40668

WOMEN & INFANTS HOSPITAL
Providence, RI 02905

CONSENT FOR THAWING AND TRANSFER OF CRYOPRESERVED EMBRYOS

FOR INPATIENTS: AFFIX PATIENT LABEL **OR** WRITE IN BOTH PATIENT NAME & MR NUMBER

FOR OUTPATIENTS: WRITE IN BOTH PT NAME & DOB

PATIENT NAME: _____

DOB OR MR #: _____

I _____ and _____
(Print Patient's name) (Print Partner's name, if applicable)
consent to the thawing of previously cryopreserved (frozen) embryos (eggs fertilized by sperm) by Women & Fertility Center (WIFC) for the purpose of transferring the thawed embryo(s) into patient's uterus to attempt a pregnancy.

PART I - PATIENT

In vitro fertilization (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. This consent describes the process of transferring previously frozen embryos created through IVF, as outlined below.

Timing of Embryo Thaw and Uterine Preparation

I understand that while preparing for transfer of embryos, I will be closely monitored by the physicians and staff at WIFC ("IVF team"). The embryos can be thawed during:

1) a natural cycle, where the timing of ovulation is determined by close monitoring through blood tests as well as ultrasound examinations, or
2) a "programmed" cycle, where similar hormones produced by the body (including, but not limited to, estrogen and progesterone) are taken to prepare the uterus for the embryo transfer.

I am aware that uterine monitoring includes frequent ultrasounds and/or daily blood drawing, which carry the risk of mild discomfort and bruising at the puncture site. I understand that transvaginal ultrasound examinations of the uterine lining are performed as necessary, and that there may be mild discomfort with this procedure.

I understand that my physician will review the risks of each of the medications that are prescribed to me. In general, the risks of these medications include (but are not limited to):

- Bone loss
- Allergic reaction
- Increased risk of clotting
- Infection at injection site (for medications given by injection)

Embryo Transfer

During embryo transfer, the embryos will be placed in my uterus. Embryo transfer is typically performed under ultrasound guidance without anesthesia. If anesthesia is required, I will sign a separate consent for anesthesia on the day of the procedure.

I understand that the transfer of embryo(s) into the uterine cavity may cause some cramping, discomfort, and, possible, a small amount of bleeding. There is also a risk of infection, which may require antibiotic treatment.

I am aware the outcome of IVF correlates with the number and quality of embryos transferred. I understand that transferring more than one embryo places me at risk for multiple gestations (more than one baby), and that the seriousness of the risk correlates directly with the number of embryos transferred.

The risks of multiple gestations include, but are not limited to:

- Preterm labor and the delivery of premature infant(s) that may require intensive care and may have long-term complications associated with prematurity
- Pregnancy-inducted diabetes
- Pre-eclampsia (a dangerous elevation of blood pressure during pregnancy)
- Miscarriage

I acknowledge that it is WIFC's policy to limit the number of embryos transferred according to age of the person providing the egg(s) at the time of freezing and embryo quality. My physician has explained that the purpose of this policy is to optimize the chance of pregnancy while reducing the rate of multiple gestations.

I am aware that an embryo transfer may not be performed in certain circumstances, including but not limited to:

- When there are no suitable embryos for transfer.
- A suboptimal natural cycle or inadequate response to supplemental hormones (if given) which prevents successful implantation in the uterus
- Unintentional loss or damage to embryos.

If embryo transfer is not performed, I understand that I will not get pregnant in this cycle.

Post-Transfer Management

In an attempt to increase the chance of successful implantation, post-transfer management includes hormone therapy (*e.g.* progesterone) either by intramuscular injection, which may cause bruising or discomfort at the injection sight, or vaginal suppository. My physician has reviewed the risks and side-effects of this medication. I will take this medication until instructed to stop by my nurse or physician.

I understand that there is no guarantee that a pregnancy will occur as a result of this treatment. My physician has discussed with me the chances of a successful outcome.

I understand that pregnancies resulting from IVF are subject to the same risks and complications as pregnancies achieved without medical intervention, including but not limited to:

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

I acknowledge that the IVF team cannot guarantee the health of any infant resulting from this procedure.

Discarded Material (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: _____

General Consent Provisions

I understand that the lists of risk 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 and their risks and benefits 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. I have had the opportunity to ask questions about HIV testing which have been answered to my satisfaction. 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 routinely done with blood donated by volunteer blood donors and that if time and my condition permits, I will be given the option to have family members donate for me. 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 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.

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

I agree to notify the Women & Infants Fertility Center of the birth of any children as a result of IVF procedures.

I am aware that the practice of medicine is not an exact science. I acknowledge that no guarantee or promise has been given to me by anyone as to the results of my treatment. I understand that the above procedures are done by the Women & Infants Fertility Center team and that my primary physician may not be the one doing them.

PART II – PATIENT AND PARTNER (IF APPLICABLE)

I/we understand that other alternative procedures, including a fresh in vitro fertilization (IVF) cycle, may exist to achieve a pregnancy. I/we are aware that I/we can elect not to transfer these embryos and instead have them thawed and discarded, or attempt to donate them, as alternatives to continued storage and/or transfer.

I/we are aware that the embryology staff uses their judgment in choosing the embryos to thaw and this may include embryos that were frozen at different stages of development. I/we may ask a staff member to check how many embryos are available for thawing. I/we understand that the number of embryos available for thawing may not be the same number of embryos available for transfer. I/we understand that embryos which are thawed successfully may not be viable on the day of transfer, and therefore, will not be transferred.

I/we acknowledge that the embryology staff may thaw more embryos than I/we desire to transfer in order to obtain the number of embryos I/we hope to transfer. I/we understand that, although unlikely, more embryos may survive the thawing process than are desired for transfer. If this happens, I/we will discuss my options with the IVF team.

I/we understand that none of the embryos may survive the freezing/thawing process and if this occurs, there will be no embryos to transfer and no chance of pregnancy in this cycle.

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)

For Partner's Signature if not signed at WIFC

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: _____