

# CONSENT FOR CRYOPRESERVATION OF OOCYTES

I, \_\_\_\_\_\_ ("Patient") hereby request to participate in the Oocyte Freezing Program (Egg Freezing Program) at the California Center for Reproductive Health (CCRH), by undergoing the following procedures:

- Ovarian stimulation with fertility drugs for the purpose of producing multiple eggs ("oocytes")
- Oocyte retrieval
- Selective freezing of oocytes for the purpose of banking (storing) such oocytes for subsequent dispensation

# **Procedures and Methodology**

I understand that in order to produce multiple oocytes I will need to undergo controlled ovarian hyperstimulation (COH) using a standard prescribed gonadotropin regimen (injectable medications). I also understand that I will be monitored on a regular basis (every several days) with vaginal ultrasound examinations and serial blood sampling. Upon attainment of a safe and measured degree of ovarian stimulation, ovulation will be triggered by injection of human chorionic gonadotropin (hCG) or Lupron (Leuprolide Acetate) followed by transvaginal ultrasound-guided needle follicle aspiration, (i.e. oocyte retrieval). This procedure will be accomplished under intravenous conscious sedation (twilight sleep anesthesia) administered and supervised by a licensed anesthesiologist. The objective is to safely obtain as many, good quality, mature ("MII") oocytes as possible. Following oocyte retrieval, all suitable MII oocytes will be frozen in a process called vitrification (rapid freezing technique).

I also understand that I will be required to undergo laboratory evaluation for certain sexually transmitted diseases including, but not limited to Chlamydia, Gonorrhea, Syphilis, Hepatitis, Human T Lymphocyte Virus (HTLV), and Human Immunodeficiency Virus (HIV) testing.

# **Possible Complications/Risks**

I understand that I will be taking injectable medication(s) (gonadotropins) on a specific schedule to stimulate my ovaries (COH) which may potentially produce temporary enlargement and cysts of my ovaries. Side effects sometimes encountered with enlargement of the ovaries and the growth of multiple follicles may be pelvic discomfort, bloating, nausea, fatigue and occasionally mood swings. Rarely, the physical changes in the ovaries could produce severe complications, such as twisting or rupture of an ovary, which may require surgical intervention, or metabolic problems (such as ovarian hyperstimulation syndrome) that could require subsequent hospitalization. As a result of taking this medication (s), there is a chance that I would be required to restrict strenuous and/or sexual activity for 1-4weeks thereafter. Use of the medications should not make menopause occur earlier than expected. A separate consent for Controlled Ovarian Hyperstimulation must be signed before ovarian stimulation begins.

My initials indicated that I consent to controlled ovarian hyperstimulation:

I understand that following ovarian stimulation with fertility medications, I will undergo follicle aspiration (oocyte retrieval). I understand that there is a very slight risk of infection, intra-abdominal bleeding, and injury to the bladder, intestines, uterine tubes, ovaries, or other pelvic structures, which could require operative repair, including major abdominal surgery. I understand that the oocyte retrieval procedure may last up to 60 minutes and will require the use of Intravenous Conscious Sedation (IVCS)/moderate sedation (twilight sleep). I understand that there are risks associated with IVCS/moderate sedation which may include adverse drug reactions, and other rare, but potentially serious injuries. A separate Consent for Follicle Aspiration must be signed before the egg retrieval procedure.

My initials indicated that I consent to the follicle aspiration procedure:

#### **Patient Acknowledgement and Consent:**

I understand that although unlikely, during the course of ovarian stimulation with fertility drugs as well as during the oocyte retrieval procedure, unforeseen conditions may occur, which necessitate additional and/or different procedures than those set forth above. I therefore authorize Eliran Mor, MD, Irene Woo, MD (and/or designee) to perform such procedures as are, in his/her professional judgment, required and desirable including, but not limited to, procedures involving pathology tests and radiology. The authority granted in this paragraph shall extend to remedying conditions that are not known at the time the procedure is commenced.

I consent to the retrieval and cryopreservation of my oocytes, exclusively for my own use. Any other dispensation of my oocytes will only occur with my explicit written authorization.

Initials

Initials



I understand that (1) every effort will be made by California Center for Reproductive Health (CCRH) and its affiliate laboratory/staff to culture immature eggs in the laboratory until eggs reach maturity (in vitro maturation), in order to be able to cryopreserve such eggs, and that (2) no guarantee exists that immature eggs will successfully mature in the embryology lab, and that (3) any of my oocytes that are deemed, at the discretion of Eliran Mor, MD or Irene Woo, MD (and/or their designee at CCRH and its affiliate laboratory), to be unsuitable, for any other reason (failure to reach maturity, degeneration...), for laboratory analyses and/or the procedures referred to herein, will be disposed of.

I understand that the facility at which eggs are stored may cease operations, resulting in the need for cryopreserved oocytes to be transferred to a different facility. I also understand that cryopreserved oocytes may be lost as a result of a laboratory accident or events beyond the control of the storage facility.

I understand that the cryopreservation of eggs does not guarantee that such eggs will survive the thawing process once I am ready to conceive using such eggs. I also understand that (1) upon thawing, eggs would have to be fertilized using a technology called intracytoplasmic sperm injection (ICSI), involving the injection of a single spermatozoa into each egg which survived the thawing process, and that (2) the ICSI process does not guarantee a successful normal fertilization of the thawed egg(s), and that (3) normal fertilization of thawed egg(s) does not guarantee successful normal development of the resulting embryo, or pregnancy, if normal embryo development is achieved and an embryo(s) is/are transferred into my uterus. I acknowledge that Eliran Mor, MD and/or Irene Woo, MD, or other member of CCRH have discussed with me in detail the expected egg survival, ICSI fertilization, embryo development, and pregnancy and live-birth rates associated with the above procedures.

# **Release**

By signing below, I/we hereby agree to release CCRH, its physicians, its affiliate laboratory, associates and/or designees, directors, officers, agents, employees and any person(s) or corporation(s) acting on behalf of CCRH, its physicians, its affiliate laboratory, directors, officers, agents, and employees, and hold them harmless from any and all liability, except due to gross negligence, resulting from their acts or omissions taken pursuant to this consent, and/or arising out of or related to the treatment described herein.

I understand that I may ask any additional questions at any time. I acknowledge that I have read and understand the foregoing and agree to proceed with the treatment/process outlined above. My signature also indicates that I have been given a copy of this consent form, and that I may request an additional copy at any time. A signed copy of this consent form will be kept in my medical record.

My/our Signature(s) on this Consent indicate that we:

- I. HAVE READ AND FREELY AND KNOWINGLY AGREE AND CONSENT TO ALL OF THE INFORMATION CONTAINED HEREIN;
- II. CLEARLY UNDERSTAND THE INFORMATION THAT I/WE HAVE BEEN GIVEN ABOUT THESE PROCEDURES INCLUDING THEIR RISKS BENEFITS AND ALTERNATIVES AS EXPLAINED TO ME/US BY MY/OUR CCRH PHYSICIAN OR NURSE, ON BEHALF OF THE PHYSICIAN;
- III. HAVE HAD THE CHANCE TO ASK ANY QUESTIONS WE HAVE ABOUT THE ABOVE OUTLINED PROCEDURES AND HAVE HAD ALL OF MY/OUR QUESTIONS ANSWERED TO MY/OUR SATISFACTION, AND;
- IV. WE HAVE BEEN GIVEN ALL THE INFORMATION I/WE DESIRED BEFORE SIGNING THIS CONSENT.

Initials

# Certification of Informed Consent for Oocyte Cryopreservation (Egg Freezing)

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
WITNESS	(print)	WITNESS SIGNATURE	DATE