Informed Consent for the Transfer of Frozen Embryos (FET)

Patient Information

Patient Name: _____ Date of Birth: _____

I/We have requested treatment from The Ronald O. Perelman and Claudia Cohen Center for Reproductive Medicine (CRM) of Weill Cornell Medicine, and understand that there are several steps involved in a frozen embryo transfer procedure. It is my/our understanding that the thawing of my/our embryos and transfer will be performed by the laboratory team at Cornell and involves the use of some or all the following procedures listed below, and that our physician and the laboratory team will determine the procedures most appropriate for me/us:

- Evaluation. Determination by standard infertility tests that I/we are suitable candidates for a frozen embryo transfer. These tests may include, but are not limited to, blood tests, ultrasound tests, and/or specialized x-rays to view the uterine cavity.
- Pre-procedure screening. Testing to ensure that there are no underlying conditions or problems in the uterus that may reduce the probability of a pregnancy. (For example: blood tests, cultures, and/or a hysteroscopy or saline sonogram).
- Fertility Drugs. Use of fertility drugs (which may be by mouth or by injection) such as oral contraceptives, clomiphene citrate, letrozole, gonadotropins, Leuprolide Acetate, Human chorionic gonadotropin (hCG) booster, estrogen and progesterone preparations to prepare the uterine lining for embryo implantation and to support an early pregnancy.
- Monitoring. Ultrasounds to measure the uterine lining and lab tests to measure hormone levels may be used to ensure that the uterine lining is adequately prepared for the embryo transfer.
- Pre-transfer Medication. Treatment with antibiotics or steroids to reduce inflammation and infection, as needed.
- Embryo Thawing. The thawing of the frozen embryos and the removal of the cryoprotectants.
- Embryo Transfer. Transfer of the embryo(s) to the female's uterus by means of a plastic catheter (tube) inserted into the uterus through the vagina.
- Post-transfer Monitoring. Obtaining blood samples and, if indicated, ultrasound examinations after the embryo transfer to determine whether a pregnancy has occurred and is proceeding normally.
- Post-transfer Medication. Treatment with progesterone preparations and, in some cases, other medications, to maintain an early pregnancy, or human chorionic gonadotropin (hCG) to support luteal function.

Monitoring Protocol

For pregnancy to occur, the embryo(s) must attach to the lining of the uterus. This process is called implantation. Adequate levels of estrogen and progesterone are required for successful pregnancy.

It is understood that I will be prepared for the transfer of the embryo(s) in either a natural (without ovarian stimulation), stimulated (clomiphene, letrozole and/or gonadotropins) or a programmed (medicated) cycle. This can occur in both cycles types: a "programmed" cycle, which is planned based on a target date for the embryo transfer, or in "natural" or "stimulated" cycles, that are carried out during the female's menstrual cycle. Therefore, in most cases, progesterone and sometimes estrogen are routinely taken. Progesterone is usually taken as an injection or as a vaginal suppository. Estrogen can be given as pills, an injection, vaginal suppositories, or a skin patch. Progesterone and/or estrogen are usually continued for several weeks after the embryo transfer until no longer needed.

I/We understand that while preparing for a FET cycle, monitoring will include frequent blood drawing and transvaginal ultrasounds. Blood drawing carries the risks of pain and bruising at the puncture site. There may be some discomfort with the transvaginal ultrasound.

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I/We understand that the programmed cycle may include the use of the following medications: Leuprolide acetate, Ganirelix, vaginal progesterone suppositories, oral estradiol, transdermal estrogen patches, intramuscular progesterone, and antibiotics. I understand that I may receive antibiotics in the form of Azithromycin (Z-Pak) or a similar antibiotic, in preparation for the embryo transfer. Side effects from the use of Azithromycin may include nausea, vomiting, diarrhea, loss of appetite, skin rash, sensitivity to the sun, and, though rare, hypersensitivity reactions may result in shock or blood abnormalities.

Embryo Transfer

After preparation of the uterine lining, which may take several weeks, the embryo transfer takes place. Most embryo transfers are done without using any anesthesia or sedation.

I/We understand that there is no guarantee that any embryo will survive the thawing process. I/We understand that if no embryos survive the thaw, the embryo transfer will be canceled.

I/We understand that embryo transfer into the uterine cavity, via a catheter, will occur after the thawing process. Vaginal or abdominal ultrasound may be used to help guide the catheter and confirm embryo placement. This may cause some cramping, discomfort and, possibly, a small amount of bleeding. Infection is a possible risk and may require antibiotic treatment.

I/We understand that there is no guarantee that any of the embryos transferred will result in a pregnancy.

I/We understand that the outcome of a FET cycle correlates with the number and quality of embryos transferred to the uterus. I/We understand that there is a risk of multiple gestation (more than one baby) following a FET cycle, and that the risk correlates directly with the number of embryos transferred. The physicians at CRM strongly encourage transferring only a single embryo at a time to reduce the possibility of a multiple gestation. In some cases, an embryo can split into two (identical twins) after transfer. Before the transfer, it is critical to discuss with your doctor how many embryos to transfer.

Post-Transfer Management

Post-transfer management may include estrogen patches, pills or injections and progesterone either by intramuscular injection or vaginal suppository. The progesterone is continued as directed by the medical team. I/We understand that during this period bloodwork for hormonal evaluations will be performed as instructed.

I/We understand that there is no guarantee that a pregnancy will occur as a result of this treatment. The chance of a successful outcome during treatment has been explained to me/us by the medical team. I/We understand that I/we am/are responsible for the costs of this treatment cycle, as well as the costs related to my/our participation in any future cycles.

Reasons for Adverse Results

Laboratory Risks

The process of freezing, storing, and thawing is complex and not all embryos will successfully survive the thawing process. The embryos may be damaged, destroyed, lost during thawing or fail to develop after thawing , and therefore be unavailable for further treatment or implantation, due to a number of potential factors, including, but not limited to: embryo-specific differences in tolerance of freezing; accidents; power outages; mechanical or equipment failure (including but not limited to loss of liquid nitrogen or other tank failures); materials (including vials, straws and other devices used to freeze and store the samples and their labels); changes of any applicable law or regulations; human error; labelling errors; inventory record loss; natural and man-made disasters; sabotage; transportation or shipping accidents or other events which may be beyond the control of CRM or its laboratory.

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In accordance with its protocols, CRM makes reasonable efforts to handle and maintain its patients' embryos, including, but not limited to maintenance and monitoring of its equipment, and materials. Despite such efforts, I/we understand that because of one or more of these potential factors, my/our embryos may become unavailable for further treatment or implantation, or that the likelihood of a pregnancy resulting from any treatment or implantation may be reduced.

Risks to the Female

I/We have been informed that although there are many known and unknown risks of undergoing frozen embryo transfer cycles. Some of these risks are:

- Medications to prepare the uterine lining may cause common side effects such as localized redness, swelling, and/or itching at the injection site. In addition, some of the possible side effects include hot flashes, irritability, vaginal dryness, headaches and/or vomiting, bloating, nausea, moodiness, appetite, weight gain, fatigue, sleepiness, headache, and sleep disorders.
- Irritation, bruising and/or infection may result from frequent blood drawing.
- Embryo transfer process cannot continue and may be cancelled, at any point, if pre-testing reveals underlying medical issues, the female intended parent develops a new medical condition, there is poor uterine lining development or other conditions arise that make the embryo transfer suboptimal.
- Embryo transfer into the uterus may be technically difficult or impossible or medically contraindicated or may be prevented by facility availability or personnel circumstances.
- If transfer occurs, the embryos may not implant and continue to develop.
- If implantation occurs, the embryos may not grow or develop normally, or a multiple pregnancy, or an ectopic pregnancy or miscarriage may result.
- If pregnancy and delivery occur, the child or children may be stillborn, have chromosomal abnormalities and/or congenital (birth) defects.
- The risks of multiple gestation 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.
- Females who become pregnant after FET may have a higher risk of blood pressure problems like pre-eclampsia in their pregnancies, although that risk may be more closely related to the type of medication used to prepare the uterus for the transfer.

Risks to the Baby

Like babies born after fresh transfer, most babies born after FET are healthy, although there may be a slightly higher overall risk of birth defects in In vitro fertilization (IVF) babies than in babies conceived naturally. When compared to babies born after fresh transfer, babies born after FET have a higher chance to be large for gestational age (LGA). LGA babies can have problems with delivery, requiring a C-section due to their size; and they can have other problems such as difficulty maintaining their blood sugar.

Psychosocial Effects of Infertility Treatment

Infertility and its treatment, including FET, can affect your emotions, your health, your finances, and your social life. Treatment is time-consuming and may strain your personal relationships and your religious or ethical beliefs. During treatment, you may feel anxious, helpless, depressed, or all alone. You may go through highs and lows. The outcome may not be what you want as a pregnancy cannot be guaranteed. In some cases, you may want to seek the help of a mental health expert to help you through the pressure treatment may present. Your team at CRM can provide resources to appropriate mental health professionals in your area.

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AGREEMENT AND CONSENT

1. Participation Agreement. I/We are voluntarily participating in an FET treatment cycle at CRM in hopes of having a child through the transfer of my/our frozen embryos. I/We acknowledge that I/we have read and fully understand this consent form and that all questions concerning the FET process have been answered to my/our satisfaction.

2. Each of us acknowledges and agrees that my/our acceptance of treatment at CRM and our continued participation is at the discretion of CRM and is dependent upon compliance with Weill Cornell Medicine's policies and procedures.

3. I/We have been advised and understand that freezing and thawing of embryos has been utilized in hundreds of centers in the world where specialized equipment and expertise are available, and that thousands of pregnancies and live births of normal infants have resulted. However, I/we also understand that there may be some effects on the offspring which, at this time, cannot be determined, including, among others, risks of genetic abnormalities and birth defects. The potential benefits from this procedure may be an increased chance of pregnancy without the necessity of multiple surgical interventions for oocyte retrieval.

4. The ability of any embryo to survive freezing and thawing is related to the quality of the embryo prior to freezing. It is difficult or impossible to predict how an individual embryo will survive and/or continue to develop and be suitable for transfer. I/We understand that freezing and thawing may result in damage to the embryo(s) including damage to embryonic reproductive cells, loss of some embryonic cells or loss of viability of the embryo as a whole; and that our choice of how many embryos to thaw may not result in the number of embryos we wish to have transferred during the FET.

5. Understanding of Risks/Adverse Effects. I/We understand the risks/reasons for adverse results. I/We have had the opportunity to discuss all the information contained in this document with our physician and/or CRM staff and all my/our questions about the procedures have been answered. Each of us understands that if pregnancy occurs, such pregnancy may result in miscarriage, ectopic pregnancies, stillbirth, congenital abnormalities, or multiple pregnancy. I/We have been informed that the process of ART can be very psychologically stressful and may result in anxiety and disappointment and that a substantial amount of our time is required during the FET process.

6. Disposal of Non-viable Embryos. I/We understand and agree that if, in the exercise of reasonable medical judgment, the embryologists and physicians at CRM determine that any of my/our embryos are non-viable or otherwise not medically suitable for embryo transfer, those embryos will be disposed of in an ethically acceptable manner, according to CRM policies and the American Society for Reproductive Medicine Ethical Standards. I/We consent to such disposition in the circumstances described.

7. Reporting Outcomes. In 1992, the Fertility Clinic Success Rate and Certification Act was passed. This law requires the Centers for Disease Control and Prevention (CDC) to gather information about IVF cycles and pregnancy outcomes in the U.S. each year. This information is used to calculate success rates which are reported each year. CRM will report the required information from your FET procedure to the CDC. Since CRM is a member of the Society of Assisted Reproductive Technologies (SART) of the American Society for Reproductive Medicine (ASRM), it will also be reported to SART. Information reported to SART about your cycle may be used for research or quality assessment according to HIPAA guidelines; your name will never be connected to your cycle information in any research that is published by ASRM or SART.

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By signing below, I/We acknowledge that we have read and understand the information and risks of frozen embryo transfer described above and I/we specifically consent to thawing and transferring of my/our embryos to my uterus to attempt a pregnancy.

I/We have been encouraged to ask questions, and any questions that I/we have asked have been answered to our satisfaction. I/We also understand that any future questions that I/we might have, may be answered by a member of the IVF team. I/We understand that this consent is valid for the current treatment cycle. If additional cycles are pursued, a new consent is required.

_____	_____	_____	_____
Patient Signature	Print Name	Date	Date of Birth

State of _____, County of _____. On this, the _____ day of _____, 20____, in the presence of a notary public, the undersigned officer personally appeared _____, known to me (or satisfactorily proven) to be the person whose name is subscribed to the within instrument, and acknowledged that he or she executed the same for the purposes therein contained. In witness hereof, I hereunto set my hand and official seal.

_____	_____
Notary Signature	Print Name

_____	_____	_____	_____
Partner Signature	Print Name	Date	Date of Birth

State of _____, County of _____. On this, the _____ day of _____, 20____, in the presence of a notary public, the undersigned officer personally appeared_____, known to me (or satisfactorily proven) to be the person whose name is subscribed to the within instrument, and acknowledged that he or she executed the same for the purposes therein contained. In witness hereof, I hereunto set my hand and official seal.

_____	_____
Notary Signature	Print Name

This consent is valid for one (1) initiated treatment cycle within ninety (90) days from the above date.