CONSENT TO FROZEN EMBRYO TRANSFER

1. **Background**

On or about ________________ (date), ________________________________ and ________________________________, (name(s) of parties requesting IVF treatment) requested ________________________________, (name of clinic and treating physician) at ________________________________, (address of clinic) to perform in vitro fertilization using:

a. Oocyte or eggs extracted from ________________________________, and
b. Sperm obtained from ____________________________________________
c. Eggs named in Section 1.a. and sperm named in Section 1.b. were fertilized in the laboratory using ________________________________, (conventional IVF or ICSI)
d. All the excess fertilized embryos described in Section 1.c above that were not transferred in the fresh cycle were frozen and currently stored at ________________________________, (name of facility where embryos are stored).
e. ________________________________ and ________________________________ (name(s) of owner(s)) is/are the owners of these frozen embryos.

For Embryo Donation Only

f. Embryos named in Section 1.d are donated to ________________________________ and ________________________________ (name(s) of recipient(s) of embryo donation) for reproductive use.

Note: Any frozen embryo transfer involving embryo donation must be accompanied by separate written consent of the owner(s) of the embryo(s).

2. **Name(s) of Party/Parties**

A. **Party/parties requesting transfer of frozen embryos**

a. **Couple**

We, ________________________________ and ________________________________ of ________________________________ County, City of ________________________________ in the state of ________________________________ are ________________________________ (husband and wife or domestic partners) and are over the age of twenty-one years. We hereby give our mutual consent to Dr. H. Christina Lee and the Family Fertility Center to perform frozen embryo transfer using embryos named in Section 1.d.

i. Frozen embryos will be thawed and transferred to the uterus of ________________________________.

ii. ________________________________ and ________________________________ are the intended parents of any and all child(ren) resulting from the frozen embryo transfer.

b. **Individual requesting transfer of frozen embryos**

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I, ____________________________________, of ______________________County, City of _______________ in the state of ___________________am over the age of twenty-one years. I hereby give my consent to Dr. H. Christina Lee and the Family Fertility Center to perform frozen embryo transfer named in Section 1.d.

i. Frozen embryos will be thawed and transferred to the uterus of ___________________________.

ii. ___________________________ is the sole intended parents of any and all child(ren) resulting from the frozen embryo transfer.

3. Purpose of Frozen Embryo Transfer

Frozen embryo transfer uses excess frozen fertilized eggs from previous fresh IVF cycle(s) to permit the establishment of a pregnancy without stimulation of the ovaries or egg retrieval. This saves the expense and inconvenience, and avoids all the medical risks to obtain additional eggs. Furthermore, the availability of frozen embryos permits patients to delay pregnancy until a more urgent medical condition, e.g. cancer, emergent surgery or severe ovarian hyper-stimulation, is under control or resolved.

4. Nature of Frozen Embryo Transfer

A. Preparation of the uterine lining

Prior to a frozen embryo transfer cycle, the uterine cavity is evaluated for any irregularity and responsiveness to hormones. The regularity of the menstrual cycle of the person to whom the frozen embryo(s) will be transferred will be assessed. These factors determine the exact method of preparing the uterine lining for frozen embryo transfer.

There are several ways to prepare the uterine lining so that embryo transfer is done when it is within the window of receptivity. In some women, no or minimal hormone supplement in a spontaneous ovulatory cycle may be a good choice. In other women, treatment with birth control pill or leuprolide acetate injection followed by estrogen and progesterone replacement may be the optimal choice. The treatment objective is to create a uterine milieu similar to a spontaneous ovulatory cycle.

Estrogen, if given, can be by oral, trans-dermal, intramuscular, or vaginal administration. Side effects of estrogen include nausea, irritation at the application site if given by the trans-dermal route, and the risk of blood clots or stroke. Progesterone is usually given by injection or by the vaginal route (Endometrin®, Crinone®, Prometrium®, or pharmacist-compounded suppositories) Progesterone has not been associated with an increase in fetal abnormalities. Side effects of progesterone include depression, sleepiness, and allergic reaction. If progesterone is given by intra-muscular injection, there is the additional risk of infection or pain at the injection site.

B. Thawing of embryos

Generally on the day of frozen embryo transfer a pre-determined number of embryo(s), as indicated in Section 5.B., is taken out of storage and thawed rapidly. The embryo(s) is then re-expanded by submerging it in a series of solutions with different concentrations of cryoprotectants, chemicals that minimize the damage of freezing. The embryo will be examined under the microscope for its ability to

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re-expand and survive. Only embryo that survives the freeze and thaw process will be transferred. If one or more embryo(s) does not survive, additional embryo(s), if available, will be taken out of storage and thaw until the total number of embryo(s) that survives and suitable for transfer meets the number specified in Section 5.B.

In some cases the re-expanded embryo(s) may have to be cultured for additional days in the laboratory until they reach a requisite stage of development.

5. Limits on the Number of Embryo(s) to Transfer

Because multiple pregnancies can be devastating to the health of both mother and children, national guidelines published by the Practice Committee of the Society in Assisted Reproductive Technologies (SART) of the American Society for Reproductive Medicine (ASRM) in 2006 recommended limits on the number of embryos to transfer (see Tables below). All clinics, including the Family Fertility Center, which are members of SART are to follow these guidelines or risk losing their membership with SART. These limits are the same for either fresh embryo transfer or frozen embryo transfer, but differ depending on the developmental stage of the embryos and the quality of the embryos and take into account the patient’s personal history.

<table>
<thead>
<tr>
<th>Embryos</th>
<th>age &lt;35</th>
<th>age 35-37</th>
<th>age 38-40</th>
<th>age &gt;40</th>
</tr>
</thead>
<tbody>
<tr>
<td>favorable</td>
<td>1 or 2</td>
<td>2</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>unfavorable</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

Recommended limits by SART on number of 5-6 day old embryos to transfer

<table>
<thead>
<tr>
<th>Embryos</th>
<th>age &lt;35</th>
<th>age 35-37</th>
<th>age 38-40</th>
<th>age &gt;40</th>
</tr>
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<td>1</td>
<td>2</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>unfavorable</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

Favorable means previous successful IVF outcome, first IVF cycle, good embryo quality, or excess embryos available for freezing.

A. Single embryo transfer

While there is no absolute guarantee to avoid multiple pregnancy, single embryo transfer is the only option to minimize the possibility of multiple pregnancy and its inherent risks to the health of mother and children and is the recommended choice for favorable prognosis in women <35 as noted in Section 5.

B. Number of embryo(s) to transfer

(name(s) of intended parent(s) in Section 2.A.a. ii or Section 2.A. b. ii) have been advised of the recommended limit on the number of embryo(s) to transfer, (see Section 5 above) and decide to have (write the number of embryo(s) to be transferred, then place initials after the number)

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__________________________embryo(s) transferred to the uterus of _________________

___________________________________________ (party named in Section 2.A.a.ii or Section 2.A.b.ii)

6. Risks of Frozen Embryo Transfer

A. Pregnancy Rate

The first term pregnancy derived from frozen human embryo was born in 1984. As of 2008 it is estimated that between 350,000 and half a million IVF babies have been born from frozen and thawed embryos in the world.

Overall pregnancy rates at the national level in the U.S. 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.

B. Inability of frozen embryo to tolerate and survive the freezing and thawing process

Current techniques deliver a high percentage of viable embryos thawed after cryopreservation, but there can be no certainty that all frozen embryos will thaw normally, be viable enough to divide and eventually implant in the uterus. Cryopreservation techniques could theoretically be injurious to human embryos.

C. Other risks to the frozen embryos

Equipment failure can occur with any technique that necessitates mechanical support systems. Any cryopreserved embryos can be destroyed or damaged as a result of malfunction of freezing equipment, storage tank, failure of utilities, fire, wind, earthquake, water, or other acts of God.

We are advised that Dr. H. Christina Lee and the Family Fertility Center provide no insurance coverage, compensation plan, or free medical care to compensate us/me if our/my embryos are harmed in any way by the freezing or thawing procedures, or while the embryos are in storage.

D. Risks to the offspring

Extensive animal data (through several generations) and limited human data to date 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.

Many studies have been conducted since 1994 to evaluate the obstetric and perinatal outcome of children born after frozen embryo transfer. (Wada et al., 1994; Sutcliffe et al., 1995; Wennerholm et al., 1997 Aytoz et al., 1999; Westergaard et al., 1999; Schieve et al., 2004; Kallen et al., 2005; Wang et al.; 2005; Belva et al., 2008; Shih et al., 2008; Pinborg et al., 2009). According to a systematic review (Wennerholm et al., 2009), and two recently published large studies: one Danish population-based cohort study (Pinborg et al., 2009) and another Finnish register-based cohort study (Pelkonen et al., 2010), the health of children born after frozen embryo transfer is comparable or even better than that of children born after

Initials_______/_______
fresh embryo transfer. Furthermore, in population-based registry studies (Westergard et al., 1999; Shih et al., 2008; Pinborg et al., 2009) major malformation rates did not show significant difference between frozen embryo transfer and fresh embryo transfer children. However, a recently published prospective hospital-based cohort study from Belgium showed a higher major malformation rate in frozen embryo transfer -ICSI children compared with fresh ICSI and frozen embryo transfer- IVF children at 2 months of age. (Belva et al., 2008)

Until very large numbers of children have been born after freezing and thawing of embryos, it is not possible to be certain that the rate of abnormalities is no different from the normal rate, especially for infrequent outcomes such as congenital anomalies and possible disturbances in development of children. Furthermore, cryopreservation does not eliminate the normal risk of obstetric complications or fetal abnormalities.

7. **Alternatives to Frozen Embryo Transfer**

Frozen embryos that are not transferred can be discarded or donated. They can be donated to other couples, anonymous or known, for the purpose of creating a pregnancy resulting in the birth a child. Or they can be donated for research purposes, including but not limited to the embryonic stem cell research which may result in the destruction of the embryos but will not result in the birth of a child.

Family Fertility Center does not offer an anonymous embryo donation program. If I/we wish to donate my/our embryos to other couple(s), whether designated or anonymous, I/we am/are solely responsible for all the fees, costs and arrangements, including but not limited to, selection of the recipient couple(s), shipping of my/our cryopreserved embryos to another facility, and all required or necessary document(s) and procedure(s) in compliance with any applicable local, state, and federal statutes in effect now or in the future.

**Special note for embryos created with gamete donors:** If embryos were formed using gametes (eggs or sperm) from a known third party donor, donation of these embryos to another couple or individual must be consistent with and in accordance with any and all prior agreements made with the gamete donor(s). If anonymous donor gametes were used, written authorization from the gamete donor must be obtained to use these gametes for anything other than reproduction or destruction of the embryos.

**IMPORTANT INFORMATION:**
Family Fertility Center will **NOT** accept any frozen embryo(s) shipped from any facility until a separate consent form titled: Consent to shipment of frozen embryo(s) to and short term storage of frozen embryo(s) at the Family Fertility Center is completed and signed by ALL owners of the frozen embryo(s) AND returned to the Family Fertility Center.
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8. Acknowledgement

I/We have had the opportunity to read and ask questions about the contents of this consent form titled: Consent to frozen embryo transfer. My /Our questions have been answered to my/our satisfaction. I/We fully understand the information provided in this document. I/We execute this consent form freely and voluntarily. I/We have not relied on any inducements, promises, or representations made by Dr. H. Christina Lee, the Family Fertility Center or its staff. By my/our signature(s) below, I/we am/are indicating my/our consent to treatment with frozen embryo transfer.

Print Name of Patient Requesting Frozen Embryo Transfer
Signature
Date

Print Name of Partner Requesting Frozen Embryo Transfer
Signature
Date

The foregoing was read, discussed, and signed in my presence, and in my opinion the individual/couple signing did so freely, and with full knowledge and understanding.

Print Name of Witness
Signature
Date

I have explained to the above couple/individual the nature and purpose of the procedure; the potential benefits, the alternatives, and possible risks associated with participation in this procedure. I have answered all questions that have been raised by the above individual/couple.

Name of Physician
Signature
Date

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9. References


