

OREGON HEALTH & SCIENCE UNIVERSITY
Division of Reproductive Endocrinology and Infertility

IN VITRO FERTILIZATION PROGRAM

INFORMED CONSENT

The IVF Procedure

We have consented to attempt to become pregnant using in vitro fertilization and embryo transfer. We understand that the following is an outline of the steps required in this procedure:

1. A determination by standard infertility tests that we are suitable candidates for the procedure.
2. The use of "fertility drugs" (Lupron, Antagon, FSH/HMG [i.e., Gonal-F, Repronex, . . .], or HCG) to produce ovulation at a predictable time.
3. Ultrasound examinations to assist in predicting the time of expected ovulation and in assessing response to fertility drugs.
4. Blood draws for hormone level determination.
5. Culdocentesis--vaginal ultrasound-directed needle aspiration of follicles to collect eggs

or

laparoscopy [insertion of a needle through the abdomen and into the ovary(ies) to obtain the egg(s)].
6. Semen specimen recovery by masturbation and laboratory treatment of the sperm to prepare them for fertilization.
7. Uterine lining support with a course of a hormone called progesterone.
8. Insemination of the egg(s) with sperm to allow fertilization to occur.
9. After fertilization, transferring the embryos into a different medium for growth.
10. After several cell divisions (fertilization and cleavage), if the embryo(s) is (are) developing normally, transferring the embryo(s) into the uterus by means of a small tube inserted through the cervix.
11. Blood sample collection two weeks after embryo transfer to determine if pregnancy has occurred and is proceeding normally.

Insemination of eggs

The embryologist will inseminate your eggs (oocytes) with sperm collected by your partner on the same day as the egg retrieval. (At your request, previously frozen sperm from your partner or from an anonymous sperm donor may be used instead.) There is a small chance (< 5%) that previously unrecognized sperm and/or egg defects will result in complete fertilization failure. If this happens, you will not have an embryo transfer. Unless otherwise specified by you, all of your eggs will be inseminated to maximize the number of embryos to be created.

I understand that _____ of my/my partner's eggs will be inseminated.

("All" or "no more than #")

Initial _____

Eggs which do not show signs of normal fertilization are routinely discarded. Your unfertilized eggs may be used for educational or research purposes at the discretion of the medical and laboratory directors of University Fertility Consultants. Under no circumstances will your eggs be transferred to or used by another patient.

We understand that fluids, cells, non-viable oocytes or abnormal (arrested, polyspermic) embryos or materials in excess of those needed for IVF may be recovered or produced during the course of our IVF cycle. We hereby authorize the Oregon Health & Science University Hospital and Clinics to use removed tissue for examination, diagnosis and research to advance scientific study and to dispose of any tissue or parts removed, except: (if none, so state).

INTRACYTOPLASMIC SPERM INJECTION (ICSI)

Intracytoplasmic sperm injection (ICSI) is a technique that may be used during an IVF cycle to facilitate the fertilization of eggs with sperm. The procedure involves the selection of a single sperm, obtained either from a fresh/frozen semen sample, testicular biopsy specimen or epididymal aspirate. Once selected the sperm is rendered nonmotile and injected into the egg using sophisticated micromanipulation techniques. The timing of fertilization and embryo development is the same as conventional IVF. The fertilization rates with ICSI are comparable to conventional IVF.

But like conventional IVF, there is no guarantee that fertilization will be successful with ICSI and it must be acknowledged that there is a small risk that some eggs may be damaged during the procedure.

ICSI was established in 1992 and since that time tens of thousands of normal children have been born from this procedure. It has not yet been established that the risk of developmental anomalies or genetic defects with ICSI is the same as non-ICSI pregnancies. The procedure itself does not appear to increase the risk of developmental abnormalities, but it is unknown if the selection of certain patients with severe male-factor infertility may carry an increased risk. It is known that some individuals with severely low sperm counts (particularly those with nonobstructive azoospermia) carry a genetic defect related to their infertility that may be passed along to their male offspring. We

encourage male-factor patients to receive genetic counseling. When you become pregnant, your physician may recommend special tests (amniocentesis, ultrasound) to screen for abnormalities. But it should be acknowledged that not all offspring abnormalities can be detected during pregnancy.

For individuals who must undergo microsurgical procedures to obtain sperm (testicular biopsy or epididymal aspiration), there are no guarantees that viable, mature sperm cells will be recovered. It should be understood that in the event that no motile, mature sperm can be found then nonmotile, immature sperm cells might be used.

We acknowledge that our questions about ICSI have been answered to our satisfaction and we consent to have ICSI performed during our IVF cycle.

Patient Signature

Partner Signature

CONVERSION OF CONVENTIONAL IVF INSEMINATION TO ICSI

Under rare circumstances the sperm sample obtained for conventional IVF insemination may be determined by the embryologists to pose a risk for fertilization failure. To prevent this high potential for fertilization failure the eggs and sperm will be prepared for intracytoplasmic sperm injection. Thus, when sperm are deemed unsuitable for conventional insemination the case will automatically revert to ICSI. **If you have specific objection to the ICSI procedure ever being used in your cycle please initial the following:**

I/We **do not permit** the use of the ICSI procedure for our IVF case in the event that the sperm sample is determined to pose a risk for fertilization failure with conventional insemination.

Patient Initials: _____

Financial Responsibility

We have reviewed the costs of treatment and will be personally responsible for all expenses. The expenses include, but are not limited to, hospital charges, laboratory charges, and physician professional fees.

Additional Risks

We understand that the following are some of the risks and discomforts associated with this procedure:

1. **Blood Drawing:** Mild discomfort and a risk of developing a bruise at the needle site.

2. **Egg Retrieval:** Possibility of bleeding, infection or moderate discomfort after the procedure. Possible damage to intestines or other abdominal organs, more likely if other pelvic surgery has been performed (Risk 1:1500). Complications may result in hospitalization. Risks associated with anesthesia are allergies, sedation, nausea/vomiting.
3. **Embryo Transfer:** Cramping and minimal risks of developing infection (less than 1%).
4. **Ultrasound Examination:** No known risks, minimal discomfort.
5. **Ovarian Hyperstimulation Syndrome:** This rare event (1%) is due to massive ovarian enlargement and may result in abdominal pain, bloating, water retention, nausea and vomiting. In its severe form, hospitalization may be required.
6. **Multiple Pregnancy:** Because more than one embryo is replaced, multiple pregnancy (40%) does occur. Multiple pregnancy is usually more risky and may require consultation and management with a high-risk obstetric specialist.
7. **Ovarian Cancer:** While concern exists that fertility medicines (oral and injectable) may increase the risk of ovarian cancer, there is, at present, no solid evidence that these medicines are directly linked to an increased risk.
8. **Psychological Stress**

Please note that some insurers may not cover hospitalization following treatment for a non-covered benefit (such as infertility treatment).

I/We understand that any of the following may occur which would prevent the establishment of a pregnancy:

1. The timing of egg recovery may be misjudged, may be unpredictable, or spontaneous ovulation may occur before egg collection thus precluding any attempt at obtaining an egg.
2. Mechanical factors or anatomical problems within the pelvis may prevent access to the ovary with the follicles.
3. Egg retrieval may be unsuccessful.
4. The egg(s) may not be normal.
5. The collection of an adequate semen sample may be impossible on the day of fertilization.
6. Fertilization may not occur.
7. Cleavage or cell division of the fertilized egg(s) may not occur.
8. The embryo(s) may not develop normally. An embryo transfer may not be performed.

- 9. Embryo transfer may be unsuccessful or the embryos may be damaged in the placement process.
- 10. Implantation and pregnancy may not occur.
- 11. A laboratory accident may result in loss of or damage to the egg(s) or embryo(s).

If pregnancy is successfully established, miscarriage, ectopic pregnancy, multiple births, stillbirth and/or congenital abnormalities (birth defects) may occur.

Multiple Pregnancy

We further understand that there is a risk of multiple pregnancy. Because more than one embryo is replaced, multiple pregnancy (40%) does occur. This is usually more risky and may require consultation and management with a high-risk obstetric specialist.

If a multiple pregnancy occurs, babies are at an increased risk for early delivery and associated health problems including vision problems, bowel disease, impaired mental function, prolonged hospitalization, and additional delayed physical and mental handicaps related to prematurity. The risks of early delivery increase with high order multiples (more than 2). Multiple pregnancy also is associated with an increase in maternal risks including increased blood pressure, diabetes, early hospitalization, and other medical problems. Caesarian delivery, bleeding, and blood transfusion are additional risks.

Because of these risks, our physicians recommend the transfer of no more than 2 embryos in most cases. There are situations, however, that may warrant the transfer of more than 2 embryos.

Selective reduction of multiple pregnancies is an option that may reduce your risks. This procedure is at additional cost, may involve travel, and carries a 1%-3% risk of losing one or all of the remaining fetuses.

Please check and initial one:

- We **are** open to selective reduction. Initial _____
- We **are not** open to selective reduction. Initial _____

All of our questions have been answered, and we know that any future questions concerning our care will be answered by our physician.

Our participation is purely voluntary. We understand that we may withdraw consent at any time. This decision will not affect our present or future care.

We have been assured that all information about us obtained during these procedures will be handled confidentially and that neither our identity nor specific medical details will be revealed by clinic personnel without our consent. Specific medical details may be revealed in professional publications as long as our identity is concealed. It has been recommended that we refrain from granting interviews or having any contact with the news media. All information provided to the media by the clinic will be controlled by the Oregon Health & Science University's Public Relations Department.

We expect this procedure to be performed with the customary standard of care. We understand the risks and benefits as outlined. Furthermore, we understand and agree that the Oregon Health & Science University shall be responsible only for acts of negligence on its part and on the part of its officers, employees and authorized agents.

The Oregon Health & Science University, as a public institution, is subject to the Oregon Tort Claims Act, and is self-insured for liability claims. If we suffer any injury, compensation would be available to us only if we establish that the injury occurred though the fault of the University, its officers, or employees. If we have further questions, we can call the Medical Services Director at (503) 494-8014.

We have read this form and consent voluntarily to participate in the Oregon Health & Science University's IVF program.

Patient Signature

Date

Partner Signature

Signature of Witness (Other than Physician)

Note: This consent form must be signed by patient and partner in the witness of an Oregon Health & Science University employee whenever possible.