Gestational Carrier / Intended Parent

**These template documents were revised before the US Supreme Court decision in *Dobbs v. Jackson* (which repealed Roe v. Wade), and therefore, SART has not reviewed the template documents and did not make any changes based on the *Dobbs* decision. SART strongly recommends that before any SART template document is put into use in a Member's practice, the document should be reviewed by the Member's local legal counsel to ensure that the language conforms to current federal, state and local laws as these may have recently changed or are in the process of being changed.**

DESCRIPTION

This document informs the gestational carrier and the intended parent (or parents) of the steps in this process and its legal and medical requirements.

TARGET

* All persons involved in treatment that uses a gestational carrier

RELEASE NOTES

* This is the 1st revision of this document
* Reviews the legal, medical and other requirements for this therapy.
* Reviews the screening and treatment of the carrier
* Risks to carrier, intended parent(s) and offspring updated based on current literature
* Wording shortened and simplified where possible
* Signature pages provided for both the Gestational Carrier (and her spouse) and the Intended Parent(s)
* allows for Witness as well as Notary verification
* To be used in conjunction with IVF or DE, and Egg or Embryo Disposition documents.

TO DO

* Modify this document according to local needs and preferences.
* Get legal review to assure conformance with State and local laws and regulations

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What you should know about Gestational Carriers

and Intended Parents

Information, Process, and Risks

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Intended Parent A:

 **Last Name**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **First Name**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Date of Birth: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ID#\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Cell phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Intended Parent B:

 **Last Name**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **First Name**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Date of Birth: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ID #\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Cell phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Gestational Carrier

 **Last Name**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **First Name**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Date of Birth: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ID #\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Cell phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Gestational Carrier Spouse

 **Last Name**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **First Name**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Date of Birth: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ID #\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Cell phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Gestational Carrier Parenting Information

Before a woman can carry a baby for someone else, all parties must sign a legal agreement. It covers pregnancies that result from an IVF embryo transfer not using the carrier’s own eggs. The carrier is called the gestational carrier or GC. The GC could be somebody known to the Intended Parents or somebody unknown to them (typically contracted from an agency).

There are many laws that apply to these agreements. You need have an agreement to be protected. This fact sheet will review the medical and mental health aspects that affect those who sign this agreement.

Legal Agreement & Consent

The GC and IP(s) must have legal counsel throughout this process. The lawyer should be an expert in third-party reproduction. He or she must also be licensed to practice law in the state or states where the members of this agreement live. If the agreement involves someone living outside of the U.S., the lawyer should also know the law in that person’s country. Ideally, and as required in some states, the GC and IPs should be represented by separate and independent legal counsel to protect their individual interests.

The gestational carrier parenting agreement will cover:

* The parental rights of every person in the agreement
* The amounts, timing and escrowing of payment (if any)
* The medical insurance coverage for the pregnancy and offspring
* The medical care and decision-making involved
* Any other facts relevant to a pregnancy, parental rights or the arrangement

As the IP(s), you need to make sure you are the official legal parents of the child. In most cases, your name(s) should appear on the birth certificate. Everyone who signs the agreement will have to take legal action to allow this to happen. This may require a court petition before the birth of the baby. You will need a lawyer who is an expert in this area.

Before treatment starts, you will need a letter of clearance from your lawyer. It will say that an agreement has been prepared, and everyone agrees to it. It will also say that the GC and IPs have gotten their own legal advice. Most important, it will show that everyone in the agreement knows and accepts the risks of going forward. Any decision regarding the termination or reduction of the pregnancy (in the case of multiple fetuses) can only be made with the informed consent of the GC.

*NOTE: The clinic cannot review the gestational carrier parenting agreement for you.*

Meeting with a professional mental health counselor

Every IP and GC has to meet with a professional mental health counselor who is experienced in third party reproduction. The goal is to discuss the proposed GC arrangement, including the reasons for choosing this treatment. You should also talk about what you expect from the GC. The counselor will also meet with the GC and her partner, if there is one.

In some cases, both the IP(s) and GC may need to see the counselor again. Certain psychological tests may also need to be done. During these visits you will talk about:

* What all parties expect before, during, and after birth—and how to talk about it
* What to do if the pregnancy results in twins or triplets
* The option of fetal-reduction or abortion for medical reasons
* Whether to tell the IP’s and GC’s children about this treatment in the future
* How to resolve conflicts if they occur

Not all women who want to be a GC can be one. The standards are high. This is because carrying someone else’s child can test your heart and your mind. It is also because the steps to complete the process can be complex.

Protecting your rights is the main reason for meeting with the counselor. It can also help to protect the emotional health of the GC and her partner and/or children. However, it cannot predict how anyone will behave in the future.

These meetings are required. Your mental health counselor must provide a letter to the clinic confirming your meetings before treatments can start.

Infectious Disease Screening

The IP(s), or someone they pick, will provide the sperm and eggs used to make embryos. These embryos will be transferred into the uterus of the GC. Anyone who provides sperm or eggs is—in the eyes of the law—a tissue donor. All donors have legal rights.

*Steps for the reproductive tissue donors:*

Before embryo transfer to the GC, the providers of the sperm and egg must get:

* A medical clinical history review
* A physical exam
* Lab tests

These are all required by law to help prevent the potential spread of diseases. The clinic staff will help with these steps and try to make them easy for you. NOTE: The lab tests must be done within 30 days of egg collection and 7 days of sperm collection. The GC may waive the 6-month quarantine requirement for sperm.

*Steps for the GC:*

Before carrying a pregnancy, the GC must get:

* A medical clinical history review
* A physical exam
* Infectious disease screening
* Other relevant tests such as Pap smear
* Psychological evaluation with a professional mental health counselor
* Sign medical release forms that authorizes the sharing of personal health information with the clinic and IPs

The review of these results will permit assessment of the risk of spreading disease to the baby. These tests will be reviewed by the IP(s), who may ask for extra testing or decline using the intended GC.

Insurance

Insurance for any pregnancy can be costly. In most cases, the IP’s health insurance will not cover the costs when a GC is involved. It will also not cover any needed treatments. The GC’s health insurance may not cover the pregnancy costs when the baby will not be the GC’s legal child. The IPs should make sure their insurance will cover the baby’s newborn care. The insurance policy should also cover any conditions that may apply to obtain such coverage.

A number of insurance agencies offer coverage for GC’s medical costs. Before starting treatments, you need to make sure that there is enough of this coverage. It should cover the pregnancy, the delivery, and the child. The clinic and its staff cannot give you advice about insurance. All they can do is tell you how to get in touch with a few insurance agencies. The clinic will ask you to prove that you have gotten enough coverage. You will need to provide a letter from your lawyer stating that you have done so.

Uterine Testing

The GC will need to have a uterine test. This may include an ultrasound, an X-ray, and/or a close look at the uterus with a video camera. In most cases, these tests are performed between day 6 and day 11 of the menstrual cycle. They are used to look for polyps or fibroids that could decrease the chances of success if not removed. Some clinics may try more than one medicine to see how the uterine lining responds.

Treatment Overview

The egg used in a gestational carrier parenting arrangement can come from the intended

mother, from an egg donor, or from an egg bank which supplies previously frozen eggs to the IPs.

Treatment for a GC cycle may include these steps:

* Birth control pills
* Prenatal vitamins, supplements, and prescription medicines
* Pituitary suppression using GnRH agonists or antagonists.
* Development of the uterine lining using skin patch of estradiol, vaginal estradiol, or injectable estradiol.
* Progesterone to prepare the uterus. Progesterone may be given as an injection or vaginal medicine.
* Transfer of the embryo(s) back into the uterus (the GC will sign a separate consent for the embryo transfer)
* Pregnancy test

The clinic will give you a detailed schedule that includes some or all of these steps.

Hormonal support of the uterine lining

* For pregnancy to occur, the embryo(s) must attach to the lining of the uterus. This process is called implantation.
* The lining depends on two hormones – estradiol and progesterone – to permit implantation and sustain pregnancy.
* Endometrial preparation can be achieved in natural, stimulated, or medicated cycles.

The important hormones to support implantation are progesterone and estrogen. Normally, the ovary makes enough of both hormones to support pregnancy.   However, in recipient cycles, achieving this synchrony requires active management. When a natural cycle is used, the embryo transfer occurs about a week after ovulation. In some cases, ovarian stimulation is chosen to induce follicle growth; in this case embryo transfer again occurs about a week after ovulation. Programmed cycles involve providing estradiol and progesterone on a fixed schedule to prepare the uterus for pregnancy. In medicated cycles, estrogen and progesterone are supplied. Estrogen is given by mouth, patch, or vaginal suppository. Progesterone is given by the intramuscular or vaginal route.  These hormones are usually continued for several weeks to support the pregnancy. There are advantages and disadvantages to each of these approaches to preparing the uterus. Considerations such as feasibility, ease, scheduling, and risk are weighed. There are certain differences in obstetric and neonatal outcomes to consider.

Embryo transfer

* After a few days of culture/development, the best-developed embryos are chosen for transfer.
* The number of embryos transferred affects the chance of pregnancy and the risk of twins or other multiple pregnancies.
* The egg source’s age and the quality of the developing embryo(s) have the greatest effect on pregnancy outcome.
* Embryos are placed in the uterus using a thin tube under ultrasound guidance.
* Extra, normally developing embryos that are not transferred can be frozen for future use.

After a few days of development, the embryo transfer takes place, or the embryos are frozen for transfer later. One or more embryos are placed in the uterus using a thin tube called a catheter. Ultrasound may be used to help guide the catheter and confirm embryo placement.

Risks of embryo transfer include infection, no further development or damage to the embryo(s). Not all embryos become pregnancies, and not all pregnancies are normal or grow in the correct place (tubal pregnancies are possible). The number of embryos to transfer is an important decision. A woman’s age and the quality of the embryo affect both the chance for pregnancy as well as the chance for multiple embryos to implant. If multiple embryos implant, a multiple pregnancy (twins, triplets, or more) will result.  In some cases, an embryo can split into two (identical twins) after transfer. Before the transfer, it is critical to discuss with your doctor how many embryos to transfer.

Risks to the GC

Overall risk to the female undergoing ovarian stimulation, oocyte retrieval, and embryo transfer is very low. In fact, the most frequent complication is ovarian hyperstimulation syndrome, OHSS, which occurs in <1.5% of cycles. OHSS is more common in women with high ovarian reserve such as women with polycystic ovary syndrome who have a high number of eggs retrieved. Other complications such as hemorrhage, transfusion, infection, or hospitalization are even more rare, <0.1% of cycles.

Risk of Medications

Common side effects of medications used for ovarian stimulation include hot flashes, vaginal dryness, nausea, headaches, and muscle aches. Some women may retain fluid (bloating) or have moodiness. Any injection can cause bruising, redness, swelling, or pain at the injection site. In rare cases, there may be a severe allergic reaction, infection at injection sites, blood clots or stroke. Reactions may vary based upon the type woman’s underlying diagnosis/medical status and medication dosages.

Infection

Although low, it is possible to see infection at medication injection sites, or after an egg retrieval or embryos transfer. This possibility is reduced by using good injection technique and taking prescribed antibiotics.

Ovarian Hyperstimulation Syndrome (OHSS)

Stimulating the ovaries can lead to OHSS, which is uncomfortable at a minimum and can lead to nausea, vomiting, trouble breathing, pain and a buildup of fluid in the belly or abdomen/stomach. Mild to moderate cases are often managed at home with medication and fluid monitoring and resolve over several days. Severe cases are rare (less than 1.5% of IVF cycles)] but can be associated with blood clots and damage to the kidneys or liver and may even lead to kidney failure or death particularly if not managed by a fertility provider. These cases require hospitalization. Measures to prevent OHSS include delaying embryo transfer, avoidance of hCG to trigger egg maturation, and taking the medication cabergoline.

Cancer

Women with infertility are known to be at increased risk of certain cancers, so whether IVF increases the risk further is difficult to assess. In current studies that take into consideration the increased risk of cancer due to nulliparity (never having been pregnant) there does not seem to be an increased risk of cancer due to the fertility drugs alone.

Risks of Pregnancy

Getting pregnant through IVF comes with certain risks. This is partly because women using IVF are often older than those who might get pregnant on their own. In addition, the cause of the infertility itself may increase certain risks. The table below indicates risk in those doing IVF relative to other infertile women. In 2019, 7% of IVF pregnancies were twin and <1% were triplets or greater).

Risks of Pregnancy with IVF

|  |  |  |
| --- | --- | --- |
|  | Singleton Pregnancies | Twin Pregnancies |
|  | Incidence in IVF Pregnancies (%) | Incidence among infertile women | Incidence in IVF Pregnancies (%) | Incidence among infertile women |
| Gestational diabetes | 8.2% | No difference | 10.7% | No difference |
| Pregnancy-induced hypertension | 12.6% | No difference | 25.5% | No difference |
| Placental complications | 5.2% | 2.6% | 4.9% | No difference |
| Primary cesarean delivery | 32.2% | 29.3% | 65.4% | 60.6% |
| Low birthweight(<5.5 pounds) | 7.7% | 6.4% | 50.4% | No difference |
| Preterm birth(<37 weeks gestation) | 10.3% | 8.2% | 53.8% | No difference |

Multiple pregnancies in general have an increased risk of pregnancy problems such as early delivery, pre-eclampsia (high blood pressure and protein in the urine), excess bleeding with delivery, and diabetes during pregnancy.

In IVF, embryos are transferred directly into the uterus. Still, tubal, cervical, or abdominal pregnancies can sometimes occur. These abnormal pregnancies may need to be treated with medication or surgery. Abnormal pregnancies within the uterus can also occur, which may also require medical or surgical intervention.

Birth Defects

The risk of all birth defects through natural or spontaneous conception is about 3-5%. In IVF babies, the risk for any birth defect is about 5-6%. There may be, specifically, an increased risk of cardiac (heart) defects. Most of the increased risk with IVF seems to be due to the pre-existing infertility in couples using IVF and older maternal age.

There are a few other potential increased risks for babies born through IVF:

*Imprinting Disorders*. These are very rare disorders caused by certain genes from the mother or the father not being expressed. An example is Beckwith-Wiedemann Syndrome, which is more common in children conceived with IVF. These disorders are extremely rare (1 out of 15,000 people). Children from IVF treatment have a small increased risk of 0.01%.

*Childhood cancers.* There does not appear to be a higher risk of most cancers in children born from IVF, but there may be a higher risk of hepatic (liver) cancer. These are very rare in children.

*Infant development.* Most studies of long-term developmental outcomes for children have been reassuring so far. However, these studies are hard to do, and they have some limitations. There may be an increased risk of cerebral palsy however this risk is mostly from prematurity and low birth weight resulting from multiple pregnancy. Some studies show an increased risk of autism associated with ICSI, but others do not.

Risks of a Multiple Pregnancy

It is riskier for a baby to be a twin or triplet than a single pregnancy. Fortunately, fewer than one in ten IVF pregnancies are multiple, and that rate is declining due to lowering the number of embryos transferred into the uterus.

Early delivery accounts for most of the extra problems associated with babies from multiple pregnancies. IVF twins deliver an average of three weeks earlier than IVF single babies, and they weigh about 2 pounds less than IVF single babies.  Triplet (and greater) pregnancies deliver before 32 weeks (7 months) in almost half of cases. Early delivery can increase the risk of cerebral palsy, retinopathy of prematurity (eye problems that result from early delivery), and chronic lung disease. Multiple pregnancies also have increased risk of growth problems in the uterus, so the babies are born a low weight.

Multiple fetuses that share the same placenta, such as most identical twins, have additional risks, such as birth defects. Twin-to-twin transfusion syndrome, where the circulation is not equal between the fetuses, may occur in up to 20% of twins who share a placenta. This can increase the risk of fetal death.

Lastly, there is an increased risk of stillbirth with multiple pregnancies. The risk of stillbirth for a singleton pregnancy is 0.54%. The risk with twins is higher at 2.3% and with triplets 5.3%. The death of one or more fetuses in a multiple pregnancy (“vanishing twin”) can happen in the pregnancy and can happen in up to 36% % of twin pregnancies. This can affect the health of the surviving fetus.

Psychosocial Effects of Infertility Treatment

Finding out that you or your partner is infertile or have a lower fertility can be very painful. Infertility and its treatment can affect your emotions, your health, your finances, and your social life. Treatment, particularly IVF, is time-consuming and may strain your personal relationships and your religious or ethical beliefs. During treatment, you may feel anxious, helpless, depressed, or all alone. You may go through highs and lows. In some cases, you may want to seek the help of a mental health expert to help you with the stress of treatment. Your clinic can provide resources to professional in your area.

Reporting Outcomes

In 1992, the Fertility Clinic Success Rate and Certification Act was passed.  This law requires the Centers for Disease Control and Prevention (CDC) to gather information about IVF cycles and pregnancy outcomes in the U.S. each year.  This information is used to calculate success rates which are reported each year.

We (the Clinic) will report the required information from your IVF procedure to the CDC.  Since our Clinic is a member of the Society of Assisted Reproductive Technologies (SART) of the American Society for Reproductive Medicine (ASRM), it will also be reported to SART.  Information reported to SART about your cycle may be used for research or quality assessment according to HIPAA guidelines; your name will never be connected to your cycle information in any research that is published by ASRM or SART.

X

Intended Parent A Signature Date

Intended Parent A Name Date of Birth

**Notary Public**

Sworn and subscribed before me on this \_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_, \_\_\_\_\_\_\_\_\_\_.

Notary Signature Date

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X

Intended Parent B Signature Date

Intended Parent B Name Date of Birth

**Notary Public**

Sworn and subscribed before me on this \_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_, \_\_\_\_\_\_\_\_\_\_.

Notary Signature Date

X

Gestational Carrier Signature Date

Gestational Carrier Name Date of Birth

**Notary Public**

Sworn and subscribed before me on this \_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_, \_\_\_\_\_\_\_\_\_\_.

Notary Signature Date

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**Statement by Witness (must be employee of Clinic and at least 18 years of age)**

I declare that the person who signed this document is personally known to me and appears to be of sound mind and acting of his or her own free will. He or she signed (or asked another to sign for him or her) this document in my presence.

*Witness Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Witness Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Date:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_