



Informed Consent Packet - In Vitro Fertilization (IVF)

This packet contains the required IVF treatment consent documents. Please read, consider and, if you agree, sign and return the attached documents. Please note that there are required initials and signatures within the attached documents.

Please note:

- Additional consents are required if frozen sperm may be utilized.
- Participation in research is voluntary.
- A new set of consent documents is required for each IVF attempt.
- CRM staff is available to answer your questions related to the consent documents.

I/We have been encouraged to ask questions, and any questions that I/we have asked have been answered to my/our satisfaction. I/We also understand that any future questions that I/we might have, can be answered by a member of the IVF team.

_____	_____	_____
Print Patient Name	Patient Signature	Date
_____	_____	_____
Print Partner Name	Partner Signature	Date



CONSENT 1: Informed Consent For In Vitro Fertilization/Embryo Transfer

PART I: Patient

I have requested to be treated at The Ronald O. Perelman and Claudia Cohen Center for Reproductive Medicine (CRM) of Weill Cornell Medicine. I understand that there are several steps involved in the in vitro fertilization (IVF) and embryo transfer (ET) procedures. I will receive medications to induce the maturation of multiple oocytes (eggs); during this time, I will undergo bloodwork and ultrasound (sonogram) monitoring to manage my IVF cycle. I will undergo an egg retrieval procedure by directed ultrasound-guided needle aspiration, under intravenous sedation or general anesthesia. Follicles that are evident on ultrasound will be aspirated and follicular fluid and eggs will be collected. My eggs will be prepared and fertilized in the laboratory using my partner's sperm or, where applicable, donor sperm. Embryos resulting from this procedure may be transferred back to me via a catheter placed through the cervix into the uterine cavity.

1. Ovulation Induction

I understand that a variety of medications are available for the induction of ovulation, including Clomiphene Citrate (Clomid/Serophene), Human Menopausal Gonadotropin (e.g., Menopur), Follicle Stimulating Hormone (e.g., Gonal-F/Follistim/Bravelle), Leuprolide Acetate (Lupron), GnRH-antagonists (Ganirelix/Cetrotide), Estrogen Patches (Climara) and Human Chorionic Gonadotropin (HCG). I understand that some of these medications are administered by intramuscular or subcutaneous injection and may cause bruising and discomfort at the injection site. Lupron may result in side effects, including fatigue, muscle and joint pain, and transient menopausal-like symptoms (headaches, hot flashes, mood swings, sweats, insomnia, fatigue, etc.). Clomiphene Citrate may result in side effects, including hot flashes, abdominal distention, bloating, headache and visual changes. Gonadotropins (Menopur/Gonal-F/Follistim/Bravelle) may have side effects, including a situation where the ovaries become over-stimulated, leading to a condition called Ovarian Hyperstimulation Syndrome (OHSS). In the most severe form of OHSS, serious complications may result, which may require hospitalization and medical intervention. Some reported complications, while rare, include ovarian torsion (twisting of the ovary), blood clots, kidney failure, fluid overload and death. I, therefore, understand the importance of maintaining close contact with the IVF team during the period of time while I receive these medications and for a minimum of two (2) weeks afterwards. Furthermore, some, but not all, studies have suggested that fertility medications might increase the risk of developing ovarian cancer.

2. Monitoring Protocol

I understand that while receiving the medications described above, I will be closely monitored by the IVF team. This monitoring may be as frequent as daily and carries the risk of mild discomfort and bruising at the venipuncture (blood draw) site. I understand that transvaginal ultrasound examinations will be performed, as necessary, and that there may be some discomfort with this procedure. I understand that if monitoring suggests a low probability for successful egg retrieval, my stimulation cycle may be stopped and no egg retrieval will be performed. Alternatively, if my response to the medications is too high, and the likelihood of OHSS is increased, the stimulation medications may be discontinued and the cycle canceled or the embryos cryopreserved (frozen).

3. Egg Retrieval

I understand that at a time determined by the IVF team, I will be admitted to New York Presbyterian Hospital as an ambulatory patient. Egg retrieval will be performed by ultrasound-guided transvaginal or, if indicated, transabdominal needle aspiration of the follicles. The vaginal wall and ovary will be punctured and the follicular fluid aspirated. The follicular fluid will be analyzed under the microscope to locate the eggs. Risks related to this procedure include infection, bleeding and injury to pelvic or abdominal organs. If an infection occurs, admission to the hospital may be necessary in order to administer intravenous antibiotics. If bleeding occurs, stitching of the vaginal puncture site may be necessary. In rare circumstances, observation in the hospital, a blood transfusion and/or laparoscopy or laparotomy (abdominal surgery) may be required to stop the bleeding and repair the injury.

For a few patients, the ovaries may not be accessible by transvaginal ultrasound, and laparoscopy or other procedure may be required to perform the egg retrieval. If this is the case, alternatives will be discussed before the procedure.

I understand that there is no guarantee that eggs will be retrieved.

I understand and agree that I will receive corticosteroids in the form of methylprednisolone, and antibiotics in the form of tetracycline or a similar antibiotic, following the egg retrieval. Research studies carried out several years ago indicated that small doses of corticosteroids and antibiotics may be beneficial in protecting the embryos from possible invasion of blood cells and bacteria following the transfer into the uterus.

Side effects are rare after treatment with corticosteroids. However, corticosteroids may mask signs of infection. New infections may appear during corticosteroid use, and there may be an inability to localize an infection, if one occurs. Side effects may include blood pressure elevation, salt and water imbalance, and increased excretion of potassium and calcium. These medications in high doses have been reported to cause mood swings, insomnia, psychological changes, psychotic manifestations, muscle weakness, impaired wound healing, increased sweating, headache, vertigo, allergic reaction, loss of muscle mass, osteoporosis and abdominal distention.

Side effects from the use of tetracycline may include nausea, vomiting, diarrhea, loss of appetite, skin rash, sensitivity to the sun, and, rarely, hypersensitivity reactions result in shock or blood abnormalities.

This consent is to be signed by you in the presence of the nurse on the day you start your IVF cycle monitoring.

Patient Signature

Date

Date of Birth

Witness Signature

Date

PART II: Patient and Partner (if applicable) Informed Consent

4. Egg Fertilization

On the day of egg retrieval, the designated sperm will be used to attempt to fertilize the eggs.

- If frozen sperm is to be used, additional consents are required.
- Authorization for the storage and use of frozen sperm is also required for the Andrology Laboratory (located on the 7th floor).

If the male partner is providing a sperm sample on the day of egg retrieval, he will be asked, and by signing below agree, to take an oral antibiotic during the first portion of the stimulation cycle. The use of oral antibiotics is to reduce the possibility that bacteria will be present in the sperm sample. The presence of bacteria in the sperm sample could interfere with fertilization and embryo development.

I/We understand that following egg retrieval, the eggs will be evaluated and prepared for the fertilization process by the embryology staff. Fertilization may be achieved by insemination or intracytoplasmic sperm injection (ICSI).

- Fertilization by insemination occurs when the eggs are exposed to prepared sperm.
- Intracytoplasmic sperm injection (ICSI) is a procedure involving the direct injection of a single sperm into each egg.

The clinical decision to proceed with insemination versus ICSI is made by the physician/embryology staff and is based on sperm and/or egg quality and/or quantity. ICSI can only be performed when the appropriate additional consent form is signed.

5. Embryo Transfer

I/We understand that the transfer of an embryo/embryos into the uterine cavity may cause some cramping, discomfort and, possibly, a small amount of bleeding. There is also some risk of infection, which 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 IVF 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 IVF, and that the 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. It is our policy 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. Remaining viable embryos may be frozen for possible transfer in a subsequent cycle. Embryo cryopreservation will only be performed when the appropriate additional consent is signed.

6. Post-Transfer Management

In an attempt to increase the chance of successful implantation, post-transfer management may include progesterone either by intramuscular injection or vaginal suppository. The progesterone will be continued, until a negative blood pregnancy test or the pregnancy is confirmed by ultrasound. I/We understand that during this period blood testing for hormonal evaluations will be performed as instructed by the IVF team.

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 IVF treatment has been explained to me/us by the IVF 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.

I/We understand that pregnancies resulting from IVF are subject to the same complications as pregnancies achieved without medical intervention, such as miscarriage, ectopic (e.g., tubal) pregnancy, preterm labor, or other complications. There is no current consensus as to whether the likelihood of certain birth defects or other abnormalities may be increased in children conceived with IVF technologies, as opposed to naturally conceived children. I/We understand that the IVF team cannot guarantee the health of any infant resulting from this procedure. Alternative options (if any) have been explained to me/us by the IVF team.

7. Discarded Material

I/We understand that any unused biological material including follicular fluid, sperm, immature and/or unfertilized eggs, 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 follicular fluid, sperm, immature and/or unfertilized eggs, 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 follicular fluid, sperm, immature and/or unfertilized eggs, 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 follicular fluid, sperm, immature and/or unfertilized eggs, 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 follicular fluid, sperm, immature and/or unfertilized eggs, and abnormal and/or arrested embryos for research. This material will be discarded in accordance with normal laboratory procedures and applicable laws.

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.

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

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 cyropreserved embryo(s) for research
- 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.

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)

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

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