

# Delaware Valley Institute of Fertility & Genetics

6000 Sagemore Drive, Ste 6102

Marlton, NJ 08053

(856) 988-0072

FAX (856) 988-0056

## Consent for Frozen Embryo Transfer Procedure

I/We \_\_\_\_\_, and, \_\_\_\_\_ wish to participate in a Frozen Embryo Transfer procedure (FET) at Delaware Valley Institute of Fertility & Genetics (DVIF&G). I/We understand that there are a number of steps to this procedure and that starting this process does not guarantee that we will complete it, achieve pregnancy or delivery of a healthy child. One of the physicians has discussed with us the etiology of our condition, and alternative therapies, if any, that are available. The steps may be performed by Dr. George Taliadouros, or other DVIF&G providers. I/We understand that additional testing may be required of the patient and his/her partner to meet practice policies prior to embryo transfer. I/We understand that the embryos obtained will be transferred to the patient by means of a small catheter, which passes through her cervix.

### A – Down regulation, cycle coordination and endometrial preparation

I/We understand that A GnRH-agonist (leuprolide acetate, Lupron) may be used to suppress the patient's natural ovulatory cycle in order to better time the embryo transfer. I/We understand that once medication has started, frequent monitoring will be required. This may include frequent blood drawing, which carries the risk of mild discomfort, bruising at the puncture site or the rare risk of infection. We also understand that ultrasound examinations of the uterus may be performed frequently. These examinations may at times be uncomfortable, but there is no risk presently known to medical science. Estrogen medication (Estrace pills, Estrogen patch, etc) will be prescribed for oral and vaginal use to thicken the uterine lining in preparation for the embryo transfer. Ultrasounds will be required to measure the thickness of the lining and assess its pattern. It is possible that the lining will not be adequate for transfer and the cycle will have to be cancelled. In this situation, a new protocol may be proposed or additional medication can be prescribed.

### B - Blastocyst culture and embryo transfer

I/We understand that the embryo will be thawed and placed in a culture dish with media in the incubator and then subsequently moved into a transfer dish prior to the procedure. In some cases, embryos are thawed and cultured over a period of time to reach the desired stage for transfer, whether that be at a cleavage stage or a blastocyst. This protocol may be especially advantageous to couples who are at risk of multiple pregnancy, since the extended culture increases the opportunity for embryologists to select the highest quality embryos. A potential disadvantage is that some embryos may be more sensitive to prolonged presence in the laboratory with the result that the embryo may not survive and embryo transfer may not occur.

For any embryo transfer, a thin catheter will be passed through the cervix of the patient and into the uterus so the embryo may be deposited there. I/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. I/We understand there is no guarantee that any of the embryos transferred will result in a pregnancy.

I/We understand that the success of IVF can often relate directly to the number of embryos transferred to the uterus. I/We also understand that IVF significantly increases the risk for multiple gestation (more than one baby), and that this risk also correlates directly with either the number of embryos transferred, their development, the age of the intended mother the number of prior attempts, and other unknown factors. I/We also understand that in rare cases, embryos may split in two, resulting in multiple fetuses; on occasion this can mean that there are more fetuses than embryos transferred. There are distinct obstetric risks to multiple gestations, the most serious of which are pre-term labor and the delivery of premature infants who require intensive care. It is the policy of this program to replace anywhere from one to three embryos in a cycle all depending on availability and factors such as your age, cycle attempt and embryonic parameters.

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### **C - Post-transfer management**

I/We understand that, in conjunction with the transfer of embryos, the patient may be given natural progesterone by intra-muscular injection, vaginal suppository, or oral capsule in an attempt to increase the chances for successful implantation. Should a pregnancy result, we understand that no harmful effects to the patient or the fetus are presently known to medical science from the use of this natural progesterone. During this period, we understand that various blood hormone levels will be evaluated. I/We understand that it will be necessary to continue taking the estrogen and progesterone until there is clear evidence that the placenta of the developing pregnancy is making sufficient amounts of these hormones to maintain the developing pregnancy.

### **D - Disposition of unwanted or unsuitable cells, fluids, spermatozoa, eggs and embryos**

Blood, blood products and cells, as well as fluids and cells contained therein obtained during follicular monitoring, egg or sperm retrieval, may be used for scientific observations. Embryos that arrest after 1-6 days after egg retrieval, that are partially degenerate or for any other reasons are considered unsuitable for embryo transfer or cryopreservation may be observed to determine cellular inclusions, genes, gene mutations, proteins and chromosomes. These studies use protocols that will cease the immediate growth of individual cells. We understand that these embryos or their cells will never be used for purposes other than those described and will never be offered to other individuals, couples, corporations or institutions. I/We also understand that these embryos or their cells are unwanted and considered abnormal.

### **E - Use of chemical substances, disposable items and mechanical devices during the procedures**

A large number of chemical substances (sugars, salts, enzymes, proteins), mechanical devices (incubator chambers, microscopes, air handling systems, filters, standard laboratory equipment) and disposable items (pipettes, petri dishes, flasks, microtools) are used during the laboratory procedures. There may be unknown risks associated with the use of any of these items that cause your procedure to fail, even though checks and quality control measures are performed on a regular basis. Thus far we do not know of any association between the use of these materials and anomalies of pregnancy and fetal development, but underlying unidentified problems may nevertheless exist. An enzyme made from cow testis called hyaluronidase is routinely used to remove nursing cells from around the eggs, and there is a chance that this enzyme may inadvertently remove the zona pellucida (the layer surrounding eggs) and cause your procedure to fail.

### **F - Risks associated with procedures**

Based on current medical knowledge, I/We understand there does not appear to be a higher incidence of birth defects associated with IVF procedures. However, there is not at present sufficient statistical data available to definitively conclude that this is so. Therefore, I/we understand that using IVF may impose risks to the fetus during development. We also understand that because more than one embryo may be transferred, there may be a higher incidence of multiple births. An embryo may split when inside the uterus, forming monozygotic twins and there may be other associated anomalies. In certain cases, fetal reduction may be considered if more embryos implant that can be medically (or personally) deemed advisable to carry through a pregnancy. I/We also understand that ectopic or tubal pregnancies may occur in the procedure. These associated procedures can also produce increased financial and emotional burdens.

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### G - Success rate and outcome

I/We understand that failure to obtain a pregnancy may result from many reasons, including the following:

- Cleavage or growth of the embryo(s) may not occur at any day of development or the embryo(s) may not develop normally.
- An unforeseen laboratory accident may result in loss or damage to the eggs, sperm, or embryo(s).
- The embryo(s) may become contaminated by infection in the semen or bacteria from the vagina or the lab.
- Some embryos may not develop well in approved commercial culture medium despite standard testing.
- Implantation of the embryo(s) in the uterus after embryo transfer may not occur or an early pregnancy may be lost after an initial positive result
- Even if a pregnancy is established, we understand that delivery of a child may not occur due to miscarriage, ectopic pregnancy (outside the uterus), stillbirth, or other complications associated with pregnancy and delivery.
- There may be unknown side-effects from any of the procedures used resulting in abnormal pregnancy or abnormal fetal development

I/We understand that the members of the IVF team cannot guarantee that a pregnancy will result from this procedure. If no pregnancy occurs, we may be offered participation in future cycles when assessment by the IVF team reveals no contra-indications. I/We understand that the IVF team cannot guarantee the normality of any infant that results from this procedure.

I/We understand that we may at any time decide to withdraw from participation in this program without prejudice. Any information obtained during this procedure and identified with us will remain confidential and will be disclosed only with our permission. Any publication resulting from this procedure will not identify us individually. Representatives of The Food and Drug Administration (FDA), The Center for Disease Control (CDC), The Department of Health of New Jersey, or other government agencies as provided by law may inspect the records.

I/We absolve DVIFG physicians and staff from any and all liability for complications related to IVF/FET therapy and complications related to pregnancy or delivery and/or the birth of a physically or mentally deficient child. Additionally, we absolve DVIFG physicians and staff from any and all liability in connection with subsequent disputes between a patient and spouse/partner or any other third party in connection with the co-disposition of any fertilized eggs or embryos in existence as a result of this IVF cycle.

