

**UNIVERSITY OF WASHINGTON MEDICAL CENTER**  
**Male Fertility Laboratory**  
**Sperm & Semen Cryopreservation Program**

Patient NAME and ID

**CONSENT FOR HUMAN SPERM OR SEMEN CRYOPRESERVATION**

INTRODUCTION

Sperm or semen cryopreservation is a method of sustaining the viability of sperm over a long period of time by cooling and storage in or above liquid nitrogen. Cryopreservation of sperm allows the sperm to be used for attempts at insemination by transfer to a woman's cervix, uterus or eggs at a later date, with the goal of causing a pregnancy. This process carries with it certain risks and benefits.

PROCEDURES

Semen will be collected by self-masturbation into an approved sterile container, at a site provided by the Men's Health Center except under special circumstances. The semen, or the sperm obtained from the semen will be processed according to established Male Fertility Laboratory protocols and any directives from the referring physician and the laboratory director. The semen or sperm will be cryopreserved and stored in or above liquid nitrogen. A semen analysis will be performed on the fresh semen. One or more portions of the semen will generally be cryopreserved as "test thaws". These "test thaws" will be warmed up (thawed) and analyzed about two or more days after cryopreservation to determine if the cryopreservation procedure adequately worked on the sample. The cryopreserved sperm, upon thawing, must meet certain criteria for motility before they will be considered adequate for use in inseminations. However, advances in assisted reproductive technologies (eg., microinjection in vitro fertilization) may allow possible use of sperm with poor or no motility.

The control and disposition of the frozen semen or sperm is directed by the patient, with exceptions being listed on the LEGAL STATEMENT: CONTROL AND DISPOSITION OF CRYOPRESERVED SPERM OR SEMEN. You will need to execute the attached legal statement regarding future control and disposition prior to cryopreservation of your sperm or semen. The physicians and scientists of the Men's Health Center and Male Fertility Laboratory will be responsible for determining the appropriate conditions and procedures for cryopreserving, storing, thawing and transferring your semen or sperm. The Male Fertility Laboratory will not be obligated to proceed with any of these procedures if current medical practice indicates that the risks outweigh the benefits.

BENEFITS

The benefits of cryopreserving and subsequently thawing sperm or semen include:

- 1) To extend the chances of causing a pregnancy from the present to a much later time;
- 2) To preserve sperm that are present or normal now, to a time when only abnormal sperm, or no sperm may be present;
- 3) To enable sperm to be inseminated under selected and optimal circumstances, without the need of your producing a semen sample at exactly that time.

Examples of situations where a patient may benefit from sperm cryopreservation include:

- a. Pending surgery, radiation therapy, chemotherapy or other medical intervention that carries a risk of impairing or destroying sperm formation or transport in the male reproductive tract, or ejaculatory function;
- b. Pending deployment to an area where the patient's life may be in danger;

- c. During vasectomy reversal (when sperm may be recovered) as a precaution against possible subsequent blocking of the vas deferens;
- d. During testicular, epididymal or vas biopsy or exploration, especially in cases of azoospermia (no sperm in semen);
- e. In cases of highly variable quality or quantity of semen, or of questionable ability to produce an ejaculate, in preparation for planned insemination; or
- f. When the male partner of a couple expects to be out of the area at the optimal time for insemination.

### RISKS

Certain emotional and physical discomfort risks may be associated with the collection of semen samples by masturbation.

There is no guarantee that your cryopreserved and subsequently thawed sperm will or may cause a pregnancy. Therefore, a major risk of insemination of frozen-thawed sperm is the failure of fertilization and pregnancy. Experience has shown that the pregnancy rate for couples using cryopreserved sperm may be the same or lower than that experienced with fresh sperm. Studies do not show increased risk of birth defects associated with the use of frozen-thawed sperm for insemination.

Cryopreservation and thawing of sperm or semen generally adversely affect some measurable characteristics of sperm. The viability and motility of frozen-thawed sperm is usually lower than that of fresh sperm. For some men, or for some semen samples, cryopreservation and thawing so adversely affects the sperm that most or all of them are left non-moving or dead. There is no accurate method to determine ahead of time how well the sperm will survive the procedure, although semen samples with normal-to-excellent sperm characteristics generally can be cryopreserved and thawed successfully.

Another risk of insemination of frozen-thawed sperm is the possible infection of the recipient woman with a bacterium, virus or other micro-organism present in your semen at the time of cryopreservation. This risk may be the same as the risk of infection from your fresh semen. However, you have an opportunity to pay for and obtain screening and testing for common sexually transmitted diseases prior to your sperm cryopreservation.

As with any technical process that requires mechanical support, failure of equipment can occur. Alarm and back-up freezer systems are utilized to decrease the possibility of sample loss. However, unforeseen situations could occur which are out of the control of the Male Fertility Laboratory. Such a situation might lead to the complete or partial loss of your sample. To date, there have been no such incidents at the Male Fertility Laboratory.

### GENERAL INFORMATION

I hereby agree and acknowledge that any of my sperm or semen which the Male Fertility Lab determines to be non-viable or otherwise not medically suitable for cryopreservation may be disposed of in a medically appropriate manner. I further agree and acknowledge that I will not direct nor allow my sperm cryopreserved by this program to be used for insemination of a woman other than my partner designated in the Legal Statement. In other words, my cryopreserved sperm has not been screened for use in, and is not to be used for donor insemination.

Any information that is obtained in connection with these cryopreservation procedures, and that can be identified with me, shall remain confidential and will be disclosed only with my permission.

My willingness to participate in the cryopreservation program will not affect my care delivered by the Men's Health Center or Male Fertility Laboratory. I am free to withdraw from the cryopreservation program at any time without affecting my care at UWMC, dependent upon the LEGAL STATEMENT: CONTROL AND DISPOSITION OF CRYOPRESERVED SPERM OR SEMEN, or its approved equivalent having been executed. I understand I can change the selection of my designated partner at any time.

I will be given a copy of this Informed Consent Form.

Patient's / Legal Representative's STATEMENT:

I acknowledge that I have read this consent, and have had the opportunity to ask questions and discuss the cryopreservation program with members of the Male Fertility Laboratory, Men's Health Center or other UW-associated clinic to my satisfaction. I understand I am free to withhold or withdraw consent for the procedure at any time.

Initial the appropriate paragraphs below:

\_\_\_\_\_ It has been explained to me and I understand if I choose not to have full screening and testing conducted prior to the time of sperm collection I will be unable, due to FDA regulation, to transfer my sperm to persons other than my sexually intimate partner at any time in the future.

\_\_\_\_\_ I choose **NOT** to have screening and testing.

or

\_\_\_\_\_ **I choose to have full testing**, medical history interview, and physical assessment for donor screening, but understand that the UWMC and MFL do not permit use of my sperm for anonymous donor insemination. I understand that I will have to pay for all such screening.

\_\_\_\_\_  
Patient / Legal Representative Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness Signature

\_\_\_\_\_  
Date

copies: Patient

Physician

Medical Record

Male Fertility Lab

**Male Fertility Laboratory  
Sperm & Semen Cryopreservation Program**

Patient NAME and ID

**LEGAL STATEMENT: CONTROL AND DISPOSITION  
OF CRYOPRESERVED SPERM OR SEMEN**

The University of Washington Medical Center Male Fertility Laboratory (hereinafter "UWMC") agrees to accept responsibility for the custody and cryopreservation of sperm or semen belonging to the patient named below provided that it is agreed by

\_\_\_\_\_ and \_\_\_\_\_  
(Male Patient "Donor") (Physician or Lab Director, UWMC)  
that the sperm and semen will be utilized according to the protocols of the UWMC.

In accepting responsibility for and custody of these tissues, the UWMC acknowledges that control and direction for disposition of this sperm or semen rests with the aforementioned Patient, provided that the only options for disposition are as listed below:

1. Insemination of the Patient's designated intimate partner, or her own or donated oocytes. Designated partner is:

\_\_\_\_\_ Address: \_\_\_\_\_  
(specify name or state 'NONE'; if "none", intimate partner must be designated at a future date before sperm can be used).

2. At any time prior to insemination the Patient may request IN WRITING that the sperm or semen be destroyed. This letter must be signed and addressed to Male Fertility Lab, UWMC, 4245 Roosevelt Way NE, Seattle WA 98105.
3. At any time prior to insemination the Patient may request in writing to transfer control for disposition to the UWMC for use in other protocols or procedures approved by the University of Washington. Use as donor sperm is not allowed.
4. At any time prior to insemination the Patient may request that the sperm or semen be released from the custody of the UWMC and transferred to the custody of another health care facility. This request is contingent upon approval by the UWMC. It will be necessary for the Patient to sign another consent form specifically authorizing transfer of his sperm/ semen to another health care facility outside the UWMC. In no case will the sperm or semen be released for any purpose involving monetary gain for the Patient or the UWMC. In no case will samples designated for intimate partner use only be allowed to be inseminated into either unknown individuals or directed recipients who are not sexually intimate with the donor.

I, \_\_\_\_\_ (Signature and Date) accept and agree to the above conditions, and further agree that control and disposition of my cryopreserved sperm or semen will be relinquished to the UWMC under the following circumstances:

1. In the event of my death, if I have made no provision for legal transfer to my designated partner, and have not specifically arranged and agreed to the posthumous use of my sperm, or
2. At any time by my written request, or
3. I have not paid charges\* or communicated with UWMC for a period exceeding two years.

\*NON-PAYMENT OF CHARGES WILL NOT PREVENT FUTURE ANNUAL CHARGES.