Male Fertility Laboratory Sperm & Semen Cryopreservation Program

CONSENT FOR RECEIPT, STORAGE AND DISPOSITION OF CRYOPRESERVED HUMAN DONOR SPERM OR SEMEN

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. Approved and tested anonymous donor sperm may be purchased by persons for their own use from certified sperm banks. These processes carry with them certain risks and benefits.

PROCEDURES

Semen or purified donor sperm prepared by a commercial, certified sperm bank is purchased by the Recipient Patient or her designated partner. These frozen samples and their accompanying FDA eligibility reports are shipped to the Male Fertility Lab (MFL) on a schedule agreeable to both the originating lab and the MFL. Prior to acceptance by the MFL, the Patient will have completed and agreed to this Consent and to the Legal Statement: Control and Disposition of Cryopreserved Donor Sperm or Semen.

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 DONOR 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 MFL will be responsible for determining the appropriate conditions and procedures for storing, thawing and transferring your semen or sperm. The MFL 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 storing and subsequently thawing donor sperm or semen are to provide the opportunity of causing a pregnancy.

RISKS

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 persons using cryopreserved sperm may be the same or slightly 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. There is no accurate method to determine ahead of time how well the sperm will survive the procedure, although semen samples with normalto-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 the semen at the time of cryopreservation. This risk may be the same as the risk of infection from fresh semen. However, the donor who provided the sample you have purchased has been

screened and tested for common sexually transmitted diseases, HIV, hepatitis and other diseases, as required by the FDA.

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 MFL.

GENERAL INFORMATION

I hereby agree and acknowledge that any of my sperm or semen which the MFL 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 to be used for insemination of a a person other than myself or my partner designated in the Legal Statement.

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 UWMC or MFL. 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 DONOR 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.

Recipient 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 MFL or other UW-associated clinic to my satisfaction. I understand I am free to withhold or withdraw consent for the procedure at any time.

Recipient Patient Signature

Date

Witness Signature

copies: Patient

Physician Medical Record Male Fertility Lab Date

Male Fertility Laboratory Sperm & Semen Cryopreservation Program

Patient NAME and ID

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

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

(Recipient Patient) and (Physician or Lab Director, UWMC) that the sperm or 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 Recipient Patient, provided that the only options for disposition are as listed below:

1. Insemination of the Recipient Patient or Patient's designated intimate partner, or her own or donated oocytes. Recipient Patient name and address are:

Address:

- 2. At any time prior to insemination the Recipient 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 Recipient Patient may request in writing to transfer control for disposition to the UWMC for use in research or other approved protocols or procedures. Use as donor sperm for insemination is not allowed. Sperm may not be re-sold by UWMC.
- 4. At any time prior to insemination the Recipient 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 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.

- 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 these 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.

*NÓN-PAYMENT OF CHARGES WILL NOT PREVENT FUTURE ANNUAL CHARGES.

I, ______ (Signature of Recipient Patient 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: