

Assisted Reproductive Procedures Consent Form
Collection of Semen, Preparation of Semen, In Vitro Fertilization (IVF)

The patient _____ and partner _____ consent to medical treatment through assisted reproductive procedure(s) as outlined below:

Procedures:

1. Diagnostic tests, such as semen analysis, blood tests to determine baseline hormone levels and infectious disease screening, PAP test, vaginal cultures and ultrasound examination of the ovary to determine baseline follicle count will be performed prior to initiating treatment.
2. Oral contraceptive pills containing estrogen and progesterone will be taken in the menstrual cycle immediately prior to the in vitro fertilization (IVF) treatment cycle to induce a baseline state for the ovaries. A synthetic hormone medication called Lupron will be taken by subcutaneous injection to temporarily suppress the pituitary gland from stimulating the ovaries. Medications containing ovarian stimulating hormones (FSH, LH, hCG) will be taken by subcutaneous injection to stimulate the growth of several ovarian follicles containing eggs.
3. Periodic blood tests will be performed to monitor the changes in hormone levels related to the growth of the ovarian follicles that contain the egg(s). Blood samples will be kept for approximately one week and then discarded.
4. Ultrasound examinations will be used to monitor the growth of the ovarian follicles and to determine when the follicles reach maturity. Ultrasonography is a diagnostic procedure that uses sound waves to provide a picture of the ovaries. Upon reaching maturity, a medication containing the hormone hCG will be taken by subcutaneous injection to induce the final maturation and ovulation of the eggs.
5. The eggs will be retrieved from the ovary, under anesthesia, 35 – 37 hours after the hCG injection (before ovulation). Eggs are retrieved using an ultrasound-guided needle passed through the back wall of the vagina into the ovarian follicles. The fluid contents of the follicles will be aspirated and the fluids will be examined to identify and retrieve the eggs. Approximately 80% of the follicles will yield an egg
6. A semen specimen from the partner will be obtained by masturbation in a room specially designed for this purpose and analyzed (diagnostic) or processed to isolate the best sperm for fertilization (therapeutic).
7. All of the retrieved eggs will be placed together with the sperm of the partner in a sterile plastic dish containing a specially formulated culture medium to facilitate fertilization. On average, 80% of the retrieved eggs will be mature and only mature eggs are capable of fertilization. On average, 80% of the mature eggs will fertilize. Excess sperm are discarded after insemination of the eggs.
8. Fertilization results are obtained the day following the egg retrieval. Unfertilized and abnormally fertilized eggs are discarded in an ethical manner. The resulting embryos will be grown in an incubator in the laboratory under strictly controlled conditions for 5 – 6 days until they reach the blastocyst stage of development. Although there is significant variation between patients, and between cycles of the same patient, on average 30-50% of the embryos will reach the blastocyst stage. In rare cases, approximately 5% of the time, none of the embryos reach the blastocyst stage.
9. Usually two, but occasionally more or less, developing embryos are transferred to the uterus on the fifth or sixth day following egg retrieval. The embryo(s) are deposited at the top of the uterus using

a small, flexible plastic tube (catheter). The embryo(s) must initiate attachment to the uterine wall and continue the implantation process in order for a successful pregnancy to occur. Extra embryo(s) of good developmental potential may be cryopreserved (frozen) for transfer in a subsequent cycle. The risks and benefits of embryo cryopreservation are explained in a separate consent form that must be signed prior to cryopreservation of embryos. If the patient and partner do not elect to cryopreserve the extra embryo(s), the extra embryos will be discarded in an ethical manner immediately following embryo transfer. Any embryos that have stopped growing or are deemed to have poor developmental potential are discarded in an ethical manner immediately after the embryo transfer.

10. Progesterone supplements, taken by intramuscular injection, will be used in the early stages of pregnancy to maintain and promote the continuation of the pregnancy.
11. Blood samples will be taken approximately 7 days and again 11 days after the embryo transfer to assess hormone levels and make sure the levels are adequate to support a pregnancy. A blood sample will be taken approximately 14 days after transfer to determine whether pregnancy has occurred and is proceeding normally.
12. If a pregnancy is initiated, twice-weekly blood tests and weekly ultrasound examinations will be performed to monitor the ongoing pregnancy. The patient is transferred to the care of an obstetrician at 12 weeks of pregnancy.

Additional Laboratory Procedures The following laboratory procedures are available as part of your treatment plan and employed as medically indicated. Please indicate below either your acceptance or refusal of these laboratory procedures. Refusal or acceptance of any or all of the option procedures will not, in any way, prevent you from receiving treatment in the North Hudson IVF Program.

1. Intracytoplasmic Sperm Injection. In cases where very few sperm are available for fertilization and/or the percentage of normally shaped sperm is less than 4% and/or the percentage of sperm with rapid forward progressive motility is less than 20% on the day of the egg retrieval, a procedure called Intracytoplasmic Sperm Injection (ICSI) may be utilized to facilitate the fertilization process. This is a procedure whereby a single sperm cell is manually injected into each mature egg. ICSI may also be used to facilitate fertilization when maternal factors such as polycystic ovarian syndrome (PCOS) affect the ability of the eggs to fertilize or to optimize fertilization when an unusually high or low number of eggs are retrieved. The ICSI procedure has been in clinical use for more than 10 years and there have been no reports indicating the ICSI procedure itself increases the incidence of miscarriage or birth defects.

Accept Reject

2. Assisted Hatching. The egg and developing embryo is contained within a protein coat. At the blastocyst stage, the embryo must "hatch" out of this protein coat in order to make direct cell-to-cell contact with the lining of the uterus to facilitate implantation. Embryos developed in vitro can experience difficulty "hatching" out of this protein coat. Accordingly, a procedure known as Assisted Hatching is routinely performed prior to embryo transfer. Assisted hatching is a technique that involves making a small hole in the protein coat of the developing embryo to facilitate the hatching process. This procedure has been in clinical use for more than 10 years and there have been no reports indicating that this procedure increases the incidence of miscarriage or birth defects.

Accept Reject

Risks:

The potential risk or discomforts of in vitro fertilization and related procedures include, but are not limited to the following:

1. Blood Sampling - Frequent blood sampling can cause discomfort and bruising at the site of venipuncture.
2. Ultrasound Examination - There are currently no known risks associated with ultrasound examination of the ovaries.
3. Semen Analysis – There are currently no known risks associated with producing a semen specimen by masturbation.
4. PAP Test – There is a slight risk of temporary vaginal bleeding associated with the sampling the surface of the cervix.
5. Vaginal Cultures - There is a slight risk of temporary vaginal bleeding associated with the sampling the surface of the cervix.
6. Mock Embryo Transfer - In preparation of the actual embryo transfer performed following in vitro fertilization of the eggs and subsequent embryonic development, a “mock” or “trial” embryo transfer is performed in a preceding cycle to determine the depth of the uterine cavity and the curvature of the cervical canal. The “mock” or “trial” embryo transfer is a non-surgical procedure that is usually painless or causes only minimal discomfort. The “mock” embryo transfer carries a slight risk of infection. The procedure usually takes approximately ten minutes to complete.
7. Medications – Several medications are used during ovarian stimulation, embryo transfer and to maintain an ongoing pregnancy. Any medication can cause side effects and the medications associated with infertility treatment are no exception. However, major side effects are very rare.

Oral Contraceptive Pills (Desogen, etc.)

This medication is a low dose estrogen/progesterone pill taken during menstrual cycle prior to initiating ovarian stimulation in order to induce a quiescent, baseline hormonal state and to prevent the development of ovarian cysts. The potential risks associated with long term exposure to oral contraceptive pills include, but are not limited to, the following: development of blood clots, heart attack, stroke, gall bladder disease and very rarely, liver tumors. Since exposure to this medication will be brief (21 days), the potential risks are very low. Side effects may include vaginal bleeding, fluid retention, spotty darkening of the skin, nausea and vomiting, change in appetite, headache, nervousness, depression, dizziness, loss of scalp hair, rash and vaginal infections.

Leuprolide Acetate (Lupron for subcutaneous injection)

This medication is a synthetic hormone that temporarily stops the body from producing other hormones that stimulate the ovaries. When the medication is stopped, hormone levels will return to normal. This medication may cause side effects that include, but are not limited to: nausea, vomiting, hot flashes, night sweats, bone pain, swelling of feet and ankles, headache or difficulty urinating. These symptoms usually disappear as the body adjusts to the medication.

Menotropins (Pergonal, Gonal F, Follistim, Repronex, etc., for subcutaneous injection)

These medications (follicle stimulating hormone and luteinizing hormone) are used to stimulate the growth of ovarian follicles and induce ovulation. These medications may cause side effects that include, but are not limited to: fever, breathing trouble, bloating, stomach pain or upset, enlarged ovaries, irritation at the site of injection and/or skin rash. These symptoms usually regress without treatment in two to three weeks after egg retrieval. Ovarian Hyperstimulation Syndrome (OHHS) is

distinct from enlarged ovaries and is characterized by an increase in vascular permeability that results in the rapid accumulation of fluid in the peritoneal cavity, thorax and potentially, the pericardium. Early symptoms of OHHS include severe pelvic pain, severe bloating, nausea, vomiting and rapid weight gain. OHHS occurs in 0.4 – 1.3% of women taking menotropins. Any patient experiencing symptoms of OHHS should immediately contact Jane Miller, M.D. at 201-907-3577.

Chorionic Gonadotropins (hCG, Profasi, Pregnyl, etc. for subcutaneous injection)

This medication (hormone) is used to induce the final maturation of the eggs and ovulation. This medication may cause side effects that include, but are not limited to: headache, stomach pain, irritability, restlessness, mood changes, fatigue, acne and pain or irritation at the injection site.

Estrogen (Estradiol Transdermal Patches)

This medication (estrogen hormone) is used to maintain the appropriate hormonal balance after the egg retrieval to maximize the possibility of implantation and continued pregnancy. This medication can cause side effects including, but not limited to, the following: dizziness, headache, lightheadedness, stomach upset, bloating and nausea. These symptoms usually disappear as the body adjusts to the medication.

Progesterone (for intramuscular injection)

This medication (progesterone hormone) is used to maintain the appropriate hormonal balance after the egg retrieval to maximize the possibility of implantation and continued pregnancy. This medication can cause side effects including, but not limited to, the following: nausea, headache, depression, itching, increased hair growth, increased sensitivity to sunlight, changes in menstrual flow, increased vaginal secretions, breast tenderness, fluid retention and pain or irritation at the injection site.

Muscle Relaxant (Valium Tablets)

This medication is used to relax the pelvic muscles immediately prior to the embryo transfer. This medication can cause side effects including, but not limited to, the following: stomach upset, blurred vision, headache, confusion, depression, impaired coordination, change in heart rate, trembling, weakness, memory loss, dreaming or nightmares. The symptoms usually disappear in a matter of hours as the medication wears off.

Antibiotics (Doxycycline Capsules)

This medication is used to prevent infection following egg retrieval. This medication can cause side effects including, but not limited to, the following: stomach upset, diarrhea, nausea, headache, vomiting and increased sensitivity to sunlight.

Corticosteroids (Medrol Tablets)

This medication is used to slightly suppress the immune system and thereby enhance embryo implantation. This medication can cause side effects including, but not limited to, the following: dizziness, nausea, indigestion, increased appetite, and weight gain, weakness or sleep disturbances. These effects usually disappear as the body adjusts to the medication.

8. Anesthesia – Certain complications may result from the use of any anesthetic agent including, but not limited to, respiratory problems, adverse reaction to the medication, paralysis, brain damage or even death.
9. Egg Retrieval - Egg retrieval is a minor surgical procedure that carries the risk of bowel or bladder perforation, internal bleeding or infection. The procedure, performed under anesthesia, usually takes 15 to 20 minutes to complete. Upon awaking from anesthesia, some patients experience slight to moderate pelvic pain. Vaginal bleeding after the egg retrieval is common. Any discomfort usually disappears within 24 hours.

10. Embryo Transfer - An embryo transfer is a non-surgical procedure that carries the slight risk of infection. The embryo transfer procedure is usually painless or only causes minimal discomfort. The procedure usually takes approximately ten minutes to complete.
11. Multiple Gestations - If more than one embryo is transferred to the uterus, multiple gestations (twins, triplets or more) may result. This may increase the risk of premature delivery and other maternal complications and increase financial and emotional cost. Pre-term delivery may also result in complications to the offspring including long-term disabilities or death. Multi-fetal reduction (termination of one or more embryos) is an available alternative, with its own attendant risks and benefits
12. Pregnancy - If pregnancy is successfully established, there is still a possibility of miscarriage, ectopic (tubal) pregnancy, stillbirth and/or congenital abnormalities (birth defects). At this time, the risk of the development of an abnormal fetus is not believed to be greater than in a naturally conceived pregnancy. In the event that any serious abnormality is discovered, the various alternative courses of action, including elective termination of pregnancy, will be outlined and discussed, with the final decision on the course of action residing with the patient. The program's statistical experience in achieving pregnancies has been explained. There is no guarantee that this procedure will result in a successful pregnancy.
13. Psychological Stress – Infertility treatment is an emotionally difficult process to go through. The relative uncertainty of treatment outcome can result in considerable anxiety. Counseling is available for those couples who feel they would benefit from talking with a professional trained in the specific issues associated with infertility.

Consent

1. I / We understand that certain diagnostic tests such as semen analysis, blood tests, ultrasound examination of the ovaries and mock embryo transfer may be performed in preparation for an attempt at In Vitro Fertilization and Embryo Transfer at North Hudson IVF Center and that these tests carry associated risks. I / We certify these risks have been explained to me/us and I / We hereby consent to participate in these diagnostic tests.
2. I / We understand that certain therapeutic procedures such as egg retrieval, semen preparation, in vitro fertilization and embryo transfer will be performed in conjunction with my treatment at North Hudson IVF Center and that these procedures carry associated risks. I certify that these risks have been explained to me and I / We hereby consent to participate in these procedures.
3. I / We understand that egg(s) will be taken from the ovaries and the sperm obtained from my partner will be mixed in the laboratory to achieve fertilization. If the eggs fertilize, and if the embryos develop appropriately, two or more embryos will be transferred into my uterus. The embryos will be transferred to the uterus using a small plastic tube inserted through the cervix. I / We hereby certify that the risks associated with these procedures have been explained to me/us and that I / We hereby consent to participate in these procedures as part my/our treatment at North Hudson IVF Center.
4. I / We understand that the reasonably known risks and consequences associated with the transfer of the embryo(s) to my uterus include a slight chance of infection. After the embryo transfer, blood tests will be required to monitor hormone levels and to determine if pregnancy has occurred. In addition, if pregnancy does result; additional blood tests and ultrasound examinations will be required to monitor the ongoing pregnancy. I / We understand that as with any pregnancy, there is a risk of complication during the pregnancy and childbirth. These include, but are not limited to the following:

- a. ectopic (tubal) pregnancy
 - b. multiple gestation
 - c. infection
 - d. hemorrhage
 - e. cesarean section
 - f. all the risks and inconveniences associated with carrying a child and giving birth to it.
5. I / We understand that if pregnancy occurs that it is important to obtain appropriate prenatal medical care and I / We agree to do so. I / We understand that my/our failure to obtain such care may adversely affect the pregnancy and / or the fetus and agree to seek appropriate prenatal care.
 6. I / We understand that that there is no guarantee that I will become pregnant as a result of the In Vitro Fertilization and Embryo Transfer procedures at North Hudson IVF Center. Any of the following conditions may occur which would prevent the establishment of pregnancy:
 - a. The response to the ovary stimulating medications may be poor and the egg retrieval may be cancelled
 - b. The time of ovulation may be misjudged and the egg retrieval may be canceled.
 - c. The attempt to obtain the egg(s) may be unsuccessful.
 - d. The egg(s) may not be mature or of sufficient quality to fertilize.
 - e. In some cases, the partner may be unable to supply a semen specimen.
 - f. Fertilization may not occur.
 - g. The embryo(s) may not develop normally.
 - h. None of the embryos may reach the blastocyst stage of development, thus the embryo transfer is cancelled
 - i. Implantation of the embryo(s) into the wall of the uterus may not occur.
 7. I / We understand that I / We am/are free to discontinue participation in the In Vitro Fertilization / Embryo Transfer Program at North Hudson IVF Center at any time, by informing the staff either verbally or in writing. I / We understand that my/our decision to discontinue participation will in no way prejudice other treatment that I / We may receive from the staff at North Hudson IVF Center.
 8. I/We understand that, in accordance with the Fertility Clinic Success Rate Act of 1993, all fertility clinics are required by federal law to report annually birth outcomes for the purpose of delivery validation and as a tool to measure and assess any potential long term affects of assisted reproductive techniques on patients and their offspring. You will be asked to provide this program with information regarding your pregnancy, labor and delivery, and birth outcome. The data that you and/or your obstetrician provide will be collected and reported anonymously with the highest regard for preserving your confidentiality.
 9. I / We understand that should the results of my treatment or any aspect of it be published in medical or scientific journals, all possible precautions will be taken to protect my/our anonymity. I / We grant permission to North Hudson IVF Center to publish information relating to my case in professional journals, providing that my name is not used.
 10. I / We understand and acknowledge that the staff at North Hudson IVF has not undertaken hereby, or in any other document or oral communication, to advise me of my legal rights, now existing or hereafter arising, and specifically disclaim any responsibility to do so. I understand that North Hudson IVF Center recommends that I consult legal counsel so as to be fully informed of my legal

rights and obligations, but if I elect not to do so, such election is hereby acknowledged to have been determined without reliance upon statements, oral or written of North Hudson IVF Center.

11. I / We confirm that the exact nature of In Vitro Fertilization / Embryo Transfer and associated procedures have been explained to me/us, together with the known risks of the procedures. I / We understand the explanation that has been given and have had the opportunity to ask any questions and to have these questions answered. Any future questions we have may be addressed to the staff of North Hudson IVF Center. I / We acknowledge that these procedures are being performed at our request and with our consent.

Signature of Patient

Signature of Partner

Print Name and Date

Print Name and Date

I have explained the procedure(s) to the patient and her husband/intimate partner including the risks, benefits and alternatives. All questions concerning the procedure(s) have been answered.

Signature of Physician

Print Name and Title

Date