Informed Consent for the Use of Donor Sperm

The following information and consent form are provided to you because you are considering using donor sperm to attempt pregnancy either by intra-uterine insemination or in vitro fertilization procedure. Please read this document carefully prior to signing and ask any questions you may have.

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 from an anonymous donor (identity not known to you) or may be from a directed donor (identity known but not intimately involved with you).

Prior to using donor sperm, you may undergo screening that includes psychological counseling, a medical history and physical examination, as well as blood tests. If the results of all the screening tests are acceptable, then 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

Because of concerns of possible transmission of infectious diseases like HIV, Hepatitis and others, donor insemination is performed exclusively using donor sperm has been frozen and quarantined. These specimens are quarantined for a period of time (6 months for non-identified donors) before they can be used. The quarantine allows time for screening and subsequent testing of the donor. The specimens from "directed" (known) donors are exempt from quarantine under the current Food and Drug Administration (FDA) guidelines. However, following the American Society for Reproductive Medicine (ASRM) guidelines, CRM recommends that known donor specimens be treated in the same manner as non-identified donor specimens.
There may be long term psychological implications to a woman using sperm from a donor and psychological counselling and support is offered.
You have decided to use donor sperm after being informed of other available therapies for infertility, including adoption and child free living. You understand that there is no guarantee that pregnancy will occur. If pregnancy results, there is no guarantee that you will have a successful delivery or healthy baby.

Donor Screening

Sperm donors are screened following FDA, New York State Department of Health and ASRM guidelines to minimize the risk that infectious agents will be transmitted to the recipient. Sperm donors are screened with a complete medical history, physical exam, and laboratory testing. 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 because 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 is not independently confirmed. Donors are screened for infectious diseases and some genetic disorders. All questions about the donor screening and testing should be directed to the sperm bank from which the samples are obtained. Known donors must undergo the same screening and testing as non-identified donors within 7 days before donation.

The screening of anonymous and directed semen donors includes testing for cytomegalovirus (CMV), a virus that is very common. Testing for past CMV exposure is done with a blood test looking for antibodies to the CMV virus. Because there are many strains of CMV, testing for antibodies does not guarantee immunity from future CMV infections. Because CMV may be transmitted in fluids like semen, there is also a theoretical risk that one could transmit this CMV virus into any woman through insemination or embryo transfer even if the woman has previously been exposed to CMV. CMV usually

causes mild, flu-like symptoms in healthy people, but it can be dangerous to a developing fetus if a woman becomes infected with the virus while pregnant.

Recipient Screening

A routine health and reproductive history from you will be obtained according to the general preconception screening standards that are applied to individuals attempting pregnancy with the use of donor sperm. A complete general physical examination will be performed, including a pelvic evaluation.

We may require each person that plans to use donor sperm for insemination or in vitro fertilization to have a visit with a psychological counselor who is familiar with ASRM guidelines regarding use of donor sperm, eggs, or embryos. We view this counseling as an opportunity to prepare you for the stresses of your treatment. The counselor can provide further support with counseling if requested. In addition to other topics related to your treatment, the counselor will discuss issues specific to receiving donor sperm including what and when to tell a child about how they were conceived.

If you are using a known sperm donor, consultation will include separate sessions for the donor and recipient(s), as well as a joint session with the donor, donor's partner, and recipient(s); expectations for communication and relationship roles between and among donor, recipient, donor-conceived persons, partners, and other family members; discussion that a donor may not be recommended for donation; and exploration of donor and recipient(s) preferences about the disposition of any remaining gametes or embryos.

CRM strongly recommends, but does not require or provide, legal counsel for all participants using known or directed sperm donation. CRM may request that you provide a legal clearance letter addressing the following considerations when using a known sperm donor: independent counsel; voluntarily agreement between parties noting no coercion or duress; sperm usage and disposition terms; expenses; and time limits.

You will need to have testing prior to initiating treatment with donor sperm to ensure your safety during the treatment and that of the anticipated pregnancy. Some of these tests will look for infection that could endanger a pregnancy. Abnormalities detected from history, physical examination, or laboratory evaluation will be discussed with you and may require more detailed evaluation and 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, Rh status and antibody screen, a Pap smear, and assessment of vaccination status for rubella and varicella. If nonimmune, then the vaccine should be administered and pregnancy should be avoided for four weeks after the last dose of vaccine. Genetic testing for several conditions you may be a carrier for are strongly recommended. If you are found to be a carrier for any of the tested conditions, then we strongly encourage testing of the donor or testing during pregnancy to minimize the risk of having a child affected with a serious genetic condition. If the donor has not or cannot be screened for any trait found on your genetic screening, then counseling with a genetic counselor is recommended to understand the natural history of the condition(s), carrier frequency, autosomal recessive inheritance, the detection rate of the screen, and the residual risk. Testing for prior exposure to CMV is strongly encouraged. If you are found to be CMV negative (no prior exposure), then using a CMV negative donor may reduce your risk of CMV, although most CMV infections are acquired in the community.

We require these screening procedures before your first cycle of treatment. For subsequent cycles you may need to repeat some or all of these tests. If more than a year has gone by since your first cycle, then we will require you to repeat your screening tests for infectious diseases and hormones.

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 an OB/GYN of your choice who may be able to

care for you during pregnancy 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.

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 or CRM. Your names and addresses 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 or required by law. In New York State, reproductive tissue bank records are open to inspection by the Department of Health 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.

The donor sperm recipient's records and cycle outcome are open to inspection by the New York 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 as required by law or court order. However, it is possible that the identity of the sperm donor and his resulting children may become apparent or available despite attempts to keep the process anonymous. In addition, any adverse outcomes, including infectious diseases in the recipients or their offspring, and genetic defects in offspring may be reported to the sperm bank or 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 CRM 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. You are advised to seek legal counsel.

Financial Responsibility

Financial responsibility for all services and medical testing is the sole responsibility of the individuals receiving these treatments. Financial responsibility for the pregnancy and any pregnancy complications (whether of the sperm recipient or the carrier) are the responsibility of the individual(s) under treatment.
CRM will make 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. CRM reserves the right to change its charges and fees.

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, chlamydia, syphilis, herpes, hepatitis, and HIV/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 a period of time (6 months for non-identified donors). This allows for retesting for HIV and other infectious diseases before releasing the samples for use. Screening procedure(s) performed on recipient and donor, including genetic screening, is limited and will not screen for all conditions or genetic defects.

Failure to Achieve Pregnancy

Your chance of achieving pregnancy with donor sperm is dependent upon many factors including whether you are undergoing natural or medicated treatment for insemination or in vitro fertilization and upon your age and infertility diagnosis. The chance of conception is also dependent on the number of ovarian follicles that the recipient 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, but it will also increase the chances that you will have a multiple pregnancy.

Pregnancy Risks

As with any pregnancy, 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 the occurrence of such defects is beyond the control of physicians. Within the normal population, approximately 10-20% of pregnancies result in miscarriages in woman under age 35 and is higher in women over 35 years. This may occur after the use of donor sperm as well. Similarly, obstetrical complications may occur in any pregnancy.

Informed Consent for Using Donor Sperm

1. Informed Consent

I/We have requested to be treated by The Ronald O. Perelman and Claudia Cohen Center for Reproductive Medicine (CRM) of Weill Cornell Medicine. I/We have considered the available options for achieving parenthood and have chosen to attempt pregnancy utilizing the sperm from a donor either by intra-uterine insemination or in vitro fertilization procedure. I/we have read the entire "Informed Consent for the use of Donor Sperm" and have had the opportunity to ask any questions I/we might have about my/our participation. My/our consent to this procedure is purely voluntary. I/we may withdraw my/our 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(s) and address(es) will be kept on file, 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 required or 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 CRM 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.

In accordance with New York State Department of Health requirements and FDA regulations, CRM will maintain medical records for a minimum of 10 years after use of sperm not resulting in a live birth, and for a minimum of 25 years after use of sperm resulting in a live birth. As required by New York State, pregnancies will be reported to the sperm bank. However, any and all personal identifiers associated with this treatment, will be protected under the Privacy Act. Information obtained and identified with me/us during this procedure, will remain confidential and will not be disclosed, except to authorized employees of the New York State Department of Health or other government agencies with my permission. I/We understand that I/we may be contacted for follow-up.

4. Legal Concerns

I/we understand that the legal status of sperm donation is 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.

CRM 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. 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. I/we understand that if I/we withdraw our consent of donor insemination, we have two options for sperm samples which may be in storage at CRM: the samples may be transferred to another clinic, or they may be discarded. I/we may be required to sign additional consents to exercise these options.

7. 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 are 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 CRM.

I/we therefore authorize the appropriate staff at the CRM to perform one or more artificial inseminations or in vitro fertilization cycles and embryo transfers with the sperm obtained from a donor for the purpose of conceiving.

My/our consent applies to mu upcoming or current treatment cycle I/we undergo within the next month. If I/we wish to undergo additional cycles after more than 1 month 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.

Patient Signature	Print Patient Name	Date
Witness Signature	Print Witness Name	Date
Partner Signature	Print Partner Name	Date
Witness Signature	Print Witness Name	Date
Donor Bank	Donor Number/Name	Number of vials at CRM