

Lucile Salter Packard Children's Hospital



Stanford
MEDICINE

Fertility and
Reproductive Health



CONSENT • REI • GESTATIONAL SURROGACY

Page 1 of 6

Medical Record Number

Patient Name

Addressograph or Label - Patient Name, Medical Record Number

I, _____ ("Surrogate"), the undersigned, am over 18 years of age.

I am participating voluntarily in the Lucile Salter Packard Children's Hospital at Stanford ("LPCH") Program for in vitro fertilization ("IVF") and gestational surrogacy because I wish to assist a couple or individual who is unable to carry a pregnancy (the "Intended Parent(s)") in achieving a successful pregnancy and birth of a child. Gestational surrogacy is an elective procedure in which one woman carries a pregnancy created by the egg and sperm of two other individuals. The Intended Parent(s) may supply the eggs and/or sperm or may arrange for eggs and/or sperm to be donated by others. The eggs will be fertilized by the sperm in a laboratory (in vitro fertilization). If fertilization occurs, LPCH will transfer the fertilized eggs into my uterus in the hope and expectation that a pregnancy will occur. I understand that the child(ren) born of me pursuant to this arrangement will not have any of my genetic material.

1. Collection of Medical Information Prior to the Surrogacy Process.

Prior to commencement of the surrogacy process, comprehensive medical information will be obtained from me, from my medical records, from physical examinations and otherwise to determine whether I am a suitable candidate for this procedure. This evaluation will include, without limitation, a blood test for Rh factor incompatibility and HIV (the virus that causes AIDS). I understand that it is possible to transmit an infectious disease, including HIV, to the fetus/child(ren) during a pregnancy, and that there is no conclusive test for detecting HIV infection. I certify that I have not, to the best of my knowledge, contracted HIV or engaged in unprotected sexual activity with someone who has HIV/AIDS or who has used intravenous drugs or otherwise been at risk for infection with HIV. In addition, I certify that I have undergone a psychological evaluation by a counselor.

Comprehensive medical information will also be obtained from the Intended Parent(s) or, if applicable, the egg and/or sperm donor. The Intended Parent(s) or, if applicable, the egg and/or sperm donor, may be tested for Rh factor incompatibility and will be tested for infectious and sexually transmitted diseases.

2. General Description of IVF and the Transfer of Embryos.

The eggs used in IVF may be withdrawn from an Intended Parent or from an ovum donor. The woman who is the source of the eggs will have ovarian stimulation with fertility drugs (human menopausal gonadotropin or recombinant human gonadotropins) to stimulate the development of multiple eggs. Compared with a natural cycle in which one egg matures, a higher number of mature eggs may be obtained in a stimulated cycle so that more than one egg may be withdrawn, fertilized and placed in the uterus.

After withdrawal of the eggs, each egg will be 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 will be added to the eggs. The eggs which have been fertilized will be incubated for an additional thirty-six (36) to one hundred twenty (120) hours during which time they will undergo cell division to form an embryo with between two (2) and sixty-four (64) cells. If the fertilization is successful, the embryo will be transferred into my uterus.



The embryos will be loaded into a transfer tube which will be passed through the cervix (opening of the uterus) into my uterus and the embryos will be gently expelled into the uterine cavity. This embryo transfer is an outpatient office procedure requiring no anesthesia. LPCH will draw a blood sample for a pregnancy test approximately two (2) weeks after the egg retrieval.

3. Preparation for Embryo Transfer.

I will receive estrogen to develop my endometrial lining and progesterone to support the lining for a pregnancy. It may be necessary to administer Leuprolide to me to synchronize my cycle with the cycle of the woman who is the source of the eggs so that my uterus is prepared for implantation at the time she is ready to have her eggs retrieved. My endometrium may be monitored by measurement of blood hormones, ultrasound measurements and/or endometrial biopsy. The risks associated with estrogen and progesterone are similar to those involved in taking birth control pills, such as bloating, breast tenderness and blood clots. Possible side effects of Leuprolide are hot flashes, vaginal dryness, insomnia, redness and small bruises at the injection site. Rare cases of allergic reaction at the injection sites also have been reported. Risks of endometrial biopsy include infection, uterine perforation and hemorrhage. Estrogens can cause blood clots, and vaginal discharge. Progesterone can be associated with mood changes (e.g. depression), bloating and gastrointestinal disturbances.

4. Embryo Culture and Associated Risks.

Consistent with the current standard of care, the IVF Program at LPCH uses a culture medium which contains a trace amount of human blood product (human serum albumin) in culturing embryos. The blood product used in the embryo culture has been subject to screening for known transmittable diseases, heat processing and a dehydration process. There is no evidence to date of transmission of disease through the culture medium or the cultured embryos. To the extent that there may be risks which are as of yet unknown, the risks should be less than those involved in a standard transfusion of human blood.

5. Embryo Transfer and Associated Risks.

One or more embryos will be transferred into my uterus through a thin catheter (hollow tube) threaded through the cervix. This procedure does not require anesthesia or any pain medication, but may cause mild cramping or discomfort as the catheter passes through the cervix.

Possible risks of the embryo transfer include loss of the embryos during the laboratory procedures, damage to the uterus including perforation of the uterus by the catheter or infection in the uterus following the procedure. A fever may be a sign of infection. Allergic reaction also can occur. Each of these is rare.

6. Other Risks Associated with IVF, Embryo Transfer and Pregnancy.

a. **Failure of IVF and the Embryo Transfer Procedures to Result in Pregnancy.** The success of the IVF and embryo transfer procedures cannot be guaranteed. Development of pregnancy is dependent on many factors some of which cannot be tested or predicted in advance, and no guarantees of pregnancy rates can be given. Any of the following may prevent pregnancy:



CONSENT • REI • GESTATIONAL SURROGACY

- i. No eggs may be retrievable because the timing of the egg withdrawal may be off or the ovaries may not respond to the medication to induce the growth of eggs,
 - ii. Efforts to obtain an egg by ultrasound-guided retrieval may be unsuccessful,
 - iii. The egg(s) may not mature in the laboratory environment,
 - iv. The male Intended Parent, if applicable, may be unable to provide a suitable semen specimen or frozen sperm samples may be of poor quality or may not survive processing well,
 - v. Fertilization may not occur or development of the fertilized egg(s) may not occur,
 - vi. The embryo(s) may not be suitable for transfer,
 - vii. Transfer of the embryo(s) may not be successful,
 - viii. The embryo(s) may fail to grow in the uterus,
 - ix. The egg(s), sperm or embryo(s) may be damaged in the laboratory,
 - x. The Surrogate's endometrium may not develop properly or the endometrium may not be receptive to the embryo(s),
 - xi. Implantation may not occur, or
 - xii. Other unforeseen circumstances may occur at any step in the procedure.
- b. **Multiple Births.** Twin or multiple pregnancy is possible if more than one embryo is transferred into the uterus. Multiple pregnancies carry with them increased risks of miscarriages, premature labor, diabetes in pregnancy, pregnancy-induced hypertension (high blood pressure) and increased financial and emotional costs. A premature newborn may die or have to stay in a special care nursery for a long period of time and may develop a variety of complications, some of which may result in permanent damage.
- c. **Blood Drawing.** I will have blood tests for hormone evaluation and a pregnancy test thirteen (13) days after egg retrieval. During blood drawing, I may experience discomfort, a slight chance of bruising and, rarely, fainting.
- d. **Complications of Pregnancy.** There are many medical risks to both the pregnant woman and the baby associated with pregnancy itself whether conceived through intercourse or through the IVF and embryo transfer procedure. Pregnancy complications, which may include, without limitation, high blood pressure, diabetes, liver disease, hemorrhage or seizures, may lead to serious permanent damage or death to the pregnant woman and/or the baby. In addition, there are risks of miscarriage, genetic defects, birth defects, or stillbirths.
- e. **Abnormalities and Birth Defects.** So far, there is no evidence that IVF and the embryo transfer procedure cause an increased chance of abnormalities in the baby. The risk of birth defects may or may not be higher than the usual risk of birth defects (2% to 5%) when conception occurs following intercourse. Synthetic progesterone has been linked to an increase in certain forms of fetal abnormalities. However, LPCH prescribes a form of progesterone which has not been associated with such increases in fetal abnormalities.
- f. **Psychological Risks.** The psychological and emotional risks of voluntary participation in an IVF and embryo transfer program to the Intended Parent(s), the Surrogate and each party's family are currently not known.



7. Intracytoplasmic Sperm Injection (ICSI).

A method of treatment of severe male subfertility called "ICSI" is available at LPCH. This method increases the probability of fertilization and consequently, the probability of embryo transfer to establish a pregnancy. To the extent that the Intended Parent or Parents choose to utilize ICSI, it may be advisable for me to undergo genetic amniocentesis if pregnant. If genetic amniocentesis is recommended by a physician, I will be asked to sign a separate consent form explaining the risks and benefits of that procedure.

8. Rights and Obligations of the Surrogate and the Intended Parent(s).

I understand that upon the birth of the child, it is intended that the Intended Parent(s) shall be the exclusive parent(s) of the child(ren) conceived by this procedure. I state my express agreement and intent that the Intended Parent(s) conclusively be presumed to be the sole legal parent(s) of any embryo(s) or child(ren) resulting from this procedure.

I hereby represent that I and my husband or partner, if any, have entered into a separate agreement with the Intended Parent(s) governing our respective rights and obligations with respect to the surrogacy arrangement. LPCH is not a party to that agreement and expresses no opinion as to its legal ramifications or enforceability. I understand that the surrogacy process cannot commence until a copy of the legal contract with the Intended Parent(s) has been provided LPCH.

9. Release of Liability.

With full knowledge of the risks, I hereby release and hold harmless LPCH, Stanford University, and the physicians, employees and agents thereof (collectively, "Stanford") from any and all claims and/or liability arising out of or in any way connected with my voluntary receipt of the medical procedures described in this consent form and my voluntary participation in the surrogacy arrangement with the Intended Parent(s), except to the extent of any negligence or willful misconduct on the part of Stanford.

10. Financial Responsibility.

I understand that LPCH is not responsible for any costs related to the surrogacy procedures or any related medical complications, should they occur. I also understand that the Intended Parent(s) have entered into a separate agreement with LPCH under which the Intended Parent(s) have accepted financial responsibility for payment of all fees related to the surrogacy procedures and any related medical complications, should they occur and to the extent that they are not covered by insurance.

11. Scope of Authorization.

I consent to the performance of the medical procedures described in this consent form until the occurrence of one of the following events: (i) death of an Intended Parent, (ii) dissolution of Intended Parents' marriage or partnership, if applicable, (iii) my successful pregnancy which results in live birth, or (iv) written notice to LPCH of withdrawal of consent by the Intended Parent(s) or by myself.



Medical Record Number

Patient Name

CONSENT • REI • GESTATIONAL SURROGACY

Page 5 of 6

Addressograph or Label - Patient Name, Medical Record Number

I acknowledge and agree that in the event of dissolution of Intended Parents' marriage or partnership or a live birth, LPCH will require the Intended Parent(s) and me to execute new consent forms prior to the performance of any additional medical procedures described herein. Notwithstanding the forgoing, I acknowledge and agree that any and all representations, covenants and agreements contained herein shall remain in full force and effect with respect to procedures performed prior to the occurrence of the event and any embryo(s), fetus(es) and/or child(ren) which have resulted from such procedures.

12. Notice Requirements.

I understand that I must provide LPCH with written notice of any of the following events no later than thirty (30) days after the occurrence of such event: (i) my successful pregnancy which results in live birth; or (ii) any change of my address. Prior to LPCH's receipt of such written notice, LPCH shall not be deemed to have knowledge of such event nor shall LPCH be liable for any actions taken which may be inconsistent with the occurrence of such event.

a. Written Notices.

All notices which are required by this consent form shall be hand-delivered or sent by registered or certified mail, postage prepaid as follows:

If to LPCH:

Lucile Packard Children's Hospital
725 Welch Road
Palo Alto, CA 94304

Attn: _____

If to Surrogate:

All notices shall be deemed received two (2) business days after hand delivery or five (5) business days after mailing in accordance with this Section.



Medical Record Number

Patient Name

CONSENT • REI • GESTATIONAL SURROGACY

Page 6 of 6

Addressograph or Label - Patient Name, Medical Record Number

MY SIGNATURE BELOW INDICATES THAT I HAVE READ AND UNDERSTOOD THE ABOVE INFORMATION AND CONSENT TO THE GESTATIONAL SURROGACY PROCEDURES DESCRIBED ABOVE. I HAVE HAD AN OPPORTUNITY TO ASK QUESTIONS AND ANY QUESTIONS HAVE BEEN ANSWERED TO MY SATISFACTION.

Signature of Surrogate

Date

Time

Signature of Witness (LPCH)

Date

Time

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 PROCEDURES ARE PERFORMED IN A HOSPITAL. THIS CONSENT IS AN IMPORTANT DOCUMENT AND SHOULD BE RETAINED WITH OTHER VITAL RECORDS.