

COOPER CENTER FOR IN VITRO FERTILIZATION
8002 Greentree Commons, Marlton, NJ 08053

Informed Consent for Frozen Embryo Transfer

This is to certify that WE: _____ (woman, referred to herein as

"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 FET) 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 FET therapy. We understand there may be other risks that are not known at this time. We understand that FET 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 FET.

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 FET 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 FET 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.

THAWING OF FROZEN EMBRYOS

At CCIVF, the clinical pregnancy success rate with frozen embryos transferred into women 39 years of age or younger in 1998 was 43.3% per transfer. This rate is approximately 5% less than the fresh rate. However, some embryos do not survive the freeze/thaw process. During your FET cycle, some or all of your stored embryos will be thawed. Each embryo will be examined to determine whether it is viable, and if so, the transfer into the patient's uterus will occur.

RISKS AND LIMITATIONS

- Establishing an IVF pregnancy using frozen-thawed embryos cannot be guaranteed for any couple.
- Some or all embryos may not survive freezing and thawing.
- Additional expenses are associated with the use of embryo freezing.
- Embryo freezing has been successfully used in animals with no known adverse results. There is, however, relatively limited experience with human embryos. Although the rate of birth defects is no higher than the general population, the risks associated with human embryo freezing, thawing and transfer are not well established at present.

Patient Initials _____
Partners Initials _____
Witness Initials _____
Date _____

FROZEN 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.

ASSISTED HATCHING OF EMBRYOS

Assisted hatching of embryos is a technique that was developed with the intent to improve the rate at which an embryo can implant inside the uterus. This procedure is performed by the embryologist prior to the time of the embryo transfer into the uterus. A small hole is made into the zona pellucida (embryo shell) by the microscopic placement of an acidic solution using a tiny probe.

Possible Limitations and Risks:

- The increased chance of success using this technique cannot be predicted.
- This being a relatively new procedure, and although unlikely, it may yield unknown risks to the baby and/or the mother. The hole in the zona may decrease the protective effect for the egg or early embryo and bacterial or viral infection may occur since the catheter used to transfer embryos has to pass the cervix, which is a potential source of infection. We believe the embryos are safe from these threats but more experience is required.
- It is conceivable that the embryo may become trapped in the artificial opening created by "hatching." In certain cases such a "pinching" action on the embryo could give rise either to loss of part of the embryo (may cause a miscarriage) or the formation of identical twins (not frequent at CCIVF).
- To prevent infection you will be prescribed two medications, Medrol (Methylprednisolone) 16-mg daily for 4-5 days and Doxycycline 100mg, two times a day for 5 days. This medication will begin prior to the embryo transfer. The dosage of corticosteroid (Medrol) is considered low, and of short duration; and although side effects are rare with the dosages used (over 2000 patients to date have received such medication without CCIVF's knowledge of any long term effects), the following medical conditions may occur after this treatment:

Side Effects of Medrol:

- A. It may mask signs of infection, and new infections may appear during use.
- B. There may be an inability to localize the infection.
- C. Blood pressure, salt and water retention, and increased excretion of potassium and calcium may occur. These effects may cause mood swings, insomnia, depression, muscle weakness, increased sweating, headache, vertigo, loss of muscle mass, osteoporosis, abdominal distention and Avascular Necrosis of the head of the femur bone.

Side Effects of Doxycycline:

- A. This is an antibiotic that is in the Tetracycline family.
- B. Nausea, vomiting, diarrhea, loss of appetite and a rash could occur.
- C. A Sensitivity to the sun, or an allergic reaction that if severe, could result in life threatening illness. A blood disease including reduced platelets could also occur.

RISKS AND LIMITATIONS ASSOCIATED WITH FET

1. The occurrence of multiple pregnancy at CCIVF for women 39 years of age and younger in 1998 was: quadruplet (4)=0.7 %, triplet (3)=12.6%, twins(2)=27.4% (an average of 3.3 embryos were transferred). The IVF staff will discuss with you their recommendation for the number of embryos to be transferred. Multiple pregnancy especially triplets and higher orders is associated with increased risk of pregnancy loss, premature delivery, infant abnormalities, handicap due to the consequences of very premature delivery, pregnancy induced hypertension and diabetes, and other significant maternal complications. These pregnancies may lead to emotional and financial strain for the family and prolonged hospitalization of the birth mother before birth and of both the mother and infants after birth. Multifetal pregnancy reduction is an option for some couples facing the challenge of multiple births.

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- 2. The CCIVF cannot guarantee that you will conceive and deliver a child. Your chance of obtaining a pregnancy will be discussed with you based on recent statistics of other patients of similar age and medical conditions. According to the 1996 ART Success Rates: 20,659 babies were born as a result of the 64,036 ART cycles. According to ASRM, the risk of birth defects in children conceived through IVF is not higher than the general population.
- 3. The risk of ectopic pregnancy (pregnancy within the fallopian tubes) is still a concern with FET therapy. At CCIVF the ectopic pregnancy rate in 1998 was less than 2 % in all groups.

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 hold harmless and indemnify, the Cooper Center for In Vitro Fertilization, its physicians, nurses, employees, and/or legal representatives from any and all liability, damages, injuries, losses, claims suits or demands by us or any one else which may result from our participation in this program, whether such injuries, damages, or losses are known, unknown, foreseen, unforeseen, patent or latent resulting from or caused by the IVF therapy, related laboratory procedures (i.e. ICSI, Assisted Hatching), complications related to pregnancy and/or childbirth, and/or the birth of a physically or mentally deficient child(ren). This release shall also apply to 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.

We understand and acknowledge the significance and the consequences of this Release and we hereby assume full responsibility for any injuries, damages or losses that may occur by the IVF Therapy.

This release dated this _____ day of _____, 200__, will be governed by the laws of the State of New Jersey.

_____	_____	_____	_____
Patient	Date	Notary Public/Witness	Date
_____	_____	_____	_____
Partner	Date	Notary Public/Witness	Date
_____	_____		
Physician performing the FET procedure	Date		
_____	_____		
Embryologist performing AH	Date		