



## INSTRUCTIONS:

This consent reviews the Egg Freezing process from start to finish, including a description of the treatment that you are undertaking and its benefits, risks, and alternatives.

- Read this informed consent document completely before signing the **Acknowledgement & Acceptance Of Treatment & Informed Consent** on page 7. If you have any questions, please speak with your doctor.
- Do not make any additions or deletions to the consent.
- Treatment **cannot** be started until all consents are signed in front of a Genetics & IVF (GIVF) staff member or a Notary Public and returned to GIVF

The goal of Oocyte Freezing (Egg Freezing) is to preserve fertility as a preventative measure to avoid age-related infertility, infertility associated with chemotherapy or radiation treatment, or for ethical and religious concerns related to freezing embryos. Eggs that have been frozen can later be thawed, fertilized and the resulting embryos transferred into your uterine cavity to attempt pregnancy.

**The Egg Freezing program includes one or more cycles of the following treatments and procedures:**

- Ovarian stimulation: taking medications to grow multiple eggs which are contained in small sacs called follicles within the ovaries
- Monitoring of ovarian response (follicular/egg development) performed with serial blood hormone tests and/or vaginal ultrasound exams
- Retrieval of eggs from the ovary or ovaries
- Oocyte Cryopreservation – freezing of unfertilized eggs for later use

## GENERAL PRE-TREATMENT RECOMMENDATIONS

During treatment, the patient should avoid any activity, behavior, or medications that could reduce the chance of conceiving and having a healthy baby. These recommendations should be followed:

- Smoking and the use of smokeless tobacco or nicotine products (e.g.: cigarettes, vaping, nicotine gum, etc.) must be avoided before and during treatment, and pregnancy.
- Recreational drugs should not be used before or during treatment or pregnancy.
- The use of alcohol should be avoided during treatment and pregnancy.
- Aspirin or aspirin-like products (e.g., Motrin, Advil, Anaprox, Naprosyn, Aleve, etc.) should be avoided during treatment. However, in certain circumstances you may be advised to take low dose aspirin (baby aspirin, 81 mg). Tylenol is safe to take before and during treatment.
- The use of all prescription and over-the-counter medications, including herbal remedies, should be discussed with your care team before starting a treatment cycle.

## EGG FREEZING TREATMENTS & PROCEDURES

Egg freezing involves several steps as outlined below. Patients are not guaranteed success at any or all of these steps, nor is a successful future pregnancy guaranteed. If optimal results are not achieved at any step, it may be recommended that the treatment be stopped, and the cycle cancelled.

### OVARIAN STIMULATION WITH FERTILTY DRUGS

- The success of an egg freezing cycle largely depends on growing several eggs at once.
- Injections of the natural hormones FSH and/or LH (gonadotropins) are used to stimulate the ovaries.
- Other medications are used to prevent early or premature ovulation.
- Sometimes the ovaries respond too strongly, and sometimes they don't respond enough.

The basic strategy of Egg Freezing relies upon the induction of the development of a large number of ovarian follicles simultaneously. Medications are administered to increase the number of follicles that develop, which will increase the number of eggs that are obtained at the egg retrieval, which will increase the number of embryos that will be available for transfer. FSH (follicle stimulating hormone) and/or LH (luteinizing hormone) injections are used for this purpose. These hormones are known as gonadotropins. Other medications are also used to prevent premature ovulation. The use of injectable gonadotropins requires careful monitoring to avoid either inadequate or excessive response.

#### Commonly used medications in an Egg Freezing cycle include but are not limited to:

- **Gonadotropins, or injectable “fertility drugs” (Follistim®/Gonal-F®/Menopur®, or human chorionic gonadotropin – Ovidrel®/Pregnyl®/Novarel®):** These are hormones that stimulate the ovary to grow several eggs (oocytes) at once over the span of 8 or more days or trigger the final development/maturation of the eggs. These injections may be given either just under the skin or directly into muscle. Monitoring ovarian response through blood tests and ultrasound during ovarian stimulation is required to assure proper dosage of drugs and the timely recovery of eggs. Taking any medicine by injection can cause bruising, redness, swelling, or pain at the injection site. In rare cases, there can be an allergic reaction. Some women have bloating or minor discomfort as the ovaries briefly become enlarged. About 1% of women will develop Ovarian Hyperstimulation Syndrome (see “Risks to the Patient” section.) Other side effects can include headaches, weight gain, feeling tired, mood swings, nausea, or clots in blood vessels. Sometimes, especially when hormone testing prior to the IVF cycle has shown that the patient has a lower number of eggs available, the medications may not help multiple eggs to grow. There may be very few or even no eggs harvested at the egg retrieval procedure, or the cycle may be canceled prior to egg retrieval.
- **GnRH-agonists (leuprolide acetate) (Lupron®):** This medication is an injection available in two forms. One is a short-acting form that needs to be injected daily, and the other is a long-acting form that lasts for 1-3 months. Leuprolide is often given to help prevent the release of eggs (by ovulation) before they can be retrieved. It can also be used to start the growth of eggs or trigger the final stages of their

development and maturation. Leuprolide is approved by the U.S. Food and Drug Administration (FDA), but not approved for use in IVF. However, it has been extensively studied and used in IVF patients for more than 20 years. Leuprolide side effects include hot flashes, vaginal dryness, nausea, headaches, and muscle aches. Some women may retain fluid or feel depressed, and long-term use can result in bone loss. Since it is taken as an injection, skin reactions can also occur where the injection is given. No serious side effects are known. If Leuprolide is given in a cycle after ovulation has occurred, you should use condoms for birth control in that month. Leuprolide has not been linked with any birth defects, but it should be stopped if you become pregnant while taking it.

- **GnRH-antagonists (Ganirelix®, Cetrotide®):** These medications are used to prevent premature ovulation. Side effects may include stomach pain, headaches, skin reactions at the injection site, and nausea.
- **Oral contraceptive pills (birth control pills):** Many treatment protocols include birth control pills for 2 to 4 weeks before starting hormone stimulation injections to suppress hormone production or to schedule a treatment cycle. Side effects include bleeding, headache, breast tenderness, nausea, and swelling. There is also a risk of blood clots or, very rarely, stroke.
- **Clomid or Letrozole:** These medicines are used in some treatments as part of the ovarian stimulation protocol or to reduce the estrogen level in the bloodstream. Short-term side effects in some women include headache, hot flashes, or increased moodiness. They are taken by mouth in pill form.
- **Other medications:** Antibiotics may be given for a short time during the treatment cycle to reduce the risk of infection from egg retrieval. Antibiotic use may cause a number of side effects including vaginal yeast infection, nausea, vomiting, diarrhea, rashes, sensitivity to the sun, or allergic reactions. Anti-anxiety medications or a muscle relaxant may be recommended prior to the embryo transfer. The most common side effect of these medicines is drowsiness.

#### Risks of Ovarian Stimulation with Fertility Drugs:

- **Ovarian Hyperstimulation Syndrome (OHSS):** Ovarian Hyperstimulation Syndrome is the most severe possible side effect of stimulating the ovaries. Signs of OHSS include increased ovarian size, nausea, vomiting, a buildup of fluid in the stomach, and breathing difficulties. In some cases, OHSS increases the level of red blood cells, and causes kidney and liver problems. In the most severe cases, it can cause blood clots, kidney failure, or death. These complications occur very rarely (in only 0.2% of all treatment cycles).
- **Torsion:** Ovarian torsion is a rare condition when the ovary and portions of the fallopian tube twist around the ligaments that hold it in place. This can cut off the blood flow to the ovary and fallopian tube. If the blood supply is cut off long enough, the tissue in the ovary may die, potentially impacting fertility. The symptoms of ovarian torsion include fever, severe lower abdominal/pelvic pain, cramping, nausea, and vomiting. It is important for anyone experiencing these symptoms to seek medical care immediately. Ovarian torsion is diagnosed by physical exam including a transvaginal ultrasound. Treatment requires emergency surgery to untwist the ovary to restore blood flow and avoid necrosis, or in severe cases, to remove the ovary.

- **Cancer:** There is some concern that using fertility drugs can cause breast, ovarian, or uterine cancer. These cancers are more common in women with infertility, so it is difficult to know whether the reason for the cancer the infertility is itself, or use of the drugs. In current studies that take into consideration the increased risk of cancer due to infertility, there does not seem to be an increased risk of cancer due to the fertility drugs alone. More studies need be done to confirm whether there is an association of cancer with use of fertility drugs.

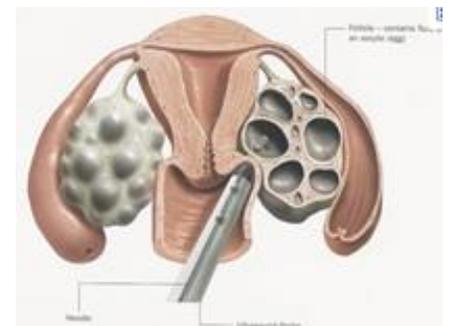
### MONITORING

During the ovarian stimulation phase of treatment, monitoring of ovarian response (follicular development) is performed using periodic blood hormone tests and/or vaginal pelvic ultrasound exams. Monitoring helps the physician determine the appropriate dose of the fertility medications and the timing of the egg retrieval. Blood drawing may be associated with mild discomfort and, possibly, bruising, bleeding, infection, or scar at the needle sites. Vaginal ultrasound examinations are usually painless and generally considered to be safe.

### TRANSVAGINAL OOCYTE (EGG) RETRIEVAL

- Eggs are removed from the ovary with a needle under ultrasound guidance.
- Anesthesia is given to make this more comfortable.
- Complications such as injury, bleeding, and infection are rare.
- Not every follicle yields an egg and not every egg is mature/healthy.

Oocyte retrieval is the removal of eggs from the ovary. Before removing the eggs, the doctor will look at your ovaries using an ultrasound probe placed into the vagina. A long needle, which can be seen on ultrasound, is then attached to the ultrasound probe. Guiding the needle into the ovaries, the doctor will aspirate fluid, eggs, and egg-supporting cells. Very rarely, the ovaries are not accessible through the vagina. In that case, the eggs might be removed by guiding the needle through the abdomen to reach the eggs. Anesthesia with IV sedation is generally used to reduce or eliminate discomfort. It is important to note that not every follicle will yield an egg and not every egg may be mature and healthy for fertilization.



#### Risks of egg retrieval:

- **Infection:** Bacteria from the vagina may be inadvertently transferred into the abdominal cavity or ovaries by the needle. This can cause an infection of the uterus, fallopian tubes, ovaries, or other intra-abdominal organs. The incidence of infection after egg retrieval is very small (less than 0.1%). If you do get an infection, you may be given antibiotics. Severe infections sometimes require surgery to remove infected tissue. Infections can reduce your chance of getting pregnant in the future. Antibiotics may be used before the egg retrieval to help reduce the chance of infection. Still, there is no way to remove the risk completely.

- **Bleeding:** The needle passes through the vaginal wall and into the ovary to obtain the eggs. Both structures contain blood vessels and there are other blood vessels nearby. This means that small amounts of blood may be lost while removing the eggs. The risk of major bleeding is small (< 0.1%). Major bleeding may require surgical repair and could result in the removal of an ovary. The need for blood transfusion is rare. Although very rare, review of world experience with IVF indicates that unrecognized bleeding has led to death.
- **Trauma:** Even with ultrasound guidance, it is possible to damage nearby organs during the egg retrieval. This includes damage to the intestines, appendix, bladder, ureters, and ovary. In some cases, a damaged organ may need to be surgically repaired or removed. Such risk of trauma during egg retrieval is very low.
- **Anesthesia:** For the egg retrieval, medications are usually administered intravenously by an anesthesiologist. You will have a discussion prior to the procedure to review your medical history as well as the risks and benefits of anesthesia. The use of anesthesia during the egg retrieval can cause unintended complications such as an allergic reaction, low blood pressure, nausea, vomiting, and in rare cases death.
- **Failure:** It is possible that no eggs are found during the retrieval process. In other cases, the eggs may be abnormal, or are of poor quality. These situations can prevent you from having a successful pregnancy.

### OOCYTE CRYOPRESERVATION (freezing of unfertilized eggs)

- Freezing of eggs provides other chances for pregnancy in the future.
- Frozen eggs do not always survive the process of freezing and thawing.
- Patients with frozen eggs MUST be in touch with the clinic once a year.
- There are yearly fees for storing frozen eggs.

Eggs will be stored at GIVF or may be transferred to the storage facility of your choice until you decide to thaw them for an in vitro fertilization (IVF) procedure. There are costs associated with egg freezing, storage and transportation which will be presented to you, and you can discuss these costs with a GIVF financial counselor.

#### Benefits of cryopreservation/freezing:

- Can allow you to prolong your child-bearing years by successfully freezing your eggs
- Can be an option for fertility preservation if your future fertility is at risk due to surgery, medical conditions, or other treatments such as cancer therapy.
- The process of freezing or storing eggs instead of embryos (fertilized eggs) addresses the ethical issues that some individuals may have with freezing and thawing embryos

**Risks of cryopreservation/freezing:**

In October 2012 the Practice Committee of the American Society for Reproductive Medicine (ASRM) reviewed the available published data and concluded that this technique should no longer be considered experimental (Fertil Steril, 2012). They also reported that there are no increases in chromosomal abnormalities, birth defects, or developmental deficits in the children born from cryopreserved oocytes (eggs). However, egg freezing is a new technology and there could be unforeseen risks realized in the future. For additional information regarding the potential risks associated with the use of frozen eggs for a future pregnancy please refer to the ***Informed Consent for InVitro Fertilization Packet***.

The entire cryopreservation process -freezing, storage, and thawing - can damage or destroy some or all cryopreserved eggs, resulting in the inability to proceed with further treatment or transfer.

It is also possible that cryopreserved eggs may be damaged, destroyed, lost, or fail to develop, and therefore be unavailable for further treatment or transfer due to a number of potential factors, including but not limited to: patient-specific differences in tolerance of gamete 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 containers 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 Genetics & IVF Institute (GIVF) or its laboratory.

**ACKNOWLEDGEMENT & ACCEPTANCE OF TREATMENT & INFORMED CONSENT**

Please agree and initial under either “Accept” or “Decline” in each section to indicate your decisions regarding the elements of treatment you agree to undertake. Both (if applicable) partners must initial each line in each section and sign each section.

I/We, the undersigned, consent to the components of Egg Freezing as indicated below:

<b>Treatment Core Components:</b>	<b>Accept</b>	<b>Decline</b>
Ovarian Stimulation and Monitoring	_____ / _____	_____ / _____
Oocyte (egg) retrieval	_____ / _____	_____ / _____
Oocyte Cryopreservation (freezing)	_____ / _____	_____ / _____
<i>Requires Agreement for Storage and Disposition of Frozen Oocytes and Acknowledgement of Storage Fees</i>		

**ACKNOWLEDGEMENT OF INFORMED CONSENT SELECTIONS & AUTHORIZATION**

I/We have been fully advised of the purpose, risks and benefits of each of the procedures indicated above and have been informed of the available alternatives and risks and benefits of such alternatives. This information has been supplemented by my/our consultation with my/our medical team. I/We have had the opportunity to ask questions and all my/our questions have been answered to my/our satisfaction.

I/We understand this Informed Consent for Egg Freezing will remain in effect until one of the following events occurs: one (1) calendar year has passed from the date of signature; death of patient; or written notice to GIVF of withdrawal of consent by the patient and/or the patient's partner, if applicable.

I/We have read the Egg Retrieval document in its entirety and have had ample time to reach my/our decision, free from pressure and coercion, and agree to proceed with my/our participation in Assisted Reproduction services as stated above

<b>PATIENT:</b>	<b>PARTNER:</b>	<input type="checkbox"/> N/A
Signature: _____	Signature: _____	
Printed Name: _____	Printed Name: _____	
Date: _____	Date: _____	
Type of Picture Identification viewed:	Type of Picture Identification viewed:	
<input type="checkbox"/> Driver’s License	<input type="checkbox"/> Driver’s License	
<input type="checkbox"/> Passport	<input type="checkbox"/> Passport	
<input type="checkbox"/> Other: _____	<input type="checkbox"/> Other: _____	

GIVF Witness Name: \_\_\_\_\_ Signature: \_\_\_\_\_

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

**Consents signed outside the Practice must be notarized and dated**

**PATIENT:**

City/County of \_\_\_\_\_

State/Commonwealth of \_\_\_\_\_

The foregoing instrument was acknowledged before me this \_\_\_\_\_ day of \_\_\_\_\_, 20 \_\_\_\_ by  
\_\_\_\_\_ (Name of person seeking acknowledgment)

Notary Public's signature: \_\_\_\_\_

Notary registration number: \_\_\_\_\_

My commission expires: \_\_\_\_\_

**PARTNER:**

N/A

City/County of \_\_\_\_\_

State/Commonwealth of \_\_\_\_\_

The foregoing instrument was acknowledged before me this \_\_\_\_\_ day of \_\_\_\_\_, 20 \_\_\_\_ by  
\_\_\_\_\_ (Name of person seeking acknowledgment)

Notary Public's signature: \_\_\_\_\_

Notary registration number: \_\_\_\_\_

My commission expires: \_\_\_\_\_