



**CONSENT FOR IN VITRO FERTILIZATION
USING A TRADITIONAL SURROGATE
(TRADITIONAL SURROGATE)**

MR-842 (9-2017)

1. I, _____, have been selected by:
(print Patient/Traditional Surrogate's full name)

_____ and _____
(print Intended Parent's name) (print Intended Parent's name, if applicable)

collectively referred to as the "Intended Parents," to serve as a Traditional Surrogate as part of the in vitro fertilization (IVF) process at Women & Infants Fertility Center (WIFC). After IVF, the resulting embryo(s) will be transferred into my uterus for the purpose of creating a child for the Intended Parents.

2. I understand that I (and my partner, as applicable) may have conflicting interests with the Intended Parents, and that WIFC requires all parties to seek independent separate legal counsel and enter into a written agreement 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 resulting offspring.

3. Definitions

- a. **Traditional Surrogate** – is the person who carries the child of Intended Parents and has a genetic link to the developing child through the use of the Traditional Surrogate's own eggs. After IVF is performed on the Traditional Surrogate, resulting embryos are transferred back into the Traditional Surrogate'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.

4. Screening Process

I understand that the sperm used in the IVF procedure is obtained from the Intended Parent(s) or a sperm donor. If donor sperm is used, additional consents forms will be signed.

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

I acknowledge that I will also 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 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. I understand that 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.

5. 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 transferred at a later date.

6. 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.

The exact number of eggs retrieved may not be determined until their final microscopic evaluation. I understand that there is no guarantee that eggs will be retrieved during this process.

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.

7. 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.

8. 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.

9. 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.

10. Future Genetic Screening

I understand that any present or future child(ren) born to me may be related (genetically, biologically or both) to a child(ren) created from use of my eggs during these IVF procedures, and that my child(ren) should have blood tests, and other appropriate genetic screening tests to determine a potential genetic relationship with a partner prior to entering into any relationship that could produce a child. I understand that my child(ren) should disclose to any partner the potential for genetic relationship and the importance of the partner undergoing blood tests and other appropriate genetic screening tests as well.

I understand that WIFC has no obligation or duty whatsoever to make any of the foregoing disclosures to any person at any time.

11. Discarded Material (**Patient/Traditional Surrogate 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:

12. 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 that 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 non-treatment, and I understand them.

I understand that as a result of the above procedures 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 these procedures 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: _____
Patient/Traditional Surrogate

Traditional Surrogate's 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)



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/Our treatment/procedure may be delayed or canceled should I/we develop symptoms, be tested positive for COVID-19 or for a variety of other 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 cancellation 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: _____