagina and which causes no discomfort. This permits the placement of the probe close to the ovaries for careful monitoring of follicle size.

Step 2: Retrieval of Oocytes (Eggs)

In most cases, the egg(s) will be harvested by ultra-sound guided transvaginal aspiration. A needle guide is placed alongside the ultrasound probe which is inserted into the vagina. A special needle is then inserted through the needle guide, penetrating the vaginal wall and directed into the ovary(ies) inside the pelvis. This procedure generally requires only mild sedation and not general anesthesia. Rare risks of this procedure include injury to other structures in my pelvis (such as bowel or blood vessels), infection or excessive bleeding.

On very rare occasions, the egg(s) may need to be harvested by laparoscopy for various reasons. If this is the case, a small incision will be made in the area of my umbilicus to allow placement of a specialized telescope (laparoscope) to visualize the ovary(ies). Other small incisions will be made near the pubic hairline for placement of a probe and an instrument to grasp the ovary(ies). 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 structures in my abdomen or pelvis (such as 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.

Following retrieval, the donor's participation ends. The egg(s) will be fertilized in a specialized laboratory with the recipient husband's sperm. If normal fertilization of the egg(s) occurs satisfactorily, up to four fertilized eggs (pre-embryos) will be transferred into the recipient's uterus five days after the egg retrieval was performed. Any remaining embryos may be cryopreserved (frozen) for a future thaw and transfer to the recipient.

Important Points to Remember

1. The ovaries may not respond to the ovulation induction protocol, thus not produce oocytes for retrieval. The cycle may have to be canceled if this happens.
2. The ovaries may overstimulate in response to this protocol producing too many follicles and estradiol levels that are too high as determined by the physician. For the donor's health and safety the cycle may have to be canceled.
3. Only a single follicle may develop as a result of the ovulation induction. The cycle may have to be canceled.
4. An attempt at egg retrieval may be unsuccessful.
5. **OVARIAN HYPERSTIMULATION SYNDROME:** (Rare risk to donor) This is a rare syndrome that occurs in only about 1% of women that are stimulated for ovulation induction using gonadotropins (Follistim, Repronex, Gonal_F or Humegon). The symptoms are categorized from mild to severe. The symptoms begin after the transfer of embryo(s) and usually occur when a pregnancy is established. As a result, the risk to the donor is very small as she should not become pregnant. **It must be understood however, that unless the donor uses some form of barrier contraception (condom, diaphragm, etc.) she could become pregnant from an egg not picked up at the time of egg retrieval. Thus it is imperative that the donor use contraception to ensure that hyperstimulation syndrome does not occur.** Immediate symptoms of ovarian hyperstimulation syndrome may include: fluid weight gain of 5-10 lbs a week after retrieval, nausea, vomiting, headaches, diarrhea, and/or visual disturbances. It is very important to report all symptoms immediately to the physician.

Other Miscellaneous Points

1. By signing the anonymous donor consent, the donor authorizes the The Center and their Physicians and associates to treat them in accordance with accepted ART (Assisted Reproductive Treatment) protocols.
2. The recipient of the oocyte(s) is responsible for all ordinary medical costs incurred during ovulation induction and oocyte retrieval. They will not be responsible for the medical expenses for any medical complications that happen because of the procedure that the donor is volunteering to undergo. The donor agrees by signing this consent form, to release the recipient, her husband, and heirs or representatives of them, from any legal liability due to emotional stress or trauma that may be suffered or from any lost wages if complications occur. The donor is reminded that this is a voluntary program, and it is suggested at the time of entry into the donor program to carry medical insurance to cover medical expenses needed after day of retrieval if appropriate. If the donor chooses not to carry medical insurance, she understands she will be financially responsible for any medical care needed following the day of oocyte retrieval and thereafter.
3. After the egg retrieval has been performed, and upon completion of the retrieval follow-up evaluation the donor's participation is considered complete. She agrees by signing this consent form to waive any rights or responsibility with regard to the collected oocytes and any resulting child(ren). If the recipient couple chooses to cryopreserve any or all of the resulting embryos(s), the donor agrees by signing this consent form that she has relinquished all rights to claim or responsibilities to or for those cryopreserved embryos(s).
4. The donor has an ethical obligation to continue to oocyte retrieval once the cycle has begun. 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 has not followed our instructions,

- in such circumstances no participation reimbursement will be made. If cancellation of the cycle is required for a medical reason as indicated by one of our physicians, in such a circumstance a partial participation reimbursement of \$400 will be made.
5. The donor is strongly counseled to abstain from sexual activity during the cycle of oocyte stimulation. If she does engage in sexual activity at or about the time of the egg retrieval without barrier contraception, there is a very good risk that she may become pregnant with the oocytes not collected at the time of retrieval resulting in a substantial risk of a high risk pregnancy. The IVF team, (the term IVF team is used in this document to refer to the physicians, and all supporting persons and any corporation they represent, whether they are directly or indirectly involved in this team effort.) the The Center, assume no responsibility for such a pregnancy. The donor by signing this consent agrees to release, the IVF team, The Center, and/or the recipient of the donated oocytes(s) from any responsibility or claim to the resulting pregnancy.
 6. Many precautions have been taken to keep the donor's name anonymous and these precautions have been disclosed to me. Even though careful precautions have been made, the identity may be revealed in error. The donor will release the IVF team, the The Center, from any legal liabilities relate to that disclosure.
 7. Should the results of my treatment or any aspect of it be published in medical or scientific journals, all possible precautions will be taken to protect the donor's anonymity. I grant permission to the IVF team to publish statistics relating to my case in professional journals, provided my name is not used.
 8. The IVF team, and/or The Center, has not undertaken or in any other document or oral communication to advise the donor of her legal rights, now existing or hereafter arising, and specifically disclaim any responsibility to do so. It is recommended that the donor consult legal counsel so as to be fully informed of her legal rights and obligations as well as the legal rights and obligations of others involved in these procedure, but if she elects not to do so, such election is hereby acknowledged to have been determined without reliance upon statements, oral or written given by representatives of the IVF team.
 9. I certify that I am at least 19 years of age and that I am no older than 34.
 10. Participation reimbursement of \$3,000 related to oocyte donation will be made upon completion of the follow-up consultation following oocyte retrieval, or as otherwise indicated in this document at a completed time in the cycle if the cycle is canceled. The donor is reimbursed by the The Center on behalf of the recipient couple.

I HAVE READ AND UNDERSTAND THIS INFORMED CONSENT AND ACKNOWLEDGE RECEIPT OF A COPY. ALL QUESTIONS THAT I HAVE ASKED, THE PHYSICIAN HAS ANSWERED IN A SATISFACTORY MANNER.

I RELEASE FERTILITY CENTER, LLC AND/OR EMBRYO SERVICES, LLC AND/OR THE IVF TEAM, AND/OR THE EMPLOYEES/ASSOCIATES THEREOF FROM ALL RISKS INCLUDING ANY MEDICAL OR EMOTIONAL RISKS OR SUBSEQUENT LOSSES RELATED TO VOLUNTARY PARTICIPATION IN THIS PROGRAM.

Donor's signature

Date

Spouse of Donor's (if married) 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

Our doctors' qualifications/training:

Joseph S. Bird, Jr., MD, F.A.C.O.G.

Medical school

East Tennessee State University - James H. Quillen College of Medicine
Major: Doctor of Medicine,
1990

Residency

University Of Tennessee College of Medicine
Chatt Unit, Dept of Obstetrics and Gynecology
Erlanger Medical Center
1990-1994

Fellowship

University of Louisville School of Medicine
Dept of Obstetrics and Gynecology
Division of Reproductive Endocrinology and Infertility
1994-1996

Dr. Bird is Board Certified and a member of American Board of Obstetrics and Gynecology since 2002 expiration/renewal year 2010.

Dr. Bird, MD, F.A.C.O.G.'s medical license expiration/renewal date 2-29-08.

Barry W. Donesky, MD, F.A.C.O.G.

Medical School

Loma Linda University, Loma Linda, CA
Major: Doctor of Medicine
1987

Internship

Loma Linda University Medical Center, Loma Linda, CA
Obstetrics and Gynecology
1987-1988

Residency

Loma Linda University Medical Center, Loma Linda, CA
Obstetrics and Gynecology
1988-1991

Fellowship

University of Maryland at Baltimore
Reproductive Endocrinology
1991-1994

Dr. Donesky is Board Certified and a member of American Board of Obstetrics and Gynecology since 2001 expiration/renewal Dec 31, 2007.

Dr. Donesky, MD, F.A.C.O.G.'s license expiration/renewal date 7-31-08.