

Anonymous Donor Sperm

Information and Consent

You are considering using anonymous donor sperm for either an insemination or in vitro fertilization procedure. Donor sperm has been utilized for many years for the treatment of male factor infertility or in the absence of a fertile male partner. Donor sperm may be used in cycles that are natural or stimulated to produce egg growth.

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 or with ICSI (intracellular sperm injection) and some of the resulting embryos will be transferred to your womb.

Prior to using donor sperm, you will undergo screening that includes psychological counseling, a cavity evaluation, medical history and physical examination, ultrasound, 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.

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 6 months before the specimens can be used. The 6-month quarantine allows time for careful screening of the donor.

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

Although the donor does not know who receives the sperm, and you do not know the identity of the donor, today technology exists that allows for you to trace the identity of the donor and for the donor to trace the identity of their offspring using DNA.

You have decided to use donor sperm after being informed of other available therapies for infertility, and including 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 independently confirmed. Donors are screened for infectious diseases. Some Donors will have DNA testing completed. If you choose a donor that positive results for genetic traits, please discuss these results with your provider BEFORE the insemination process.

Most patients obtain donor sperm from commercial Sperm Banks. After you have completed your selection you will need to purchase the samples directly from the sperm bank and arrange to have them shipped to Strong Fertility Center.

Recipient Screening

You will need to have a consultation with an approved psychological counselor to discuss issues specific to the use of donor sperm. The purpose of the counselor visit is to screen for issues that may arise during the therapy, both successful and otherwise. An important part of the process is the protection of offspring which may result from the therapy. The recipient agrees that in rare instance the evaluation from the counselor results in not recommending treatment. The physician team is not held liable for the acceptance of the recommendation, which again, is felt to be in the best interest of a child.

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). If evidence of any type of infection is found, 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 status, and rubella titer. 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 may require you to repeat your screening tests.

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 staff. Your names and address will be kept on file, 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 as authorized by law. Reproductive tissue bank records shall be open to inspection in some jurisdictions, and shall be kept for at least as long as required by law. 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.

In some jurisdictions, the donor sperm recipient's records and cycle outcome are open to inspection by the 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 by to any person or entity, except as required by law or court order. 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 Strong Fertility Center to inform the sperm bank if a pregnancy results from the donation.

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.

Financial Responsibility

Financial responsibility for all services and medical care are the sole responsibility of the individuals receiving these treatments.

Prior to arranging the purchase of sperm, the laboratory staff should be contacted so that the shipping of the sample(s) is expected. Financial responsibility for the pregnancy and any pregnancy complications (whether of the female partner or the carrier) are the responsibility of the individual(s) under treatment.

Strong Fertility Center 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. Strong Fertility Center reserves the right to change its charges and fees.

Consults with other health professionals

We require each person that plans to use donor sperm for artificial insemination or in vitro fertilization to have a visit with a psychological counselor. Our staff will provide names of counselors who are familiar with ASRM guidelines regarding use of donor sperm, eggs or embryos, and have agreed to see persons considering Donor Insemination. We view this counseling as an opportunity to prepare you for the stresses of your treatment. Individuals 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 and when 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 individuals anticipating the use of donor sperm to have genetic screening. The particular genetic screening may 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/or a board-certified perinatologist *before starting your treatment*. All women over the age of 45 will require a cardiac evaluation. If you have a history of any other significant illness, you will need a consultation with another relevant specialist *before starting your treatment*.

Procedures

The procedures for intrauterine insemination and in vitro fertilization are discussed in their respective informed consent forms. Additional consent forms may need to be understood and signed.

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 6 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 women 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.

For women under age 35, about 15 to 20% of women will become pregnant in each cycle of treatment. We anticipate that half 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 produce (ovulate) in a cycle. More eggs will lead a greater chance of pregnancy. It can also increase the chances that you will have a multiple pregnancy.

Pregnancy Risks

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

Within the normal population, approximately 20% of pregnancies result in miscarriages in woman under age 35; 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

1. <u>Informed Consent</u>

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

2. Risks and Benefits



In addition to reading this document, I/we have been advised 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/we have been advised to undergo psychological counseling regarding the process.

3. Confidentiality

Except as required by law, I/we have been assured that all information about me/us obtained during this treatment will be handled confidentially and neither my/our identity nor specific medical or psychological details will be revealed without my consent. I/we have been told that my/our name and address will be kept on, and that this, or any other information which would directly or indirectly identify me/us will not be disclosed or released to any person or entity without my/our written informed consent, except as permitted by law.

Reproductive tissue bank records shall be open to inspection as specified by law. Statistics concerning my/our treatment (without names or personal information) will be included in information that the CLINIC provides to the Society for Assisted Reproductive Technology and the Centers for Disease Control and Prevention if my therapy includes Assisted Reproductive Technologies. Any other use of information about my/our treatments or me/us would require my/our specific consent. Specific medical details may be revealed in professional publications as long as my/our identity is concealed.

4. <u>Legal Concerns</u>

I/we 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.

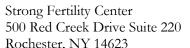
Strong Fertility Center may inform the sperm bank if a pregnancy results from the donation. This is important from the standpoint of giving the sperm bank information to prevent them from using the same donor too many times. The anonymity of the donor and recipient is maintained of course.

5. Risk of Injury

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

6. <u>Hold Harmless</u>

I/we understand and agree that Strong Fertility Center does not assume responsibility for the physical and mental characteristics of any child or children born as a result of using donor sperm. I/we hereby agree to indemnify and hold harmless my/our physicians, care givers, and CLINIC 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 Strong Fertility Center from liability arising out of its professional malpractice during the course of my treatment.





7. Voluntary Participation

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

8. Understanding

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

I/we therefore authorize the appropriate staff at Strong Fertility Center to perform one or more artificial inseminations or in vitro fertilization cycles and embryo transfers with the sperm obtained from an anonymous donor(s) for the purpose of conceiving.

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



Strong Fertility Center 500 Red Creek Drive Suite 220 Rochester, NY 14623

I request and consent to use of anonymous donor sperm in hopes of achieving a pregnancy.

X	
Patient Signature	Date
Patient Name	Date of Birth
X	
Spouse / Partner Signature	Date
Spouse / Partner Name	Date of Birth
Statement by Witness (must be employee	
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