Informed Consent for Oocyte (Egg) Cryopreservation

Patient Information:

Patient Name: _____ Date of Birth: _____

Part 1:

I have requested to be treated at The Ronald O. Perelman and Claudia Cohen Center for Reproductive Medicine (CRM) of Weill Cornell Medical College. I understand that there are several steps involved in the ovarian stimulation, oocyte retrieval and oocyte cryopreservation procedures. I will receive medications to induce the maturation of multiple oocytes ; during this time I will undergo multiple blood tests and ultrasound (sonogram) procedures to determine my response to these medications. I will undergo an oocyte retrieval procedure by vaginal ultrasound-guided needle aspiration under intravenous sedation or general anesthesia. Follicles that are evident on ultrasound will be aspirated; follicular fluid and oocytes will be collected. My oocytes will be prepared and cryopreserved, for my own future use.

I understand that CRM suggests that I consult with a CRM staff psychologist in advance of proceeding with oocyte cryopreservation.

1. Ovulation Induction

I understand that a variety of medications are available for the induction of ovulation, including Clomiphene Citrate (Clomid/Serophene), Human Menopausal Gonadotropins (e.g., Menopur), Follicle Stimulating Hormone (e.g., Gonal-F/Follistim/Bravelle), Leuprolide Acetate (Lupron), GnRH-antagonists (Ganirelix/Cetrotide), Letrozole, Estrogen Patches (Climara/Vivelle), and Human Chorionic Gonadotropins (hCG). I understand that these medications are given orally or by intramuscular or subcutaneous injection, which 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. 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 CRM team during the period of time while I receive these medications and for a minimum of two 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 CRM 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. There is no apparent medical risk associated with the use of transvaginal ultrasound. I understand that if monitoring suggests a low probability for successful oocyte retrieval, my stimulation cycle may be stopped and no oocyte retrieval will be performed. Alternatively, if my response to the medications is too high, and the likelihood of hyperstimulation is increased, the stimulation medications may be discontinued and the cycle canceled.

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3. Oocyte Retrieval

I understand that at a time determined by the CRM team, I will be admitted to New York Presbyterian Hospital as an ambulatory patient. Oocyte retrieval will be performed by transvaginal ultrasound guided needle aspiration of the follicles. I understand that anesthesia will be administered during the procedure. 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 oocytes.

Risks related to this procedure include infection and/or bleeding. 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. The risks of the use of anesthesia during the oocyte retrieval include an allergic reaction, low blood pressure, nausea or vomiting, and in rare cases death.

For a few patients the ovaries may not be accessible by transvaginal ultrasound and laparoscopy or other procedure would be required to perform the oocyte retrieval. This will be discussed before the procedure.

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

I understand that following the oocyte retrieval, I may experience mild abdominal discomfort and/or light vaginal bleeding (these are normal). I understand that if I experience severe abdominal pain, heavy bleeding, and/or a temperature of over 100 degrees F, I should contact CRM immediately at 646-962-2764.

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

I have been encouraged to ask questions, and any questions that I have asked have been answered to my satisfaction. I also understand that any future questions I might have, may be answered by a member of the CRM team.

_____	_____	_____
Patient Signature	Date	Date of Birth

Part 2: Informed Consent for Oocyte (Egg) Cryopreservation

Patient Information:

Patient Name: _____ Date of Birth: _____

Oocyte Cryopreservation

I understand that once the Embryology Team has identified the oocytes, the oocytes will be cryopreserved by vitrification. The cryopreserved oocytes will remain stored in the CRM Embryology Laboratory.

Use of Oocytes

I understand that when I am ready to attempt to achieve a pregnancy, some or all of my cryopreserved oocytes can be thawed. I understand that there is no guarantee that any of the oocytes will survive the freezing and thawing procedure, fertilize or produce a baby. The live birth rate per oocyte thawed using these cryopreservation techniques depends on the age at which the oocyte(s) were cryopreserved.

I understand that the oocyte(s) will be fertilized with a sample of my partner's or my chosen donor's sperm. I understand that intracytoplasmic sperm injection (ICSI) will be utilized to achieve fertilization. I understand that I may receive hormonal medications to mature the lining of my uterus in preparation for embryo transfer as well as antibiotics to prevent infection from the embryo transfer. I understand that I will undergo blood testing and vaginal ultrasound examination to determine my response to these medications as well as the proper time to perform the oocyte thaw, fertilization and embryo transfer. I understand that the embryo transfer will occur by placing the embryos into the uterus via a catheter (a thin, flexible tube) placed through the cervix.

I understand that this process may result in more embryos than can be transferred in one cycle. In some cases, the embryos may be of sufficient quality to be cryopreserved for use in a future cycle. The CRM team will advise on appropriate follow-up.

I understand that it is recommended that I utilize modern prenatal care, which may include chorionic villus sampling (CVS) or amniocentesis.

I understand that the thaw, fertilization and embryo transfer procedures described above are the current standards of practice and that CRM cannot guarantee what the standards of practice will be when I choose to utilize my cryopreserved oocytes.

I understand that the thaw, fertilization and transfer of previously cryopreserved oocytes will require additional consent documents at the time of the procedures.

Discarded Material

I understand that any unused biological material, including cells, blood, follicular fluid, immature oocytes and/or nonviable oocytes, will be discarded after the oocyte retrieval. This material, which would normally be discarded, may be used for training purposes and/or research; no embryos or pregnancies will be generated. I understand that to protect my privacy, all identifiers associated with the biological material will be removed prior to its use for training purposes and/or research. I understand that I may, at any time, decline donation of this material, without prejudice.

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Please indicate your choices below in each of the items listed:

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

____I hereby CONSENT to allow the clinic to utilize the unused biological material for quality control and training purposes before they are discarded.

OR

____I hereby DO NOT CONSENT to allow the clinic to utilize the unused biological material 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 hereby CONSENT to allow the clinic to utilize the unused biological material for research. None of this material will be utilized for research unless you sign a specific research consent form.

OR

_____I hereby DO NOT CONSENT to allow the clinic to utilize the unused biological material for research. This material will be discarded in accordance with normal laboratory procedures and applicable laws.

III. Oocyte Disposition

I understand that if I decide not to or am unable to use these cryopreserved oocyte(s) for my own reproductive purposes (transferred into myself or into a gestational carrier), current alternatives include:

1. Discarding the cryopreserved oocyte(s)
2. Donating the cryopreserved oocyte(s) for approved research studies
3. Donating the cryopreserved oocyte(s) to another individual in order to attempt pregnancy (In this case, additional infectious disease testing and screening close to the time of oocyte retrieval is needed due to Federal and State requirements)

A. In the event of my death or incapacitation, the ownership of and/or rights to the cryopreserved oocyte(s) shall revert to CRM. In this event, I elect to:

- ❑ Discard the cryopreserved oocyte(s)
- ❑ Donate the cryopreserved oocyte(s) for research purposes
- ❑ Donate the cryopreserved oocyte(s) to a designated individual

Donate to: Name _____
Address _____
Telephone _____
Email _____

In the event the designated individual is unable or unwilling to accept the cryopreserved oocyte(s), the clinic will determine the details and individual designation of any donation. I agree that, if it is not possible to carry out my chosen option and/or I cannot be contacted in the case of a catastrophic event occurs, the clinic is authorized to discard my cryopreserved oocyte(s).

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B. I understand that CRM will not fertilize the oocyte(s) after I reach fifty (50) years of age. After this age, I elect to:

- ❑ Discard the cryopreserved oocyte(s)
- ❑ Donate the cryopreserved oocyte(s) for research purposes
- ❑ Transfer the cryopreserved oocyte(s) to a designated storage facility at my expense
- ❑ Donate the cryopreserved oocyte(s) to a designated individual

Donate to: Name _____
Address _____
Telephone _____
Email _____

In the event the designated individual is unable or unwilling to accept the cryopreserved embryos, the clinic will determine the details and individual designation of any donation.

NOTE: Donating oocyte(s) for research or to another individual may not be possible or may be restricted by law. While efforts will be made to abide by your wishes, no guarantees can be given that your cryopreserved oocyte(s) will be used for research or donated to another individual. In these instances, if your oocyte(s) are not eligible or we cannot abide by your wishes, your cryopreserved oocyte(s) will be destroyed and discarded by the lab in accordance with laboratory procedures and applicable laws.

Fees

I understand that the fees associated with ovarian stimulation and oocyte cryopreservation are my responsibility. I understand that it is my responsibility to contact the CRM Billing Department regarding fees.

I understand that I am responsible for paying quarterly fees to CRM in order to continue the storage of my cryopreserved oocyte(s). I agree to provide CRM with an updated address and telephone number when I move.

I understand that if the fees associated with oocyte storage have not been paid for a period of one (1) year and CRM is unable to contact me after reasonable efforts have been made (via registered mail at last known address), my cryopreserved oocyte(s) may be destroyed by CRM in accordance with normal laboratory procedures and applicable law.

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

I have been encouraged to ask questions, and any questions that I have asked have been answered to my satisfaction. I also understand that any future questions I might have, will be answered by a member of the CRM team.

_____ _____
Patient Signature Date