

PRE-CYCLE TESTS

All tests listed require an appointment and must be current within one year. Some tests may be combined in the same appointment. Some of these tests may be covered by your insurance if they are considered "diagnostic tests" and not treatment.

Semen Analysis

A semen sample needs to be collected in a sterile specimen container which is 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 the specimen. Abstaining longer than 3 or 4 days may adversely affect the specimen.

Day 3 Labs

Please call our office the day your period starts and tell the receptionist that you need to schedule your Day 3 Labs. This blood work helps determine how responsive your ovaries may be to stimulation medications. If your period starts on Friday, someone will meet you at the office over the weekend to draw your labs. If your period starts on Saturday or Sunday, call the office Monday morning for an appointment. These tests are recommended at your doctor's discretion, typically for women over the age of 30.

IVF Profile Labs

Both husband and wife must be tested. Your lab appointments may be scheduled at the same time or at separate times. Women can have this lab drawn at the same time as Day 3 Labs.

Saline-infused Ultrasound and HSG

These tests are best performed after your period is over (when bleeding has stopped) and are usually scheduled between days 6 and 11 of your cycle. Your doctor may recommend one or both tests, based on your specific condition and history.

The saline-infused ultrasound also serves as a practice transfer or "trial run" for an actual embryo transfer after your egg retrieval. Your doctor will measure the depth of the uterine cavity and the curvature of the cervical canal so that your embryo transfer will be a smooth, easy procedure when the time comes.

CONSULTATIONS WITH EMBRYOLOGIST

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

CONSENT FORMS

There are five parts to the consent forms, which are included at the end of this book. The first is the consent for the IVF cycle and embryo transfer. 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.

HISTORY

You will receive a booklet with detailed questions about your medical and obstetrical history including prescription medications. Please complete and return it to the office.

ORIENTATION

Once you choose to participate in an upcoming cycle, members of our IVF Team will work with you and your spouse to help both of you better understand testing, procedures and monitoring. You'll also have a chance to tour the procedure and recovery rooms and be given tips to prepare for retrievals and transfers. The IVF Team strives to keep you informed and wants you to feel as comfortable and confident as possible.

In addition, you'll both learn how to give medication injections and retrieve voicemail messages after labs and scans. Two different kinds of injections are used during an IVF cycle. A tiny **subcutaneous** injection given just under the skin (much like insulin for diabetics) is used for most ovarian stimulation medications and Estrogen as well as some "trigger" shots. An **intramuscular** injection is given in the upper outer buttock muscle with a longer needle to reach the muscle and is necessary for certain "trigger" shots as well as for Progesterone in ethyl oleate or oil. Neither injection is difficult, but some hands-on demonstrations typically alleviate any fears about giving (or getting) these injections at home. Just make an appointment with Jan Lambert or another IVF Team member. You'll also find detailed injection instructions included in this book.

MASSAGE THERAPY

Your IVF package includes two full-body massages to help increase blood circulation and relaxation and your chances for success. Your first massage should be scheduled just before you start your stimulation medication. The best time for your second massage is between your egg retrieval and your embryo transfer.

GANIRELIX PROTOCOL

Your doctor will choose a protocol to fit your particular situation. Some of the things taken into consideration are your age, your lab results, your previous stimulation responses and your reason for infertility, if known.

The Ganirelix Protocol is used for the majority of our patients. The variation within the Ganirelix Protocol is the amount of Follistim you will be taking. This protocol begins by starting birth control pills or estrogen patches on day 3 of your menstrual cycle or as directed by your doctor. At the time of your baseline scan, you will begin taking one baby aspirin each day. Both husband and wife also will each start a round of prescribed oral antibiotics, also.

You will continue the pills or patches for at least nine days and up to several weeks. Because the level of estrogen in the pills is low, you can expect some breakthrough bleeding or spotting, which is normal while you are on the pills or when you stop taking the pills and may continue through the first couple days of stimulation. Just after stopping your pills or patches but before starting your stimulation medication, you will need to schedule a baseline scan and lab appointment to make sure your ovaries are quiet and your estrogen level is low.

You will be instructed when to stop your pills or patches and will start your Follistim and Menopur approximately four days later. Please refer to your Injection Instructions or contact Jan Lambert or another member of the IVF Team if you have questions about mixing or administering your shots. You will take a directed number of units of Follistim in the morning and another directed dose of Follistim along with Menopur in the evening. You will maintain these doses for 3 days, then schedule another ultrasound scan and lab appointment on the fourth day of medication.

You can go ahead and take your morning dose before coming into the office on day 4 of your cycle. From that point, you will come in to the office for scans and labs every other day. During each visit, your follicles will be measured for growth by ultrasound, and your estrogen level will be evaluated.

Ganirelix will be added to your daily medication regime based on your estradiol level and the size of your follicles. This normally occurs about mid-point in your stimulation. Your doses of Follistim and Menopur may be adjusted as your cycle progresses, so you will need to check our office voicemail system after 6 p.m. on the day of each office visit, even if you just stop in to have blood drawn. Messages will include your lab results along with instructions about what to do next. **REMINDER:** To access the Fertility Center's voicemail system from any phone at any time, just dial 423-899-0500, press 4, then press 1 and enter your seven-digit home telephone number (without area code). Your phone number is your ID code. Listen to the message, then hang up.

It takes an average of 7 to 10 days for most people to be ready for their "trigger" injection (Novarel, Ovidrel or Lupron). These medications trigger the eggs within the follicles to mature to 18-20mm and eventually release from their follicles 36 to 39 hours later. Because we want to allow for the maturation of the eggs but don't want the eggs to release, we will plan your egg retrieval within 36 hours after this injection.

It is very important that you take your trigger injection at the exact time instructed.

TYLENOL

Rest assured that you can use regular or extra-strength Tylenol in recommended doses throughout your IVF cycle and even after pregnancy to relieve any minor discomfort resulting from injections or procedures.

DAY OF "TRIGGER" SHOT

After being on the Follistim for a week or more, you will be instructed to take your trigger injection at a specific time. This will be either Novarel (hCG), which is one intramuscular injection and/or Lupron, which is two subcutaneous injections.

Your retrieval will be scheduled 36 hours later.

DAY OF EGG RETRIEVAL

The day BETWEEN your "trigger" injection and your egg retrieval, you will take NO INJECTIONS (except a second shot if Lupron was ordered for your trigger). The night before your egg retrieval, you will not eat or drink ANYTHING after midnight, including chewing gum. Anesthesia will **not** put you to sleep if you have ingested anything.

Plan to arrive at the Fertility Center in Chattanooga **one hour** before your scheduled retrieval. Enter through the main lobby and register with the receptionist. Your husband may collect his specimen at home just prior to coming in and bring it with you. If so, you may wish to pick up a specimen container at the office PRIOR to your egg retrieval day. We'll put the specimen in the incubator upon your arrival. If your husband has concerns about being able to collect on the day of retrieval, you may freeze a semen specimen ahead of time for back-up, just in case; however, the cost for the freezing is \$420 and includes one year of storage.

After checking in on retrieval day, you will be escorted back to the Embryo Services/IVF Wing. You will be asked to change into a hospital gown, which opens in the back. The only things you are allowed to keep on are your socks. Anesthesia will come in and ask you some questions about your medical history, then start an IV. You will walk over to the procedure room for the retrieval and will go to sleep once you're settled. After your retrieval, you will wake up fairly quickly and be transported on a stretcher to the recovery room where your husband will join you and you will rest for about 30 minutes. You will be offered something to drink, and your IV will be discontinued and you can prepare to go home.

Before you leave, we will tell you how many eggs were retrieved and give you a prescription and written discharge instructions, including when to begin your progesterone shots. You may not drive for 24 hours after anesthesia. You will probably nap off and on for the rest of the day. We recommend not eating a full meal until suppertime, but you can snack on soup, crackers, toast, etc. to avoid post-anesthesia vomiting.

DAY OF EMBRYO TRANSFER

You will receive a voicemail after 6 p.m. the day after your egg retrieval with a report on how many eggs have fertilized. You have the option of having all retrieved eggs fertilized or only a set number fertilized. The following day, the embryos should begin cell division to become 6 to 8 cells by day 3 after retrieval. Depending on how many embryos have developed, we may do your transfer on day 3 or we may wait until day 5 to allow the embryos to self-select. The best 2 to 3 embryos will be selected by the embryologist and photographed, and your doctor will go over his recommendations for how many can be safely transferred to your uterus. You will have the opportunity to have a discussion with your physician and the embryologist, if you wish, about how many embryos you are comfortable having transferred. The remaining embryos that are not transferred (as well as any eggs that were not fertilized) will be frozen, unless you have requested no cryopreservation. If development stops and the embryos degenerate, they will be discarded after day 6.

For your embryo transfer, you will return to the same Chattanooga facility about 15 to 30 minutes prior to your scheduled transfer. You may eat and drink as you please beforehand. You will be asked to undress from the waist down only, and wrap up in a blanket. 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 may accompany you to the procedure room where we do your transfer. Your feet will be placed in stirrups, and a sterile speculum 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 again receive written discharge instructions.

You will return to our office for a progesterone level check in a few days and then again for a pregnancy test nine days after 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.

IVF CYCLE – STANDARD PROTOCOL

- Notify office the day your period begins.
- Schedule labs on Day 3 of your period, if needed.
- Start Birth Control Pills, one daily, as directed by your doctor and/or calendar AFTER your Day 3 Labs. Breakthrough bleeding or spotting is normal.
- Stop pills as directed by your doctor and/or calendar.
- Make appointment for baseline scan & labs AFTER taking last birth control pill and prior to stimulation.
- Have a massage.
- Start stimulation shots approximately 4 days after stopping the pills.
- Make appointment for IVF scan & lab after 3 days of stimulation.
- Make appointments for scans & labs every other day until “trigger” shot (approximately 8 to 10 days from start of stimulation).
- Give “trigger” shot within 10 minutes of time designated by doctor.
- Undergo egg retrieval 36 hours after “trigger” shot.
- Start progesterone shots.
- Have a massage.
- Undergo embryo transfer 3 to 5 days after retrieval procedure.
- Return to the office for a pregnancy test 9 to 11 days after transfer procedure.
- Schedule prenatal checkups through your 12th week of pregnancy.

At the end of your first trimester of pregnancy, you will be referred to a OB/GYN doctor.

Keep in mind that timing is critical during an IVF cycle for the safety of your health as well as for the success of procedures. Take your medications as directed, alter doses if recommended, schedule your lab appointments, and check for messages from the office staff. If you do not receive a phone call or message by the evening of any day you have lab work, please call the office and page the on-call doctor.

PRESCRIPTION

Listed below are the medications that may be included in your prescription. Please notify a member of the IVF Team when you are ready to have your prescription called in to a pharmacy.

Prenatal Vitamins

Baby Aspirin

Zithromax

Follistim AQ – 600IU

Menopur

Ganirelix

Lupron

Vivelle DOT – 0.1mg estrogen patches

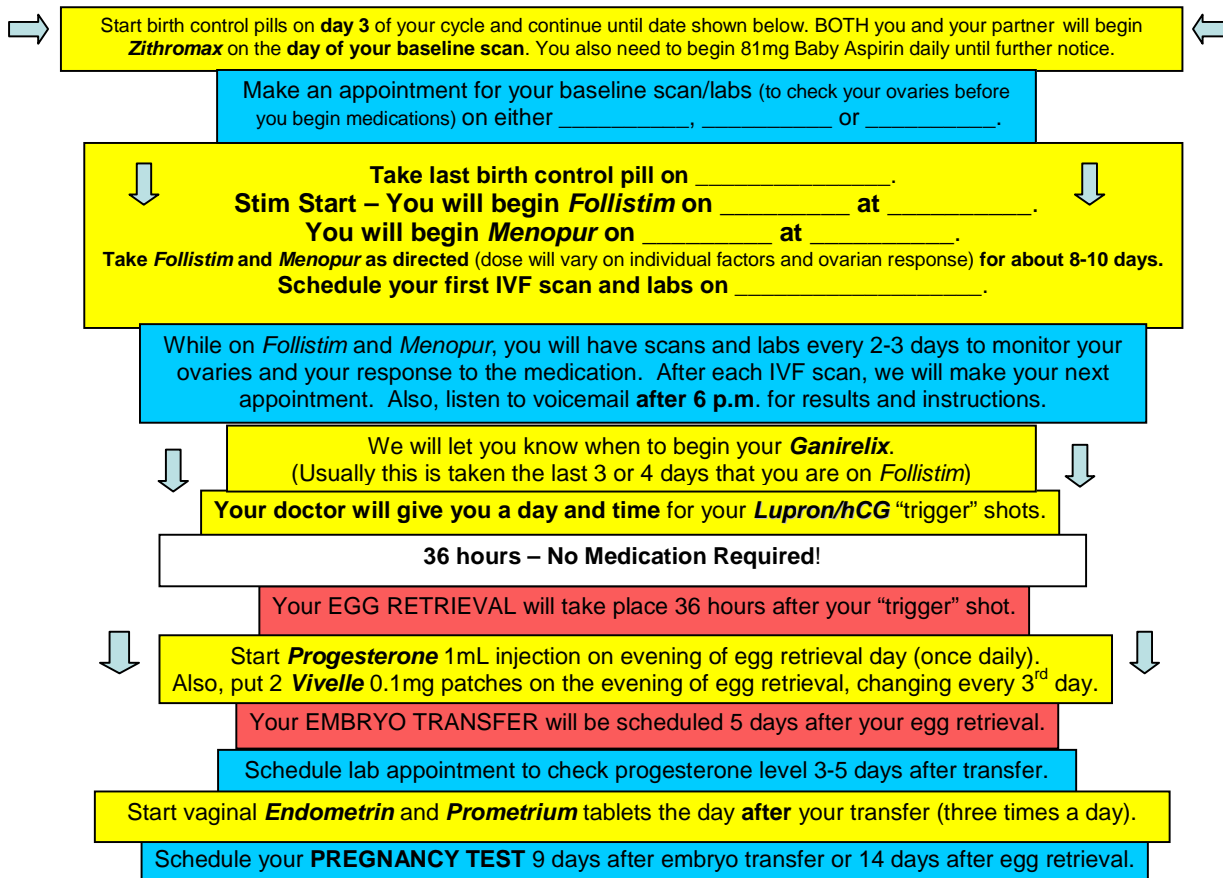
Progesterone in ethyl oleate or oil – 50mg/ml

needles and syringes for mixing and administration

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. These pharmacies strive to facilitate your medication needs in the most helpful and understanding way possible.

SAMPLE IVF CALENDAR

FOLLISTIM-GANIRELIX PROTOCOL



Medications

Office visits

Procedures

CYCLE CHARTS

Month _____

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

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

Month _____

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

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

INJECTION INSTRUCTIONS

Learning to give an injection is a simple process. The hardest injection to give is the FIRST one. Be sure to assemble your supplies before starting in order to avoid having to stop and get something you need.

Basic supplies include:

- ✓ alcohol and cotton balls or alcohol wipes
- ✓ your medication
- ✓ syringes and needles
- ✓ SHARPS disposal box or another safe container
- ✓ heating pad
- ✓ band-aids (optional)

You will need to take your medication by either subcutaneous injection (tiny needle) or intramuscular injection (larger, longer needle). Most people find it easy to give themselves subcutaneous injections but need another person to administer intramuscular injections. Your spouse, a friend or neighbor or even a co-worker may be willing to learn how to give these injections.

Remember, the IVF Team is available to provide hands-on instructions and demonstrations prior to your cycle for you and anyone planning to give your injections.

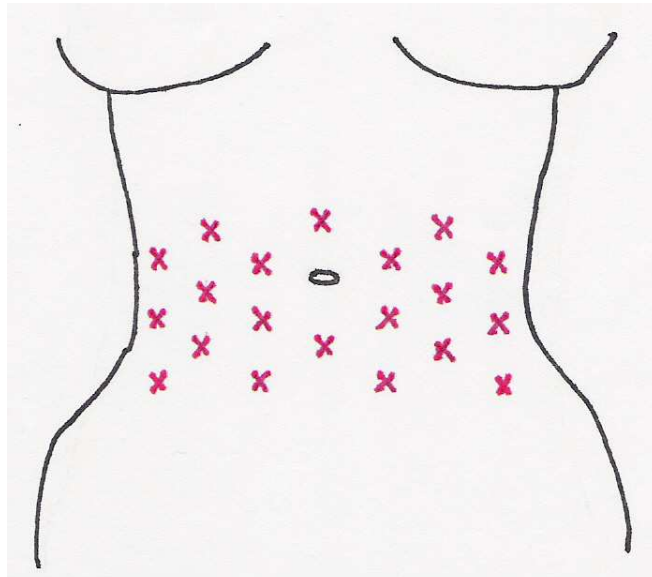
You won't necessarily use the entire amount of every prescribed medication, so don't be concerned if you have leftover doses. Unopened medications can be added to our "For Sale" list so other patients can contact you if they wish to purchase items from you. Alternatively, you can donate leftover items to the Fertility Center.

NOTE: ml = cc

SITES FOR INJECTIONS

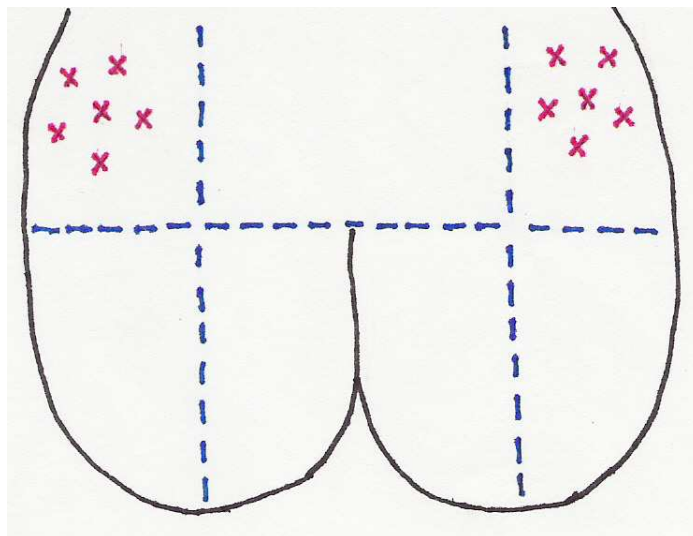
Subcutaneous

Injections given just under the skin into the fatty tissue with $\frac{1}{2}$ inch - $\frac{5}{8}$ inch needle. Stay 2 inches away from the belly button.



Intramuscular

Injections given into the hip muscle with $1\frac{1}{2}$ inch needle. Stay away from the spine.



FOLLISTIM

*Store cartridges in refrigerator. Start when calendar indicates or IVF Team instructs.
Use Follistim pen as syringe. Each cartridge holds either 300 or 600 units.
Refer to calendar or doctor's orders for dosage amount and frequency.
Vary injection sites to minimize tenderness.*

Injection Instructions – Subcutaneous

1. Assemble supplies:
 - alcohol swabs/cotton balls
 - Follistim cartridge(s) from refrigerator
 - Follistim pen and needles
 - disposal container
 - band-aid (optional)
2. Take Follistim cartridge(s) out of refrigerator to warm to room temperature for at least 15 minutes before proceeding.
3. Wash your hands.
4. Remove cartridge of Follistim from the box and insert it cap down into the Follistim pen. Screw the pen closed while making sure the blue arrow and yellow dot line up.
5. Peel the paper cover off one of the pen's needles and twist it onto the pen while pushing firmly. Remove the external cover and save it for removing needle later.
6. Dial the appropriate dose on the top of the pen.
7. Remove the needle cap and save it.
8. Select an area near your belly button (about two inches away) and swab with alcohol. Let it dry.
9. Pinch up the skin and quickly insert the needle with a dart-like motion into the cleaned area. Push down on the top of the pen to inject the Follistim, then remove the needle from the skin.
10. Apply pressure to the site(s) with a clean, dry cotton ball for a minute or two. Cover with a band-aid, if needed.
11. Recap the needle and put on the external cover, then twist (counterclockwise) and pull the needle off. Dispose of needle in container.
12. You may leave the pen with a partially used cartridge inside it on the counter at room temperature until time for your next injection.
13. If first cartridge did not contain a complete dose of medication, repeat steps 4, 5, 7-11 with a second cartridge. Use a new needle as well as a new injection site. Each pen will let you dial an entire dose but then will only inject the amount available in the pen. Once a new cartridge is loaded, you don't need to dial again – just administer the shot.

MENOPUR

Store at room temperature. Refer to doctor's orders for dosage amount as well as timing of injections. Vary injection sites to minimize tenderness.

Injection Instructions – Subcutaneous

1. Assemble supplies:

- alcohol swabs/cotton balls
- Menopur vials
- Sodium Chloride diluent vial
- Q-Cap
- syringe
- 27GA ½ -inch needle (gray hub)
- disposal container
- band-aid (optional)

2. Wash your hands. Remove caps of vials and wipe vial tops with alcohol.
3. Open syringe package. Remove Q-Cap from blister pouch, taking care not to touch the ends. Twist smaller end of Q-Cap onto syringe.
4. Pull out the plunger to volume of diluent to be removed from vial, typically 1.0 ml.
5. Insert spiked end of Q-Cap and syringe into the rubber stopper of the diluent vial. Push plunger down to transfer air from syringe into diluent vial. Turn vial and cap/syringe upside down and withdraw 1.0 ml of diluent from vial.
6. Remove Q-Cap and syringe from diluent vial. Discard empty vial.
7. Insert Q-Cap and syringe into rubber stopper of Menopur vial. Slowly push plunger to inject diluent into Menopur vial. Gently swirl until powder is dissolved – do not shake.
8. Turn Menopur vial and syringe upside down and withdraw contents into syringe.

NOTE: Up to six vials of Menopur may be combined into one syringe prior to an injection. After the first vial of Menopur is diluted, each additional vial of Menopur can be prepared by repeating steps 7 and 8 using the solution already in the syringe.

9. Twist Q-Cap off syringe. Twist 27GA needle onto syringe. Remove cap from needle and save.
10. To eliminate air bubbles, withdraw slightly on plunger and tap on side of syringe with needle pointed upward. Press down on plunger to push air out of needle and a small drop forms on the tip before injecting.
11. Select an area near your belly button (about two inches away) and swab with alcohol. Let it dry.
12. Pinch up the skin and insert the needle with a dart-like motion into the cleaned area. Inject the diluted Menopur and remove the needle from the skin.
13. Apply pressure to the site with a clean, dry cotton ball for a minute or two. Cover with a band-aid, if needed.
14. Cap needle and dispose with syringe in container. Discard vials.

GANIRELIX

*Store at room temperature. Start when calendar indicates or IVF Team instructs.
Use prefilled syringes. Refer to calendar or doctor's orders for dosage amount.
Give one injection a day within 24 hours of previous dose.
Vary injection sites to minimize tenderness. One syringe equals 250mcg (one dose).*

Injection Instructions – Subcutaneous

1. Assemble supplies:
 - alcohol swabs/cotton balls
 - Ganirelix syringe
 - disposal container
 - band-aid (optional)
2. Wash your hands.
3. Remove cap from needle and save. To eliminate air bubbles, tap on side of the syringe with the needle pointed upward. Push the air out before injecting.
4. Select an area near your belly button (about two inches away) and swab with alcohol. Let it dry.
5. Pinch up the skin and insert the needle with a dart-like motion into the cleaned area. Inject the Ganirelix and remove the needle from the skin.
6. Apply pressure to the site with a clean, dry cotton ball for a minute or two. Cover with a band-aid, if needed.
7. Cap needle and dispose with syringe in container.

LUPRON/HCG TRIGGER

Store Lupron and hCG in refrigerator. Use prefilled syringe(s).

IVF Team will instruct when to administer your trigger shots.

Take within 10 minutes of instructed time – do NOT deviate.

These are “trigger” shots to prepare for your egg retrieval 36 hours after injection(s).

Injection Instructions – Subcutaneous

1. Assemble supplies:
 - alcohol swabs/cotton balls
 - Lupron and hCG injections (in prefilled syringes)
 - disposal container
 - band-aid (optional)
2. Wash your hands.
3. Remove cap from needle and save. You may be given needles to attach to the syringes, from the pharmacy. To eliminate air bubbles, tap on side of the syringe with the needle pointed upward. Push the air out before injecting.
4. Select an area near your belly button (about two inches away) and swab with alcohol. Let it dry.
5. Pinch up the skin and insert the needle with a dart-like motion into the cleaned area. Inject the Lupron and remove the needle from the skin.
6. Apply pressure to the site with a clean, dry cotton ball for a minute or two. Cover with a band-aid, if needed.
7. Cap needle and dispose with syringe in container.
8. Repeat steps 3 through 7 if two injections are prescribed.
9. The hCG “trigger” shot is injected into hip. You will be given this medication from the office.
10. Repeat step 3 with prefilled syringe of hCG.
11. Select area in upper-outer part of hip.
12. Insert needle quickly into the skin, to the hub. Pull back slightly on the plunger, you will probably see an air bubble come back into the syringe, inject hCG.

PROGESTERONE IN ETHYL OLEATE

Store at room temperature. Take first injection the evening of retrieval, then once or twice daily as directed by IVF Team. 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

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

**INFORMED CONSENT: IN VITRO FERTILIZATION AND
EMBRYO TRANSFER**

We are giving our consent for ovulation induction, oocyte retrieval, in vitro fertilization and embryo transfer by the members of the Assisted Reproductive Technology Program at the Fertility Center, LLC and Embryo Services, LLC, hereafter referred to as the "ART Program".

We are voluntarily asking to participate in the ART Program to become pregnant through In Vitro Fertilization/Embryo Transfer (IVF/ET). We have been unable to become pregnant through conventional treatments. We understand that this consent extends from the initial period of participation in the program until (1) treatment is completed, (2) a physician makes a determination based on previous cycle response(s) that this treatment will result in a very small chance for pregnancy or no chance at all, or (3) until we decide to discontinue participation.

An IVF/ET cycle includes the following steps or procedures:

1. Ovulation induction
2. Retrieval of oocytes
3. Collection of sperm by masturbation
4. In vitro fertilization of the oocytes
5. Transfer of embryo(s) into the uterus
6. Preservation and storage of unused embryo(s)
7. Support of early pregnancy with progesterone

In other words, the production of oocytes or eggs is stimulated through medication. Then the eggs from the ovary or ovaries are taken out of the body, mixed with sperm to allow fertilization, allowed to grow in the laboratory for a few days and transferred back into the uterus. A pregnancy may not occur from this treatment, or one or more embryos may grow into a full-term baby or babies.

Leuprolide acetate (Lupron) or Antagon are injected daily to suppress some hormones from the pituitary gland. We understand that the long-term effects of these medications or their effects on the developing embryo(s) are not known. However, information available within the scientific medical community at this time suggests no significant long-term effects on women or developing embryo(s).

In order to harvest more than one egg per treatment cycle, fertility medications called gonadotropins (Follistim, Repronex, Gonal-F or Humegon) are administered 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 during ovary stimulation to prevent this problem.

NOTE: Currently 1 out of every 424 women in the United States will develop ovarian cancer in her lifetime. 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. Further research is needed to determine if a direct association exists between the use of fertility drugs and the development of ovarian cancer.

Other adverse reactions that have been reported with ART are: allergic sensitivity, pain, rashes, ectopic pregnancy, headaches, fluid retention, weight gain, irritability, depression, fatigue and visual disturbances. Any of these side effects should be reported to your physician immediately.

Serial blood tests and ultrasound scans of ovaries are used to assess growth of the developing follicles. When the size of the follicles is optimal, an injection of human chorionic gonadotropin (hCG-Novarel, Pregnyl, Profasi or Ovidrel) or leuprolide acetate (Lupron) will be given to trigger final maturation of the egg(s).

In most cases, the egg(s) will be harvested by ultra-sound 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 ovaries 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 egg(s) 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 ovaries. Other small incisions will be made near the pubic hairline for placement of a probe and an instrument to grasp the ovaries. 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, infection or excessive bleeding.

To prepare the lining of the uterus (endometrium) for implantation of the embryo, daily injections of progesterone are started the day after oocyte retrieval. Progesterone is a natural hormone normally produced by the ovaries after ovulation. Progesterone is to be taken until the pregnancy test is performed. If the test is positive, the progesterone should be continued through the twelfth week of pregnancy, since it helps decrease miscarriage rates. The injections may be changed to a vaginal pill form after the pregnancy test.

The Food and Drug Administration (FDA) has advised that progesterone should not be given to pregnant women. Although difficult to prove causality, some abnormalities have been reported in babies of mothers taking progesterone during pregnancy. However, the abnormalities described were caused by synthetic (man-made) progesterone whereas progesterone injections are no different than the hormone produced by the ovaries. The natural form of progesterone has been extensively used in IVF/ET programs without evidence of an increase in the frequency of birth defects compared with the general population.

Following retrieval, the egg(s) will be fertilized in a specialized laboratory with sperm. If normal fertilization of the egg(s) occurs, the fertilized eggs (pre-embryos) will be transferred into the uterus three to six days after egg retrieval. This is done by inserting a specialized plastic catheter into the uterine cavity through the cervix. Infection is an extremely rare consequence of this procedure.

Alternately, on rare occasions, the physician may recommend that the embryos be transferred into the fallopian tubes by means of laparoscopy, a procedure known as ZIFT (zygote intrafallopian transfer) or TET (Tubal Embryo Transfer). This may allow a more natural entry of the embryos into the uterus than by cervical transfer especially if the passage of the catheter through the cervix is difficult. The risks associated with ZIFT or TET are the same as for the laparoscopy mentioned above. If a woman becomes pregnant after transfer of pre-embryo(s) into the uterus by this method, the risk of miscarriage is approximately 23% (which is not higher than naturally-occurring pregnancies) and the risk of tubal ectopic pregnancy is approximately 5%.

It is possible that more embryos can result from an IVF cycle than are wanted to be transferred. It is important, therefore, that plans for these supernumerary embryos are 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 previous consent is signed for donation), 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 ovaries may not respond to ovulation induction, and the cycle may need to be canceled.
- The ovaries may over stimulate in response to this protocol. If too many follicles are produced and/or estradiol levels are too high as determined by the physician, the cycle may need to be canceled.
- Ovarian Hyperstimulation Syndrome may occur, and the cycle may need to be canceled to avoid risks.
- If only a single follicle develops as a result of ovulation induction, the cycle may need to be canceled.
- An attempt at oocyte retrieval may be unsuccessful.
- An adequate semen specimen may not be produced.
- Fertilization may not occur or may be of very poor quality.
- The embryo(s) may not cleave/divide after fertilization.
- The embryo(s) may not implant in the uterus after the transfer.
- The embryo(s) may not develop normally, resulting in a very early miscarriage (chemical pregnancy) or a clinically-evident miscarriage.
- An ectopic pregnancy (tubal pregnancy) may occur.
- A laboratory accident may result in loss of or damage to the oocyte(s), sperm or embryo(s).
- The pregnancy may result in the birth of a baby(ies) with congenital anomalies.
- When more than one embryo is transferred into the uterus, multiple pregnancy (twins, triplets, etc.) with subsequent risks may occur.

Should the results of the treatment or any aspect of it be published in medical or scientific journals, all reasonable precautions will be taken to protect the patient's anonymity. We therefore grant permission to the ART team to publish statistics relating to our case in said journals, provided our names are not used.

Insurance coverage for any or all of the aforementioned procedures may not be available. We understand that should our insurance policy exclude these treatments from coverage, we will be responsible for all expenses resulting from this treatment. We are advised that if physical injury results from participation in the program, the Fertility Center and/or Embryo Services will provide acute care but will not provide free medical care or compensation for injuries.

We have had an opportunity to ask questions, and the physician(s) and embryologist(s) have answered them to our satisfaction. We also have received information about alternative procedures to allow us to become pregnant, if they exist. We understand that adoption is also an option. We understand that we may withdraw our consent at any time.

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: IN VITRO FERTILIZATION AND EMBRYO TRANSFER

**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 TWO
Revised 5/09 and copied as a PDF for website