

COOPER CENTER FOR IN VITRO FERTILIZATION

8002 Greentree Commons, Marlton, NJ 08053

Informed Consent for Cryopreservation(freezing) of Embryos

This is to certify that WE, _____ (woman, referred to herein as "patient")

and partner _____ (man, referred to herein as "partner"), hereby agree and have elected to use embryo cryopreservation (freezing) as a component of our in vitro fertilization (IVF) therapy at the Cooper Center for In Vitro Fertilization (referred to herein as CCIVF").

GENERAL INFORMATION

In the course of an IVF treatment cycle, more viable embryos may be produced than are desired for embryo transfer in that same cycle. If so, these "excess" embryos can be preserved by freezing and stored for future use. In addition, there are conditions under which the physician managing your treatment will recommend that all embryos be frozen and that no embryo replacement be performed during your IVF treatment cycle. One such reason for this recommendation would be if the patient were at high risk for severe ovarian hyperstimulation syndrome(OHSS) at the time of your oocyte retrieval. The establishment of a pregnancy intensifies the symptoms of OHSS and the syndrome is easier to manage if the patient is not pregnant. In this situation, all viable embryos will be frozen and the replacement of thawed embryos will be performed only after the patient has recovered from the hyperstimulation.

Embryos may be frozen immediately after fertilization at the pro-nuclear stage, during early cleavage (2-8 cell stage) and after 4 to 5 days of culture at the blastocyst stage. If the patient and partner consent to cryopreservation, laboratory personnel will determine the stage at which any embryos are frozen in conjunction with the physician managing your treatment.

The embryos will be stored in the frozen condition until the patient and partner request their use and the physician responsible for your care determines that appropriate conditions exist in the patient for transfer of the embryos into the patient's uterus. At that time, some or all of the embryos will be thawed. Each embryo will be examined to determine whether it is viable, and if so, the transfer into the patient's uterus will occur.

At CCIVF, the clinical pregnancy success rate with frozen embryos transferred into women 39 years of age or younger in 1998 was 43.3% per transfer. This rate is approximately 5% less than the fresh rate. However, some embryos do not survive the freezing process (less than 4% at the pro-nuclear stage). Potential benefits of embryo freezing are an increased opportunity of achieving a pregnancy without undergoing multiple egg retrievals, a reduced risk of a multiple pregnancy (twins or more) by reducing the number of embryos transferred during the IVF treatment cycle, and better management of complications associated with the IVF treatment cycle such as OHSS as described above.

Patient Initials _____

Partners Initials _____

Witness Initials _____

Date _____

RISK AND LIMITATIONS

- Establishing an IVF pregnancy using frozen-thawed embryos cannot be guaranteed for any couple.
- Some or all embryos may not survive freezing and thawing.
- Additional expenses are associated with the use of embryo freezing.
- Embryo freezing has been successfully used in animals with no known adverse results. There is, however, relatively limited experience with human embryos. Although the rate of birth defects is no higher than the general population, the risks associated with human embryo freezing, thawing and transfer are not well established at present. Failure of storage containers can result in the loss of liquid nitrogen and damage or kill all of the embryos. Embryos are stored in industry standard semen storage tanks, that are monitored daily for liquid nitrogen level and maintained at greater than 75% of their capacity. Also the tanks are monitored by an alarm system which will signal laboratory personnel should liquid nitrogen levels become dangerously low. Even so, there is the potential that a tank might fail due to a spontaneous loss of vacuum or rupture of the container. Also disasters such as fires and storms as well as criminal acts could damage the building housing the tanks and/or the tanks themselves. Any such event could result in the loss of the specimens.
- You must agree to accept future disposal of any remaining unused frozen embryos.

We understand and agree that frozen fertilized eggs and/or embryos will be stored by CCIVF for a maximum of five years. The storage fee for the first six months of storage will be due at the time of egg retrieval. We also understand that after the initial six-month storage period, we will be required to pay the storage fee for the next six-(6) months in advance and at six-(6) month intervals thereafter. Such fees are non-refundable in whole or in part. We agree to pay any storage fees as such fees become due.

We agree to immediately update CCIVF should our address change and agree that our failure to maintain a current address with CCIVF and/or the inability of CCIVF to collect annual storage fees will signify our desire to terminate storage of frozen embryos. We agree to immediately update CCIVF should our relationship status change (divorce, separation etc.). In such an event, or following the fifth anniversary of cryopreservation, whichever comes first, the frozen embryos will be disposed of in the manner we have indicated in the separate disposition consent. This disposition consent must be returned to CCIVF, signed and notarized, within 3 days of the cycle where the embryos are frozen.

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Patient Initials _____
Partners Initials _____
Witness Initials _____
Date _____

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CONSENT

We have read and understand this document and additional informational information provided. We have had the chance to discuss this document with the physicians and other staff members of CCIVF. The staff has answered to our satisfaction any and all of our questions regarding the cryopreservation of our embryos We acknowledge that no guarantee or assurance has been made to the results that may be obtained. We further acknowledge that this document is by no means a complete record of our conversations with CCIVF physician(s), and staff. We understand and accept the conditions, risks and limitations of participating in the CCIVF program. We therefore voluntarily consent to cryopreserve any and all extra embryos created during our IVF cycle.

RELEASE

We agree to hold harmless and indemnify, the Cooper Center for In Vitro Fertilization, its physicians, nurses, employees, and/or legal representatives from any and all liability, damages, injuries, losses, claims suits or demands by us or any one else which may result from our participation in this program, whether such injuries, damages, or losses are known, unknown, foreseen, unforeseen, patent or latent resulting from or caused by the IVF therapy, related laboratory procedures (i.e. ICSI, Assisted Hatching), complications related to pregnancy and/or childbirth, and/or the birth of a physically or mentally deficient child(ren). This release shall also apply to any and all liability in connection with subsequent disputes arising between patient and partner or any other third party in connection with the control and/or disposition of any fertilized eggs or embryos in existence as a result of this therapy, or the custody and/or support of any child(ren) born from this therapy.

We understand and acknowledge the significance and the consequences of this Release and we hereby assume full responsibility for any injuries, damages or losses that may occur by the IVF Therapy.

This release dated this _____ day of _____, 200__, will be governed by the laws of the State of New Jersey.

___ Additional consent forms have been signed designating the origin of the oocytes (eggs) and or sperm used to form the embryos that will be cryopreserved.

_____ Patient	_____ Date	_____ Notary Public/Witness	_____ Date
_____ Partner	_____ Date	_____ Physician performing the IVF procedure	_____ Date