40676

WOMEN & INFANTS HOSPITAL
Providence, RI 02905

CONSENT FOR IN VITRO FERTILIZATION USING A GESTATIONAL CARRIER (GESTATIONAL CARRIER)

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 #: _____

MR-839 (9-2017)

1. I, _____, have been selected by:
(print Gestational Carrier's name)

_____ and _____
(print Patient's name) (print Patient's Partner's name, if applicable)

collectively referred to as the "Intended Parents," to serve as a Gestational Carrier as part of the in vitro fertilization (IVF) process at Women & Infants Fertility Center (WIFC).

2. After IVF, the resulting embryo(s) will be transferred into my uterus for the purpose of carrying a child for the Intended Parents.

3. I understand that I (and my partner, if applicable) may have conflicting interests with the Intended Parents. I understand that WIFC requires all parties to seek independent legal counsel and enter into an written agreement before the IVF process begins to address all areas of agreement, concern and conflict which may arise, including but not limited to actions to be taken in the event of a multiple pregnancy of twins or more, and the parental rights of the resulting offspring.

4. Definitions
   a. **Gestational Carrier** - the person who carries an Intended Parent(s)' child and has no genetic link to the developing child. After IVF is performed, the resulting embryo(s) are transferred into the Gestational Carrier's uterus.
   b. **Embryo** – an egg fertilized by sperm.
   c. **Cryopreservation** – a preservation process through freezing.
   d. **In Vitro Fertilization** (IVF) – a process whereby egg growth is stimulated in the ovaries with the resultant eggs being retrieved and fertilized by sperm in the laboratory.
   e. **Embryo Transfer** – the placement of embryos into the uterus.

5. Uterine Preparation

I am aware that medications are used to coordinate my cycle to the availability of the embryos. If pregnancy occurs, I will continue to take these medications for a period of time.

I understand that my physician will review the risks of each of the medication 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 medication delivered by injection)

6. Embryo Transfer

During the 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 to the uterus. I understand that there is a risk of multiple gestation (more than one baby) following IVF, 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 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 the pregnancy)
- miscarriage

I acknowledge that it is WIFC's policy to limit the number of embryos transferred according to maternal age and embryo quality. WIFC 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 an embryo transfer is not performed if there are no suitable embryos. This occurs because there no eggs are retrieved, the eggs do not fertilize or because the embryos are not developing normally. If an embryo transfer is not performed, I understand that I will not get pregnant in that cycle.

7. Post-Transfer Management

In an attempt to increase the chance of successful implantation, post-transfer management includes hormone therapy (*e.g.* progesterone and estrogen) either by oral administration, intramuscular injection, which may cause bruising or discomfort at the injection sight, vaginal suppository. My physician has reviewed the risks and side-effects of this medication. I will take this medication until a negative blood pregnancy test or the pregnancy is confirmed by ultrasound.

I understand that there is no guarantee that a pregnancy will occur as a result of this treatment. The chance of a successful outcome during IVF treatment has been explained to me by my physician.

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

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

- miscarriage
- stillbirth

I acknowledge that WIFC cannot guarantee the physical or mental health of any infant resulting from this procedure.

8. Screening Process

I understand that the eggs and/or sperm used in the IVF procedure are obtained from the Intended Parents and/or donor(s).

I am aware that WIFC follows a screening process prior to the transfer of reproductive tissue from one patient to another. I will have a complete evaluation and screening for infectious disease, including tests to screen for HIV, hepatitis, and other tests WIFC deems appropriate. Other studies as indicated by medical and/or family history may also be obtained.

I acknowledge that WIFC will perform the same or similar screening tests on the Intended Parents.

I understand that to more fully limit the risk of infection, the Intended Parents may choose to cryopreserve and retest embryos prior to transfer. I understand that if the embryos to be transferred into my uterus are not frozen and quarantined for six months prior, I assume the low risk of acquiring HIV and other infectious diseases. I understand that neither oocytes (eggs) nor fresh sperm used to fertilize the eggs are frozen and quarantined prior to IVF. If donor sperm is used, the sperm is quarantined, but the eggs are not quarantined prior to IVF.

I am aware that WIFC does not make any guarantee about the reliability of the information provided by the Intended Parents in the above-described screening process. I understand that WIFC is not responsible for the accuracy or reliability of information obtained from the Intended Parents during the screening process.

I acknowledge that WIFC cannot and does not assume any responsibility or liability for the Intended Parents' actions or inactions during the screening process.

9. General 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 and the risks and benefits of these alternative options have been explained to me, including procedures that are not performed here, and other non-medical options such as non-treatment, and I understand them.

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I understand that, should there be bleeding from the transfer, I may require a blood transfusion. 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 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 procedures, eggs, sperm, 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 monitoring and embryo transfer will be done by the Women & Infants Fertility Center team and that my primary physician may not be the one doing this.

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

Time: _____ A.M./P.M. Date: _____ Signature: _____
Gestational Carrier

Gestational Carrier's Partner's Acknowledgment (if applicable):

Time: _____ A.M./P.M. Date: _____ Signature: _____
Gestational Carrier's Partner

Print Name: _____
Gestational Carrier's Partner

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FOR OUTPATIENTS: WRITE IN BOTH PT NAME & DOB

PATIENT NAME: _____

DOB OR MR #: _____

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)

For Gestational Carrier's Partner's Acknowledgment 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: _____

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: _____