

# RECIPIENT PREPARATION FOR IVF CYCLE WITH DONOR EGGS

*Most checklist items require an appointment.  
Some steps can be combined and completed on the same day.*

Patient name: \_\_\_\_\_

- |                         |   |
|-------------------------|---|
| _____                   | Financial Consultation  |
| <i>appointment date</i> |   |
| _____                   | Strict Criteria Morphology Semen Analysis                           |
| <i>appointment date</i> |   |
| _____                   | IVF Profile Labs (male)   |
| <i>appointment date</i> |   |
| _____                   | IVF Profile Labs (female)   |
| <i>appointment date</i> |   |
| _____                   | Saline-Infused Ultrasound or Practice Transfer                      |
| <i>appointment date</i> | <i>**must be done between day 6 and day 11 of menstrual cycle**</i> |
| _____                   | IVF Registration and Medical History                                |
| <i>appointment date</i> | <i>**must be done before psychological consult**</i>                |
| _____                   | Embryology Consultation and Consents Notarized                      |
| <i>appointment date</i> |   |
| _____                   | Psychological Consultation  |
| <i>appointment date</i> |   |
| _____                   | Prescriptions   |
| <i>appointment date</i> |   |
| _____                   | Massage   |
| <i>appointment date</i> |   |

## FINANCIAL CONSULTATION

Your first step is to plan and prepare for the financial aspects of your IVF cycle. Please schedule this appointment a Financial Consultant early on in your pre-cycle process, since several weeks may be required to finalize your payment agreement. All financial details must be in place before you can proceed with your cycle. This step can be completed on the same day as one of your other office visits, if you wish. Just communicate with the front desk to ensure that appointments and arrangements are made for each step.

## SEMEN ANALYSIS

Our clinic uses a strict criteria morphology semen analysis to determine the percentage of normally shaped sperm in a sample. We also assess how many total sperm are present (for example, 25 million), how many sperm are moving, and how fast they are moving. These test results are needed prior to participation in an IVF cycle.

A semen sample must be collected by masturbation in a sterile specimen container (available through our offices). The specimen may be collected at home as long as it is delivered to the office within **one hour** of collection. It is recommended that you abstain from sex for 2 to 3 days prior to collecting for the specimen. Abstaining longer may adversely affect the specimen results. A second semen sample will be needed to fertilize the donor's eggs during the IVF cycle.

Studies have shown that Vitamins C and E help improve sperm quality. The longer these supplements are taken, the better the results. Recommended doses are 1,000 mg daily of C and 400 IU daily of E. Other fertility tips for men include eliminating tobacco, limiting alcohol and bicycling, avoiding hot tubs and chemicals, checking for prescription side effects, and enjoying frequent sex.

## IVF PROFILE LABS

Blood work on both men and women is required for participation in our program as well as all other IVF programs across the country. These labs include screening for HIV, RPR (Syphilis), Hepatitis B and C, Blood Type and Rh. In addition, women are screened for Rubella, Cystic Fibrosis Carrier and CMV Titer. If a female patient has had these tests done prior to the current cycle but longer than one year ago, labs must be redone. None of the male labs need to be repeated.

Your egg donor will have had these same tests done in addition to several others, such as screens for Chlamydia, Gonorrhea, nicotine and other drugs.

### SALINE-INFUSED ULTRASOUND AND PRACTICE TRANSFER

The saline-infused ultrasound is a test that evaluates the inside of the uterine cavity. It is done in our office by either Dr. Bird or Dr. Donesky and is accomplished by opening the vagina with a speculum and injecting warm saline into the uterus by way of a tiny, flexible catheter placed through the cervical opening. The filling of the uterus is observed on ultrasound to detect any irregularities, such as fibroids or septums. This test is best performed after your period is complete (bleeding has stopped) so it is usually scheduled **between day 6 and day 11** of your menstrual cycle. The procedure is relatively painless, but some patients experience cramping. To help avoid discomfort, you may take Ibuprofen one hour before your procedure.

If you have never had a saline-infused ultrasound or if your last one was done more than six months ago, your doctor may recommend repeating the procedure. The SIUS also serves as a “practice” for the actual embryo transfer. The depth of the uterine cavity and the curvature of the cervical canal are measured for a reference to help facilitate a smooth transfer of an embryo.

### IVF REGISTRATION AND MEDICAL HISTORY

You will meet with one of our IVF Team members to register to participate in an IVF cycle and become familiar with the steps involved. You will receive a booklet with detailed questions about your medical and obstetrical history including prescription medications. Please complete and return the booklet to our office as quickly as possible. You may contact anyone from our IVF team throughout the cycle. They are more than happy to answer questions, clarify information, provide instructions for giving progesterone injections, and prepare you for the transfer procedure.

### EMBRYOLOGY CONSULT

Susan Walker will review the results of your semen analysis to help plan for the best scenario to achieve fertilization during your IVF cycle. She'll also explain how the lab will be communicating with you while your embryos are in the incubator. Additionally, she will go over the consent forms with you before you sign or notarize any paperwork.

## CONSENT FORMS

There are five parts to the consent forms, which are included at the end of this book. The first is the consent to use eggs from an anonymous donor for an IVF cycle. The second is the consent for the cryopreservation (freezing) of extra eggs and embryos. The third is a legal statement specifying what should be done with any frozen eggs or embryos in the event that you and your spouse divorce. The fourth is the consent for assisted hatching of the embryos before transfer. The fifth is consent for intracytoplasmic sperm injection (ICSI), which may not be necessary for everyone but requires signed consents if needed. Please begin to think about these issues and talk with your spouse to ensure the two of you are in agreement before signing any forms. Also speak with your doctor about any questions you have regarding your consents. All consents must be signed, notarized, copied and placed in your chart **before** you can proceed with your IVF cycle.

## PSYCHOLOGICAL CONSULT

Our doctors strongly recommend that each couple participating in an IVF donor egg cycle schedule an appointment with our Licensed Clinical Therapist Ann Ramey to discuss the emotional issues that many men and women face when creating a child with the participation of an anonymous egg donor. Ann will help answer your questions, minimize your concerns and prepare both of you to move forward with this life-changing decision.

## MASSAGE THERAPY

Your IVF package includes one full-body massage to help increase blood circulation and relaxation and your chances for success. The best time to schedule your massage is the day before or the day of your embryo transfer. There is no additional charge to you for this optional service.

## PRESCRIPTION

Listed below are the medications that may be included in your prescription as well as the prescription for your egg donor. Please notify a member of the IVF Team when you are ready to have your prescription called in to a pharmacy. You will have unlimited refills on most items. If the pharmacy contacts you to find out where to send your medications, you may request that your donor's medications be shipped directly to our office and that your medications be delivered to your home.

### FOR WOMEN

Prenatal Vitamins

Baby Aspirin

Vivelle DOT – 0.1mg estrogen patches

Progesterone in ethyloleate or oil – 50mg/ml

Prometrium

Endometrin

needles and syringes for mixing and administration

### FOR MEN

Zithromax

### FOR DONOR

Follistim, Ganirelix, Novarel (hCG), Zithromax, Darvocet and Phenergan

**Specialty mail-order pharmacies are the Fertility Center's pharmacies of choice.** They provide the **best prices** for fertility medications and supplies. They also offer **home delivery including overnight services**, have a **pharmacist available 24 hours a day, seven days a week** and have a **toll free number**. You are encouraged to call specialty pharmacies if you have medication questions about your ordered prescriptions just as you would phone your local pharmacy.

## UTERINE PREPARATION

Begin taking your prenatal vitamins as soon as your prescription is filled. You will need to call our office when your period starts to make an appointment for a baseline scan and lab. We'll use a vaginal ultrasound to check for cysts on your ovaries and draw blood to determine your progesterone level. Your scan and lab must be done within three days of starting your period, or your body will take over production of hormones and your uterine lining will be out of sync for your embryo transfer. After your baseline scan and lab, you and your husband will both begin taking your prescribed antibiotic.

Once we confirm that your ovaries are quiet and that your progesterone is low, you will apply two estrogen patches to your lower abdomen. You will replace these patches every third day while slowly increasing the number of patches until your lining has thickened appropriately to be receptive to an embryo transfer. When changing your patches, attach the new ones to different areas to allow your skin to recover from the previous patches. Adhesive residue can be removed easily with baby oil. If your lining is not thickening adequately, estrogen tablets in vaginal suppository form may be added to your medication protocol.

You will be given a calendar schedule that details when to administer and replace your patches and when to schedule appointments for scans and labs. Samples of calendars are included in this book.

Once your lining is ready, you will be instructed to start your progesterone injections. These intramuscular injections must be taken twice a day, and the start of these injections must be coordinated with the stage in which your embryos were frozen. Once you start progesterone injections, you will decrease your patches to two every third day. If you have any questions about your progesterone injections or need a refresher course on administering the shots, refer to your injection instructions or contact Jan Lambert or another member of our IVF Team.

If your transfer results in a pregnancy, you will use estrogen patches and some type of progesterone supplements (oral, vaginal, etc.) throughout your first trimester (12 weeks). Your prescription will include refills.

## DAY OF DONOR'S RETRIEVAL

You will be notified when your donor gets "triggered" for her egg retrieval, and you will be told when to deliver a sperm specimen to our office. Men need to be available to bring in a semen specimen at the time given on the day of the retrieval. This specimen may be collected at home as long as it's brought to our office within one hour. Once your donor has been "triggered," please abstain from sex until after the sperm specimen has been collected.

## EMBRYO TRANSFER

You will receive a phone call the day after your donor's retrieval with a report on how many eggs have fertilized. The following day, the embryos should begin cell division, and by day 5 after retrieval we expect them to become blastocysts ready to be transferred. Typically, the best two embryos are selected by the embryologist and photographed. Your doctor will go over his recommendations for how many embryos can be safely transferred to your uterus. You will have the opportunity to discuss with your physician and the embryologist, if you wish, how many you are comfortable having transferred.

The remaining embryos that are not transferred will be frozen, unless you have requested no cryopreservation. If embryo development stops and degeneration begins, the embryos will be discarded.

Please arrive at the Fertility Center in Chattanooga about 15 to 30 minutes prior to your scheduled transfer. You may eat and drink as you please beforehand since this is a non-surgical procedure with no anesthesia. You will be asked to undress from the waist down only and given a blanket to wrap around you. We prefer to do your transfer with your bladder full, so once you get to the Center, PLEASE DON'T EMPTY YOUR BLADDER. Blood will be drawn to check your progesterone level.

Your husband or a guest may accompany you to the procedure room where we do your transfer. Your feet will be placed in stirrups, and a sterile speculum will be inserted into your vagina (similar to a PAP smear). Your doctor will take a few minutes to rinse the cervix and vaginal canal, and swab it to remove any cervical mucous that might be present and trap the embryos. The embryologist will load all the embryos that are being transferred into a very soft, flexible, tiny catheter that will be passed through the cervical opening and up into the endometrial uterine cavity. Monitored by abdominal ultrasound, the embryos will be deposited toward the top of the uterus, and the catheter will be withdrawn. The embryologist will check the catheter under the microscope to make sure none of the embryos remain, and then your legs will be taken down from the stirrups. You will scoot over to a stretcher and be taken to the recovery room where you will rest for about 20 minutes before going home. You will need someone to drive you home, and you will receive written discharge instructions.

You will return to our office for a pregnancy test about nine days after your transfer. If that test is positive, you have just completed four weeks of gestation. A full-term pregnancy typically lasts a total of 40 weeks from the first day of your last period. But in cases of assisted reproduction, your cycle is controlled with medications and you may not have had a period before your IVF cycle. As a result, you need to count backwards 14 days or two weeks from your egg retrieval day to mark the day that represents that beginning of your last period. In simpler terms, you begin week five of your 40-week term the day after your positive pregnancy test.

## **PROGESTERONE IN ETHYL OLEATE**

*Take first injection the evening of retrieval, then once or twice daily as directed.*

*Store at room temperature. Use one needle to draw and another to inject.*

*Rotate hips and vary injection sites to avoid tenderness.*

*Give injections into the hip muscle only – never in the arms or legs.*

### **Injection Instructions – **Intramuscular****

1. Assemble supplies:
    - electric heating pad
    - alcohol swabs/cotton balls
    - Progesterone in ethyl oleate      **\*\* (if in oil, see note at bottom of page)\*\***
    - 3 cc/ml syringe
    - 22GA 1½ inch needle (black hub) for drawing up medication
    - 25GA 1½ inch needle (blue hub) for injecting medication
    - disposal container
    - band-aid (optional)
  2. Keep injection site on heating pad for 5-10 minutes. Place medication vial in a glass of warm water for 3-5 minutes.
  3. Wash your hands.
  4. Remove lid and swab top of Progesterone vial with alcohol.
  5. Twist 22GA needle (black hub) onto syringe.
  6. Turn vial upside-down, then inject needle into vial and draw up 1 ml.
  7. Change your needle, twisting on the 25GA needle (blue hub).
  8. To eliminate air bubbles, tap on side of syringe with needle pointed upward. Push air out of needle before injecting.
  9. Select an area in the upper-outer part of your hip that has been warmed-up with the heating pad and swab with alcohol. Allow it to dry.
  10. Insert the needle quickly through the skin to the hub. Pull back slightly on the plunger. You will probably see an air bubble come back. Inject the Progesterone.
- NOTE: If you see blood when you pull back the plunger, remove the needle from the hip and replace it with a new needle. Don't throw away your medication, even if there's a drop of blood in it. Move to the other hip and try again.
11. Withdraw needle. Apply pressure to the site with a clean, dry cotton ball for a minute or two. Cover with a band-aid, if needed.
  12. Keep injection site on heating pad for 5-10 minutes.

**\*\* For Progesterone in oil :**      use 18GA 1½ inch needle (pink hub) to draw  
use 22GA 1½ inch needle (black hub) to inject

# CYCLE CALENDAR

Month \_\_\_\_\_

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

My baseline uterine lining scan appointment is \_\_\_\_\_  
(date)

My second lining scan appointment is \_\_\_\_\_  
(date)

**REMINDER:** Don't forget to check for voicemail messages.  
Dial (423) 899-0500, then press 4, 1, and your 7-digit home phone number.

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**Fertility Center, LLC  
and  
Embryo Services, LLC**

**INFORMED CONSENT: ANONYMOUS DONOR OOCYTE (EGG)  
Oocyte Recipient Form**

We, \_\_\_\_\_(recipient wife) and \_\_\_\_\_ (recipient husband), have voluntarily engaged the services of the physicians and members of the Assisted Reproductive Technologies Program of the Fertility Center, LLC and Embryo Services, LLC (herein after referred to as "The ART Program") to perform In Vitro Fertilization using oocytes obtained from the ovaries of an anonymous donor and fertilized with the recipient husband's sperm. The oocyte donor has been recruited by the ART program. We understand that this consent extends from the initial period of participation in the IVF Program until the donor cycle has been completed, or the physician makes a determination that based on previous cycle responses this is a treatment that will result in a very small chance for pregnancy or no chance at all, or until we decide to discontinue participation in the ART program. We realize that within thirty days prior to the transfer date, the egg donor must undergo the FDA mandated tests to confirm she continues to test negative for a number of STDs as well as for HIV. Should she test positive, we realize the cycle must be cancelled. We understand the FDA does not give any exceptions to the requirement to cancel a cycle due to a final positive testing.

An anonymous donor oocyte (egg) cycle includes the following steps or procedures:

1. Ovulation induction of an anonymous donor
2. Preparation of recipient wife's uterus
3. Retrieval of oocyte(s) from the anonymous donor
4. Collection of recipient husband's sperm
5. In vitro fertilization of the oocyte(s)
6. Transfer of embryo(s) into the recipient wife's uterus
7. Support of early pregnancy

In other words, oocyte(s) removed from the anonymous donor's ovaries are taken outside the body, mixed with the husband's sperm to allow fertilization, allowed to grow in the laboratory for a few days and transferred back into the wife's uterus (or tubes on occasion). The recipient may not become pregnant from this treatment, or one or more embryo(s) may grow into a full-term baby or babies.

This program follows the guidelines of the American Society for Reproductive Medicine. The anonymous donor must be between the ages of 19 and 34. If the recipient wife is age 40 or older, it is recommended that she consult with a perinatologist (high-risk pregnancy specialist) to understand any potential risks that a pregnancy may pose to her health. It is strongly recommended that we also consult with a psychologist to assess and explore the emotional issues surrounding this non-traditional method of family-building. We will be required to undergo screening for infectious diseases in accordance with guidelines established by the American Society for Reproductive Medicine with testing for HIV, Hepatitis and Syphilis. The recipient wife also will be tested for immunity to Rubella (German measles) and for blood type. Other tests that may be required include an evaluation of the uterine cavity to ensure a normal environment for implantation, and measurements of the depth of the cavity.

The anonymous donor also will be tested for the infections diseases mentioned above as well as Chlamydia and Gonorrhea and will be screened for drug use, including nicotine.

### **Step 1: Ovulation induction of donor**

Agents to promote the simultaneous maturation of a number of oocytes in the donor's ovaries will be administered to her daily at dosages according to her particular needs. In general, the purpose of using these agents is to improve the efficiency of obtaining fertilizable oocytes. The agents may include:

A) Leuprolide acetate (LUPRON): This is a hormone synthetically made in a laboratory. It is very similar to a substance called GnRH which is naturally produced in the brain. Lupron will be injected daily to suppress some hormonal output from the pituitary gland. The long-term effects of this medication on the donor or the effects on the developing embryo(s) are not fully known. However, information available within the scientific medical community at this time suggests no significant long-term effects on the donor or on the developing embryo(s).

B) In order to harvest more than one egg per treatment cycle, the donor will be given fertility medications called human menopausal gonadotropins (Pergonal, Humegon) and/or urofollitropins (Follistim or Gonal F) daily by injection. These medications cause the ovaries to develop multiple eggs, which grow in fluid-filled sacs called follicles. Occasionally, these medications can over stimulate the ovaries resulting in Ovarian Hyperstimulation Syndrome. This consists of ovarian enlargement which in some cases may be accompanied by abdominal distention and abdominal pain. In rare cases, the syndrome may become severe. Severe hyperstimulation causes accumulation of fluid in the abdomen and sometimes around the lungs which may cause breathing difficulties. Even more rarely, the ovary can bleed or undergo twisting which may require surgery. The fluid shifting can affect blood clotting and in very rare cases can be life threatening. Treatment consists of hospitalization, blood work, bed rest, and aspiration of the fluid. Careful monitoring with ultrasound and blood tests is very important to the prevention of this problem. Other adverse reactions that have been reported are: allergic sensitivity, pain, rash, ectopic pregnancy, headaches, fluid retention, weight gain, irritability, depression, fatigue, and visual disturbances. Any of these side effects should be reported to a physician immediately.

*NOTE: Currently 1 out of 424 women in the United States will develop ovarian cancer in their lifetime. Some recent studies have suggested an association between fertility drugs and the development of ovarian cancer. However, it has been known for some time that the risk of ovarian cancer is increased in women who do not become pregnant and deliver. Some of those women will have taken fertility drugs, but it is still unclear whether it is the infertility itself or the fertility drugs which are responsible for this association. The most recent data available suggests that if there is an increased risk of developing ovarian cancer as a result of taking fertility medications, that risk is very low provided that the use is not of long-term duration. Further research is needed to determine if a direct association exists between the use of fertility drugs and the development of ovarian cancer.*

C) The donor will undergo serial blood tests and ultrasound scans of her ovary(ies) to assess growth of the developing follicles. When the sizes of the follicles are optimal, an injection of human chorionic gonadotropin (hCG-Novarel, Pregnyl, Profasi or Ovidrel) will be given to trigger mechanisms that result in final maturation of the oocyte(s) and the rupture of the follicles. The oocytes must be harvested at their final stage of maturity but before rupture occurs.

During the process of ovulation induction, there will be daily blood samples from a vein in the donor's forearm obtained over a period of 7 to 14 days. Each sample requires a maximum of 10ml (2-3 teaspoons) of blood. Unfortunately, with repeated sampling, bruises are not uncommon. At appropriate times, the donor will undergo pelvic sonograms (ultrasound) to determine the size of the follicles. This technique involves the use of sound waves inaudible to the human ear. These are not harmful to the body in general or the ovaries in particular. The waves are sent and their echo is received by a long narrow device (probe) that is gently placed in the vagina and which causes no discomfort. This permits the placement of the probe close to the ovaries for careful monitoring of follicle size.

### **Step 2: Preparation of recipient wife's uterus**

In most cases, Leuprolide is not needed; however, it may be necessary to administer Leuprolide to temporarily stop hormone production from the ovaries which could interfere with the recipient's ability to get pregnant. It also may be used to synchronize her cycle with the anonymous oocyte donor in preparation for implantation. If needed, the medication will be administered as daily subcutaneous injections starting on day 21 of the first period after the beginning of the IVF cycle. This agent will be given simultaneously with other agents and until the donor's oocytes are collected. Possible side effects that may be experienced during the administration of Leuprolide are hot flashes, vaginal dryness, redness and small bruises at the injections site. Rare cases of allergic reactions at the injection sites also have been reported.

Preparation of the recipient wife's uterus for placement of the fertilized oocyte(s) includes treatment with estrogen and progesterone to substitute for ovarian production. This includes estrogen patches applied to the body in increasing/decreasing amounts as well as progesterone in oil injections as prescribed by the physician. The risks of taking these hormones are similar to the risks involved in taking the birth control pills. No unusual side effects have been reported. Frequent blood tests and an ultrasound study of the recipient's uterine lining will be necessary during this protocol.

### **Step 3: Retrieval of oocytes**

In most cases, the oocytes (eggs) will be harvested by ultrasound-guided transvaginal aspiration. A needle guide is placed alongside the ultrasound probe which is inserted into the vagina. A special needle is then inserted through the needle guide, penetrating the vaginal wall and directed into the ovary(ies) inside the pelvis. This procedure generally requires only mild sedation and not general anesthesia. Rare risks of this procedure include injury to other structures in the pelvis (such as bowel or blood vessels), infection or excessive bleeding.

On very rare occasions, the eggs may need to be harvested by laparoscopy for various reasons. If this is the case, a small incision will be made in the area of the umbilicus to allow placement of a specialized telescope (laparoscope) to visualize the ovary(ies). Other small incisions will be made near the pubic hairline for placement of a probe and an instrument to grasp the ovary(ies). A needle will be inserted through the lower abdominal wall into the pelvis for aspiration under direct visualization with laparoscope. Rare risks of this procedure include injury to other structures in the abdomen or pelvis (such as bowel or blood vessels), infection or excessive bleeding. Should one of these rare complications occur, there is a chance that the donor's own fertility could be compromised.

During oocyte retrieval (as with any invasive procedure), complications may occur that may require a larger operation (either laparoscopy or laparotomy) to take care of the complication(s).

With either the ultrasound approach or the laparoscopic approach, physicians may fail to retrieve oocytes either because the donor's ovaries did not respond to the stimulation, or because they could not be collected due to technical problems. The recipient may choose to donate oocytes to other couples if the donor has too many follicles or may choose to cryopreserve excess embryos for future potential use. These issues need to be decided in advance before the cycle begins, to allow for proper scheduling and coordination. These alternatives are offered on a voluntary basis and by no means will there be a penalty or will care be denied should there be a refusal to donate excess oocytes.

Following retrieval, the donor's participation ends.

#### **Step 4: Collection of sperm**

Semen will be obtained from the recipient husband by masturbation in close proximity to the laboratory. Alternatively, the semen may be collected at home or at another site provided that the specimen can be in the laboratory within 45 minutes of ejaculation. If the semen is collected at a site other than at the laboratory, it will be necessary to sign an affidavit form testifying that this is the semen of the recipient's husband. The specimen will be processed by the laboratory and used to fertilize the oocytes by incubating them in a suitable culture medium. If for some reason a specimen cannot be produced, "male factor" condition exists (low number of sperm and low motility), or an unexpected poor specimen is produced, donor sperm can be used. This issue must be discussed with the physician before the cycle begins, and separate blood tests and matching of donor that must be accomplished well in advance of the donor's oocyte retrieval.

#### **Step 5: In vitro fertilization of the oocyte(s)**

After processing the sperm, it will be incubated with the oocyte(s) for fertilization. Subsequently, any resulting embryo(s) will be allowed to develop into a pronuclear stage (4 to 8 cells) for transfer. This may or may not occur within 2 to 3 days, depending on the quality and maturity of the oocytes initially collected and other factors not yet identified.

#### **Step 6: Transfer of the embryo(s) into recipient wife's uterus**

Following several cell divisions, replacement of the embryo(s), if any, will be made into the recipient's uterus by means of a small plastic tube inserted through the vagina and cervix and into the uterus. She will be asked to remain on the transfer table for approximately 20 minutes after the transfer and remain at limited activity (no strenuous activity or heavy lifting) for three days following the transfer. The risks of this procedure are a very small risk of infection, which may manifest itself with a fever. Allergic reactions can also occur. Excess embryo(s) may be frozen for use in subsequent IVF cycles. Another option would be to donate excess embryos anonymously to another couple. Separate consent forms need to be signed in advance of the procedure.

#### **Step 7: Support of early pregnancy**

Should a positive pregnancy test occur following the embryo transfer, the progesterone in oil and possibly by mouth will be extended through the 70th day (until the twelfth week of pregnancy) to provide hormonal support for the early pregnancy. After the twelfth week of pregnancy, the placenta should be well established and will take over the function of hormone production for the pregnancy. It must be understood that should a pregnancy occur, several blood tests and two ultrasounds will be needed to assess normal growth and to document the number of fetuses and fetal heartbeats.

It is possible that more embryos can result from an IVF cycle than the number desired to be transferred. Plans for these supernumerary embryos must be made before the cycle begins. As the chances of multiple pregnancy increases significantly without further improvement in pregnancy rates when three or more embryos are transferred back into the uterus, the ART Program's policy is to transfer no more than three embryos until a woman reaches the age of 39. The remaining embryos can be cryopreserved (frozen), discarded, offered for donation (provided a suitable recipient is found and consent for donation is signed), or used for research projects by the ART Program as allowed by government rules and regulations.

**IT IS OUR INTENTION THAT ANY EMBRYOS NOT USED IN THE INITIAL FRESH EMBRYO TRANSFER SHALL BE ONE OF THE FOLLOWING** *(please initial a decision for each):*

That the embryos be frozen for later use by us.

YES \_\_\_\_\_ (requires additional consents)

NO \_\_\_\_\_

That the embryos be discarded immediately after the embryo transfer.

YES \_\_\_\_\_ (requires additional consents)

NO \_\_\_\_\_

That the embryos be donated for use by other infertile couples, if otherwise permitted by applicable law. We waive any and all claims to the right of any children that may result from these embryos. Any children from this process are the legal children of the recipient couples. In the case of donation, both donor and recipient remain anonymous to each other. This alternative is offered on a purely voluntary basis and the patient is never denied care should they refuse to donate embryo(s).

YES \_\_\_\_\_ (requires additional consents)

NO \_\_\_\_\_

That the embryos be utilized in research projects permitted under the policies and applicable legal requirements of the ART Program at the Fertility Center and Embryo Services.

YES \_\_\_\_\_ (requires additional consents)

NO \_\_\_\_\_

These issues must be discussed with the physician before the medications are started. If we do not wish to discard, to cryopreserve, or to donate supernumerary embryos to couples or research, we understand we have the right to only expose a limited number of oocytes to the sperm.

We understand that if we limit the number of eggs inseminated, we may end up with (1) no fertilized eggs and consequently no pre-embryos for transfer, or (2) a lesser number of eggs fertilized than originally inseminated, which may decrease the chances of successful pregnancy.

We indicate here our wish for \_\_\_\_\_ (all or a specific number) eggs to be inseminated.

\_\_\_\_\_ (initials)

If pregnancy occurs following these procedures, the risk of multiple births is approximately 24% (twins 20%, triplets 4%, quadruplets less than 0.4%). After discussion of the chances of multiple pregnancy and its attendant risks, we have decided to have \_\_\_\_\_ (range) fertilized eggs (pre-embryos) transferred into the uterus.

\_\_\_\_\_ (initials)

We understand that thousands of babies have been born around the world through IVF since 1978, and that there is no indication of any increase in the rate of abnormalities in the children born as a result of IVF. The incidence of abnormalities appears to be no greater than that for babies born as a result of natural conception (about 3%). A genetic amniocentesis or chorionic villus sampling is recommended to women older than 34 years. Any abnormality in our baby(ies) born as a result of IVF is our sole responsibility, and we will not hold the ART Program liable.

## **IMPORTANT POINTS TO REMEMBER**

- The anonymous donor's ovaries may not respond to the ovulation induction protocol, resulting in insufficient oocytes for retrieval. If this happens, the cycle may have to be canceled.
- The anonymous donor's ovaries may overstimulate in response to this protocol, producing too many follicles and estradiol levels that are too high as determined by the physician for the health and safety of the donor. If this happens, the cycle may have to be canceled.
- Only a single follicle may develop as a result of the ovulation induction. If this happens, the cycle may have to be canceled.
- An attempt at oocyte retrieval from the donor may be unsuccessful.
- The husband may fail to produce a semen sample for fertilization of the oocyte(s).
- Fertilization may not occur or there may be very poor fertilization, thus eliminating or decreasing the chance for pregnancy. These scenarios are most likely to occur with a "male factor" infertility diagnosis and rarely occur with a normal semen sample.
- The embryo(s) may not cleave and divide after fertilization.
- The embryo(s) may not implant after transfer.
- The embryo(s) may not develop normally, resulting in a very early miscarriage (biochemical pregnancy) or a clinically evident miscarriage.
- An ectopic pregnancy (tubal pregnancy) may occur.
- A laboratory accident may result in loss of and damage to the oocyte(s), sperm, or embryo(s). However, such an occurrence is not expected as great care is taken with all specimens.
- The pregnancy may result in the birth of a baby(s) with congenital anomalies. The odds for such an outcome are the same as those in the general population. A genetic amniocentesis or chorionic villus sampling may be done where appropriate.
- As more than one embryo is transferred into the uterus (or tubes), multiple pregnancy (twins, triplets, etc.) with subsequent risks may occur.
- The egg donor can be at risk for ovarian hyperstimulation syndrome. This is a very rare syndrome that occurs in only 1% of women that are stimulated for ovulation induction using gonadotropins (Pergonal, Humegon, Follistim or Gonal F). The symptoms begin after transfer of embryos(s) and usually occur with pregnancy, and most of these pregnancies are multiples. Because the donor is instructed to use barrier contraception during this cycle, she should not become pregnant herself; thus, her chance for ovarian hyperstimulation is very low. However, should her ovaries stimulate excessively, she still could be at some risk from the hCG (Profasi) injection itself. If she overstimulates prior to the egg retrieval, it may be necessary to withhold hCG and thus cancel the cycle.
- The donated oocytes are from an anonymous individual. There will be an effort to match the general physical characteristics of the donor with the recipient couple's own general physical characteristics. In addition, we understand the donor will be queried about familial genetic diseases, illegal drug use, and contagious diseases, but no guarantee about the reliability of the history given by the donor can be made.
- The physical and mental characteristics of any child(ren) resulting from these procedures cannot be guaranteed. The recipient couple, as well as their successors, offspring, and assigns, hereby release and agree to hold harmless from liability the physicians, staff and associates of the ART Program for the following: complications resulting from the anonymous oocyte donor procedures and transfer and from pregnancy or childbirth; any mental, emotional and physical problems suffered; and/or physical or mental disability of child(ren) produced following these procedures.
- The anonymous oocyte donor will agree to screening as recommended by the American Society for Reproductive Medicine to attempt to detect any infectious diseases which might be transmissible to the recipient. The anonymous oocyte donor will be psychologically screened and screened for illegal drug use. Any potential donor will be rejected for donation if any of these tests show evidence of potential to transmit an infectious disease or if the psychological tests indicate other than altruistic reasons for oocyte donation. However, these tests are not 100 percent accurate. The American Society for Reproductive Medicine lists as an option to test the donor for HIV before the cycle begins and then to freeze all the embryos(s) before reimplanting them into the recipient's uterus six months later after the donor can be retested. This would almost eliminate the chance to transfer the HIV virus. Although this is an option, the pregnancy rate would be decreased to the pregnancy rate of cryopreserved embryo(s) that are implanted.
- The oocyte donor will be counseled to abstain from sexual activity during the cycle of oocyte donation, but her abstaining from sexual activity can not be assured.

- The recipient couple indicates by signing this consent form their agreement to release the anonymous donor from any legal or financial responsibilities from an established pregnancy or medical costs related to that pregnancy and delivery. The couple's heirs will release the anonymous donor from any financial and legal responsibility for the child(ren) from conception forward for that/those child(ren). The couple and their heirs also release the physicians, associates and staff of the ART Program from any financial responsibilities for the child(ren) from conception forward in time.
- The recipient couple are financially responsible for all costs incurred before and including the day of retrieval, including complications involving a more involved surgery (in case of uncontrolled bleeding), immediate hospitalization for recovery of the more involved surgery, and any medications needed for all procedures. The recipient couple will not be financially responsible for medical expenses incurred after the day of oocyte retrieval except for expenses involved in recovery from a more involved procedure occurring on the day of oocyte retrieval.
- There is little information available regarding overall pregnancy rates in this specific type of procedure. The success rate may be similar to that achieved in other types of in vitro fertilization procedures. The ART Program does not guarantee that its success rate will be similar to that of other programs.
- Insurance coverage for any or all of the IVF procedures may not be available, so the recipient couple is personally responsible – individually and collectively – for all medical and hospital expenses incurred by or for wife, husband and anonymous oocyte donor in connection with the IVF procedures. Efforts have been made in good faith to accumulate all costs related to this treatment on the financial disclosure given previously. However, some costs may be unavailable for disclosure due to the inability to always accurately predict the extent and nature of needed procedures and potential complications. Additionally, all costs are subject to change without notice.
- The recipient couple is free to discontinue participation in the ART Program at any time, either verbally or in writing. Their decision to discontinue participation will in no way prejudice other treatment that may be received from the Fertility Center or Embryo Services. If there is a decision to discontinue participation in the program, the recipient couple will be personally responsible for all the expenses incurred during the period of time prior to such discontinuation, including anonymous oocyte donor screening and/or treatment.
- The results or any aspect of treatment may be published in medical literature. If publication of data occurs, all reasonable precautions will be undertaken to protect the anonymity of all parties. The ART Program team has permission to publish statistics related to cases in said journals as long as names are not used.
- Anonymity is required for the donor as well as the recipient of the oocytes. The anonymous donor has signed a consent and agreement not to try under any circumstances to contact the recipient and is aware that absolutely no information will be given to her from this program concerning the recipient couple. The anonymous donor has agreed to relinquish any rights to responsibility or claims to any child(ren) or embryo(s) resulting from her donation of oocyte(s).
- The anonymous donor has been counseled that when the cycle has begun, it is ethically responsible for her to complete that IVF cycle to the best of her ability. If the donor is unable to fulfill this obligation and complete retrieval for any personal reason, other than as is medically indicated by one of our physicians, or if the donor has not followed our instructions, no participation reimbursement will be made. If cancellation of the cycle is required for a medical reason as indicated by one of our physicians, including poor ovulation induction, a partial participation reimbursement of \$400 will be paid to the donor by the recipient couple.
- The physicians, associates and staff of the ART Program have not undertaken hereby or in any other document or oral communication to advise the recipient couple of their legal rights, now existing or hereafter arising, and specifically disclaim any responsibility to do so. It is recommended that the recipient couple consult legal counsel so as to be fully informed of their legal rights and obligations and the legal rights and obligations of others involved in this program, but if they elect not to do so, such elections are hereby acknowledged to have been determined without reliance upon statements, oral or written, of the ART Program team.
- The recipient and her husband release the physician, associates and staff of the ART Program from any responsibilities or legal liabilities related to the recruiting of anonymous donors from the surrounding community.
- The recipient and her husband are at least 18 years old.

**WE HAVE HAD AN OPPORTUNITY TO ASK QUESTIONS, AND THE PHYSICIAN(S) AND EMBRYOLOGIST(S) HAVE ANSWERED THEM TO OUR SATISFACTION.**

**WE RELEASE THE PHYSICIANS OF THE FERTILITY CENTER AND/OR EMBRYO SERVICES AS WELL AS THEIR EMPLOYEES/STAFF/ASSOCIATES THEREOF FROM ANY MEDICAL OR EMOTIONAL RISKS AND/OR LOSSES RELATED TO VOLUNTARY PARTICIPATION IN THIS PROGRAM.**

**WE HAVE READ THIS FORM AND ACKNOWLEDGE RECEIPT OF A COPY.**

\_\_\_\_\_  
**Patient's signature**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Spouse's signature**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Notary's signature**

\_\_\_\_\_  
**Date**

**Commission Expires On**

\_\_\_\_\_  
**Date**

I have thoroughly reviewed the information contained in this consent with the above named persons and believe they have made an informed decision regarding assisted reproductive treatment.

\_\_\_\_\_  
Staff Signature

\_\_\_\_\_  
Date

***INFORMED CONSENT: OOCYTE RECEIPT***

**Fertility Center, LLC  
and  
Embryo Services, LLC**

**INFORMED CONSENT: CRYOPRESERVATION OF EMBRYOS**

We are giving our consent for cryopreservation of human embryo(s) following in vitro fertilization. This procedure is intended to initiate a successful pregnancy after cryopreservation of embryos in their early stages of development. We understand that participation in this program is voluntary. If we elect not to participate in this program, our decision will neither prejudice nor harm our present or future relations with the Assisted Reproductive Technology Program at the Fertility Center, LLC, or Embryo Services, LLC, hereafter referred to as the "ART Program," nor result in any penalty or loss of benefits to which we are otherwise entitled. We have reviewed this form carefully and asked questions before deciding to participate.

We have been selected as possible participants because we are currently participating or considering participation in the ART Program at the Fertility Center and Embryo Services. The freezing procedure may be utilized if we produce more embryos during our In Vitro Fertilization (IVF) or Zygote Intrafallopian Transfer (ZIFT) cycle than we desire to accept for embryo transfer in that same cycle or if we produce more eggs in a Gamete Intrafallopian Transfer (GIFT) cycle than can be transferred in that same cycle. If so, these embryos, which result from the fertilization of eggs from the wife by sperm from the husband (or donor gametes, if so selected) will be frozen using a technique called cryopreservation.

Embryos not transferred during the IVF/GIFT/ZIFT cycle and deemed good quality by the physician and laboratory personnel will be frozen.

The embryos will be stored in the frozen condition until such time as we request their use and the physician determines that appropriate conditions exist in us (specifically, the wife) for transfer of the embryo(s) to the uterus. At that time, some or all of the embryos will be thawed. After thawing, embryos are hydrated and treated in a manner similar to that used in the IVF laboratory for non-frozen embryos. Each embryo will be examined to determine whether it is medically appropriate to transfer, and if so, the transfer into uterus or tubes may be performed. Freezing and thawing of embryo(s) probably reduces to some degree the chance of an embryo implanting. The overall chance of pregnancy with frozen and thawed embryos in the ART program is currently approximately 60% per transfer.

If we become pregnant with the initial IVF/GIFT/ZIFT cycle, the unused embryos may be stored frozen at Embryo Services for no longer than five years from their initial freezing. We can request during any subsequent cycle within five years that the embryos be thawed and transferred.

Embryo freezing has been successfully used in animals through more than one generation with no known adverse results, but there is relatively limited (less than 15 years) experience with human embryos. Although no defects have been reported from births resulting from frozen embryos, the long-term risks associated with human embryo freezing, thawing and transfer are not well established at present.

If pregnancy does occur, CVS (removal of a small amount of placental tissue) or Amniocentesis (removal of a sample of fluid surrounding the baby) is available to identify certain potential chromosomal (genetic) abnormalities. Our physician will advise us if such testing is indicated. If an abnormality were to exist, the physician and geneticist will discuss the implication of such findings with us.

As with any technique that requires mechanical support systems, equipment failure can occur. Unforeseen situations causing damage to or loss of embryos, including human error, could occur despite the best efforts of the ART Program and its staff. Neither the ART Program, nor the Fertility Center, their directors, employees, officers and agents or consultants, including Embryo Services, are to be held liable for any destruction, damage or improper freezing, maintenance, storage, withdrawal, thawing, and/or delivery caused by or resulting from any malfunction of the storage tank, failure of utilities, strike, cessation of services or other labor disturbances, or war, acts of a public enemy, or other disturbance, any fire, wind, earthquake, water, or other acts of God, or the failure of any other laboratory.

IVF and embryo cryopreservation and transfer are new areas in which legal principles and requirements have not been firmly established. Based on currently accepted principles regarding legal ownership of human sperm and ova, we have been advised that each embryo resulting from the fertilization of the wife's ovum by the husband's sperm shall be considered the joint property of both of you, as the wife and the husband, who are deemed to be the legal owners.

As the owners of any and all such embryos, the consents of both of us (wife and husband) will be required concerning the disposition of any and all such embryos except in circumstances where you both, in accordance with applicable laws, agree to alternative arrangements for utilization or disposition of the embryos or such use or disposition is controlled by applicable law or the final decision of a court or other governmental authority having jurisdiction over such decisions. Certain uses or disposition may also require approval by the ART Program at the Fertility Center or Embryo Services. Future legal decisions or government regulations may prohibit embryo cryopreservation or alter this agreement.

The ART Program at the Fertility Center and Embryo Services has prepared a proposed statement regarding disposition of the embryos in a number of possible circumstances entitled "Legal Statement," which we are requested to execute. A copy of that statement is attached to the consent form, which is separate from this document. If we have questions regarding any of the provisions of the Legal Statement, it is recommended that we consult with our attorney prior to executing the statement. Regardless of whether we choose to execute the Legal Statement, we have been urged specifically to provide for disposition of any embryos that are not utilized for purposes of attempting to initiate a pregnancy, in the event of any subsequent change in our health or our marital status. It has been suggested that we maintain a copy of the statement and form in a place, such as a safe deposit box with other important documents, and that if we have personal legal counsel, we also give a copy to our attorney.

We understand that we retain the right to change our decisions regarding the use and disposition of any frozen embryos at any future time by written notice to the ART Program at the Fertility Center, which will notify Embryo Services. The ultimate disposition of these embryos will also be subject, in the event of a change in our marital status or other events interfering with fulfillment of our present intentions, to applicable laws and court decisions (such as a decree of dissolution) affecting the ownership or control of the embryos.

We understand that it is our responsibility to maintain contact at least yearly with the ART Program at the Fertility Center, pay the cryopreservation storage fee to Embryo Services, and to inform the physicians of our current address and telephone number. **If the physicians or associates at the ART Program are repeatedly unable to contact us and we do not contact them in writing over a period of two years, we understand that the ART Program or Embryo Services will discard our embryos. We understand and agree not to hold the ART Program at the Fertility Center or Embryo Services liable for the discarding of our embryos if we fail to meet the requirements established in this document.**

We have the right to arrange for and direct the shipment of the frozen embryos to another medical institution for thawing and transfer. Notwithstanding the foregoing, we release the ART Program at the Fertility Center and Embryo Services from any responsibility for damages resulting from improper shipping or handling of the frozen embryos, or from the negligence of the receiving program. We also have the right to claim our embryos in a frozen state for other personal disposition including thawing and discarding. (additional consents required)

We further agree that if during the period of storage of our frozen embryos we should both die or otherwise become permanently incapable of determining the fate of our stored frozen embryos, the disposition of the embryos shall be made at the discretion of the ART Program in accordance with our written intentions regarding use and disposition of these embryos contained within this document.

Embryo Services will be custodian of our frozen embryos. The ART Program will keep the embryos for up to five years from their initial freezing stored with Embryo Services. We agree to pay in advance \$900.00 for the cost of freezing and up to one year of storage. After the year, we will pay \$360.00 per year in advance for storage to Embryo Services. Prices are subject to change without notice.

**Disposition:** We understand and agree that if at the end of the period of storage stated above any frozen embryos should remain unused for intrauterine transfer, or if during the period of storage we should both die or become permanently incapable of determining the fate of our stored frozen embryos, or if a storage fee remains unpaid for 365 days, then and in that event, after no less than ninety (90) days advance notice to us through certified U.S. mail to our last known address, but without further consent or authorization on our part, our frozen embryos will become the property of the ART Program. The disposition of these embryos will then take place at the discretion of the ART Program in accordance with our written intentions regarding use and disposition of these embryos contained within this document. If we have agreed to the embryo donation option as described above, our embryos would become eligible for donation to another infertile couple (who will remain unknown to us), in which case we would relinquish any claim of maternal and/or paternal rights to the donated embryos or any resulting children. We understand that it may be necessary to destroy the embryos for lack of suitable recipients or incomplete screening of us.

Any information obtained during these procedures that can be identified with us will remain confidential and will be disclosed to individuals not directly connected with this project only with our written permission. We understand that photographs or videotapes may be taken of the embryos during the cryopreservation procedures as a permanent record and for possible use at medical meetings or with the lay public for educational purposes. We understand that confidentiality will be maintained. We understand that we have the right to review these records at any time. Furthermore, a government agency, including the FDA, may choose to review the data at any time to ensure that the protocol has not deviated from the accepted guidelines concerning this practice.

**AGREEMENT:**

We are making a decision whether or not to participate in embryo cryopreservation. Our signature on this informed consent form indicates that we have read and understand the information provided in this form, that we have received a copy of the "Legal Statement," that we have been verbally informed about the project, that we have had a chance to ask questions, that we have decided to participate and that we consent to the procedures or treatments described above.

Due to the importance of the time schedule for selecting fertilized eggs to be cryopreserved, this informed consent form must be completed, signed, and returned prior to the day of egg retrieval. **FAILURE TO DO SO MAY RESULT IN NO CRYOPRESERVATION OF FERTILIZED EMBRYOS.**

\_\_\_\_\_  
Patient's signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Spouse's signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Notary's signature

\_\_\_\_\_  
Date

Commission Expires On

\_\_\_\_\_  
Date

I have thoroughly reviewed the information contained in this consent with the above named persons and believe they have made an informed decision regarding assisted reproductive treatment.

\_\_\_\_\_  
Staff Signature

\_\_\_\_\_  
Date

**INFORMED CONSENT: CRYOPRESERVATION OF THE EMBRYOS**

**Fertility Center, LLC  
and  
Embryo Services, LLC**

**LEGAL STATEMENT: CRYOPRESERVATION OF EMBRYOS**

We hereby agree to the following:

- In the event that our marriage is dissolved because of dissolution proceedings or death; or
- In the event that the wife experiences menopause or a hysterectomy or for any other reason becomes or is determined to be incapable of achieving implantation of the embryos; and
- In the absence of any other legally enforceable agreement or other document or a directive from a court addressing this issue,

IT IS AGREED THAT OWNERSHIP AND CONTROL OF THE EMBRYOS SHALL BE HELD BY:

*(Both please initial choice)*

- |           |       |   |
|-----------|-------|---|
| YES _____ | _____ | Wife, but if she is unable or unwilling to assume such ownership or control, then by husband; but if he is unable or unwilling to assume such ownership and control, then by the ART Program at the Fertility Center; or                                  |
| NO _____  | _____ |   |
| YES _____ | _____ | Husband, but if he is unable or unwilling to assume ownership or control, then by wife; but if she is unable or unwilling to assume ownership and control, then by the ART Program at the Fertility Center; or  |
| NO _____  | _____ |   |
| YES _____ | _____ | Husband and wife jointly, but if one is unable or unwilling to assume such ownership and control, then by the other solely; and if both are unable or unwilling to assume such ownership and control, then by the ART Program at the Fertility Center; or |
| NO _____  | _____ |   |
| YES _____ | _____ | The ART Program at the Fertility Center.  |
| NO _____  | _____ |   |



**Fertility Center, LLC  
and  
Embryo Services, LLC**

**INFORMED CONSENT: ASSISTED EMBRYO HATCHING**

**Consent:**

We have been informed that we may elect Assisted Embryo Hatching (AEH) in an effort to facilitate embryo implantation. By signing this consent, we indicate our consent to the use of AEH and confirm our understandings regarding this process.

**AEH Explained:**

We understand that the two to eight cell stage embryo is surrounded by the zona pellucida. AEH involves the creation of a gap in the zona pellucida. It is hoped that this gap will facilitate the break through or hatching of the embryo. We understand that in the AEH procedure, mechanical force or the use of a very small amount of acid is used to create an opening in the zona pellucida.

**Risks and Benefits of AEH:**

All the questions which we have about this procedure have been answered in the manner which we understand. In this regard, we have been specifically informed of the following:

**A: Risks:**

We understand that implantation is a complex biological process and how AEH affects this process is not fully understood. We understand that it is unclear to what extent the normal implantation process is biologically associated with AEH. We also understand that within the normal human population, roughly five percent of children with physical and/or mental defects are born and that congenital defects can and do occur in the absence of AEH.

**B: Benefits:**

Potential benefits from this procedure indicate an increase in the chance of achieving pregnancy, especially in women over the age of 35 or women that have thick or hard zona pellucida.

**No Guarantee of Success:**

We understand that no representations guaranteeing creation of an in vitro fertilization pregnancy through AEH have been made to us.

**Continued Participation:**

We understand that we may withdraw this consent to AEH at any time without prejudicing our right to continued treatment by the Fertility Center and/or Embryo Services. A withdrawal by us shall not be retroactive. By electing AEH at this time, we are consenting to use this procedure in our future IVF attempts, unless and until we have withdrawn our consent.

**Confidentiality:**

We have been assured that any information obtained from our participation in this procedure which can identify us will remain confidential. However, we agree that scientific data or medical information resulting from this procedure that does not identify us may be presented at meetings and/or other published documents so that the information can be useful to others. We understand that any significant developments learned by the Fertility Center and/or Embryo Services during the course of our treatment pursuant of this consent will be provided to us if it relates to our willingness to continue to participate.

**IN SIGNING THIS AGREEMENT, WE CERTIFY THAT WE HAVE READ AND FREELY AND KNOWINGLY AGREE TO EVERYTHING STATED IN THIS AGREEMENT AND THE EXPLANATIONS WE HAVE RECEIVED REGARDING THE USE OF AEH.**

\_\_\_\_\_  
**Patient's signature**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Spouse's signature**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Notary's signature**

\_\_\_\_\_  
**Date**

**Commission Expires On**

\_\_\_\_\_  
**Date**

I have thoroughly reviewed the information contained in this consent with the above named persons and believe they have made an informed decision regarding assisted reproductive treatment.

\_\_\_\_\_  
Staff Signature

\_\_\_\_\_  
Date

***INFORMED CONSENT: ASSISTED EMBRYO HATCHING***

**Fertility Center, LLC  
and  
Embryo Services, LLC**

**INFORMED CONSENT:  
INTRACYTOPLASMIC SPERM INJECTION**

**Consent:**

We, the undersigned, have been counseled that the likelihood of our sperm and oocytes (eggs) achieving fertilization is low with conventional in vitro fertilization (IVF) techniques. We, therefore, give our consent for the direct injection of sperm into the oocytes (eggs) through a procedure known as Intracytoplasmic Sperm Injection (ICSI).

**ICSI Explained:**

The procedure is performed by the use of very small micro-needles that are mounted on special “robotic” arms that translate large movements into very small ones. One smooth needle is used to hold the egg in place with gentle suction. With a second sharp needle, the sperm is picked up tail-first and the needle is advanced into the center of the egg. The sperm is then injected and the needle withdrawn.

**Risks and Benefits of ICSI:**

All the questions which we have about this procedure have been answered in the manner which we understand. In this regard, we have been specifically informed of the following:

**A: Risks:**

The intent of intracytoplasmic sperm injection (ICSI) is to overcome the initial barriers to fertilization of oocytes presented by the outer layer of the egg. Defects in these steps of fertilization have been found to be present in certain instances – especially male factor infertility. The direct injection of sperm into oocytes may itself cause damage to the oocytes rendering them incapable of implantation and pregnancy.

Our sperm and/or eggs may contain defects located further along the fertilization process than the step of sperm entry into the egg. Thus while ICSI can bypass the problem of sperm entry, it still may not produce normal fertilization. Men with low numbers of normally functioning sperm have been found to have a higher incidence of small genetic abnormalities on a region of the “Y” chromosome thought to be important to the production of normal sperm. Assisting the sperm from these individuals in the fertilization process is likely to increase the probability of these abnormalities being transmitted to the next generation. Studies have shown that whereas these abnormalities are present in about 1% of the population, children that were conceived through the ICSI procedure have an approximately 2% incidence of a similar genetic abnormality. All studies to date have shown that children born from these procedures are indistinguishable in development and intelligence from their peers who have been conceived naturally or through conventional IVF. The concern is that when the male children of ICSI pregnancies grow up, they will have the same infertility problems as their fathers.

**B: Benefits:**

The intent of intracytoplasmic sperm injection (ICSI) is to overcome the initial barriers to fertilization of oocytes presented by the outer layers of the egg. Defects in these steps of fertilization have been found to be present in certain instances – especially male factor infertility. Examples include low count, motility, progression or morphology. Additionally, ICSI can overcome the presence of sperm antibodies that block the sperms ability to bind and (or) penetrate the egg.

**IN SIGNING THIS AGREEMENT, WE CERTIFY THAT WE HAVE READ AND FREELY AND KNOWINGLY AGREE TO EVERYTHING STATED IN THIS AGREEMENT AND THE EXPLANATIONS WE HAVE RECEIVED REGARDING THE USE OF ICSI.**

\_\_\_\_\_  
**Patient's signature**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Spouse's signature**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Notary's signature**

\_\_\_\_\_  
**Date**

**Commission Expires On**

\_\_\_\_\_  
**Date**

I have thoroughly reviewed the information contained in this consent with the above named persons and believe they have made an informed decision regarding assisted reproductive treatment.

\_\_\_\_\_  
Staff Signature

\_\_\_\_\_  
Date

***INFORMED CONSENT: INTRACYTOPLASMIC SPERM INJECTION***

BOOK SIX  
Revised 10/11 and copied as a PDF for website