

CONSENT TO CRYOPRESERVATION AND STORAGE OF HUMAN EMBRYOS

1. Name(s) of Party/Parties

A. Party/parties requesting freezing of embryos

a. Couple

We, _____ and _____ of _____ County, City of _____ in the state of _____ are _____ (married or domestic partners) and are over the age of twenty-one years. We request and authorize Dr. H. Christina Lee, and/or such assistants as she may designate to use the services of the Family Fertility Center to perform assisted reproductive technologies (ART), also known as in-vitro fertilization (IVF), because we have been unable to become pregnant and/or have a child on our own, and other treatments have failed or are not appropriate.

We hereby give our mutual consent to Dr. H. Christina Lee and the Family Fertility Center to cryopreserve our fertilized eggs that are not transferred in our in-vitro fertilization treatment cycle. The cryopreservation procedure (i.e. freezing) is a means of preserving the fertilized eggs for transfer, donation, destruction, or any other disposition in the future.

b. Individual requesting freezing of embryos

I, _____, of _____ County, City of _____ in the state of _____ am over the age of twenty-one years. I request and authorize Dr. H. Christina Lee, and/or such assistants as she may designate to use the services of the Family Fertility Center to perform assisted reproductive technologies (ART), commonly known as in-vitro fertilization (IVF), because I have been unable to become pregnant and/or have a child on my own, and other treatments have failed or are not appropriate.

I hereby give my consent to Dr. H. Christina Lee and the Family Fertility Center to cryopreserve my fertilized eggs that are not transferred in my in-vitro fertilization treatment cycle. The cryopreservation procedure (i.e. freezing) is a means of preserving the fertilized eggs for transfer, donation, destruction, or any other disposition in the future.

B. Party/Parties participating in the creation and storage of fertilized eggs or embryos

- a. Oocyte or eggs will be extracted from _____
- b. Sperm will be obtained from _____
- c. Eggs from 1.B. a and sperm from 1.B.b will be fertilized in the laboratory.

d. (i) Couples

_____ and _____ are the joint owners of any and all of the frozen embryos.

OR

(ii) Individual

_____ is the sole owner of any and all of the frozen embryos.

Initials _____ / _____

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2. Purpose of Freezing (Cryopreservation) Embryos

Since multiple eggs (oocytes) are often produced during ovarian stimulation, on occasion there are more embryos available than are considered appropriate for transfer to the uterus. These embryos, if viable, can be frozen for future use. This saves the expense and inconvenience of stimulation to obtain additional eggs in the future. Furthermore, the availability of cryopreservation permits patients to transfer fewer embryos during a fresh cycle, reducing the risk of high-order multiple gestations (triplets or greater). Other possible reasons for cryopreservation of embryos include freezing all embryos in the initial cycle to prevent severe ovarian hyperstimulation syndrome (OHSS), to maximize implantation rate when abnormal findings are noted during the fresh cycle, to wait for results of pre-implantation genetic testing (PGT) or to preserve fertility potential when an individual is about to undergo certain necessary medical treatment known to affect future fertility (e.g., cancer therapy or surgery). In summary:

Indications for freezing embryos

- To reduce the risks of multiple gestation
- To preserve fertility potential in the face of certain necessary medical procedures
- To increase the chance of having one or more pregnancies from a single cycle of ovarian stimulation
- To minimize the medical risk and cost to the patient by decreasing the number of stimulated cycles and egg retrievals
- To temporarily delay pregnancy and decrease the risk of ovarian hyper-stimulation syndrome by freezing all embryos, when the risk is high.
- To maximize implantation rate due to abnormal findings noted during the stimulated cycle.
- To wait for results of pre-implantation genetic testing.

3. Nature of Freezing Embryos

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.” Fertilized oocytes (embryos) can be frozen at different stages: pronuclear stage, cleavage stage or blastocyst stage. Depending on the stage at which embryos are frozen, freezing of the embryos can be performed anywhere from the first to the sixth day after fertilization. In general, only normally-developing embryos will be frozen. The embryos will be transferred through a series of solutions with increasing concentration of several cryoprotectants, substances known to protect embryos against damages from freezing, and then frozen. After the embryos are frozen, they are stored at a very cold temperature in liquid nitrogen (−196 °C; −321 °F). After a frozen embryo is thawed for intrauterine transfer, it is treated in a manner similar to that used in the IVF laboratory for non-frozen fresh embryos. Any thawed embryo which does not appear to be viable will not be transferred.

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4. Risks of Freezing Embryos

A. Pregnancy Rate

The first term pregnancy derived from frozen human embryo was born in 1984. As of 2017, it is estimated that over 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 is at least comparable if not higher than with fresh embryos since vitrification is widely used as the preferred method of cryopreservation.

B. Risks of cryopreservation to the embryo

Current cryopreservation techniques deliver a very high percentage of viable embryos after freezing and thawing, but there is no guarantee that all frozen embryos will tolerate and survive the process.

Some embryos may not thaw normally, be viable enough to divide, and/or eventually implant in the uterus. Some embryo(s) may not be recovered or found after freezing and thawing. In other words, cryopreservation could be injurious to some human embryos.

C. Other risks to the frozen embryo

Equipment failure can occur with any technique that necessitates mechanical support systems. Any cryopreserved embryos can be lost, damaged, or destroyed 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 lost, damaged, or destroyed 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.

Until very large numbers of children born after freezing and thawing of embryos have been followed over a long period of time, 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.

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5. Alternative to Freezing Embryos

Any embryo that is not transferred or frozen has to be discarded. There is no other means to preserve these excess embryos.

An alternative to freezing any excess embryos not transferred in the fresh cycle will be to inseminate a limited number of oocytes on the day of oocyte retrieval. Any remaining mature oocytes that are not inseminated can be frozen. These frozen mature and unfertilized eggs can be thawed at a later time, cultured to maturity if needed, and injected with human sperm to allow fertilization. We have been advised to further discuss this option with Dr. H. Christina Lee if we are interested in this alternative.

6. Time-Limited Storage of Embryos at the Family Fertility Center

Maximum duration of embryo storage at the Family Fertility Center for each group or partial group of embryos is **not to exceed one year**. A group of embryos is all embryos cryopreserved as a result of a single oocyte retrieval procedure. At the end of the one year storage period, I/We elect to **(check one box only, then sign below the choice selected)**:

- i. Transfer to a long-term storage facility at my/our own expense **without further notice**.

Signature of partner/individual _____ Date _____

Signature of partner _____ Date _____

Additional consent forms to authorize transfer of embryos to a long-term storage facility must be completed prior to the IVF procedure.

Currently the long-term storage facility utilized is Reprotch located at 1944 Lexington Ave, N., Suite 300, Roseville MN 55113 (www.reprot.com). Dr. H. Christina Lee and the Family Fertility Center have no financial interest in and receive no incentive, bonus or payment from the long-term storage facility. We release Dr. H. Christina Lee and the Family Fertility Center from any responsibility for damages resulting from shipping or handling of the cryopreserved embryos.

Additionally, I/we agree to undergo at my/our own expense any and all testing for relevant communicable diseases and agents mandated by federal, state and local laws and the long-term storage facility.

I/We have the right and the responsibility to arrange for and direct the shipment of the cryopreserved embryos to another medical institution for thawing and transfer. Notwithstanding the foregoing, I/we release Dr. H. Christina Lee and the Family Fertility Center from any responsibility for damages resulting from shipping or handling of the cryopreserved embryos. I/We also have the right to claim my/our cryopreserved embryos for other personal disposition including thawing and discarding.

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ii. Donate all the frozen embryos to Family Fertility Center for research in quality improvement purposes only. This will result in the destruction of the frozen embryos but will not result in the creation of stem cell or the birth of a child. In the event no suitable research is available, all frozen embryos will be discarded and destroyed **without further notice.**

Signature of partner/individual _____ Date _____

Signature of partner _____ Date _____

iii. Donate all excess embryos to Family Fertility Center for reproductive purpose. **(A separate consent to donate the embryos for reproductive purpose must be signed prior to oocyte retrieval.)**

Signature of partner/individual _____ Date _____

Signature of partner _____ Date _____

iv. _____ Destroy all the frozen embryos **without further notice.**

Signature of partner/individual _____ Date _____

Signature of partner _____ Date _____

7. Nonpayment of Cryopreservation Storage Fees

Maintaining embryo(s) in a frozen state is labor intensive and expensive. There are fees associated with freezing and maintaining cryopreserved embryo(s). Cryopreservation and storage fees at the Family Fertility Center must be paid fully in advance. Failure to pay these fees for more than 3 months (90 days), constitutes my/our express authorization to Family Fertility Center to **destroy all the frozen embryos without further notice.**

8. Disposition of Frozen Embryos

Because of the possibility of separation, divorce, death or incapacitation after embryos have been produced, it is important to decide on the disposition of any embryos (fresh or cryopreserved) that remain in the laboratory in these situations. Since this is a rapidly evolving field, both medically and legally, Family Fertility Center cannot guarantee what the available or acceptable avenues for disposition will be at any future date.

Currently, the alternatives are:

1. Discarding the cryopreserved embryo(s).
2. Donating the cryopreserved embryo(s) for approved research studies.

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- 3. Donating the cryopreserved embryos to another couple in order to attempt pregnancy. (In this case, additional infectious disease testing and screening may be required due to Federal or State requirements.)
- 4. Use by one partner with the contemporaneous permission of the other for that use.

Note:

- Embryos cannot be used to produce pregnancy against the wishes of the partner. For example, in the event of a separation or divorce, embryos cannot be used to create a pregnancy without the express, written consent of both parties, even if donor gametes were used to create the embryos.
- Embryo donation to achieve a pregnancy is regulated by the FDA (U.S. Food and Drug Administration) as well as state laws, as donated tissue; certain screening and testing of the persons providing the sperm and eggs are required before donation can occur.
- Any change to the disposition of embryos after this form is completed must be made in writing with signature(s) of all owner(s) of the embryos
- The will of any person with frozen and stored embryos should specify wishes on disposition of the embryos and be consistent with this consent form. Any discrepancies will need to be resolved by court decree.

A. Death of one of the partners/spouses

In the event one of the partner/spouses dies prior to use of all the embryos, we agree that the surviving partner/spouse will have complete control on the use of the frozen embryo(s) for any purpose, including implantation, donation for research, or destruction. This may entail maintaining the embryos in storage, and the fees and other payments due the clinic for these cryopreservation services.

Signature of partner _____ Date _____

Signature of partner _____ Date _____

B. Death of both partners/spouses or death of an individual who is the sole owner of the frozen embryos

In the event that both partners die at the same time or otherwise become incapable of determining the fate of the stored cryopreserved embryos; or in the event an individual who is the sole owner of the frozen embryos dies, prior to use of all the embryos, I/we agree that the embryos should be disposed of in the following manner **(check one box only, then sign below the choice selected):**

Initials _____ / _____

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i. Destroy all the frozen embryos.

Signature of partner/individual _____ Date _____

Signature of partner _____ Date _____

ii. Donate to another couple or individual for reproductive purposes.

Signature of partner/individual _____ Date _____

Signature of partner _____ Date _____

If I/we wish to donate 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 before these embryos may be used for anything other than reproduction or destruction of the embryos.

iii. Award for research purposes, including but not limited to embryonic stem cell research, which may result in the destruction of the embryos but will not result in the birth of a child.

Signature of partner/individual _____ Date _____

Signature of partner _____ Date _____

iv. Other disposition (please specify): _____

Signature of partner/individual _____ Date _____

Signature of partner _____ Date _____

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Default Disposition

I/We understand and agree that in the event no suitable recipient/research project for our donated embryo(s) for the purpose we elected above are identified, as determined by the Family Fertility Center, the clinic is authorized, without further notice to me/us, to destroy and discard all my/our embryos.

C. Divorce or dissolution of relationship

In the event of a divorce or dissolution of the relationship between the two joint owners of the embryos during the period of storage, we agree that absent court decree or settlement agreement in writing between both parties to the contrary, our cryopreserved embryos will not be released to one of the partners or their representative, appointee, or assignee for any purpose without the written consent of **both** of us.

We further agree that a settlement agreement in writing signed by **both** of us OR a court decree will be presented to the Family Fertility Center directing the disposition of all the frozen embryos. This may entail maintaining the embryos in storage, and the fees and other payments due the clinic for these cryopreservation services.

Signature of partner/individual _____ Date _____

Signature of partner _____ Date _____

9. Fees for Freezing and Storage

I/We have reviewed and accept the current fee schedule for services rendered in conjunction with the cryopreservation and storage of embryos. I/We hereby give my/our mutual consent to Dr. H. Christina Lee and the Family Fertility Center to cryopreserved and store my/our excess embryos.

I/We have reviewed and accept the storage agreement and fee schedule from the long-term storage facility. I/We hereby give my/our mutual consent to Dr. H. Christina Lee and the Family Fertility Center to ship and transfer my/our embryos to the long-term storage facility at the end of one year storage period at the Family Fertility Center **without further notice.**

10. Maintain Contact with the Family Fertility Center

I/We understand and accept that it is my/our responsibility to notify the Family Fertility Center of any change of my/our address and/or phone number(s), and that no more than one (1) attempt will be made by the Family Fertility Center via certified mail at last known address regarding the disposition of my/our stored embryo(s). Return undeliverable mail and/or failure to respond to delivered certified mail within 30 business days shall constitute my/our express authorization to Family Fertility Center to **destroy all frozen embryos without further notice.**

Initials _____ / _____

CONSENT TO CRYOPRESERVATION AND STORAGE OF HUMAN EMBRYOS

PRINT ADDRESS AND PHONE NUMBER OF ALL OWNERS OF FROZEN EMBRYOS

Names of owner of frozen embryos Cell Phone Office Phone

Names of owner of frozen embryos Cell Phone Office Phone

Street Address

City State Zip Code Home phone

11. Acknowledgement

This consent form is freely and voluntarily executed by me/us. I/We have not relied on any inducements, promises, or representations made by Dr. H. Christina Lee, the Family Fertility Center or its staff.

Our signatures below certify the disposition selections I/we have made above. I/we understand that I/we can change my/our selection sin the future, but any change must be made in writing. If there is more than one owner to the embryos, the writing must be signed by all owners of the embryos.

Print name of owner of frozen embryos Signature Date

Print name of owner of frozen embryos Signature Date

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

Print name of witness Signature of Witness Date

Ha-Lin Christina Lee, M.D. Date

Initials _____ / _____