

Hudson Valley Fertility
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Patient Name: _____
DOB: _____

INFORMED CONSENT FOR THE PARTICIPATION IN AN ASSISTED REPRODUCTIVE TECHNOLOGY (ART) PROCEDURE

ART stands for Assisted Reproductive Technology. There are many types of ART procedures. This consent form will outline the types of procedures that you may undergo at Westchester Fertility. Dr. Levine will tell you which procedures he believes are most likely to help you achieve your goal of becoming pregnant. Please read each part of this consent carefully and ask any questions that you need to understand your planned ART procedure.

SCREENING

Before you can undergo your ART procedure, you and your male partner will need to have testing to assist us in ensuring your safety during your treatment and anticipated pregnancy. Some of these tests will look for infections that could endanger a pregnancy or contaminate the embryology laboratory and endanger other pre-implantation embryos (to be referred to as pre-embryo). We will test you for sexually transmitted disease, hepatitis, and HIV (the virus that causes AIDS). We are required to ask you to sign a separate consent for HIV screening. If we find evidence of any type of infection, we will discuss the results of your tests with you and, if needed, refer you for treatment.

In addition to infectious disease screening, we will ask you to have tests that we would recommend for any woman anticipating pregnancy or infertility treatments. These tests include blood typing and Rh, rubella titer, complete blood count (CBC), blood chemistries (SMAC), and a Pap smear.

Your pre-embryo will have a better chance of implanting if the inside of your uterus is normal. Studies that will help us confirm that your uterus is normal are: hysterosalpinogram (HSG), hysteroscopy or hysterosonogram (HSN). If you have not had one of these studies in the last year, we will ask you to have one.

We define a treatment cycle as beginning when you start taking medications and ending when you are either pregnant or have started to have your period. Your male partner must have a semen analysis performed by our laboratory within six months of the start of (each of) your treatment cycle(s).

You will have baseline blood tests done to evaluate your ovarian reserve. These are tests of your follicle-stimulating hormone (FSH) and estradiol (E2) that we perform early in your menstrual cycle, around the third day of your period. Many reference laboratories perform FHS and E2 tests, but each lab reports their results differently. In addition to FSH and estradiol, your pretreatment baseline tests will also include a pregnancy test. If your baseline tests are abnormal, you will discuss this with Dr. Levine and he will inform you of the potential ramifications of this upon your treatment success.

Financial consultation should be completed prior to baseline evaluation.

Consults with other Health Professionals

We recommend that each couple that plans to have ART procedures at Westchester IVF consider undergoing psychological screening and have a visit with a counselor.

We may ask some couples anticipating ART procedures to have genetic screening. This particular genetic screening will differ from couple to couple. If you do need genetic screening, we will advise you of the risks and benefits of screening.

Pregnancy itself can be a health risk. If you are over the age of 45 or have any significant illness (such as asthma, diabetes or multiple sclerosis), we will ask you to be cleared by your internist and a board-certified perinatologist of your choice *before starting your treatment*. All women over the age of 45 will require a cardiac stress test. If you have a history of any other significant illness, you will need a consultation with another relevant specialist *before starting your treatment*.

We require all of these screening procedures before your first cycle of treatment. For subsequent cycles you may need to repeat a few of these tests. If more than a year has gone by since your first cycle, we will require you to repeat all of your screening tests. At the end of the screening, you will meet with Dr. Levine to review the results of your tests, discuss plans for your treatment cycle and give your physician an opportunity to prescribe your medications.

THE CYCLE

Beginning your Treatment Cycle

You must have an appointment for a calendar with one of our nurses in order to start a treatment cycle. We will base your calendar on the type of treatment that you plan to have and on the approximated date of your next menstrual cycle. Please call the office to schedule your baseline blood tests on day 2 or 3 of your menstrual bleeding (not spotting).

If your baseline studies are normal, you will schedule a protocol appointment with our nurse for your cycle instructions and prescriptions for medications based on the orders written by Dr. Levine. Final payment for your cycle will be due at this time.

Medications

You will use several different types of medications during your treatment cycle. Follicles are small fluid-filled sacs in your ovary that contain your eggs. You will use "fertility" drugs to help you mature several follicles during your treatment cycle. All injectable fertility drugs have FSH (follicle stimulating hormone), a hormone that will stimulate the growth of your ovarian follicles. Some of them have LH (luteinizing hormone), a hormone that may increase the production of estrogen. Some of these medications are given by intra-muscular injection that may cause bruising or discomfort at the injection site. Dr. Levine will have ordered your medications based on the best estimation of which drugs are most likely to help you have a good response. One of our nurses will give you instructions on administration of injectable medications. It may be necessary for your partner or another person to give these injections and they will also need to be trained to do this. Risks and benefits of your medications will be reviewed with you in your pre-cycle meeting with Dr. Levine. Risks that you should be sure to review in detail with Dr. Levine are hyper-stimulation, multiple pregnancy, and a possible relationship between fertility drugs and later development of ovarian cancer (discussed below).

Hyper stimulation

Excessive ovarian enlargement and accumulation of fluid characterize severe hyper-stimulation. Fluid can accumulate in your abdomen, tissues, and sometimes in your chest cavity. When this fluid accumulation is severe you may need hospitalization and/or possible drainage of excess fluid from your abdomen or chest. Reported complications, while extremely rare, have included blood clots, kidney failure, fluid overload, and death. We will occasionally cancel treatment cycles or recommend freezing all of the pre-embryo and avoiding a fresh transfer if we are concerned that hyper-stimulation is likely to occur. More often, we are able to modify your medications or the timing of your egg retrieval to minimize the risk of hyper-stimulation. It is very important to maintain close contact with our nurses and Dr. Levine during the time you receive these medications and for at least 2 weeks afterwards

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Multiple Pregnancy

Multiple pregnancy is a serious risk of ART treatment. Additional risks associated with multiple pregnancy include: pre-term labor, pre-term rupture of membranes and intrauterine growth restriction. These complications may be associated with a higher risk of lung disorders and neurological or development problems. At Westchester Fertility, we try to minimize the risk of multiple pregnancy by transferring the minimum number of preembryos that we believe will give you a good chance of pregnancy. Compared to single pregnancies, multiple pregnancies are more likely to result in premature birth or fetal death or injury.

Multi-fetal reduction

One remedy of multiple pregnancy is multi-fetal reduction. Multi-fetal reduction is the process of eliminating of one or more fetuses if you become pregnant with a multiple pregnancy. Fetal reduction is generally carried out at 10 to 12 weeks' gestation. The pregnancies are visualized on ultrasound and the gestational sac that is technically easiest to reach is injected with potassium chloride, which will stop the fetus' heart. After fetal reduction there is a possibility of losing the entire pregnancy, which is thought to range from 10 to 15%.

Ovarian Cancer

Ovarian cancer is a life threatening disease. For women over the age of fifty years the annual risk is about 50/100,000. Recent research has suggested that the use of fertility drugs may be associated with an increased risk of developing ovarian cancer later in life. The magnitude of rise in risk of ovarian cancer secondary to fertility drug use has not been well quantifies. Women who were never pregnant have a higher risk of ovarian cancer than women who have ever been pregnant do. If you achieve pregnancy after using fertility drugs, the epidemiological evidence suggests that your risk of ovarian cancer will be decreased to the rate of other women who have been pregnant.

Other Medication Risks

Blood drawing may result in mild discomfort and a risk of developing a bruise at the needle site. Vaginal ultrasound examinations of the follicles may be uncomfortable but there is no known risk associated with them. The doctor covering the IVF practice will tell your physician about your progress on the stimulation. Each afternoon of the day of your visit to Westchester Fertility, one of our nurses will contact you to tell you how much medication to take that evening.

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Monitoring

You will need repeated morning visits to Westchester Fertility once you begin your treatment cycle. Your first visit for monitoring will generally be on the sixth day after you began injecting the fertility drugs. On these visits you will have blood tests to monitor your estrogen production and ultrasound examinations to measure growth of your follicles. Blood drawing may result in mild discomfort and a risk of developing a bruise at the needle site. Vaginal ultrasound examinations of the follicles may be uncomfortable but there is no known risk associated with them. Each afternoon of the day of your visit to Westchester Fertility, a nurse will contact you to tell you how much medication to take that evening.

Cancelled Cycles

At Westchester Fertility, although pregnancy rates are good if we have two or three pre-embryos to transfer, they are very low if we have only one preembryo. If we believe that you are growing very few follicles, we may advise you to cancel your cycle in order to avoid the possibility of a one preembryo transfer. Patients who have cancelled cycles can choose to try again another time. If you were unable to complete this treatment cycle you should discuss plans for your future treatment cycle with Dr. Levine.

Retrieval

On the day of retrieval you will come to Westchester Fertility for egg recovery by ultrasonographic-guided procedure. Most patients will have general anesthesia for their retrieval. You will need to sign a separate consent for the retrieval procedure. Ultrasound-guided egg retrieval is performed by passing a needle through the uppermost part of your vagina and aspirating the fluid from each of your follicles. After we aspirate the fluid, the embryologist will examine each sample for eggs. The average number of eggs we retrieve is eight to ten.

Oocyte retrieval may result in injury to your ovaries, fallopian tubes, uterus, bladder or bowels. After your egg retrieval you may experience bleeding. Bleeding could be from your ovaries or from injury to blood vessels. There are also risks associated with anesthesia, which you should discuss with your anesthesiologist on the day of your egg retrieval.

Semen or Sperm Collection

Your partner will need to be available on the retrieval day to provide a semen specimen. If your partner has difficulty producing a specimen by masturbation please inform us so we can make arrangements to have him freeze a specimen before you start your cycle. In some cases, sperm will be collected by testicular sperm extraction (TESE). Your male partner's urologist will perform the TESE procedure. Financial arrangements for TESE must be made with the urologist.

Laboratory Procedures

During your egg retrieval, the embryology team will examine follicular fluid aspirated from your follicles to find your eggs. Each egg is about the size of a sharpened pencil point. When you wake up from your retrieval, we will tell you how many eggs we were able to retrieve.

If your male partner is capable of producing more than 10 million sperm per milliliter in his ejaculate, the embryologists will most likely inseminate your eggs by placing your male partner's sperm and your eggs together in a small bubble nutrient fluid known as *media*. The eggs and sperm will be kept warm in an incubator overnight and we will check for fertilization the following day.

ICSI (intra-cytoplasmic sperm injection)

ICSI is a generally accepted procedure within the medical community. Using ICSI, our embryologist can help couples achieve fertilized eggs when the male partner's sperm count is very low. With ICSI the embryologist will draw individual sperm into a thin glass needle and then inject the sperm into the egg(s). A major risk of ICSI is that your partner could pass on conditions that are associated with his low sperm count to your children. You should discuss this issue with Dr. Levine.

Assisted Hatching

Our embryologist use assisted hatching to help embryos emerge from the thin clear protein shell that naturally surrounds them. After examining your pre-embryo will decide if they can improve your chances of pregnancy by using assisted hatching. The embryologist will perform assisted hatching by holding each pre-embryo in a pipette and exposing it to a fluid that will dissolve a small area of the shell of the pre-embryo. There is a small risk of damage to the pre-embryo when assisted hatching is used. If the embryologist does not believe that assisted hatching will be helpful for you, there is no reason to expose your pre-embryo to the risk of assisted hatching procedure.

Day three embryo transfer

If the cycle progresses well, you will undergo egg retrieval. The eggs will be fertilized with the male partner's sperm and the fertilized eggs will be watched in the laboratory. After several cell divisions the embryologist will determine if the fertilized eggs are dividing normally. If your pre-embryo continue to grow, we will keep them in culture for at least three days. After three days, we will usually transfer three pre-embryo. If our embryologist believes that your pre-embryo are of poor quality of your age is over forty years of age, we may advise you to transfer more than three pre-embryo.

You will not need anesthesia for the embryo transfer. Embryo transfer is usually no more uncomfortable than a Pap smear. Dr. Levine will transfer your pre-embryo into your uterus by means of a small tube, called a transfer catheter, inserted through your cervix. Dr. Levine may use an ultrasound image to help ensure that he places the transfer catheter properly in your uterus. Your bladder will need to be full for the embryo transfer. A full bladder will improve the ultrasound images of the transfer catheter. If your uterus is tipped forward, a full bladder will help straighten the natural angle of the uterus to your vagina, making it easier for Dr. Levine to pass the catheter. In some cases, the physician may need to use an instrument to grasp and pull on your cervix in order to straighten the uterine vaginal angle.

Some risks associated with embryo transfer include discomfort and a minimal risk of developing a uterine infection.

Blastocyst transfer to reduce multiple pregnancy

As a pre-embryo divides, it passes through different stages of growth. First: one cell, then two, four, eight and so on. Most pre-embryo are six to eight cells after three days of culture. Extended culture will allow the pre-embryo to continue to divide and grow to a small ball of cells known as a *morula* and then to a hollow sphere of cells known as a blastocyst. Inside the blastocyst is a bundle of cells known as an *inner cell mass* that could develop into a baby.

Our purpose in extending the culture of pre-embryo to the blastocyst stage is to reduce the risk of multiple pregnancy. Blastocyst stage pre-embryo are thought to have a greater chance of establishing pregnancy. Preliminary evidence from other institutions suggests that among appropriate candidates, couples who have two blastocysts transferred on day five will at least have the same chance of pregnancy as couples who have three to eight cell pre-embryo transferred on day three.

Women who are less than 36 years and who have more than ten eggs retrieved or have six dividing pre-embryo on day three of culture are eligible for blastocyst transfer. If the embryologist believes that blastocyst transfer is appropriate in your case, your pre-embryo will be kept in culture for five to seven days. When two healthy blastocysts have developed, we will transfer them to your uterus using the same technique that is described above.

Extended culture gives our embryologist an opportunity to select your pre-embryo that are most likely to achieve pregnancy. One risk of using extended culture is that none of the pre-embryo will develop to the blastocyst stage. We will not transfer pre-embryo that stop growing while in culture. *If you choose to attempt to grow your pre-embryo to the blastocyst stage, there is a risk that you will have no pre-embryo to transfer.*

Cryopreservation of Embryos

Cryopreservation is the freezing of pre-embryo that result from our ART procedure. If your treatment cycle results in more healthy pre-embryo that can safely be transferred to your uterus you will have several options: 1) cryopreserve the pre-embryo for future use, 2) donate pre-embryo to another couple 3) donate the pre-embryo for research, or 4) discard the pre-embryo. If you decide in favor of cryopreservation, the pre-embryo will be stored in the frozen state until they are thawed and the surviving pre-embryo transferred to your womb. There is an additional charge for the cryopreservation of the pre-embryo. After the first year of storage, there will be a yearly fee for ongoing storage for up to 5 years. After 5 years we will ask you to either use your pre-embryo or transfer them to a long-term storage facility. We will ask you to sign an additional consent for cryopreservation of your embryos.

Most pre-embryo are cryopreserved on day 3 after retrieval at what is called the cleavage stage. We will only cryopreserve pre-embryo that are in good quality. We are able to cryopreserve pre-embryo in approximately 30% of IVF cycles and it is much less likely in women over 38 years of age. If you have additional pre-embryo that are not of adequate quality to be cryopreserved, it may be recommended that we culture those preembryos for several more days to see if they develop to the blastocyst stage, and to cryopreserve them at that stage.

Extended culture for additional embryos

The purpose of extended culture in this case is to see if any of your pre-embryo are capable of growing to blastocyst. These pre-embryo are not of adequate quality to cryopreserve them at the day 3 or cleavage stage. Those pre-embryo that develop to the blastocyst stage will be cryopreserved (usually 2 to 3 days after the initial transfer) for later use. Pre-embryo that are cryopreserved at the blastocyst stage are thought to have at least as good a chance of resulting in pregnancy as those cryopreserved at the cleavage stage.

We anticipate that many pre-embryo that fall into this category will be unable to sustain growth to the blastocyst stage and will be discarded when they arrest in their development. We will not cryopreserve pre-embryo that stop growing while in culture.

Post-Transfer Management

Beginning after the retrieval, and continuing after the transfer, natural progesterone is supplemented either by an intramuscular injection, vaginal suppository, or orally in an attempt to increase the chances of successful implantation. The progesterone will be continued until the pregnancy test, and if pregnancy is confirmed, it is continued until the placental production of progesterone becomes dominant (about 8 weeks gestation). During this time, blood levels will be taken and ultrasounds will be performed to confirm an intrauterine pregnancy.

Barriers to Successful Pregnancy

ART procedures are comprised of many individual steps. Failure in any one of these steps could result in your not achieving a pregnancy in this treatment cycle. Specific potential barriers to success are as follows:

- Poor response to ovulation inducing agents.
- Unsuccessful egg retrieval.
- Abnormal eggs.
- Inability of your partner to produce semen or acquire sperm of sufficient quality or quantity.
- Failure of fertilization.
- Traumatic or failed embryo transfer.
- Failure of implantation of your preembryos.
- Loss or damage to oocytes or preembryos.

Costs of Art

Please contact our financial services representative for IVF fees.

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INFORMED CONSENT FOR PARTICIPATION IN AN ASSISTED REPRODUCTIVE TECHNOLOGY PROCEDURE

1. Informed Consent

We have read the entire ART consent and have had the opportunity to ask Dr. Levine any questions I might have about our participation. Our consent to this procedure is purely voluntary. We may withdraw our consent at any time and our present or future care will not in any way be affected by our decision.

2. Risks and Benefits

In addition to reading the document "INFORMED CONSENT FOR PARTICIPATION IN AN ASSISTED REPRODUCTIVE TECHNOLOGY PROCEDURE," I have been advised by my physician of the risks and benefits of undergoing the procedure required for in-vitro fertilization and the possible alternatives thereto, as well as the risks and benefits of becoming pregnant.

3. Disposal and Use of Genetic Material

Some of my blood or some tissues that would otherwise be discarded such as follicular fluid, immature eggs, unfertilized eggs, abnormally fertilized eggs or follicular cells may be used for quality improvement or research purposes. No viable preembryos will be used for research. I will not be identified on any of those studies. These studies will not compromise the success of my ART cycle. Any evaluation of genetic data or possible future embryo research would require an additional specific consent signed by me.

My decision will NOT affect my treatment in any way.

I consent to such research I do not consent to such research.

Disposition of Embryos in the event of Divorce or Separation

Please check who will be responsible for the disposition of the Embryos:

Patient Recipient Partner/Husband

Disposition of Embryos in the event of Death of both patient and patient's husband/partner

Please check one:

Donate to Research Dispose Embryo Donation

4. Confidentiality

Except as required by law, we have been assured that all information about us obtained during this treatment will be handled confidentially and neither our identity nor our specific medical or psychological details will be revealed by our physician (s) or Westchester Fertility without our consent. Any other use of information about our treatments or us

would require our specific consent. Specific medical details may be revealed in professional publications as long as our identity is concealed.

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5. Risk of Injury

I have also been informed that should I suffer any physical injury as a result of my participation in this medical treatment, the necessary medical facilities are available. I cannot expect to receive any payment for hospital expenses or financial compensation for such injury.

6. Hold Harmless

I hereby agree to indemnify and hold harmless our physicians, caregivers, and Westchester Fertility from any cost, claim, liability, or expense arising out of the transfer of preembryos to my uterus, or out of complications of conception, childbirth or delivery, or from the birth of a child abnormal in any respect, or from any adverse consequences which may arise in connection with or as a result of my participation in assisted reproductive technology procedures. Nothing contained herein shall be construed to relieve Westchester Fertility from liability arising out of its professional malpractice during the course of our treatment.

6. Voluntary Participation

I voluntarily agree to undergo an assisted reproductive technology procedure under the conditions outlined above.

7. Understanding

We confirm that we have read this form, fully understand its contents. In addition, we confirm that we have had the opportunity to ask any questions and that all of our questions have been answered to our satisfaction. We acknowledge receipt of a copy of this form. Our consent applies only to one cycle of treatment. If we wish to undergo additional cycles we will have another informed consent discussion with Dr. Levine and sign again.

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Female Partner (print)

Signature

Date

Partner (print)

Signature

Date

Witness (print)

Signature

Date

Physician Certification: I hereby certify that I have explained the nature, purpose, benefits, risks of, and alternatives to the proposed treatment, have offered to answer any questions and have fully answered such questions. I believe that the patient fully understands what I have explained and answered, and has consented to undergo the proposed treatment.

Physician (print)

Signature

Date

Initial: Woman _____ Partner _____ Date _____

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