

**CONNECTICUT FERTILITY ASSOCIATES
OVULATION INDUCTION AND OVUM ASPIRATION
CONSENT BY OVUM DONOR/GENETIC MOTHER
(Gestational Carrier Arrangement)**

Female Name: _____ **SS#:** _____ - _____ - _____

Partner Name: _____ **SS#:** _____ - _____ - _____

I (we), the undersigned, request, authorize and consent for ovulation induction and ovum aspiration at Connecticut Fertility Associates (CFA), and, as appropriate, its employees, contractors, and consultants and authorized agents.

I (we) have been unable to become pregnant through natural or assisted reproductive technology means. Therefore, I will undergo drug therapy to induce my body to create eggs. I also will undergo an aspiration procedure to remove the eggs from my body. I have requested that my physicians combine my eggs with my husband's/partner's sperm, and that the resulting embryo or embryos be placed in the uterus of

_____ **(the Gestational Carrier).**

I (we) have decided to use the Gestational Carrier after having pursued other available therapy for infertility. We have considered the alternatives of adoption or continuing our relationship without children. We understand that there is no guarantee that pregnancy will occur. If pregnancy occurs, there is no guarantee that it will proceed to term. If more than an embryo is implanted, more than one baby may develop, resulting in multiple births.

We have consulted with a lawyer, and have, entered into an agreement with the Gestational Carrier (and her husband if applicable) regarding the legal status of the child or children that may be born as a result of the procedures described in this consent.

I (we) understand each of the following steps involved in the process.

1. Fertility Medications

Blood and/or urine hormone tests will be utilized to predict the time that I would ovulate, usually one tube of blood per day for an average of six to eight days is obtained. Certain drugs will be used to stimulate my ovaries to produce eggs at a predictable time. Human Menopausal Gonadotrophins, (including Gonal F, Follistim, Bravelle, Pergonal, ReproNex). ReproNex or Pergonal are purified, freeze-dried preparations of two hormones - follicle stimulating hormone (FSH) and the luteinizing hormone (LH). Gonal F, Follistim, and Bravelle are also purified freeze-dried preparations, but primarily contains the FSH with insignificant amounts of the LH. These human menopausal gonadotrophins work to produce ovarian follicular growth and maturation. HCG (Pregnyl, Profasi, Ovidrel) are longer-acting forms of LH, which is used to achieve egg maturation prior to ovulation or sometimes used to maintain corpus luteal function. These drugs are administered by intramuscular subcutaneous injection immediately after reconstitution with a supplied diluent (sodium chloride for injection).

I (we) am (are) responsible for taking the prescribed human menopausal gonadotrophins on specific days of my menstrual cycle. I (we) may either administer the drugs to myself or my significant other may administer them to me. Prior to beginning a stimulation cycle, a nurse or doctor will instruct me on the technique of intramuscular injections.

I (we) understand that the use of the fertility drugs (Gonal-F, Follistim, Bravelle, Fertinex, Pergonal, Repronex; hCG such as Pregnyl, Profasi or Ovidrel) has short-term risks. Occasionally one may develop hot flashes and/or temporary visual changes such as blurring and accommodation changes with the use of these drugs. The ovary will grow to a larger size during this process. Ovarian cysts commonly occur and cause pain and discomfort in the lower abdomen. Rarely, overstimulation or hyperstimulation may cause abdominal swelling and fluid retention to lead to hospitalization and in

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extreme cases can cause cardiovascular collapse (shock and even death). The risks of these complications are extremely rare. Several days prior to and after the collection of eggs, one typically will have lower abdominal pressure and physical activity must be reduced, since these cysts may rupture and cause problems requiring surgery.

Recent reports have suggested that women who were never pregnant and who subsequently became pregnant and when had developed ovarian cancer were more likely to have used medications intended to increase fertility compared to women who did not have ovarian cancer. On the other hand, breast feeding and pregnancy reduce the risk of developing ovarian cancer. The use of fertility drugs and its association with ovarian cancer is unknown. Presently, there are studies that suggest an association of ovarian cancer in women who receive fertility drugs. There are other studies however that do not show such an association. However, there are no studies to date that clearly illustrate no association between fertility drugs and ovarian cancer. The actual risk of an average woman under the age of 45 developing ovarian cancer is 15/100,000. For women over the age of 50 the risk is about 50/100,000.

2. Egg Retrieval (Ovum Aspiration)

Transvaginal ultrasound examination will be used in predicting the expected time of my ovulation. I will then be admitted to the IVF Unit to obtain an egg or multiple eggs from my ovary just prior to the expected time of ovulation. A small needle will be passed directly into the ovary containing follicles via an ultrasonically-guided procedure. This technique will be performed on an outpatient basis under intravenous sedation and analgesia. Throughout the procedure, my heart, blood pressure, and blood oxygenation will be constantly monitored by a pulse oximeter and an EKG machine. A physician (anesthesiologist) will be in attendance at all times. If the ovaries cannot be adequately visualized for ovum recovery by this method, a laparoscopy may be offered. A laparoscopy requires a small umbilical puncture in order to place a scope directly into the abdomen and utilizes general anesthesia. Anesthesia contains the risk of nausea, respiratory depression, and headaches.

Several days prior to and after the collection of the eggs, I may have lower abdominal pressure sensation and therefore I should not be physically or sexually active because the cysts may rupture and cause problems requiring surgery.

I (we) understand that during my oocyte retrieval there is a possibility of damage to abdominal organs including bowel, bladder, blood vessels, uterus, fallopian tubes, cervix, and possible formation of scar tissue by my attempted ovum retrieval. This could result in a remote possibility of an open surgical procedure, blood transfusion, or antibiotic therapy to correct any injury incurred.

To minimize any risk of infection antibiotics are utilized to minimize this risk. This may result in an allergic reaction, which may present as a rash. In its most severe form, an allergic reaction may be life threatening. The utilization of tetracycline/doxycycline is associated with an increased sensitivity to the sun, and therefore caution should be taken to avoid prolonged sun exposure. The utilization of antibiotics may also be associated with nausea, vomiting, diarrhea, loss of appetite and vaginal yeast infections.

3. Fertilization of Eggs, and Embryo Implantation in the Gestational Carrier

The laboratory will receive a sperm specimen from my husband and treat the sperm to prepare for fertilization. The laboratory will then combine the egg(s) and sperm together to allow fertilization to occur.

After several cell divisions, and after it is deemed that the embryo is developing normally, an embryo or embryos will be transferred to the Gestational Carrier. I (we) hereby consent to the implantation of my genetic material into the womb of the Gestational Carrier.

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4. Embryo Transfer to the Gestational Carrier

Embryo transfer involves minimal discomfort, spotting, and minimal risk of developing an infection. If assisted hatching is performed, corticosteroids are utilized and may be associated with mood changes (mood swings, insomnia, and depression), GI disturbances, masking signs of infection, interference with the metabolism of sugars (carbohydrates), and vaginal yeast infections.

I (we) understand that the use of fertility drugs typically results in the placement of multiple embryos into the uterus; and that this can result in multiple pregnancy (twins, triplets, or more), with an increased risk of miscarriage, premature labor, and premature birth

I (we) also understand the following may occur, which would prevent the formation of an embryo or embryos and the establishment of pregnancy in the Gestational Carrier:

- a. My attempted cycle may be canceled for medical indications.
- b. Attempted egg retrieval may be unsuccessful (no eggs retrieved).
- c. The egg or eggs may not be normal even if retrieved.
- d. My partner may be unable to produce a semen specimen.
- e. Fertilization may not occur and no embryos develop.
- f. Cleavage or cell division of the fertilized egg(s) may not occur and development of the embryo(s) arrest.
- g. The embryo(s) may not develop normally.
- h. Implantation of the embryo within the uterus of the Gestational Carrier may not occur.
- i. ICSI or assisted hatching may result in damage or loss of oocytes or embryos.
- j. The embryo transfer may fail.
- k. Implantation may not occur.
- l. An event may occur in the laboratory resulting in loss or damage to some or all of the eggs or embryos. We (I) understand that we are entitled to financial compensation should an accident occur. The program will account for all gametes and embryos.
- m. If pregnancy is successfully established, miscarriage, multiple gestation, stillbirth and/or congenital abnormalities (birth defects) may occur. The occurrence of congenital defects resulting from this procedure is about the same as if pregnancy occurred naturally (2–3%). A pregnancy may also implant outside of the uterus, in a fallopian tube or cervix (ectopic pregnancy) or elsewhere and require medical or surgical intervention.
- n. Psychological stress.

I (we) also understand that within the normal human population, a certain percentage (approximately 3—4%) of children are born with physical or mental illness and that the occurrence of such illness is beyond the control of physicians. The Assisted Reproduction Program at Columbia University, College of Physicians & Surgeons and their physicians do not assume responsibility for the physical and/or mental characteristics of any child or children born as a result of embryo transfer to the Gestational Carrier. I understand that within the normal population, approximately 10—20% of pregnancies result in miscarriages and that this may occur after in vitro fertilization and embryo transfer. Similarly, obstetrical complications may occur in any pregnancy. I also understand and accept that the procedure carries with it a small risk of sexually transmitted diseases being transmitted to the Gestational Carrier and/or child or children, including but not limited to hepatitis and Human immunodeficiency Virus (HIV).

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During pregnancy and delivery, the same types of complications can arise as with a child conceived through sexual intercourse. It is possible that pregnancy could result in the birth of a child or children with undesirable traits or hereditary tendencies, or possess any other problems or disabilities of children conceived by sexual intercourse. I understand and agree to care for the child or children regardless of any possible problems.

The Gestational Carrier will be tested for syphilis, hepatitis and HIV. I will also undergo these tests. I understand that if a screen is positive, I will not be a candidate for the procedures. Appropriate medical referral will be made.

5. Separate Legal Agreement

We have consulted with a lawyer to address the many legal concerns arising from the gestational surrogacy arrangement involving the transfer of our embryo into the Gestational Carrier. Our lawyer has explained to us the legal ramifications of gestational surrogacy arrangements. I (we) have entered into an agreement with the Gestational Carrier and her husband, which addresses the legal and practical issues involved in this arrangement, including the parentage of any child or children born, and the payment of medical expenses I (we) understand that the Gestational Carrier has certain personal rights regarding her body, including the right to undergo a fetal reduction or abortion procedure, to terminate the pregnancy.

This informed consent, therefore, is not a contract to cure, a warranty of treatment, or a guarantee of conception. I absolve, release, and hold harmless, Connecticut Fertility Associates and their associated physicians, and affiliates, from any and all liability for the mental or physical nature or character of any child or children conceived or born under the procedures described in this document, for legal liability regarding the gestational surrogacy arrangement, and for affirmative acts or acts of omission which may arise during the performance of the procedures described here. I warrant that no monetary payment or gifts were given to the gestational carrier in exchange for her participation in this procedure.

I (we) understand the above-mentioned benefits and risks of the use of fertility medications and ovum aspiration, and embryo transfer, and give my consent to the use of the medications and procedures described above.

I (we) have been assured that all information obtained will be handled confidentially and neither my identity nor specific medical details will be revealed by my physicians without my consent. Specific medical details may be revealed in professional publications as long as my identity is concealed.

I (we) agree that the center will furnish emergency medical care determined to be necessary by the medical staff I agree to be responsible for the cost of the care described here, either personally or through medical insurance or other form of medical coverage. I (we) also agree to cover the costs associated with the embryo transfer to the Gestational Carrier, either personally or through medical coverage. Finally, I (we) understand that no monetary compensation for wages lost as a result of injury will be paid to me by Connecticut Fertility Associates.

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We (I) have been encouraged to ask questions until they have been answered to my satisfaction. Any further questions can be addressed to Connecticut Fertility Associates or to its Medical Director, Dr. Michael B. Doyle at 203-373-1200, or 203-855-1200.

Signature of Ovum Donor/
Genetic Mother

Date

Signature of Witness

Date

Signature of Genetic Father/
Partner

Date

Signature of Witness

Date

Note: Each Signature must be witnessed separately.

This consent has been read by and discussed with the patient and her partner, where applicable.

Signature of CFA Physician

Date