

Consent for Ovulation Induction Therapy using Fertility Enhancing Medications

Patient Name: _____ **Patient Number:** _____

Ovulation induction therapy is a technique used to increase the number of eggs matured within the ovaries in a cycle. Commonly used fertility enhancing medications include oral medications such as **Letrozole** and **Clomiphene Citrate**. The injection used to trigger ovulation is **Ovidrel**. Blood tests and ultrasound examinations are required to monitor the effects of these medications. There are a variety of side effects and risks associated with the use of these medications and they are described below:

Side Effects:

Women using these medications may experience various side effects. The most common are:

- Nausea, vomiting, diarrhea, abdominal cramps and bloating
- Breast tenderness
- Mood swings
- Flu-like symptoms including fever, chills, muscle aches, joint pain and headache.
- Abdominal bloating with associated pelvic discomfort
- Increased incidence of migraine headaches
- Pain, rash and/or swelling at the injection sites
- Fatigue

Risks:

Individuals using the above medications may also experience the following risks:

Ovarian Hyperstimulation Syndrome: (OHSS) may include the following:

Cyst formation: The medications above mentioned, when prescribed may result in large cysts forming in the ovaries. In the majority of cases, ovarian cysts induced by fertility enhancing medications tend to disappear spontaneously requiring no intervention. In very rare instances, in less than 1% of cycles, these cysts can result in significant abdominal discomfort which may result in the need for a blood transfusion and the loss of one or possibly both ovaries. Torsion or twisting of the ovaries occurs in less than 1% of the time. The ovary can twist on itself cutting off its own blood supply. Surgery is required to untwist the ovary or even remove it.

Fluid Shifts: Fluid shifts within the body may require hospitalization for observation and treatment. The high levels of estrogen associated with the use of these medications may alter the way in which the body handles fluids. More specifically, the blood vessels which supply the ovaries may become "leaky" resulting in the accumulation of fluid within the abdominal cavity (ascites) and around the lungs (pleural effusion). The accumulation of fluid within the abdominal cavity may result in abdominal distention and discomfort with associated shortness of breath. In severe cases, removal of this fluid from the abdomen and from the spaces around the lungs may be required. The leaky vessels may also result in the individual becoming dehydrated. Intravenous fluid administration may be required to maintain adequate blood flow to vital organs such as the kidneys.

Severe dehydration could result in irreversible organ failure and blood clot formation leading to a pulmonary embolism or stroke. There are extremely rare reports of death occurring as a result of complications of OHSS. Ovarian Hyperstimulation Syndrome is a risk which is inherent to ovulation induction therapy; prevention cannot be guaranteed. At times, when monitoring shows that the risk of OHSS is unacceptably high, the cycle may be cancelled. Severe OHSS will rarely occur if HCG administration is withheld.

Multiple Pregnancy:

Individuals utilizing ovulation induction drugs are at an increased risk for multiple pregnancy. The risk is also influenced by the patient’s age and diagnosis. Therefore, the risk of multiple risk of multiple pregnancy varies from patient to patient. Women taking Letrozole have 3-4 % chance of multiple pregnancy, Clomiphene Citrate have a 5-8% chance of multiple pregnancy compared to a 1-2% chance in the general population. Multiple births using oral medications such as Letrozole and Clomiphene Citrate are almost exclusively twins – triplets are rare.

Multiple pregnancies often result in an increased risk of miscarriage, premature labor and premature birth. A premature delivery may jeopardize the life and long-term health of a child and may result in substantial costs both emotionally and financially. Multiple pregnancies may also increase the occurrence of pregnancy related complications such as high blood pressure and diabetes. Multiple pregnancy also increases the likelihood that a cesarean section will be required.

Parents raising children resulting from multiple pregnancy may be at an increased risk for major mood disorders such as anxiety and depression.

Ovarian Cancer:

Currently there are studies which suggest that women who use fertility medications are at an increased risk of developing cancer of the ovaries. Unfortunately, there have been concerns raised by the medical community which questions the validity of these findings. Infertility alone brings an increased risk of ovarian cancer. At this point in time there is insufficient evidence to determine whether or not a relationship exist between the use of fertility medications and an increased risk of ovarian cancer. Such a relationship may exist but the current data available is insufficient to definitely prove or disprove a relationship. There is no guarantee that a future link will not be found.

Zika Virus:

In South Florida, there is a small risk of Zika Virus transmission. Zika virus spreads to people primarily through the bite of an infected Aedes species mosquito. Zika can also be passed through sex from a person who has Zika to his or her sex partners and it can be spread from a pregnant woman to her fetus. Many people infected with Zika will not have symptoms or will only have mild symptoms. The most common symptoms are fever, rash, joint pain, or red eyes. Symptoms can last for several days to a week.

Zika infection during pregnancy can cause fetuses to have a birth defect of the brain called microcephaly. Other problems have been detected among fetuses and infants infected with Zika virus before birth, such as defects of the eye, hearing deficits, and impaired growth. There have also been increased reports of Guillain-Barré syndrome, an uncommon sickness of the nervous system, in areas affected by Zika. There is no vaccine to prevent Zika. The best way to prevent diseases spread by mosquitoes is for patients to protect themselves and their spouses from mosquito bites. All patients undergoing fertility treatments should refer to the CDC website for information on Zika and how to best prevent mosquito bites.

I have read the above information. I have also been given literature provided by the American Society for Reproductive Medicine which discusses in detail the use of ovulation induction medications and their side effects and risks. I have had the opportunity to ask questions about ovulation induction with fertility enhancing medication and have had these questions answered to my satisfaction. I understand that there are risks associated with the utilization of the above medications and by signing below I accept these risks. I acknowledge that injectable ovulation medications are being prescribed with my knowledge and consent.

Signature of Patient: _____ **Date:** _____

****Payment is Your Responsibility****

We are happy to contact your insurance company as a courtesy to explore the details of your infertility coverage. But please understand that this is in no way a guarantee of benefits. Due to the complexities of insurance, any financial estimate we provide for our services, medications or lab services are not guaranteed.

Signature of Patient: _____ **Date:** _____

Signature of Physician: _____ **Date:** _____