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**KENTUCKY FERTILITY LABORATORY ("KFL")
SPERM CRYOPRESERVATION INFORMED CONSENT AND AGREEMENT**

Patient: _____
Printed Name

_____/_____/_____
Date of Birth

This Agreement is a contract between the above-named patient (hereinafter referred to as I, my, mine, or myself) and KFL for the purpose of the cryopreservation of sperm by KFL on behalf of myself. KFL is to be responsible only for the appropriate identification and cryopreservation of my sperm.

Part I – Informed Consent

A. Introduction

Sperm cryopreservation is a method that may sustain the viability of sperm. Sperm can be cryopreserved before vasectomy, radiotherapy, or chemotherapy, thereby preserving fertility potential. Sperm can also be cryopreserved for a future infertility treatment (IUI or IVF) your partner is undergoing.

B. Procedures

Sperm cryopreservation will be performed as follows:

1. Sperm Collection

In accordance with the procedures for collection and identification established by KFL, the sperm will be received and cryopreserved by KFL as described in the section on freezing and storage. Also, sperm can be retrieved from epididymis or testes by aspiration or surgery.

I understand that the number of collections shall be determined by me, my physician, and KFL. KFL will advise me of sperm quality, but ultimately, the decision to stop collections will be left to my judgment.

In general, six inseminations of 10 to 20 million motile sperm are required to maximize the chance of initiating a pregnancy by artificial insemination. A good quality specimen is one that has a large concentration of sperm with high motility.

Some or all specimens may not be of sufficient quality to be used for artificial insemination. In those instances with lower number of motile, viable sperm, assisted reproductive technologies, such as In Vitro Fertilization, have produced successful pregnancies. Additional information can be obtained from an infertility specialist, urologist, or oncologist.

2. Freezing and Storage

KFL shall cryopreserve my sperm in their laboratory according to their standard operating procedures. Frozen sperm vials are then transferred to storage containers where they remain until the vials are thawed.

3. Collection of Blood for HIV I & II, Hepatitis B and Hepatitis C

Due to the potential for cross contamination of samples during storage and exposure of employees during the handling of samples, it is necessary to test all storage patients for infectious diseases. Therefore, I understand that it will be necessary to collect a small amount of my blood to test for the HIV 1 & 2 virus, Hepatitis B virus, and Hepatitis C virus. I am responsible to notify the bank if I have ever tested positive for HIV, Hepatitis B, or Hepatitis C. Sperm will be stored at KFL only if my blood work is negative or nonreactive for HIV, Hepatitis B, Hepatitis C. Patients who test positive for an infectious disease can have their samples transferred to a commercial storage facility that specializes in storing samples that test positive.

C. Benefits

On average, 30 to 70% of motile sperm survive the cryopreservation process, though results can be higher or lower. The average pregnancy rate after insemination with good quality frozen-thawed sperm is approximately 10% per cycle, but can vary depending on the sperm quality and female recipient's age and reproductive health.

Assisted reproductive technologies, such as In Vitro Fertilization, can improve the pregnancy rate when the sperm quality is low quality or when there are limited amounts of stored specimens. Pregnancy rates depend upon many factors. With good factors and with good quality sperm, the pregnancy rate is 40 to 50%; any adverse factors will decrease this rate.

D. Risks

The major risk from this procedure is the failure of fertilization or failure of achieving a successful pregnancy.

Infants resulting from the insemination of frozen-thawed sperm do not appear to have risk of birth defects higher than observed in fresh inseminations conceptions or in naturally conceived pregnancies. I understand that such defects are a risk of any pregnancy and therefore may occur in pregnancies resulting from frozen sperm inseminations.

I understand that the freezing system or storage tanks can fail and the sperm may be compromised and/or destroyed. Every commercially reasonable attempt will be made to safeguard the sperm samples. I understand that, beyond such commercially reasonable efforts, KFL cannot guarantee the safety of the frozen sperm. I also understand that KFL cannot guarantee viability of sperm or the initiation of successful pregnancy after clinical use or that, if a pregnancy is initiated, any resulting fetus will be carried to term or, if born alive, be healthy or free of birth defects or other conditions.

I understand that KFL is not liable if sperm is destroyed by factors beyond KFL's control such as war, earthquake, tornadoes, hurricanes, fire, water, equipment failure, or other acts. I am advised that KFL does not provide insurance coverage, a compensation plan, or a free medical plan if I or my sperm samples are harmed by the cryopreservation procedure.

E. General

I understand that sperm cryopreservation is a clinical procedure that has been requested by me and/or my physician. It is understood that I have discussed this procedure with my physician.

Sperm cryopreservation is designed so that an attempt can be made to initiate a successful pregnancy after the specimens have been thawed. The methods used will depend upon the decisions made between my physician and myself.

I understand that participation in the sperm cryopreservation procedure is voluntary and gives me some opportunity for the initiation of a pregnancy at a later date.

I understand that the information obtained during the course of providing services under this Agreement will be kept confidential in accordance with applicable law and, to the extent permitted by applicable law without separate authorization from me, may be used for publication or educational purposes.

I understand FDA regulations can restrict and regulate the use of my semen sample. I understand that in order for my sample to be used as a directed donation (use by a non-intimate partner), I must be screened and tested for communicable diseases, as outlined by the FDA in 21 CFR 1271.

I have read this informed consent carefully and know that I can ask questions from the staff of KFL or my physician about anything which is unclear before I decide to participate in this procedure or continue to store samples.

Part II – The Agreement

1. Cryopreservation of Sperm

I agree to provide sperm samples to be cryopreserved by KFL using its laboratory procedures. Cryopreserved sperm may be referred to as frozen sperm/sperm/sperm/samples/specimens in this agreement. I understand that sperm may not survive after thawing and that the surviving sperm, if any, may not have the capacity to initiate a viable pregnancy.

If I am transferring frozen sperm to KFL from another facility for purposes of receiving the services described above, I have read, signed, and had witnessed KFL's form entitled "Consent For Transfer Of Specimen(s) From Another Facility," a copy of which is available for my review.

2. Ownership and Advance Directive

The legal status of frozen human sperm is unclear. It may be advisable to seek assistance from my personal attorney. If any of the selected uses or dispositions outlined in this document are subsequently prohibited by law, then such selected uses or dispositions shall be deemed null and void. In the event I contest the legality of any provision of this document with respect to the use of frozen sperm, KFL will continue to preserve the frozen sperm at my expense, based on KFL's fee structure, which KFL may adjust from time to time. In the event of failure of the contesting party to make any payment due within sixty (60) days after KFL sends an invoice to the most recent address that KFL has on file for the contesting party, it is agreed that said sperm may be discarded by KFL.

I will be owner and controller of the frozen sperm until my death. In the event of my death, I would like my cryopreserved sperm to be (sign **one** of the below choices)

A. Destroyed upon proof of death _____
Signature

B. Maintained in storage for use by my spouse _____
(fill in name and DOB of spouse)

who will assume all of the obligations and terms described in this contract

Signature

3. Cryopreservation Fees

I understand that the fee for freezing my sperm sample and storing it for the initial year is **[\$500.00]**. I will be billed for storage no matter the number of canes that I have in storage. After the first year, I agree to pay **[\$500.00]** per year in advance for storage to KFL. The current storage fee is subject to change each year. In situations where fees associated with sperm storage have not been paid within sixty (60) days after KFL sends an invoice to the most recent address that KFL has on file for me, my sperm may be considered to be abandoned and may be discarded by KFL in accordance with normal laboratory procedures, American Society for Reproductive Medicine guidelines and applicable law.

4. Utilization and Disposition of My Sperm

- a) Any time prior to clinical use, I may direct KFL to destroy my sperm, or release the specimens into my custody, or donate for research by completing, signing, and having witnessed KFL's form entitled "Change Of Instructions For Disposition Of Specimen(s)," a copy of which is available for my review. I understand that if my sperm is discarded in accordance with the terms of this Agreement, no offspring will result from them and we will have no further rights or claims to them. I have freely, voluntarily and willingly made my decisions regarding the disposal of my sperm and release KFL from all claims of any nature arising from, or relating to, the sperm.
- b) I recognize that I may, at any time, request the transfer of my frozen sperm to another facility by completing, signing, and having witnessed KFL's form entitled "Consent For Specimen(s) To Be Picked Up And Delivered To Another Facility," a copy of which is available for my review. I understand that such transfer will obligate me to pay the tank rental fee and any other charges specified in the form.
- c) In the event of my death, my spouse has 60 days after my death to provide necessary documentation as described in Part II, Section 2 'Ownership'.
- d) Unless otherwise directed, as long as I continue to participate according to this agreement the frozen sperm will be stored. If I terminate this Agreement in writing, I must complete, sign, and have witnessed, within sixty (60) days of termination, either KFL's form entitled "Consent For Specimen(s) To Be Picked Up And Delivered To Another Facility" or KFL's form entitled "Change In Instructions For Disposition Of Specimen(s)," both of which are available for my review. If I fail to complete either such form within sixty (60) days, my sperm may be considered to be

abandoned and may be discarded by KFL in accordance with normal laboratory procedures, American Society for Reproductive Medicine guidelines and applicable law.

5. My Responsibility

- a) **I will keep KFL informed, in writing, upon each change of my current address and telephone number for billing purposes and any other matter which require notice to me.**
- b) I will pay the cryopreservation fees and the subsequent storage fees within 60 days after invoicing. In situations where fees associated with sperm storage have not been paid within sixty (60) days after KFL sends an invoice to the most recent address that KFL has on file for me, my sperm may be considered to be abandoned and may be discarded by KFL in accordance with normal laboratory procedures, American Society for Reproductive Medicine guidelines and applicable law.
- c) I will ask any questions that I may have from KFL and my physicians regarding the cryopreservation, storage, or use of my frozen samples.
- d) I have the final decision whether to store the specimens initially or to continue storing the frozen sperm specimens.
- e) I will pay all legal fees, collection agency fees, and other cost arising if I breach this agreement or related to any claim, action, or proceedings arising out of or in connection with this Agreement or my participation in cryopreservation.

6. Termination of This Agreement Shall Occur Upon:

- a) The release of all stored sperm by KFL to myself, a physician, or another facility, as described in Part II, Section 4 'Utilization and Disposition of My Sperm'.
- b) The written direction from me or my surviving spouse to destroy all stored sperm as described in Part II, Section 4 "Utilization and Disposition of My Sperm'.
- c) My death, unless KFL had received within sixty (60) days after my death, a written notarized notice from my spouse that she is seeking to take ownership of my sperm.
- d) The discontinuance of operations of KFL for any reason.
- e) I am also free to withdraw from or terminate this Agreement in writing without prejudice or penalty, provided that this Agreement shall continue to govern the rights and obligations of both parties for all events occurring prior to the date of withdrawal or termination, including without limitation any fees that may have accrued prior to termination, and shall continue to govern the disposition of my sperm as described herein.

7. Responsibility of KFL

- a) It is the intention of KFL to operate indefinitely. However, KFL may discontinue operations for any reason. In that event, if I have not arranged for the transfer of my frozen sperm to another facility by completing, signing, and having witnessed, within sixty (60) days of KFL's sending a notice of discontinuance of operations to my most recent address on file with KFL, KFL's form entitled "Consent For Specimen(s) To Be Picked Up And Delivered To Another Facility," KFL will discard the frozen sperm.
- b) I acknowledge that I have read the information consent section of this agreement and I have been advised that KFL cannot guarantee viability of sperm or the initiation of successful pregnancy after clinical use. I understand I cannot claim any damages related to storage of my sperm from KFL, its personnel or its officers.

8. Assignment

I may not assign any of my rights or obligations hereunder to any other person or entity. KFL may assign all of its rights and obligations under this Agreement to another person or entity at any time.

9. Reliance

I understand and agree that KFL shall rely upon this Agreement and decisions made by me in this Agreement. KFL shall not be obligated to contact me prior to acting pursuant to the direction and authorization in this Agreement. KFL shall have no duties except those which are expressly set forth in this Agreement, and its duties shall not be changed, unless KFL has given its prior written consent thereto.

[Signatures follow on next page]

Part III – Acknowledgement

I have fully read the proceeding informed consent and agreement for the storage of cryopreserved sperm specimens. I agree to and understand all aspects of this document. I have asked all questions that I may have had about the cryopreservation, storage, and subsequent use of my specimens from KFL and my physician. I commit my signature below in agreement of the aforementioned statement and document:

Patient Signature: _____ **Date:** _____

Patient Printed Name: _____

Patient Address: _____

Patient Phone Number: _____

Notary Public's or Fertility Center Staff Signature **Date:** _____

Witness Printed Name: _____