The Fertility Center of Colorado
6160 Tutt Blvd., Suite 210
Colorado Springs, CO 80923
719-636-0080 FAX 719-636-3030

INFORMED CONSENT FOR ANONYMOUS OOCYTE DONATION

Donor Name _____ SS# _____

The undersigned female oocyte donor, _____, has volunteered to donate oocytes (eggs) to be given to an anonymous recipient couple. These eggs will be inseminated with sperm (from the recipient's husband/partner, or an anonymous sperm donor, as directed by the recipient couple) in the laboratory and the resulting embryo(s) will be placed in the recipient's uterus with the goal of establishing a pregnancy. Some of the resulting embryos may be frozen for a period of time, to be thawed and placed in the recipient's uterus at a later date.

The oocyte donor understands that the identity of the recipient couple will not be revealed to her, nor will her identity be provided to the recipient couple.

On May 25, 2004, the FDA issued a final ruling entitled, "Eligibility Determination for Donors." The regulation outlines the required tests and screening which must be performed on those patients donating sperm, oocytes and embryos. The regulations apply only to those tissues collected on or after May 25, 2005. The requirements by the FDA represent a change in the testing and screening protocols previously followed and we want you to be aware of such changes. Should you decide not to consent to the testing and screening required by the FDA, restrictions may be applied to the donation of your sperm oocytes, and embryos. In following the recommendations outlined by the FDA, we feel that the level of patient care will be improved.

Egg Donation Process:

The process required in order for the oocyte donor to donate eggs is as follows:

1. Initial screening: The oocyte donor is between the ages of 21 and 32, and has normal regular menstrual periods. The oocyte donor has a negative history for genetically transmitted (inheritable) diseases, sexually transmitted diseases, current infection, organ transplants, malignancy (cancer), substance abuse (drugs, alcohol, cigarettes, etc.), medication use, prior chemotherapy or radiation therapy or any unusual risk for anesthesia.

   The oocyte donor has been interviewed and educated by the staff of the Fertility Center of Colorado (hereafter referred to as TFCC). The oocyte donor has been provided with all the necessary information and all of their questions have been answered to their satisfaction. The oocyte donor has completed the Donor Application & Medical/Genetic History Form and has provided TFCC with a recent color photograph to aid in the matching process.

   The oocyte donor understands that she will be placed on a waiting list of potential egg donors. The oocyte donor may or may not be called to participate, depending on the recipient program needs, at the sole discretion of Dr. Eric Silverstein.

2. Pre-donation screening: The oocyte donor understands that when a suitable matching recipient comes into the program, she may be recalled. Laboratory tests for sexually transmitted disease, nicotine, illicit drug use, as well as genetic screening (such as cystic fibrosis), will be obtained when appropriate. The oocyte donor understands that a physical exam by Dr. Silverstein will be necessary which will include cervical cultures. The oocyte donor understands she will provide her medical history, genetic history, and have laboratory tests done to include Hepatitis B, Hepatitis C, syphilis, HIV, blood type and Rh, cystic fibrosis, chlamydia, and gonorrhea. Other screening laboratory tests for specific genetic disorders may be indicated based on genetic history and/or ethnicity. Other testing may become recommended in the future, and may be required.

   The oocyte donor has completed the Donor Application & Medical/Genetic History Form and reviewed and signed attesting to its accuracy and completeness. The oocyte donor understands that she will be required to avoid alcohol, excessive caffeine, smoking, and illicit drug use. The oocyte donor will be responsible for any damages to TFCC, or to the recipient/recipient couple, caused as a result of the oocyte donor's misrepresentation, or lack of full disclosure, to TFCC, or to the recipient/recipient couple, regarding the oocyte donor's health, genetic and hereditary character, or social history.

   The oocyte donor understands that an antibody test for AIDS (HIV) will be performed on her. The oocyte donor has been informed about the HIV antibody test and has been counseled as to the implications of a positive and negative result. At the time the HIV test is performed, the oocyte donor will be required to sign the Consent for HIV Antibody Screening Test form. The oocyte donor understands that the HIV test result will be part of her medical record. The oocyte donor understands that both her test results and her medical record are confidential to the extent later described in Medical Records in this document; however, the oocyte donor understands that if her test result is positive, her physician is required by law to report her name to the State Health Department which, in turn, will contact her about counseling for her spouse and/or sexual partner(s). This is also the case when the syphilis test results are positive. The oocyte donor understands the benefits and the risks of the test. The oocyte donor agrees to have this test done and have the result recorded in her medical record.

   The oocyte donor understands that she will be interviewed about emotional and social factors by a psychologist. Prior to or following the interview, one or more psychological assessment tests may be given. The oocyte donor understands that the full psychological implications of being an egg donor are unknown and agrees that TFCC cannot, and will not, be held responsible for any negative psychological consequences as a result of being an egg donor.

3. Follicle stimulation procedures: The oocyte donor understands that the egg donation procedure requires that she participate each day for approximately 20-28 days. Participation prior to the oocyte retrieval will involve subcutaneous and/or intramuscular injections, venipuncture, and vaginal ultrasound examinations. Ultrasound examinations involve the use of high-frequency sound waves to measure the development of the eggs in the ovary. This procedure is done by placing the ultrasound transducer into the vagina. In addition, a blood sample will be drawn on each of these days. Visits to the clinic are an essential part of the oocyte donor's participation and may need to be scheduled with one day's notice. Birth control pills are usually started to prevent

ovulation from occurring prior to the egg retrieval. Subsequently, Lupron® is administered for the same purpose. Lupron® is a subcutaneous injection given once and sometimes twice a day. It will be continued for the duration of time that gonadotropins (Follistim®, Gonal-F®, Bravelle®, Menopur®, and/or Repronex®) are used. Once the follicles have developed to the appropriate stage (which usually occurs between the 9th and 12th day of the stimulation cycle), the oocyte donor will be given an injection of another hormonal medication, human chorionic gonadotropin (hCG or Ovidrel®). Approximately 35-36 hours later, the egg retrieval procedure will begin. The oocyte donor understands that TFCC cannot be certain of the actual dates required for blood work, ultrasounds, or retrieval, and it is the responsibility of the oocyte donor to make herself available at the requested time.

4. Egg retrieval procedure: The egg retrieval procedure is done in the operating room at HealthSouth Surgery Center with anesthesia medications given intravenously to help reduce any discomfort. There may be some discomfort associated with the egg retrieval procedure. The procedure itself involves placing an ultrasound transducer in the vagina to locate the eggs. A needle attached to the ultrasound transducer is then passed through the vaginal wall and ovary into each individual follicle and the follicular fluid is withdrawn and then examined under the microscope for the egg. A typical egg retrieval takes 20-60 minutes. In most patients, conscious sedation is used by way of an IV through which narcotics (i.e. Demerol®, Fentanyl®, or morphine), antiemetics (anti-nausea medications, i.e. Phenergan® or Zofran®), amnestics (medications to lessen memory of the procedure, i.e. Valium® or Versed®), and appropriate reversal agents (i.e. Narcan®) may be administered. If a severe form of Ovarian Hyperstimulation Syndrome is likely, you will not receive hCG and an egg retrieval will not be performed. See Informed Consent for Gonadotropins.

Some Significant and/or substantial risks of this particular procedure include, but are not limited to:

1. Blood drawing: Mild discomfort and a risk of developing a bruise at the needle site.

2. Allergic reactions: Allergy or sensitivity to latex products, skin cleansing products, adhesives, bandages, ointments, anesthetic medications, or other medications used during or after the procedure.

3. Fertility medications: Birth control pills, leuprolide acetate (Lupron®), Folliste m®, Gonal-F®, Repronex®, Bravelle®, and human chorionic gonadotropin (hCG) are drugs routinely used in infertility treatment. Hot flashes, headache, vaginal dryness, and mood changes are side effects associated with Lupron®. "Hyperstimulation syndrome," or ovarian enlargement, and drug sensitivity with fever and/or local irritation at the injection site are possible side effects of Follistim®, Gonal-F®, Repronex®, and Bravelle®. Headache or pain at the injection site may occasionally occur with hCG injections. The oocyte donor is required to read, understand, and sign the Informed Consent for Fertility Medications.

4. Ovarian Hyperstimulation Syndrome (OHHS): Occurring in small percentage of cycles, the chance of OHSS is increase in women with polycystic ovarian syndrome and in conception cycles. When severe, it can result in blood clots, kidney damage, ovarian

twisting (torsion), and chest and abdominal fluid collections. In severe cases, hospitalization is required for monitoring. This situation, while possible, is not typical. Occasionally, drawing fluid out of the chest or abdominal cavity may be necessary. There have been reports of death or serious consequences of clot formation, such as stroke, throughout the world. Fortunately, this is extremely rare but has implications in regard to future health and fertility potential. If severe form of Ovarian Hyperstimulation Syndrome develops as a result of the ovarian stimulation, you will not receive hCG and an egg retrieval will not be performed. See Informed Consent for Fertility Medications.

5. Pain, bleeding, and infection: There are reported cases of infections and/or bleeding that ultimately led to the need for antibiotic therapy, and/or surgical intervention that may include the removal of the tubes, ovary(s), and uterus because of their severity. These reported instances are extremely rare. Some degree of pain is frequently associated with the procedure.

6. Nerve injury: Nerve injury or other types of pressure point injuries may result from body position and lying still during surgery.

7. Anesthesia risks: The risks associated with anesthesia and sedation include, but are not limited to, the following:

    - If you receive an injection or have an IV (intravenous line) placed, you may experience infection, bleeding, swelling, or scarring at the site of needle insertion.
    - Nausea, vomiting, or other gastrointestinal symptoms.
    - Certain herbs, medications, and medical conditions are associated with complications during anesthesia. It is important that you inform your clinician of all herbs and medications that you take, and that you discuss with your clinician your medical history, including previous experiences with anesthesia.
    - Anesthesia may affect abilities such as driving and decision-making for up to 48 hours. You should avoid activities that require these skills for this period of time.
    - Aspiration, oversedation, and/or respiratory depression.

8. Retrieval risks: The risks associated with ultrasound directed follicular aspiration include the potential for intra-abdominal bleeding, infection, or laceration of blood vessels, bladder, urinary tract, or intestines. Also, there is a small risk of some blood in the urine or vaginal bleeding following the procedure. Ovarian bleeding occurs rarely, but could lead to open abdominal surgery for control of blood loss, or to repair damaged tissue. Theoretically, loss of a bleeding ovary could result. Every effort to prevent these occurrences will be taken and the possibility of this outcome is very small.

9. Estrogen level risks: Excessively high estrogen levels as a result of the ovarian stimulation may result in mood changes, nausea, fatigue, or increased predisposition for blood clot formation.

10. Serious risks and possible death: There is a small risk of lung infections, blood clots, strokes, heart attacks, and possible death. These risks, however, are very small.

11. Risk of conception: It is understood that during the stimulation and retrieval process, it is possible for some eggs to release and be captured by the fallopian tube(s). It is strongly recommended that the oocyte donor abstain from sexual intercourse from the time gonadotropins are started until ensuing menses begins. It is understood that a conception, including a multiple pregnancy, is more likely if sexual intercourse occurs during this time.

Medical Records:
Medical records will be processed according to the standard medical record keeping practices of TFCC. In addition, separate confidential files summarizing the details of the treatment cycle will be maintained under the control of TFCC. It is possible that selected summaries of the observations made during the course of many treatment cycles will be published in the scientific literature. However, no details will be given as to individual patient identification. It is also possible that the medical records may be audited by outside agencies such as the Federal Food and Drug Administration or the American Society for Reproductive Medicine.

The oocyte donor understands that both her test results and her medical record are confidential and will only be shared with healthcare providers directly involved in her care, and with the recipient and her husband/partner, or as otherwise authorized by the oocyte donor, or as required by law, without personal identifying information being revealed to the extent allowed by law.

Data from your Assisted Reproductive Technology (ART) procedure will also be provided to the Centers for Disease Control and Prevention (CDC). The 1992 Fertility Clinic Success Rate and Certification Act requires that the CDC collect data on all assisted reproductive technology cycles performed in the United States annually and report success rates using these data. Because sensitive information will be collected on you, CDC applied for and received an "assurance of confidentiality" for this project under the provisions of the Public Health Service Act, Section 308(d). This means that any information that CDC has that identifies you will not be disclosed to anyone else without your consent. All cycles must be reported and patients may not opt out of having their information included.

Expenses, Charges, Payments and Cancellation Policy:
The oocyte donor understands the full cost of the usual procedures, supplies, and professional services involved in this program will be paid by the oocyte recipient and that none of these routine expenses will be her responsibility.

For the direct and indirect expenses involved in this procedure, the oocyte donor will receive compensation as follows:

1. Should the oocyte donor decide to stop the cycle herself, she will receive no financial compensation.
2. Should the oocyte donor be found to have falsified information, used illicit drugs, or smoked cigarettes, the cycle will be canceled with no financial compensation to the oocyte donor. **The oocyte donor may also become responsible for any services provided prior to the cancellation.**

3. There are certain medical conditions, such as an abnormal response to the hormone stimulating agents, which would prevent an egg retrieval procedure from being safely or adequately performed. If the oocyte donor's cycle is canceled by the staff at TFCC after Lupron® is started, she will receive $500.00, to be paid by the recipient. If the oocyte donor's cycle is canceled by the staff at TFCC after gonadotropins (Follistim®, Gonal-F®, Bravelle®, Menopur®, Repronex®) are started, she will receive $750.00, to be paid by the recipient.
4. If the oocyte donor completes the egg retrieval, no matter what the outcome, she will receive between $3000.00 and $5000.00 in accordance with the number of cycles she has done. The oocyte donor understands and agrees that once the oocytes are removed from her ovaries, those eggs are the property of the oocyte recipient couple.
5. The oocyte donor understands that should she suffer a physical injury as a result of her participation in the program, the recipient couple is responsible for the charges incurred for her medical care. The oocyte donor understands that the recipient couple will purchase a temporary insurance policy to help cover any complications. It is possible that the oocyte donor's insurance may cover all or part of these charges, but the recipient/recipient couple is solely responsible for any unpaid monies. The oocyte donor understands that she/they will not expect to receive any financial compensation for such items as lost wages, loss of consortium, or any other economic or non-economic loss, that may occur as a direct or indirect result of this procedure, and waives any rights or causes of action to recover such damages.
6. The oocyte donor understands that there is no direct benefit to the oocyte donor from donation. The oocyte donor will be paid a nominal fee for the oocyte donor's time and inconvenience, but will receive no remuneration for the donated eggs.

Statement of Voluntary Participation:

The oocyte donor has read the information contained in this form and has had sufficient opportunity to discuss her medical condition and treatment with the undersigned physician. All of the oocyte donor's questions have been answered to their satisfaction, and they believe that they have been given adequate information upon which to base an informed consent for anonymous oocyte donation.

The oocyte donor understands that she can withdraw this consent at any point without changing the care she receives. The oocyte donor's consent for this procedure is voluntary.

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Waiver:

1. The oocyte donor hereby relinquishes any claim and waives any rights which she might have over such oocytes, embryos, child, or children produced as a result of the donation of her oocytes. The oocyte donor understands that as an oocyte donor, by law, the oocyte donor is not a parent of a child conceived by means of assisted reproduction. The oocyte donor makes this agreement and these representations with the understanding that others are relying upon them.
2. The oocyte donor acknowledges by her signature below that they have read the foregoing informed consent, and that all questions have been answered to their satisfaction and that they have been advised to, and have had the opportunity to, consult with legal counsel of their choosing.
3. The oocyte donor's questions concerning her participation in this program have been answered by Eric H. Silverstein, M.D. or one of the staff of TFCC. The oocyte donor understands that her participation is purely voluntary and that her refusal to participate or her withdrawal from the program at any time will not involve any penalty or loss of benefits to which she is otherwise entitled.
4. The oocyte donor understands that TFCC cannot be held responsible for any loss due to circumstances beyond TFCC's control including, but not limited to, sickness, injury, acts of God, inclement weather, equipment failure resulting in loss of sperm/oocyte/embryo viability, or any other unforeseen circumstances that prevent essential personnel from being able to attend on the day of the procedure which may adversely affect the outcome of the Assisted Reproductive Technology (ART) treatment.
5. The oocyte donor understands that is a laboratory test result is abnormal or a cyst develops, the egg retrieval may be delayed or canceled, and/or additional laboratory tests may be required before proceeding with an egg retrieval.
6. The oocyte donor agrees to accept a compensation of $ _____ for the completion of this oocyte donation cycle.

_____
Patient Name (Please Print)

_____
Address

_____
City, State, Zip Code

_____ _____
Patient Signature Date

_____ _____
Witness Signature Date

As one of the members of the Fertility Center of Colorado, by my signature, I indicate that the foregoing consent was read, discussed, and signed in my presence.

_____ _____
Authorized Representative Date

PHYSICIAN DECLARATION: I, or an authorized member of my staff, have explained the contents of this document to the patient, and have answered all the questions of the patient. To the best of my knowledge, I feel that the patient has been adequately informed and has consented.

_____ _____
Physician Signature Date