

**COLUMBUS CENTER FOR REPRODUCTIVE
ENDOCRINOLOGY & INFERTILITY, L.L.C.**

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Prakash Thiruppathi, M.D.

IN-VITRO FERTILIZATION WITH EMBRYO TRANSFER CONSENT

Patient's Name: _____ DOB: _____

Spouse's Name: _____ DOB: _____

We wish to participate in Columbus Center for Reproductive Endocrinology & Infertility's In Vitro Fertilization program in hopes of conceiving a child. We understand that several medical procedures will be performed as part of the In Vitro Fertilization program and that either of us have the right to withdraw consent to further participation in this program and it will not adversely affect our relationship with the Columbus Center for Reproductive Endocrinology & Infertility, the physician, or its staff caring for us. We understand that this is an established treatment, however, there is no guarantee that a successful pregnancy will result. We have opted for this treatment since conventional therapy has failed or is unacceptable.

Procedure

We understand that to stimulate the ovaries to grow multiple eggs' (follicles) injections of hormones must be administered. We understand that we will be taught on self-administering these medications. The injections may need to be administered several times a day. The amount of hormones and follicular growth will be monitored by almost daily blood work and ultrasounds. We understand that it is our responsibility to be available for these visits, even on weekends and holidays, if instructed by my physician.

When the follicles have grown to an appropriate size determined by my physician, we will be instructed either by Prakash Thiruppathi, M.D. or a member of the Columbus Center for Reproductive Endocrinology & Infertility's staff to administer the HCG injection at a designated time.

We understand that egg(s) from the ovaries will be taken from the female by means of Transvaginal Culdocentesis (procedure in which a long needle is utilized under sonographic control to aspirate the eggs from the ovaries). The procedure is performed while the patient is sedated by a Board Certified Anesthesiologist. After the eggs are retrieved, they will be inseminated with my husband's sperm in hopes of creating embryos. In some cases, a micromanipulations procedure, ICSI (Intra-Cytoplasmic Sperm Injection), will be utilized for fertilization. After the embryos have been

incubated for three to five days, the physician will implant the designated number of viable embryos into the wife's uterus through the vagina and cervix.

The wife will be placed on Progesterone injections in hopes of creating a thicker uterine lining. Approximately 12-14 days after the embryo transfer, a blood test will confirm if a pregnancy has occurred and is progressing normally.

Risks of In Vitro Fertilization with Embryo Transfer

We understand that with any type of procedure, this treatment has potential risk as well.

Fertility Medications: The most common side effect is increased stimulation to the ovaries. Twenty percent of patients receiving fertility medications can incur ovarian enlargement, which causes pain due to abdominal distention, but to those treated, the problem is generally resolved on its own in about one week. Severe ovarian enlargement, known as Hyperstimulation Syndrome, can cause accumulation of fluid in the abdomen and lungs and can cause breathing difficulties. The fluid difficulties can cause increased clotting in the blood, which could be life threatening. Fortunately, Hyperstimulation Syndrome only occurs in 1-2% of patients undergoing treatment. Hospitalization may occur in severe cases. Patients using fertility medications may have reactions such as pain, rash, swelling at the injection site and ectopic pregnancy. The HCG injection can cause headaches, irritability, restlessness, depression, and fatigue. Lupron can cause menopausal symptoms such as hot flashes. Some recent studies have suggested that fertility medications may increase the risk of ovarian cancer. These studies involve a small number of patients and the results cannot be wholly accepted. Other studies have also been done which do not agree with the increased risk.

Egg Retrieval: Transvaginal Ultrasound Guided Needle Aspiration of the eggs carries the possibilities of bleeding, infection, and injury to the bladder or abdominal structures that may require surgery, either immediately or in the future. Infection may further impair fertility or result in a loss of fertility potential.

Embryo Transfer: This procedure may cause discomfort and has the risk of infection or bleeding. In addition, there is a possibility that the embryo(s) transferred may implant into the fallopian tube causing an ectopic pregnancy requiring surgical management.

Multiple Pregnancies: This risk can occur after the transfer of more than one embryo. The risk of multiple pregnancies after transferring three (3) embryos is 20% for twins and less than 5% for triplets. Multiple pregnancies (twins or more) carry higher than normal risks for premature delivery, which may be associated with emotional and financial strain for the parents. The number of neonatal deaths and the number of long term handicaps are several times more frequent in multiple pregnancies. A triplet or higher gestation has the increased risk of premature delivery, which may be too soon for survival of the infants. A procedure known as selective reduction may be considered to reduce the number of pregnancies.

We understand that any of the following may occur which would prevent the establishment of a pregnancy:

- a. Spontaneous ovulation may occur before egg collection thus precluding any attempt at obtaining an egg.
- b. Mechanical factors or anatomical problems within the pelvis may prevent access to the ovary with the follicles.
- c. Egg retrieval may be unsuccessful.
- d. The egg(s) may not be normal.
- e. The collection of an adequate semen sample may be impossible on the day of fertilization.
- f. Fertilization may not occur.
- g. Cleavage or cell division of the fertilized egg(s) may not occur.
- h. The embryo(s) may not develop normally. An embryo transfer may not be performed.
- i. Implantation and pregnancy may not occur.

Alternate Forms of Treatment

We understand that if we choose not to proceed with In-Vitro Fertilization with Embryo Transfer, the chances of obtaining a pregnancy at this time are low or nonexistent. All the other possible procedures to enable pregnancy have been explained, offered or attempted. We also understand that adoption through other resources may be available to us.

Treatment Decisions

We understand that all decisions regarding each step of the procedure involved such as stimulation, fertilization and implantation, will be made by our physician based on his individual medical judgment. We understand that our physician may decide not to proceed with the procedure because of possible complications or risks to the patient, husband, or potential child.

Legal Status

We understand that due to the relatively new nature of In-Vitro Fertilization with Embryo transfer, many legal issues surrounding the procedure have not been resolved and the legal status of any resulting child in terms of legitimacy or otherwise is uncertain. It is our intent and understanding that any resulting child is our legitimate child and we accept legal custody and responsibility for any child or children we may have as a result of this procedure.

Medical Expenses

We understand the risks involved with participating in the In-Vitro Fertilization program. We understand that our physician and the medical facilities are available for treatment. We understand that Columbus Center for Reproductive Endocrinology & Infertility is not financially responsible for any treatment that is not outlined in the procedure section of this consent form.

Financial Expenses

We have been given a “Cost Information Sheet” outlining our financial responsibility. We understand that our insurance may not reimburse Columbus Center for Reproductive Endocrinology & Infertility for some or any of the procedures. We understand that it may be necessary to have procedures such as ICSI and Assisted Embryo Hatching performed which is not usually incurred by all patients. We understand it is our financial responsibility to reimburse Columbus Center for Reproductive Endocrinology & Infertility for all procedures not covered by out insurance.

I, the prospective mother, understand that a successful pregnancy in the In-Vitro Fertilization program requires strict adherence to my physician’s directions and specifically agree that I will not take any drugs/medications without my physician’s consent from the onset of this procedure until the termination thereof by giving birth or by mutual consent with my physician.

We understand that if pregnancy is established, it may result in miscarriage, stillbirth, birth defects or tubal pregnancy. We understand that eggs, sperm, or embryos may be lost due to reasons unforeseen, such as equipment malfunction, power failure and natural disasters (fire, flood, tornado, etc.). We will not hold Columbus Center for Reproductive Endocrinology & Infertility, Prakash J. Thiruppathi, or its staff responsible for any loss.

We understand that data from your ART procedure will also be provided to the Centers of 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 this data. Because sensitive information will be collected on you, CDC applied for and received an “assurance of confidentiality” for this project under the provision 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.

We have read and understand the above consent regarding our participation in the In-Vitro Fertilization program. We understand the risks involved with this type of treatment including, but not limited to, failure to achieve pregnancy, miscarriage, birth defects, stillbirth, infection, Hyperstimulation Syndrome, and the loss or destruction of any eggs, sperm or embryo(s). In view of these risks and uncertainties of this treatment, we agree not to hold Columbus Center for Reproductive Endocrinology & Infertility, Prakash Thiruppathi, M.D., any staff member or representative responsible for any outcome that may arise with our treatment.

We agree that this procedure has been explained in detail to our satisfaction that we both have had the opportunity to ask any questions concerning the In-Vitro Fertilization program and that all our questions have been answered to our satisfaction. We understand that we are free to refuse to participate or withdraw from the In-Vitro Fertilization program at any time. By signing below, we voluntarily consent to participate

in this treatment in hopes of creating a child, given the potential risks and inconveniences.

Signature of Wife

Signature of Husband

Wife's Printed Name

Husband's Printed Name

Time and Date Signed

Time and Date Signed

Signature of Witness

Witness' Printed Name

Time and Date of Signature

PHYSICIAN'S SIGNATURE

I, the patients physician, or his/her representative, verify that the matters referred to in the above consent and release form have been explained to both the wife and husband, that any necessary information concerning the In-Vitro Fertilization program, the risks and uncertainties associated with such treatment, and other alternate forms of treatment which may be available. I have answered all questions presented to me by the above couple to their satisfaction. I, as their physician, and my staff will make all reasonable efforts to keep information obtained about their treatment confidential, unless compelled by law. The couple has voluntarily consented, in front of a witness, to participate in this treatment and me.

Prakash J. Thiruppathi, M.D.

Date and Time