

**Associated Fertility and Gynecology**

Shelby Cooper, MD  
7910 West Jefferson, Ste. 301  
Fort Wayne, Indiana, 46804

**Assisted Reproductive Technologies(s) Consent Form**

Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_ Time: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Female: First Name: \_\_\_\_\_ Last Name: \_\_\_\_\_

Male Partner First Name: \_\_\_\_\_ Last Name: \_\_\_\_\_

We have been unable to conceive by natural means and by other methods attempted. We therefore authorize and request Associated Fertility & Gynecology, PC, and Shelby Cooper, M.D. to use assisted reproductive procedures such as IVF-ET (in vitro fertilization) and/or GIFT (gamete intrafallopian transfer) and/or ZIFT (zygote intrafallopian transfer) for treatment of our infertility.

I. Procedure

We understand and consent to the following steps and processes involved in this/these procedure(s) which have been fully explained to us by Dr. Shelby Cooper and/or his staff:

- A. Obtaining medical records, lab tests, history and physical examinations, etc. to determine whether or not we are candidates for the contemplated procedure(s).
- B. Various drugs will be prescribed to me for induction and stimulation of growth and maturation of my follicles (eggs) within my ovaries.
- C. Blood samples will be taken throughout the process to evaluate hormonal levels that indicate the development of the follicles, and assist in determining medication doses and timing of medications/ procedures.
- D. Ultrasound studies will be performed on me periodically to assist in the same manner as I.C., which will provide visual images of the follicles, lining of the uterus and other pelvic structures.
- E. When at least one follicle is sufficiently developed, I will be given an injection of hCG (human chorionic gonadotropin) and one and one half days later have a procedure for retrieval of my oocytes (eggs). This will usually be done by ultrasound directed aspiration or rarely by laparoscopy. Transvaginal ultrasound guided aspiration of the follicles is performed by placing a needle through a "guide" on the ultrasound probe, through the vaginal wall and into the follicles in the ovaries. Laparoscopy is an operative procedure in which a small "telescope" is placed through the abdominal wall allowing visualization of the inside of the pelvis and is used for GIFT (or ZIFT) procedures. Laparoscopy may become necessary for IVF oocyte retrieval if for any reason transvaginal retrieval is not appropriate.

F. Conscious sedation will be used for transvaginal oocyte retrieval. General anesthesia may be used for the GIFT (or ZIFT) procedure and laparoscopic oocyte retrieval, but conscious sedation is usually used with local anesthesia for the incisions.

G. The collected eggs will be evaluated and transferred to a culture dish.

H. A semen specimen will be obtained from the husband and prepared in the laboratory for the insemination or ICSI. Under unusual circumstances sperm obtained and frozen earlier may have to be used for the insemination or ICSI.

I. In the GIFT procedure, the sperm and eggs are placed into a catheter and transferred into the fallopian tube(s). In the fallopian tube the egg and sperm come together and fertilization is allowed to happen naturally. The fertilized egg then moves down the tube and into the uterus where implantation occurs. (With ZIFT, the 2 PN egg is transferred into the fallopian tube to proceed to growth and division, and subsequently be transported by the tube to the uterus.)

J. In the IVF procedure, the eggs will be inseminated or "micromanipulated" with procedures such as ICSI. The eggs are placed in culture dishes with processed sperm to allow fertilization. Following the pronuclear check for fertilization, the eggs will be transferred into another media for growth. The embryos will be cultured for 72 hours or up to 5 days for blastocyst development.

K. After normal development, an appropriate number of embryos will be placed into the uterus using a small catheter placed through the cervix, or by other means, which may be developed in the future. Embryos transferred at 72 hours may require assisted hatching before transfer.

L. Following IVF, GIFT (or ZIFT), the patient may be given various medications to support the luteal phase (second half) of my cycle.

M. Various blood tests will be taken to monitor the patient's condition as well as to determine whether or not pregnancy has occurred. Blood tests are used to monitor hormone levels during ovarian stimulation.

N. Ultrasound examinations will be used to evaluate my condition and progress.

O. Cells and/or body fluids may be discarded or analyzed; including semen, seminal fluid, follicular fluid, granulosa cells, peritoneal fluid, unfertilized eggs, etc.

P. With the patient's consent, embryos may be cryopreserved (see section on cryopreservation).

Q. With the patient's consent, rescue ICSI (intracytoplasmic sperm injection performed the second day) may be performed for failure of fertilization of the inseminated eggs.

## II. Risks and Complications:

A. Drugs used for induction of ovulation may cause over-stimulation of the ovaries, causing them to become massively enlarged. This may cause risks of rupture or torsion of the ovary, which could result in loss of the ovary. These drugs may also cause Hyperstimulation Syndrome, which may result in discomfort, fluid shifts within the body or even blood clots. This may necessitate bed rest or even hospitalization.

B. Laparoscopy/laparotomy have associated risks of injuries to any structure of the abdomen or pelvis as well as risks of infections, blood transfusions, reaction to medications, and postoperative hoarseness, pneumonia, blood clots and discomforts related to the surgery itself.

C. Transvaginal follicle aspiration also carries the risks of injuries to the bladder, blood vessels, bowel and ovaries. Laparoscopy/laparotomy may be necessary to deal with these complications should they occur.

D. Anesthesia carries the risks of drug reactions, respiratory problems, injury to vocal cords, teeth, or eyes; and even paralysis, brain damage or death.

E. There is a possibility that the fertilized egg will implant in the tube or abdomen resulting in an ectopic pregnancy, necessitating surgical intervention (laparoscopy/laparotomy). Also, miscarriage may occur which could require a D&C.

F. Pain, anxiety, depression and other psychological events may occur.

G. Multiple gestations may occur with the associated risks of this condition. These risks include possibility of miscarriage, premature labor and delivery, medical complications associated with the multiple gestations, extensive monitoring and medical care, the associated costs of treating and monitoring these conditions, as well as many other potential risks not enumerated in this text.

Options for high order multiple gestation may include continuing the pregnancy in its natural state, terminating the pregnancy or selective embryo reduction. We understand that neither Associated Fertility and Gynecology, P.C. or any of its employees will be responsible for any of these events. We further understand that arrangements for any termination of pregnancy will be entirely the patient's responsibility.

## III. We understand that a variety of occurrences may prevent pregnancy including:

A. Failure of adequate development of follicles, early LH surge or misjudged time of medications or oocyte retrieval. Cycle cancellation may also occur with these conditions

B. Attempt at oocyte retrieval, gamete transfer (or zygote) transfer may fail for a number of reasons.

C. The husband may be unable to provide an adequate semen specimen, or the backup specimen may not be adequate or may not have been collected.

D. Fertilization and/or cleavage may not occur for a number of reasons.

E. The embryo(s) may not be suitable for transfer.

F. Embryo transfer may not be successful.

G. Unforeseen events may occur which unfortunately may result in loss or damage to the egg(s), sperm, zygote or embryo (pre-embryo(s)).

IV. We understand that even if pregnancy is achieved, there are still risks of genetic abnormalities and birth defects. Current literature suggests that these events are no more common with IVF-ET, GIFT (and ZIFT) than with natural fertilization. Miscarriage and ectopic pregnancy may occur with somewhat more frequency than in the general population.

V. We understand that if pregnancy is achieved, we will need to have obstetrical care by an obstetrician of our choosing.

VI. We acknowledge that any children resulting from this procedure will be considered by us as our natural child whom we will be legally responsible for in all respects.

VII. We understand that we are solely responsible for any and all expenses incurred as a result of the procedure(s) as well as all the medication, testing, and other associated events. We also understand that insurance may not cover any or only a portion of these services.

VIII. We understand that the physician or staff have not made or implied any guarantee or warranty to us regarding the outcome or success of this procedure nor of the diagnostic procedures or treatment associated with the procedure.

IX. We understand that the physician/staff will make all reasonable efforts to keep all information obtained about us during the course of treatment confidential, unless expressly authorized by myself or as compelled by law.

X. We acknowledge that we have an adequate understanding of the IVF/GIFT(/ZIFT) procedure(s) and process, and have been informed of usual and most frequent risks and hazards inherent and the treatments associated with it. We also understand that there may be risks not known at this time. We have had ample time and opportunity to ask questions, and questions have been adequately answered.

XI. We have requested and given our consent to the physician and his staff to perform the IVF-ET/GIFT(/ZIFT) procedure and expressly release him and his staff from all liability and responsibility which may result in injury or death from complications in induction of ovulation, oocyte retrieval, transfer of eggs and sperm, subsequent embryo development, pregnancy and childbirth or from the birth of one or more infants abnormal in any manner, or of other adverse consequences to any of us or to our children which might arise in connection with or as a result of the procedure or any tests or treatments associated with it.

XII. We have read and fully understand this consent form and sign it freely and voluntarily.

Signed Female Partner \_\_\_\_\_ Date \_\_\_\_/\_\_\_\_/\_\_\_\_

Witness \_\_\_\_\_ Date \_\_\_\_/\_\_\_\_/\_\_\_\_

Signed Male Partner \_\_\_\_\_ Date \_\_\_\_/\_\_\_\_/\_\_\_\_

Witness \_\_\_\_\_ Date \_\_\_\_/\_\_\_\_/\_\_\_\_