

Consent Form for Oocyte Recipient
Palm Beach Center for Reproductive Medicine/Palmetto Fertility Center of South Florida

We _____, the Female Partner, and _____, the Male Partner, together, the commissioning couple, desire to participate in the in vitro fertilization (IVF) oocyte recipient program at the Palm Beach Center for Reproductive Medicine/Palmetto Fertility Center of South Florida, Inc. (Palmetto Fertility Center), under the medical care and supervision of Scott Roseff, M.D. and/or Michael Graubert, M.D.

Indications and purpose of treatment: We understand that donor egg IVF is indicated when the Female Partner's own oocytes are either not present or not functioning well enough to achieve pregnancy. We understand that donor oocyte in vitro fertilization (IVF) is a multi-step process in which fertility medications are used to induce multiple oocytes (eggs) to develop in a donor's ovary. The eggs are removed from the donor's ovaries in an egg retrieval procedure and cultured with designated sperm in the laboratory to create human embryos. The embryos are subsequently transferred back into the womb of the Female Partner in hopes of achieving a pregnancy. We understand that beginning this process does not guarantee that we will complete the IVF process or that the Female Partner will become pregnant. We understand that we may at any time decide to withdraw from participation in this program without prejudice.

Pre-treatment Recommendations:

The Female Partner should avoid any activity, behavior, or medication during treatment that would reduce the chances of conceiving or increase the risk to an unborn child. Below are recommendations for the woman participating in this treatment:

1. The Female Partner should take a prenatal vitamin on a daily basis. This vitamin contains folic acid which reduces the chance of giving birth to a child with a neural tube defect (e.g. spina bifida).
2. Smoking must be avoided before and during treatment. It is also contraindicated during pregnancy.
3. Recreational drugs are absolutely contraindicated.
4. Ingestion of aspirin or aspirin-like products (e.g. Motrin, Advil, Anaprox, Naprosyn, Aleve, etc.) should be avoided during treatment. Tylenol is a suitable alternative. Baby aspirin is allowed.
5. The use of alcohol should be eliminated.
6. The use of all prescription and over-the-counter medications should be discussed with a physician before starting a treatment cycle.

Risks of this procedure: We understand that there are several processes involved in the donor egg IVF procedure, and potential risks and complications are listed below:

Preparation of the Endometrium

In order to properly time the embryo transfer, the Female Partner (Oocyte Recipient) must have the endometrium (uterine lining) hormonally prepared to allow implantation to occur. A birth control pill is often used to hormonally synchronize the Recipient to the Donor. This pill can cause nausea, breast tenderness, and an increased risk of thrombosis (clotting) and consequences of these. The first injectable medication administered is leuprolide acetate (Lupron). If applicable, a pregnancy test may be needed prior to starting Lupron. This medication is injected subcutaneously on a daily basis. With continued administration of Lupron, the pituitary gland is temporarily depleted of hormones, essentially putting the ovaries to rest. After the medication is administered for 7 or more days, a menstrual period often occurs. A blood hormone test and sonogram will be checked to confirm that the Lupron has had the desired effect. When the oocyte donor starts the IVF medications, the Female Partner (Oocyte Recipient) will be started on estrogen to stimulate the growth of the lining of the uterine cavity called the endometrium. The day the egg

Initials: _____ Female Partner _____ Male Partner

donor undergoes the egg retrieval, the oocyte recipient will stop the Lupron, continue the estrogen and be started on progesterone to help prepare the endometrium for implantation. We understand that while receiving the medications listed above, the Female Partner will be closely monitored by the IVF team. We understand that this monitoring will include daily blood drawing, which carries the risk of mild discomfort, infection, and bruising at the puncture site. We understand that ultrasound examination of the ovarian follicles and the uterus will be performed frequently. Several medications will be administered to achieve the desired goal. If pregnancy occurs, the estrogen and progesterone are continued until approximately the third month of pregnancy. The estrogen and progesterone medications that are prescribed are natural hormones and do not increase the risk of congenital anomalies.

Side Effects: The use of these medications can cause side effects such as nausea, vomiting, hot flashes, headaches, mood swings, joint pains and visual symptoms. A rare risk of estrogen administration is the formation of blood clots, which can compromise the blood supply to vital organs, causing serious problems including (and not limited to) stroke or heart attack. Any of these conditions may cause death or serious long-term disability. Most studies of low-dose estrogen usage by women do not show an increased risk of these complications. Allergic reactions are always a possibility. Injections can result in local discomfort and, in rare cases, abscess formation.

Sperm Collection

We understand that before the start of a cycle, the Male Partner will be asked to supply a semen sample for analysis by our laboratory. He may be asked to take a specific antibiotic during the first part of the cycle to treat bacteria that may be present in order to increase the chances of a successful fertilization. This oral antibiotic may cause either gastric upset or an allergic reaction. We understand that some men may not be able to produce semen specimens of sufficient quantity/quality to proceed with IVF. In some cases, the male may provide a second sample a few hours later. We understand that we have the option to freeze semen specimens as a "back-up" for IVF. We understand we also have the option to use donor sperm from an outside source for IVF. We understand that having sperm of insufficient quantity/quality from any source would lead to the cancellation of the IVF cycle.

Additional Medications

We understand that our physicians will prescribe antibiotics for the Female Partner (usually Azithromycin for five days) and corticosteroids (usually Medrol 16 mg per day for four days), both beginning on the day the donor receives hCG. These drugs are administered to protect the embryos from bacterial contamination and attack by immune cells. The risks for oral antibiotics include gastric upset and the potential for allergic reactions. The Medrol given to the Female Partner is considered a small dose. The only notable side effect has been the occurrence of vaginal yeast infection. It can cause a metallic taste in the mouth and facial flushing as well. We understand that Medrol may under certain circumstances mask signs of infection, cause mood disturbances or gastric upset, and increase sensitivity to the sun, including hypersensitivity reactions.

IVF Laboratory

We understand that once retrieved the donor's eggs will be evaluated and prepared for insemination by the embryology team of the IVF program. We understand the donor oocytes will be fertilized with the sperm of either the Male Partner or donor sperm as we have designated. We understand that not all eggs will be of sufficient quality to achieve fertilization, and that it is possible that none of the eggs may fertilize. Lack of fertilization may also be due to defects within the sperm. Despite adequate fertilization, some embryos do not develop normally and are not candidates for transfer back into the uterine cavity. Embryos are grown in the laboratory for 3 to six days before embryo transfer. Based on the appearance of our embryos, the IVF team may determine that the techniques of assisted hatching or blastocyst transfer may be useful.

Release: We understand that Palm Beach Center for Reproductive Medicine/Palmetto Fertility Center is not responsible for any loss, damage, destruction, or disappearance of oocytes or embryos due to laboratory or equipment accidents, human error, fire, theft, or local and natural disasters. We hereby release Palm Beach Center for Reproductive Medicine/Palmetto Fertility Center and its employees and/or agents from any and all liability in the event of the loss, damage, or destruction of the sperm, oocytes, or embryos.

Assisted Hatching

We understand that the IVF team may determine that after three days of growth, our embryos may be candidates for selective assisted hatching before embryo transfer is done. Selective assisted hatching may be advantageous for some embryos by promoting their implantation into the uterine lining. Selective assisted hatching may be indicated in women older than 35 years of age, women with elevated follicle stimulating hormone (FSH) levels or abnormal ovarian reserve testing, and couples with prior in vitro fertilization procedures that did not result in pregnancy (IVF failures). We understand that some or all of our embryos may benefit from this procedure. After the embryologist determines which embryos may benefit from assisted hatching, we understand that the actual procedure involves the use of a micromanipulator to pick up the embryo and a medical laser to create a small opening in the zona pellucida, which may allow the embryo to successfully "hatch" out of its hard shell and implant into the womb.

We understand the risks of assisted hatching include potential for harm to occur to our embryos during the hatching process. Although damage to the embryos is uncommon, single cells within the embryo may be damaged. Information available at this time indicates that this does not appear to affect the overall developmental potential of the embryo. The potential rise in the implantation rate for assisted hatching may raise the risk for a multiple gestation. Assisted hatching may also increase the chances of having identical twins.

Blastocyst Culture

We understand that the IVF team may determine our embryos are candidates for blastocyst culture and transfer. During standard IVF treatment, embryos are cultured for three days in the laboratory to the 6-10 cell stage and then transferred back into the uterus. If an embryo is grown for 5 or more days in the laboratory, it becomes a blastocyst (approximately 50 cell stage embryo). Blastocyst culture is a technique in which embryos are cultured in the laboratory to a later stage of development. Transfer of blastocyst embryos into the uterine cavity may increase the rate of embryo implantation and subsequent pregnancy. Because fewer blastocyst embryos are transferred into the uterus in comparison to standard IVF, the overall risk of conceiving a multiple pregnancy might also be lower.

We understand that while the IVF team believes there are benefits to having our embryos undergo blastocyst culture and transfer, the procedure may also have risks or disadvantages. Because the embryos are grown to a later stage in the laboratory, some couples may not be candidates for blastocyst transfer because none of their embryos reached that stage. The major risk of blastocyst transfer is having no embryos to transfer or cryopreserve (freeze). In this case no pregnancy can occur.

Embryo Transfer

We understand that approximately three to six days after egg retrieval our embryos will be placed into the uterine cavity of the Female Partner (Oocyte Recipient). A thin catheter will be passed through the cervix and into the uterus so the embryos may be deposited there. We understand that this may involve some cramping and discomfort and possibly a small amount of bleeding. Infection could be introduced at the time of the catheter insertion into the uterus, requiring antibiotic therapy. We understand there is no guarantee

that any of the embryos thus transferred will result in a pregnancy. We understand that the success of IVF relates directly to the **number** of embryos transferred to the uterus. We also understand that IVF significantly increases the risk of conceiving a multiple gestation (more than one baby), and that this risk also correlates directly with the number of embryos transferred into the uterine cavity. It is the policy of this program to transfer from 2-4 embryos in a given cycle, although this may vary on an individual basis. Any additional viable embryos may be cryopreserved (frozen) for possible replacement in a subsequent cycle. We understand that a separate consent for the cryopreservation must be completed if the embryos are to be cryopreserved. Despite all best efforts, some embryo transfers cannot be completed successfully. We understand that some embryo transfers can be extremely difficult due to problems with the cervix (opening to the womb) and may result in failed embryo transfers. These embryos may be frozen (cryopreserved) and transferred at a later date.

Management After Embryo Transfer

We understand that after embryo transfer in the Female Partner, she will be given natural progesterone by intramuscular injection, vaginal suppository or gel, or oral capsule in an attempt to increase the chances for successful implantation. Estrogen supplementation will be given, too, generally via the intramuscular route. There may be pain and bruising at the injection site of intramuscular medication, as well as the potential for an allergic reaction. Progesterone suppositories or gels may cause local irritation in the vagina and bleeding. During this period, we understand that various blood hormone levels may be evaluated to regulate the hormone levels.

Potential Outcome and Likelihood of Success: We understand a pregnancy resulting from this procedure cannot be guaranteed. If pregnancy occurs, we understand that the Female Partner will be followed with serial blood tests and ultrasounds to monitor the health of the developing fetus or fetuses. Should a pregnancy result from IVF, we understand that we might suffer a miscarriage or an ectopic (tubal) pregnancy, or any of the other complications that beset any pregnancy. Likewise we understand that the IVF team cannot guarantee the normality of any infant who results from this procedure. The national pregnancy rate for donor egg IVF is approximately 40%. We understand these rates vary in individual IVF programs. If we achieve a pregnancy with donor egg IVF, we understand the risk of delivering twins is approximately 30%, and the risk of delivering triplets is approximately 5% (but this is dependant on the number of embryos we elect to transfer). Multiple pregnancies can be associated with an increased rate of complications in comparison to single pregnancies; the most serious of which are pre-term labor, premature rupture of the membranes, and the delivery of premature infants who require intensive care.

Alternative procedures: We understand that there are alternative treatments to donor egg IVF including, and not limited to: not undergoing treatment, adoption, and childfree living.

Reporting/Confidentiality: Federal requirements for participation in certain organizations require IVF programs to report their IVF cycle-specific data to the Centers for Disease Control (CDC). This may require the IVF team to follow-up with a phone call to you to determine the outcome of your pregnancy should it occur. We understand that all of our IVF cycle-specific data will be provided to the CDC using a unique personal identifier that will be confidential and protected under the U.S. Privacy Act. Likewise, we understand that any research publication resulting from this procedure will not identify us individually.

I agree not to seek the identity of the woman who is donating oocytes to me. I understand that my identity and the identity of the oocyte donor will be kept confidential unless disclosure is required by law. I understand that the oocyte donor will not be given any information on the fertilization or pregnancy outcome.

Initials: _____ Female Partner _____ Male Partner

Release: I understand that the oocyte donor has waived and relinquished any and all parental or custodial rights to any child or children who may result from the fertilization and implantation of embryos as a result of this procedure. Likewise, I release the oocyte donor from liability for any problem that may occur during pregnancy or after birth including, and not limited to: any mental or physical disabilities, financial support, care, custody or living expenses, education, health, and welfare of the child or children born as a result of the donor egg procedure.

Financial: We understand that insurance coverage for any or all of the above treatment may not be available and that we will be personally responsible and will make payment for all the expenses of this treatment. The expenses may consist of operating room charges, laboratory charges, and physician professional fees. Some insurance carriers only pay a portion of the expenses of treatment. We will be responsible for payment in full of all charges regardless of insurance coverage or other determinations by our carrier.

Dr. Graubert's office (Palmetto Fertility Center) is regulated pursuant to the rules of the Florida Board of Medicine as set forth in rule Chapter 64B8, F.A.C., Standards of Care for Office Surgery.

We wish to have **assisted hatching** if the IVF team feels we meet the criteria.

 Yes **Initials:** _____ **Female Partner** _____ **Male Partner**
 No **Initials:** _____ **Female Partner** _____ **Male Partner**

We wish to have **blastocyst transfer** if the IVF team feels we meet the criteria.

 Yes **Initials:** _____ **Female Partner** _____ **Male Partner**
 No **Initials:** _____ **Female Partner** _____ **Male Partner**

We certify by our initials on the previous pages and by our signatures that we have read and fully understand the Oocyte Recipient Consent and the procedure(s) initialed above. We certify that the risks and alternatives to the procedure were fully explained to us. We recognize that we are free to ask questions, our participation is voluntary, and that we may withdraw at any time. We hereby agree to participate in the IVF procedure subject to the following limitations and conditions:

Female Partner's
Signature _____ Date _____

Male Partner's
Signature _____ Date _____

Witness's
Signature _____ Date _____

Initials: _____ **Female Partner** _____ **Male Partner**