

**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