Consent for Controlled Ovulation Stimulation

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Print Patient's Name Date

I, the undersigned, request, authorize and consent to ovulation induction by Women's Fertility Center and, as appropriate, its employees and authorized agents.

Controlled ovarian stimulation is a technique used to help a woman ovulate if she is anovulatory or to increase the number of eggs matured within the ovaries during a cycle if a woman is ovulatory. Commonly utilized medications include gonadotropins, hCG and GnRH analogs and antagonists. These medications are all given by injection. In addition, in order to monitor the effects of these medications, several blood tests and ultrasound examinations are required. There are various side effects and risks associated with the utilization of these medications which are described below.

The most common side effects are: 1) gastrointestinal symptoms including nausea, vomiting, diarrhea, abdominal cramps, bloating, 2) breast tenderness, 3) mood changes, 4) allergic reactions involving flu-like symptoms including fever, chills, muscle aches, joint pains, headaches or pain, rash, swelling and/or irritation at the site of injection, 5) abdominal bloating with associated pelvic discomfort and 6) increased incidence of migraine headaches and 7) fatigue. Additional side effects associated with the utilization of GnRH analogs are hot flashes and, rarely, transient impairment of short term memory. All of the above side effects generally disappear after discontinuation of the medications.

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

1. OVARIAN HYPERSTIMULATION SYNDROME (OHSS). OHSS may include:

    - Cyst formation - The medications described above may result in large cysts forming on the ovaries. In the majority of cases, ovarian cysts induced by gonadotropin stimulation disappear spontaneously and require no intervention. In very rare instances (< 1% of cycles) these cysts could cause significant abdominal discomfort which could result in the need for hospitalization for observation purposes. A cyst could rupture requiring

emergency surgery to stop bleeding. Rarely, this could result in a need for blood transfusions and possible loss of one or both ovaries (0.1% of cycles).

- Fluid shifts - Fluid shifts within the body may require hospitalization for observation and treatment (1%-3% of cycles). 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) or around the lungs (pleural effusion).

  This accumulation of fluid may result in abdominal distension and discomfort with associated shortness of breath (due to the diaphragm being pushed upward by the accumulation of fluid in the abdomen). In severe cases, removal of this fluid from the abdomen or from the space around the lungs may be required using a small needle (0.5% of cycles). The "leaky" vessels may also result in the individual becoming dehydrated because the fluid is in the wrong place (i.e., in the abdomen instead of in the blood vessels). 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 or blood clot formation leading to a pulmonary embolus (blood clots in the lung) or stroke (less than 0.1% of cycles). There are extremely rare reports in the literature of death occurring as a result of complications of OHSS. OHSS 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, a cycle may be canceled. Severe OHSS will rarely occur if hCG administration is withheld.

2. MULTIPLE PREGNANCY. Individuals utilizing ovulation induction are at an increased risk for multiple pregnancy. The risk of multiple pregnancy is also influenced by the patient's age and diagnosis and, therefore, the risk of multiple pregnancy varies from patient to patient.

   The incidence of multiple pregnancy in individuals utilizing these medications is approximately 25% and the incidence of triplets or a higher order multiple is less than 5% of pregnancies. Multiple pregnancy 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 financially and emotionally.

Pregnancies with more than one baby in the uterus may also increase the occurrence of pregnancy related medical complications for the mother 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 births may be at increased risk for major mood disorders such as anxiety and depression.

3. OVARIAN AND BREAST CANCER. Currently there is insufficient evidence to determine whether or not a relationship exists between the utilization of fertility medications and an increased risk for breast and/or ovarian cancer. However, infertility alone is a risk factor for both breast and ovarian cancers. Such a relationship may in fact exist but, the current data available is insufficient to definitively prove or disprove such a relationship. We cannot guarantee that a future link will not be found.

In addition to the use of medication for ovulation induction, alternative treatment options are available including adoption and no treatment which have been discussed with my physician. I understand the risks and benefits as outlined.

I have read the above information. I have had the opportunity to ask questions about ovulation induction 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 ovulation induction is being performed with my knowledge and consent. I have been encouraged to ask questions until they have been answered to my satisfaction. Any future questions can be addressed to Dr. Nora Miller at (203)-286-6810.

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Signature of Patient Date

This consent has been discussed with the patient.

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Signature of Nora Miller, MD Date