

INFORMED CONSENT FOR THE USE OF INJECTABLE FERTILITY DRUG THERAPY

Gonal-F, Follistim, Menopur, Repronex, and similar medications are injectable drugs used during ovulation induction for "superovulation" or in-vitro fertilization. Human chorionic gonadotropin (hCG), another medication given in conjunction with these injectable fertility drugs, is used to cause the release of, or final maturation of, the eggs. These powerful drugs directly stimulate the ovaries. For this reason, careful monitoring must be undertaken during this therapy.

Any treatment can have risks and side effects. The main risks of these drugs include multiple pregnancies (possibly resulting in the need for fetal reduction) and the development of the ovarian hyperstimulation syndrome. Rarely, these therapies may result in ectopic (outside of the normal location) or heterotopic (inside the uterus as well as outside of the uterus) pregnancy. Since these fertility drugs may be derived from or processed with human and/or animal (bovine, or cow) sources, the remote possibility of disease transmission exists. Approximately 20-50% of pregnancies obtained with these drugs have resulted in multiple births. Most of these (approximately 75%) are twins, but the chance of higher multiples (such as triplets, quadruplets, or more) exists. Although ovarian follicle growth is monitored with blood hormone determinations, sonography (ultrasound pictures), and clinical assessment, it is impossible to completely eliminate the risk of the above side effects. Alternatives, procedures, material risks, and potential consequences of fertility drug treatments will be discussed with you in greater detail, and at length, by Dr. Roseff or his designee, **prior** to the start of your therapy.

Some reports have mentioned a possible association between "fertility drugs" and the subsequent development of ovarian cancer. These reports are not conclusive, however, and further studies are presently underway.

The ovarian hyperstimulation syndrome is associated with the administration of these medications. This has been categorized into mild (approximate incidence 90%), moderate (approximate incidence 10%), and severe (approximate incidence 1%) forms. In the mild form, the ovaries are enlarged, and abdominal discomfort and swelling develop. This generally does not require therapy. The moderate form results in extensive ovarian enlargement and fluid accumulation in the abdomen. This may require bed rest and close monitoring. Severe hyperstimulation syndrome can be life threatening. With this, there is massive ovarian enlargement, extensive accumulation of abdominal fluid, vomiting, accumulation of fluid around the lungs, and difficulty urinating. If untreated, the severe hyperstimulation syndrome has been reported to cause death in a limited number of cases worldwide. Hospitalization and aggressive fluid management are required for treatment. Since the risk of hyperstimulation increases **after** hCG is given to patients with many follicles and very high blood estrogen levels, hCG may need to be withheld if these occur. Also, ovarian enlargement may uncommonly lead to torsion, or twisting of the ovary and tube. Torsion generally causes severe pain in the region of the ovary, and may necessitate major surgery with the need to remove the affected ovary/tube. **"Pelvic rest" may help to minimize some of these complications, and it is therefore recommended that you rest as much as possible between the time you receive hCG and your pregnancy test.**

Prior to the administration of hCG, you will be apprised of the number of eggs that have developed. You will be given the option at that point of continuing with or canceling the cycle.

Your signature below indicates that you have read this informed consent, accept the risks of injectable drug therapy, fully understand the information herein, and that all of your questions have been answered to your satisfaction by Dr. Roseff or his designee.

(Print Patient Name)

(Patient Signature)

(Date)

(Print Witness Name)

(Witness Signature)

(Date)