

COOPER CENTER FOR IN VITRO FERTILIZATION

8002 Greentree Commons, Marlton, NJ 08053

Informed Consent for In Vitro Fertilization and Embryo Transfer

This is to certify that WE, _____ (woman, referred to herein as "patient")
"Patient" and partner _____ (man, referred to herein as "partner"),
hereby agree and have elected to undergo a standardized treatment of care known as in vitro fertilization and embryo transfer (referred to herein as IVF-ET) at the Cooper Center for In Vitro Fertilization, PC (referred to herein as CCIVF). We understand that the following statements represent our understanding and acceptance of the risks and limitations that are involved in the use of IVF-ET therapy. We understand there may be other risks that are not known at this time. We understand that IVF-ET is a procedure which provides the chance by which an infertile person or couple may conceive and bear children. We understand that we are participating in this procedure willingly and have explored other options such as adoption and non-treatment and wish to participate in IVF-ET.

The CCIVF is an active member of the Society for Assisted Reproductive Technology (SART). The organization is affiliated with the American Society for Reproductive Medicine (ASRM). In 1992, the U.S. Congress passed the Fertility Clinic Success Rate and Certification Act, which requires the Centers for Disease Control and Prevention (CDC) to publish pregnancy success rates for fertility clinics in the United States. We understand and agree that specific information will be released to SART concerning our IVF-ET cycle. All personal identifiers will be protected under the Privacy Act.

We understand and agree that our acceptance into the IVF program and our continuing participation is within the sole discretion of the medical staff of the CCIVF. We understand that we can withdraw from the program at any time without affecting the availability of other present or future medical evaluations or treatments within CCIVF. The physicians at the CCIVF may terminate IVF therapy when, in their best medical judgment, it is prudent to do so. The physician in charge will consult with Patient and Partner prior to such termination and will discuss options for future therapy.

We understand and agree that IVF-ET and its associated procedures (medications, hormone testing, ultrasound testing) is often not covered by medical insurance. We understand and agree that we are financially responsible and able to pay for this therapy and will promptly pay all charges that are not covered by medical insurance. We are aware that there will be charges we must pay before the first medications are administered in any separate treatment cycle.

We understand and agree that CCIVF may participate in the advancement of medical education which may require on a rare occasion, other medical personnel (physicians, residents, medical students, embryologists) to observe laboratory procedures or the IVF-ET procedure on me or on my behalf. Your verbal permission will be obtained prior to any non-CCIVF staff being present during the IVF-ET procedure. We consent to the collection and publication of information and data and the making of photographic presentations (slides of embryos, laboratory procedures, etc.) done for the purpose of furthering medical education and research. We understand that at no time will our identity be revealed.

During the egg retrieval procedure, the physician/surgeon may become aware of conditions or complications which were unforeseen or not known before the start of the procedure. I (patient) therefore authorize and request the physician/surgeon to perform such additional or different operations or procedures as are necessary or appropriate in the exercise of professional judgement to treat, cure or diagnose such conditions.

Patient Initials _____

Partners Initials _____

Witness Initials _____

Date _____

OVERVIEW IVF-ET PROCESS

Phase 1 Screening Process

This includes but is not limited to the initial consultation with the physician, blood testing for infectious diseases (HIV, Hepatitis, and Syphilis), a semen analysis and cultures. A recent Hysterosalpingogram (dye test of the fallopian tubes) and a mock embryo transfer and cervical cultures are completed prior to the start of the IVF-ET procedure.

Phase 2 Egg Recruitment

Due to the inefficient process of human reproduction, it is desirable to collect many eggs (oocytes) during the IVF procedure. Fertility medications are taken usually by injection for a period of 2-3 weeks prior to the IVF procedure. There are many fertility medications currently available. The CCIVF physician will prescribe the appropriate medication for you at the time of consultation. In addition to the fertility medication, many patients will take a Gn-Rh-a prior to or at the same time as the fertility medications. This is given to prevent early release of the egg(s) and to assist with uniform growth of the egg(s). A one-time injection of human chorionic gonadotropin (hCG) is taken 32-36 hours prior to the egg retrieval.

Phase 3 Egg Retrieval

The most common method of removing the eggs from the ovary is called an Ultrasound Guided Trans-Vaginal procedure. A vaginal ultrasound monitor is used to visualize both ovaries, a needle is directed through the vaginal wall directly into the ovary. Each follicle is punctured with the needle, suction is applied which removes the follicular fluid which contains the egg. The procedure usually lasts 45 minutes. Either a Certified Registered Nurse Anesthetist (CRNA) or a Registered Nurse (RN) administers sedation. Separate anesthesia consent will be presented to you by the CRNA prior to the procedure. Occasionally, the ovary is situated in an area that is not accessible from the vagina and thus it may be necessary that the egg retrieval be done using Trans-Abdominal approach.

Phase 4 Sperm Collection and Insemination of the Eggs

A semen specimen will be produced by masturbation and processed by the andrology/embryology staff. The eggs are inseminated a few hours after the retrieval. It is recommended that at least one week prior to the egg retrieval, a semen specimen be frozen (cryopreservation) and stored for emergency use (illness, inability to produce a specimen).

Phase 5 Incubation and Fertilization of the Eggs

The eggs and sperm will be placed together in a special culture fluid and kept warm in our laboratory. The eggs will be examined 16-20 hours later to evaluate how many eggs have fertilized. At the CCIVF, our average fertilization rate (non-ICSI) is approximately 62%. For example if you have 10 eggs and 6 eggs fertilized into embryos, you would be within the normal range of fertilization at the CCIVF.

Phase 6 Embryo Transfer

The transfer of the embryos usually occurs 72 hours (3 days) after the egg retrieval. This is usually a painless procedure that is completed after the patient drinks fluid (full bladder). The trans-abdominal ultrasound is used to see the uterus. The physician inserts a tiny plastic catheter containing the embryos and places the catheter through the cervix (opening of the uterus) into the uterus. A period of bed rest is necessary after this procedure.

Patient Initials _____
Partners Initials _____
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Date _____

- 7. The risk of **ectopic pregnancy** (pregnancy within the fallopian tubes) is still a concern with IVF-ET therapy. At CCIVF the ectopic pregnancy rate in 1998 was less than 2 % in all groups.
- 8. The risk of **ovarian cancer** for most women is 1% in their lifetime. The risk after use of ovarian stimulating drugs may increase to 3% according to some estimates. Ovarian cancer appears to have an inherited pattern, women with a maternal history of ovarian cancer can have risks as high as 50% for the disease. Women that have successfully conceived a child or women that have breastfed their children or women that have used oral contraceptives have been reported to have a lower associated risk of ovarian cancer. According to ASRM "until resolution of the current controversy regarding the relative risk of ovarian tumors associated with the use of ovulation inducing agents, it is necessary that the physician caution the woman that the use of (fertility medications) may increase her lifetime risk of malignant ovarian tumors.

EMBRYO DISPOSITION

We consent to the use (approved research) and subsequent disposal of eggs or embryo(s) that are judged to be not viable or not growing normally, unfertilized eggs, and/or eggs fertilized by too many sperm. In addition, we consent to the disposal of or use of other cells, body tissue and fluids that may have been obtained during the IVF process for research purposes.

We understand and accept that we also have the following choices as to the final outcome and placement of our potentially viable embryos that are not used (surplus embryos) in our IVF therapy. We authorize the CCIVF physicians and/or staff involved in this procedure to: (select only one choice), signatures must be notarized if not signed in the presence of a CCIVF staff member.

Option # 1 Freeze (cryopreserve) the embryos for our use at a future time. An additional consent form outlining additional requirements and fees for freezing must be signed if this option is selected.

We select option #1 _____
Patient Partner Witness/Notary

Option # 2 Use the embryos for scientific study permitted under the policies and applicable legal requirements of the Cooper Center for IVF.

We select option #2 _____
Patient Partner Witness/Notary

Option # 3 Donate the embryos to other infertile women or couple(s). We recognize that donated embryos will be frozen for storage. This option is only possible if we complete additional medical and genetic screening. We consent that CCIVF may dispose of the donated embryos in any manner deemed appropriate by CCIVF if a suitable woman cannot be identified to receive them.

We select option #3 _____
Patient Partner Witness/Notary

CONSENT

We have read and understand this document and additional informational information provided. We have had the chance to discuss this document with the physicians and other staff members of CCIVF. The staff has answered any and all of our questions regarding IVF to our satisfaction. We acknowledge that no guarantee or assurance has been made to the results that may be obtained. We further acknowledge that this document is by no means a complete record of our conversations with CCIVF physician(s), and staff. We understand and accept the conditions, risks and limitations of participating in the CCIVF program. We therefore voluntarily consent to undergo the procedures associated with this therapy.

RELEASE

We agree to: pardon, release, indemnity, protect and hold harmless the Cooper Center for In Vitro Fertilization, it's officers, directors, and employees from any and all liability for any adverse outcome, however remote, arising from IVF therapy including but not limited to complications related to the IVF therapy, complications related to pregnancy and/or childbirth, and/or the birth of a physically or mentally deficient child. Additionally we release, discharge and acquit harmless the Cooper Center for In Vitro Fertilization, its officers, directors, and employees from any and all liability in connection with subsequent disputes arising between patient and partner or any other third party in connection with the control and/or disposition of any fertilized eggs or embryos in existence as a result of this therapy, or the custody and/or support of any child(ren) born from this therapy.

Patient	Date	Notary Public/Witness	Date
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Partner	Date	Notary Public/Witness	Date
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Physician performing the IVF procedure	Date
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