

UNIVERSITY OB/GYN ASSOCIATES

**CONSENT TO PARTICIPATE IN THE
IN VITRO FERTILIZATION / GAMETE INTRA FALLOPIAN TRANSFER
PROGRAM AT THE FERTILITY CENTER AT
NORTON HEALTHCARE PAVILION**

Female Partner _____ Date: _____

Male Partner _____ Date: _____

I have been unable to become pregnant naturally and other methods of treatment have not produced a pregnancy. My partner and I hereby authorize University OB/GYN Associates, the Fertility Center at Norton Healthcare Pavilion to treat my infertility by use of techniques known as in vitro fertilization (IVF) and conceptus(i) transfer (commonly know as the "test tube baby" technique) and/or gamete intra fallopian transfer (GIFT) a variation of the "test tube baby" technique. We request, authorize, and consent to its use to attempt to become pregnant.

II. We understand and consent to the following steps involved in this/these procedure(s) as have been explained to us by Dr. _____.

Ia Comprehensive medical information will be obtained from us, including medical records, physical examinations, laboratory test, etc. to determine whether we are suitable candidates for the procedure(s).

Ib I will be prescribed an ovulation-inducing drug to stimulate growth and maturation of eggs (follicles) in my ovaries.

Ic Ultrasound examination will be conducted. Ultrasonography is a diagnostic procedure using sound waves that provide a "picture" of the ovaries and the growing follicle(s).

Id Blood samples will be collected for hormonal evaluation to assist in predicting follicle/egg readiness.

Ie When it is determined that at least one ovarian follicle is sufficiently developed, I will be given an injection of human chorionic gonadotrophin (hCG) and one and one-half days later will undergo retrieval of eggs either by laparoscopy or ultrasound. Laparoscopy is an outpatient operative procedure where by a small tube containing a light and viewing system is introduced through the navel to see the ovary and to withdraw the egg(s). Transvaginal ultrasound-guided aspiration is a procedure in which a needle is introduced into the pelvis through the vagina and follicles are aspirated. Laparoscopy is required with GIFT.

If General anesthesia will be used for laparoscopy retrieval. Either general anesthesia or sedation will be used for ultrasound retrieval.

Ig The egg(s) will be evaluated and transferred to a culture dish.

Ih A semen specimen from the male partner is obtained and prepared in the laboratory.

Ii In the GIFT procedure, the egg(s) and sperm are separately placed into a catheter and are then transferred into the fallopian tube(s). The egg and sperm come together in the fallopian tube(s) where the fertilization process is allowed to happen naturally. The resulting embryo(s) then move down the tube(s) and into the uterus for implantation.

Ij In the IVF procedure, sperm will be placed in a culture dish with the egg(s).

Ik Following normal fertilization, the egg(s) will be transferred to another media for growth.

II After normal development, an appropriate number of conceptus(i) will be transferred into my uterus using a small catheter, which is inserted through the cervix.

Im Two weeks after conceptus(i) transfer, pregnancy will be monitored by obtaining two or more blood samples.

In Any of the following bodily fluids or cells that would normally be discarded may be analyzed to better understand gamete maturation and fertilization: blood, seminal fluid, follicular fluid, sperm, granulosa cells, eggs that failed to fertilize after insemination or that fertilized abnormally (parthenogenesis or polyspermia). In some cases additional blood will be collected for research purposes.

II The following are some of the risks and discomforts associated with the various procedures. Current success rates are no greater than 35% for term pregnancy. The major risk of this procedure is that the technique may not succeed and that my partner and I will be disappointed. We may expect frustration, anxiety and depression, which may be severe.

IIa Ovulation inducing drugs may result in over-stimulation of the ovaries, which may cause pain due to the over-growth of one or more ovarian follicles and may cause ascites (fluid in the abdomen) which may require hospitalization and treatment with intravenous fluids. Other risks may include tenderness or infection of the injection sites, allergic reactions, nerve injury and failure to respond or excessive response which would result in cancellation of the cycle. Rarely ovaries can become so enlarged that rupture or twisting occurs which could require surgery.

IIb Blood tests may cause mild discomfort and a risk of developing a bruise at the needle site.

IIc At the extremely low energy levels utilized in diagnostic ultrasound no adverse effects of this procedure have been detected to date.

IId Laparoscopy/laparotomy may be associated with infection of the incision site or pelvic organs. It is possible to have perforation of bowel or bladder, internal bleeding, or formation of scar tissue – some of these risks may require immediate major surgery, others may require blood transfusion, antibiotic treatment, or delayed surgery.

IIe Aspiration of eggs(s) under ultrasonographic guidance may cause pain of short duration. Small amounts of blood in the urine may be seen a day following the procedure. Perforation of blood vessels, bladder or bowel, which may require laparoscopy or laparotomy to correct, may occur.

IIf Numerous possible complications from various drugs and procedures used in anesthesia may occur. These complications may include respiratory problems, paralysis, brain damage or even death. Other risks and hazards, which may result from the use of general anesthesia, range from minor discomfort to injury to vocal cords, teeth, or eyes.

IIg These are the possibility that the early embryo(s) may implant into a fallopian tube causing an ectopic (tubal) pregnancy that would require laparoscopy or major surgery for treatment. Miscarriage may also occur, which may require dilation and curettage.

IIh The transfer of multiple eggs into the fallopian tube(s) or embryos into the uterus increases the chance of success but may result in a multiple pregnancy with an increased risk of miscarriage(s), premature labor and an increased financial and emotional cost. (Recently it was mathematically estimated that the risk of multiple pregnancies for a five(5) embryo transfer was 38% for twins, 19% for triplets, 5% for quadruplets and 0.5% for quintuplets.)

Iii These may be psychological anguish and distress for which psychological/psychiatric therapy may be required.

III. We understand that any of the following may occur which would prevent pregnancy:

IIIa The time of ovulation may be misjudged, may be unpredictable, or ovulation may have already occurred in the monitored cycle, thus preventing any attempt to obtain an egg.

IIIb The operation to obtain an egg(s) may be unsuccessful.

IIIc The male partner may be unable to provide a suitable semen specimen. (If this is anticipated please bring it to our attention so that a semen specimen could be obtained in advance and frozen until needed.)

IIId Fertilization may not occur.

IIIe Cleavage or cell division of the fertilized egg(s) may not occur.

IIIf The egg(s) may not be normal or suitable for insemination.

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

IIIh Transfer of the embryo(s) may not be successful.

IIIi Implantation of the early embryo into the uterine lining may not occur.

IIIj Unfortunately, unforeseen events may occur that result in loss or damage to the egg(s)/sperm or pre-embryo(s).

IV We understand that even if pregnancy is achieved through the procedure, there are still risks of genetic defects or birth defects. However, there is no indication at present that in vitro fertilization and conceptus(i) transfer or GIFT when compared to the general infertility population increases the occurrence of these. Miscarriage, ectopic pregnancy and prematurity may be more common.

V We understand that if pregnancy is achieved follow-up obstetrical care must be undertaken by an obstetrician.

- VI We acknowledge that any child born from this procedure(s) will be considered by us in all respects our natural child, for whom we will be legally responsible.
- VII We understand that insurance coverage for any or all of the treatments and laboratory fees associated with the procedure may not be available and that we will be personally responsible for all expenses associated with this procedure(s), regardless of insurance coverage.
- VIII We understand that the serum used in the IVF/GIFT process is derived from the blood of multiple donors. Although all currently available precautionary measures are taken to assure the safety of donated blood, transmission of blood borne diseases remains possible.
- IX We understand that the physician and his/her associates will, unless otherwise compelled by law, or expressly authorized by us, make all reasonable efforts to keep information obtained about us during the course of treatment confidential. We agree that specific medical details may be revealed in professional publications as long as our anonymity is maintained.

Data from your IVF/GIFT procedure will also be provided to the Centers for Disease Control and Prevention (CDC). The 1992 Fertility Clinic Success Rate and Certification Act requires that CDC collect data on all assisted reproductive technology cycles performed in the United States annually and report success rates using these data. Because sensitive information will be collected on you, CDC applied for and received an "assurance of confidentiality" for this project under the provisions of the Public Health Service Act, Section 308(d). This means that any information that CDC has that identifies you will not be disclosed to anyone else without your consent.

These data will be used for epidemiological analysis and for the purpose of publishing an annual report as required. On a periodic basis, clinical programs will be subject to external validation by SART of their reporting activities, which will include review by appropriate professionals from outside the program staff. This review may include, but not be limited to, examination of medical and laboratory records, comparison of data in the reporting databases with data in the medical record, and direct communication with patients included in the reporting database. Patients may be contacted by professional reviewers as part of routine data validation and asked to confirm information provided in the database. Please indicate, by initialing below, your preference in participation in the data validation process:

- X We acknowledge that we have an adequate understanding of the IVF/GIFT process and have been informed of the usual and most frequent risks and hazards inherent in the procedure and the treatments associated with it. We understand that there may be some risks that are not known at this time. We have had the opportunity to ask questions and our questions have been answered to our satisfaction.
- XI We understand that the physician and his/her associates have not made or implied any guarantee or warranty to us about any particular result or success of IVF/GIFT or any result of any operative or diagnostic procedure or treatment associated with the process.
- XII We understand that in the event that one of the known contributing parties should disagree concerning whether or not the embryo(s) should be returned, the embryo(s) will be appropriately discarded or used for scientific purposes, at the discretion of the IVF Program Director.

XIII We understand that in the event that the male partner should die before embryo transfer, an advanced directive hereby selected by the male partner will determine the disposition of the embryo(s). These options will include:

- a. embryo transfer
- b. cryopreservation
- c. scientific observation
- d. disposal

MALE PARTNER TO CIRCLE SELECTED OPTION AND INITIAL.

XIV We understand that in the event that the female partner should die before embryo transfer, an advanced directive hereby selected by the female partner will determine the disposition of the embryo(s). These options will include:

- a. cryopreservation
- b. scientific observation
- c. disposal

FEMALE PARTNER TO CIRCLE SELECTED OPTION AND INITIAL.

XV In consideration for the IVF/GIFT procedure to which we consent and request the physician to perform, we expressly release him/her and his/her staff, the Fertility Center at Norton Healthcare Pavilion and University OB/GYN Associates from all liability and responsibility which may result in injury or death from complications in: transfer of egg(s) and sperm, subsequent embryo development, childbirth or delivery, or from the birth of one or more infants abnormal in any way, or from any other adverse consequences to any of us or our children which might arise in connection with or as a result of this procedure or any tests or treatments associated with it, except that we expressly understand and expect that this procedure and the treatments associated with it will be performed by the physician and his/her associates in full accordance with the customary standard medical care.

XVI If you have any questions, please contact the Fertility Center at Norton Healthcare Pavilion at (502) 271-5999; Dr. Steven T. Nakajima (IVF Program Director) at (502) 271-5999; Dr Alberto Carrillo (IVF Laboratory Director) at (502) 271-5999 x 1405. The University Human Studies Committee (502)-852-5188 is also available as an impartial third party to speak with you regarding any questions or complaints that you may have.

