

Specialists In Reproductive Medicine & Surgery, P.A.

www.DreamABaby.com • Fertility@DreamABaby.com

Excellence, Experience & Ethics



Egg Donor Consent for Therapy Southwest Florida Egg Donation & Surrogacy Program

This is to certify that I, _____ hereby agree to a form of treatment commonly known as the **Egg Donation**.

I understand that egg donation provides a means by which some previously infertile women may conceive and deliver children. After a detailed and complete discussion with the medical staff of *Specialists in Reproductive Medicine & Surgery, P.A.*, (SRMS), I hereby request this procedure be performed understanding that there are potential risks and benefits.

I hereby agree to donate my oocytes (eggs) and authorize SRMS to use them for the following purposes:

- Designated Recipient (Name of Individual: _____)
- An infertile woman/women selected by SRMS

While I cannot receive any specific financial *payment* for egg donation, the recipient has agreed to reimburse me for reasonable costs associated with the ovarian stimulation and removal of my eggs. The following reimbursement schedule will apply:

- \$1000.00** Initiation of the ovarian stimulation cycle
- \$2000.00** Completion of the egg retrieval procedure

I understand that the full cost of the supplies and professional services will be paid for by the egg recipient and none of these expenses will be my personal responsibility.

I understand that the Florida Statutes require that human tissue donated for transfusion or transplantation into another must be tested for Human Immunodeficiency Virus (HIV) as well as other communicable disease. Specific standards of medical care also dictate that I may be repetitively screened for inheritable diseases. I consent to be tested for such diseases.

I also clearly state that I have not engaged in any of the following:

- Bisexual activity
- Recreational intravenous drug use
- Sexual activity in exchange for money or drugs
- Sexual activity or exposure from an open wound within the previous 12 months with individuals who had or were at risk for carrying HIV or Hepatitis

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- Been treated for a sexually transmitted disease within the last 12 months
- Had a tattoo or body piercing in non-sterile conditions within the last 12 months
- Incarcerated in jail for more than 72 hours.
- Been with a partner who had been treated for syphilis or gonorrhea within the past 12 months
- Received a human organ or tissue transplant
- Have consumed animal brains (yes this really is a question!)
- History of changed in cognition, speech or gait

General Steps:

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

Medications:

The use of “fertility drugs” such as Letrozole (Femara), Human Menopausal Gonadotropins (Repronex, Follistim, Gonal-F, Menopur, and Bravelle), Human Chorionic Gonadotropin, HCG (Profasi, Pregnyl, Novarel, Ovidrel), Leuprolide (Lupron) and/or Ganirelix Acetate may be administered. Most of these hormones are the same as, or very similar to, the natural hormones which are released during a normal menstrual cycle. The medications are usually administered orally or by injection. Specific information about each drug will be provided. The frequency of administration varies, but some medications may be given twice each day.

Antibiotics are administered orally during the month of egg retrieval. In addition, the egg donor will also receive intravenous (IV) antibiotics during the egg retrieval procedure.

Medications may be given prior to surgical procedures by direct or IV injection which will relax the egg donor, minimize discomfort, help to prevent nausea or infection and may include but are not to be limited to Diazepam (Valium), Midazolam (Versed), Lidocaine (Xylocaine), Cefazolin (Ancef), Fentanyl (Sublimaze), Meperidine (Demerol), and Promethazine (Phenergan).

Blood Specimens:

Blood specimens are frequently needed every third day and occasionally every day. Bruising at the needle site may occur.

Egg Retrieval:

The vaginal ultrasound is used to guide a slender needle, which enters the vaginal space and then the ovary itself. This procedure is accomplished using local and IV medications.

Fertilization:

A wide variety of procedures may be performed in combining the donor eggs and the sperm and then placing them in the woman’s uterus or Fallopian tube:

IVF (In Vitro Fertilization)

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The eggs and sperm are placed together in a culture dish to accomplish fertilization. Some of the fertilized embryos are then later transferred into the uterine cavity through the use of slender catheters.

I understand that all healthy retrieved eggs will be exposed to sperm.

Micromanipulation:

A wide variety of assisted technologies have developed including micromanipulating eggs, sperm and embryos to enhance fertilization and improve on rates of implantation. The following are some examples:

ICSI (Intra Cytoplasmic Sperm Injection)

Single sperm are directly injected into the donated egg to maximize fertilization. This procedure is commonly performed where there are significant male-factor concerns.

AH (Assisted Hatching)

The outer covering of the embryos is dissolved in a specific region to allow the cell mass to “hatch” and implant on the uterine wall.

The above procedures may be combined in order to maximize the chances for pregnancy.

Eggs, Embryos, Body Tissues and Fluids:

Eggs and/or embryos that appear structurally abnormal will not be transferred to the uterus nor preserved by cryopreservation techniques. Abnormal eggs and/or embryos have a high frequency of genetic abnormalities and if placed in the uterine cavity, will frequently be miscarried or result in the formation of an abnormal offspring. The abnormal eggs and/or embryos may be examined in an attempt to understand the reasons for their abnormal development. I, therefore, consent to the disposal of egg(s) or embryo(s) that are not capable of surviving. In addition, I consent to the disposal or utilization of other cells, body tissues or fluids that may be obtained during the egg donation procedures.

Embryo Cryopreservation and Final Disposition:

When possible, any excess embryos that are not transferred will be frozen in liquid nitrogen for future use. The recipient couple will have a number of choices regarding the frozen embryos including, but not necessarily limited, to the following:

- Thawing the embryos for transfer (i.e., personal use).
- Donating them to science.
- Donating the embryos to single women, single men or lesbian/homosexual/heterosexual couples.
- Donating the embryos to stem cell research.

If the couple decides to donate the embryos to stem cell research, additional information and consents may be required from you at a later date and you agree to assist in this process.

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It is also possible that additional information and blood testing may be required when the embryos are donated to needy patients or to stem cell research. You also agree to assist in this process should you be called upon to do so.

While exceptions do occur, it is the policy of SRMS to strongly discourage the outright destruction of embryos created and stored within the practice.

Potential Complications:

Ovarian Hyperstimulation:

These concerns are specifically addressed in “Ovarian Hyperstimulation Precautions.” If hyperstimulation develops, complications can include low blood pressure, abnormal blood clotting, abdominal pain with fluid retention, swelling and very rarely death.

Egg Retrieval:

Neither removing the eggs via a slender needle placed through the vaginal walls under ultrasound guidance nor the transfer of the actual eggs/sperm/embryos are high-risk procedures. Pelvic discomfort and slight vaginal bleeding may be experienced. Infrequent and rare surgical complications include, but are not necessarily limited to, infection, blood loss, the incision of vital organs and anesthetic risks. AT SRMS, the surgical complication rate with the egg retrieval procedure is less than 1%. Additional concerns are detailed in the SRMS Operative Consent form.

Unexpected Events:

I understand that, despite reasonable precautions, any of the following may occur which would prevent the establishment of an egg donor pregnancy:

- Realizing this is an elective procedure, my physician reserves the right to cancel my cycle at anytime if he feels my health is at risk.
- The time of ovulation may be miscalculated thus making it impossible to obtain the already ovulated egg(s).
- Even with ideal timing, some follicles do not contain eggs.
- The eggs may not be normal or they may not fertilize.
- Even if fertilization occurs, cell growth and division may not occur.
- Even if cell growth and division occurs, the embryo may not develop normally.
- If the embryo transfer is delayed, it will not be possible to maintain the life of the embryo.
- Loss or damage to the eggs/sperm/embryos may occur during the actual transfer process.
- Even if the embryos develop and are placed back into the uterine cavity, 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 sperm, eggs or embryo.
- The medical staff SRMS 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:

Egg donors undergo a psychological evaluation prior to the stimulation cycle. I am aware that the preparation for and the egg donation procedure itself may have psychological consequences involving my family, my friends and myself. Psychological counseling for me is always

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available upon request during the egg donation process and for up to six weeks following the retrieval procedure.

Inadvertent Consanguinity:

It is theoretically possible that an egg donor could donate enough times to statistically increase the risks of half-brothers and sisters (same egg donor mother but different fathers) could meet and reproduce.

According to existing guidelines, it is recommended that we limit a single donor from producing no more than 15 offspring per 500,000 population. ***We here at SRMS limit a single donor to no more than six successful donated offspring.*** Please recall that we here at SRMS cater to a large population conservatively estimated at over 1,000,000 throughout Southwest Florida, not including other states and countries. According to guidelines, we could easily have over 30 offspring per egg donor before retiring the donor.

Legal Concerns:

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

Should I suffer a physical injury as a result of the donation process, unless otherwise agreed upon, the recipient assumes the responsibility for all of my reasonable medical expenses.

There are no parental rights of the egg donor to the offspring from egg donation here in the state of Florida. For this and other reasons, Florida is a particularly ideal location for egg donation and surrogacy.

Upon the signing of this consent, I relinquish any and all rights that I may have with regard to the donated eggs and acknowledge that any baby/babies born will be considered the child/children of the birth mother (egg recipient). Simply stated, once the eggs are removed from my body, they become the property of the recipient.

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 and that new and useful information may be obtained from our procedures. Therefore, realizing that our identity will **not** be disclosed, I agree to the taking and publication of photographs, slides or videotapes and/or the active/passive participation of medical/laboratory guests SRMS. I 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.

Data from your ART 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

Egg Donor Consent for Therapy (*cont.*)

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.

The egg recipient, unless specific arrangements have been made, will never be told our identities.

The confidentiality of the medical records will be maintained in accordance with Florida law.

General Concerns:

I understand that the practice of medicine is not an exact science and while my physician has recommended egg donation.

I understand that I may elect not to continue with the egg donation procedures at any time and that this decision will not affect present or future medical care at SRMS. Likewise, I acknowledge that our acceptance and continued participation in the program is at the sole discretion of the ART team.

I have read the above materials and understand the possible complications of the proposed procedures. I have had the opportunity to ask questions and to inquire about the risks and benefits of the egg donation program. My questions have been answered to our satisfaction and I understand the information given to us.

I understand that this **Egg Donor Consent For Therapy** is to be considered valid for **all** future egg donation procedures, unless specifically revoked by us.

If I am married, I agree to have my husband review this contract and sign below.

Relationship:

I fully understand and agree that I am not an employee of SRMS, or any recipient, and that in my relationship with SRMS or any recipient, my status is that of a patient, or if any anything additionally or alternatively, as that of an independent contractor. I also understand and agree that I shall be issued a Form 1099 to evidence any compensation or remuneration received by me with respect to this Egg Donor Consent for Therapy. I further understand that I, not SRMS or a recipient, am solely and exclusively responsible for any and all taxes, or other obligation(s) resulting from any compensation or remuneration received by me as a result of the herein Egg Donation process. I also understand and agree that I am free to pursue full-time employment for pay while going through an egg donation cycle and am only required to visit SRMS for specified appointments.

Egg Donor Consent for Therapy (cont.)

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

| | | |
|--------------------------------------|--------------------------------------|------------------------|
| _____ Egg Donor's Signature | _____ Egg Donor's Name (print) | ____/____/____ Date |
| _____ Partner's Signature | _____ Partner's Name (print) | ____/____/____ Date |
| _____ Nurse Coordinator Signature | _____ Nurse's Name (print) | ____/____/____ Date |
| _____ Practitioner's Signature | _____ Practitioner's Name (print) | ____/____/____ Date |

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