**Egg Freezing**

Informed Consent Form

Embryos and sperm have been frozen and thawed with good results for many years. Egg (oocyte) freezing is a newer technology, therefore there is not as much data available about potential risks.

In some studies, pregnancy rates have been higher when fresh eggs are used compared to frozen eggs. The rates have also been reported to be higher with frozen embryos rather than frozen eggs.

# **Good reasons to freeze eggs**

* Cancer treatment such as chemotherapy, radiation, and/or surgery to reproductive organs.
* Elective fertility preservation. The pregnancy rates with egg freezing drop off steeply at age 38 or older.
* Absence or lack of adequate sperm to fertilize eggs on the day of egg retrieval procedure.
* Some patients prefer to freeze eggs instead of embryos
* Some genetic disorders, such as the BRCA mutations, may lead to increased risk for breast and ovarian cancer and possible early removal of ovaries. It is unclear if genetic disorders might cause genetic problems in the child.
* Early menopause or premature ovarian failure

# **Egg Freezing Process**

Vitrification (fast freezing) of eggs involves freezing the eggs obtained from the egg retrieval procedure. The surrounding cumulus cells will be removed from the eggs, and the eggs will be assessed for maturity. Typically, only mature eggs will be vitrified. The embryologists will move the eggs through several drops of cryoprotectant solutions (solutions that contain substances that protects damage to cells during freezing), place onto a device, plunge into liquid nitrogen, where they will be stored in cryostorage tanks until you are ready to thaw the eggs in the future.

**Thawing Frozen Eggs**

Eggs may only be thawed only after you sign the ***Egg Thaw Authorization*** form for each future egg thaw. The signature/s must be notarized by a Notary Public or witnessed by a Main Line Fertility employee.

Eggs that are determined by MLFC to be of poor quality or unsuitable for future attempts at pregnancy will be discarded.

After thawing, each egg will be examined to determine if it is suitable for intracytoplasmic sperm injection (ICSI). ICSI must be performed on all thawed eggs due to the changes of the egg’s zona pellucida (shell). Thawed eggs will not fertilize by standard insemination.

Intracytoplasmic Sperm Injection (ICSI)

* ICSI does not guarantee normal fertilization.
* There may be an increased risk of genetic problems in children born from ICSI.
* ICSI will not improve any defects in the eggs.

ICSI involves the injection of a single sperm into the interior of an egg using an extremely thin glass needle. The sperm must be healthy, and the egg must be mature.

ICSI is utilized after thawing eggs.

ICSI may be associated with a slightly higher risk of birth defects. The risk of birth defects after ICSI is still quite low (4.2% compared with 3% in children conceived naturally). Experts are still debating the impact of ICSI on the mental and physical development of children. Most recent studies have not detected differences in the development of children born after ICSI, regular IVF, or natural conception.

The eggs that fertilize will be cultured in a lab incubator for 3 to 5 days to determine which one/s will develop into the best quality embryo/s. The physician will determine which embryo/s are deemed suitable for transfer to the uterus.

Extra good quality embryos will be vitrified, if applicable. **In the future, frozen embryos will be thawed only after you and your partner (if applicable) sign the *Embryo Thaw Authorization* form for each frozen embryo transfer cycle.** The signature/s must be notarized by a Notary Public or witnessed by a Main Line Fertility employee.

Embryos that are determined to be of poor quality or unsuitable for future attempts at pregnancy will be discarded.

Possible risks of the procedure

* Not all eggs will survive the freezing and thawing process
* Not all eggs that survive the thawing process will fertilize
* Not all fertilized eggs (embryos) will develop into an embryo suitable for transfer to the uterus (womb)
* Not all transferred embryos will result in a pregnancy
* When eggs are vitrified, they may come in contact with liquid nitrogen. Theoretically, this may cause a possible risk of infection if the liquid nitrogen has been infected by a micro-organism, however there has never been an infection reported this way.

There is currently no scientific evidence that the freezing, storing and thawing of the eggs adversely affects the embryo, however there may be abnormalities associated with the use of frozen eggs that are not yet known.

# **Is there any risk to children conceived from the use of frozen eggs?**

A large study of mainly the slow freeze method looked at the risk to children conceived from the use of frozen eggs. It showed that there was no extra risk of birth defects compared to most births in the USA. A second study was done on the vitrification (fast-freeze) method. It showed no significantly higher risk of birth defects or low birth weight (less than 5 ½ pounds) compared to children born after IVF cycles using fresh eggs. Not much is known about children born after egg freezing in older women. There is also no data on follow-up years after birth.

# **Summary**

* Egg freezing is no longer classified as new or experimental by the American Society of Reproductive Medicine (ASRM)
* Pregnancy rates may be lower with frozen eggs than with fresh eggs
* Younger women who freeze their eggs are expected to have better success rates than older women who freeze their eggs
* There are many good reasons to support freezing eggs rather than embryos, including but not limited to the following: elective egg freezing, ethical concerns, lack of sperm available for insemination, fertility preservation prior to cancer treatment, and presence of genetic disorders.
* Women who freeze eggs in order to have a child later in life should be aware of the limited data about success rates

# **Alternatives**

I may choose not to freeze my eggs.

# **Agreement regarding storage and disposal of the eggs**

I/We hereby understand and agree that before eggs will be vitrified, I/We must execute additional consents/directives with MLFC with respect to the terms and conditions of the eggs’ storage, transfer, disposition, and disposal. I/We have been provided with a copy of the Agreement and understand that this is a legally binding document. I/We fully understand the Agreement’s provisions and have had the opportunity to have questions answered prior to signing this agreement. I/We do acknowledge that I/We have been afforded the opportunity to consult with independent legal counsel regarding any specific legal questions/concerns.

Patient Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Partner Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Patient Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Partner Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# **Financial**

I/We have had the opportunity to fully discuss the financial and insurance coverage issues relating to this procedure with MLFC. I/We agree to be responsible for all expenses related to this procedure, including all charges not covered by our insurance. ***Patients and partners will continue to be responsible for all unpaid cryostorage fees even if eggs or embryos are discarded.***

I certify that I have read the foregoing or it has been read to me, that I fully understand the contents, and that all of my questions have been answered to my satisfaction.

Patient Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Partner Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Patient Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Partner Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# **Risks of Storage**

Foreseen and unforeseen circumstances (e.g. natural disasters, storage tank malfunctions, equipment failure, and power loss) may cause the egg(s) to thaw, be damaged, and/or not survive. We understand that under no circumstances will MLF/MLFC reimburse any payments made towards frozen egg or embryo storage in the event of a loss due to the aforementioned events. We agree to absolve, release, indemnify, protect and hold harmless Main Line Fertility and their respective members, medical staff, managers, agents, and employees in event that any embryo and/or egg(s) frozen and stored with MLF/MLFC are damaged or destroyed as a result of the events detailed herein, or other potential unforeseen circumstance.

Patient Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Partner Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Patient Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Partner Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# **Consent**

I have read and understood the information provided regarding the egg freezing process and its risks. I hereby request, consent to, and authorize the Main Line Fertility Center and its employees to perform the freezing of my eggs in conjunction with my ART procedure. In authorizing this procedure, I acknowledge having received and signed the ***Assisted Reproductive Technology (ART) – Risk and Consent*** and the ***Disposition of Eggs Consent*** forms. I have had the opportunity to discuss fully with a Physician the nature and purpose of this procedure, the risks and benefits, and my other options relating to disposition of my eggs.

**By signing below, I confirm the choices I have made in this agreement. I understand that I can change those choices in the future. This will require a written and notarized agreement. I/we acknowledge that I/we have read and understood the information provided above regarding the egg freezing and storage process and its risks, and I/we agree and consent to freezing of my eggs by the Main Line Fertility Center as my signature/s below testifies**:

*If signed out of the office:*

X

Patient Signature Date

Patient Name Date of Birth

**Notary Public**

Sworn and subscribed before me on this \_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_, \_\_\_\_\_\_\_\_\_\_.

Notary Signature Date

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X

Spouse / Partner Signature (if applicable) Date

Spouse / Partner Name (if applicable) Date of Birth

**Notary Public**

Sworn and subscribed before me on this \_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_, \_\_\_\_\_\_\_\_\_\_.

Notary Signature Date

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*If signed in the office:*

**Statement by Witness (must be employee of Clinic and at least 18 years of age)**

I declare that the person(s) who signed this document is/are personally known to me and appear(s) to be of sound mind and acting on their own free will. They signed this document in my presence.

\_\_\_\_\_\_ Photo ID checked

\_\_\_\_\_\_Form of photo ID: valid Driver’s License Passport Non-Driver’s License

**Patient** **Partner**

Witness Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Witness Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_