Consent form for Intracytoplasmic Sperm Injection (ICSI)

The ART Institute of Washington at Walter Reed Army Medical Center

A - We understand that the purpose of this document is to give our consent to the embryology team at The ART Institute of Washington at Walter Reed Army Medical Center to perform intra-cytoplasmic sperm injection (ICSI) using the sperm and eggs of our IVF procedure.

B - We understand that the ICSI procedure is performed when the sperm may not be judged adequate to achieve fertilization using conventional insemination (putting the eggs and sperm closely together). It is also used to increase the chances of fertilization in those cases where fertilization has failed or was substantially reduced in a prior IVF cycle. ICSI is also used in cases where sperm has to be retrieved from the epididymis or testicle because spermatozoa are not present in the semen. Occasionally, it is decided to do ICSI because it allows for closer observation of the eggs compared to standard insemination.

C - We understand that physicians and scientists of The ART Institute of Washington at Walter Reed Army Medical Center believe that the ICSI procedure will be beneficial to us because the chances of successful fertilization will improve, and thereby increase our chances of pregnancy. However, we understand that there is no guarantee that we will achieve fertilization or that any embryos which are transferred will implant and result in a pregnancy.

D - Other consent agreements for IVF, cryopreservation and assisted hatching are not altered by this consent form. Our decision to request the ICSI procedure in no way affects our ability to complete any other component of an IVF cycle.

E - We understand that ICSI involves the following:
- Obtaining the male specimen that contains the sperm by masturbation, from frozen samples, or through surgical aspiration.
- Preparation of the sperm to purify the sample and obtain the optimal number of sperm for the micro-injection procedure.
- After egg retrieval, enzymes will be used to remove the granulosa cells surrounding the eggs. This enzyme has been used in a large number of studies and has very rarely been known to cause removal of the zona pellucidae (outside layer) from some eggs that are unusually sensitive to the enzyme. Inadvertent zona removal at this stage is likely to be detrimental.
- Only mature eggs that are ripe and ready to be fertilized are suitable for ICSI, so they will be separated from the other eggs. Normally, three quarters or less of the eggs are mature. In rare cases, none are mature. The mature eggs will then be grasped with a holding pipette using a micromanipulator.
- A single sperm will be picked up with a small injection pipette from a droplet containing a highly viscous fluid made with a substance called PVP. Hypothetical problems have been described in the medical literature about the use of PVP, including the potential for reduced fertilization and/or increased chromosomal abnormalities. In general, these risks are considered small.
- With the narrow injection pipette, one sperm will be inserted into each egg.
- The egg(s) will be returned to the incubator, and will be examined 14 to 18 hours later to determine if fertilization has occurred.
F - We understand that the female partner will also receive antibiotics for three days, that will usually be doxycycline 100mg two times per day beginning on the day of retrieval. This drug is to protect the embryos from bacterial contamination and attack by immune cells. There will be no other differences from the standard IVF protocol, when embryo replacement typically occurs three or 5 days after retrieval.

G - We understand that ICSI may involve the following risks or disadvantages:

- The eggs may be damaged during the ICSI procedure. Serious damage that threatens egg viability actually occurs in less than 10% of the eggs. Some batches of eggs may be over-sensitive resulting in higher damage rates.
- The exact likelihood of fertilization for any single egg or individual patient cannot be accurately predicted. However, fertilization rates currently exceed 65% per egg and over 95% of couples usually have some embryos to transfer. Nevertheless, failure of fertilization or embryo transfer may occur.
- Even when embryos are transferred, there is no guarantee that pregnancy will occur.
- This technology is still new, and there may be unknown risks to the baby or mother.
- There appears to be a very slight risk of transmitting abnormal numbers of X or Y chromosomes present in the sperm cell to the fetus, since in spermatozoa from some men, these so-called sex chromosomes are present in abnormal numbers.
- Patients with very low sperm counts or without spermatozoa in their semen may transmit similar fertility problems to the male fetus and male babies born. In some groups this occurs in up to 10% of patients. Genetic transmission of abnormal gene(s) occurring on the Y chromosome and their anomalies are known as Y deletions. The highest risk of infertility transmission is in certain men with very low sperm counts and in others where there are no spermatozoa present in the semen sample and who require testicular sperm retrieval.
- While there seems to be no higher overall incidence of congenital malformations in children born after ICSI with using either regular sperm or epididymal or testicular spermatozoa, the risk cannot be totally ruled out.

H - Disposition of unwanted or unsuitable spermatozoa and eggs

In the event that we have unused or unripe spermatozoa, we understand that these may be subjected to further observation and appropriately discarded. Under no circumstances will these spermatozoa be used for fertilization purposes or donation to other individuals, couples, corporations or institutions. In the event that we have unripe, unfertilized or abnormally fertilized eggs, we understand that these may be subjected to further observation and appropriately discarded. We understand that these eggs will never be used in part or whole for fertilization purposes or donation to other individuals, couples, corporations or institutions and that any further culture will be ceased immediately after observation. We also understand that these eggs are unwanted and considered abnormal.

I - At any time prior to egg retrieval, we understand that we may cancel our consent for performance of the ICSI procedure; however, once egg retrieval has taken place, irrevocable steps for the performance of ICSI will occur. Any information obtained during this procedure and identified with us will remain confidential and will be disclosed only with our permission. Any publication resulting from this procedure will not identify us individually. Representatives of The Food and Drug Administration (FDA), The Center for Disease Control (CDC) and The Departments of Health of Washington DC and Maryland may inspect the records.
J - We hereby attest that we have read this entire consent form, or that it has been read to us, so that we understand it completely. We further attest that any and all questions of ours regarding this procedure have been answered to our complete satisfaction.

Name female partner ____________________  Signature _____________________

Name male partner ____________________  Signature _____________________

Name physician ____________________  Signature _____________________

Name witness___________________  Signature _____________________

Date: _________________________