

COOPER CENTER FOR IN VITRO FERTILIZATION

8002 Greentree Commons, Marlton, NJ 08053

Informed Consent for Laboratory Procedures Associated with In Vitro Fertilization and Embryo Transfer

	<i>Initials</i>	<i>Patient</i>	<i>Partner</i>
Insemination of Oocytes (eggs):	Conventional Methods (standard)	_____	_____
	Intracytoplasmic Sperm Injection (ICSI)	_____	_____
Other Laboratory Techniques:	Assisted Embryo Hatching	_____	_____
	The Use of Special Culture Media	_____	_____
	Other (add. consent req.) _____	_____	_____

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 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 the above noted Laboratory Procedures during our IVF-ET cycle. We understand there may be other risks that are not known at this time. We understand that in addition to the IVF-ET procedure, these laboratory techniques may provide 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.

Additional consent forms may be required in certain situations such as: patients receiving oocytes (eggs) from another woman that is either anonymous or known to the patient as well as the partner receiving sperm from another man that is either anonymous or known to the partner.

The Embryology Laboratory staff of the CCIVF consists of a highly capable, well trained and experienced staff. The Laboratory has been in existence as the CCIVF since 1991 and has completed more than 4,000 oocyte (egg) retrievals and approximately 2,500 frozen embryo transfers during that time. Pregnancy success rates dramatically improved during the year of 1997. Depending on your individual and combined infertility risk factors (age, and documented infertility factors) your chance of achieving a pregnancy and delivering a child can be determined by the CCIVF medical staff based upon the recent program statistics.

CCIVF Laboratory has met all required minimum standards as detailed in the *Revised Minimum Standards for In vitro Fertilization, Gamete Intrafallopian Transfer, and Related Procedures 1998*. The American Society of Reproductive Medicine (ASRM) devised these guidelines in an effort to standardize the laboratory procedures used during the IVF-ET process. This document details guidelines for: Personnel education, experience and special training, quality assurance, maintenance of equipment, general safety, record keeping and informed consent. The CCIVF has achieved the distinction of acquiring both the CAP and CLIA certifications.

Witness Initials _____
Date _____

A detailed explanation of Assisted Hatching of Embryos, Conventional Insemination of Oocytes (eggs), Intracytoplasmic Sperm Injection (ICSI) of Oocytes, the use of Special Culture Media, as well as other specific techniques that may be suggested to improve your chances of pregnancy.

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.

CONVENTIONAL (STANDARD) INSEMINATION OF OOCYTES (EGGS)

Once the eggs have been retrieved, and the sperm has been processed, they will be placed together in a culture fluid and kept warm in an incubator in our laboratory. This process is called insemination. The eggs will be examined 16-20 hours after insemination for signs of fertilization.

Patient Initials _____

Partners Initials _____

Witness Initials _____

Date _____

INTRACYTOPLASMIC SPERM INJECTION (ICSI)

Intracytoplasmic sperm injection (ICSI) is a laboratory procedure that was developed to overcome infertility caused by severe male factor. Eggs and sperm are obtained by using standard methods during an in vitro fertilization treatment cycle. Sperm are then prepared in a manner to select and retain only the most active sperm in a small volume of culture medium. Substances known to increase the motility of sperm may be added to the nutrient liquid used to prepare sperm in cases where the movement of the sperm is reduced. After exposing the mature eggs to an enzyme that removes the cumulus cells which surround the egg, each egg is placed under a microscope and held in place by gentle vacuum with a small glass tube called a micropipette. A single sperm is then drawn up into an extremely sharp, hollow glass needle along with a very small amount of the nutrient liquid medium. The needle is then quickly passed through the zona pellucida (the gel-like shell of each egg) and the cell membrane to inject the sperm into the center of the egg by using a special microscope assembly. Approximately 16-18 hours after ICSI, the eggs are examined under the microscope for any sign of damage and to assess for the presence of two distinct pronuclei, which indicates normal fertilization.

Indications for ICSI:

- Very low numbers of motile sperm
- Sperm that are positive for antisperm antibodies
- Prior or repeated fertilization failure or poor fertilization rates using conventional insemination methods
- The use of frozen sperm collected prior to cancer treatment or vasectomy
- The use of sperm which has been surgically collected from the testicle (epididymis)

Possible Limitations and Risks:

- Long term risks to the child are not completely known at this time. Ongoing studies are being conducted at this time to determine if there are significant risks to the child conceived using ICSI. To date there does not seem to be any good evidence to suggest that a child is at risk for genetic abnormalities but there is also no guarantee that all babies will be normal.
- In the cases of male factor infertility where the sperm count is almost zero, the inability to produce sperm may be due to a genetic abnormality on the Y chromosome of the male. Studies have indicated that this genetic defect may be passed on to the male offspring of the couple.
- Damage to the egg may occur during the actual injection of the sperm into the cytoplasm.
- Fertilization and or success cannot be predicted or guaranteed.

Patient Initials _____
Partners Initials _____
Witness Initials _____
Date _____

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 to our satisfaction any and all of our questions regarding the laboratory procedures that may be used during our in vitro fertilization cycle. 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 the completion of the laboratory procedures initialed within this document.

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.

____ In addition to the consent form(s): Consent for IVF, Consent for Cryopreservation and Consent for Laboratory Procedures, I/We has signed other consents.

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

Embryologist performing AH / Date