CONSENT • DONOR OOCYTES

Medical Record Number

Patient Name

Addressograph or Label - Patient Name, Medical Record Number

I/We_____(Donor) and _____(Donor's partner, if applicable), the undersigned, are over eighteen (18) years of age.

I/We understand that we are participating voluntarily in a program to donate eggs to women who are unable to produce eggs of their own or whose eggs are unlikely to lead to a normal pregnancy (referred to herein as "Recipients"). I/We understand that the donated eggs will be fertilized in a laboratory by the Recipient partner's sperm or donor sperm, as designated by the Recipient. If fertilization occurs, the fertilized egg(s) will then be transferred into the uterus of the Recipient in the hope and expectation that a pregnancy will occur.

I/We understand that I/we waive any right and relinquish any claim to the donated eggs or any embryo(s), pregnancy or child(ren) that may result from them. I/We agree that the Recipient of the egg(s) may regard the donated eggs as her own and any resulting embryo(s) and child(ren) as her own. I/We will not attempt to discover the identity of the Recipient, if she is anonymous, or any resulting child(ren), if the Recipient is anonymous.

I/We understand that the identity of the Recipient (unless already known) will not be disclosed to me/us, nor will my/our identity be revealed to the Recipient (unless already known). I/We understand, however, that Lucile Salter Packard Children's Hospital at Stanford ("LPCH") will disclose such information if required to do so by Court order, and failure to do so would subject LPCH to liability for contempt. No entry will be made in my (the Donor's) personal medical record as to the disposition of any eggs obtained and, other than my Donor number, no entry will be made in the personal medical record of the Recipient as to the source of the donated eggs.

Notwithstanding anything to the contrary herein, I/we understand that I/we may consent to be contacted by LPCH in the event that any child resulting from eggs that I have donated requires the donation of tissue, bone marrow or an organ for which I am a possible donor match. I/We understand that consent to such contact does not obligate me (the Donor) to reveal my identity, to be tested to determine whether I am such a match, or to donate such tissue, marrow or organ. (Donors may indicate their wishes concerning contact in Section 9 of this form.)

I/We understand that it may be necessary for my physician to keep certain records as part of the hospital record concerning the source and disposition of donated eggs. I/We agree that medical details related to this procedure may be revealed in professional publications, as long as my/our anonymity is preserved.

I/We understand that prior to commencement of the egg donation process, comprehensive genetic and medical information will be obtained from me (the Donor), from my medical records, from physical examinations and otherwise, to determine whether I am a suitable candidate for this procedure. I/We will have a blood test for HIV (the virus that causes AIDS) and other infectious diseases. Because I/we understand that there is no conclusive test for detecting HIV infection, I/we also hereby certify that I/we have not, to my/our best knowledge, contracted HIV, engaged in unprotected sexual activity with someone with HIV/AIDS or who has used intravenous drugs, or otherwise been at risk for infection with HIV. Furthermore, I/we hereby agree not to engage in unprotected sexual intercourse or use intravenous drugs during my/our participation in the egg donation program. In addition, I (the Donor) will undergo a psychological evaluation by a counselor. I/We hereby certify that the genetic and medical history information I/we have provided is complete and accurate to the best of my/our knowledge.

Description of Egg Donation, its Risk and Side Effects

1. Description of Oocyte (Egg) Retrieval.

Egg donation for in vitro fertilization and embryo transfer has become an established treatment for many infertile couples. At LPCH, persons donating eggs have ovarian stimulation with human menopausal gonadotropin, such as Fertinex or recombinant human gonadotropins (such as Gonal F or Follistim) to stimulate the development of multiple eggs. Compared with natural cycles in which only one egg (oocyte) matures per cycle, a higher number of fertilizable eggs may be obtained in stimulated cycles. Lupron (Leuprolide Acetate) or Synaral are also used to prevent a premature LH (Luteinizing hormone) surge and premature release of the eggs. Ovulation is triggered by an injection of human chorionic gonadotropin (hCG), usually between one and two weeks after starting the fertility medications. The Donor has serial pelvic ultrasound examinations to monitor the development of eggs and possibly blood tests to assess the estrogen (estradiol) production by the ovaries. The ultrasound and estradiol findings determine the time to inject the human chorionic gonadotropin (hCG). The eggs are harvested by ultrasound-guided vaginal aspiration 35 hours after the hCG administration. Usually these procedures are performed on an outpatient basis using intravenous sedation. In a few cases, general anesthesia might be used for retrieval.

Each follicle usually contains one egg surrounded by granulosa cells. The granulosa cells surround the egg in its development. After withdrawal, each egg is examined microscopically and placed in a culture dish in an incubator under controlled temperature and atmosphere in preparation for fertilization. After a length of time dependent on the degree of egg maturation, a specially prepared suspension of sperm is added to the eggs. If the fertilization is successful, the fertilized egg (now called an embryo) will be transferred into the Recipient's uterus.

2. Inducing Growth of Multiple Eggs.

Growth of multiple eggs is achieved by ovarian stimulation using various combinations of drugs. Fertinex, Gonal F, Follistim, and hCG (commonly referred to as "fertility drugs") in various combinations are used to trigger development of several egg follicles in the ovaries. Proper timing and dosage of these drugs and timing of the recovery of the eggs may necessitate frequent examinations, blood tests and ultrasound tests during the 5 to 10 days before the egg harvest. The possible risks and side effects of the fertility drugs used include:

a. Overstimulation of the ovaries. This is unusual occurring in 0.55 to 2% of the patients treated with fertility drugs. This problem may occur slowly or very suddenly and, in server cases, the swelling of the ovaries can cause pain, fluid accumulation in the abdomen and lungs, or bleeding in the abdomen from ruptured follicle cysts. In severe cases this might require hospital treatment or, very rarely, even surgery to stop bleeding from an ovary or to repair or remove a swollen ovary that has twisted. However, when the ovarian follicles are emptied if their fluid by ultrasound-guided aspiration, as is the case in egg donation, such sever problems from overstimulation of the ovaries are quite rare.

b. Blood clots in an artery. Formation of a blood clot in an artery of the body or brain could cause damage to the tissue depending on that artery for its blood flow. In the brain this would be called a stroke, in the heart, a heart

attack. It is not known whether fertility drugs are a direct cause of artery blood clots, and the number of cases reported for this problem is small, a few cases among many thousands of patients treated.

c. Allergic reactions. Possible allergic reactions to fertility drugs include rash, fever, itching, difficulty in breathing (asthma) or shock. Allergic reactions are quite rare.

d. Bloating. Some patients have bloating and abdominal discomfort similar to the accumulation of fluid that may occur before a menstrual period. This excessive accumulation of body water might cause serious medical problems for a woman who has serious heart or kidney disease, epilepsy, migraine headaches or asthma. Premenstrual syndrome symptoms such as irritability, restlessness, depression, fatigue, swelling, and headache may occur with fertility drugs. One study has raised the possibility of an association (as distinct from a cause and effect relationship) between the use of fertility drugs and ovarian cancer. The study was based on a very small number of subjects and many, including the study author, have agreed that the presumed association is very tenuous. I/We acknowledge that we have received a copy of the informational sheet "Fertility Drugs and the Risk of Ovarian Cancer."

e. Blood drawing. Several blood samples may be required to assess the level of estrogen hormone produced by the growing follicles. During blood drawing, women may experience discomfort, a slight chance of bruising and, rarely, fainting.

3. Ultrasound-Guided Egg Retrieval.

Ultrasound-guided egg retrieval is the most common way to retrieve the eggs. It is an outpatient procedure which is usually performed with intravenous sedation, although on occasion general anesthesia may be utilized. The ultrasound-guided egg retrieval involves insertion of a needle through the top of the vagina. By viewing the needle path on the ultrasound screen, it is possible to puncture the follicles with the tip of the needle and aspirate the eggs. The total length of time necessary for the procedure is approximately 15-30 minutes. After the procedure, the Donor will be taken to a recovery area. There may be some discomfort in the lower abdomen. Acetaminophen (Tylenol) can provide some relief.

a. Risks of ultra-sound guided egg aspiration. Ultrasound-guided egg aspiration involves placing instruments inside the abdominal cavity. This carries a risk of injury to the structures within the abdomen including the bowel, bladder, blood vessels and nerves, as well as the uterus, tubes and ovaries. Serious damage is rare (less than one case in 1,000), but would require further surgery to repair. Postoperative complications are not common but might include infection inside the abdomen or pain in the abdomen. The risk of death as a result of ultrasound-guided egg aspiration is extremely rare and less than the risk of dying from an auto accident during one year.

b. Risks of general anesthesia (if applicable). Complications of general anesthesia (in the unlikely event that it is utilized) are very rare in young healthy patients, but serious permanent damage or even death can occur with general anesthesia. For the first 24 to 36 hours after general anesthesia, it is common to have drowsiness, nausea, fatigue, muscle soreness or malaise.

c. Failure of attempt at egg recovery. Hormone testing, examinations and ultrasound testing provide the most accurate predictions of egg maturity currently possible. Nevertheless, test results and ultrasound are not 100% accurate. Despite the most careful evaluation, eggs may not be retrieved or the egg retrieved may not be at the correct stage of development for successful fertilization.

d. Pain. If the egg harvest is done under conscious sedation, the Donor may experience mild to moderately severe pain when the eggs are withdrawn. Pain medication will be injected into an intravenous line to decrease the pain.

4. Other Risks.

a. Psychological. The psychological and emotional risks of voluntary participation in an egg donation program to the Donor and/or her partner and family are currently not known.

b. Undesired Pregnancy. I/We understand that abstinence from coitus (sexual intercourse) during the egg donation treatment cycle is the only sure way of preventing an undesired pregnancy. I/We understand that if I (the Donor) become pregnant, I/we will be responsible for the pregnancy, any costs related thereto and any child(ren) which result(s). I/We understand that pregnancy increases the risk of overstimulation of the ovaries in patients receiving fertility drugs.

5. Stipend or Compensation.

I/We understand that LPCH will not provide any stipend or compensation to me/us for the time, inconvenience and trouble on my/our part and will not be involved in or responsible for any such compensation arrangements.

6. Financial Responsibility.

I/We understand that the Recipient is financially responsible for the costs of all services and items provided by LPCH as part of the egg donation procedure. I/We also understand that the Recipient is financially responsible for the costs of all services and items provided by LPCH and its physicians to treat any medical complications which I (the Donor) may experience as a result of the egg donation procedure which are not covered by my medical insurance. I/We understand that LPCH is not responsible for any costs related to the egg donation procedure or medical complications, should they occur. Without limiting the foregoing, I/We understand that LPCH, in its sole discretion may arrange for insurance to cover certain costs related to medical complications which I (the Donor) may experience which are not covered by my medical insurance, and that the Recipient will be solely financially responsible for any applicable premium for any such insurance. I (the Donor) certify that I have the following medical insurance which will cover the costs of medical complications, if any arising from the egg donation process.

7. Legal Status.

I/We understand that the legal status of egg donation us as yet uncertain and that there may be future changes in the law, including, without limitation, with respect to anonymity. I/We have had the opportunity to seek independent legal counsel.

8. Release of Liability.

I/We hereby release LPCH, Stanford University and the employees thereof (collectively, the "Stanford") from any medical, psychological, emotional or legal risks related to my/our voluntary participation in the egg donation program, except insofar as such risks are caused by negligence or misconduct on the part of Stanford.

9. Wishes Concerning Future Contact

❑ I/We consent to be contacted by LPCH in the event that a child who results from an egg that I have donated requires the donation of tissue, bone marrow or an organ for which I (the Donor) am a possible donor match. I/We understand that consent to such contact does no obligate me (the Donor) to reveal my identity, to be tested to determine whether I am such a match, nor to donate any such tissue, marrow or organ.

❑ I/We do not consent to be contacted by LPCH in the event that a child who results from an egg that I have donated requires the donation of tissue, bone marrow or an organ.

*If neither box is marked, LPCH shall not contact Donor under these circumstances.

10. Statement of Donor and Partner (if applicable)

MY/OUR SIGNATURES BELOW INDICATE THAT I/WE HAVE READ AND UNDERSTOOD THE ABOVE INFORMATION. I/WE HAVE HAD AN OPPORTUNITY TO ASK QUESTIONS AND ANY QUESTIONS HAVE BEEN ANSWERED TO MY/OUR SATISFACTION. I/WE UNDERSTAND THAT I/WE MAY WITHDRAW FROM THE PROGRAM AT ANY TIME WITHOUT AFFECTING MY/OUR FUTURE THERAPY OR CLINICAL CARE AND THAT THERE WILL BE NO PENALTY FOR SUCH WITHDRAWAL.

I_____(name of donor) do hereby donate _____(number, if applicable) of my ova (eggs) to LPCH on behalf of _____(a_____recipient who is unknown to me or name of recipient if known) for_____ (specify purpose). I wish the disposition of any unused donated ova (eggs) to be determined by the Recipient.

_____

Data from your ART procedure will also be provided to the Centers for Disease Control and Prevention (CDC). The 1992 Fertility Clinic Success Rate and Certification Act requires that CDC collect data on all assisted reproductive technology cycles performed in the United States annually and report success rates using these data. Because sensitive information will be collected on you, CDC applied for and received an "assurance of confidentiality" for this project under the provisions of the Public Health Service Act, Section 308(d). This means that any information that CDC has that identifies you will not be disclosed to anyone else without your consent.

AS REQUIRED UNDER CALIFORNIA STATE LAW, THE ORIGINAL OF THIS CONSENT SHALL BE KEPT IN YOUR MEDICAL RECORD AND A COPY PROVIDED TO YOU FOR YOUR RECORDS AND TO THE HOSPITAL IF THE PROCEDURE TO REMOVE THE OVA IS PERFORMED IN A HOSPITAL. THIS CONSENT IS AN IMPORTANT DOCUMENT AND SHOULD BE RETAINED WITH OTHER VITAL RECORDS.

Signature of Donor	**Date**	**Time**
Signature of Donor's Partner (if applicable)	**Date**	**Time**
Signature of Physician Removing ova	**Date**	**Time**
Signature of Witness (LPCH)	**Date**	**Time**