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Name: _____
DOB: _____
Physician:_____

INFORMED CONSENT FOR USING AN ANONYMOUS DONOR'S SPERM: UNMARRIED RECIPIENT

You are considering using anonymous donor sperm for either an insemination or in vitro fertilization procedure at Delaware Valley Institute of Fertility & Genetics. Donor sperm has been utilized for the treatment of severe male factor infertility or in the absence of a fertile male partner for many years. Donor sperm may be used in artificial insemination cycles that may be unstimulated, or stimulated with antiestrogens agents (Clomiphene citrate, tamoxifen) or gonadotropins (fertility medications), or during an IVF cycle.

Donor insemination is usually performed in a medical setting with semen acquired from a licensed sperm bank by a physician or other medical professional. Donor sperm may also be used with in vitro fertilization where eggs will be inseminated in a dish with donor sperm and some of the resulting preimplantation embryos (to be referred to as pre-embryos) will be transferred to your womb. The program is conducted with an understanding that all parties concerned will respect the confidentiality of both the donors and the recipients.

Prior to using donor sperm for artificial insemination or in vitro fertilization, you will undergo screening (described below) that includes psychological counseling, a medical and gynecological history and physical examination, and blood tests. If the results of all of the screening tests are acceptable, you will be able to pursue treatment with donor sperm.

In addition to this Donor Sperm Consent form, you will be required to review the informed consent forms for the specific procedure for which you are using the donor sperm and to sign them with your primary physician. These include the Assisted Reproductive Technology (ART) consent or the Intrauterine Insemination consent forms.

SPECIAL CONSIDERATIONS

Until the 1980s, donor insemination was usually performed using fresh semen. Today, because of concerns of possible transmission of infectious diseases like HIV, donor insemination is performed using frozen donor sperm. These specimens are quarantined for at least six months before the specimens can be used. The six-month quarantine allows time for careful screening of the donor.

The long term and psychological risks to a woman using sperm from an anonymous donor are thought to be minimal.

You have decided to use donor sperm after having pursued other available therapy for infertility, and having considered the alternative of adoption. You understand that there is no guarantee that pregnancy will occur. If pregnancy results, there is no guarantee that it will proceed to term.

Donor Screening

You will be notified of relevant portions of the donor's medical record. This is important for your decision in choosing a donor and may also be important to the medical treatment of any child born as a result of the donation. Most of the information in the donor's medical record is obtained by questioning of the donor, rather than by performing diagnostic tests, and the validity of the information may not be confirmed. Donors are screened for infectious diseases as required by the Federal Drug Administration (FDA) and Centers for Disease Control (CDC), and for certain genetic disorders, where indicated by the policies and procedures at the individual sperm bank.

Delaware Valley Institute of Fertility & Genetics can only use frozen semen obtained from an FDA registered Reproductive Tissue Bank. You may contact our Nurse Manager for a list of currently approved Sperm Banks. She can provide you with copies of catalogs of donors from approved sperm banks to help you select a donor. After you have completed your selection, you will need to purchase the samples through the Nursing Team at Delaware Valley Institute of Fertility & Genetics and have them shipped for temporary storage prior to the start of your treatment cycle.

Recipient Screening

You will be offered the opportunity to have a consultation with our affiliated psychological counselor to discuss issues specific to the use of donor sperm (see Consults with Other Health Professionals, below).

You will need to have testing prior to initiating treatment with donor sperm in order to ensure your safety during the treatment and anticipated pregnancy. Some of these tests will look for infections that could endanger a pregnancy. You will be tested for sexually transmitted diseases, hepatitis, and HIV (the virus that causes AIDS). You will be required to sign a separate consent for HIV screening. If evidence is found of any type of infection, the results will be discussed with you and, if needed, you will be referred for treatment.

In addition to infectious disease screening, other tests may be required that would be recommended for any woman anticipating pregnancy or infertility treatments. These tests include blood typing and Rh, rubella titer, complete blood count (CBC), and cervical cultures. We require all of these screening procedures before your first cycle of treatment. For subsequent cycles you may need to repeat a few of these tests. If more than a year has gone by since your first cycle, we will require you to repeat your screening tests.

At the end of screening, you will meet with your Reproductive Endocrinologist to review the results of your tests, discuss plans for your treatment cycle, and give your physician an opportunity to prescribe your medications.

Confidentiality

Except as required by law, all information about you obtained during this treatment will be handled confidentially and neither your identity nor your specific medical or psychological details will be revealed by our physician(s) or Delaware Valley Institute of Fertility & Genetics without your consent. Your name and address will be kept on file by Delaware Valley Institute of Fertility & Genetics, and this, or any other information which would directly or indirectly identify

you, will not be disclosed or released to any person or entity without your written informed consent, except to authorized employees of the New Jersey State Department of Health or as permitted by law. Reproductive tissue bank records shall be open to inspection by the Department of Health and shall be kept for at least seven years after the use of reproductive tissue that does not result in a live birth, and at least 25 years for those procedures that result in a live birth. Any other use of information about your treatments or about you would require your specific consent. Specific medical details may be revealed in professional publications as long as your identity is concealed.

Financial Responsibility

Financial responsibility for all services and medical treatments given by Delaware Valley Institute of Fertility & Genetics physicians and staff, laboratory services, and hospital costs associated with medical care are the sole responsibility of the woman receiving these treatments. In addition, if the services of a sperm donor are also necessary in the conduct of the medical therapy, the woman desirous of having the child(ren) bears the responsibility for purchasing and arranging transport of the donor sperm from the sperm bank. Financial responsibility for the pregnancy and any pregnancy complications (whether the female partner or the carrier) are the responsibility of the woman under treatment.

The clinical and financial staff of Delaware Valley Institute of Fertility & Genetics makes every effort to accurately predict the cost of services before they are rendered, but the costs may vary depending on unforeseen circumstances and of complications of the treatment. Delaware Valley Institute of Fertility & Genetics reserves the right to change its charges and fees. Delaware Valley Institute of Fertility & Genetics financial staff will work with the recipient to determine the likely insurance reimbursement for care rendered, but the ultimate responsibility for payment rests with the woman under treatment, not the insurance company.

The donor sperm recipient's records and cycle outcome are open to inspection by the New Jersey State Department of Health. The recipient's name and address and any other information which would directly or indirectly identify the recipient will not be disclosed or released to any person or entity, except with the informed written consent of the recipients or to authorized employees of the New Jersey State Department of Health, or as permitted by law. In addition, any adverse outcomes, including infectious diseases in the recipients or their offspring, and genetic defects in offspring, will be reported to the sperm donor if there is any possibility that the donor's reproductive tissue contributed to the adverse outcome. It is the policy of Delaware Valley Institute of Fertility & Genetics to inform the sperm bank if a pregnancy results from the donation. This is important from the standpoint of giving the sperm bank information to prevent the sperm donor samples from being used if a large number of pregnancies have resulted from multiple donations to prevent potential consanguinity (procreation between related persons). The anonymity of the donor and the recipient is maintained of course.

It is understood that the legal status of the donor is somewhat uncertain and that the laws may change, especially with respect to anonymity. I have had the opportunity and have been advised to seek legal counsel.

Consults with other health professionals

We offer each woman that plans to use donor sperm for artificial insemination or in vitro fertilization at Delaware Valley Institute of Fertility & Genetics the opportunity to have a visit with a psychological counselor. Infertility treatment can be very stressful. We view this counseling as an opportunity to prepare you for the stresses of your treatment. Women who are identified by the counselor as needing further support may choose to have continued counseling. In addition, the counselor will discuss issues specific to receiving donor sperm, including what to tell a child about how they were conceived. These issues are worth thinking about before beginning treatment with donor sperm.

We may ask some women anticipating the use of donor sperm to have genetic screening. The particular genetic screening will differ from woman to woman. If you do need genetic screening, we will offer to refer you to a genetic counselor that will advise you of the risks and benefits of screening.

Pregnancy itself can be a health risk. If you are over the age of 45 or have any significant illness (such as asthma, diabetes, or multiple sclerosis), we will ask you to be cleared by your internist and a board-certified perinatologist of your choice *before starting your treatment.* All women over the age of 45 will require a cardiac stress test. If you have a history of any other significant illness, you will need a consultation with another relevant specialist *before starting your treatment.*

We require all of these screening procedures before your first cycle of treatment. For subsequent cycles you may need to repeat a few of these tests. If more than a year has gone by since your first cycle, we will require you to repeat all of your screening tests.

At the end of screening, you will meet with your Reproductive Endocrinologist to review the results of your tests, discuss plans for your treatment cycle, and give your physician an opportunity to prescribe your medications.

Procedures

The procedures for intrauterine insemination and in vitro fertilization are discussed in their respective informed consent forms. You will be required to complete the additional appropriate consent form in addition to this one prior to beginning your treatment using donor sperm.

Risks

The use of donor sperm carries with it the risk of sexually transmitted diseases including but not limited to gonorrhea, syphilis, herpes, hepatitis, and acquired immune deficiency syndrome (AIDS). The risk for infectious disease with the use of donor sperm is extremely small as the sperm donors are tested prior to giving the sperm specimens, and again after the sperm has been frozen and quarantined for six months. This allows for retesting for HIV and other infectious diseases before releasing the samples for use.

Failure to Achieve Pregnancy

Your chance of achieving pregnancy with donor sperm is dependent upon whether you are undergoing unstimulated or stimulated insemination or in vitro fertilization and upon your age and infertility diagnosis. The most common reason for needing donor insemination is a couple with absence of functional sperm. In most cases there is no reason to believe that the woman herself has a fertility problem. Because of this, it may not be necessary for you to undergo complete fertility testing before starting your cycle of treatment.

Only 15 to 20% of women will become pregnant in each cycle of treatment. We anticipate that 50% of women will achieve pregnancy within four cycles of donor insemination. The chance of pregnancy in these cases may depend on the quality of the frozen sperm. If you have undergone more than four cycles of insemination and have not yet conceived, you should make an appointment with your physician to discuss the possibility that you may have other conditions that are preventing a pregnancy. For example, if you have not had a test to make sure your fallopian tubes are open, your physician may recommend such a test at that time.

The chance of conception is dependent on the number of ovarian follicles that a woman produces. Medications can be used to increase the number of eggs that you ovulate in a cycle. More eggs will lead to a greater chance of pregnancy. It can also increase the chances that you will have a multiple pregnancy.

Pregnancy Risks

As with any pregnancy, after a treatment cycle, if pregnancy is successfully established, miscarriage, ectopic pregnancy, stillbirth, multiple births, congenital abnormalities (birth defects), and/or genetic abnormalities may occur. Within the normal human population a certain percentage (approximately 4%) of children are born with physical or mental defects, and that occurrence of such defects is beyond the control of physicians.

Within the normal population, approximately 20% of pregnancies result in miscarriages and this may occur after the use of donor sperm as well. Similarly, obstetrical complications may occur in any pregnancy.

Informed Consent for Using an Anonymous Donor's Sperm: Unmarried Recipient

1. Informed Consent

I have read the entire "Informed Consent for Using an Anonymous Donor's Sperm: Unmarried Recipient" and have had the opportunity to ask any questions I might have about my participation. My consent to this procedure is purely voluntary. I may withdraw my consent at any time and my present or future care will not in any way be affected by my decision.

2. Risks and Benefits

In addition to reading this document, I have been advised by my physician of the risks and benefits of undergoing the procedures required and the possible alternatives thereto, as well as the risks and benefits of becoming pregnant. I have been offered to undergo psychological counseling regarding the process.

3. Confidentiality

Except as required by law, I have been assured that all information about me obtained during this treatment will be handled confidentially and neither my identity nor my specific medical or psychological details will be revealed by my physician(s) or Delaware Valley Institute of Fertility & Genetics. I have been told that my name and address will be kept on file by Delaware Valley Institute of Fertility & Genetics, and that this, or any other information which would directly or indirectly identify me will not be disclosed or released to any person or entity without my written informed consent, except to authorized employees of the Department of Health or as permitted by law.

Reproductive tissue bank records shall be open to inspection by the Department of Health and shall be kept for at least seven years after the use of reproductive tissue that does not result in a live birth, and 25 years for those procedures that result in a live birth. Statistics concerning my treatments (without my name or personal information) will be included in information that Delaware Valley Institute of Fertility & Genetics provides to the Society for Assisted Reproductive Technology and the Centers for Disease Control and Prevention. Any other use of information about my treatments or me would require my specific consent. Specific medical details may be revealed in professional publications as long as my identity is concealed.

4. Legal Concerns

I understand that the legal status of sperm donation is as yet uncertain and that there may be changes in the law, especially regarding anonymity, in the future. I have been advised, and have had the opportunity, to consult my own legal counsel. I have also had the opportunity to consult with a physician and psychologist/counselor.

It is the policy of Delaware Valley Institute of Fertility & Genetics to inform the sperm bank if a pregnancy results from the donation. This is important from the standpoint of giving the donor information to prevent him from donating sperm if a large number of pregnancies have resulted from multiple donations to prevent consanguinity (procreation between blood relatives). The anonymity of the donor and recipient is maintained of course.

5. Risk of Injury

I have also been informed that should I suffer any physical injury as a result of my participation in this medical treatment, the necessary medical facilities are available. I cannot expect to receive any payment for hospital expenses or any financial compensation for such injury.

6. Hold Harmless

I understand and agree that Delaware Valley Institute of Fertility & Genetics and its physicians do not assume responsibility for the physical and mental characteristics of any child or children born as a result of using donor sperm. I hereby agree to indemnify and hold harmless my physicians, caregivers, and Delaware Valley Institute of Fertility & Genetics from any cost, claim, liability, or expense arising out of the use of donor sperm, or out of any complications of conception, childbirth or delivery, or from the birth of a child abnormal in any respect, or from any adverse consequences which may arise in connection with or as a result of my participation in the use of donor sperm. Nothing contained herein shall be construed to relieve Delaware Valley Institute of Fertility & Genetics from liability arising out of its professional malpractice during the course of my treatment.

7. Voluntary Participation

I have read the entire Donor Sperm consent and have had the opportunity to ask any questions that I might have about my participation. I agree to use donor sperm under the conditions outlined above. My consent to this procedure is purely voluntary. I may withdraw my consent at any time and my present or future care will not in any way be affected by my decision. I acknowledge receipt of a copy of this form.

8. Understanding

I confirm that I have read this form, fully understand its contents, and that all blank spaces above have been completed prior to my signing. In addition, I confirm that I have had the opportunity to ask any questions and that all of my questions have been answered to my satisfaction. I further agree that I am assuming the entire responsibility for any child or children conceived or born. I agree that I will not seek support for the child or children, or any other payment from the donor, physicians or nurses associated with Delaware Valley Institute of Fertility & Genetics.

I, _____, authorize the physicians of Delaware Valley Institute of Fertility & Genetics to perform one or more artificial inseminations, in vitro fertilization cycles and embryo transfers with the sperm obtained from an anonymous donor(s) for the purpose of conceiving.

_____	_____	_____
Name of Recipient (print)	Signature	Date
_____	_____	_____
Witness (print)	Signature	Date

My consent applies to any treatment cycle I undergo within the next 12 months. If I wish to undergo additional cycles after more than 12 months from now, I will have another informed consent discussion with my physician and sign again. If at any time during this period I want another copy of this form, it will be provided.

Physician certification: I hereby certify that I have explained the nature, purpose, benefits, risks of, and alternatives to the proposed treatment, have offered to answer any questions and have fully answered such questions. I believe that the patient fully understands what I have explained and answered, and has consented to undergo the proposed treatment.

_____ Date_____
Physician obtaining consent