Frozen Donor Embryo Transfer Consent

Embryo Donation International, P.L.

Introduction:

We have agreed to undergo a **Frozen Donor Embryo Transfer (FDET)**, also known as a **Frozen Embryo Transfer (FET)**. **Embryo Donation International, P.L. (EDI)** will thaw the selected donated embryo(s) and place them into a uterus to create a pregnancy.

Number of Embryos To Transfer:

The goal is to achieve a singleton pregnancy and delivery, which is safest for us and the **Donor-Conceived Person (DCP)**. EDI will not intentionally create a multiple pregnancy. With our input, EDI will ultimately determine the number of embryos to transfer and typically recommends transferring no more than one or two embryos at a time.

Preimplantation Genetic Testing for Aneuploidy (PGT-A):

Some donated embryos have undergone a process called PGT-A, where a few cells are removed from the embryo before it is frozen. These cells are sent to a specialized laboratory, where the DNA is tested to determine whether the embryo has the normal number of chromosomes—either 46,XX (female) or 46,XY (male). Embryos that are genetically tested as normal generally implant slightly more often and have a somewhat lower chance of miscarriage. However, PGT-A tested embryos are not perfect. The results can be wrong about 1–2% of the time, and even embryos with normal PGT-A results still fail to implant and are miscarried.

We must understand this and avoid placing too much importance on whether PGT-A testing was performed.

Natural Cycle Transfers:

First, it is essential to understand that both natural and medicated embryo transfer cycles have the same success rates. EDI will determine which cycle options are available for our care.

In a natural cycle, EDI will monitor our body for signs of ovulation using blood tests and ultrasounds.

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When a natural rise in **luteinizing hormone (LH)** is detected—or if a **human chorionic gonadotropin (hCG)** trigger shot is given—EDI will estimate the time of ovulation and schedule the embryo transfer accordingly. Natural cycles are best suited for those with regular menstrual cycles and reliable ovulation. If ovulation does not occur on its own, medication may be used to help. One benefit of this approach is that progesterone injections are not needed. However, a major drawback is the difficulty of scheduling our travel plans and the transfer procedure in advance. If the transfer must occur outside of EDI's expected timeframes, additional costs may apply. For this reason, natural cycle transfers are less commonly performed.

Medicated/Replacement Cycle Transfers:

This method is more predictable and easier to schedule, especially for patients with irregular or absent cycles, and for those who live a distance from EDI. In a medicated or replacement cycle, estrogen and progesterone are administered to prepare the uterine lining for embryo implantation and pregnancy. Because the ovaries are not involved, ovulation is not necessary with this process. Blood tests and ultrasounds to confirm that the uterus is responding appropriately. With a successful pregnancy, hormone levels are maintained until 10 weeks of gestation. Medicated cycles protocols are commonly used at EDI.

Oral Contraceptives:

To help control our menstrual cycle and prepare for a medicated or replacement cycle, we may be prescribed **oral contraceptive pills (OCPs)** for a few weeks before starting hormone treatment. This is commonly done to better time the embryo transfer.

Even though many have taken OCPs before, it is helpful to review possible side effects, even with short-term use:

- Breakthrough bleeding: This can be light or heavy and is very, very common. Expect it.
- Breast tenderness: Just as estrogen and progesterone can make breasts sore and full, OCPs can do the same.
- Nausea: Mid-range dose pills are commonly prescribed. Taking the medication at night may help reduce this.
- Headaches: Taking the OCPs at night might be best. Acetaminophen (Tylenol) is fine to take.
- Mood changes: Some complain of temporary mood changes.

In very rare cases, OCPs can increase the risk of serious conditions like blood clots, heart attacks, or strokes. We should contact EDI if we experience symptoms such as chest pain, lower leg swelling, shortness of breath, severe headaches, or sudden vision changes. Smoking increases the risk of blood clots, especially in those over 35, so stopping smoking is strongly advised.

Estrogen:

Estrogen is a natural hormone that helps prepare and thicken the lining of the uterus for the implantation of a donated embryo. Estrogen is commonly prescribed in oral, patch, or injectable forms.

Individuals with active breast or uterine cancer, active liver disease, or existing blood clots should not use estrogen. Just like OCPs, smoking increases the risk of blood clots, especially in those over 35, so stopping smoking is strongly advised.

Common side effects of estrogen may include breast tenderness, nausea, headaches, mood swings, and bloating. Severe side effects listed with OCPs above can also occur with estrogen. Short-term use rarely causes significant problems, and our estrogen levels during a natural pregnancy are much

higher than the levels seen during the FDET procedure.

Progesterone:

The hormone progesterone is released from the ovary after ovulation and further modifies the uterine lining, thereby allowing the transferred embryo to implant and grow. Administration is commonly by daily injections, vaginal suppositories, orally, or vaginal gel. Progesterone is absolutely necessary for successful implantation and early embryonic growth.

Some women may complain of mood swings, bloating, nausea, and breast tenderness when taking progesterone. Other common side effects depend on the method of administration:

- **Oral progesterone**: May cause drowsiness or fatigue; taking it at bedtime is recommended.
- **Vaginal progesterone**: Common symptoms include vaginal irritation, discharge, or burning with urination.
- **Injectable progesterone**: Often causes pain, swelling, or lumps at the injection site. It is essential to administer progesterone directly into the muscle, as it will otherwise form an oil-filled sphere that is highly irritating. Occasional allergies occur, and the drug must be stopped and a new progesterone prescribed.

In a natural cycle transfer, vaginal progesterone may be used to supplement the body's own hormone production and is typically continued until 8 weeks of gestation. In a medicated/replacement cycle, injectable progesterone is necessary to mimic the high levels produced by the ovaries and is usually continued until 10 weeks of gestational age.

Monitoring of the Cycle:

If we live near an EDI location, all required ultrasounds and blood tests will be conducted at EDI, or an affiliate. If we live farther away, EDI will help us arrange for these tests to be done locally in preparation for our embryo transfer. If we have access to a nearby IVF program, EDI will usually prefer to coordinate our monitoring through that program. Although local OB/GYN offices or radiology centers may be used, IVF programs are generally better equipped for monitoring.

Thawing and Embryo Survival:

There are generally two methods for freezing embryos. The first is an older method called “slow-freeze.” The second technique, which is used more frequently today, employs a rapid-freeze process known as “vitrification.” Approximately 33% of the slow-frozen embryos and 5-10% of the vitrified embryos will not survive thawing. Regardless of the original freezing method used, the implantation rates of embryos are nearly identical once they survive thawing.

Assisted Hatching:

The outer coating of the early embryo(s), called the **zona pellucida (ZP)**, tends to harden when embryos are frozen and thawed. **Assisted Hatching (AH)** is a procedure in which a small segment of the ZP is thinned or removed using a laser, chemicals, or a gentle mechanical process. AH is thought to improve implantation rates by allowing the early embryo to escape the outer ZP covering and implant on the uterine wall. The risks of AH may be a higher rate of identical twinning (3% or less) or rare damage to the embryo.

Embryo Transfer Procedure:

The embryo(s) are loaded into a transfer catheter and placed into the uterine cavity with a slender catheter. No sedation or pain medicine is needed. An abdominal ultrasound with a full bladder will

help your clinician guide the catheter into the uterus to achieve the highest implantation rates. The whole procedure commonly takes 15-20 minutes. Most recipients experience mild discomfort from the full bladder, the speculum, and the pressure of the abdominal ultrasound.

Embryo Identification and Handling:

We understand that errors in labeling or handling may occur, and, in rare cases, this could result in the wrong embryos being thawed or transferred. The original labeling and handling were completed by another clinic or storage facility—not by EDI—and we understand that EDI cannot be held responsible for those extraordinarily rare mistakes. EDI relies on the accuracy of information provided by external facilities. We will not hold EDI accountable for errors beyond their knowledge or control.

Activity and Exercise After Embryo Transfer:

Studies have shown-

- Strict bed rest after embryo transfer may ***lower*** the chances of success. For this reason, EDI recommends that we get up and move around normally after the transfer procedure.
- Regular exercise is reasonable following transfer. New exercise programs are discouraged.
- For all pregnancies, not just IVF pregnancies, hot tubs and saunas are often discouraged because raising core body temperature may result in birth defects and miscarriages.
- Showers and baths are safe.

Some data suggests-

- Skydiving and scuba diving should not take place after embryo transfer. This warning is suggested for all pregnancies.

In an abundance of caution-

- No studies show that sex after embryo transfer lowers the chance of implantation. Still, some couples choose to wait until the pregnancy is doing well before resuming sexual activity.
- High-intensity exercise may need to be reduced out of an abundance of caution.

Since implantation may fail, or an early pregnancy be miscarried, EDI suggests that we engage in activities post-transfer that will not make us feel guilty should our ultimate results be negative. We should engage in activities we feel comfortable with following the embryo transfer procedure.

Indemnification

Should any conflict arise between this Consent and any related Consent Forms, the terms of this Consent shall prevail. Laws involving embryo donation continue to evolve. EDI will comply with all applicable State and Federal laws, which may change without notice. Changes in the law will take priority over the statements in this consent. We understand that embryo donation is an evolving and unsettled legal area, with few states providing explicit regulatory frameworks. We further understand that embryo donation procedures and this Consent are subject to the laws of the State of Florida and the United States, as they exist now and may exist in the future. The venue for all legal actions shall be Lee County, Florida.

We, as Recipients, waive and release any rights, claims, or causes of action, known or unknown, now existing or arising in the future against EDI. Further, we agree to protect, defend, indemnify, and hold harmless EDI, its affiliates, its directors, officers, agents, employees, and contractors from any expenses, claims, liabilities, attorney fees, damages, losses, penalties, fines, or interest arising from

or related to this Consent and/or the donation and use of the embryos, including but not limited to injury or death to persons or embryos and property damage, except in cases of gross negligence or willful misconduct.

If EDI is sued or found liable for any amounts owed to another party (including any child or children born through ART procedures) arising from a claim, we will reimburse EDI for all related costs. This reimbursement includes, but is not limited to, damages, settlements or judgments, court costs, attorney's fees, and any other financial losses that are claimed or ordered against EDI related to medical procedures performed by EDI or for EDI, as described in this Consent.

In Summary:

We understand that the practice of medicine is not an exact science. There is no guarantee that the FDET procedure will result in a successful pregnancy and delivery.

We have read the above materials and understand the possible complications of the proposed procedures. We have had the opportunity to ask questions regarding the risks and benefits of the embryo donation program. Our questions have been answered to our satisfaction, and we understand the information provided.

We understand that this Frozen Donor Embryo Transfer Consent will remain valid for all future transfer procedures unless we expressly revoke it.

_____	_____	___/___/___
Recipient's Signature	Recipient's Name (print)	Date
_____	_____	___/___/___
Partner's Signature (if applicable)	Partner's Name (print, if applicable)	Date
_____	_____	___/___/___
EDI Representative Signature	EDI Representative Name (print)	Date

If you have any concerns regarding this process, please contact EDI at Recipient@EmbryoDonation.com.

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