

REPRODUCTIVE ENDOCRINE ASSOCIATES OF CHARLOTTE, P.C.

Consent Form for Intracytoplasmic Sperm Injection (ICSI)

INFORMED CONSENT

We, _____ and _____
(Print names as appear on driver’s license)

understand that the purpose of this document is to give our consent to REPRODUCTIVE ENDOCRINE ASSOCIATES OF CHARLOTTE, P.C. (“REACH”) and the embryology team associated therewith to perform a procedure known as Intracytoplasmic Sperm Injection (ICSI) described more fully below.

A. We understand that the Intracytoplasmic Sperm Injection (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, the ICSI procedure is performed because it allows for closer observation of the eggs compared to standard insemination.

B. We understand that the scientists associated with REACH 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.

C. Neither of the other consent agreements for assisted hatching, nor the IVF Agreement which we may have executed, are altered by this consent form. Our decision to request the use of the ICSI procedure in no way affects our ability to complete any other component of an IVF cycle.

- D. We understand that ICSI involves the following:
- (1) Obtaining the male specimen that contains the sperm by masturbation, from frozen samples, or through surgical aspiration.
 - (2) Preparation of the sperm to purify the sample and obtain the optimal number of sperm for the micro-injection procedure.
 - (3) 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 zonae pellucidae (outside layer) from some eggs that are unusually sensitive to the enzyme. Inadvertent zona removal at this stage could be detrimental.

- (4) Only mature eggs that are ready to be fertilized are suitable for the ICSI procedure. Therefore, mature eggs will be separated from the other eggs. Normally, three-quarters (3/4) 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.
 - (5) A single sperm will be picked up with a small injection pipette and inserted into each mature egg cell.
- E. We understand that by consenting to the ICSI procedure, physicians will prescribe an antibiotic for the Male Partner to be taken during the Female Partner's stimulation cycle to reduce the risk of bacterial contamination in the semen specimen.
- F. We understand that the female partner will also receive antibiotics for four (4) days - beginning on the day of retrieval. These drugs are prescribed to protect the embryos from potential bacterial contamination and attack by immune cells within the female reproductive anatomy (vagina, cervix, uterus). No other differences from the standard IVF protocol are anticipated.
- G. We understand that the ICSI procedure may involve the following risks or disadvantages:
- (1) The eggs may be damaged during the ICSI procedure. Serious damage that threatens egg viability usually occurs in less than ten percent (10%) of the eggs. Some batches of eggs may be over-sensitive resulting in higher damage rates.
 - (2) The exact likelihood of fertilization for a single egg or individual patient cannot be accurately predicted. However, fertilization rates currently exceed sixty-five percent (65%) per egg and over ninety-five percent (95%) of couples usually have some embryos to transfer. Nevertheless, failure of fertilization or embryo transfer may occur.
 - (3) Even when embryos are transferred, there is no guarantee that pregnancy will occur.
 - (4) The ICSI procedure is currently regarded to be a safe and standard therapeutic option in assisted reproduction technologies, but there may be unknown risks which future research may disclose.
 - (5) The physical union of the egg and sperm by the ICSI procedure cannot correct any abnormal chromosomal or genetic abnormalities already present in the sperm or egg. Any sperm or egg containing genetic or chromosomal defects (either known or unknown) which are used to create an embryo, may then perpetuate such abnormalities into the embryo.

- (6) Men with very low sperm counts or without spermatozoa in their semen may transmit similar fertility problems or other defects by way of underlying genetic defects to male offspring. The highest risk for transmitting such genetic defects is in certain men with extremely low sperm counts, or those who have no spermatozoa present in the semen sample and who require testicular sperm retrieval.
- (7) The quantity of corticosteroids given to the Female Partner is considered a small dose. Several thousand patients have been treated with this regimen in cycles where there was some zona manipulation. We understand that these corticosteroids may mask signs of vaginal yeast infection and new infections may occur during use. Also, blood pressure may increase, salt and water retention may occur, and excretion of potassium and calcium may be accelerated, though such complications would be extremely unlikely with the use of such low doses of steroids used for IVF-ICSI treatment. Nevertheless, in certain rare cases, the corticosteroids may cause one or more of the following: mood swings, insomnia, depression, psychotic manifestations, muscle weakness, impaired wound healing, increased sweating, headache, vertigo, allergic reaction, loss of muscle mass, osteoporosis and abdominal distention, nausea, vomiting, diarrhea, loss of appetite, rashes, sensitivity to the sun, and hypersensitivity reactions resulting in shock, and blood diseases (including reduced platelets or fractured red cells).

H. In the event that we have unused or immature spermatozoa, we understand that such genetic material may be subjected to scientific observation or discarded without further observation. 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 immature, unfertilized or abnormally fertilized eggs, we understand that these items of genetic material may be subjected to scientific observation or discarded without further observation.

I. 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 the ICSI procedure 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.

J. **Execution of Consent**

By signing this form below we expressly indicate and certify the following:

- 1. That we have read and understand each and every provision herein;
- 2. That we have been given the opportunity to review this document with any and all third parties of our choosing;
- 3. That we have been given an opportunity to ask any and all questions;

4. That for each question we have asked, we have received a satisfactory answer;
5. That we know that we may ask additional questions at any time in the future;
6. That we may discontinue this program at any time in the future; and
7. That we are over the age of twenty-one (21).

Female Partner's Signature

Date

Male Partner's Signature

Date

REACH representative verifying completion of consent

Date

Witness – if signed outside of REACH

Date