WOMEN & INFANTS HOSPITAL
Providence, RI 02905

CONSENT FOR IVF WITH EMBRYO TRANSFER

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 ____ have requested treatment by the physicians and
(Print Patient's name)
staff of the Women & Infants Fertility Center (WIFC) for the purpose of attempting a pregnancy. I consent to allow the WIFC physicians and staff ("IVF team") to perform in vitro fertilization (IVF) procedures on me for the purpose as outlined in the document below.

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, or the eggs or embryos will be cryopreserved (frozen) and transferred at a later date.

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 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.

Embryo Transfer

During embryo transfer, the embryos are placed into 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 an embryo(s) into the uterine cavity may cause some cramping, discomfort and, possibly, a small amount of bleeding. There is also a risk of infection, which may require antibiotic treatment.

I am aware that the outcome of IVF correlates with the number and quality of embryos transferred into the uterus. I understand that transferring more than one embryo places me at risk for multiple gestations (more than one baby), and that the seriousness of this 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 infants that may require intensive care and may have long- term complications associated with prematurity
- pregnancy-induced 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 maternal age and embryo quality. My physician has explained that the purpose of this policy is to maximize the chance of pregnancy while reducing the rate of multiple gestations. I understand that any remaining viable embryos may be frozen and stored for possible transfer in a subsequent cycle. If I want to freeze and store my embryos, I will need to sign an additional consent form.

Embryo transfer is not performed when there are no suitable embryos. This occurs because no eggs are

retrieved, the eggs do not fertilize or because the embryos do not develop normally. If an embryo transfer is not performed, I understand that I will not get pregnant in that 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 chance 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 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 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 my 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.

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 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.

I acknowledge that this form has been explained to me and I understand its contents. I understand that this consent is valid for one (1) year from the date of signing and that I will complete a targeted consent form with each cycle. I have had the opportunity to ask questions which have been answered to my satisfaction.

Time: ______ A.M./P.M. Date: ______________ Signature: ________________________________
Patient

Partner's Acknowledgment (if applicable):

Time: ______ A.M./P.M. Date: ______________ Signature: ________________________________
(Partner)

Print Name:______________________________
(Partner)

Provider's Acknowledgement:

I confirm that consent, as described above, has been given by this patient.

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.

Time: ______ A.M./P.M. Date: ______________ Signature: ________________________________
(Interpreter)

Print Name:______________________________
(Interpreter)

<u>For Partner's Acknowledgment 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: ______________________________

40735

WOMEN & INFANTS HOSPITAL
Providence, RI 02905

PATIENT CONSENT FOR FERTILITY TREATMENT DURING COVID-19 AT WOMEN & INFANTS FERTILITY CENTER

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 #: ______________________

C19-40735 (5-2020)

COVID-19 has been declared a worldwide pandemic by the World Health Organization. Although the exact mode of transmission is not entirely known, COVID-19 is contagious and is believed to spread by person-to-person contact. Despite taking reasonable preventative measures that are aimed to prevent the spread of COVID-19, an inherent risk of becoming infected with COVID-19 by virtue of proceeding with fertility treatment still exists.

By seeking treatment at Women & Infants Fertility Center I ______________________________
(Patient's Name)
(or ____________________________ for ____)
(Legal Guardian) (Patient's Name)

and ________________________________ (if applicable) acknowledge and understand:
Partner's Name

1. Despite all precautions offered to me/us or taken by my/our providers, there is no guarantee that I/we will not be exposed to and/or infected with COVID-19.
2. Use of personal protective equipment (PPE) can minimize risk but does not eliminate the risk of transmission of COVID-19.
3. Possible exposure to COVID-19 may result in the following: a positive COVID-19 diagnosis, extended quarantine/self-isolation, additional tests, hospitalization that may require medical therapy, Intensive Care treatment, possible need for intubation/ventilator support, short-term or long-term intubation, other potential complications, and/or the risk of death.
4. The impact of COVID-19 on pregnancy for both the mother and baby is not fully known. I/we acknowledge that any febrile illness in early pregnancy may increase the risk of miscarriages and birth defects and that pregnant women appear to be at greater risk of severe complications from other respiratory viral infections such as influenza.
5. Even if I/we have been tested for COVID-19 and received a negative test result, the tests in some cases may fail to detect the virus, there is a chance I/we may have contracted COVID-19 after the test and I/we acknowledge that I/we may still transmit the undetected virus to another person.
6. My/Ourtreatment/procedure may be delayed or canceled should I/we develop symptoms, be tested positive for COVID-19 or for a variety of others reasons including changing regulations and restrictions surrounding COVID-19, availability of staff, the availability of adequate PPE or other reasons. If treatment is modified or canceled this can interfere with the ability to become pregnant through treatment as well as have financial consequences including not being reimbursed for expenses already incurred.
7. I/we are expected to follow reasonable precautions set forth by the WIFC such as wearing a facemask at all times in the clinic and to observe social distancing and proper handwashing both inside and outside of the clinic during the course of treatment.
8. These precautions may also include the request to self-quarantine and to pursue any testing for patient, or partner if applicable, related to COVID-19 before treatment. I/we understand that it may be necessary to obtain this testing at an outside lab and there may be extra costs associated with this testing.
9. Failure to comply with these requests, follow recommended precautions, as well as exposure to, developing symptoms of, or testing positive for COVID 19 may result in the delay or cancelation of treatment.
10. If treatment is delayed or canceled, this can have financial consequences including not being reimbursed for expenses already incurred.

11. The staff at WIFC is providing fertility treatment and I/we are responsible for obtaining other healthcare needs through other providers including routine gynecologic and primary care, any ongoing obstetric care, and any care related to COVID-19.
12. I/we have the option to postpone fertility treatment to minimize the risk of acquiring COVID-19.

I/we have been counseled about resources available to provide further information about COVID-19. I /we have had the opportunity to read this form, or have it read to me/us, and I/we understand it. I/we have had the opportunity to ask questions and they have been answered to my/our satisfaction. Understanding all of the above, I/we desire to proceed with fertility treatments.

Time: ________ AM / PM Date: _______________ Signature: _________________________

(Patient or Legal Guardian)

Relationship: _______________________

Time: ________ AM / PM Date: _______________ Signature: _________________________

Partner, if applicable

Provider's Acknowledgement:

I confirm that consent as described above, has been given by this patient (or Legal Guardian) and partner.

Time: ________ AM / PM Date: _______________ Signature: _________________________

(Provider)

Print Name: ________________________

(Provider)

Interpreter's Acknowledgement (if applicable):

I confirm that consent as described above, has been given by this patient (or Legal Guardian) and partner.

Time: ________ AM / PM 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: ____________________________