

Informed Consent for Storage of Embryos Transferred from an Outside Facility

1. Please read the entire document carefully and initial each page to indicate you have read and understand the information presented. Please select and initial choices where indicated.

2. After reading the document, complete the contact information on the final page and sign, in the presence of a Fertility Center staff member or Notary, indicating acceptance and understanding.

- Freezing of viable embryos not transferred after egg retrieval provide additional chances for pregnancy.
- Frozen embryos do not always survive the process of freezing and thawing.
- Ethical and legal dilemmas can arise when couples separate or divorce; disposition agreements are essential.
- It is the responsibility of each couple with frozen embryos to remain in contact with the clinic on an annual basis.

 I/We have voluntarily chosen to transfer our frozen embryos to Kentucky Fertility Institute, LLC- Fertility for the purposes of attempting to achieve pregnancy. We understand that no guarantee can be made about the quality, or condition of embryos transferred from another facility.

Overall pregnancy rates at the national level with frozen embryos are lower than with fresh embryos. This, at least in part, results from the routine selection of the best-looking embryos for fresh transfer, reserving the 'second-best' for freezing. There is some evidence that pregnancy rates are similar when there is no such selection.

When it is determined that frozen embryos will be thawed and placed in the patient's uterus, it must be done during a controlled ovarian cycle. Prior to thawing the embryos a strategy will be developed between the patient and physician on how to synchronize the uterus to provide an optimal environment for embryo implantation and how many embryos to thaw. Such synchronization may require monitoring by frequent blood or urine testing and ultrasound examinations, and the embryos will only be thawed and placed if conditions are determined to be adequate by the physician.

Risks of embryo cryopreservation: There are several techniques for embryo cryopreservation, and research is ongoing. Traditional methods include "slow," graduated freezing in a computerized setting, and "rapid" freezing methods, called "vitrification." Current techniques deliver a high percentage of viable embryos thawed after cryopreservation, but there can be no certainty that embryos will thaw normally, nor be viable enough to divide and eventually implant in the uterus. Cryopreservation techniques could theoretically be injurious to the embryo. Extensive animal data (through several generations), and limited human data, do not indicate any likelihood that children born of embryos that have been cryopreserved and thawed will experience greater risk of abnormalities than those born of fresh embryos. However, until very large numbers of children have been born following freezing and thawing of embryos, it is not possible to be certain that the rate of abnormalities is no different from the normal rate.

Because of the possibility of you and/or your partner's separation, death or incapacitation, it is important to decide on the disposition of any embryo(s), fresh or cryopreserved that remain in the laboratory. Since this is a rapidly evolving field, both medically and legally, the clinic cannot guarantee what the available or acceptable avenues for disposition will be at any future date. At the present time, the alternatives are:

- 1) Discarding the cryopreserved embryo(s)
- 2) Donating the cryopreserved embryo(s) for approved research studies.
- 3) Donating the cryopreserved embryos to another couple in order to attempt pregnancy (You may be asked to undergo additional infectious disease testing and screening recommended by the FDA if you select this option.)

Embryos are understood to be your property, with rights of survivorship. No use can be made of these embryos without the consent of both partners (if applicable).

a) **In the event of divorce** or dissolution of the marriage or partnership, the ownership and/or other rights to the embryo(s) will be as directed by court decree and/or settlement agreement. If divorce or dissolution of the marriage / partnership occurs, the Fertility Center will require notarized documentation of changes in ownership and/or rights to the embryos before proceeding with any disposition.

b) **In the event of the death or incapacitation of one partner**, the embryo(s) will become the sole and exclusive property of the surviving partner.

c) **In the event of death or incapacitation of both partners or of a last surviving partner**, the embryo(s) shall become the sole and exclusive property of the clinic. In this event, I/we elect to:

(please select and initial one choice)

	patient	partner
1) Thaw and discard the embryo(s)	_____	_____
2) Donate the embryo(s) for research	_____	_____
3) Donate the embryos to another couple	_____	_____

d. Cryopreserved embryo storage

Maintaining embryo(s) in a frozen state is labor intensive and expensive. There are fees associated with freezing and maintaining cryopreserved embryo(s) in addition to those associated with IVF. Patients/couples who have frozen embryo(s) must remain in contact with the clinic on an annual basis in order to inform the clinic of their wishes as well as to pay fees associated with the storage of their embryo(s). In situations where there is **no contact with the clinic for a period of greater than one year or fees associated with embryo storage have not been paid for a period of one year** and the clinic is unable to contact the patient after reasonable efforts have been made, the **embryo(s) will be considered to be abandoned** and may be destroyed by the clinic in accordance with normal laboratory procedures and applicable law.

The Kentucky Fertility Institute, LLC has not been designed as a long term storage facility for embryos. Embryos will be maintained on-site for a minimum of one year. After that time, depending on space constraints, embryos may be sent to an independent, off-site storage facility. It is the responsibility of the patient to pay any associated shipping and storage fees required by the off-site storage facility.

I/We understand that before I (female patient) reach 50 years of age (DATE __/__/__), the cryopreserved embryo(s) must be:

- 1) thawed and transferred
- 2) donated to another couple
- 3) donated to research
- 4) discarded or
- 5) transferred to another storage facility

If no disposition has occurred by the above date, I/we hereby waive any and all interest in said cryopreserved embryo(s) and the cryopreserved embryo(s) shall become the sole and exclusive property of the clinic. In this event I/we elect to: **(please select and initial one choice)**

- | | | |
|---|---------|---------|
| | patient | partner |
| 1) Discard the cryopreserved embryo(s) | _____ | _____ |
| 2) Donate the cryopreserved embryo(s) for research | _____ | _____ |
| 3) Donate the cryopreserved embryos to another couple | _____ | _____ |

e. Donated or research embryo fate

In certain situations, donating embryo(s) for research or to another couple may not be possible or may be restricted by law. While efforts will be made to abide by your wishes, no guarantees can be given that embryo(s) will be used for research or donated to another couple. In these instances, if after 3 years no recipient or research project can be found, or your embryos are not eligible, your embryo(s) will be discarded by the lab in accordance with laboratory procedures and applicable laws.

Signatures (Indicates understanding and consent to have embryos stored at University Women’s Healthcare, based on material presented within this document; do not sign until the entire consent has been read, understood and each page initialed)

Female Patient	Partner (if applicable)	Date	
_____	_____	_____	Embryo Storage

Notary/Fertility Center Witness	_____	_____
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Current Telephone #s _____	Current Address _____
_____	_____

References <http://www.sart.org/>