

WOMEN & INFANTS HOSPITAL

Providence, RI 02905

CONSENT FOR FRESH DONOR OOCYTE- RECIPIENT (KNOWN DONOR)

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-832 (9-2017)

Ι	and		have
(Print Recipie	ent's name)	(print Partner's name, if applicable)	
elected to undergo in vit	ro fertilization (IVF) at th	e Women and Infants Fertility Center	(WIFC) with the
use of donor eggs from		("Donor.")	
	(Print Donor's name)		

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. I/we believe the use of eggs from Donor ("donor eggs") offers the best option to attempt to attain a pregnancy, and understanding the other options and alternatives available, consent to proceed with using known donor eggs in combination with IVF to achieve a pregnancy.

PART I - RECIPIENT

Uterine Preparation

My physician has explained that there is a specific time-frame within the menstrual cycle during which an embryo (an egg fertilized by sperm) can implant. The first step in this process is to synchronize my uterus with the Donor's stimulation cycle so that my uterus is prepared for the embryo transfer. Hormones are then used to build and stabilize my uterine lining (the part of my uterus where the embryo will implant). My physician determines the best protocol for uterine preparation based on a number of factors, including my age and menstrual status (i.e. pre-menopause, menopause, etc.)

Preparation of the uterus occurs in four phases:

- Premenstrual Phase medications are used to suppress my menstrual cycle and to synchronize me with the Donor
- Phase 1: Building phase I receive medication such as estrogen to thicken my uterine lining. After receiving this medication, an ultrasound is performed to ensure that the uterine thickness is adequate.
- Phase 2: Endometrial stabilization I begin taking progesterone at a time predetermined by my physician prior to the embryo transfer to prepare my uterus for implantation. I understand that I start taking the progesterone on a specific day as determined by my physician. I agree that I will not take progesterone until instructed by my nurse or physician.
- Post-transfer phase Progesterone is required to maintain the pregnancy even after implantation. I will continue to take progesterone and estrogen after the embryo transfer and I agree that I will not discontinue its use until I have been specifically instructed to stop by my nurse or physician.

Risks of hormone therapy:

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

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- Increased risk of clotting
- Infection at injection site (for medication delivered by injection)

Fertilization of the eggs with sperm

I understand that following successful egg retrieval from the Donor, 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. If ICSI is indicated, I will sign a separate consent form.

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

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retrieved from the Donor, the eggs do not fertilize, or 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 chances 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 WIFC cannot guarantee the health of any infant resulting from this procedure.

Discarded Material (Recipient and Partner, if applicable, to initial below) 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.

General Consent Provisions

My/our limitations are:

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 to IVF 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 adoption or

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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 medical and/or family history may also be obtained.

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 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. However, given that no oocyte (egg) retrieval will be performed on me, the chances of bleeding or hemorrhage and the need for transfusion are extremely remote.

I acknowledge that the physicians at the Women & Infants Fertility Center are only managing infertility and that I am responsible for obtaining 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/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 this.

PART II: RECIPIENT AND PARTNER, IF APPLICABLE

Use Of Known Donor Eggs

I/we understand that WIFC follows a screening process prior to the transfer of reproductive tissue from one patient to another. I/we understand that Donor is required to complete a profile detailing personal, medical and family history to the best of Donor's ability. Donor and Donor's partner (if applicable) will undergo an evaluation, including blood tests, to screen for HIV and other infectious diseases, a psychological consultation, and a history and physical examination, and any other tests the WIFC physicians deem appropriate.

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I/we acknowledge that, although WIFC uses the donor eggs in the IVF procedures, WIFC does not guarantee, warranty or make any other assurances as to the quality of the egg(s) other than the fact that the source of the egg is from the Donor.

I/we are aware that it is still possible that any child(ren) born as a result of the use of Donor's eggs may be mentally or physically abnormal or may have undesirable hereditary tendencies, characteristics or conditions and there is no way for WIFC to warrant or guarantee that any such child(ren) will be free from hereditary, sexually transmitted or other infectious disease or conditions, or that Recipient will be free from sexually transmitted or other infectious diseases or conditions as a result of the procedures.

I/we understand that complications may occur that prevent the establishment of a pregnancy during this cycle, including but not limited to:

- Inability to retrieve eggs from the Donor
- Unintentional loss or damage to the retrieved eggs
- Donor is unable or unwilling to donate for personal reasons

I/we acknowledge my/our obligation to any child(ren) born as a result of our act to achieve a pregnancy using donor eggs, and agree to care for, support, financially and otherwise, and treat the child(ren) born as a result of these procedures, in all respects, as if my/our naturally conceived child(ren).

I/we understand that any present or future child(ren) born as a result of these procedures may be related (genetically, biologically or both) to the present or future child(ren) of the Donor, and that my/our 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/we understand that my/our 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/we understand that WIFC has no obligation or duty whatsoever to make any of these disclosures to any person at any time.

I/we understand that WIFC makes no representation, express or implied, with respect to the nature of the legal relationship of any embryos created or any child(ren) born as a result of the use of donated eggs. I/we understand that I/we should consult with legal counsel in this regard.

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

Time:	_ A.M./P.M. Date:	Signature:	Recipient
Time:	_ A.M./P.M. Date:	Signature:	Partner, if applicable

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Provider's Acknowledgement:		
I confirm that consent, as described above, has been	n given by this patient (and partner, if applicable.)
Time: A.M./P.M. Date:	Signature:	(Provider)
	Print Name:	
Interpreter's Acknowledgement (if applicable):		
I confirm that consent as described above, has been		
Time: A.M./P.M. Date:	Signature:	(Interpreter)
	Print Name:	(Interpreter)
For Partner's Signature when 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:		



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

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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 se	eking treatment at Womer	& Infants Fertility Co	enter I	
		•	(Patient's Name)	
(or		for	· · · · · · · · · · · · · · · · · · ·)
	(Legal Guardian)		(Patient's Name)	
and_		(if applic	able) acknowledge and understand:	
_	Partner's Name		, 5	

- 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:	
	9		ntient or Legal Guardian)
		Relationship:	
Time:	AM / PM Date:	Signature:	
			Partner, if applicable
Provider's	Acknowledgement:		
I confirm th	at consent as described above,	has been given by this patie	ent (or Legal Guardian) and partner.
Time:	AM / PM Date:	Signature:	
			(Provider)
		Print Name:	
			(Provider)
Interpreter	's Acknowledgement (if appli	cable):	
I confirm th	at consent as described above, l	has been given by this patier	nt (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 all and being duly sworn under the penalty of perjury	
act and deed this day of	
NOTARY PUBLIC:	
MY COMMISSION EXPIRES:	