

**WAKE FOREST UNIVERSITY HEALTH SCIENCES  
CENTER FOR REPRODUCTIVE MEDICINE**

**CONSENT TO PARTICIPATE IN THE *IN VITRO* FERTILIZATION-EMBRYO TRANSFER  
PROGRAM**

I \_\_\_\_\_, after consultation with my physician, request to participate in the In Vitro Fertilization (IVF)-Embryo Transfer (ET) procedures at the Wake Forest University Health Sciences Center for Reproductive Medicine (“Center”).

**PROCEDURE**

I understand and consent to the following steps and procedures:

1. Stimulation and maturation of multiple egg development by medications. Antagon/Lupron will be used to prevent the premature release of eggs. Medications used to stimulate multiple egg development (ovulation induction), include but are not limited to, Bravelle®, Follistim®, Gonal-F®, Pregnyl® or other hCG (human chorionic gonadotropin) products will be used to allow the eggs to go through the final maturation process prior to egg retrieval. The medications are primarily in the form of daily injections. The patient is responsible for the administration of medications.
2. Blood samples and ultrasounds which will be performed periodically to evaluate the development of the eggs.
3. Removal of egg(s) by an ultrasound guided needle under conscious intravenous (I.V.) sedation.
4. Obtaining sperm samples from donor agency.
5. Mixing of eggs and sperm to form embryos (*in vitro* fertilization). Additional procedures known as micromanipulation may be needed. These include ICSI (intracytoplasmic sperm injection) and assisted hatching. ICSI is used when the sperm sample is not sufficient (poor sperm count and/or motility) to allow normal fertilization. This procedure involves the lab selecting individual sperm to inject into each egg. Assisted hatching is used in cases in which the zona (coating around the embryo) is too thick to allow for normal attachment of the embryo to the uterus. Assisted hatching is also recommended for patients who are thirty-six or over. Both ICSI and assisted hatching require additional consent and additional charges.
6. Transfer of embryos to the uterine cavity. The normal number of embryos transferred into the patient at one time to attempt a pregnancy is generally two to three. In the event that surplus embryos are formed, I may request that the remainder be cryopreserved. The Center, in consultation with the patient, will determine how many embryos are transferred into the patient at one time and how many are cryopreserved.
7. Daily injections of progesterone. These injections will begin after egg retrieval and continue until the day of the pregnancy test. Progesterone is used to prepare the uterine lining for implantation of embryo(s).

8. Optional cryopreservation of extra embryos for later thawing and use. If I choose not to have our embryos cryopreserved, then the Center will fertilize only a limited number of eggs with donor's sperm and discard the remaining eggs. I understand that in this circumstance, if pregnancy is not achieved following transfer of the embryos into the patient, then to make another attempt I must repeat the steps requiring ovulation induction, retrieval of eggs and obtaining sperm samples.

## **REASONS FOR IN VITRO FERTILIZATION**

I have been advised that IVF is a treatment for many causes of infertility, including but not limited to; tubal disease/blockage, ovulation disorders, unexplained infertility, and male factor infertility. IVF is usually used when simpler, less invasive methods have not resulted in a pregnancy. IVF may also be used as a first line treatment in couples with severe male factor infertility. It may also be used in conjunction with pre-implantation genetic diagnosis (PGD) for couples who are at risk for passing on genetic disorders to their children.

## **ALTERNATIVES**

I have been advised of alternatives to assisted reproduction including adoption, child-free living and further treatment with less costly therapies.

## **RISKS**

I have been advised of the following risks:

The patient may not produce a sufficient number of healthy eggs. This may result in the canceling of my IVF procedure. I may request the Center to arrange for an egg donor through another ART Center providing donor egg services for any subsequent IVF cycles.

I understand that I will be liable for the costs involved in obtaining the donor sperm. If donor eggs are necessary, I understand that additional testing will need to be done, which may delay my cycle. I also understand that I may be required to meet with the Center psychologist to discuss the use of either donor sperm or donor eggs.

Risks and side effects of the medications used for the development and maturation of eggs are outlined below. Side effects of Lupron® include hot flashes and vaginal dryness or spotting. A side effect of the ovulation induction agents (i.e. Follistim®, Gonal-F®, Bravelle®, Repronex®) and hCG is hyperstimulation of the ovaries. Symptoms of such hyperstimulation include lower abdominal pain, pressure, and weight gain. Hyperstimulation is usually relieved by discontinuing the medication. In severe cases of hyperstimulation there may be the accumulation of fluid in the abdomen or in the lung cavity. Severe hyperstimulation requires hospitalization for bed rest, pain medication, fluid replacement, and monitoring. Rare instances of unusually severe hyperstimulation can be life-threatening. The risk of severe hyperstimulation following egg retrieval is lower than that associated with cycles where eggs are released spontaneously. Other side effects of the ovulation induction agents include, but are not limited to, nausea, mood swings, hot flashes, breast tenderness, and fatigue, and local irritation at the injection site. There is some concern in the medical literature that the use of ovulation induction agents may increase a person's risk of developing ovarian cancer. Women with a history of infertility, independent of their use of ovulation induction agents, do have a higher incidence of ovarian cancer. Pregnancy and past use of oral contraceptives appear to have some protective effect.

Risks of vaginal ultrasound egg retrieval include, but are not limited to, the possibility of bleeding, injury to internal organs, or infection that may require antibiotic treatment. Discomfort may be experienced during the retrieval. Bleeding, organ injury and infection may require surgery, although this is rare; however, surgery and anesthesia, if required, pose risks which include potentially life-threatening conditions. In addition, there is also the small possibility that no eggs will be retrieved. This may be due to premature release of the eggs, or pre-existing pelvic scarring or technical difficulties preventing the safe recovery of eggs.

Risks of ICSI include, but are not limited to, damage to the eggs or failure of the eggs to fertilize. Either of these may result in canceling the cycle. There is a 2-5% risk of birth defects with natural conception. ICSI pregnancies have an additional 1-2% (therefore, a combined 3%-7% risk of birth defects. ICSI does not appear to increase the risk of miscarriage.

Risks of assisted hatching include, but are not limited to, damage to the embryo(s). This may result in the cycle being canceled.

The side effects of progesterone injections, include but are not limited to, breast tenderness, irritability, nausea, depression, the development of acne, and irritation at the injection site.

There are no known medical risks to embryos which are cryopreserved and later thawed. As with any technique requiring mechanical support systems, equipment failure can occur. The Center does not assume responsibility for any destruction or damage caused by such failure. With current freezing techniques, approximately sixty (60) to eighty (80) percent of the frozen embryos may be viable after thawing.

The risks associated with transfer of the embryos back into the patient's uterine cavity are uterine cramping, infection, and perforation of the uterus.

The risk of miscarriage from *in vitro* fertilization pregnancies may be higher than that in normal pregnancies.

The risk of multiple births from a pregnancy achieved through *in vitro* fertilization is higher than in normal pregnancies. There is about a twenty-five (25) - thirty (30) percent chance that, if pregnancy is achieved and carried to term, twins will be born. The risk of triplets, quadruplets, or quintuplets is about three percent.

Studies have shown that there are no known ill effects to the offspring born by *in vitro* fertilization. The long-term effects are yet to be determined. The incidence of birth defects associated with IVF appears to be no greater than in the general population.

### **Pregnancy and Follow-Up**

The Center has not given me any assurance that I may become pregnant through the assistance of the Center.

Should IVF result in a pregnancy, I understand that the pregnancy will be monitored by the Center until a heartbeat(s) is detected. Once this milestone has been reached, I will be released to an obstetrician for care. I understand that the Center is required to obtain follow-up information from my obstetrician regarding the pregnancy and its outcome.

## **Termination and Rights to Withdrawal**

My participation in the program at the Center may be terminated by any of the following:

1. I test positive for the presence of HIV or hepatitis.
2. I request in writing to withdraw from the program at the Center.
3. My physical or mental condition renders me permanently incapable of receiving a transfer of embryos or of carrying a pregnancy to term. The Center retains sole discretion to make this determination.
4. Upon my death.
5. I fail to pay any charges assessed by the Center, including annual storage embryo storage, except that there shall be no termination for this reason until the Center has notified me in writing of the accrual of unpaid charges, sent to the most recent address I have given to the Center.
6. I request the transfer of any cryopreserved embryos to another *in vitro* fertilization/ cryopreservation Center. I am responsible for any charges incurred by the Center in said transfer.
7. I request the transfer of any cryopreserved embryos to myself (with appropriate storage during transfer). I am responsible for any charges incurred by the Center in said transfer.
8. The *in vitro* fertilization or cryopreservation procedures are discontinued by the Center. In this event, I will be notified in writing by the Center by mail, sent to the most recent address I have given to the Center. I will have ninety (90) days to request the Center to transfer the cryopreserved embryos to another Center at the Center's expense, or to me; otherwise, the Center will have the right to determine the disposition of the cryopreserved embryos in accordance with the options discussed under **Disposition**.
9. If I have not decided on disposition of my embryos within three years from the date of cryopreservation, the Center retains the right to transfer embryos to an outside storage facility operating under accepted standards and prevailing law regarding the storage of human embryos.

## **Disposition**

Upon termination of my participation in the Center, there are three alternatives for the disposition of cryopreserved embryos:

1. I can donate our cryopreserved embryos to an outside agency for embryo adoption by another couple.
2. I can request transfer at my expense to another IVF program or outside storage facility operating in accordance with the guidelines of the American Society of Reproductive Medicine and accepted standards of care for human embryos.
3. I can request that the embryos be given to us with appropriate storage arrangements (at our expense).

I understand center does not discard medically viable embryos.

I understand and agree that when the embryos are determined to be nonviable by the Center, the Center will dispose of them,

### **Signature Statement**

Medical records of the patient enrolled in the program at the Center are confidential and will not be released except as authorized by the patient or by law. However, I consent to the Center's photographing or videotaping the procedures performed by the Center as set out in the attached Authorization of Use or Disclosure of Protected Health Information. Such photographs or videotapes will be retained as documentation of our care and treatment, and they may also be used for educational purposes by medical doctors, medical students, and non-physician staff employed by or associated with the Center. My identity will not be released outside the Center with such photographs or videotapes.

I understand that The Center is a part of the Wake Forest University Baptist Medical Center, which is medical teaching facility. Accordingly, residents and medical students may observe or participate in the procedures performed by this Center.

If I make the Center or its officers, employees or agents a party to any litigation arising from any disagreement to my rights to the cryopreserved embryos I will be jointly and severally liable for the reasonable attorney's fees and other costs incurred by the Center in such litigation.

I agree to keep my most current mailing address on file with the Center at all times during my participation in this Center and for at least one year thereafter. I also consent to the Center obtaining pregnancy out-come information from our obstetrician should a pregnancy result from this procedure.

**I am personally responsible for all costs and expenses incurred due to my participation in this Center. I am aware that my insurance may not reimburse me for the Center's services.**

I understand that if I choose to have embryos frozen, I must sign the ***CONSENT TO EMBRYO CRYOPRESERVATION***, which is located below. I understand that if I do not sign this consent, the Center will fertilize only a limited number of eggs.

I understand and agree that if I choose to allow the Center to perform ICSI or assisted hatching I must sign the ***CONSENT TO MICROMANIPULATION (ICSI and ASSISTED HATCHING)*** which is located below. I also understand that if I do not sign this consent, these procedures will not be used and this may result in no embryos or embryos that may not be viable.

I will pay the Center's prevailing charges for cryopreservation and maintenance of my embryos. Cryopreserved embryos will be kept by the Center for as long as they are medically recognized to be viable.

I hereby consent to participate in the *in vitro* fertilization ("IVF") procedure at Wake Forest University Health Sciences, Center for Reproductive Medicine. I acknowledge receipt of this Consent and the accompanying explanatory material "ART: Assisted Reproductive Technologies" at least seventy-two (72) hours before signing this Consent and that I have read said document. I acknowledge and agree that all my questions concerning the Center, *in vitro* fertilization, cryopreservation, micromanipulation, and costs related to these procedures have been answered to my satisfaction by the Center's staff.

I agree that North Carolina law will govern the procedures described above.

An executed copy of this form has been provided to me for my records.

\_\_\_\_\_  
Patient Date

\_\_\_\_\_  
Witness Date

**CONSENT TO EMBRYO CRYOPRESERVATION**

I agree to the cryopreservation of additional embryo(s) as outlined above. If at any time prior to the egg retrieval, I decide not to have any embryos cryopreserved, I will notify the Center of this decision.

I also acknowledge that should I have embryos cryopreserved, I am responsible for paying the yearly storage fee assessed by the Center for Reproductive Medicine/Wake Forest University Health Sciences.

\_\_\_\_\_  
Patient Date

\_\_\_\_\_  
Witness Date

**CONSENT TO MICROMANIPULATION INCLUDING  
ICSI and/or ASSISTED HATCHING**

I agree to the use of micromanipulation using ICSI (intracytoplasmic sperm injection and/or assisted hatching as outlined above. I understand that these two procedures will only be used if the laboratory personnel feel that is it necessary to assist with the fertilization of the eggs or to assist with the implantation of embryos. If at any time prior to the egg retrieval, I decide I do not want micromanipulation performed, I will notify the Center of this decision.

I also acknowledge that should micromanipulation be used, there will be an additional charge or charges for these procedures. In the event our insurance does not pay for these procedures, I understand that I will be responsible for paying these charges.

\_\_\_\_\_  
Patient Date

\_\_\_\_\_  
Witness Date

revised 12/01/04