

Date:

Consent for In Vitro Fertilization

I/We _____ and _____ being married / unmarried / single, authorize the Dr.'s at CNY Fertility Center and their designated assistant to perform in vitro fertilization and embryo transfer, and the procedures necessary for in vitro fertilization.

By signing this consent form the patient and, in the case of a married or unmarried couple, her husband or sperm donor partner, are agreeing to participate in the CNY Fertility Center Program. This document contains important information concerning the risks of procedures involved in IVF. Do not sign this form until you have read it thoroughly, you understand what it means, and all of your questions have been answered to your satisfaction.

- 1. Purpose:** In vitro fertilization is a specialized service which helps some couples achieve pregnancy. No guarantees or promises can be made that pregnancy will be achieved, or that the outcome of pregnancy will be successful.
- 2. Fertility Drugs:** Drugs to stimulate or enhance egg cell growth will be administered to the patient. Side effects of such fertility drugs may include bloating, fluid retention, ovarian cyst formation, multiple pregnancy, headache, lethargy, or pain at the injection site, among others. Rare side effects may include visual disturbances, hot flashes, blood clots, stroke or hyperstimulation of follicles. Egg cells may fail to develop in spite of fertility medications. Some older literature suggests a possible link with these drugs and ovarian cancer, yet most recent evidence is reassuring.
- 3. Ovum Recovery (egg harvest):** After egg cells (follicles which are cysts in the ovaries that contain eggs) have matured, the patient will have their eggs collected at CNY Fertility Center. Methods which may be utilized for egg cell collection include transvaginal aspiration (TVA) or, transabdominal aspiration (TAA).

TVA utilizes a needle guided by ultrasound which is passed through the wall of the vagina to puncture the follicle and aspirate the egg cell. TAA utilizes a needle guided by ultrasound which is passed through the abdominal wall to puncture the follicle and aspirate the egg cell. Analgesia and local or regional anesthesia will be given for pain relief. This is a procedure performed at the center. In addition to the risks of anesthesia, TVA/TAA risks may include internal bleeding, infection, damage to bowel, bladder or blood vessels, pain or vaginal bleeding.

In rare cases bleeding from the ovary, may necessitate a surgical procedure to stop the bleeding. Repair may be performed through a laparoscope or a laparotomy may be necessary to stop bleeding. Transfer to a local hospital may be necessary if complications occur; possibly at additional cost to you or your insurance company.

4. **In Vitro Fertilization:** Recovered egg cells are placed into a synthetic culture medium with sperm cells provided by the patient's husband or partner, or, by a commercial sperm bank. Risks involved include the possibility that fertilization may not occur, cleavage or cell division of the fertilized egg may not occur; or the embryo may not develop normally. Also, even with due care, a laboratory accident may result in loss or damage to the egg cells, sperm, fertilized egg, or embryo. Further risks inherent in the use of donor sperm from a sperm bank include genetic disorders and communicable diseases, including but not limited to hepatitis, AIDS and other sexually transmissible diseases.

5. **ICSI (intracytoplasmic sperm injection).** This is a procedure developed to help couples with male factor infertility or previous low or failed fertilization cycles. With ICSI, one sperm is physically injected into the center of the egg. This is now a routine procedure performed even with normal sperm to increase the chances of fertilization.

AH (Assisted Hatching) : This has been applied to developing in vitro embryos for the purpose of assisting implantation. A small slit is made in the developing embryo shell to enhance implantation. Embryos will be evaluated after fertilization and before embryo transfer for this procedure.

I understand that these procedures are new and all potential complications from micromanipulation may not yet be known. Consenting to these procedures does not guarantee that any of them will be performed. The necessity of these procedures will be determined by the physician and embryologist during the treatment cycle.

6. **Embryo Transfer:** Egg cells which are fertilized and continue to develop are transferred with a small amount of medium into the patient's (or designated gestational carrier's) uterus. The transfer procedure, which usually does not require anesthesia, may cause cramping and vaginal bleeding. Other rare risks include perforation of the uterus, or infection. After transfer, supplemental medications and blood analyses may be required. The transferred embryos may not implant in the uterus. The number of embryos to be transferred will be determined by the patient, the physician and the embryologist immediately prior to the embryo transfer so as to maximize the possibility of pregnancy and minimize the risk of multiple gestations. We have been informed of the risks of multiple pregnancy and realize that there is no guarantee that this will successfully limit the chance of multiple gestations.

7. **Consent For Embryo Cryopreservation.** If excess embryos are available, they may be cryopreserved for future use. By signing the appropriate section on the last page you are requesting embryo cryopreservation in conjunction with in vitro fertilization at CNY Fertility Center. Embryos chosen for cryopreservation are at the sole discretion of the physician and embryologists.

a) Risks: In addition to the risks associated with IVF, there may be other risks in connection with cryopreservation which are not recognized or fully understood at this time. In consideration of receiving cryopreservation services, you are acknowledging and assuming all such risks, and you are agreeing to release CNY Fertility Center from all liability for embryo damage, pregnancy outcome, and offspring abnormalities, whether or not caused by negligence on the part of CNY Fertility Center.

b) CNY Fertility Center Responsibilities: Will exercise reasonable care in the maintenance of cryopreserved embryos. Even with reasonable care, however, laboratory accidents, equipment failures and other events lead to embryo loss or damage.

c) Disposition: Except as stated in this consent, cryopreserved embryos will be either:

- transferred to you or a designated gestational carrier during a subsequent cycle, or
- disposed of at your direction if you elect not to have them transferred.

d) Contracts: The IVF program will contact you yearly during the time that cryopreserved embryos are stored, in order to assure the program records are current. You are responsible for notifying the Program in writing of any address change. In the event that the Program is unable, despite reasonable efforts, to contact you for a period of one year, the program will assume responsibility for disposition of the embryos at its sole discretion.

e) Costs: You are fully responsible for all costs associated with maintenance of cryopreserved embryos. Failure to pay such costs will be deemed a forfeiture of your rights with respect to the embryos. The Program may then assume responsibility for their disposition, in its sole discretion.

- 8. Other Risks:** Even under ideal conditions, not all IVF attempts result in pregnancy, and approximately 25% of these pregnancies may result in miscarriage requiring D&C (surgical scraping of the uterus) to stop bleeding. There is also the possibility of an ectopic pregnancy (pregnancy outside the uterus), which would necessitate surgery. If a pregnancy is established, complications of pregnancy may occur. If several fertilized eggs are placed into the uterus, the possibility of multiple gestation and multiple birth is increased, resulting in increased risk of fetal wastage and premature birth. IVF may involve unknown or unforeseen risks to the fetus. Although current experience and study suggests that the frequency of fetal malformations following IVF is not greater than the malformation frequency in other pregnancies, available

information is currently too limited to discount the possibility of risks to the fetus related to these procedures.

9. **Financial Obligations:** By signing this form the patient and, in the case of a married or unmarried couple, her husband or partner, acknowledge full, personal responsibility for all professional fees, facility fees, laboratory fees, and other costs incurred in IVF procedures, as well as any expenses relating to complications, miscarriages, ectopic pregnancy, prematurity, or birth defects. Our center will assist in obtaining any available insurance reimbursement.
10. **Confidentiality:** Medical records are confidential, under New York State laws and regulations. Your name and address will remain on file at the tissue bank, and shall not be disclosed to any person or entity, except upon written informed consent, or to authorized employees of New York State Department of Health (NYSDOH) or as permitted by law.
11. **General Provisions:** The information provided in this document is not intended to be exhaustive. Risks other than those described may occur. Techniques and protocols may be altered to reflect innovations in IVF procedures. Further questions may be asked by the patient at any time, and all questions will be answered. You, or both of you as the case may be, may revoke consent or withdraw from the IVF Program at any time.
12. **Authorization for Disclosure of Information:** I authorize Dr. Kiltz to disclose complete information concerning his medical findings and treatment of the undersigned, from the initial office visit until the date of the conclusion of such treatment, to those individuals who, in Dr. Kiltz's sole determination, are required to receive such information for the purpose of medical treatment, medical quality assurance, peer review and/or research.
13. Data from your ART procedure will also be provided to the Society for Assisted Technology (SART) and to the Centers for Disease Control and Prevention (CDC). The 1992 Fertility Clinic Success Rate and Certification Act requires that 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 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.
By signing this document, the patient and, if applicable, her husband or partner acknowledge that the disposition of blood, semen, egg cells and other specimens utilized in IVF procedures is within the sole discretion of CNY Fertility Center.

CNY Fertility Center

- ❖ **Sperm used for these procedures, and referred to in this consent form will be obtained from (*select appropriate source*):**
 - The husband
 Collect Here or *Collect at Home* or *Frozen Sample* or *Sperm Aspiration*
 - Sexual partner (unmarried)
 Collect Here or *Collect at Home* or *Frozen Sample* or *Sperm Aspiration*
 - An anonymous donor
Sperm Donor ID # _____
 - A known donor

In the event I cannot deliver the sperm specimen in person for IVF, I give my wife or partner permission to deliver my sperm to CNY Fertility Center.

- ❖ **Consent for ICSI (intracytoplasmic sperm injection): (Refer to section 5)**
I agree to have ICSI performed: YES NO
- ❖ **Consent for AH (assisted hatching): (Refer to section 5)**
I agree to have AH performed: YES NO
- ❖ **Consent for Cryopreservation (freezing) of embryos: (Refer to section 7)**
I agree to have any excess embryos cryopreserved: YES NO

Disagreement: Although circumstances may be remote, you are required to select ***either A or B*** for the two questions below.

A) In the event of disagreement, marital separation, or divorce, which one of you (wife or husband; patient or partner) will exercise the exclusive rights to the cryopreserved embryos?
_____ (enter full name)

OR

B) In the event of our separation or divorce we agree that the embryos will be destroyed. ____ / ____ (initials of wife and husband).

In the event of the death of both partners, the embryos will be destroyed. CNY Fertility Center shall have no liability for acts undertaken reasonable and in good faith in accordance with such determination.

By signing below I acknowledge that I have received, read, had all questions answered and understand the CNY Fertility Center IVF Consent Form.

Patient Signature

Partner Signature

Witness Signature

Patient Name (print)

Partner Name (print)

Witness Name (print)

Date: ____ / ____ / ____

Date: ____ / ____ / ____

Date: ____ / ____ / ____