

**REPRODUCTIVE SPECIALTY LABORATORY OF MIDDLE TENNESSEE, L.L.C.**  
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**INFORMED CONSENT FOR CRYOPRESERVATION AND PREFREEZE  
AGREEMENT FOR THE DISPOSITION OF HUMAN EMBRYOS**

Patient's Name: \_\_\_\_\_

Partner's Name: \_\_\_\_\_

Address: \_\_\_\_\_  
City State Zip Code

Choose **ONE** of the following options for embryo cryopreservation. If you choose option 1, 2, or 3, also complete pages 2-7 of the Informed Consent for Cryopreservation and Prefreeze Agreement for the Disposition of Human Embryos.

\_\_\_\_\_ 1. Inseminate all eggs; freeze any blastocysts that develop from remaining embryos after embryo transfer.

\_\_\_\_\_  
Patient Partner Date

\_\_\_\_\_ 2. Inseminate all eggs; freeze any blastocysts that develop from remaining embryos after embryo transfer for anonymous donation to another infertile couple(s). I will not be charged for cryopreservation or embryo storage.

\_\_\_\_\_  
Patient Partner Date

\_\_\_\_\_ 3. Inseminate all eggs; discard any embryos remaining after embryo transfer. Do not cryopreserve.

\_\_\_\_\_  
Patient Partner Date

\_\_\_\_\_ 4. Limit the number of eggs inseminated to \_\_\_\_\_, and discard the rest with the intention of transferring \_\_\_\_\_ embryos at the time of embryo transfer. Discard any embryos remaining in culture after transfer. Do not cryopreserve.

\_\_\_\_\_  
Patient Partner Date

This agreement will be governed by and construed in accordance with the laws of the state of Tennessee, which is the place of operation of RSL.

\_\_\_\_\_  
Patient's signature Date Partner's signature Date

\_\_\_\_\_  
Physician's signature Date Witness's signature Date

## **INFORMED CONSENT FOR CRYOPRESERVATION AND PREFREEZE AGREEMENT FOR THE DISPOSITION OF HUMAN EMBRYOS**

The purpose of this document is twofold: (1) To inform you about cryopreservation of human embryos so that you can make an informed decision about whether to use this procedure, and (2) to make provision, in a prefreeze agreement, for the ultimate disposition of the cryopreserved embryos resulting from this procedure.

### **I. Informed Consent for the Cryopreservation of Human Embryos**

#### IVF Procedures

The procedures for IVF-ET have been described in the consent document for Assisted Reproductive Technology (ART) procedures. There are no differences in these procedures in a cycle in which cryopreservation will be used.

#### Purpose of Cryopreservation

Cryopreservation means preserving the biological integrity of cells by freezing them, in other words, keeping them in a state of suspended animation for use at a later date. The purpose of cryopreservation in an ART program is to preserve excess embryos that are not replaced during the initial transfer procedure, for replacement at a later time.

#### Cryopreservation Procedures

Cryopreservation will be performed at the blastocyst stage. An embryo may develop to the blastocyst stage after 5 to 6 days of culture. On average, about one-quarter of the untransferred embryos will progress to the blastocyst stage and are cryopreserved, but the actual number for individual couples may vary. The procedure for cryopreservation involves the identification of the embryos to be frozen and the addition of a cryoprotective solution for protection during freezing. Each embryo is placed in a cryovial, carefully labeled with identifying information and then placed in the freezing chamber of a programmed cell-freezer. At the end of the automatic freezing cycle, the cryovial containing the embryo is placed into liquid nitrogen in a special storage container.

#### Transfer Procedure

A cycle in which frozen embryos are transferred is much simpler than a normal IVF cycle. Drugs (Estrogen, Progesterone, etc.) are used to stimulate the lining of the uterus to mature. Blood will be drawn for estradiol determination and an ultrasound will be performed to examine the lining of the uterus. Embryos are thawed when the lining is mature, and the estradiol level is appropriate. If viable, they are transferred the same day. The transfer procedure is not different than in a normal IVF cycle.

## RISKS OF CRYOPRESERVATION:

### Risks to the Patient and Partner

There are no known risks to the Patient and Partner from the cryopreservation procedure itself. However, when a thawed embryo is placed in the uterus, the risks to the Patient are the same as for a regular IVF transfer and include but are not limited to infection, bleeding, ectopic pregnancy, multiple birth, miscarriage and failure to achieve pregnancy. As in regular IVF, the best chance of pregnancy occurs when multiple embryos are placed in the uterus. If pregnancy occurs, the risks to the Patient during pregnancy and delivery are the same as they are in any pregnancy conceived without assistance with the same number of fetuses.

### Risks to the Embryo

There is a risk that a frozen embryo may be found to be nonviable when thawed and therefore unusable. Currently, about 75% of the embryos survive the freezing and thawing procedure. To the extent that viability can be detected, embryos will be inspected microscopically for viability. The normal procedures available for detecting viability and embryo quality, which are routinely performed in IVF, will be performed. Evidence, to date, from cryopreservation worldwide reveals no increased risk of abnormalities in babies born through this technique, however future studies may reveal risks which are unknown at this time.

It is not known how long embryos may be stored without death or an increased risk of abnormal development. Embryos will be kept in cryo-storage for no longer than the reproductive life span of the Patient, but you are encouraged to make early use of any frozen embryos.

We understand that it is possible that human error or mechanical failure could occur with automatic freezing machines and storage containers, and the embryos as a result, would die. We further understand, however that Back-up systems are available to decrease the likelihood of mechanical failure and malfunction, but circumstances beyond your control could develop and result in the death of stored embryos. In the event this does occur, you will be notified by the physician.

## BENEFITS OF CRYOPRESERVATION:

The option of cryopreservation has proven to be a useful procedure in reducing the risk of multiple pregnancies by reducing the number of embryos in the initial transfer procedure. Pregnancy rates following the transfer of frozen-thawed blastocysts are similar to rates achieved during the initial transfer procedure.

### Alternatives to Cryopreservation

If embryo cryopreservation is not an option you wish to consider, the other options are given on page one of this document. However, if embryo cryopreservation is not considered, each subsequent attempt to achieve pregnancy through embryo replacement would involve ovarian hyperstimulation, daily blood tests and ultrasound monitoring, ultrasound-guided egg retrieval and in vitro fertilization.

## Agreement of Patient and Partner to Participate

We have read this document. We have had the opportunity to ask our physician questions and he/she has answered all questions to our satisfaction. We have had the opportunity to discuss this document with our attorney. We voluntarily choose to participate, and we understand that we may revoke our consent at any time prior to beginning the procedure. It is further expressly agreed that we hereby release the Reproductive Specialty Laboratory of Middle Tennessee, L.L.C. (RSL) and its personnel and medical staff from all responsibility and liability for the consequences, if any, resulting from our participation in this procedure. We understand that all reasonable efforts to maintain confidentiality will be made.

### **II. Prefreeze Agreement for the Disposition of Cryopreserved Human Embryos**

- A)** Patient and Partner are expected to provide the principle input for the ultimate disposition of the cryopreserved embryos. However, this input cannot be an absolute right but must be consistent with the interests of good medicine, good public policy and good ethics. The ultimate use or disposition of cryopreserved embryos is subject to applicable laws and court decisions, existing at that time, that affect the legal status or control of embryos.

If you have any questions regarding any of these provisions, it is recommended that you consult with your attorney prior to executing this document. It is also suggested that you maintain a copy of this document in a place, such as a safety deposit box, where you keep other important documents and that you also give a copy to your attorney.

Certain situations may arise that could alter the original intent of the IVF-Cryopreservation procedure, that is, the Patient and Partner's joint reproductive goal of bearing a child. If the original intent can no longer be fulfilled, then one of five (5) standard options for the disposition of cryopreserved embryos becomes operational. These are to be selected by the Patient and Partner before cryopreservation takes place.

These options specify that cryopreserved embryos should be:

- Option 1:** Made available to the other partner for control as to their use or disposition.
- Option 2:** Made available to other couples for donation on an anonymous basis.
- Option 3:** Discarded without further development or examination in a manner consistent with the disposal of other human tissue.

Patient and Partner, as a couple, must choose one option for each of the following situations. (Please indicate the option number and initials of both Patient and Partner and the date).

(1) In the event of death, disability or legal incapacity of the patient, you hereby acknowledge and agree to:

Option # \_\_\_\_\_  
Patient Partner Date

(2) In the event of death, disability or legal incapacity of the partner, you hereby acknowledge and agree to:

Option # \_\_\_\_\_  
Patient Partner Date

(3) In the event of death, disability or legal incapacity of both of you, you hereby acknowledge and agree to:

Option # \_\_\_\_\_  
Patient Partner Date

(a) If option 1 is selected, you hereby acknowledge and agree that cryopreserved embryos should be made available to \_\_\_\_\_ for control as to their use or disposition.

Patient Partner Date

(4) In the event of legal separation or divorce, you hereby acknowledge and agree to:

Option # \_\_\_\_\_  
Patient Partner Date

(a) If option 1 is selected, you hereby acknowledge and agree that cryopreserved embryos should be made available to the \_\_\_\_\_ for control as to their use or disposition. (Patient or Partner)

Patient Partner Date

(5) In the event that you decide not to use any stored embryos in an attempt to initiate pregnancy, or the Patient reaches her 50th birthday, you hereby acknowledge and agree to:

Option # \_\_\_\_\_  
Patient Partner Date

**B)** Since the length of time that cryopreserved embryos may be stored without death or abnormal development is unknown, you should make a decision regarding use at an early date. You acknowledge and agree that additional IVF cycles will not be attempted before all stored cryopreserved embryos are thawed for a frozen embryo replacement cycle(s), unless agreed to by your NFC physician.

Patient Partner Date



Our Current address and telephone numbers for receiving all written notices from RSL is as follows:

Address: \_\_\_\_\_  
City State Zip Code

Telephone: Home: ( ) \_\_\_\_\_

Patient: Work: ( ) \_\_\_\_\_ Cell: ( ) \_\_\_\_\_

Partner: Work: ( ) \_\_\_\_\_ Cell: ( ) \_\_\_\_\_

**G)** In the event that you have failed to pay current or delinquent cryopreservation charges and/or storage fees after notification by mail at your last known address, you acknowledge and agree that any stored embryos not used by you prior to that day may be disposed of by RSL, in its sole discretion through its authorized representative, as may be permitted under applicable law and RSL policies existing at that time.

\_\_\_\_\_  
Patient Partner Date

We have read this document, understand it and have had the opportunity to ask questions and all questions have been answered to our satisfaction. We have had the opportunity to discuss this document with our attorney prior to signing.

This agreement will be governed by and construed in accordance with the laws of the state of Tennessee, which is the place of operation of RSL.

\_\_\_\_\_  
Patient's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Partner's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Physician's Signature

\_\_\_\_\_  
Date

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

\_\_\_\_\_  
Date