I _____ and _____
(Print Patient's name) (Print Partner's name, if applicable)
have requested treatment by the physicians and staff of the Women & Infants Fertility Center (WIFC) for the purpose of fertility preservation. I/we consent to allow the WIFC physicians and staff ("IVF team") to perform in vitro fertilization (IVF) procedures and cryopreserve (freeze) the resulting embryos (eggs fertilized by sperm) for the purpose as outlined in the document below.

Part I – Patient

Fertility Preservation of Embryos

Patients diagnosed with a condition requiring treatments that may damage their ovaries' ability to produce healthy eggs (gonadotoxic therapy) may be candidates for procedures which will potentially preserve their ability to become pregnant. The most established strategy for preservation of female fertility is for a patient to undergo a cycle of IVF and create embryos for future use. All embryos created during this process are cryopreserved (frozen) until such time as the patient is medically able to undergo Embryo Transfer (receiving the embryo(s) back into the uterus).

Introduction to In Vitro Fertilization (IVF).

IVF is a process whereby egg growth is stimulated in the ovaries with the resultant eggs being retrieved and fertilized by sperm in the laboratory. The purpose of this consent is to describe an IVF cycle which typically includes the following steps or procedures:

A) Medications to grow multiple eggs;
B) Retrieval of eggs from the ovary(ies);
C) Insemination of eggs with sperm;
D) Culture and cryopreservation (freezing) of any resulting fertilized eggs (embryos);
E) Placement ("transfer") of one or more embryo(s) into the uterus; and
F) Support of the uterine lining with hormones to permit and sustain pregnancy.

These steps are further discussed below.

Medications (hyperstimulation), monitoring and blood tests.

The use of "fertility drugs," such as oral contraceptive pills, GnRH-agonists, gonadotropins, GnRH-antagonists, human chorionic gonadotropin (hCG), progesterone, estradiol, letrozole, and antibiotics, has been explained to me, and their respective risks and side effects have been discussed. I understand that some of these drugs may be used "off label" (not approved by the FDA for this use). I am aware that some of these medications are self-administered at home by intramuscular or subcutaneous injection and may cause bruising and discomfort at the injection site.

I understand that complications may arise as a result of taking fertility drugs. Complications from taking these medications include, but are not limited to:

- infection
- ovarian enlargement and/or hyperstimulation*
- damage to the ovaries
- adverse or allergic drug reaction
- very rarely, blood clots, stroke, heart attack, and/or death

My physician has discussed with me and I understand that *Ovarian Hyperstimulation Syndrome (OHSS) can be a serious risk/complication from taking fertility drugs. Symptoms of OHSS include increased ovarian size, ovarian torsion (twisting of the ovary), nausea and vomiting, accumulation of fluid in the abdomen, breathing difficulties, an increased concentration of red blood cells, kidney and liver problems, and in the most severe cases, blood clots, kidney failure, or death. In severe form of OHSS, serious complications may require hospitalization and medical intervention.

I acknowledge the importance of maintaining close contact with the IVF team during the period of time while I receive these medications and for a minimum of two (2) weeks afterwards. While taking any of the above medications, I will be closely monitored by the IVF team with blood tests and ultrasounds. This monitoring may be daily and carries the risk of mild discomfort and bruising at the venipuncture (blood draw) site.

I am aware that transvaginal ultrasound examinations will be performed, and that there may be some discomfort with this procedure. If monitoring suggests a low probability for successful egg retrieval, my stimulation cycle may be stopped and no egg retrieval will be performed. Alternatively, if my physician thinks that I am at risk for severe OHSS, the stimulation medications may be discontinued and the cycle canceled.

Transvaginal Oocyte (Egg) Retrieval

Oocyte (egg) retrieval is the removal of eggs from the ovaries through use of a transvaginal ultrasound probe and a needle. At a time determined by the IVF team, I will be admitted to Women & Infants Fertility Center as an ambulatory patient. If anesthesia is required for egg retrieval, I will sign a separate anesthesia consent form on the day of procedure. Rarely, the ovaries are not accessible by the transvaginal route, and transabdominal retrieval is necessary.

Risks of egg retrieval include, but are not limited to:

- Infection: Bacteria normally present in the vagina may be inadvertently transferred into the abdominal cavity by the needle and may cause an infection of the uterus, fallopian tubes, ovaries or other intra-abdominal organs. Treatment of infection could require the use of oral or intravenous antibiotics. Severe infections occasionally require surgery to remove infected tissue. Infections can have a negative impact on fertility.

- Bleeding: Small amounts of blood loss are common during egg retrievals. Major bleeding may

require surgical repair. The need for blood transfusion is rare; however, in very rare circumstances, unrecognized bleeding can lead to death.

- Trauma: Despite the use of ultrasound guidance, it is possible for organs or structures within the abdomen to be injured. Injury to internal organs or structures may result in the need for additional treatment, including but not limited to admission to the hospital, blood transfusion or surgery.

I understand that there is no guarantee that any eggs will be retrieved during this process. If eggs are not retrieved, I understand I will not get pregnant during this cycle.

Following egg retrieval, I may experience mild abdominal discomfort and/or light vaginal bleeding. I understand that if I experience severe abdominal pain, heavy bleeding, and/or a temperature of over 100.5 degrees F, I need to contact WIFC immediately. If I am experiencing a true medical emergency, I understand I should call 9-1-1 or go directly to the closest emergency department.

Fertilization of the eggs with sperm

I understand that following successful egg retrieval, the eggs are evaluated and prepared for the fertilization process by the embryology staff. Fertilization is achieved by insemination (placing the sperm around the egg) or intracytoplasmic sperm injection (ICSI-injecting a single sperm into the egg).

- If frozen sperm or donor sperm is used, additional consents are required.
- Authorization for the storage and use of frozen sperm is also required for the laboratory

I am aware that the physician/embryology staff makes the decision to proceed with insemination versus ICSI. This decision is based on sperm and/or egg quality and/or quantity available for fertilization. ICSI is only performed after an additional consent form is signed.

General IVF Consent Provisions

I understand that the lists of risks and complications related to the above procedures are not complete and that my physician has discussed with me that other unforeseen risks do exist and that additional procedures may be required. I consent to those procedures which my physician deems necessary.

Alternative options to IVF and the risks and benefits of these alternative options have been explained to me by the IVF team, including procedures that are not performed at WIFC, and other non-medical options such as adoption or non-treatment, and I understand them.

I understand that evaluation, including tests for HIV and hepatitis, will be performed as a routine part of the IVF process. Other studies as indicated by medical and/or family history may also be obtained.

I understand that I may require a blood transfusion as a result of these procedures. I understand that blood transfusions are done with blood donated by volunteer donors. I understand there are unforeseen complications associated with a transfusion, including but not limited to transfusion transmitted diseases (HIV, AIDS), allergic reactions, chills, fever, heart, lung or kidney problems or even death. The

associated risks and benefits of a blood transfusion have been discussed with me. I acknowledge that blood transfusion treatment alternatives have been discussed with me.

I acknowledge that the physicians at the Women & Infants Fertility Center are only managing infertility and that I am responsible for obtaining my general medical and gynecologic care through other physicians.

I understand that Women & Infants Hospital is a teaching hospital where fellows, residents and advanced practicing medical and nursing students may observe and/or perform IVF and its related procedures under the direct supervision of licensed practitioners of accredited teaching programs.

Part II – Patient and Partner, if applicable

Embryo Cryopreservation

As a part of the IVF for Fertility Preservation (Embryos) process, I/we understand that all embryos will be cryopreserved (frozen) for use at a future date. I/we consent to cryopreservation (freezing) of all embryos by WIFC for possible transfer in a subsequent cycle.

I/we understand that some embryos may not reach the stage of development where they can be frozen. The IVF physicians and/or embryology staff determine which excess embryo(s), if any, are appropriate for freezing.

The risks and benefits of cryopreservation have been discussed with me/us and I/we understand them. I/we understand that complications can happen as a result of the process. Complications include, but are not limited to:

- Damage to embryos – I/we understand that the embryos may be damaged during the freezing process, or during the storage period. If an embryo is damaged, it will not successfully survive the thaw and is not transferred back to attempt pregnancy.
- Loss of embryos – I/we understand that embryos can be lost during the culture, freezing or storage period.
- Failure of embryo(s) to develop normally after thawing. Embryos that do not develop normally are not transferred back to attempt pregnancy.

I/we acknowledge that embryos may be damaged as a result of the malfunction (failure to work properly) of equipment used in the embryology laboratory, and this damage is beyond the control of WIFC.

I/we are aware that there is no guarantee that pregnancy will occur following the transfer of any thawed embryo(s).

I/we understand that any pregnancy following the transfer of any thawed embryo(s) is subject to the same risks and complications as pregnancies achieved without medical intervention. These complications include, but are not limited to:

- ectopic pregnancy (pregnancy occurring outside of the uterus and is life threatening)
- preterm labor
- pregnancy with birth defects
- miscarriage
- stillbirth

Alternative options to cryopreservation and the risks and benefits of those alternative options have been explained to me/us and I/we understand them. These alternatives may include, but are not limited to:

- discarding excess embryo(s);
- donating excess embryo(s) to another person (This option requires Food and Drug Administration (FDA)-approved screening and testing prior to donation.);
- donating excess embryo(s) for research;
- transporting frozen embryo(s) to another facility.

I/we understand that the lists of risk and complications related to the above procedures are not complete and that my/our physician has discussed with me/us that other unforeseen risks do exist and that additional procedures may be required. I/we consent to those procedures which my/our physician deems necessary.

I/we acknowledge that I/we are responsible for all costs and fees incurred for embryo freezing and storage.

<u>Discarded Material</u> (Patient and Partner, if applicable, to initial below)

_____ _____
patient initial partner initial

In the hope that I/we may help others, I/we donate for teaching or research purposes any unused biological material including follicular fluid, sperm, immature and/or unfertilized eggs, abnormal and/or arrested embryos (those which have stopped developing) which otherwise would be routinely discarded. I/we understand that no new pregnancies will be generated using this material. I/we understand that by agreeing to this donation there is no additional risk to me/us. I/we also understand that I/we may refuse to donate this material and the treatment given would not be affected.

My/our limitations are: _____

I/we consent to the taking of photographs, videotapes and/or illustrations of my/our procedures, eggs, embryos, etc. and other medical problems for diagnostic, educational or scientific purposes, provided my/our identity is not revealed.

I/we are aware that the practice of medicine is not an exact science. I/we acknowledge that no guarantee or promise has been given to me by anyone as to the results of the above treatment and procedures. I/we understand that the above procedures are done by the Women & Infants Fertility Center team and that

my/our primary physician may not be the one doing them.

I/we acknowledge that this form has been explained to me/us and I/we understand its contents. I/we have had the opportunity to ask questions which have been answered to my/our satisfaction.

Time: _____ A.M./P.M. Date: _____ Signature: _____
Patient

Time: _____ A.M./P.M. Date: _____ Signature: _____
Partner, if applicable

Provider's Acknowledgement:

I confirm that consent, as described above, has been given by this patient and partner, if applicable.

Time: _____ A.M./P.M. Date: _____ Signature: _____
(Provider)

Print Name:_____
(Provider)

Interpreter's Acknowledgement (if applicable):

I confirm that consent as described above, has been given by this patient and partner, if applicable.

Time: _____ A.M./P.M. Date: _____ Signature: _____
(Interpreter)

Print Name:_____
(Interpreter)

<u>For Partner's Consent if not signed at WIFC</u>

STATE OF _____
COUNTY OF _____

Then personally appeared before me the above named _____, and being duly sworn under the penalty of perjury acknowledged the foregoing to be his/her free act and deed this _____ day of _____, 20____.

NOTARY PUBLIC: _____
MY COMMISSION EXPIRES: _____