

Consent Form for Embryo Thaw and Transfer Cycle
Palmetto Fertility Center and Palm Beach Center for Reproductive Medicine

We _____ and _____ understand that this consent gives Michael Graubert, M.D. and the IVF team at the Palmetto Fertility Center of South Florida, Inc. (Palmetto Fertility Center) permission to thaw our embryos in preparation for transfer into the uterine cavity.

We understand embryos that have been previously frozen following in vitro fertilization (IVF) can be thawed and transferred into the woman's uterus in an attempt to achieve a pregnancy. The technique involves thawing the frozen embryos and then transferring viable embryos into the woman's uterus for continued growth. This document explains the technique and describes the major and foreseeable risks of the technique and the responsibilities of those who participate in our program.

Pre-treatment Recommendations:

Patients should avoid any activity, behavior or medication during their treatment that would reduce their chances of conceiving or increase the risk to an unborn child. Below are recommendations for all women/couples attempting pregnancy.

1. Women should take a prenatal vitamin on a daily basis. This vitamin should contain 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 adult-strength aspirin or aspirin-like products (e.g. "Motrin", Advil", Anaprox", Naprosyn", Aleve", etc.) should be avoided during treatment. Tylenol is a suitable alternative.
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.
7. HIV (human immunodeficiency virus) screening is strongly recommended for all couples undergoing infertility treatment. HIV is the virus that causes acquired immunodeficiency syndrome (AIDS). A woman infected with HIV can pass the virus to her unborn child. Please let the physician know if you are interested in having this test performed.

Description of treatment:

This treatment involves several steps, as outlined below. Patients are not guaranteed success at any or all of these steps. If optimal results are not appreciated at any step, it may be recommended that the treatment be stopped and the cycle canceled.

I. Maturation of the Uterine Lining

A. Medicated Approaches

A medicated approach can be used to mature the lining of the uterus. The advantages of a medicated approach in contrast with a non-medicated approach are that there is more control of the stimulation and less of a chance of having to cancel the cycle.

Lupron/Estrogen

Lupron is an injectable medication that initially stimulates the pituitary gland to release FSH and LH, which are the hormones that regulate ovulation. With continued administration of Lupron, the pituitary gland is temporarily depleted of FSH and LH, putting the ovaries to rest. After the Lupron has had this desired effect, estrogen is administered by injection (Delestrogen). After the estrogen has been administered for a long enough duration, either vaginal or intramuscular progesterone is begun. Generally the embryo transfer is performed on the fourth to sixth day after the initiation of progesterone administration. Lupron, estrogen and progesterone are not FDA-approved for this purpose (These medications have been approved for other indications). Lupron is approved for the treatment of endometriosis and uterine fibroids. Estrogen and progesterone medications have been approved

for hormone replacement in menopausal women.

B. Monitoring

During this phase of the treatment, monitoring may be performed with blood hormone levels and vaginal ultrasound exams to help us determine the timing of your embryo transfer. The need for monitoring requires the woman's presence in the vicinity of Palm Beach Center for Reproductive Medicine for a few weeks prior to and after the expected time of the embryo transfer.

C. 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. Some women may have an allergic reaction to the drugs. A rare risk of estrogen administration is the formation of blood clots, which can compromise the blood supply to vital organs, causing serious problems. These problems may include a 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.

II. Thawing of the Frozen Embryos

On the day of the scheduled embryo transfer, straws containing the frozen embryos will be removed from the storage tank and thawed. After the thawing is completed, the embryos are examined to determine their viability. The chance of pregnancy following this treatment is related to the number and quality of the embryos that are transferred. In an effort to provide the best chance of pregnancy, it may be necessary to thaw out a number of straws containing the frozen embryos. This will allow the best quality embryos to be selected for the transfer. The embryos not selected to be transferred cannot be frozen again and, therefore, will be discarded. On average, 70-80% of frozen embryos will survive the thawing. However, it is possible that none of the embryos will survive the thawing.

III. Embryo Transfer

On the day of the embryo transfer, Dr. Graubert will discuss the results of the thawing and a decision will be made regarding the number of embryos that will be transferred. Embryos not transferred at this time will be discarded. To perform the embryo transfer the woman is placed in the same position as if she was having a pelvic exam. A speculum is placed in the vagina and the cervix is visualized. The vagina and cervix are rinsed with a solution. Then, the embryologist will load the embryos into a catheter, which the physician inserts through the cervical canal and into the uterine cavity. The catheter is examined by the embryologist to confirm that the embryos have been discharged from the catheter into the uterine cavity. The woman will be kept in a lying position for about 30 minutes before being discharged home. Activity should be limited the day of the embryo transfer and the next day. Thereafter, normal activity can be resumed.

IV. Treatment Following the Embryo Transfer

Following the embryo transfer, progesterone will be administered. Progesterone is a very important hormone that prepares the lining of the uterus for implantation. Natural progesterone is available and can be administered vaginally or by intramuscular injection. If pregnancy occurs, the progesterone is continued until at least the 10th week of pregnancy along with estrogen. Studies have shown no increased risk of abnormalities developing in an unborn child or health risks to a woman who takes natural progesterone supplements during pregnancy. Almost two weeks after embryo transfer, a blood pregnancy test will be done. If this test is found to be positive, repeat blood testing may be done several days later. If the test results are encouraging, vaginal ultrasound examinations will be done at appropriate intervals after the embryo transfer to determine the status of the pregnancy.

Treatment Outcome

The chance of success is dependent on many factors, some of which include: the age of the woman, the diagnosis, the number of previous cycles of treatment, and the number and quality of embryos that are transferred.

An overview of some of the more common risks of pregnancy is discussed below:

Miscarriage - The risk of miscarriage in the general population is 15-20%. The risk of miscarriage increases with the age of the woman. Studies have shown either no increase or a slight increase in the risk of miscarriage in women who conceive with IVF. Most miscarriages are associated with lower abdominal cramping and bleeding and do not necessarily

require treatment. In some cases, however, complete removal of the pregnancy tissue must be accomplished by a surgical procedure called a dilatation and curettage (D&C). This procedure is usually performed under anesthesia in the operating room and involves placing instruments into the uterine cavity to remove the pregnancy tissue.

Tubal (Ectopic) Pregnancy - Approximately 6-7% of pregnancies that result from IVF treatment are located outside of the uterine cavity. The majority of ectopic pregnancies are present in the fallopian tube. The chance of tubal pregnancy is greater in women with damaged tubes. If a woman has a tubal pregnancy, she may need surgical treatment, which may involve the removal of the involved tube. Medical treatment with Methotrexate may be an option in selected cases.

Multiple Pregnancy - When more than one embryo is transferred, the possibility of multiple pregnancy exists. The chance of a multiple pregnancy increases with the number of embryos that are transferred. Approximately 65-70% of pregnancies following the transfer of multiple embryos results in the birth of only one baby. Of the 30-35% of pregnancies that are multiple, approximately two-thirds are twins and one-third are triplets. The chance of a quadruplet pregnancy is 1-2%. All multiple pregnancies are associated with an increased risk of every complication of pregnancy including but not limited to miscarriage, toxemia, congenital anomalies, gestational diabetes in the mother, and premature labor and birth. Premature birth is the single greatest cause of death or disability in newborn infants. In contrast to a single intrauterine pregnancy, a multiple pregnancy may pose increased emotional and financial hardship for a couple. If a multiple pregnancy develops, the couple may consider being referred to a specialist who can perform a multi-fetal reduction procedure. This procedure, which is performed at three months of pregnancy, is performed to reduce the number of pregnancy sacs to a lower and safer number. Although this procedure is successful 90-95% of the time, a miscarriage may result.

Other Risks - Most infants who have been born following in vitro fertilization are normal. The rate of congenital abnormalities (birth defects) in the general population is 2-3% and is not different in babies conceived with IVF. It is important to be aware that genetic abnormalities, structural abnormalities, mental retardation and other abnormalities may occur following IVF or pregnancies that are conceived naturally.

Psychological Risks - Undergoing treatment with IVF is psychologically stressful. Anxiety and disappointment may occur at any of the phases described above. Significant commitment of time and, finances may be required.

There are many complex and sometimes unknown factors, which may prevent the establishment of pregnancy. Known factors which may prevent the establishment of pregnancy following this treatment include, but are not limited to, the following:

1. Proper timing of the transfer may not be possible and the cycle may be cancelled.
2. The embryos may not survive the thawing process.
3. Embryo transfer into the uterus may be technically difficult or impossible.
4. If transfer is performed, implantation(s) may not result.
5. If implantation occurs, the embryo(s) may not grow or develop normally.
6. Equipment failure or malfunction, infection, technical errors and/or human errors or other unforeseen factors may result in loss or damage to embryos.

Acknowledgement of Informed Consent and Authorization

We acknowledge that we, the undersigned, are voluntarily undergoing treatment, individually and as a couple, at Palmetto Fertility Center, in order to conceive a child through the replacement of thawed frozen embryos and that we will acknowledge our natural parentage of any child born to us through this technique.

We acknowledge that we have read and fully understand this written material, we have considered other treatment alternatives, and all of our questions concerning this treatment have been fully answered to our satisfaction.

We are aware that there are other centers in the area that offer this treatment and we have freely chosen to have our treatment at Palmetto Fertility Center in collaboration with Palm Beach Center for Reproductive Medicine (Scott Roseff, MD, FACOG).

We have been informed of and we accept the responsibilities, conditions and risks involved in participating in the Program as set forth in this document and as explained to us by the staff of Palm Beach Center for Reproductive Medicine. In addition, we consent to the techniques and procedures used to attempt accomplishing thawing of frozen embryos for embryo transfer as they have been described in this document and as they have been explained by the staff of Palm Beach Center for Reproductive Medicine.

We understand that we may withdraw from the Program at any time. We acknowledge and agree that our acceptance into treatment and our continued participation is within the discretion of Palm Beach Center for Reproductive Medicine and/or Palmetto Fertility Center.

Patient and Spouse/Partner for himself/herself and for his/her heirs, spouse executors, administrators, agents, representatives, successors and assigns whatsoever, hereby release and forever discharge Dr. Roseff and Palm Beach Center for Reproductive Medicine, its shareholders, directors, officers, employees, agents, and representatives whatsoever, from and hereby waive all actions, causes of action, obligations, costs, expenses, attorneys' fees, damages, losses, claims, liabilities, defenses, offsets or demands whatsoever arising out of or relating to, directly or indirectly, the handling, freezing, storage, release, loss, damage or destruction of the embryos whatsoever at Palmetto Fertility Center.

We agree to indemnify, defend and hold harmless Dr. Roseff and Palm Beach Center for Reproductive Medicine, its shareholders, directors, officers, employees, agent and representatives whatsoever from expenses, attorneys' fees, damages, losses, claims, liabilities, defenses, offsets or demands whatsoever arising out of or relating to the handling, freezing, storage, release, loss, or damage or destruction of the embryo's whatsoever at Palmetto Fertility Center.

We shall indemnify, defend and hold harmless Dr. Roseff and Palm Beach Center for Reproductive Medicine its shareholders, directors, officers, employees, agent and representatives from and against any loss or damage, including, without limitation, expenses, attorneys' fee, claims liabilities, offsets or demands whatsoever sustained by Dr. Roseff and Palm Beach Center for Reproductive Medicine as a result of any proceeding or dispute of any nature or kind involving the ownership, storage, use or other disposition of the embryos.

We understand that should this cycle be unsuccessful, it may be determined that further treatment with IVF may not be indicated. We also understand that we are financially responsible for any medical expenses that are not covered by our insurance policy.

We understand that medical information concerning our cycle may be reviewed as part of an ongoing quality assurance program and could be used in a publication. In accordance with federal law, information concerning outcomes of our treatment will be submitted to a national registry for future publication.

Female Partner's Signature _____

Date _____

Male Partner's Signature _____

Date _____

Witness's Signature _____

Date _____