

CONSENT FOR IN VITRO FERTILIZATION AND EMBRYO TRANSFER USING CRYOPRESERVED EGGS

I, _____ (Female Partner) and _____ (Partner, Spouse) wish to use cryopreserved (frozen) eggs to achieve pregnancy by thawing cryopreserved eggs, fertilization of thawed eggs, and transfer of resulting embryos into the uterus. We understand that this process is in vitro fertilization (IVF) with previously frozen eggs and subsequent embryo transfer (ET), to be called herein "IVF-ET using frozen-thawed eggs".

I/We understand that achieving pregnancy using cryopreserved eggs requires the preparation of the uterus (in a medicated or natural menstrual cycle), followed by the thawing of eggs, fertilization of eggs, and embryo transfer into a recipient's (Female Partner or gestational surrogate) uterus. I/We acknowledge that egg survival after thawing and normal fertilization of frozen-thawed eggs cannot be guaranteed, nor can pregnancy be guaranteed following embryo transfer if eggs survive the thawing process and are fertilized normally. I/We consent to allow the Reproductive Fertility Center (RFC), its affiliate laboratory, and physicians to thaw our cryopreserved eggs, and to fertilize them with sperm for the purpose of embryo transfer and pregnancy.

Procedural Overview

I/We understand that in an IVF-ET cycle using frozen-thawed eggs, the uterus must be prepared for implantation for several weeks (typically 2) prior to thawing of eggs, and embryo transfer. In a medicated IVF-ET cycle using frozen-thawed eggs this is normally first achieved using estrogen in the form of oral tablets, intramuscular injections, or transdermal patches. Typically, on the day of egg thawing (several days prior to embryo transfer) progesterone is added in the form of vaginal suppositories or intramuscular injections. The purpose of estrogen treatment is to thicken the endometrial lining (the inside lining of the uterus) and make it receptive to embryos, while progesterone serves to prepare the uterus for embryo implantation. In a medicated IVF-ET cycle using frozen-thawed eggs, both estrogen and progesterone administration continues through the 9th to 10 weeks of gestation. Additional medications used in the cycle may include medications to suppress ovulation, and low dose oral corticosteroids, along with a low dose aspirin tablet. Estrogen and progesterone treatment may cause mild mood changes, bloating, breast tenderness, and fatigue. Side effects are rare after treatment with steroids but low dose oral steroids can cause acne, blurred vision, sleep disturbance, muscle weakness, stomach upset, bloating, and irritable mood. Monitoring for an IVF-ET cycle using frozen-thawed eggs may include frequent blood drawing and transvaginal ultrasounds.

Intracytoplasmic Sperm Injection (ICSI)

Intracytoplasmic sperm injection (ICSI) is a specialized assisted reproductive technique (ART) employed in the IVF laboratory whereby a single sperm is injected into an egg to achieve fertilization. The most common indication for ICSI is male factor (low quality sperm). However, other clinical situations such as unexplained infertility, poor prior fertilization in the IVF lab using standard fertilization techniques, and a low egg count are also common indications. Specifically, in IVF-ET cycles using frozen-thawed eggs, ICSI is the preferred method of egg fertilization as multiple studies have illustrated that it is superior to standard insemination in optimizing fertilization rates. A separate Consent for Intracytoplasmic Sperm Injection must be signed before ICSI can be performed on frozen-thawed eggs.

Our initials indicated that we consent to Intracytoplasmic Sperm Injection (ICSI) of frozen-thawed egg(s): _____
Initials

Assisted Hatching

Assisted hatching (AH) is a specialized laboratory procedure whereby the shell surrounding the embryo, called the zona pellucida, is weakened using micromanipulation instruments in order to facilitate the hatching (release from its shell) of the embryo(s), so as to improve the chance of implantation in the uterus. Several studies have suggested improved implantation rates of embryos conceived from frozen-thawed eggs when assisted hatching is employed prior to embryo transfer. The risks associated with assisted hatching include the potential of increased incidence of multiple gestations, and the possible damage/destruction of the embryos. A separate consent for Assisted Hatching must be signed before embryo transfer of embryos conceived from frozen-thawed eggs.

My initials indicate that I consent to assisted hatching of embryos conceived from frozen-thawed eggs: _____
Initials

Embryo Transfer

I/We understand that there is no guarantee than any eggs will survive the thawing process, and that if no eggs survive the thaw, the embryo transfer will be canceled. I/We also understand that there is no guarantee that any frozen-thawed eggs will fertilize or that normal fertilization will occur, and that if no normal fertilization of frozen-thawed eggs occurs the embryo transfer will be canceled. I/We further understand that if frozen-thawed eggs survive the thaw and are fertilized normally, no guarantee can be made that resulting embryos will survive in culture medium and would be suitable forembryo transfer.

The embryo transfer procedure involves the placement of a catheter containing embryo(s) into the uterine cavity through the cervix (opening to the womb). Occasionally embryos resulting from frozen-thawed eggs may be transferred into the fallopian tubes in a procedure called zygote intrafallopian transfer (ZIFT), or tubal embryo transfer (TET). Trans-cervical embryo transfer may lead to minimal to no discomfort, and on occasion scant vaginal bleeding. A separate consent for Embryo Transfer must be signed before embryo transfer of embryos conceived from frozen-thawed eggs.

My initials indicate that I consent to embryo transfer of embryos conceived from frozen-thawed eggs: _____
Initials

I/We understand that there is no guarantee that any of the embryos conceived from frozen-thawed eggs will result in a pregnancy once transferred to the uterus. I/We understand that as in any assisted reproductive technique (ART) treatment, the transfer of a single or multiple embryo(s) into the uterus in an IVF-ET cycle using frozen-thawed eggs may result in a risk of multiple gestation (more than one baby). The risks of multiple gestations include, but are not limited to, preterm labor and the delivery of premature infants who may require prolonged hospitalization and who may have long-term complications associated with prematurity. It is RFC’s policy to limit the number of embryos transferred according to maternal age and embryo quality in order to maximize success rates and minimize the risk of a multiple gestation.

I/We understand that pregnancies resulting from IVF-ET using frozen-thawed eggs may be subject to the same complications as pregnancies achieved with standard in vitro fertilization (IVF)/embryo transfer and those achieved without medical intervention, such as miscarriage, ectopic pregnancy, preterm labor, or other complications. There may be a risk of infants having developmental problems or congenital birth defect as a result of any ART treatment, including egg cryopreservation and thawing/ICSI/embryo transfer. I/We understand that until recently egg freezing was considered experimental by the American Society of Reproductive Medicine (ASRM). Despite the removal of the “experimental” label from egg freezing in October 2012 by ASRM, the number of children born worldwide from egg freezing cycles is substantially smaller than from IVF and frozen-embryo transfer cycles and as such, limited information exists on the safety of egg freezing and the well-being of children born from embryos conceived using frozen-thawed eggs. However, initial human experience and extensive experience in domestic animal species have not yet demonstrated an increase in developmental or congenital anomalies in offspring born following embryo cryopreservation beyond that observed in other ART treatments (such as IVF and embryo transfer), suggesting that similar outcomes would be expected for children born from frozen-thawed eggs. I/We understand that the health of any infant resulting from this procedure cannot be guaranteed. Separate consents for Assisted Reproductive Techniques and Egg Cryopreservation must be signed before the egg freezing procedure.

Initials

RELEASE

I/We agree to absolve, release, indemnify, protect and hold harmless RFC, its affiliate laboratory, its physicians, officers, directors, agents and employees, from any and all liability, claims or damages including legal fees, arising from any adverse outcome, however remote, resulting from IVF-ET using frozen thawed eggs; including but not limited to the loss or destruction of eggs and/or resulting embryos, the birth of a physically or mentally disabled child or subsequent disputes between the parties regarding the custody and/or support of any children ultimately born as a result of this procedure.

Initials

Certification of Informed Consent for In Vitro Fertilization-Embryo Transfer Using Frozen-Thawed Eggs

Your signature below indicates that you have read the preceding consent, that you have had the opportunity to ask questions, and that your questions have been answered to your satisfaction.

_____ PATIENT NAME (print)	_____ PATIENT SIGNATURE	_____ DATE
_____ PARTNER NAME (print)	_____ PARTNER SIGNATURE	_____ DATE
_____ WITNESS (print)	_____ WITNESS SIGNATURE	_____ DATE