Gestational Surrogacy: Commissioning Couple-Intended Parent Consent For Therapy, EDI

Southwest Florida Egg Donation & Surrogacy Program

This is to certify that we, _____ & _____ (Commissioning Couple) or I, _____ (Intended Parent) hereby agree to a form of treatment commonly known as **Gestational Surrogacy**.

I/We understand that Gestational Surrogacy provides a means for Commissioning Couples/Intended Parents, who are otherwise unable to conceive and deliver children in the conventional manner, to raise a child. After a detailed and complete discussion with the medical staff of Embryo Donation International (EDI), I/we hereby agree to undergo Gestational Surrogacy procedures understanding that there are potential risks and benefits of the procedures.

Gestational Surrogacy General Information:

The following is a general outline of the steps that may be required to perform the Gestational Surrogacy realizing the list is not inclusive of all possibilities, but includes the most common concerns.

Donated Embryos:

The embryos will be graded on structural criteria based on current scientific knowledge. Embryos that appear structurally abnormal will not be transferred to the uterus nor preserved by cryopreservation techniques. Abnormal embryos have a high frequency of genetic abnormalities and if placed in the uterine cavity, will frequently miscarry or result in the formation of an abnormal offspring. The abnormal embryos may be examined in an attempt to understand the reasons for their abnormal development. We, therefore, consent to the disposal of embryo(s) that are not capable of surviving.

Potential Complications:

Blood Work:

Bruising at the needle site may occur.

Embryo Transfer:

12611 World Plaza Lane, Bldg. 53 • Fort Myers, Florida 33907 USA
Info@EmbryoDonation.com • www.EmbryoDonation.com
800-334-2184 • 239-275-5728 • 239-275-5914 (fax)

The process of placing the egg/sperm or fertilized embryos into the uterus is a low-risk procedure. Pelvic discomfort and vaginal bleeding may occur.

Multiple Gestations:
Twins, triplets or more may occur when ART is used to achieve a pregnancy. The generally accepted risk is up to 20-25%. We understand that all multiple gestation pregnancies are high-risk for such complications as, but not necessarily limited to, premature labor/birth, bed rest, hospitalization, nausea/emesis, anemia, hypertension, pre-eclampsia, gestational diabetes and a surgical delivery. Options such as fetal reduction may allow one, two or three of the infants to survive. We understand that we may need to leave the state to find individuals skilled in this procedure. We will try to minimize these risks to the GS.

Pregnancy Loss:
Any pregnancy may result in a spontaneous miscarriage and ART is no exception. A stillbirth is also possible but does not seem to occur more frequently when ART is used when compared to the general population. Young women loose only 10% of their pregnancies while older women may loose up to 60% of established pregnancies. If a pregnancy loss occurs, it may be necessary to have a surgical procedure to safely remove the non-viable intra-uterine contents.

Ectopic Pregnancy:
The general incidence for an ectopic pregnancy, usually located in the fallopian tube, in patients using ART is 3%. If an ectopic pregnancy occurs, medication may be provided to the GS to dissolve the pregnancy although surgery is sometimes necessary to remove the ectopic pregnancy.

Once pregnant, there is a 1:100-200 risk for having a concomitant intra-uterine and ectopic gestation called a **heterotopic** pregnancy. If this occurs, surgery is usually needed to remove the ectopic pregnancy while trying to conserve the intra-uterine pregnancy.

Abnormal Gestations:
There has been a recent study (El-Chaar D, et al. Fertil Steril 2009;92:1557-61) that suggests there may be an increased chance of a major malformation (i.e., heart, intestine and skeletal) of around 1% higher in successful infertile patients than the rate seen from fertile parents (2.9% compared to 1.9%). This 1% increase seems to be present in those patients who simply took ovulation medications, had inseminations as well as those who had IVF. It is totally uncertain if this increased risk is due to the infertility treatment or simply a problem in the infertile population itself.

We offer no guarantee that the child will be normal, but millions of children worldwide have been created by the IVF process and the children are generally as healthy as those conceived in the more natural settings. In addition, while infertile women seem to have smaller children though IVF, when embryos are placed into a healthy GS, the average size of the baby is entirely normal.

There have been some studies which indicate the average ART pregnancy will deliver somewhat earlier with a smaller-for-gestational-age baby compared to those conceived through natural means. This probably due to the fact that the patients are simply at higher risk for problems due to the issues that made them subfertile in the first place. These findings have not

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been found with Gestational Surrogacy procedures indicating a normal uterine environment improves the chances of a normal outcome.

Additional data has been published that indicates some male-factor problems may be passed on to the children. This seems to occur at a very low rate, but can occur. The overall outcome is usually similar to that of the father (i.e., reproductive issues). Fertility and other medical issues may occur to the male child or the female offspring may carry a generic problem that could eventually affect her children. Once again, the medical outcomes are usually no different than the male partner who originally provided the sperm!

Pregnancy:
Any pregnancy has the potential for risk and complications. Such issues as preterm labor, preeclampsia, gestational diabetes, preterm delivery and Cesarean Section are possible. The Gestational Surrogacy process itself does not seem to increase any of these risks over a normally conceived pregnancy.

Delivery:
Any delivery has the potential for complications including bleeding, infection and Cesarean Section. The Gestational Surrogacy procedure itself does not seem to increase these risks over a normally conceived pregnancy.

Unexpected Events:

We understand that, despite reasonable precautions, any of the following may occur which would prevent the establishment of a pregnancy:

- Realizing this is an elective procedure, my physician reserves the right to cancel my cycle at anytime if he feels my health or the health of the GS are at risk.
- If the embryo transfer is delayed, it will not be possible to maintain the life of the embryo after thaw.
- Although extraordinarily rare, loss or damage to the embryos may occur during the actual transfer process.
- Even if the embryos develop and are placed back into the uterine cavity of the GS, actual implantation of the embryos on the walls of the uterus may not occur.
- While the most extremes of precautions are taken, a laboratory accident may result in the loss or damage of the embryos.
- The medical staff EDI will not be held accountable for acts of God, which do not allow for any of the outlined procedure(s) to take place.

Psychological Concerns:

We are aware that the preparation for and the Gestational Surrogacy process itself may have serious psychological consequences with respect to, but not limited to the Commissioning Couple/Intended Parent, the mother-child, the father-child, the mother-father as well as other family relationships. Psychological counseling is always available upon request.

We are aware that the Gestational Surrogacy may have serious psychological consequences with respect to, but not limited to, the GS, the GS-child, the GS-Commissioning Couple/Intended Parent,

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the GS-Partner as well as other family relationships. Psychological counseling is always available upon request. In general, however, the majority of GS' feel quite fulfilled in their attempts to help others.

Legal Concerns:

We shall indemnify EDI for any attorney's fees, court costs, damages, judgments, or any other losses or expenses incurred by EDI, or for which EDI, may be responsible with respect to any 'third party" claim, legal action or defense thereto, arising out of the Gestational Surrogacy procedures herein contemplated, including, but not limited to any claim or legal action brought by the child or children resulting from the Gestational Surrogacy procedures.

Education, Publication and Confidentiality Concerns:

It is possible that our participation in this program may aid in the development of techniques that will assist other couples/individuals and that new and useful information may be obtained from our procedures. Therefore, realizing that our identity will **not** be disclosed, we agree to the taking and publication of photographs, slides or videotapes and/or the active/passive participation of medical/laboratory guests EDI. We realize that specific medical details maybe included in medical discussions or publications without our consent as long as reasonable efforts are made to conceal our identity. ***Only with prior consent will our identity be purposefully disclosed.*** These photographs may be used for general documentation of the medical records or for educational purposes, i.e., publications and/or lectures at a national, state or local level.

The confidentiality of the medical records will be maintained in accordance with Florida law. EDI is mandated by Federal statutes to obtain confirmation of all delivery data on the Gestational Surrogacy pregnancies. We agree to forward any needed information to fulfill the Federal statutes including, but not necessarily limited to, a copy of the birth certificate & a copy of the birth announcement, the newborn sex, newborn weight and any information regarding pregnancy, delivery and newborn complications. We agree that our records may be reviewed by outside agencies including, but not necessarily limited to, the Federal Food and Drug Administration (FDA) or the Society of Assisted Reproductive Technologies (SART). Upon occasion, we understand that these same agencies may contact us to confirm the pregnancy outcome.

Data from your Gestational Surrogacy procedure will also be provided to 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 preformed 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.

Alternatives:

I/We understand that there may be other alternatives in obtaining a child rather than Gestational Surrogacy such as, but not limited to, adoption. Many individuals who would like to adopt, however, are unable to do so and Gestational Surrogacy remains one of their only options.

General Concerns:

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I/We understand that the practice of medicine is not an exact science and while our physician has recommended Gestational Surrogacy, **there is no guarantee that the procedures will result in a successful pregnancy and delivery.**

We understand that we may elect not to continue with the Gestational Surrogacy procedures at any time and that this decision will not affect present or future medical care at EDI. Likewise, we acknowledge that our acceptance and continued participation in the program is at the sole discretion of the EDI medical team.

I/We have read the above materials and understand the possible complications of the proposed procedures. We have had the opportunity to ask questions and to inquire about the risks and benefits of the Gestational Surrogacy program. Our questions have been answered to our satisfaction and we understand the information given to us.

I/We understand that this Consent for Gestational Surrogacy Therapy is to be considered valid for **all** future Gestational Surrogacy procedures, unless specifically revoked by us.

All of the blanks in this consent have been filled prior to the signing of the signatures below:

_____	_____	___/___/___
Commissioning Parent Signature	Commissioning Parent Name (print)	Date
_____	_____	___/___/___
Commissioning Parent Signature (when applicable)	Commissioning Parent Name (print) (when applicable)	Date
_____	_____	___/___/___
EDI Coordinator Signature	EDI Coordinator Name (print)	Date
_____	_____	___/___/___
Physician Signature	Physician Name (print)	Date

Revised: 10/16/2013
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