

## Consent Form for Letrozole (Femara)

Letrozole is a medication that has been approved by the FDA for treatment of breast cancer. It is called an aromatase inhibitor and it works by lowering the production of estrogen.

Recent studies in Europe and Canada have shown that Letrozole can induce ovulation in infertility patients. In the United States, the commonly prescribed medications for ovulation induction or super ovulation are Clomiphene Citrate and the injectable medication gonadotropin. Letrozole has not been approved by the FDA for use in infertility patients, so its use is called "off label". The manufacturer of Letrozole has stated that use in pregnancy is contraindicated and theoretically can increase the risk of miscarriage and birth defects.

### Benefits:

The half life of Letrozole is very short (2 days) compared to Clomiphene Citrate. This means the medication is metabolized more rapidly and the side effects are less. Letrozole does not affect the cervical mucus or endometrial lining as much as Clomiphene. This means better transport of sperm in the cervix and a more favorable lining for implantation.

### Risks:

A study conducted in 2005 reported a 4.7% birth defect rate. This is the same as reported in the general population of a 3-5% risk of birth defects. The risk of a miscarriage using Letrozole may be slightly increased over the general population, but is similar to the miscarriage rate in infertile women with polycystic ovarian disease.

Letrozole works by increasing the number of ovarian follicles (cysts). Occasionally a cyst may persist into the next cycle. This may prevent treatment of a new cycle. These cysts usually resolve without problems or treatments.

### Side Effects:

The most common side effect is hot flashes. Other less common side effects are nausea, headaches, bloating, muscle aches, blurred vision and fatigue. These side effects may occur in approximately 10-20% of patients and are self limited to that cycle.

### Alternatives:

The alternative treatments to Letrozole are Metformin (Glucophage), Clomiphene Citrate and Gondotropins (FSH, FSH/LH).

I understand that the FDA has not approved the use of Letrozole for ovulation induction and that the manufacturer of Letrozole recommends against its use for ovulation induction. I understand that there is no guarantee that I will ovulate or become pregnant while taking Letrozole. I have read and I understand the above information and have had an opportunity to ask questions and discuss the risks with the physician.

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Patient's signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness

\_\_\_\_\_  
Date