



**CONSENT FOR OOCYTE (EGG)
RETRIEVAL AND CRYOPRESERVATION**

I _____ (or _____
(Print Patient's name) (Print Legal Guardian's name)
for _____), am entering into a treatment program
(Print Patient's name)
with the Women and Infants Fertility Center (WIFC) to retrieve and cryopreserve (freeze) my oocytes
(eggs) for use to attempt pregnancy in the future.

I understand that there are several steps to this process, which are further described 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 the 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

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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.

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.

Cryopreservation (Freezing) of Eggs

I understand that once the Embryology Team has identified any viable eggs, those eggs are cryopreserved (frozen) by a process called vitrification (ultra-rapid freezing). The frozen eggs are stored in the WIFC Embryology Laboratory.

The risks and benefits of cryopreservation have been discussed with me and I understand them. I understand that complications can occur as a result of the process. Complications may include, but are not limited to:

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- Damage to eggs: Eggs may be damaged during the freezing process, or during the storage period. If an egg is damaged, it will not successfully survive the thaw and is not used to attempt pregnancy.
- Loss of eggs: Eggs may be lost during the culture, freezing or storage period.

I acknowledge that eggs may be damaged as a result of the malfunction (failure to work properly) of equipment used in the embryology laboratory, and this damage is beyond the control of WIFC.

I understand that I am responsible for the costs and fees incurred for egg cryopreservation and storage.

Use of Oocytes

When I am ready to attempt pregnancy, some or all of my cryopreserved eggs are thawed. I understand that there is no guarantee that any of the eggs will survive the freezing or thawing process, fertilize or produce a baby. My physician has discussed the current success rates of these procedures with me.

I understand that the egg(s) will be fertilized with a sample of my partner's sperm or my chosen donor's sperm.

I acknowledge that I may receive hormonal medications to mature the lining of my uterus to prepare for embryo (egg fertilized by sperm) transfer. I will undergo blood testing and vaginal ultrasound examination to determine my response to the hormonal medications and to determine the proper time to perform the egg thaw, fertilization and embryo transfer.

I am aware that the fertilization process may create more embryos than are transferred in one cycle. In some cases, the embryos may be of sufficient quality to be frozen for use in a future cycle.

I understand that the thaw, fertilization and embryo transfer procedures described above are the current standards of practice and that WIFC cannot guarantee what the standards of practice will be when I choose to use my frozen eggs.

I understand that the thawing and fertilization of previously frozen eggs, and embryo transfer will require that I have additional discussions with the WIFC team and that I sign additional consent documents.

Oocyte Disposition

I understand that WIFC will not fertilize my frozen egg(s) after I reach a certain age. If I do not use my frozen egg(s) (transferred into myself or into a gestational carrier), current alternatives include:

- Discarding the frozen egg(s)
- Donating the frozen egg(s) for approved research studies
- Donating the frozen egg(s) to another individual (subject to various Federal and State requirements)
- Transferring the frozen egg(s) to a designated storage facility at my expense.

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I acknowledge that the availability of the above identified options may change over time.

Discarded Material

In the hope that I may help others, I donate for teaching or research purposes any unused biological material which otherwise would be routinely discarded. I understand that no embryos or pregnancies will be generated using this material. I understand that by agreeing to this donation there is no additional risk to me. I also understand that I may refuse to donate this material and the treatment given would not be affected.

My 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 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, are performed as a routine part of the IVF process. Other studies as indicated by my 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 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 egg retrieval or 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, etc. and other medical problems for diagnostic, educational or scientific purposes, provided my identity is not revealed.

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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 this.

I acknowledge that this form has been explained to me 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 or Guardian

Relationship: _____

Provider's Acknowledgement:

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

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 the patient (or Legal Guardian).

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
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FOR OUTPATIENTS: WRITE IN BOTH PT NAME & DOB

PATIENT NAME: _____

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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: _____