

**CONSENT TO FREEZING AND STORAGE OF HUMAN OOCYTES**

**1. Name of party**

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 oocyte retrieval and cryopreserve and store my unfertilized oocytes.

**2. Purpose of cryopreservation and storage of oocytes**

Cryopreservation, commonly called freezing, is a procedure by which cells are suspended in a solution of salts and a mixture of organic compounds called cryoprotectants, substances known to protect against damages from freezing, cooled to a very low subzero temperature (usually -196°C in liquid nitrogen), stored for some period of time, then warmed and recovered to resume their normal function. Cryopreservation of oocytes is a means of preserving the unfertilized oocytes, or more commonly called eggs, for fertilization, transfer, donation, destruction, or any other disposition in the future.

I am requesting freezing of my oocytes for the purpose of:

a. \_\_\_\_\_ Fertility Preservation

Reason for fertility preservation

i. \_\_\_\_\_ I have been diagnosed with cancer or other medical disease which will be treated with either pelvic radiation or medications known to increase my risk of ovarian failure after treatment.

ii. \_\_\_\_\_ I do not plan to have children now but wish to preserve my ability to do so at a later time.

b. \_\_\_\_\_ Preserving extra oocytes that are not fertilized in an in-vitro-fertilization cycle to avoid the dilemma of freezing and/or discarding extra fertilized oocytes that are not transferred.

**3. Nature of cryopreservation and storage of oocytes**

Oocytes can be frozen using traditional slow freeze or newer rapid freeze methods. At the Family Fertility Center, oocyte cryopreservation is performed using a rapid freezing method, called vitrification. Generally only mature oocytes will be frozen although emerging studies are showing immature oocytes can be frozen albeit at a lower rate of successful fertilization and development. In vitrification, the oocytes will be transferred through a series of solutions with increasing concentration of several cryoprotectants and then frozen rapidly. After the oocytes are frozen, they are stored at a very cold temperature in liquid nitrogen (-196 °C; -321 °F).

When a frozen oocyte is thawed for the purpose of producing an embryo, it must be fertilized by injecting it with sperm, also called intracytoplasmic sperm injection, because freezing lead to hardening of the shell of the oocyte making it difficult for sperm to penetrate the shell. After the thawed oocyte is fertilized, it is

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treated in a manner similar to that used in the IVF laboratory for non-frozen fertilized oocytes. Any thawed oocyte which does not appear to be viable will not be fertilized.

**4. Risks of cryopreservation and storage of oocytes**

Freezing a cell subjects it to a host of physical-chemical changes that can destroy the cell. In the case of an oocyte, it is rendered more vulnerable to freezing because of its fragile cell membrane and a lower surface area to volume ratio. It is a known fact that freezing hardens the zona or the shell of the oocyte, making it necessary to inject it with sperm in order to achieve fertilization. In addition, freezing can lead to disruption of mitotic spindles, structures crucial to proper division of the chromosomes of the oocyte.

**A. Pregnancy rate**

The first pregnancy (twin) derived from a frozen human oocyte was reported in 1986. As of 2012 it is estimated that several thousand babies have been born from frozen and thawed oocytes in the world. The largest study on pregnancies derived from vitrified oocytes from oocyte donors (young women in their mid twenties) was published in 2010, reporting survival rate of vitrified oocytes in the 90% range, with pregnancy rate comparable to fresh oocytes from oocyte donors.

After an extensive review of available medical literature in the world, the Practice Committees of the American Society for Reproductive Medicine(ASRM)and the Society for Assisted Reproductive Technology (SART) concluded in October of 2012 that there is good evidence that fertilization and pregnancy rates are similar between fresh and vitrified/warmed oocytes as part of IVF/ICSI for young women.

**B. Inability of the oocyte to tolerate and survive the freezing and thawing process**

Current techniques deliver a high percentage of viable oocytes thawed after cryopreservation, but there can be no certainty that all frozen eggs will thaw normally, be viable enough to be fertilized, divide, and eventually implant in the uterus.

**C. Other risks to the frozen oocytes**

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

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

**D. Risks to the offspring**

In its October of 2012 Practice Committee publication: Mature oocyte cryopreservation, a guideline, ASRM/SART found that although data are limited, no increase in chromosomal abnormalities, birth defects, and developmental deficits has been reported in offspring born from cryopreserved oocytes when

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compared to pregnancies from conventional IV/ICSI and the general population. It further concluded that "evidence indicates that oocyte vitrification and warming should no longer be considered experimental".

Until very large numbers of children have been born after freezing and thawing of oocytes, 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.

**5. Alternatives to cryopreservation and storage of oocytes**

Alternatives to freezing oocytes for fertility preservation include the use of donor oocytes or freezing strips of ovarian tissue followed by transplantation onto the same person at a later time after treatment of cancer or other diseases that are known to result in a high risk of ovarian failure.

Alternatives to freezing any excess oocytes not fertilized in the fresh cycle will be to discard all the excess oocytes or fertilize all the oocytes and freeze the excess embryos instead. These frozen fertilized oocytes, or embryos, can be thawed and transferred at a later time.

I have been advised to further discuss these options with Dr. H. Christina Lee if I am interested in these proposed alternatives.

**6. Time-limited storage of cryopreserved oocytes at the Family Fertility Center**

Maximum duration of oocyte storage at the Family Fertility Center for each group or partial group of oocytes is **not to exceed one year**. A group of oocytes is all oocytes cryopreserved as a result of a single oocyte retrieval procedure. Before or by the expiration of one year storage period, I elect to

**(Check one box and mark initials next to the box):**

\_\_\_\_\_ Donate all the frozen oocytes to Family Fertility Center for research in quality improvement purposes only. This will result in the destruction of the frozen eggs 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 eggs will be discarded and destroyed **without further notice**.

\_\_\_\_\_ Destroy all the frozen oocytes **without further notice**.

\_\_\_\_\_ Transfer to a long term storage facility at my own expense **without further notice**. Currently the long term storage facility utilized is Reprotch located at 1944 Lexington Ave, N., Suite 300, Roseville MN 55113 ([www.reprot.com](http://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.

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**Transfer to a long term storage facility**

All forms required for future transfer of oocytes to a long term storage facility must be executed **prior to the oocyte retrieval procedure**. Additionally, I agree to undergo at my 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 have the right and the responsibility to arrange for and direct the shipment of the cryopreserved oocytes to another medical institution for thawing, fertilization and transfer or another long term storage facility for storage or other disposition. I agree and accept the sole responsibility to execute and complete all necessary documents from the receiving facility **before the oocyte retrieval procedure**. I shall send copies of such documents to the Family Fertility Center so the transfer can be completed. Notwithstanding the foregoing, I release Dr. H. Christina Lee and the Family Fertility Center from any responsibility for damages resulting from shipping or handling of the cryopreserved oocytes.

**7. Nonpayment of cryopreservation storage fees**

Maintaining oocyte(s) in a frozen state is labor intensive and expensive. There are fees associated with freezing and maintaining cryopreserved egg(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 express authorization to Family Fertility Center to **destroy all the frozen eggs without further notice**.

**8. Disposition of cryopreserved oocytes while in storage at the Family Fertility Center**

Because of the possibility of death or incapacitation after oocytes have been placed in storage at the Family Fertility Center, it is important to decide on the disposition of any frozen oocytes that remain in the laboratory in these situations.

Currently, the alternatives are:

1. Discarding the cryopreserved oocyte(s).
2. Donating the cryopreserved oocyte(s) for approved research studies.
3. Donating the cryopreserved oocyte(s) to another individual or couple in order to attempt pregnancy. (In this case, additional infectious disease testing and screening may be required due to Federal or State requirements.)

**Note:**

- Oocyte 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 oocytes are required before donation can occur.
- Any change to the disposition of oocytes after this form is completed must be made in writing with signature of the owner of the oocytes

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- It is strongly recommended that any person with frozen and stored oocytes should have a properly executed will specifying wishes on disposition of the oocytes. Such wishes must be consistent with this consent form. Any discrepancies will need to be resolved by court decree. This may entail maintaining the oocytes in storage at the Family Fertility Center and incurring additional costs for storage while waiting for a court decree.

**A. Death or incapacitation of the individual owner of the frozen oocytes**

In the event that I, the individual owner of the frozen oocytes, die or otherwise become incapable of determining the fate of the stored cryopreserved oocytes during the time when the frozen oocytes are stored at the Family Fertility Center, I agree that the oocytes should be disposed of in the following manner **(check ONE box and mark initials next to the box):**

\_\_\_\_\_ Destroy and discard all the frozen oocytes immediately.

\_\_\_\_\_ Donate to another couple or individual for reproductive purposes.

If I wish to donate my oocytes to other couple(s) or individual(s), whether designated or anonymous, I am solely responsible to complete the arrangement **before the oocyte retrieval procedure**. This includes but not limited the selection of the recipient couple or individual, arrangement for shipping of my cryopreserved oocytes to another facility, completion of 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, and payment of fees and cost related to the donation.

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

All forms required for transfer of oocytes to any research institution must be executed **prior to the oocyte retrieval procedure**.

Other disposition (please specify): \_\_\_\_\_

**B. Default disposition**

**I understand and agree that in the event none of my elected choices are available, as determined by the Family Fertility Center, the clinic is authorized, without further notice to me, to destroy and discard my oocytes.**

**9. Fees for freezing and storage**

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**11. Acknowledgement**

**I have had the opportunity to read and ask questions about the contents of this document. I understand the information provided and all my questions are answered to my satisfaction. I execute this consent form freely and voluntarily. I have not relied on any inducements, promises, or representations made by Dr. H. Christina Lee, the FFC, or its staff. By my signature below, I am indicating my consent to freezing my eggs (oocytes) with storage and disposition elections as indicated in Sections 6 and 8 above. I understand that I can change my selections in the future, but any change must be made in writing.**

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Print Name of owner of frozen oocytes                      Signature                      Date

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

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Print Name of Witness                      Signature of Witness                      Date

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Ha-Lin Christina Lee, M.D.                      Date

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**CONSENT TO FREEZING AND STORAGE OF HUMAN OOCYTES****12. References**

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