GENETICS & IVF Institute

INFORMED CONSENT: INTRAUTERINE INSEMINATION (IUI)

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INSTRUCTIONS:

- Read this consent completely before signing on page 5. If you have any questions, please speak with your doctor. Treatment **cannot** be started until all consents are signed.
- Consents must be signed in front of a Genetics & IVF (GIVF) staff member or a Notary Public, or through a GIVF-initiated ID verified DocuSign.

INTRODUCTION:

The main goal of IUI is to allow a patient the opportunity to become pregnant using their own eggs and sperm from either a partner or from a donor.

This document explains the IUI treatment process and describes the risks, benefits, and alternatives including the risks that this treatment might pose to you and your offspring. While we try to disclose all known risks, there may be risks which are not yet clarified or even suspected at this time.

An IUI cycle typically includes the steps and procedures outlined below. Patients are not guaranteed success at any or all these steps. If optimal results are not achieved at any step, it may be recommended that the treatment should be stopped, and the cycle cancelled.

- Follicle development, ovulation, and maturation of the uterine lining using either a medicated or non-medicated approach
- Monitoring of follicular (egg) and uterine lining development with blood hormone tests, vaginal pelvic ultrasound exams, and/or urine pregnancy tests
- Washing of fresh sperm or thawing of frozen sperm
- Insemination of the sperm into the uterus using a small catheter

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:

- A prenatal vitamin with at last 0.8 mg of Folic Acid should be taken daily before beginning treatment, optimally for at least one month prior to conception to help prevent some major birth defects of the baby's brain (anencephaly) and spine (spina bifida)
- 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, 81mg). 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.

INTRAUTERINE INSEMINATION TREATMENT COMPONENTS

OVULATION INDUCTION/OVARIAN STIMULATION VS. NATURAL CYCLE

- A medicated IUI is when ovulation induction or ovarian stimulation is achieved using medications which are usually oral pills, or less frequently, gonadotropin injections.
- In some patients, a non-medicated natural cycle IUI may be used
- Monitoring visits are usually needed to assess the progress of the follicles (eggs) and uterine lining development.

Oocytes (eggs) are present in the ovaries within fluid-filled cysts called "follicles". During a patient's menstrual cycle, usually one mature follicle develops, which results in the ovulation of a single egg. Several hormones including follicle stimulating hormone (FSH) and luteinizing hormone (LH) influence the growth of the ovarian follicle. These hormones are produced by the pituitary gland, which is located at the base of the brain. FSH is the main hormone that stimulates the growth of the follicle, which produces an estrogen hormone called *estradiol*. When the follicle is mature, a large amount of LH is released by the pituitary gland. This LH surge matures the egg and leads to its release or "ovulation" 36-40 hours after its initiation. After ovulation the ovary produces the hormone *progesterone* to help the uterine lining become receptive to an embryo for successful implantation and pregnancy.

There are two types of IUI cycles as detailed below:

MEDICATED IUI CYCLE:
Medications are administered to induce or stimulate/enhance follicular (egg) development and ovulation. There are several medications that can be used for this purpose:

- **Clomid or Letrozole** (oral pills): These medications are the most commonly used with IUI to induce or stimulate/enhance follicular (egg) development. They are usually taken for a short course of 5 days starting at the beginning of the menstrual cycle.
- **Gonadotropin injections (Follistim, Gonal-F, or Menopur):** These medications can be used alone or in conjunction with the above oral pills also to induce or stimulate/enhance follicular (egg) development.
- **Human Chorionic Gonadotropin (Ovidrel/HCG) "Trigger shot"**: Induces final maturation of the egg and its subsequent release or "ovulation."

NATURAL CYCLE IUI:
Non-medicated or natural cycle IUI is less commonly used than the medicated approach as it hasn't been shown to be significantly beneficial in the infertility population. But if a patient has regular menstrual cycles, no history of infertility, and using donor sperm, a non-medicated natural cycle IUI may be considered as the initial treatment. With this approach, ovulation is monitored with an ovulation predictor kit (OPK), or blood tests and vaginal pelvic ultrasound examinations. When ovulation is imminent, the IUI treatment will be planned at the appropriate time. In contrast to the medicated approach, there may be a lower chance of pregnancy because only one egg is released for possible fertilization, but there is also a much lower chance of a multiple pregnancy for that same reason.

Risks of Ovarian Stimulation with Fertility Drugs:
The use of the above listed medications can cause side effects such as nausea, vomiting, hot flashes, headaches, mood swings, abdominal bloating and cramping, visual symptoms, memory difficulties, joint problems, weight gain

and weight loss, all of which are temporary. Rare allergic reactions are also possible. Other possible side effects include the following:

- **Ovarian Hyperstimulation Syndrome (OHSS):** Ovarian Hyperstimulation Syndrome is the most severe possible side effect of stimulating the ovaries and is more of a concern when using injectable medications than oral medications. Signs of OHSS include increased ovarian size, nausea, vomiting, a buildup of fluid in the abdomen/pelvis, 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) and close monitoring can help identify patients at higher risk which could result in cycle cancelation.
- **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 infertile patients, so it is difficult to know whether the reason for the cancer is the infertility itself, or the 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 research is needed to confirm whether there is an association of cancer with use of fertility drugs.

INTRAUTERINE INSEMINATION PROCEDURE

Intrauterine insemination, or IUI, is a procedure where sperm is introduced directly into the uterine cavity using a small catheter, around the time of ovulation, in the hope of producing a pregnancy. Before the IUI, the sperm specimen will need to be prepared by the laboratory.

On the day of the IUI treatment, a semen sample is obtained from a partner or directed donor (by masturbation, home collection, or on-site collection), or by thawing previously cryopreserved (frozen) sperm. The semen sample is then processed ("washed") to isolate motile sperm. Next the isolated motile sperm are loaded into an insemination catheter (a soft plastic catheter). A speculum is inserted into the patient's vagina to visualize and clean the cervix. The insemination catheter is then inserted past the cervical canal and into the uterine cavity, where the sperm are deposited.

After the catheter and speculum are removed, the patient will be asked to lay flat or slightly inverted and rest for a short period before leaving the clinic (usually 10 minutes). Once the insemination appointment is complete, normal activity can be resumed including using the restroom.

Because a catheter is inserted into the uterine cavity during the insemination treatment, there is always the risk of a pelvic infection following the procedure. Symptoms can include fever/chills, malodorous or purulent vaginal discharge, and abdominal/pelvic pain. The estimated incidence of infection after IUI is extremely rare at less than 0.5%. Treatment could require the use of oral or intravenous antibiotics, and in severe cases, surgery. Infections can have a negative impact on future fertility.

ADDITIONAL RISKS TO THE PATIENT AND OFFSPRING

The development of a pregnancy following this treatment (success rate) is dependent on many factors including: the age of the patient, the infertility diagnosis, the number of previous cycles of treatment, the number of follicles that develop, and the quality of the sperm used. As in naturally conceived pregnancies, IUI pregnancies may have complications from childbirth or delivery, or other adverse consequences.

RISKS OF PREGNANCY

Miscarriage - There is no increased risk of miscarriage associated with this treatment. The risk of miscarriage in the general population is 15-20% and increases with the age of the female patient due to egg age and quality.

Ectopic Pregnancy – In ectopic pregnancy, the embryo implants outside of the uterus, most commonly in the fallopian tubes. This is potentially life threatening and can require medical or surgical treatment. While the risk of ectopic pregnancy is higher in infertile patients, it is not associated with the IUI procedure itself.

Multiple Pregnancy - The administration of ovulation induction or ovarian stimulation medications can result in the ovulation of more than one egg, which increases the chance of a multiple pregnancy. The chance of multiple pregnancy ranges from 8-25%, which is in part dependent on the medication that is used. For instance, following clomiphene citrate treatment the multiple pregnancy rate ranges between 8-12%. When the injectable medications are used (gonadotropins) the multiple pregnancy rate is higher between 20-25%. Of the multiple pregnancies, approximately 80% are twins and the remainder (20%) are triplets and quadruplets. The chance of quadruplets is less than 2% of all pregnancies. Rarely, more than quadruplets can result. All multiple pregnancies are associated with an increased risk of most complications of pregnancy including but not limited to miscarriage, hypertension, preeclampsia/toxemia, congenital anomalies, gestational diabetes and premature labor and birth. Premature birth is the single greatest cause of death or disability in newborn infants. In contrast to a single intrauterine pregnancy, a multiple pregnancy may pose increased emotional and financial hardship. An IUI cycle may be canceled if during monitoring the risk of multiple pregnancy is assessed to be very high.

If a multiple pregnancy develops, the patient (or couple if applicable) may consider being referred to a specialist who can perform a multi-fetal reduction procedure. This procedure, which is performed at approximately three months of pregnancy, is done to reduce the number of pregnancy sacs to a lower and safer number. Although this procedure is successful 90-95% of the time, a complete miscarriage may result. The best time to discuss the risks of multiple pregnancy and multifetal pregnancy reduction with your physician is before your treatment cycle begins.

Other Risks - Within the normal human population, a certain percentage of children (approx. 3-5%) are born with congenital malformations or birth defects. Children born from IUI (with or without the use of fertility medications) are comparable to those conceived naturally and, although no increased incidence of abnormalities have been noted to date, this remains a possibility. Genetic counseling and prenatal testing is advised as per standard guidelines for any naturally conceived pregnancy. No guarantee can be given regarding the male partner's sperm or the female partner's egg(s), or for the physical or mental characteristics of any child or children conceived or born following the IUI procedure.

ACKNOWLEDGEMENT OF INFORMED CONSENT & AUTHORIZATIONS

I/We understand this Informed Consent for Intrauterine Insemination will remain in effect for one (1) calendar year from the date of signature; until the patient's successful pregnancy which results in a live birth; or, until written notice to GIVF of withdrawal of consent by the patient and/or the patient's partner, if applicable.

By signing this document, I/we acknowledge that I/we have been fully advised of the purpose, risks, and benefits of the treatment procedures, and have been informed of the available alternatives and risks and benefits of such alternatives. I/We have read the Intrauterine Insemination Informed Consent document in its entirety and 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 are voluntarily seeking treatment in order to achieve a pregnancy 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

PATIENT

Signature: _____

Printed Name: _____

Date: _____

Type of Picture Identification viewed:

☐ Driver's License ☐ Passport

☐ Other: _____

PARTNER ⚐ N/A

Signature: _____

Printed Name: _____

Date: _____

Type of Picture Identification viewed:

☐ Driver's License ☐ Passport

☐ Other: _____

GIVF Witness Name: _____

Title: _____

Signature: _____

Date: _____

Or notarized below:

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: _____

Registration #: _____

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: _____

Registration #: _____

My commission expires: _____