

Human Embryo Cryopreservation Program

South Jersey Fertility Center

Consent

I/we _____ (patient)(s) of South Jersey Fertility Center, request that my/our embryo(s) be cryopreserved (frozen). I/we understand that embryo cryopreservation is the process by which embryos from In-Vitro Fertilization are frozen prior to being placed into the uterus in a subsequent cycle. The potential benefit of this procedure is to allow the chance of pregnancy in a subsequent cycle, without the need for additional procedures to produce or retrieve eggs. The following will outline the important aspects of embryo cryopreservation at South Jersey Fertility Center.

Indications

Cryopreservation may be performed during an In-Vitro Fertilization cycle if excess embryos are obtained and one of the following conditions occurs:

1. Excess embryos available for cryopreservation at the completion of a fresh IVF cycle
2. A serious medical illness
3. Adverse reactions to medications, such as hyperstimulation of the ovaries
4. Complications related to the egg retrieval procedure
5. Medical treatment such as surgery, chemotherapy or radiation
6. Inability to synchronize egg retrieval and embryo transfer during an egg donation cycle
7. Patient's request
8. Other situations deemed appropriate by the physician

Procedures

The embryos resulting from the fertilization of the eggs from the female partner with the sperm from the male partner (or from donor sperm if indicated), will be frozen using a technique called cryopreservation. It is the policy of South Jersey Fertility Center not to cryopreserve only one embryo. Cryopreservation is conducted as follows: Any excess embryos of sufficient quality will be transferred to a special solution containing a substance (cryoprotectant) that protects them during the freezing process. The embryos will be frozen in a specially designed machine to -30 to -40 degrees centigrade and then will be transferred to storage containers and maintained at a temperature of -196 degrees centigrade until such time as the physicians of South Jersey Fertility Center and the couple decide that it is appropriate to transfer them back to the uterus. At that time, after both partners sign written consent, some or all of the frozen embryos will be thawed and the freezing solution will be removed. Each embryo will be examined to determine if it is appropriate to transfer it to the uterus and if so, the transfer will occur. Those embryos that do not appear to be viable will not be transferred and will be discarded. In some cases, more embryos will survive the thawing process than will be transferred back to the uterus, and in these cases the embryos of sufficient quality may be cryopreserved again.

Risks

Many laboratories worldwide, including South Jersey Fertility Center, have demonstrated the ability to cryopreserve human embryos and to establish pregnancy after transfer. Studies evaluating the pregnancies achieved by the use of human cryopreserved embryos have not demonstrated a significant increase in the risk of fetal abnormalities. Cryopreservation will not eliminate the normal risk of obstetric complications or fetal abnormalities but cryopreservation does not appear to create an increased risk.

Rev. 6/05 Initials: _____/_____

Disposition of Cryopreserved Embryos

Based on currently accepted legal principals, human embryos created by In-Vitro Fertilization of eggs from the female partner of a couple with sperm from the male partner of a couple, are the joint property of the couple. In the case of donated eggs, sperm or embryos, ownership is assumed by the recipient individual or couple. As the owners of any or all such embryos, the consent of both partners of a couple is required concerning the use or disposition of these embryos, except in circumstances where both in accordance with applicable laws and the limitations set forth in this informed consent form, the parties agree to an alternative arrangement for utilization or disposition of the embryos, or where such use or disposition is controlled by applicable laws or final decisions of a court or other governmental authority having jurisdiction over such decisions.

Current scientific understanding indicates that successful pregnancies can occur from cryopreserved embryos even after they have been frozen for many years. The disposition of cryopreserved embryos must therefore be determined by the owner(s) in advance of the procedure, taking into account possible future events. These events include, but are not limited to:

1. Voluntary withdrawal from the Human Embryo Cryopreservation program
2. Separation or divorce of a couple
3. Death of one or both partners of a couple
4. Change of health of the female partner that, in the opinion of the physicians of South Jersey Fertility Center, makes it unsafe or impossible for her to carry a pregnancy
5. Disagreement among the partners of a couple regarding the disposition of cryopreserved embryos
6. Failure of an individual or couple to pay storage fees for a period of 60 days following written notice of non-payment by South Jersey Fertility Center at the latest address on file
7. Loss of contact between South Jersey Fertility Center and the owner(s) for more than 60 days
8. Five (5) years have elapsed from the date of cryopreservation, unless this date is extended by mutual agreement of all parties in writing
9. Female partner enters natural menopause or reaches the age of 50 years

10. Medical or scientific evidence indicates that the risk associated with implantation exceeds the benefits
If for any reason the owner(s) no longer wish to attempt to initiate a pregnancy with the cryopreserved embryos, or if any of the reasons listed above occur, one of the following options for the disposition of these embryos must be selected by circling the letter preceding the statement, and initialing after the statement. Both members of a couple must initial after the statement. If any or all of the events listed 1-10 above occur, the cryopreserved embryos will be:

] A. Thawed and discarded. Initials: _____/_____

B. Donated to an anonymous individual or couple selected at the discretion of the physicians of South Jersey Fertility Center. I/we recognized that despite my/our desire to donate these embryos, it may not be possible to find an appropriate individual or couple for these embryos to be donated to. In this case I/we agree to allow South Jersey Fertility Center to dispose of the embryos. Initials: _____/_____

C. Other: _____

_____ Initials: _____/_____

Initials: _____/_____

A couple may withdraw their consent and discontinue participation in the cryopreservation program at any time without prejudice. A written request to terminate participation in the cryopreservation program must be signed by both partners of the couple that produced the cryopreserved embryos and notarized before the embryos are disposed of. In the event of separation or divorce, the owner(s) understand that legal ownership of any stored embryos must be determined in a property settlement and will be released as directed by order of a court of competent jurisdiction. The owner(s) must keep their most recent mailing address on file at South Jersey Fertility Center and update in writing each change of address or prolonged absence from the last address on file. Unless and until superseded in writing, the current mailing address is the address shown on this form. If the operation of South Jersey Fertility Center discontinues, the owner(s) may have the embryos transferred to another recognized laboratory; however, the embryos will be thawed if the owner(s) do not desire the embryos to be transferred or the owner(s) cannot be reached within 60 days. No shipping, mailing, or transport of cryopreserved embryos by courier or any means of transportation will be carried out between South Jersey Fertility Center and any other institution, laboratory or facility. All risks, arrangements and expenses for such transport and for the subsequent fate of the cryopreserved embryos shall be the sole responsibility of the owner(s). Failure of the owner(s) to carry out the arrangements for such transfer within 60 days after the agreement will render the physicians of South Jersey Fertility Center the custodians of the cryopreserved embryos and they may dispose of those embryos as they see fit.

It is understood that as with any technique necessitating mechanical support systems, equipment failure can occur. South Jersey Fertility Center, its physicians, employees or consultants are not to be held liable for any destruction, damage, misuse or improper testing, freezing, maintenance, storage, withdrawal thawing, and/or delivery caused by or resulting from any gross negligence, malfunction of the storage tank, any failure of utilities, any strike, cessation of services, or other labor disturbance, any war, acts of a public enemy, or other disturbances, any fire, wind, earthquake, water, or acts of God or the failure of any other laboratory. It is also understood that South Jersey Fertility Center provides no insurance coverage, compensation plan or free medical care plan for compensation if the embryos are harmed in any way by this cryopreservation procedure. South Jersey Fertility Center reserves the right to discontinue the operations of the cryopreservation program for scientific, financial or other considerations. South Jersey Fertility Center will give written notice to the owner(s) by US mail sent to the latest address on file. If the notice is returned for insufficient address or similar reason or if no written response is received within 60 days after mailing, or if the response so provides, it is agreed that South Jersey Fertility Center may proceed as though there has been a termination of participation and may dispose of the embryos.

In executing this agreement, it is specifically agreed and understood that neither the doctors nor South Jersey Fertility Center shall be expected or obligated to participate in any use or disposition of such embryos which is contrary to the established policies of South Jersey Fertility Center or is in conflict with the applicable laws or ethical standards established in the field of In Vitro Fertilization. Both partners agree and acknowledge that any sperm, eggs or embryos which the physicians of South Jersey Fertility Center determine in the exercise of reasonable medical judgment are not viable or otherwise not medically suitable for continued use in the In Vitro Fertilization program may be disposed of in accordance with the South Jersey Fertility Center policies. From time to time, as part of ongoing protocols for quality control and competency training, procedures may be performed on excess sperm, eggs or embryos prior to their disposal. These procedures may include, but are not limited to intacytoplasmic sperm injection, assisted hatching, blastomere biopsy or cell fragment removal.

Financial Obligation

The fees for cryopreservation include 1.) the fee for the cryopreservation procedure and 2.) the fee for storage of the embryos for six months. It is understood that both fees are to be paid prior to the cryopreservation procedure itself. Should the transfer of embryos occur prior to the end of six month's time, a refund of the balance will be given. At the end of six month's time, if the embryos have not been transferred, another six month fee must be paid. Failure to meet storage fees or loss of contact with prospective parents for more than 60 days after the anniversary of the initial cryopreservation date, will result in thawing of all the embryos.

Initials: _____/_____

Informed Consent

In making this decision to participate voluntarily in the cryopreservation program, I/we agree to be bound by the terms and conditions set forth herein. I/we agree to defend, indemnify and hold harmless South Jersey Fertility Center and its physicians for all claims, judgment, or actions brought by a third party including attorney fees and costs of suits regarding the preservation or destruction of cryopreserved embryos.

I/we recognize that the embryo cryopreservation is available as an option in the In Vitro Fertilization program and my/our participation is voluntary. Declining cryopreservation will in no way reduce the quality of medical care I/we receive from South Jersey Fertility Center. I/we state that I/we have read and understood the information provided in this form. I/we understand it is my/our responsibility to notify South Jersey Fertility Center of any change in my/our address and phone number listed below. I/we had a verbal explanation by the physicians of South Jersey Fertility Center about the contents of this informed consent. I/we had a chance to ask questions and all of the answers were clearly explained to me/us and understood by me/us. You must circle either A or B below:

A. I/we request cryopreservation of suitable excess embryos as described above.

Initials: _____/_____

B. I/we request that my/our excess embryos NOT be cryopreserved and that they may be disposed of in accordance with the policies of South Jersey Fertility Center.

Initials: _____/_____

Date_____ Time_____ Signature of Female Partner_____

Date_____ Time_____ Signature of Male Partner_____

Date_____ Time_____ Signature of Witness_____

Date_____ Time_____ Signature of Physician_____

Current Address:

Current Phone Number _____