

The Fertility Center of Colorado

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**CONSENT FOR INTRA-CYTOPLASMIC
SPERM INJECTION INTO EGGS**

Patient Name _____ SS# _____

Partner Name _____ SS# _____

This agreement is a contract made and to be performed at Colorado Springs, Colorado, between _____ ("Patient"), _____ ("Partner"), and the Fertility Center of Colorado ("the Center").

DESCRIPTION

Patient and partner wish to try to achieve a pregnancy by means of *in vitro* fertilization under the Center's Assisted Reproductive Technologies ("ART") Program and are enrolled therein. The Center offers its Intra-Cytoplasmic Sperm Injection Program ("the ICSI Program") to qualified ART patients as an option upon the terms and conditions of this agreement. The Center's ART and ICSI Programs are designed to aid couples who are infertile due to one or more conditions.

Micromanipulation of the oocytes (eggs) for assisted fertilization is a technique designed to bring the sperm and egg closer together, increasing the chances of fertilization for certain infertile couples. The procedure is performed by piercing the zona pellucida (the egg "shell") and the cell membrane of the egg with a microneedle. A single sperm is injected into the egg.

To enable the staff to focus on the mission of the Center and to help keep patient costs affordable, reasonable limitations must be placed upon liability. Paragraph I-C is included below to benefit all patients of the Center, including Patient and Partner.

Patient and Partner acknowledge that they have consulted or had opportunity to consult with such advisors as were necessary to enable them to decide to participate in the ICSI Program, to enter into this Agreement, and to sign the related consent forms.

In consideration of the premises and the rights and obligations created hereunder, Patient and Partner and the Center agree as follows:

PART I – AGREEMENT

- A. The male Partner agrees to provide his sperm, and the female Patient agrees to provide her oocytes (eggs) to the Center to be used by the Center in accordance with this Agreement. (If donated sperm or eggs are to be used, a separate form is required to be signed and attached hereto.) The Center shall use its laboratory procedures in an effort to achieve fertilization of one or more of the eggs.

- B. Patient and Partner may be selected as participants in this treatment protocol for one of the following reasons: (i) previous *in-vitro* fertilization (IVF) attempt(s) have failed to result in fertilized eggs or resulted in a low percentage of fertilized eggs; (ii) we have semen parameters too poor acceptance in the standard IVF procedure; or (iii) sperm quality is borderline and we wish to undergo micromanipulation to try to enhance the number of pre-embryos available for transfer.
- C. In consideration of being accepted into the Programs of the Center, Patient and Partner waive, to the maximum extent permitted by law, any and all claims which they or either of them may hereafter be entitled to assert to recover damages from the Center, or any personnel thereof, for mental suffering, emotional distress, failure to achieve pregnancy, representations as to the likelihood or rate of success in achieving pregnancy, or any related cause of action or basis for liability. No assurance has been, or can be, given as to achieving the pregnancy of the Patient.
- D. If Patient or Partner or both of them shall make the Center or any of its officers a party to any litigation arising from any disagreement between Patient and Partner as to the rights of either or both of them hereunder as to each other or as to the Center, Patient and Partner shall be liable for the reasonable attorney's fees and other costs of the Center in such litigation unless the Center is found therein to have (i) breached this Agreement, (ii) acted arbitrarily and capriciously so as to justify being made a party to the legal proceedings, or (iii) committed a tort (wrong) against Patient and/or Partner.
- E. In consideration of the foregoing and in reliance on the reasonable accuracy of information given by Patient and Partner in their application for the ART Program, the Center accepts Patient and Partner into the Center's ICSI Program, subject to obtaining their informed consent below.

**PART II – INFORMED CONSENT FOR
INTRA-CYTOPLASMIC SPERM INJECTION INTO EGGS**

- A. We (the undersigned Patient and Partner) understand that ICSI is a clinical procedure performed under the direction of the Fertility Center of Colorado ("the Center"). We understand that participation in this clinical procedure is voluntary. If we elect not to participate, our decision will not affect our relations with the Center or result in any penalty or loss of benefits to which we are otherwise entitled.
- B. We further understand that this procedure is intended to benefit us personally by creating additional opportunities for the initiation of pregnancy.
- C. We understand that the micromanipulation techniques may damage an egg resulting in its loss of fertilizability and/or viability. Also, we understand that the ability of the manipulated eggs to establish pregnancy after transfer in the human has not been fully determined. It is unknown if manipulation of the egg will increase the risk of obstetric complications or fetal abnormalities. We understand that any pregnancy may produce an infant with a birth defect; this includes any pregnancy that results from the above described therapy. Birth defects can be minor (such as an extra rib) or major (such as a defect in the development of the heart, lungs or kidneys that is incompatible with life). We understand that a birth defect, whether or not resulting from this procedure, may not be detected by prenatal testing.
- D. Micromanipulation of the egg requires specialized equipment specifically designed to perform the very small intricate movements utilized during the procedure. We understand that prior to manipulation, eggs may be treated with a solution containing hyaluronidase, an enzyme which will remove the cumulus cells surrounding the egg and which will allow visualization of the egg itself. The egg will be held in place by an egg-holding pipette while the microneedle is introduced to the egg. After the egg is manipulated, it is released and

washed in fresh culture medium. All subsequent treatment will be the same as for non-manipulated eggs. Any pre-embryos developing normally after this procedure may be transferred to the uterus or cryopreserved.

- E. Any information obtained during these procedures that can be identified with us will remain confidential and will be described to individuals not connected with this project only with our written permission. We understand that photographs or videotapes may be taken of the pre-embryos during the ICSI procedures as a permanent record and for possible use at a medical meeting or with the lay public for educational purposes. We understand that confidentiality will be maintained. We understand that we have the right to review these records at any time, and we authorize any appropriate government agency to do so.
- F. We understand that with any technique necessitating mechanical support systems, equipment failure can occur. Neither the Center nor its directors, employees, or consultants are to be held liable for any destruction or damage, caused by or resulting from any malfunction of the mechanical systems, failure of utilities, strike, cessation of services or other labor disturbance, any fire, wind, earthquake, water, or other acts of God, or the failure of any other laboratory equipment.
- G. We are advised that the Center provides no insurance coverage, compensation plan, or free medical care plan to compensate us if we or our pre-embryos are harmed in any way by this micromanipulation procedure. If we believe that we have been harmed, we may contact the Center, which will be glad to review the matter with us.
- H. We understand that all costs for infertility testing and any and all IVF procedure (including the manipulation techniques described herein) will be our responsibility.
- I. We have read this document carefully and know we should ask questions about anything which is unclear before we decide whether to be participants in this procedure. Our signatures below mean that we freely agree to participate in this treatment. We understand and accept the risks involved in the use of Intra-Cytoplasmic Sperm Injection to increase the chances of becoming pregnant. We understand no warranty or guarantee has been made to us as to the results of this procedure.

Signed:

_____ (Patient) Date _____

_____ (Witness) Date _____

_____ (Partner) Date _____

_____ (Witness) Date _____

The Fertility Center of Colorado:

_____ Date _____

Authorized Representative