

## CONSENT FOR INTRACYTOPLASMIC SPERM INJECTION (ICSI)

Intracytoplasmic sperm injection (ICSI) is a specialized assisted reproductive technique (ART) employed in the in vitro fertilization (IVF) laboratory whereby a single sperm is injected into an egg to achieve fertilization. The most common indication for ICSI is male factor (low quality sperm). However, other clinical situations such as unexplained infertility, poor prior fertilization in the IVF lab using standard fertilization techniques, and a low egg count are also common indications. On occasion, the quality of sperm on the day of egg retrieval may be found to be reduced despite no known male factor, prompting ICSI to be done in an effort to optimize fertilization of eggs.

In preparation for ICSI the sperm specimen is processed to filter out abnormally shaped and slow moving sperm. Once a sperm that meets the correct parameters for a normal sperm is found, it is drawn into an injection pipette. In order to perform ICSI, each egg must first be stripped of the multiple cells surrounding it (cumulus cells), in order to assess its maturity. Mature eggs are then placed in a laboratory dish containing a growth medium and mineral oil. Each egg is in turn held in place with small glass tools (pipettes) and using an exceptionally fine hollow needle (injection pipette) containing a single sperm, each egg is then injected. The needle bypasses both the outer shell (zona pellucida) and the cell membrane of the egg, and the sperm is deposited into the body of the egg (cytoplasm). Upon completion of the procedure, the injected egg is placed into culture medium in the incubator. A fertilization check is typically performed the next morning to determine which eggs fertilized normally. Only normally fertilized eggs (embryos) are maintained in culture for a later transfer into the uterus, or for freezing (embryo cryopreservation) for future use. All unfertilized eggs or abnormally fertilized eggs will be discarded.

The risks associated with ICSI include, but are not limited to (1) the destruction of the egg by mechanical trauma, environmental exposure or handling, (2) abnormal fertilization resulting in a non-viable embryo (reported incidence may be as high as 25% compared to 7 to 10% for non-treated eggs), (3) failed fertilization despite treatment (reported to be less than 15%), and (4) increased risk for major congenital anomalies and/or chromosomal or genetic abnormalities in resulting pregnancies. The expected benefit of ICSI includes increased fertilization success and the establishment of pregnancy for couples otherwise unable to conceive.

ICSI is a relatively new procedure with the oldest ICSI babies reported to be born in 1993. The general population risk of babies born with a major congenital anomaly is 2-3% (without assisted reproduction). Studies have shown that the overall risk of major congenital malformation in children born after ART is around 30% higher (about 4% overall risk) than that in children conceived spontaneously. Furthermore, some studies have suggested an even greater risk of major congenital anomalies in children born after ICSI over the risk with standard IVF (up to 50% greater risk, or about 6% overall risk). In cases of severe male infertility (men having less than 5 million sperm per milliliter), men may have chromosomal or genetic abnormalities which could potentially be passed on to their children through ICSI. Increased prevalence of microdeletions (errors) on the Y- chromosome of male children born to couples who employed ICSI has been detected, along with an increase in the frequency of sex chromosome abnormalities (XXY, XYY) (at a rate of 1-2% increase); or autosomal (non sex chromosome) translocations. Couples who wish to have ICSI done have the option of having chromosomal and genetic testing performed on the male partner prior to undertaking IVF. Furthermore, it is recommended that couples who conceived with ICSI pursue prenatal diagnostic testing such as chorionic villus sampling (CVS) or amniocentesis to detect chromosomal abnormalities.

Initials \_\_\_\_\_

**Certification of Informed Consent for Intracytoplasmic Sperm Injection**

Your signature below indicates that you have read the preceding consent, and that you understand the potential risks and benefits of ICSI, that you have had the opportunity to ask questions, and that your questions have been answered to your satisfaction.

\_\_\_\_\_  
PATIENT NAME (PRINT)

\_\_\_\_\_  
PATIENT SIGNATURE

\_\_\_\_\_  
DATE

\_\_\_\_\_  
PARTNER NAME (print)

\_\_\_\_\_  
PARTNER SIGNATURE

\_\_\_\_\_  
DATE

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WITNESS (print)

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WITNESS SIGNATURE

\_\_\_\_\_  
DATE