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MR-838 (9-2017)

WOMEN & INFANTS HOSPITAL
Providence, RI 02905

CONSENT FOR IN VITRO FERTILIZATION USING A GESTATIONAL CARRIER (PATIENT/INTENDED PARENTS)

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 #: ______________________________

1. I, ____________________________________ and __________________________________
(Print Patient's name) (Print Partner's name, if applicable)
collectively referred to as the "Intended Parents" consent to allow the physicians and staff at Women & Infants Fertility Center (WIFC) to perform in vitro fertilization (IFV) using a gestational carrier for the purposes of achieving a pregnancy.

2. I/we understand that after IVF, the resulting embryo(s) will be transferred into the uterus of __________________________________, who I/we select to carry my/our child(ren).
(Print Gestational Carrier's name)

3. I/we understand that I/we may have conflicting interests with each other (if applicable) and with the Gestational Carrier. I/we understand that WIFC requires all parties to seek independent legal counsel and enter into a 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 legal rights to the resulting embryo(s) and/or child(ren).

4. Definitions
   a. **Gestational Carrier** - the person who carries an Intended Parent(s)' child(ren) and has no genetic link to the developing child(ren). 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.

PART I – PATIENT

5. In-Vitro Fertilization (IVF) Process

An IVF cycle using a gestational carrier 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 Gestational Carrier's uterus; and
F) Support of the Gestational Carrier's 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 administered 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 physicians and staff at WIFC ("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. 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 used for embryo transfer 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.

6. 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: ____

7. 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 by the IVF team, including procedures that are not performed here, and other non-medical options such as adoption or non-treatment, and I understand them.

I understand that I may require a blood transfusion as a result of the above procedures. I understand that blood transfusions are routinely done with blood donated by volunteer blood donors and that if time and my/our 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/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: INTENDED PARENTS

8. Uterine Preparation

I/we understand that medications are used to coordinate the Gestational Carrier's cycle to the availability of the embryos. If pregnancy occurs, the Gestational Carrier continues to take these medications for a period of time.

9. Embryo Transfer

During the embryo transfer, the embryos are placed into the Gestational Carrier's uterus. I/we are aware that the outcome of IVF correlates with the number and quality of embryos transferred into the uterus. I/we understand that transferring more than one embryo increases the risk of 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:

- Pre-term 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/we acknowledge that it is WIFC's policy to limit the number of embryos transferred according to maternal age and embryo quality. The WIFC team has explained that the purpose of this policy is to maximize the chance of pregnancy while reducing the rate of multiple gestations. I/we understand that any remaining viable embryos may be frozen and stored for possible transfer in a subsequent cycle.

Embryo transfer is not performed if there are no suitable embryos. This occurs because 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/we understand that the Gestational Carrier will not get pregnant in this cycle.

10. Post-Transfer Management

I/we are aware that there is no guarantee that a pregnancy will occur as a result of this treatment. My/our physician has discussed with me/us the chances of a successful outcome.

FOR INPATIENTS: AFFIX PATIENT LABEL OR
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PATIENT NAME: ____________________________

DOB OR MR #: _____________________________

I/we 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/we acknowledge that the IVF team cannot guarantee the physical or mental health of any infant resulting from these procedures.

11. Screening Process

The eggs and/or sperm used in the IVF process are obtained from the Intended Parents and/or donor(s). If donor eggs and/or sperm are used, I/we will need to sign additional consent forms.

I/we are aware that WIFC follows a screening process prior to the transfer of reproductive tissue from one patient to another. I/we will have a complete evaluation and screening for infectious diseases, 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/we acknowledge that WIFC performs the same or similar screening tests on the Gestational Carrier.

I/we understand that to more fully limit the risk of infection, I/we may choose to cryopreserve the embryo(s) and retest them prior to transfer to more fully limit the risk of infection.

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

I/we understand that WIFC cannot and does not assume any responsibility or liability for the Gestational Carrier's actions or inactions during the screening process.

I/we acknowledge that this form has been explained 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: ______________________________

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: _____________________________