

Female Patient Name _____ Social Security # _____

Partner's Name _____ Social Security # _____

THE CENTER FOR HUMAN REPRODUCTION (CHR)—ILLINOIS/NEW YORK CITY*



ASSISTED REPRODUCTIVE TECHNOLOGIES PROGRAM

Description, Explanation and Informed Consent

We _____ have been informed that our infertility may be treatable by Assisted Reproductive Technologies (A.R.T.). The members of the Center for Human Reproduction (CHR) staff, including physicians, nurses, procedure staff, clerical and laboratory personnel are known as the ART team. We understand that by signing this form, we evidence our consent to the use, by the ART team, of assisted reproductive technology procedures in connection with our participation in the Assisted Reproductive Technologies Program.

DESCRIPTION AND EXPLANATION OF PROGRAM

We understand that the ART program involves the use of the following procedures:

- Determination by standard infertility tests that we are suitable candidates for ART. These tests may include, but are not limited to blood tests, ultrasound tests, specialized x-rays to view the uterine cavity and sperm function tests.
- Use of "fertility drugs" to cause the development of more than one oocyte at a predictable time. Fertility drugs include clomiphene citrate, human menopausal gonadotropin (Repronex, Pergonal, Humegon), highly purified human follicle stimulating hormone (Metrodin, Fertinex), recombinant human follicle stimulating hormone (Gonal F, Follistim), leuprolide acetate (Lupron) so called antagonists (Antagon) and human chorionic gonadotropins (Profasi, Novarel).
- Treatment with antibiotics and/or glucocorticoids (steroids) to reduce inflammation and infection.
- Ultrasound examinations, combined with blood tests, to determine the expected time of oocyte maturation (progress of development) and ovulation. The ultrasound exams are performed transvaginally, with exceptions at times for abdominal scanning.
- Collection of oocytes from the Woman's ovary(ies) by placing a needle into the ovary and aspiration of follicular contents using ultrasound guidance. This is done while the woman is sedated (asleep) by an anesthesiologist.
- If applicable, collection and preparation of sperm obtained from the male partner by masturbation.
- Combining sperm and oocytes in an attempt to achieve fertilization in the laboratory (in vitro fertilization) or in the Woman's body (gamete intrafallopian transfer---GIFT). If reduced fertilization is expected or there is a history of fertilization failure, a micromanipulation procedure called Intracytoplasmic Sperm Injection (ICSI) may be performed in an effort to enhance fertilization.
- After fertilization occurs, embryos are allowed to develop in culture for several cell divisions until the embryologists and physicians determine that they are suitable for transfer to the woman's uterus or fallopian tubes. In some situations, a micromanipulation technique, called Assisted Zona Hatching (AZH), is performed prior to embryo transfer to increase the likelihood of establishing a pregnancy.
- Transfer of the embryo(s) to the woman's uterus by means of a plastic catheter (tube). In some situations, fertilized oocytes or early cleavage stage embryos are transferred to the fallopian tube(s) using either of two procedures called Zygote Intrafallopian Transfer (ZIFT) or Tubal Embryo Transfer (TET). Either of these two procedures are performed during a laparoscopy, a surgical procedure under general anesthesia.
- Obtaining blood samples, and if indicated, ultrasound examinations several times in the subsequent 8-12 weeks to determine if pregnancy has occurred and is proceeding normally.
- Treatment with progesterone to maintain early pregnancy or with human chorionic gonadotropin (HCG) to support luteal function.

* Per NY State Law doing business as the Medical Offices for Human Reproduction (MOHR)

RISKS/ REASONS FOR ADVERSE RESULTS

"Recent studies have suggested that IVF may be associated with an increased risk of having children of low birth weight and with twice the usual risks of birth defects. Even though we believe that these risks are due to underlying infertility, and not the IVF procedure itself, such a direct cause and effect relationship can at this point not be ruled out."

Each of us has been informed that neither becoming pregnant nor a successful outcome of the pregnancy can be assured as a result of assisted reproductive technology procedures. We have also been informed that the world wide pregnancy rate following ART is approximately 20%. We have been informed that the practice of medicine is not an exact science and that no guarantees have been made to us as a result of this procedure. We have also been informed that there are many complex and sometimes unknown factors that may limit pregnancy rates in ART. Some of the known risk factors include:

1. Irritation, redness or swelling may result from the injection of fertility and other medications.
2. Hemorrhage, hematoma and/or infection may result from frequent blood drawing.
3. Medications may cause allergic reactions or anaphylactic shock.
4. Follicles containing oocytes may not develop during the treatment (monitoring) cycle or response to the drug may be inadequate and oocyte retrieval may be canceled.
5. Too many follicles may develop and a condition known as Ovarian Hyperstimulation Syndrome (OHSS) may occur.
6. Pelvic scarring or adhesions and/or technical problems may prevent retrieval of one or more oocytes.
7. Ovulation may occur prior to oocyte retrieval and oocytes may be lost, making obtaining the oocyte(s) impossible.
8. One or more oocytes may not be obtained after attempts to aspirate the follicles.
9. The oocytes may not be viable or mature.
10. Hemorrhage or infection may occur during or after the attempt to aspirate oocytes from follicles.
11. The male partner may not be able to produce a semen sample at the appropriate time or the sample may not be adequate for use.
12. Fertilization of the oocyte(s) may not occur or may occur but be abnormal.
13. Embryo development (cell division, cleavage) may not occur or occur but be abnormal.
14. Embryo transfer to the uterus or fallopian tube(s) may be technically difficult or impossible or medically contraindicated.
15. If transfer occurs, the embryo(s) may not implant and not continue to develop.
16. Administration of progesterone may cause the woman to feel pregnant. Side effects include bloating, nausea, depression, increased appetite, weight gain, fatigue, headache and sleep disorders.
17. If pregnancy occurs, it may result in a multiple pregnancy or an ectopic pregnancy or a pregnancy which ends in miscarriage.
18. If pregnancy and delivery occur, the child or children may be stillborn, have chromosomal abnormalities and/or congenital (birth) defects.
19. Psychological stress may result in anxiety and disappointment.
20. A substantial amount of time and effort is required of participants in the ART program.
21. Many of the standard products used to stimulate the development of follicles and growth of the oocytes/embryos are derived from biologic origins. While these products are manufactured under the strictest guidelines of the Federal Drug Administration, the Center for Human Reproduction cannot be held responsible for unspecified product recalls.
22. The long-term effects of the administration of fertility drugs is not known. The long-term effects of fertility drugs is still being evaluated, including the potential long terms risks of ovarian and breast cancer.
23. The long term effects on children born as a result of the Assisted Reproductive Technologies is not known.
24. Equipment failure, infection and/or human error or other unforeseen circumstances may result in loss of or damage to oocyte(s), sperm and embryo(s).
25. Unusual circumstances (e.g., lack of personnel due to severe weather conditions) may necessitate the cancellation of any or all parts of an ART cycle.

AGREEMENT AND CONSENT

We understand and agree that, if in the exercise of reasonable medical judgment, the embryologists and physicians involved in the ART Program determine that any of our sperm, oocytes or embryos are non-viable or otherwise not medically suitable for use or embryo transfer, such embryos, sperm, or oocytes will be disposed of in an ethically acceptable manner, according to the Center for Human Reproduction policies and the American Society for Reproductive Medicine ethical standards. We consent to such disposition in the circumstances described.

We have been informed that Intracytoplasmic Sperm Injection (ICSI) and Assisted Zona Hatching (AZH) are specialized procedures that may be indicated in addition to the assisted reproductive technology procedures already described.

We understand that intracytoplasmic sperm injection (ICSI) is a procedure employed when previous cycles of ART have resulted in fertilization failure or a severely reduced fertilization rate or when semen parameters suggest that this may occur during our ART cycle. The procedure involves the isolation of a single sperm cell from the man's semen specimen, followed by microsurgical injection of a single sperm into an oocyte retrieved from the woman. We have been informed that, while ICSI is no longer considered experimental by the American Society for Reproductive Medicine, the long-term effects of the procedure have not been fully evaluated. However, we acknowledge that the procedure is practiced in centers worldwide where the specialized equipment and expertise for the procedure is available and thousands of children have been born as a result of the procedure. We understand that possible adverse effects of the procedure include damage/breakage of the oocyte during the procedure or failure to isolate sperm cells. We understand that the selection of sperm for injection is arbitrary with the theoretical potential for increased risks of chromosomal abnormalities or birth defects, including eventual infertility in offspring. We understand that the use of the procedure cannot completely eliminate the risk of fertilization failure. We further understand that there may be some effects on the offspring, which at this time cannot be determined.

We have been informed that Assisted Zona Hatching (AZH) is a micromanipulation procedure performed on embryos just prior to transfer to the uterus of the Woman. We are aware that in this procedure, small cuts are made in the outer shell of the embryo (zona pellucida) to enhance the possibility that the embryo will hatch out of its shell and implant in the uterine wall. The procedure may be indicated in situations where there has been failure (failure to conceive) in previous cycles of ART, where there is an elevated follicle stimulating hormone (FSH) level, where the woman is 39 years old or older, or her embryos are of poor quality or the zona pellucida (shell) is thickened. We acknowledge that the procedure has been demonstrated to enhance implantation in some cases and has resulted in many live births worldwide, although the long term risks are still unknown. We understand that one or more embryos may be damaged during the procedure, and that hatching may, theoretically, expose the embryo(s) to invasion by other cells or microorganisms

We understand that, in general, medical history and results of fertility evaluations, obtained prior to the ART procedure, will suggest that ICSI and/or AZH are indicated, but that in some cases, observations made by the ART Team during the cycle itself may cause reevaluation of the need to utilize these techniques. We understand and agree that, unless we have specifically indicated that we will not consent to the use of these procedures and be financially responsible for them, the utilization of these procedures is at the discretion of the ART team. We understand that the costs of these procedures are in addition to the costs of a typical ART cycle and that, if they are employed, we may be financially responsible for the procedure if insurance coverage is not available. We also understand that the procedures are utilized at the discretion of the ART team based on their assessment of medical history and/or observations made during the ART cycle.

We understand that if micromanipulation procedures are required for our ART cycle, we will be financially responsible for the additional costs incurred.

Female Partner
Initials _____ Initials _____

As part of our ART cycle, we request that micromanipulation techniques, including intracytoplasmic sperm injection and/or assisted zona hatching, be used if indicated. We acknowledge that we have received information regarding the approximated and anticipated financial costs of such procedures and we accept all financial responsibility if our insurance does not cover these procedures, including any increased costs that may arise regardless of the success of such procedures.

Female Partner
Initials _____ Initials _____

We decline the use of all micromanipulation techniques during our ART cycle.

We agree to disclose such financial information as is required to determine our financial status and ability to pay for such procedures. We understand that delinquent accounts may be referred to an attorney or collection agency and agree to pay reasonable attorney fees, collection costs and other costs related to collection of delinquent accounts.

We understand the risks/reasons for adverse results. All of our questions about the ART procedures have been answered. We understand that our infertility may be treatable by ART and we voluntarily agree to participate in the ART program at The Center for Human Reproduction. We also confirm that we were fully informed about alternative treatment options, if such exist.

We represent that we will acknowledge our parentage of any child born to us through the ART program.

We voluntarily participate in the ART program in hopes of having a child through these technologies. We acknowledge that we have read and fully understand this consent form and that all questions concerning the Program have been answered to our satisfaction.

By participating in this program. We accept the responsibilities, conditions, and risks involved as set out in this document and as explained to us by members of the ART Team. In addition, we consent to the techniques and procedures required to attempt assisted reproductive technologies as they have been described in this document and as they have repeatedly been explained to us by the ART program staff.

Each of us understands that, depending upon the basis of our continued infertility, alternative means of conceiving a child may not be possible. However, if alternative means do exist in our particular situation, we have been made aware of those means and the risks inherent in each. We still desire to use the ART technique as our method of choice. We make this choice with the knowledge that the practice of anesthesia, medicine, and surgery is not an exact science and state that no one has given us promises or guarantees about treatment or care to be received or their results.

Each of us acknowledges and agrees that our acceptance into the ART Program and our continued participation is at the discretion of the ART Team. We also understand that we can withdraw from the ART Program at any time without affecting the availability of other present and future medical care at CHR. We are financially able to participate in the ART Program and acknowledge that we have been given a general description of the costs of our care in the ART program and for which we agree to be responsible. We also understand that we are financially responsible for any related medical, professional or laboratory fees.

It is possible that our participation in the ART Program may aid in the development of techniques that may help other infertile couples and/or that new and useful information in medical sciences may be obtained. Therefore, we consent to the taking and publication of photographs and/or audiovisual taping of laboratory procedures involving our participation in the program for the purpose of advancing medical education and research, provided our identity is not disclosed or apparent from the materials. We also consent to the admittance, for the purpose of observation, of other physicians and health care personnel

during any medical procedures performed on us during the ART Program. All information obtained during the procedure will be handled confidentially and neither our identity nor specific medical details will be revealed without our consent. We understand that we will receive no compensation for such participation. No personal information may be provided to the media by the Center for Human Reproduction without our consent, which may compromise the confidentiality of our medical record.

Federal law requires that all ART programs report cycle specific data to the Centers for Disease Control (CDC). We understand that to collect these data, it may be necessary for the Center for Human Reproduction to contact us for follow up after completion of our ART cycle. We understand that all personal identifiers submitted with our cycle specific data will be protected under the Federal Privacy Act. However, we further understand that we can elect to not have any personal identifiers reported.

Female Partner We do **NOT** authorize the use of personal identifiers in cycle
Initials _____ Initials _____ specific data for submission to the Centers for Disease
Control.

Female Partner We authorize the use of personal identifiers in cycle specific
Initials _____ Initials _____ data for submission to the Centers for Disease Control.

Each of us has been informed that, if we should suffer any physical injury as a result of participation in this program, all medical facilities are available for treatment. We understand, however, that we cannot expect to receive from the ART Team, The Center for Human Reproduction, or its employees any reimbursement for hospital expenses or any financial compensation for such injury.

All of our questions regarding the Center for Human Reproduction consent on Assisted Reproductive Technologies Program (A.R.T.) have been answered. Each of us has read the consent and acknowledges receipt of a copy of this consent.

Date Signature of Female Patient Female Name – Print

Date Signature of Partner Partner Name – Print

As one of the members of The Center for Human Reproduction, by my signature indicate that the foregoing consent was read, discussed and signed in my presence.

Date Signature of Witness (Female Patient) Witness Name – Print

Date Signature of Witness (Partner) Witness Name – Print

NOTE: If you or your partner are unable to have this consent witnessed by a staff member at CHR or FULLY UNDERSTAND THE CONSENT, please notify the CHR medical staff. We will provide you with further information and a witness. If you wish to sign the consent outside of CHR, please have the consent notarized.

State of _____, County of _____ ss., I, the undersigned, a Notary Public in and for the said County in the

State aforesaid; DO HEREBY CERTIFY that _____
(Female Patient / Partner)

personally known to me as the same persons whose names are subscribed to the foregoing document appeared before me this day in persons, and acknowledged that he and she signed, sealed and delivered the said document as his and her free and voluntary act, for the use and purposes therein set forth.

Given under my hand and official seal this _____ day of _____, 20_____,
Commission expires on: _____, 20_____.

(Notary Public)

(Notary Seal)