FERTILITY CENTER, LLC
7407 Ziegler Road – Chattanooga, TN 37421
10408 Jackson Oaks Way – Knoxville, TN 37922

INFORMED CONSENT

ANONYMOUS EGG DONOR

OVERVIEW

NAME: _____ (herein after referred to as the "Donor") voluntarily agrees to participate in the Assisted Reproductive Technology (ART) Program at the Fertility Center, LLC and/or Embryo Services, LLC (herein after referred to as the "Center" and including physicians, embryologists, members of the IVF team, associates and all supporting persons and any corporation they represent, whether participation is direct or indirect) in order to undergo ovarian stimulation with medication prescribed to produce oocytes (or eggs) solely for the purpose of donating all of the eggs retrieved in each stimulation cycle to the unknown "Intended Parents" who represent that person or persons whom the Center selects, at its sole discretion, to be the recipient or recipients of Donor's eggs. 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 eggs for the Intended Parents use, or until the Donor decides to discontinue participation in the program.

Parental Rights

Upon the removal of her eggs by the Center, the Donor desires and understands that any and all actual or potential parental rights she may have be and hereby are terminated without further action or court order. The Donor understands and agrees that by giving up her parental rights, she will be treated as if she is not the legal mother of any child who may be born as a result of the use of her eggs. The Donor understands and agrees that any children conceived or born from the use of her eggs are morally, ethically, legally and contractually the children of the Intended Parents, which may ultimately be multiple individuals or couples.

The Donor hereby renounces and disavows any claim, right and interest in any children born from the use of her eggs. The Donor understands that she will not be given any information regarding how her eggs are used nor will she be told if any pregnancies occur as a result of her donated eggs.

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Ovulation Induction

Eggs removed from the Donor's ovaries are taken outside the body and mixed with the sperm from an Intended Parent, or in some cases donor sperm, to allow for fertilization. The resulting embryos are allowed to grow in the laboratory for a few days, then are transferred back into the uterus of an Intended Parent. This program follows the guidelines of the American Society for Reproductive Medicine for Unknown Oocyte Donation Programs.

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 fertilizable eggs. Agents may include:

- Leuprolide Acetate (Lupron) – This synthetic hormone manufactured in a laboratory 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 the Donor's pituitary gland. The long-term effects of this medication on donors or the effects on the developing eggs or embryos are not known. However, information available within the scientific medical community at this time suggests no significant, lasting effects on donors, eggs or embryos.

- Follistim, Bravelle and/or Menopur – In order to harvest more than one egg per treatment cycle, the Donor will be given fertility medications daily by injection. These medications cause the ovaries to develop multiple eggs, which grow into fluid-filled sacs called follicles. Occasionally, these medications can overstimulate 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, sometimes causing breathing difficulties. Even more rarely, the ovary can bleed or undergo twisting that 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 help prevent overstimulation. Other adverse reactions that have been reported include allergic sensitivity, pain, rashes, ectopic pregnancies, headaches, fluid retention, weight gain, irritability, depression, fatigue and visual disturbances. Any of these side effects should be reported to a physician immediately.

Regarding ovulation-inducing medications related to the development of ovarian cancer, please note: *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 are 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.*

The Donor will undergo serial blood tests and ultrasound scans of both ovaries to assess growth of the developing follicles. When the size of the follicles are optimal, an injection of human chorionic gonadotropin (hCG), typically Novarel and/or Lupron, will be given to trigger mechanisms that result in 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.

During the process of ovulation induction, there will be frequent blood samples from a vein in the Donor's forearm(s) 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 (ultrasounds) 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 to the ovaries in particular. The waves are sent and their echo is received by a long, narrow probe that is gently placed in the vagina, causing no discomfort. This permits the placement of the probe close to the ovaries for careful monitoring of follicle size. Physicians at the Center determine the best time for retrieval.

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Retrieval of Oocytes (Eggs)

In most cases, the eggs will be harvested by ultrasound-guided transvaginal aspiration. A needle guide is placed alongside the ultrasound probe that is inserted into the vagina. A special needle is then inserted through the needle guide, penetrating the vaginal wall and directed into the ovaries 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 the abdomen or pelvis (such as bowel or blood vessels), infection or excessive bleeding.

On very rare occasions, the eggs 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 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 structures in the 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 eggs will be fertilized with sperm in a specialized laboratory. If normal fertilization of the eggs occurs satisfactorily, embryos will be transferred into the uterus of an Intended Parent five days after the egg retrieval.

Egg Use and Storage

The Donor understands and agrees that once her eggs are retrieved, all become the sole property of the Center, which has the sole authority to make all decisions regarding the use of those eggs. She will not be told the number of eggs that were retrieved nor will she be privileged with any specifics about how the eggs are used in the future or how many pregnancies result.

At the Center's discretion, all donated eggs and any resulting embryos may be used for any and all of the following purposes: transfer/implantation into the uterus of one or more Intended Parents, whose identities will remain unknown to the Donor; transfer/implantation into a surrogate chosen by any of the Intended Parents, whose identities will remain unknown to the Donor; cryopreservation (freezing, storage and future thawing, as needed for additional transfers); medical research; and/or subsequent donation of created embryo(s) to known or unknown couples for the purpose of achieving a pregnancy; and/or destruction, if no longer needed or viable to achieve pregnancy. All eggs are stored in accordance with FDA guidelines.

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Important Points to Remember

- The ovaries may not respond to the ovulation induction protocol and thus not produce eggs for retrieval. The cycle may have to be canceled if this happens.

- 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.

- Only a single follicle may develop as a result of the ovulation induction, possibly requiring the cycle to be canceled.

- An attempt at egg retrieval may be unsuccessful.

- A **rare** risk to donors is Ovarian Hyperstimulation Syndrome that occurs in only about 1% of women that are stimulated for ovulation induction using gonadotropins. The symptoms are categorized from mild to severe and 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. 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 pounds a week after retrieval, nausea, vomiting, headaches, diarrhea, and/or visual disturbances. It is very important to report all symptoms immediately to a physician.

- By signing this consent, the Donor authorizes the Center to treat her in accordance with accepted ART protocols.

- The Intended Parents receiving the eggs are responsible for all ordinary medical costs incurred by the Donor during ovulation induction and egg retrieval. Intended Parents will **NOT** be responsible for the medical expenses for any medical complications that happen because of the procedures that the Donor is volunteering to undergo. The Donor agrees by signing this consent form to release the Intended Parents and their spouses and heirs or representatives from any legal liability due to emotional stress or trauma that may be suffered or from any lost wages in the event that complications occur. The Donor is reminded that this is a voluntary program, and she is encouraged to carry medical insurance to cover medical expenses that might be needed after day of retrieval. If the Donor chooses not to carry medical insurance, she will be financially responsible for any medical care needed following the day of egg retrieval and thereafter.

- After the egg retrieval has been performed and upon completion of the retrieval follow-up evaluation, the Donor's participation is considered complete.

- The Donor is strongly counseled to abstain from sexual activity during the cycle of egg 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 Center assumes no responsibility for such a pregnancy. The Donor agrees by signing this consent to release the Center and/or the Intended Parents from any responsibility or claim to the resulting pregnancy.

- Many precautions have been taken to keep the Donor's name confidential. Even though careful safeguards are in place, an identity may be revealed in error. By signing this consent, the Donor releases The Center from any legal liabilities related to that disclosure.

- Should the results of 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. By signing this consent, a donor grants permission to The Center to publish statistics relating to her case in professional journals, provided her name is not used.

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- The Center has not undertaken, here or in any other written document or oral communication, to advise the Donor of her legal rights, now existing or hereafter arising, and specifically disclaims 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 procedures; but if she elects not to do so, such election is hereby acknowledged to have been determined without reliance upon statements by the Center.

- The Center will pay the Donor the amount of $3,000 in exchange for her time and effort while undergoing controlled ovarian stimulation, retrieval procedures and testing. The Donor will receive this compensation following her release from care at the time of her post-op visit. In compliance with Federal guidelines, the eggs retrieved are not being "purchased" but rather the Donor is being compensated solely for her time and effort. The Donor will receive payment in full regardless of the quantity or quality of the eggs retrieved.

- The Donor has an ethical obligation to continue on to egg retrieval once a 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 the Center's physicians, or if the donor has not followed the Center's instructions, no participation reimbursement will be made in such circumstances. If cancellation of the cycle is required for a medical reason as indicated by one of the Center's physicians, a partial participation reimbursement of $400 will be made.

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Legal Considerations

I AM AT LEAST 21 YEARS OF AGE AND NO OLDER THAN 33. I AM VOLUNTARILY PARTICIPATING IN THIS PROGRAM AND HAVE READ AND UNDERSTAND AND AGREE TO THIS INFORMED CONSENT AND ACKNOWLEDGE RECEIPT OF A COPY. THE PHYSICIAN HAS ANSWERED ALL QUESTIONS THAT I HAVE ASKED IN A SATISFACTORY MANNER.

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.

I RELEASE THE CENTER FROM ALL RISKS INCLUDING ANY MEDICAL OR EMOTIONAL RISKS OR SUBSEQUENT LOSSES RELATED TO VOLUNTARY PARTICIPATION IN THIS PROGRAM.

_____ _____ /_____ /_____
Patient Name (Print) Date of Birth

_____ _____ /_____ /_____
Patient Signature Date

_____ _____ /_____ /_____
Partner Name (Print) Date of Birth

_____ _____ /_____ /_____
Partner Signature Date

Notary Public

Sworn and subscribed before me on this _____ day of _____, _____.

_____ _____
Notary Signature My Commission Expires

Alt. Witness 1 _____ Date _____ /_____ /_____

Alt. Witness 2 _____ Date _____ /_____ /_____

Initials: _____ /_____