

**MASSACHUSETTS GENERAL HOSPITAL
VINCENT REPRODUCTIVE MEDICINE AND IVF**

INFORMED CONSENT FOR INTRACYTOPLASMIC SPERM INJECTION (“ICSI”)

INTRODUCTION

Intracytoplasmic sperm injection (ICSI) is a procedure which is designed to supplement traditional IVF to improve the chance of fertilization of the female's eggs. It is ordinarily used in circumstances where the male's semen reflects low sperm counts or inactive sperm, or where the male's semen analysis is otherwise abnormal. It may also be useful for couples where standard IVF has led to poor or no fertilization.

THE ICSI PROCESS

ICSI differs from standard IVF in several ways, although all of the aspects of the ICSI process which differ from the standard IVF procedure take place in the IVF laboratory. In traditional IVF, to fertilize the eggs, each egg is placed in a fluid and surrounded by up to 50,000 sperm. In ICSI, a single sperm is injected directly into an egg.

In ICSI, the eggs must reach a certain stage of maturity before the sperm can be safely injected to allow normal fertilization. To check whether an egg is developed to the proper stage of maturity, in preparation for ICSI, the outer cells surrounding the egg are first removed with a special enzyme solution, and the egg is evaluated under the microscope. It is possible that none of the eggs retrieved through this process will be suitable for ICSI. Also, once the cells surrounding an egg are removed, that egg may not be utilized for traditional IVF.

On the afternoon of the day of retrieval of the eggs, the mature eggs which have been selected for ICSI are placed under a microscope and a single sperm is immobilized so that it can be directly injected into a mature egg. All healthy mature eggs are injected in similar fashion. The next day, the eggs are evaluated for evidence of fertilization, just as in standard IVF. Typically, 70% of the mature eggs undergoing ICSI will fertilize.

Most ICSI cases will be planned and discussed with you far in advance of the egg retrieval. Still, there are times when the semen specimen produced at the time of egg collection is unexpectedly poor. In these cases it may be suggested that you switch from standard IVF to the ICSI procedure. The decision as to whether to proceed with ICSI is one which should be discussed between you and your partner, as well as the physician. In general, the decision should be made prior to the time of initiating any IVF medication.

RISK FACTORS AND TREATMENT OUTCOMES

1. Degeneration, damage or loss of the egg or embryo, which precludes further use.
2. Possible abnormal fertilization. The ICSI procedure may result in damage to the egg causing it to develop abnormally.
3. Possible failed fertilization. Even with the use of ICSI, it is possible that fertilization will not occur.
4. Studies have shown that some cases of male infertility may be genetic. Therefore, there is the possibility that infertility may be passed on to the offspring. Some studies show an increased risk of chromosomal and other abnormalities in babies born as a result of the ICSI procedure. If pregnancy is achieved, testing can be performed to determine the chromosomal makeup of the fetus. **If you would like additional information concerning genetics and inheritance, you should ask your physician to refer you to a genetic counselor prior to the start of your treatment cycle.**
5. The patient must take a four-day regimen of methylprednisolone (a steroid). The use of steroids may improve implantation of micro-manipulated embryos. Methylprednisolone is a commonly known medication considered safe when properly used. Many people treated with this protocol have reported no adverse reactions. And we understand that the use of methylprednisolone could cause the following side effects, although they are more common when the drug is administered for a longer duration or at higher doses: mood swings, insomnia, depression, psychotic manifestations, muscle weakness, permanent hip damage, requiring replacement, impaired wound healing, increased sweating, headaches, vertigo, allergic reaction, loss of muscle mass, osteoporosis, and abdominal distention. Other side effects of methylprednisolone may also mask signs of infection, make one susceptible to a new infection, and make it difficult to localize the source of an infection.
6. Other, currently unforeseeable, risks and side effects may occur.

CONSENT

This consent will function as an addendum to the consent form entitled Informed Consent for In Vitro Fertilization, which we executed previously. We, the undersigned, have read this document, understand the purposes, risks, and benefits of this procedure and have been given the opportunity to ask questions about it, which have been answered to our satisfaction. We consent to fertilization of our embryos using ICSI.

Female

Male/Partner

Print Name

Print Name

Date of Birth

Date of Birth

Date

Date