Informed Consent for Transfer of Embryos from Thawed Oocytes (FOT)

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) to use my frozen oocytes (eggs) for the purposes of achieving a pregnancy. I/We understand that there are several steps involved in using these frozen oocytes outlined below.

Timing of oocyte thaw

I/We understand that while preparing for transfer of embryos from thawed oocytes (TETO), I will be closely monitored by the IVF team. The oocytes can be thawed during a natural cycle, where the timing of ovulation is determined by close monitoring of blood tests as well as ultrasound examinations, or during a "programmed" cycle where similar hormones produced by the body will be given to you to prepare the uterus for the embryo transfer. This monitoring will include frequent/daily blood drawing, which carries the risk of mild discomfort and bruising at the puncture site. It is understood that transvaginal ultrasound examinations of the uterine lining will be performed as necessary, and that there may be mild discomfort with this procedure, although there is no risk presently known to medical science. I (female partner) may also be asked to collect urine samples for additional hormone analysis. I/We understand that none of the oocytes may survive the freezing/thawing process and if this occurs, there will be no embryos to transfer and no chance of pregnancy.

I/We understand that the programmed cycle will include the use of a combination of medications used to prepare the uterine lining and these may include (but are not limited to) leuprolide acetate (Lupron), ganirelix acetate (Ganirelix), transdermal estradiol patches, oral estrogen, and either vaginal suppositories or intramuscular injections of progesterone. Low doses of corticosteriods and antibiotics will also be prescribed which may be beneficial in protecting the embryos following transfer into the uterus. I/We understand that I will receive corticosteroids in the form of methylprednisone, and antibiotics in the form of tetracycline or a similar antibiotic in preparation for the embryo transfer.

The use of Lupron may result in fatigue, muscle and joint pain, or transient menopausal-like symptoms (headaches, hot flashes, mood swings, sweats, insomnia, etc.).

Estrogen treatment may result in headache, nausea, weight gain, breast tenderness, or irritation of the skin. Estrogens may increase the risk of endometrial cancer. Studies have reported increased risks of myocardial infarction, stroke, invasive breast cancer, pulmonary emboli, and deep vein thrombosis in postmenopausal women treated with oral conjugated estrogens combined with medroxyprogesterone acetate. It is unknown whether these findings apply to younger women.

The following side effects, although extremely rare, may occur after treatment with corticosteroids: Treatment may mask signs of infection; new infections may appear during corticosteroid use; there may be an inability to localize an infection, if one occurs. Blood pressure elevation, salt and water retention, and increased excretion of potassium and calcium may occur. These medications in high doses have been reported to cause mood swings, insomnia, depression, psychotic manifestations, muscle weakness, impaired wound healing, increased sweating, headache, vertigo, allergic reaction, loss of muscle mass, osteoporosis, and abdominal distention.

The use of tetracycline may result in the following dose-related side effects: Nausea, vomiting, diarrhea, loss of appetite, rash, vaginal yeast infection, and sensitivity to the sun. Hypersensitivity reactions resulting in shock, blood diseases including reduced platelets or fractured red cells which can result in anemia or bleeding. All medications can also result in allergic reactions.

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Fertilization

The oocytes will be thawed and fertilized in the laboratory with a sample of my male partner's or donor sperm. Intracytoplasmic sperm injection (ICSI) will be utilized as this is necessary to achieve fertilization when using frozen oocytes.

Embryo Transfer

I/We understand that after the oocytes are thawed and fertilized, a few of the resulting embryos will be transferred into my uterine cavity via a catheter passed through the cervix. This may cause some cramping, discomfort, and possibly a small amount of bleeding. Infection is an exceedingly rare, but possible result of the catheter insertion and may require antibiotic treatment. If infection occurs, it may lower the chances for pregnancy.

I/We understand that there is no guarantee that the transferred embryos will result in a pregnancy. I/We understand that transferring multiple embryos places me at risk for multiple gestation (more than one baby), and that the severity of the risk correlates directly with the number of embryos transferred. There are risks to both the mother as well as the babies of women who conceive pregnancies with twins or greater including preterm labor and the delivery of premature infants who require intensive care, with the possibility of life-long complications associated with prematurity. It is the policy of the Center for Reproductive Medicine to limit the number of embryos transferred according to age of the person providing the egg(s) at the time of freezing as well as the quality of the embryos being replaced. These limits minimize the possibility of conceiving a high-order multiple pregnancy while optimizing the chance of achieving a pregnancy.

Post-Transfer Management

In an attempt to maximize the chance of successful implantation, estrogen patches and/or progesterone may be continued until a pregnancy is confirmed by ultrasound and blood tests reveal that the pregnancy is able to make enough hormone to support itself. In a programmed cycle, this usually occurs at approximately 10-12 weeks of gestation. In a natural cycle, these hormone supplements may not be necessary. I/We understand that after embryo transfer and up to the time when these hormonal supplements are discontinued, I will be asked to have blood tests for hormonal evaluation as well as regular ultrasound examinations performed as instructed by the program.

It is hoped that a pregnancy will result from this procedure, but it cannot be guaranteed. The chances for a successful outcome have been explained to me/us by the IVF Team. If no pregnancy occurs, 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.

Should a pregnancy result from the procedure, I/we understand that I might suffer a miscarriage or an ectopic (tubal) pregnancy, or any of the other complications that might occur during any pregnancy. Although to date, pregnancies from oocytes that have previously been frozen have not demonstrated an increased incidence of fetal abnormalities compared to babies conceived naturally, I/we understand that the IVF team cannot guarantee the normalcy of any infant that is born following this procedure.

Alternative options (if any) have been explained to us by the IVF team including procedures that are not performed here, and other non-medical options such as adoption or non-treatment.

Since the total number of babies born from frozen eggs is small, the absolute risk of the egg cryopreservation procedure is currently unknown and careful monitoring of the pregnancy and children born from eggs that were previously frozen will be recommended. Chorionic villus sampling (CVS), to sample the growing placenta, or amniocentesis will be recommended to confirm the pregnancy is chromosomally normal. Finally, I/we understand that pregnancy has risks, and the effect of using frozen oocytes compared to fresh oocytes with in vitro fertilization on pregnancy outcome is, as of yet, unknown.

I/We understand that I/we may at any time, without prejudice, decline from participation in this treatment.

Patient Information:

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The IVF team is obligated to provide information about the Medical Center's policy in the event that physical injury occurs. If as a result of my participation I (female partner) experience physical injury from known or unknown risks of the procedure as described, immediate medical care and treatment, including hospitalization if necessary, will be available. However, no monetary compensation is available and I/we will be responsible for all costs of such medical treatment, either directly or through medical insurance and/or other forms of medical coverage. NOTE: For questions about medical coverage, please contact your insurance company.

Please see the Weill Cornell Physicians Notice of Privacy Practices regarding your protected health information. I/We understand that I/we may be contacted for follow-up.

Discarded Material

I/We understand that any unused biological material including sperm, and abnormal and/or arrested embryos (those which have stopped developing) will be discarded after the IVF treatment. This material, which would normally be discarded, may be used for training purposes and/or research; however, no new embryos or pregnancies will be generated. I/We understand that I/we may, at any time, decline donation of or the use of this material, without prejudice.

Please initial your choices below:

I. You may donate this material for quality control and training.

____/____ I/We hereby CONSENT to allow CRM to utilize the unused biological material including sperm and abnormal and/or arrested embryos for quality control and training purposes before they are discarded.

OR

____/____ I/We hereby DO NOT CONSENT to allow CRM to utilize the unused biological material including sperm, and abnormal and/or arrested embryos for quality control and training purposes before they are discarded. This material will be discarded in accordance with normal laboratory procedures and applicable laws.

II. You may donate this material for research.

____/____ I/We hereby CONSENT to allow CRM to utilize the unused biological material including sperm, and abnormal and/or arrested embryos for research. None of this material will be utilized for research unless you sign a specific research consent form.

OR

____/____ I/We hereby DO NOT CONSENT to allow CRM to utilize the unused biological material including sperm, and abnormal and/or arrested embryos for research. This material will be discarded in accordance with normal laboratory procedures and applicable laws.

I/We have been encouraged to ask questions, and agree that 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, will be answered by a member of the IVF team.

_____	_____	_____
Patient Signature	Date	Date of Birth
_____	_____	_____
Partner Signature	Date	Date of Birth

CONSENT 2: Informed Consent for Embryo Cryopreservation

Patient Information:

Patient Name: _____ Date of Birth: _____

I/We understand that it is the policy of The Ronald O. Perelman and Claudia Cohen Center for Reproductive Medicine (CRM) of Weill Cornell Medicine to limit the number of embryos transferred according to maternal age and embryo quality. The purpose of this policy is to maximize the chance of pregnancy while reducing the rate of multiple gestations. I/We understand that should the IVF procedure result in excess embryos (beyond the number selected for transfer), the excess embryos may be cryopreserved (frozen) for possible transfer in a subsequent cycle. The determination to freeze the excess embryo(s) is made by the IVF physicians and/or embryology staff.

I/We acknowledge that I/we are responsible for all costs and fees incurred for embryo cryopreservation, including, but not limited to, the cost of the cryopreservation process and fees for embryo storage.

I/We understand the possibility exists that some embryos may not reach the stage of development where they can be cryopreserved. In addition, I/we understand that some cryopreserved embryos may not survive the process of freezing and thawing. Normal development may not resume following the thawing process, or some or all embryos may not be suitable for transfer. There is no guarantee that pregnancy will occur following embryo transfer. CRM cannot guarantee the normality of any pregnancy that develops following the transfer of any thawed embryo(s).

I/We understand that it is possible that the viability of the embryo(s) may be compromised as a result of the malfunction of equipment used in the embryology laboratory that is beyond the control of CRM.

I/We agree that any resulting cryopreserved embryo(s) is/are the property of both partners (if applicable), with rights of survivorship. No use can be made of the embryo(s) without the consent of both partners (if applicable).

a. In the event of divorce or dissolution of the marriage/partnership (if applicable), the ownership and/or other rights to the cryopreserved embryo(s) will be as directed by the court decree and/or settlement agreement.

b. In the event of the death of one partner, the ownership and/or rights to the cryopreserved embryo(s) shall revert to the surviving partner (if applicable).

c. In the event of the death of both the patient and partner (if applicable), the ownership of and/or rights to the cryopreserved embryo(s) shall revert to CRM. In this event I/we prefer to: (please **initial** your choice)

    1. _____ _____ Discard the cryopreserved embryo(s)

    2. _____ _____ Donate the cryopreserved embryo(s) for research

Patient Information:
Patient Name: _____ Date of Birth: _____

d. It is agreed that before the 55th birthday of the patient (___/___/___), the cryopreserved embryo(s) must be thawed and implanted, donated, transported elsewhere or otherwise discarded. If no disposition has occurred by the above date, I/we hereby waive any and all interest in said cryopreserved embryo(s) and the cryopreserved embryo(s) shall become the sole and exclusive property of CRM. In this event, I/we prefer to: (please **initial** choice)

1. _____ _____ Discard the cryopreserved embryo(s)

2. _____ _____Donate the cryopreserved embryo(s) for research

If I/we elect not to utilize the cryopreserved embryo(s) for a future pregnancy attempt, I/we will make a decision about disposition, prior to the 55th birthday of the patient. Currently, the options for embryo disposition include:

1. discarding the cryopreserved embryo(s); or
2. donating the cryopreserved embryo(s) to another person (This option requires New York State Department of Health and Food and Drug Administration (FDA) screening and testing prior to donation.); or
3. donating the cryopreserved embryo(s) for research; or
4. transporting the cryopreserved embryo(s) to another facility.

CRM cannot guarantee or predict disposition options that will be available in the future.

I/We understand and acknowledge that in order to stop embryo storage and related storage billing, I/we must request, complete, and return original notarized embryo disposition documents.

Pursuant to NYSDOH Part 52-8.7(f), reproductive tissue stored for a client-depositor shall not be destroyed or released for other purposes as a result of nonpayment of storage fees or for any other reasons, without documentation that the client-depositor was given at least 30 days' written notice by certified mail, return receipt requested.

It is understood and agreed that all parties will abide by any applicable federal or state requirements and regulations. I/We understand and agree that any embryos created are regulated by the Food and Drug Administration and the New York State Department of Health, and any changes in federal or state rules and regulations may affect the future use of embryos created during this cycle.

I/We have been encouraged to ask questions, and agree that 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.

_____	_____	_____
Patient Signature	Date	Date of Birth
_____	_____	_____
Partner Signature	Date	Date of Birth

CONSENT 3: Informed Consent for Intracytoplasmic Sperm Injection (ICSI)

Patient Information:

Patient Name: _____ Date of Birth: _____

I/We, as part of my/our ongoing treatment at The Ronald O. Perelman and Claudia Cohen Center for Reproductive Medicine (CRM) of Weill Cornell Medicine, give the embryology staff at CRM permission to perform intracytoplasmic sperm injection (ICSI), if it is reasonably determined that ICSI would improve the chances of fertilization. ICSI is a procedure where a single sperm is placed directly into the oocyte (egg) using a microneedle. The clinical decision to proceed with ICSI is made by the physician/embryology staff and is based on sperm and/or egg quality and/or quantity.

ICSI may be performed in the event of any of the following, and as deemed necessary by the CRM Team: low sperm count; low sperm motility; poor sperm morphology; the use of frozen sperm; the use of donor sperm; the use of surgically retrieved sperm; sub-optimal fertilization in a prior IVF cycle; low egg yield; use of donor eggs; or the use of previously cryopreserved eggs.

During ICSI, spermatozoa are deposited in a viscous solution that will slow their motion, allowing for visualization and selection. The eggs are treated with an enzyme to remove the granulosa cells (cells surrounding the egg). ICSI can only be performed on mature eggs. A single sperm is then injected directly into the cytoplasm (center) of the egg. I/We understand that there is a risk of damage to the egg(s) when ICSI is performed. However, typically, fewer than seven percent (7%) of eggs are damaged by ICSI. When ICSI is performed, most eggs fertilize normally. I/We understand that some eggs may fail to fertilize or fail to develop normally.

I/We understand that likelihood of success cannot be based solely on semen and/or egg characteristics. I/We understand that ICSI, as well as all assisted reproductive technologies, may increase the chances of high order gestations, including identical and non-identical twin pregnancies.

I/We acknowledge and agree that I/we are responsible for all costs and fees for ICSI.

I/We have been encouraged to ask questions, and agree that 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.

_____	_____	_____
Patient Signature	Date	Date of Birth
_____	_____	_____
Partner Signature	Date	Date of Birth

CONSENT 4: Informed Consent for Assisted Embryo Hatching

Patient Information:

Patient Name: _____ Date of Birth: _____

I/We, as part of our ongoing treatment at The Ronald O. Perelman and Claudia Cohen Center for Reproductive Medicine (CRM) of Weill Cornell Medicine, give the embryology staff at CRM permission to assess our embryos microscopically and to perform assisted embryo hatching should it be determined that the procedure is necessary. I/We understand that, the embryology staff will examine the zona pellucida (the shell-like layer surrounding the embryo) and the general appearance of each embryo. These assessments are required to determine whether assisted hatching may be indicated for embryos selected for transfer. The need for performing assisted hatching is determined by the embryology staff.

The natural process of embryo hatching involves the shedding of the zona pellucida. Embryo hatching directly affects the ability of an embryo to implant into the uterine lining. To perform assisted embryo hatching the Embryology Team uses an acidic solution or laser to weaken the zona pellucida.

I/We understand that assisted embryo hatching has been used on thousands of embryos. I/We understand that there is a risk of damage during the manipulation. Single cells of the embryo(s) are damaged in less than 1% of all cases.

I/We understand that the technique may yield unknown risks. Removing the zona pellucida may decrease its protective effect for the embryo. I/We understand that the likelihood of success with this procedure cannot be predicted. Some research has reported an increase in monozygotic twinning.

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 I/we might have, will be answered by a member of the IVF team.

_____	_____	_____
Patient Signature	Date	Date of Birth
_____	_____	_____
Partner Signature	Date	Date of Birth