
USF IVF Consent for Gestational Carriers and Intended Parents

Surrogate Parenting Agreements

A surrogate parenting agreement is a formal contractual relationship between a woman and another individual or couple in which the woman agrees to carry a pregnancy for another individual or couple through an IVF embryo transfer using genetic material that does not include her own eggs. The woman is designated as the “gestational carrier” or GC, and the individual(s) who desire to have a child are designated as the intended parent(s) (IP or IPs). In addition to the medical procedures, there are multiple laws and regulations that should be addressed in order to protect everyone involved. This document will review the various medical and mental health aspects of all of the participants.

Contract & Legal Concerns

The gestational carrier and intended parent(s) must have ongoing legal counsel by an appropriately qualified legal practitioner who is experienced with third-party reproduction and licensed to practice in the State of Florida.

A legal contract prepared by such counsel must be in place prior to commencement of an IVF cycle and any subsequent embryo transfer. This contract should contain information designating the roles of all participants involved with respect to parental rights. Additionally, the contract should address all relevant issues, including but not limited to, the amounts, timing and escrowing of compensation (if any), insurance coverage for the pregnancy and offspring, medical care and decision making, and any other information relevant to a pregnancy, parental rights or the arrangement. The clinic staff is not able to provide legal advice.

All parties involved should be aware that the state of the law pertaining to gestational carrier arraignments and parental rights resulting from such arrangements differs from state to state. Each participant (the GC with any spouse) and the Intended Parent(s), should retain and be represented by a lawyer with relevant experience in family law and gestational carrier contracts. The participants will have to take legal actions to allow the intended parent(s)' name(s) to be recognized as the legal parents and hopefully entered on the child's birth certificate. This may require a court petition prior to the birth of the baby and should be handled by an experienced reproductive technology law attorney. The clinic, and any employees or contractors, are not able to review the contract for completeness or content. A letter of clearance from the respective attorneys will be required prior to treatment with a statement that a valid legal contract has been prepared, negotiated, and properly entered into to the satisfaction of the intended parent(s) and the gestational carrier (and any spouse), that the GC and IPs have had independent counsel, and all participants understand and assume the risks of proceeding.

Mental health professional

One of the most important first steps is for the intended parents to meet with a mental health professional to discuss the proposed GC arrangement, including the reasons for choosing to pursue this treatment, as well as the relationship and expectations they have with the gestational carrier. In a later meeting, the mental health professional will meet with the gestational carrier and her partner. Based on the meetings with the clinical mental health professional, additional appointments or psychological testing may be required. Mental health professionals used for evaluation of the IP's and GC need to be experienced with "third-party reproduction," including being familiar with the appropriate professional guidelines. The visits will explore topics such as communication and expectations of all parties before, during, and after birth, consideration of pregnancy with multiples (twins/triplets), and potential fetal-reduction or abortion for medical reasons. Additional topics may also include consideration of future disclosure to the IP's and GC's children, and conflict resolution in the event of unforeseen conflicts.

Not all prospective surrogates are approved, even those with the best of intentions. The standards for a gestational carrier are high because of the emotional and psychological issues involved in carrying someone else's child, and because the steps to complete the process can be complex. The purpose of the evaluation is to protect the interests and emotional health of both the gestational carrier (and where relevant, her partner and children) and the intended parents, but cannot predict future behavior. The appointments are mandatory, and a letter from the clinical mental health professional must be received by University of South Florida IVF and Reproductive Endocrinology (USF IVF) before treatments proceed.

Infectious Disease Screening

The intended parent(s), or a designated donor, will provide gametes (sperm and eggs) to be used to make embryos that will be transferred into the uterus of the gestational carrier. The person providing the gametes is considered to be a tissue donor with regard to state and federal regulations for infectious disease screening. The word "donor" in this sense does not imply the transfer of legal rights. Before the tissues may be transferred to the gestational carrier, the providers of the sperm and egg must undergo the appropriate clinical history review, examination, and laboratory testing in accordance with state and federal regulations. The U.S. Food and Drug Administration (FDA) have issued strict guidelines that must be followed. These extra steps are in place as a precaution to prevent the spread of infectious diseases. These extra steps do not usually interfere with the procedures, and the clinic staff will help you coordinate the testing and evaluation to minimize the impact on your treatment.

For the individual providing sperm or eggs, the infectious disease screening will consist of a physical exam looking for evidence of infectious diseases or high-risk behaviors that may increase the risk for infectious diseases. A clinical history assessing infectious disease risk will be completed as well. Infectious disease testing will have to be completed at an FDA-approved lab within 30 days of egg collection and 7 days of sperm collection. The gestational carrier may waive the 6-month quarantine requirement for sperm.

The gestational carrier will undergo infectious disease screening and evaluation of other relevant tests in preparation to carry a pregnancy. The state and federal guidelines do not regulate the testing and evaluation of the gestational carrier. The evaluation will be performed to assess the risk of infectious disease transmission to the baby. The tests will be reviewed with the intended parent(s), and they may request additional testing as desired.

Insurance

Insurance coverage for any pregnancy and possible complications can be expensive. Usually, the intended parent(s)' insurance policy will not cover the pregnancy or any associated treatments when a gestational carrier is involved. The gestational carrier's insurance may not cover the pregnancy expenses when the baby will not be the legal child of the gestational carrier. The intended parents should also make sure their policy will cover the baby's newborn care, and any conditions that may apply to obtain such coverage. Several insurance agencies offer insurance coverage for gestational carriers' medical expenses. It is your responsibility as a participant to a gestational carrier arrangement to ensure there is adequate insurance coverage in place for the pregnancy, delivery and child before proceeding with treatments. The clinic and clinical staff cannot provide you with advice regarding insurance coverage other than the contact information for various insurance agencies. The clinic will require that you confirm through your attorneys within your letter of clearance that you have obtained adequate insurance coverage.

Uterine Testing

The gestational carrier will need to complete uterine evaluation which may include an ultrasound, saline infusion sonogram, hysterosalpingogram, and/or a hysteroscopy. These tests are usually performed between day 4 and day 12 of the menstrual cycle. The test is used to look for polyps or fibroids that could decrease the chances of success if they are not removed. Some clinics may utilize a trial of medications to evaluate the response of the uterine lining (endometrium).

Treatment Overview

The individual providing eggs will undergo medications that will increase the number of eggs available for treatment. This treatment will be identical to in vitro fertilization (IVF) with the exception that the embryos will be placed into the uterus of the gestational carrier. A description of the IVF process and risks is attached to this document.

The instructions below provide an overview of the treatment for a gestational carrier. The clinic will provide a detailed treatment schedule.

A gestational carrier cycle may include some or all of these steps:

- Oral Contraceptive Pills (OCP's) - same as birth control pills
- Prenatal vitamins, supplements, and prescription medications
- Pituitary suppression using GnRH agonists or antagonists (e.g., leuprolide, Lupron®, ganirelix, Cetrotide®)
- Development of mature endometrium (uterine lining) using oral estradiol, transdermal estradiol, vaginal estradiol, or injectable estradiol.
- Progesterone for luteal phase support. Progesterone may be given as an injection or vaginal preparation (Prometrium®, Crinone®, Endometrin®)
- Transfer of the embryo(s) back into the uterus
- Pregnancy test

Oral Contraceptive Pills (OCP's)

The gestational carrier will begin using oral contraceptive pills (OCP's), which are birth control

pills, at the beginning of the menstrual cycle. Some people experience spotting or bleeding while on the pills, and this is normal. The OCP's prevent ovulation and help to regulate the timing of the cycle. After 1 to 4 weeks on pills, the gestational carrier will come in to the clinic for an ultrasound to make sure that the endometrial lining is thin, and that there are no large cysts on the ovaries that might interfere with the treatment.

Prenatal Vitamins and Other Medications

The gestational carrier will need to begin taking prenatal vitamins if not already using them. Folic acid alone may also be used. It's also important not to use any non-steroidal anti-inflammatory medications once the treatment starts. These medications may hinder implantation of the embryos. Examples of this type of medication are ibuprofen (Advil® Motrin®) and naproxen sodium (Aleve®). It is all right to use acetaminophen (Tylenol®). Any medications prescribed by other physicians, or any over-the-counter medications, including herbal remedies, should be brought to the attention of the physicians. The gestational carrier should only take medications that are considered safe during pregnancy.

Pituitary Suppression Using GnRH agonists and antagonists

Approximately two weeks after beginning the OCP's, GnRH agonists or antagonists (leuprolide, Lupron®, ganirelix, Cetrotide®) may be started. These medications suppress the pituitary gland, preventing natural hormones from interfering with the lining of the uterus. Potential side effects of pituitary suppression are hot flashes, headaches, vaginal dryness, and mood changes. There are no known long-term effects of using this medication as prescribed in a gestational carrier cycle.

Development of Mature Endometrium (uterine lining)

After the oral contraceptives are stopped, a menstrual period will start. This menses may be lighter than usual. At this point an ultrasound and blood test evaluation is commonly performed. If normal, the estrogen will be started. Additional estrogen in the form of shots, pills, or suppositories may be prescribed in certain circumstances. Vaginal discharge may increase as estrogen level increases, and some people feel more emotional during this time as well. Ultrasound and blood testing will be performed periodically to evaluate the development of the endometrium.

Progesterone for Luteal Phase Support

The most noticeable side effect of progesterone is constipation. The best intervention for this is to increase fluid intake, especially water and other non-caffeinated beverages. Progesterone can also mimic symptoms of pregnancy, such as breast tenderness and nausea. This medication makes the uterus undergo final preparation for receiving an embryo. The gestational carrier typically starts progesterone on the same day the egg collection takes place for the intended mother or egg donor.

The Embryo Transfer

The embryo transfer is performed by placing a small catheter in the uterus. This procedure is usually painless. Pregnancy tests are done 9-11 days after embryo transfer. If pregnancy results are positive, supplemental hormones may continue until 10 weeks of pregnancy. USF IVF will calculate a final day for these additional hormones.

Potential Risks and Disadvantages

Medications

The risks associated with the medications, both oral and injectable, include mood changes, weight gain, headaches, hot flashes, vaginal dryness, discomfort and bruising at injection sites, increased vaginal discharge, breast tenderness, nausea, and constipation. A few people may have an allergic reaction to the progesterone, which may include hives, a rash, and itching. Rarely, high doses of estrogen can increase the risk of blood clots, liver disease, gallbladder disease, or increased growth of any estrogen-sensitive tumor that may be present. There may be other risks which, at the present time, have not yet been identified. The occurrence of any of the above may also result in increased financial cost and emotional strain. Blood sampling may result in bruising or infection. The embryo transfer may be slightly uncomfortable and carries a minor risk of infection. Ultrasound exams may cause discomfort. There are no other known risks associated with ultrasound.

Multiple Pregnancies (Twins, Triplets, and More)

There is a risk of multiple pregnancies that increases with the number of embryos transferred. The clinic makes a recommendation about the number of embryos to transfer into the uterus based on the goal of maximizing the chance of a pregnancy and minimizing the risk of multiples. The intended parent(s) and the gestational carrier have input on the number of embryos to transfer and everyone, including the physician, must be in agreement.

Pregnancy Problems and Complications

All pregnancies are at risk of complications. Complications may increase the health risk to the gestational carrier or result in risk to the baby/babies. Fertility treatments may increase some of these risks. There are also risks of malformations or birth defects that are common to all pregnancies. There may be unknown long-term side effects as a result of this procedure, including those that could occur in subsequent generations as a result of currently unknown genetic problems associated with the embryos. A detailed discussion of these risks is beyond the scope of this document, but any specific questions regarding risks should be addressed with the physician.

Roadblocks

There are several things that could occur which would prevent completion of the cycle, and/or prevent pregnancy. Some potential gestational carriers may be identified before the cycle as unsuitable for pregnancy due to medical, psychological or social reasons. Treatment may be stopped at the discretion of our physician for a variety of medical reasons before transfer. There may be no embryos surviving or no actively dividing embryos available for transfer. Laboratory procedures may result in loss or damage to the embryos. Certain infectious diseases may prevent the transfer of embryos to the gestational carrier. The actual embryo transfer may be difficult or impossible to accomplish. If embryos are transferred, pregnancy may still not occur. If pregnancy does occur, it may not continue until full term. Should a miscarriage or ectopic pregnancy occur, additional medical care may be necessary and may result in additional costs.

X

Patient Signature

Date

Patient Name

Date of Birth

X

Spouse / Partner Signature

Date

Spouse / Partner Name

Date of Birth

X

Gestational Carrier Signature

Date

Gestational Printed Name

Date of Birth

Physician Signature

Date