Delaware Valley Institute of Fertility & Genetics
6000 Sagemore Drive – Suite 6102
Marlton, NJ 08053
(856) 988-0072
FAX (856) 988-0056

IVF-ET CONSENT WITH OOCYTE CRYOPRESERVATION

I,_____, desire to retrieve oocytes by Assisted Reproductive Technologies (ART) and therefore request and authorize the Delaware Valley Institute of Fertility & Genetics, its physicians, nurses and other professional personnel and agents to perform all necessary procedures and any additional services which they may deem necessary. I understand that there are risks and complications associated with each method of ART and they have been presented and discussed with us to our satisfaction by the Delaware Valley Institute of Fertility & Genetics personnel. There are several types of ART including, but not limited to, In Vitro Fertilization & Embryo Transfer, commonly referred to as IVF. After discussing the other options with our physician, I decided to attempt pregnancy using IVF.

The procedures involved in these methods may include but are not limited to the following:

1. Suppression of hypophysial/pituitary function with GnRH analogs
2. Hyperstimulation of the ovaries with human menopausal gonadotropins (HMG), highly purified urinary products, or recombinant gonadotropins
3. Ultrasonographic guided transvaginal oocyte (egg) retrieval

The timing of these procedures is critical and adherence to the doctor's instructions is important. In spite of the effort, implantation and pregnancy might not occur. Even if pregnancy is established, miscarriage and stillbirth may still occur at a rate of 25%. Pregnancy outside the uterus (ectopic pregnancy) occurs at a rate of 1%. Heterotopic pregnancy, one pregnancy in the womb and another in the fallopian tube at the same time, occurs at a rate of less than 1%. If either an ectopic or heterotopic pregnancy occurs, surgery may be required to remove the abnormal pregnancy.

Suppression of hypophysial/pituitary function with a GnRH analog such as Lupron, Antagon or Cetrotide**.** I will receive daily injections under the skin in order to suppress the pituitary gland and thus avoid any interference with my treatment. I will follow my doctor's instructions to start, discontinue and adjust the dosage of the GnRH analog. In spite of these precautions, there are rare instances where the pituitary gland interferes with the treatment, and the treatment cycle may be canceled. The GnRH analogs are approved by the Federal Drug Administration (FDA) for the treatment of endometriosis, leiomyomas, and prostate cancer but they are not approved for their use in IVF. The adverse reactions of this medication were presented and were discussed with us to our satisfaction and all our questions were answered.

_____ / _____

Hyperstimulation of the ovaries with human menopausal gonadotropins (HMG) such as Repronex, purified urinary products such as Bravelle, and genetically engineered gonadotropins such as Gonal F and Follistim. Gonadotropins are taken subcutaneously daily and HMG intramuscularly daily in an attempt to induce growth and development of multiple oocytes (eggs) in the ovaries. These medications might fail to induce the appropriate response from the ovaries and the treatment cycle might be canceled. On the other hand, they might induce inappropriate high response from the ovaries, which is called ovarian hyperstimulation syndrome (OHSS). If OHSS is likely to occur, my doctor may cancel the treatment cycle. This syndrome includes: 1. Ovarian enlargement, due to cyst formation; 2. Abdominal enlargement, due to fluid collection; 3. Fluid collection in the chest and the tissues; 4. Rupture of ovarian cyst with internal bleeding that may require abdominal surgery and removal of ovarian cysts and/or ovaries; 5. Abdominal pain; 6. Blood clot formation in different organs; 7. Bloating; 8. Pulmonary distress; 9. Gastrointestinal symptoms. The OHSS is usually mild and self-limited but in rare cases (less than 1%), it becomes severe and requires hospitalization, intravenous fluid injection and close monitoring. In very rare cases it can become life threatening.

Monitoring of hyperstimulation of the ovaries with blood samples and transvaginal ultrasounds. Obtaining blood samples causes mild discomfort and occasional bruising at the needle site. Ultrasound has no known risks and causes only mild discomfort.

Egg retrievals at DVIF&G are done under MAC (Monitored Anesthesia Care) anesthesia. Each case is assigned a certified registered nurse anesthetist to administer the anesthesia and monitor vital signs throughout the procedure. These services provided to you will need to be paid in full prior to the procedure via check, cash, or certified check. You may submit a receipt for the paid services to your insurance company for possible reimbursement. Please check with the office manager for pricing on these services.

Transvaginal oocyte (egg) retrieval is accomplished under the guidance of ultrasound. A needle is placed through the vaginal wall into the abdominal cavity and then is directed into the ovaries. The contents of the ovarian follicles (cysts) are aspirated and the oocyte is recovered along with the fluid of the cyst. This procedure is done under sedation and anesthesia. The oocyte retrieval may fail to provide any eggs. There is also a small chance of infection and antibiotics are given for five days starting the day of the hCG injection. During this procedure, the bladder, bowel, uterus, tubes and blood vessels can be injured. In rare circumstances, surgical intervention and repair may be required.

If we wish to attempt fertilization of the retrieved oocytes, then, on the day of oocyte retrieval, my husband and/or partner,_____, may provide a semen specimen at the office. He may be asked to take a specific antibiotic during the first part of the stimulation cycle to treat bacteria present in order to increase chances for a successful fertilization. I understand that he might not be able to provide a specimen or the semen specimen may be inadequate for use in ART procedures. For this reason, he may be required to provide a semen specimen prior to the oocyte retrieval, which will be cryopreserved for use as a backup.

_____ / _____

After the IVF procedure, the retrieved oocytes (eggs) will be incubated with the processed and prepared sperm for fertilization or assisted fertilization, such as ICSI, may be required**.** If fertilization takes place and subsequent embryos develop appropriately, the embryos will be transferred. At this time, we wish to attempt fertilization of _____ mature oocytes. The resultant embryos are transferred into the uterus (womb) with a plastic catheter and I will lie on my back as indicated. After that period of time, I will resume the normal daily activities but I will avoid any vigorous activities for 48 hours. I understand that the transfer of embryos into the uterus may not be technically possible. If a decision was already made and the appropriate documents have been prepared and signed, then those embryos and any additional embryos may be frozen and preserved for future use. If no cryopreservation takes place, then the resulted embryos will be discarded following OSHA guidelines.

After the retrieval of the oocytes, I will receive progesterone intramuscular injections for a minimum of 12 – 14 days. These injections are given to prime the uterus (womb) to accept the embryos and also to support an early pregnancy. If pregnancy occurs, then progesterone may be required for up to 8 weeks. Side effects of these injections are local irritation and abscess, allergic reaction, depression, somnolence, jaundice and skin lesions.

If I have decided not to fertilize and subsequently transfer and/or cryopreserve embryos in this cycle, but rather cryopreserve the acceptable oocytes, then I will sign separate consent for this procedure. Cryopreserved oocytes will remain frozen until a time when consent is received to thaw or dispose. Upon thawing, depending on disposition request, the oocytes may be fertilized, culture, and transferred; discarded; or transferred to another facility. No progesterone supplementation or any other preparation for transfer will take place during the current cycle, unless a selective number of oocytes are used in current cycle

CERTIFICATION

I hereby certify that I have read all of the informational pages attached hereto. I understand the information provided herein about the IVF Laboratory, the egg retrieval procedure and the embryo replacement procedure. I have had the opportunity to address all of our questions and concerns and I have received satisfactory answers thereto. I agree to undergo IVF treatment. In so doing, I assume the obligation to comply with the stated requirements and restraints and I accept all of the risks. Our participation is voluntary. Our participation is not pursuant to any contractual agreement with any other individual or entity.

_____	_____	_____
Patient Name	Patient Signature	Date
_____	_____	_____
Physician's Name	Physician's Signature	Date