FAMILY FERTILITY CENTER **www.familyfertility.com**
H. Christina Lee, M.D., J.D., H.C.L.D., F.A.C.O.G. **Medical and Laboratory Director**
95 Highland Avenue, #100 Telephone (610) 868-8600
Bethlehem, PA 18017 Fax (610) 868-8700

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.

Initials_____/_____

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b. Individual requesting transfer of frozen embryos

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 cryopreserved fertilized eggs (embryos) 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 optimal 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

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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 according to protocol established by the laboratory that performed the freezing. Generally the embryo(s) is thawed while simultaneously 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 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

In an effort to prevent the obstetrical and neonatal complications associated with multiple pregnancies, some countries have enacted law regulating the number of embryos to transfer. At the moment of this writing, no such law has been enacted in the U.S. at the federal, state or local level. Because multiple pregnancies (see Section 4. D.e.) can be devastating to the health of both mother and children, national guidelines are published by the Practice Committee of the Society in Assisted Reproductive Technologies (SART) of the American Society for Reproductive Medicine (ASRM). Following are the recommended limits on the number of embryos to transfer (see Tables below) by the ASRM as of 2017. 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 differ depending on the developmental stage of the embryos and the quality of the embryos and take into account the patient's personal history.

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Recommendations for the limit to the number of embryos to transfer.

ASRM Limits on number of embryos to transfer
Fertil Steril Vol. 107 No. 4 /April 2017

	Age (years) of woman			
Prognosis	**<35**	**35-37**	**38-40**	**41-42**
Cleavage-stage embryos [a]				
Euploid	1	1	1	1
Other favorable [b]	1	1	≤3	≤4
All others	≤2	≤3	≤4	≤5
Blastocysts [a]				
Euploid	1	1	1	1
Other favorable [b]	1	1	≤2	≤3
All others	≤2	≤2	≤3	≤3

a. Patients with a favorable diagnosis:
1. In patients of any age, transfer of a euploid embryo has the most favorable prognosis and should be limited to one.
2. Patients under the age of 35 should be encouraged to receive a single-embryo transfer, regardless of the embryo stage.
3. For patients between 35 to 37 years of age, strong consideration should be made for a single-embryo transfer.
4. For patients between 38 and 40 years of age, no more than three cleavage-stage embryos or two blastocysts should be transferred. In cases where euploid embryos are available, a single-blastocyst embryo transfer should be the norm.
5. Patients 41-42 years of age should plan to receive no more than four cleavage-stage embryo s or three blastocysts. In cases where euploid embryos are available, a single-blastocyst transfer should be the norm.

b. Other favorable: Any ONE of these criteria:
1. Fresh cycle: expectation of 1 or more high-quality embryos available for cryopreservation
2. Previous live birth after an IVF cycle.
3. Frozen embryo (FET) cycle: availability of vitrified day-5 or day-6 blastocysts, euploid embryos, 1st FET cycle, or previous live birth after an IVF cycle.

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 patients with a favorable prognosis 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)

_____embryo(s) transferred to the uterus of

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

Signature of partner/individual _____ Date _____

Initials_____/_____

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Signature of partner _____Date_____

6. Risks of Frozen Embryo Transfer

A. Pregnancy Rate

The first term pregnancy derived from frozen human embryo was born in 1984. With the introduction of rapid freezing technique, also known as vitrification, pregnancy rate with frozen embryo transfer rate is at least similar if not surpassing fresh embryo transfer rate.

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 recovered or found after thaw, and/or 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. Majority of these studies showed that the health of children born after frozen embryo transfer is comparable or even better than that of children born after 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.

Until very large numbers of children have been born after freezing and thawing of embryos and followed long into their adulthood, it is not possible to be absolutely certain that the rate of abnormalities is no

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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 offers an anonymous embryo donation program. If you wish to donate your embryos to our embryo donation program for other couple(s), whether designated or anonymous, please discuss with our staff and learn more about our embryo donation program. A separate consent to donate your embryo(s) for reproductive purpose titled Consent to Embryo Donation for Reproductive Purpose must be completed and returned to us. After reviewing your medical records, we shall determine if your embryo(s) are suitable for donation. If your frozen embryos are stored elsewhere, you are responsible to arrange the shipping of your cryopreserved embryos to our facility, as well as 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 by the intended recipient person/couple, 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

Signatures of patient and her partner must be witnessed in the presence of either a notary public or a staff member at the Family Fertility Center. All signatures must be signed within six months from frozen embryo transfer. No frozen embryo transfer will be performed until these signatures are properly executed.

State of_____

County of_____

Sworn and Subscribed to before me,

Date_____**20**_____

_____

Signature & Seal of Notary Public

State of_____

My commission expires_____

Initials_____/_____

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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

Initials_____/_____

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Initials_____/_____