

CONNECTICUT FERTILITY ASSOCIATES



CONSENT FOR IN VITRO FERTILIZATION AND EMBRYO TRANSFER

Female Name: \_\_\_\_\_ SS#: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Partner Name: \_\_\_\_\_ SS#: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

We (I), the undersigned, request, authorize and consent to the procedure of **In Vitro Fertilization (IVF)** and **Embryo Transfer (ET)** by Connecticut Fertility Associates (CFA), and, as appropriate, its employees, contractors, and consultants and authorized agents. We (I) understand that the following is an outline of the steps required in these procedures.

We (I) have reviewed the following document in detail, and give full, informed consent for all of the procedures stipulated below. We (I) understand that in the event that these procedures may need to be repeated over time, that the consents outlined herein are valid and binding for a period not to exceed one (1) year from the date of our (my) signature(s); and that beyond that, we (I) will be asked and required to reaffirm our (my) informed consent. We (I) also understand that at any time prior to **one year** of the enforcement of these documents, that we (I) can change our (my) consent by notifying in writing the CFA IVF staff.

The following steps required for IVF-ET are outlined below:

1. Determination that we (I) are (am) a suitable candidate for IVF.
2. If indicated, suppression of ovarian activity using the GnRH agonist (Lupron) or antagonist (Antagon).
3. **“Fertility drugs”** (Gonal-F, Follistim, Bravelle, Fertinex, Pergonal, Repronex; HCG such as Pregnyl, Profasi or Ovidrel; and/or a GnRH agonist or antagonist) will be used to induce the recruitment of multiple follicles at a predictable time. Blood and/or urine hormone tests will be utilized to predict the optimal time for egg removal. Usually one tube of blood per day for an average of six to eight days is obtained.
4. Ultrasound examinations to assist in predicting the time of expected ovulation.
5. Admission to CFA’s IVF Unit to **retrieve egg(s)** from the ovary just prior to the expected time of ovulation. A small needle will be passed directly into the ovary containing follicles via an ultrasound-guided puncture. This technique is performed on an outpatient basis under intravenous sedation and analgesia. Throughout the procedure your heart, blood pressure, and blood oxygenation will be constantly monitored by pulsemeter and an EKG machine. At all times a physician will be in attendance. If the ovaries cannot be adequately visualized for ovum recovery by this method, the laparoscopic technique will be offered. This technique utilizes general anesthesia. The egg can then be aspirated and transported to our laboratory.
6. Providing a sperm specimen from my partner by masturbation and laboratory treatment of the sperm to prepare them for fertilization process.
7. Mixing the egg and sperm together (conventional insemination) to allow **fertilization** to occur.

Certain circumstances may exist to predict that your eggs are unlikely to become fertilized using conventional technique. In these cases, a procedure called intracytoplasmic sperm injection (ICSI) is used. ICSI differs from routine IVF in that instead of combining sperm and eggs together and allowing fertilization to occur, sperm are specially prepared and then individually injected into an

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egg by means of a microscopic glass needle. This technique greatly increases the chances that the eggs will be fertilized and can help overcome my fertilization defect.

We (I) understand that there are associated risks with ICSI and any of the following may occur which would prevent ICSI from being performed, or prevent the establishment of pregnancy:

- a. Mature oocytes (eggs) are required to perform ICSI; therefore if none are retrieved, ICSI may not be possible.
- b. Viable sperm may not be available for use in ICSI.
- c. Fertilization may not occur.
- d. Injury to the eggs(s).
- e. Cleavage or cell division of fertilized egg(s) may not occur.
- f. The fertilized eggs may not develop normally.

If pregnancy is successfully established, miscarriage, ectopic pregnancy, stillbirth, multiple births, and/or congenital abnormalities (birth defects) may occur that are unrelated to this procedure, at the same rate as if unassisted fertilization had occurred. In situations where the male factor is the result of a genetic defect, the ICSI procedure may permit fertilization to occur normally, but the genetic defect may be passed on to resulting offspring. There is insufficient information at this time as to whether the occurrence of these are increased or decreased by this procedure.

8. After several cell divisions when it is deemed that the embryo is developing normally, the **embryo(s) will be transferred** (placed) into the uterus by means of a small catheter tube inserted through my cervix either two, three, or five days following retrieval.

In certain situations the zona pellucida (the outer shell surrounding the embryo) is abnormally thick and/or hardened and embryos are not able to break out of the zona pellucida. This condition, which may compromise the ability of the embryo to implant in the uterine wall, is improved with a procedure called **assisted hatching**. Assisted hatching differs from routine IVF in that after the embryo(s) has begun to develop, microscopic instruments are used to make a break in the zona. This procedure (which must be performed on day 3 following egg retrieval) involves opening a small hole in the zona pellucida using micromanipulation techniques. This procedure may make it easier for the embryo(s) to emerge from their zona pellucida giving them an improved chance for implantation.

Criteria for performing selective assisted hatching include appearance of the embryo and zona pellucida. A thickened zona is commonly seen with advanced maternal age. Literature suggests that the procedure may benefit older women, those with elevated day 3 FSH levels, and some cases of unexplained infertility.

There are risks associated with this technique. The embryo may be damaged during the process reducing the number of embryos available for transfer. Despite the use of assisted hatching, implantation may not occur.

Embryo transfer may occur up to five to six days following my retrieval which is referred to as a **blastocyst culture**. Blastocyst culture involves placing embryos into culture in the laboratory for additional days to observe their continued development prior to freezing or transfer. The literature indicates that this technique maybe useful in selecting the most viable embryos, resulting in transfer of fewer embryos with a corresponding reduction in the risk of multiple pregnancies. In some cases, one or more of the embryos may cease their development prior to reaching the

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blastocyst stage. This may result in fewer embryos for transfer and, in some cases, no embryo transfer at all.

We (I) acknowledge that we (I) have discussed the possibility of the need for these procedures with our (my) physician and understand and agree that it will be utilized based on the best medical judgment of the Connecticut Fertility Associates staff at the time of our (my) procedure.

We (I) understand that we (I) will be notified if blastocyst culture is to be performed.

We (I) understand that the embryo transfer involves the placement of a small catheter (the size of a straw) into the uterus. The pre-selected embryos and a small amount of fluid that the embryos have been cultured in will be introduced through the catheter to help achieve a possible pregnancy. This may cause minor cramping and possible (but rare) complications including bleeding and infection.

The transfer of several embryos can result in multiple pregnancy (twins, triplets, or more), with an increased risk of miscarriage, premature labor, and premature birth. A premature delivery may jeopardize the life and long term health of a child and may result in substantial costs both financially and emotionally. Pregnancies with more than one baby in the uterus may also increase the occurrence of pregnancy related medical complications for the mother such as high blood pressure and diabetes. Multiple pregnancy also increases the likelihood that a cesarean section will be required.

We (I) understand Connecticut Fertility Associates adheres to the American Society of Reproductive Medicine (ASRM) "Guidelines on the Number of Embryos Transferred". According to these guidelines, the number of embryos transferred, in each case, will be determined in consultation with the physician, based on our (my) individual circumstances.

We (I) understand that rarely, embryo(s) can also implant outside of the uterus, in a fallopian tube or cervix (ectopic pregnancy) or elsewhere and require medical or surgical intervention.

9. Daily progesterone will be given to supplement the hormonal status after embryo transfer is performed. The use of intramuscular or vaginal progesterone is used to maintain the uterine lining. Early reports suggested a possible association between birth defects and the use of synthetic progesterone. The progesterone utilized in this procedure is naturally occurring and is similar to that which is normally produced by the ovary and there is no evidence of an increased risk of birth defects. Baby aspirin, antibiotics, and steroids are used as well, in selected cases.

10. A blood pregnancy test will be performed during the second week after the embryo transfer.

We (I) have been informed that if our (my) cycle results in more embryos than may be transferred, then we (I) have a choice to freeze our excess embryos (**cryopreservation**), which may be thawed and transferred back to my uterus in the future. We (I) understand that the potential benefit of cryopreservation is the possibility of establishing a pregnancy without going through an additional egg retrieving procedure. Cryopreservation of embryos has been used for many years with no evidence of adverse effects. Although there is less experience with human embryos, there is no evidence of adverse effects in children born as a result of transfer of frozen embryos. It is anticipated that about two-thirds frozen embryos will survive the thaw process. We understand that equipment failure or other unforeseen circumstances may arise which could have a negative impact on the survival of the embryos while they are still in storage. If the embryo(s) doesn't appear viable after thawing, it will not be transferred.

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We (I) also understand that pregnancy may not result due to any of the following possible events:

- a. My attempted cycle may be cancelled for medical indications or an inadequate response.
- b. Ovulation may occur spontaneously before my oocyte retrieval.
- c. An attempted egg retrieval may be unsuccessful (no eggs retrieved).
- d. The eggs may not be normal even if obtained.
- e. My partner may be unable to produce a semen specimen.
- f. Fertilization may not occur.
- g. Cleavage or cell division of the fertilized egg may not occur.
- h. The embryos may not develop normally.
- 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.

We (I) also understand that the following are some of the risks and discomforts associated with this procedure:

- a. Blood drawing: mild discomfort and a little risk of developing a bruise at the needle site.
- b. Ultrasound examination: no known risks associated with this procedure at the present time, aside from minimal discomfort
- c. The use of GnRH analogue is associated with hot flashes, body aches, vaginal dryness and other menopausal-like symptoms.
- d. 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 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.

The use of fertility drugs typically results in the placement of multiple embryos into the uterus. As discussed above, this can result in multiple pregnancy (twins, triplets, or more), with an increased risk of miscarriage, premature labor, and premature birth.

The long-term effect of fertility drugs and its association with ovarian cancer is unknown. Presently, there are no studies to date that clearly illustrate an association between fertility drugs and ovarian cancer.

- e. 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

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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.

- f. Risks of anesthesia which includes nausea, respiratory depression, and headaches.
- g. The growth of human embryos requires a source of protein. CFA may in rare cases use a protein product derived from human blood. The manufacturing process involves several purification steps including heat treatment with detergents, and treatment with ethanol which is thought to render these products free of infectious disease agents such as the hepatitis virus and the virus responsible for AIDS. These blood products are used to treat up to one million patients every year for shock, burns, and many other medical emergencies. These products are thought to be extremely safe due to screening and purification procedures utilized; however, there is a theoretical risk that the agents responsible for causing various infectious diseases could still be transmitted by utilization of these blood-derived products.
- h. 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. 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.
- j. Psychological stress.

We (I) understand that all other possible alternative procedures to allow me to become pregnant have been explained, offered, and/or attempted including adoption or no treatment at all. The advantage to me from participating in this procedure will be the opportunity for the possibility of conception, though we (I) understand that the program does not guarantee a pregnancy or a successful pregnancy. We (I) have discussed the program's current success rates with our physician.

We (I) understand and agree that the confidentiality of medical records, including photographs, X-rays or recordings, will be maintained in accordance with applicable state and federal law. Federal law requires that data concerning IVF cycles be released to the Centers for Disease Control Prevention (CDC) for external auditing. This data reporting may include identifying information. Specific medical details may be revealed in Professional publications as long as my identity is concealed.

We (I) understand that some of my blood, follicular fluid and follicular cells (not eggs or embryos) may be used for research purposes. These studies will not compromise the success of the IVF cycle.

We (I) also understand that:

- a. The Connecticut Fertility Associates will furnish emergency medical care determined to be necessary by the medical staff of this facility;

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- b. We (I) will be responsible for the cost of such care either personally or through my medical insurance or other form of medical coverage;
- c. No monetary compensation for wages lost as a result of injury will be paid to me by Connecticut Fertility Associates.
- d. We (I) expect this procedure to be performed with not less than the customary standard of care. We (I) understand the risks and benefits as outlined, and further understand and agree that Connecticut Fertility Associates shall be responsible only for acts of negligence on its part and the part of its employees, contractors, and consultants, and authorized agents.
- e. We (I) understand, agree, and acknowledge that we (I) are (am) not married to individuals who are not parties to this informed consent. This request is purely voluntary. I understand that I may withdraw my consent at any time and that my present or future care will not in any way be affected by my decision.
- f. We (I) may receive a copy of this consent form, which remains enforceable and valid for one year from the date of signing.

**Intracytoplasmic Sperm Injection (ICSI)**

We (I) acknowledge that we (I) have discussed the possibility of the need for ICSI with our (my) physician and understand, agree, and consent that **ICSI may be utilized** based on the best medical judgment of CFA staff at the time of our (my) procedure. We (I) understand that we (I) will be notified if ICSI is performed.

- Yes
- No

Female Initials \_\_\_\_\_

Partner Initials \_\_\_\_\_

**Assisted Hatching (AH)**

We (I) acknowledge that we (I) have discussed the possibility of the need for the selective assisted hatching procedure with our physician and understand, agree and consent that **assisted hatching may be utilized** based on the best medical judgment of CFA staff at the time of the procedure. We (I) understand that we (I) will be notified if AH is performed.

- Yes
- No

Female Initials \_\_\_\_\_

Partner Initials \_\_\_\_\_

**Embryo Freezing (Cryopreservation)**

We (I) acknowledge that we (I) have discussed the possibility of embryo freezing with our (my) physician and understand, agree and consent that **embryo freezing (cryopreservation) may be utilized** based on the best medical judgment of CFA staff; and that only viable embryos will be cryopreserved. We (I) understand that to consent to embryo freezing, we (I) must also execute a separate, informed consent form entitled Disposition of Embryos, which will be provided to us (me) prior to embryo transfer; and that if freezing does occur, that we will be notified as such.

- Yes
- No

Female Initials \_\_\_\_\_

Partner Initials \_\_\_\_\_

