Frozen Embryo Transfer Info & Consent

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DESCRIPTION

This document informs the Intended Parent(s) about the Frozen Embryo Transfer process in detail, including the risks. It then asks the Intended Parent(s) to consent to this therapy with its risks.

TARGET

* All Intended Parents undergoing IVF; single or couples

RELEASE NOTES

* This is the 1st version of this document

TO DO

* Modify this document according to local needs and preferences.
* Get legal review to assure conformance with State and local laws and regulations
* Delete this page

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Frozen Embryo Transfer

 Consent & Information

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

**Intended Parent A:**

 Last Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ First Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Date of Birth: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ID#\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Cell phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Intended Parent B:**

 Last Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ First Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Date of Birth: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ID #\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Cell phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**FET Cycle Plan** 🞏 FET Date (month/year): ­­­­­\_\_\_\_\_\_/\_\_\_\_\_\_

 🞏 AZH (Assisted Zona Hatching) Initials: \_\_\_\_\_\_/\_\_\_\_\_\_\_

**I/We wish to have \_\_\_\_\_\_\_ (how many) embryo(s) transferred to the uterus**

🞏 Thaw only \_\_\_\_\_\_\_ (how many) embryos

Initials: \_\_\_\_\_\_/\_\_\_\_\_\_\_

🞏 Thaw necessary number of embryos to have \_\_\_\_\_\_ embryos to transfer

Initials: \_\_\_\_\_\_/\_\_\_\_\_\_\_

🞏 Thaw only male embryo(s). If a male embryo does not survive the thaw, do not thaw additional embryo(s).

🞏 Thaw only female embryo(s). If a female embryo does not survive the thaw, do not thaw additional embryo(s)

🞏 Thaw embryo of preferred sex 🞏 male OR 🞏 female. If an embryo of the preferred sex does not survive the thaw, and there are no more embryos of the preferred sex, thaw additional embryo(s) of opposite sex.

Frozen Embryo Transfer (FET) is an assisted reproductive technology (ART)/ treatment that thaws frozen embryos and places them into a woman’s uterus to achieve implantation and pregnancy.

Description of Frozen Embryo Program

Freezing human embryos is a procedure that can be utilized to preserve embryos so that they may be transferred later. Embryos may be transferred in the cycle in which the eggs were harvested (fresh transfer), or after freezing and then thawing the embryos (Frozen Embryo Transfer, or FET). In some cases, all embryos resulting from a cycle may be frozen, with no fresh transfer. In other cases, only surplus embryos are frozen after a fresh transfer is done. Each approach has its advantages and disadvantages. For example, freezing embryos and delaying transfer until later has been shown to decrease the chance for ovarian hyperstimulation syndrome (OHSS) and increase the pregnancy rate in women who have a robust response (producing many eggs and having high estrogen levels) in the IVF cycle. Freezing the embryos gives the endometrium (uterine lining) time to recover from the high hormone levels. Freezing embryos may also be necessary to allow preimplantation genetic testing. However, a fresh transfer may decrease the time to pregnancy, since there is no required wait for the transfer; and the associated costs may be lower, as well.

I/We understand that the freezing process requires the treatment of embryos with chemicals known as cryoprotectants and that these chemicals must be removed from the embryo(s) before transfer into the woman’s uterus or fallopian tube(s). It is my/our understanding that the thawing of my/our embryos will be performed by the laboratory team at THE CLINIC and involves the use of some or all the following procedures, and that our physician and the laboratory team will determine the procedures most appropriate for me/us:

* Evaluation. Determination by standard infertility tests that I/we are suitable candidates for a frozen embryo transfer. These tests may include, but are not limited to, blood tests, ultrasound tests, and/or specialized x-rays to view the uterine cavity.
* Pre-procedure screening. Testing to ensure that there are no underlying conditions or problems in the uterus that may compromise a pregnancy. (For example, infectious disease labs and/or a hysteroscopy or saline sonogram).
* Fertility Drugs. Use of fertility drugs (which may be by mouth or by injection) such as oral contraceptives leuprolide acetate, estrogen preparations and progesterone preparations to prepare the uterine lining for embryo implantation and to support an early pregnancy.
* Monitoring. Repeat ultrasounds to measure the uterine lining and lab tests to measure hormone levels may be used to ensure that the uterine lining is properly prepared for the embryo transfer.
* Pre-FET Medication. Treatment with antibiotics and/or glucocorticoids (steroids) to reduce inflammation and infection, as needed.
* Embryo Thawing. The thawing of the frozen embryos and the removal of the cryoprotectants.
* Assisted Zona Hatching. In some cases, a micromanipulation technique called Assisted Zona Hatching (AZH or AH) is performed prior to the embryo transfer to increase the likelihood of establishing a pregnancy.
* Embryo Transfer. Transfer of the embryo(s) to the woman’s uterus by means of a plastic catheter (tube) inserted into the uterus through the vagina.
* Post-FET Monitoring. Obtaining blood samples, and if indicated, ultrasound examinations in the six (6) to eight (8) weeks after the embryo transfer to determine whether a pregnancy has occurred and is proceeding normally.
* Post-FET Medication. Treatment with progesterone preparations and, in some cases, other medications, to maintain an early pregnancy, or human chorionic gonadotropin (hCG) to support luteal function.

Hormonal support of the uterine lining

* For pregnancy to occur, the embryo(s) must attach to the lining of the uterus. This process is called implantation.
* Adequate levels of estrogen and progesterone are required for successful pregnancy.

In FET cycles, reduced production of progesterone and estrogen is occasionally seen and must be supported by medication to build up the uterine lining. This can occur in both “programmed” cycles, which are planned based on a target date, for the embryo transfer, and in “natural” or “stimulated” cycles, that are carried out during the woman’s menstrual cycle. Therefore, in most cases, progesterone and sometimes estrogen are routinely taken. Progesterone is usually taken as an injection or as a vaginal suppository. Estrogen can be given as pills, an injection, vaginal suppositories, or a skin patch. Progesterone and/or estrogen are usually continued for several weeks after the embryo transfer help support the pregnancy.

Assisted Zona Hatching

* Assisted hatching involves making a small hole in the outer shell (zona pellucida) that surrounds the embryo.
* Hatching may make it easier for embryos to be released from the shell and implant in the uterus.

The cells that make up the early embryo are enclosed by a shell called the zona pellucida.  Normally, as the embryo grows, this shell breaks open and releases the embryo.

“Assisted hatching” makes it easier for the embryo to escape the shell. This is done in the embryology laboratory by making a small hole in the shell with a needle or a laser. Assisted hatching may have some risks, including more identical twinning, and (rarely) damage to the embryo.

Embryo transfer procedure

* The number of embryos transferred affects the chance of pregnancy and the risk of twins or other multiple pregnancies.
* The woman’s age and the quality of the developing embryo(s) have the greatest effect on pregnancy outcome.
* Embryos are placed in the uterus using a thin tube.

After preparation of the uterine lining, which may take several weeks, the embryo transfer takes place. Most embryo transfers are done without using any anesthesia or sedation. During a simple vaginal procedure, one or more embryos are placed in the uterus using a thin tube called a catheter. Vaginal or abdominal ultrasound may be used to help guide the catheter and confirm embryo placement.

How Many Embryos to Transfer

The number of embryos to transfer is an important decision. A woman’s age and the quality of the embryo affect both the chance for pregnancy as well as the chance for multiple embryos to implant. If multiple embryos implant, a multiple pregnancy (twins, triplets, or more) will result.  In some cases, an embryo can split into two (identical twins) after transfer. Before the transfer, it is critical to discuss with your doctor how many embryos to transfer.

Guidelines for the maximum number of embryos to transfer are given below.

RECOMMENDED LIMITS ON THE NUMBER OF EMBRYOS TO TRANSFER

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Age: | <35 | 35-37 | 38-40 | 41-42 | > 42 |
| Cleavage-stage embryos |  |  |  |  |  |
| * Normal # chromosomes
 | 1 | 1 | 1 | 1 | 1 |
| * From Egg Donor <35
 | 1 | 1 | 1 | 1 | 1 |
| * Other favorable\*
 | 1 | 1 | ≤3 | ≤4 | Not known |
| * All others
 | ≤2 | ≤3 | ≤4 | ≤5 | Not known |
| Blastocyst-stage embryos |  |  |  |  |  |
| * Normal # chromosomes
 | 1 | 1 | 1 | 1 | 1 |
| * From Egg Donor <35
 | 1 | 1 | 1 | 1 | 1 |
| * Other favorable\*
 | 1 | 1 | ≤2 | ≤3 | Not known |
| * All others
 | ≤2 | ≤2 | ≤3 | ≤3 | Not known |

\*Other favorable = any ONE of these criteria: Fresh cycle: expectation of 1 or more high-quality embryos available for freezing or previous live birth after an IVF cycle; Frozen embryo transfer cycle: availability of vitrified day-5 or day-6 blastocysts, Euploid embryos, 1st FET cycle, or previous live birth after an IVF cycle. Data from: ASRM Practice Committee. Guidelines on number of embryos transferred. Fertil Steril 2013; 99:44.

Reasons for Adverse Results

*Laboratory Risks*

The process of freezing, storing, and thawing is complex and not all embryos will be successfully frozen, or, if frozen, not all embryos will successfully thaw. Upon thaw, the embryos may be damaged, destroyed, lost or fail to develop, and therefore be unavailable for further treatment or implantation, due to a number of potential factors, including, but not limited to: patient-specific differences in tolerance of freezing; accidents; power outages; mechanical or equipment failure (including but not limited to loss of nitrogen or other tank failures); materials (including vials, straws and other devices used to freeze and store the samples and their labels); changes of any applicable law or regulations; human error; labelling errors; inventory record loss; natural and man-made disasters; sabotage; transportation or shipping accidents or other events which may be beyond the control of THE CLINIC or its laboratory.

In accordance with its protocols, THE CLINIC makes reasonable efforts to handle and maintain its patients’ embryos, including, but not limited to maintenance and monitoring of its equipment, and materials. Despite such efforts, I/we understand that because of one or more of these potential factors, my/our embryos may become unavailable for further treatment or implantation, or that the likelihood of a pregnancy resulting from any treatment or implantation may be reduced.

In some cases, THE CLINIC may not own or operate the laboratory responsible for freezing or storage of your embryos and, therefore, cannot be responsible for laboratory processes beyond its knowledge and control. If this is true for your treatment, you may be asked to sign further documents with the laboratory.

*Risks to the Woman*

I/We have been informed that although there are many complex and sometime unknown factors that may limit pregnancy rates in frozen embryo transfer cycles, some of the known factors that may prevent the establishment of a pregnancy include:

* Medications to prepare the uterine lining may cause common side effects such as localized redness, swelling, and/or itching at the injection site. In addition, some of the possible side effects include hot flashes, irritability, vaginal dryness, headaches and/or vomiting, bloating, nausea, moodiness, appetite, weight gain, fatigue, sleepiness, headache, and sleep disorders.
* Irritation, bruising and/or infection may result from frequent blood drawing.
* Embryo transfer process cannot continue and may be cancelled, at any point, if pre-testing reveals underlying medical issues, the female intended parent develops a new medical condition, there is poor uterine lining development or other conditions arise that make the embryo transfer suboptimal.
* Embryo transfer into the uterus may be technically difficult or impossible or medically contraindicated or may be prevented by facility availability or personnel circumstances.
* If transfer occurs, the embryos may not implant and continue to develop.
* If implantation occurs, the embryos may not grow or develop normally, or a multiple pregnancy, or an ectopic pregnancy or miscarriage may result.
* If pregnancy and delivery occur, the child or children may be stillborn, have chromosomal abnormalities and/or congenital (birth) defects.
* Women who become pregnant after FET may have a higher risk of blood pressure problems like pre-eclampsia in their pregnancies, although that risk may be more closely related to the type of medication used to prepare the uterus for the transfer.

*Risks to the Baby*

* IVF babies may be at a slightly higher risk for birth defects and genetic defects.
* IVF has a greater chance of multiple pregnancy, even when only one embryo is transferred.
* A multiple pregnancy is the greatest risk to your baby when using IVF.

Like babies born after fresh transfer, most babies born after FET are healthy, although there may be a slightly higher overall risk of birth defects in IVF babies than in babies conceived naturally. When compared to babies born after fresh transfer, babies born after FET have a higher chance to be large for gestational age (LGA). LGA babies can have problems with delivery, requiring a C-section due to their size; and they can have other problems such as difficulty maintaining their blood sugar

*Psychosocial Effects of Infertility Treatment*

Infertility and its treatment, including FET, can affect your emotions, your health, your finances, and your social life. Treatment is time-consuming and may strain your personal relationships and your religious or ethical beliefs. During treatment, you may feel anxious, helpless, depressed, or all alone. You may go through highs and lows. The outcome may not be what you want as a pregnancy cannot be guaranteed. In some cases, you may want to seek the help of a mental health expert to help you through the pressure treatment may present. Your clinic can provide resources to appropriate mental health professionals in your area.

AGREEMENT AND CONSENT

1. Participation Agreement. I/We are voluntarily participating in an FET treatment cycle at THE CLINIC in hopes of having a child through the transfer of my/our frozen embryos. I/We acknowledge that I/we have read and fully understand this consent form and that all questions concerning the FET process have been answered to my/our satisfaction.
2. Each of us acknowledges and agrees that my/our acceptance of treatment at THE CLINIC and our continued participation is at the discretion of THE CLINIC and dependent upon compliance with THE CLINIC’s policies and procedures.
3. I/We have been advised and understand that freezing and thawing of embryos has been utilized in hundreds of centers in the world where specialized equipment and expertise are available, and that thousands of pregnancies and live births of normal infants have resulted. However, I/we also understand that there may be some effects on the offspring which, at this time, cannot be determined including risks of genetic abnormalities and birth defects. The potential benefits from this procedure may be an increased chance of pregnancy without the necessity of multiple surgical interventions for oocyte retrieval.
4. The ability of any embryo to survive freezing and thawing is related to the quality of the embryo prior to freezing. It is difficult or impossible to predict how many of our thawed embryos will survive and/or continue to develop and be suitable for transfer. I/We understand that freezing and thawing may result in damage to the embryo(s) including damage to embryonic reproductive cells, loss of some embryonic cells or loss of viability of the embryo as a whole; and that our choice of how many embryos to thaw may not result in the number of embryos we wish to have transferred during the FET.
5. Understanding of Risks/Adverse Effects. I/We understand the risks/reasons for adverse results. I/We have had the opportunity to discuss all the information contained in this document with our physician and/or THE CLINIC staff and all my/our questions about the ART procedures have been answered. Each of us understands that if pregnancy occurs, such pregnancy may result in miscarriage, ectopic pregnancies, stillbirth, congenital abnormalities, or multiple pregnancy. I/We have been informed that the process of ART can be very psychologically stressful and may result in anxiety and disappointment and that a substantial amount of our time is required during the FET process.
6. Disposal of Non-viable Embryos. I/We understand and agree that if, in the exercise of reasonable medical judgment, the embryologists and physicians at THE CLINIC determine that any of my/our embryos are non-viable or otherwise not medically suitable for embryo transfer, those embryos will be disposed of in an ethically acceptable manner, according to THE CLINIC policies and the American Society for Reproductive Medicine Ethical Standards. I/We consent to such disposition in the circumstances described.
7. Reporting Outcomes. In 1992, the Fertility Clinic Success Rate and Certification Act was passed.  This law requires the Centers for Disease Control and Prevention (CDC) to gather information about IVF cycles and pregnancy outcomes in the U.S. each year.  This information is used to calculate success rates which are reported each year. THE CLINIC will report the required information from your IVF procedure to the CDC.  Since THE CLINIC is a member of the Society of Assisted Reproductive Technologies (SART) of the American Society for Reproductive Medicine (ASRM), it will also be reported to SART.  Information reported to SART about your cycle may be used for research or quality assessment according to HIPAA guidelines; your name will never be connected to your cycle information in any research that is published by ASRM or SART.

By signing below, I/We acknowledge that we have read and understand the information and risks of frozen embryo transfer described above and I/we specifically consent to thawing and transferring of my/our embryos to my uterus to attempt a pregnancy.

*If signed out of the office:*

X

Intended Parent A Signature Date

Intended Parent A Name Date of Birth

**Notary Public**

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

Notary Signature Date

---------------------------------------------------------------------------------------------------------------------

X

Intended Parent B Signature Date

Intended Parent B Name Date of Birth

**Notary Public**

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

Notary Signature Date

*If signed in the office:*

**Statement by Witness (must be employee of** THE CLINIC**)**

I declare that the person who signed this document is personally known to me and appears to be of sound mind and acting of his or her own free will. He or she signed (or asked another to sign for him or her) this document in my presence.

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

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

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