

Patient Informed Consent

Intracytoplasmic Sperm Injection (ICSI)

INTRODUCTION

We are unable to achieve a successful pregnancy because of a diagnosis of severe male factor infertility. We desire to attempt to achieve fertilization by micromanipulation (“assisted fertilization”). We hereby request and authorize the Geisinger Medical Center (“GMC”) and Fertility Center physicians (“Physicians”) and such other assistants as they may designate to perform intracytoplasmic sperm injection (“ICSI”).

In authorizing these procedures we acknowledge that we have had the opportunity to discuss fully with the Physicians the nature and purpose of the procedure, the risks, the alternatives, the risks to the alternatives and that all of our questions have been answered to our satisfaction. Based on our discussions with the Physicians and the written materials explaining the procedure supplied to us, we understand the following concerning ICSI:

NATURE AND PURPOSE OF THE PROCEDURE

- 1) The micromanipulation procedures that will be performed on the oocytes will be direct cytoplasmic injection. To perform these procedures, highly specialized equipment is used in which microsurgical instruments are manipulated with the aid of a microscope.
- 2) In direct cytoplasmic injection, a single sperm cell is directly injected into the oocyte. Following this procedure, the oocytes are incubated for several hours and are subsequently inspected for the presence of fertilization. If fertilization does occur, then the fertilized oocytes are inspected for cleavage and transferred in a manner similar to that employed for non-microinjected embryos.

RISKS OF THE PROCEDURE

- 1) Fertilization is not guaranteed.
- 2) Understand that with any technique necessitating mechanical support systems, equipment failure can occur. Neither the IVF team nor GMC are to be held liable for any destruction, damage caused by or resulting from any malfunction of the micromanipulation equipment or failure of utilities.

- 3) Understand that the world experience in ICSI procedures is limited to date. No assurances can be made whatsoever concerning the viability of microinjected oocytes or of the absence of congenital abnormalities in a fetus developing from microinjected eggs.
- 4) It appears unlikely that the mechanical manipulation of eggs and sperm during ICSI should lead to structural abnormalities in liveborn children. Current data provide no evidence for such a teratological effect of ICSI.
- 5) Male partners in ICSI programs are at an increased risk of carrying chromosomal aberrations. There is a risk for any child conceived through ICSI, of inheriting a defective Y chromosome from the father, and the expression of infertility associated with it.
- 6) It is recommended that all couples in whom a pregnancy has been established by ICSI follow up with chorionic villus sampling (CVS) or amniocentesis.

ALTERNATIVES

The Physicians have reviewed the alternatives to this procedure with us, including the risks and benefits of these alternatives.

CONFIDENTIALITY

We understand that GMC and the Physicians are actively involved in medical education and research. We agree that information concerning our treatment may be used in medical publications provided that our identities or identifying information is not revealed. All procedures carried out under this program will remain confidential between the involved couple and professional personnel.