

Consent Form for In Vitro Fertilization
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) program at the Palm Beach Center for Reproductive Medicine/Palmetto Fertility Center of South Florida, Inc. (Palmetto Fertility Center), and undergo treatment by Scott Roseff, M.D. and/or Michael Graubert, M.D.

Indications and purpose of treatment: We understand that in vitro fertilization (IVF) is a multi-step process in which eggs in the human ovary are induced to develop with fertility medications, removed from the ovary in an egg retrieval procedure, and cultured with sperm in the laboratory to create human embryos. The embryos are subsequently transferred back into the womb in hopes of achieving a pregnancy. IVF has become the standard for treating many types of male and female infertility, and we understand that by standard infertility testing and treatments, we are suitable candidates for this procedure. We also 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 risks to an unborn child. Below are recommendations for the woman participating in this treatment:

1. The patient 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. One may take baby aspirin.
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 in vitro fertilization procedure, and potential risks and complications are listed below:

Ovulation Induction

In order for IVF to be successful, fertility medications will be used to induce the development of more than one egg. This is termed ovulation induction. We understand that a variety of medications are available for the induction of ovulation process including clomiphene citrate (Clomid, Serophene), human menopausal gonadotropins (Menopur), follicle stimulating hormone (Gonal-F, Follistim), human chorionic gonadotropin (hCG, Novarel), GnRH-agonists (Lupron), and GnRH antagonists (Ganirelix Acetate, Cetrotide). We understand that some women have a poor response to ovulation induction agents and may not stimulate enough eggs to undergo IVF. Since these medications must be given by intramuscular (in the muscle) or subcutaneous (under the skin) injections, we understand there may be bruising or discomfort at the injection site, as well as allergic reactions.

We understand that some ovaries may be extremely sensitive to fertility medications and can enlarge more than expected. This is called ovarian hyperstimulation syndrome (OHSS). If the IVF team notices these symptoms early in the cycle, they may withhold the hCG injection and cancel the cycle to reduce the risks of this disorder. Additionally, embryos may be cryopreserved rather than transferred to reduce the risks of this

Initials: _____ Female Partner _____ Male Partner

disorder. If hyperstimulation is mild to moderate, the symptoms will be managed at home on rest. In the severe form of OHSS, dehydration, large amounts of fluid accumulation in the abdomen and lung cavities, blood clotting disorders, and kidney damage can occur. We understand that if severe OHSS occurs, hospitalization may be necessary for careful monitoring including the need for drainage of fluid from the abdomen. In addition, I understand that OHSS may include intensive monitoring and treatment in the Intensive Care Unit (ICU). Rarely, torsion (twisting) of the ovary may occur, cutting off the blood supply to the ovary. If this takes place, it may necessitate surgery to either untwist or remove the fallopian tube and/or ovary.

We understand there may be a link between the use of fertility drugs and ovarian cancer. This includes reports of an increase in borderline ovarian cancer in women who use both clomiphene and injectable gonadotropins for prolonged periods of time. However, we have been advised by the IVF team that exposure to these medications will be minimized as much as possible.

Monitoring Protocol

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 and bruising at the puncture site. We understand that ultrasound examination of the ovarian follicles and the uterus will be performed frequently. These examinations may at times be uncomfortable, but there is presently no known risk to the eggs or a developing embryo from ultrasound technology. We understand that if monitoring suggests a low probability for successful egg retrieval, the stimulation cycle will be stopped and no egg retrieval will occur.

Sperm Collection

We understand that before the start of an IVF cycle, the Male Partner will be asked to supply a semen sample for analysis by our laboratory. He will be asked to take a specific antibiotic during the first part of the stimulation cycle to treat bacteria that may be present in order to increase chances for 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 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 quality from any source would lead to the cancellation of the IVF cycle.

Egg Retrieval

We understand that at a time determined by the IVF team, the Female Partner will have a transvaginal egg retrieval procedure by Michael D. Graubert, M.D. or one of his associates. This uses an ultrasound guided needle puncture of the ovarian follicles through the wall of the vagina under conscious sedation (IV sedation). This procedure can cause mild to moderate discomfort. We understand that complications during this procedure are uncommon, but can involve the risk of complications from anesthesia as well as injury to bowel, bladder, or blood vessels. Some blood vessel or organ injuries may require additional surgery to repair. Limited bleeding from the ovary may occur, but the need for transfusion is rare. The risk of complications from anesthesia may include paralysis, adverse reactions to medication and in infrequent cases, death. Infections following transvaginal egg retrieval are also possible but rare. We understand the Female Partner will receive an antibiotic around the time of retrieval to reduce the risk of infections, and the antibiotic may result in side effects or allergic reactions. Despite seeing normal development of follicles on ultrasound, not all follicles are capable of being retrieved due to effects of medication or technical difficulties. We understand that we cannot be guaranteed that eggs will be recovered after egg retrieval.

Medications After Egg Retrieval

We understand that our physicians will prescribe antibiotics for the Female Partner and corticosteroids beginning on the day of retrieval. 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. We understand that this medication may under certain circumstances mask signs of infection, cause mood disturbances or gastric upset, and increase sensitivity to the sun, including hypersensitivity reactions. Also, Medrol can cause a metallic taste in the mouth as well as facial flushing.

IVF Laboratory

We understand that once retrieved, the eggs will be evaluated and prepared for insemination or injection (ICSI) by the embryology team of the IVF program. 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 your 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 are 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 the 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 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). 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 rate of 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. 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 correlates with the **number** of embryos transferred to the uterus. We also understand that IVF significantly increases the risk for 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 estrogen supplementation as well as natural progesterone by intramuscular injection, vaginal suppository, vaginal gel, or oral capsule in an attempt to increase the chances for successful implantation. There may be pain and bruising at the injection site of intramuscular progesterone, as well as the potential for an allergic reaction. Progesterone suppositories and gel may cause local irritation in the vagina, and this can result in bleeding. During this period, we understand that various blood hormone levels will 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 that results from this procedure. The national pregnancy rate for IVF is approximately 30% when age is not taken into account. We understand these rates vary in individual IVF programs. If we achieve a pregnancy with IVF, we understand the risk of delivering twins is approximately 30%, and the risk of delivering triplets is approximately 5%. 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 and the delivery of premature infants who require intensive care or die.

Alternative procedures: We understand that there are alternative treatments to IVF, including other advanced infertility techniques such as gamete intrafallopian transfer (GIFT). Although IVF and GIFT pregnancy rates may be similar, the risks with GIFT may be higher than IVF due to the need for general

anesthesia and a laparoscopic procedure. GIFT is not indicated in cases of women with fallopian tube disease. Other fertility procedures such as ovulation induction and intrauterine insemination carry similar medication risks as IVF, but generally have lower potential pregnancy rates. We also understand that the alternatives to IVF include, and are 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 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.

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.

The Palmetto Fertility Center of South Florida 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 In Vitro Fertilization 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**