

## Consent for Injection of Sperm into Human Oocytes (ICSI)

Name of Patient: \_\_\_\_\_

Name of Partner: \_\_\_\_\_

We, the Patient and Partner named above, are each over the age of twenty-one (21) years. By our signatures below, we request and authorize the performance of intracytoplasmic sperm injection. We acknowledge that the following has been fully explained to us by Regional One Health, its physicians, and employees and agents:

**Description:** Intracytoplasmic sperm injection (ICSI) is a laboratory technique to assist the process of normal fertilization in selection patients undergoing in vitro fertilization (IVF) therapy. ICSI can be applied in cases of male infertility, immunological infertility, or when there is failure of fertilization with conventional sperm insemination during previous or present treatment.

A single sperm is drawn up into a very narrow, sharp glass needle and is injected with a minimum of culture medium into the liquid center of the egg (cytoplasm). After the egg is manipulated in this manner, it is released and washed in fresh culture medium. All subsequent treatments will be the same as for non-manipulated eggs. Normally developing pre-embryos derived from ICSI will be transferred into the uterus. If agreed to by the patient, any non-transferred pre-embryos of good quality may be cryopreserved for future attempt(s) to achieve pregnancy (see *Consent for Cryopreservation of Embryos*).

**Inclusion Criteria:** We may be participants for this procedure for one of the following reasons:

1. Fertilization failure in a previous IVF treatment;
2. Semen parameters deemed too poor for conventional egg insemination techniques;
3. Sperm quality is borderline and we wish to undergo manipulation to try to enhance the number of pre-embryos available for transfer;
4. Sperm will be obtained through an epididymal aspiration or testicular biopsy;
5. Antisperm antibodies are present which may reduce the chance of spontaneous fertilization through conventional insemination; and/or
6. Use of frozen, thawed sperm.

In addition, we recognize that ICSI may be performed on one-day-old eggs if there is unexpected lack of fertilization or a poor fertilization rate using conventional insemination techniques. This is called "Rescue ICSI" when done the day after the initial insemination technique. These embryos do have a lower probability of implantation but have been successful in some cases.

**Risks and Benefits:** ICSI was initially developed in Belgium in the late 1980s. Researchers in Belgium have reported a major malformation rate of 2.6% among 877 children born through ICSI. In a study from New York, the rate of major malformations was 1.6% among 578 children achieved through this technique. These rates are not higher than the major malformation rate of children conceived spontaneously through intercourse.

Recent investigations have suggested that men with severely impaired sperm production have a relatively high prevalence of Y chromosomes submicroscopic deletions (these men are missing very small segment(s) of the Y chromosome). One 1997 study reported that these deletions were found in 7% of men who had no sperm in their semen, 10% with sperm counts less than 1 million/mL, and 8% of men with sperm counts between 1 million/mL and 5 million/mL. Men who have low or absent sperm counts due to an obstructive process (such as vasectomy or congenital absence of the vas deferens) should not have this problem. In a very small study published in 1996, 9% of ICSI-derived sons had Y chromosome deletions. Hence, men with partial Y chromosome deletions may have boys with similar genetic defects after assisted reproduction. These boys may have problems with infertility when they reach adulthood.

ICSI is normally performed on the day that the eggs are collected. When ICSI is performed on the day after the egg collection on eggs that unexpectedly failed to fertilize with conventional insemination, there may be a greater chance of a chromosome abnormality in the resulting pre-embryo. This is thought to be possible due to the effect of aging on the egg.



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Form No. ROH.561 (Created 5/15) \*OB0481\*

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Affix Patient Label

Patient's Initials \_\_\_\_\_

Partner's Initials \_\_\_\_\_

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We understand that ICSI is intended to benefit us personally by creating additional opportunities for the initiation of pregnancy. We recognize that piercing the cell membrane of the egg may lead to irreparable damage and degeneration of the egg and may yield abnormal pre-embryos. We understand that additional medical studies must be performed worldwide to determine with certainty whether manipulation of the egg through ICSI does or does not increase the risk of fetal abnormalities or obstetric complications. We acknowledge that a blood chromosomal test can be performed to determine if there is a Y chromosomal deletion in the male partner who has no or few sperm in his semen due to non-obstructive causes. In addition, we understand that amniocentesis and/or detailed early second trimester ultrasounds can be performed to detect genetic or structural abnormalities of the fetus during early pregnancy.

We further understand that, with any technique necessitating mechanical support systems, equipment failure can occur. Neither Regional One Health nor UT Regional One Physicians, Inc., and their respective physicians, employees, consultants, or agents are to be held liable for any destruction or damage caused by or resulting from any malfunction of equipment, failure of utilities, strike, cessation of services, or other labor disturbance; any war, acts of public enemy, or other disturbance; any fire, wind, earthquake, flood, or other acts of God; or the failure of any other laboratory.

Besides the risks listed above, there may be others that are unforeseeable at this time.

We accept the risks described above and hereby release, discharge, indemnify and forever hold harmless Regional One Health, UT Regional One Physicians, Inc., and their respective employees, agents, directors, officers, and contractors from any and all liability and responsibility of any nature whatsoever that may result from complications of pregnancy, childbirth, or delivery, or from the birth of an abnormal infant or infants in any respect, or from the heredity or hereditary tendencies of such infant or infants, or from any other adverse consequences that may arise in connection with or as a result of any procedure described herein.

**Costs and Payments:** We understand that the cost of ICSI will be our responsibility.

**Voluntary Consent:** We certify that we have read this consent form or it has been read to us and that all questions have been answered by the physician. We each acknowledge and affirm that we have given our consent and signed this consent form without coercion or compulsion and of our own free will.

\_\_\_\_\_  
Patient Signature Date

\_\_\_\_\_  
Partner Signature Date

\_\_\_\_\_  
Patient Printed Name

\_\_\_\_\_  
Partner Printed Name

\_\_\_\_\_  
Witness Signature Date

\_\_\_\_\_  
Witness Printed Name



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### Physician Attestation

The above mentioned Patient and Partner (if applicable) have been informed and counseled by me and others regarding the risks and benefits of the relevant treatment options, including non-treatment. The Patient and Partner (if applicable) expressed understanding of the information presented during the discussion.

\_\_\_\_\_  
Physician Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Physician Printed Name

[Notary Page to follow]



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**Consent for Injection of Sperm into Human Oocytes (ICSI)**

[Notary Page for: Consent for Injection of Sperm  
Into Human Oocytes (ICSI)]

STATE of \_\_\_\_\_ )  
 ) :SS  
COUNTY of \_\_\_\_\_ )

The foregoing instrument was acknowledged before me this \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_, by  
\_\_\_\_\_, referred to in this consent form as "Patient".

My commission expires: \_\_\_\_\_ .

\_\_\_\_\_  
Notary Public

STATE of \_\_\_\_\_ )  
 ) :SS  
COUNTY of \_\_\_\_\_ )

The foregoing instrument was acknowledged before me this \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_, by  
\_\_\_\_\_, referred to in this consent form as "Partner".

My commission expires: \_\_\_\_\_ .

\_\_\_\_\_  
Notary Public



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