

OHSU FERTILITY CONSULTANTS
OREGON HEALTH AND SCIENCE UNIVERSITY

Affix Patient
Identifying Label
Here

**IN VITRO FERTILIZATION
(IVF) PROGRAM
INFORMED CONSENT**

Affix Male Partner's
Identifying Label
Here

The IVF Procedure

I/we consent to attempt to become pregnant using *in vitro* fertilization and embryo transfer. I/we consent to the procedures associated with our infertility care and assume the responsibilities and risks of these procedures. I/we acknowledge that we have had the following risks and discomforts explained to us verbally and/or in writing by the medical staff at the OHSU Fertility Consultants:

- Fertility Drugs:** The cycle will require the use of fertility drugs (e.g. Lupron, Antagon, Repronex, hCG, progesterone) to produce the development of multiple eggs and promote uterine receptivity for pregnancy.
- Ovarian Hyperstimulation Syndrome:** This rare event (1%) can cause ovarian enlargement and may result in abdominal pain, bloating, water retention, nausea and vomiting. In its severe form, hospitalization may be required. *Please note that some insurers may not cover hospitalization following treatment for a non-covered benefit (such as infertility treatment).*
- Ultrasound Examination and Blood Drawing:** Ultrasound examinations will be used to assist in predicting the time of expected ovulation and in assessing response to fertility drugs. There are no known risks, minimal discomfort to this procedure.
Blood draws will be done for determination of hormone levels. Mild discomfort may be encountered and there is a risk of developing a bruise at the needle site.
- Egg Retrieval:** vaginal ultrasound-directed needle aspiration of follicles will likely be used to collect eggs. There is a 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.
- Embryo Transfer and Multiple Pregnancy:** There may be cramping and there is a small risk of developing an infection (less than 1%). Because more than one embryo is often replaced, multiple pregnancy (15%) does occur. Multiple pregnancy is usually more risky and may require consultation and management with a high-risk obstetric specialist. The risk of ectopic pregnancy (implantation outside the uterine cavity) is about 1-2%. Blood sample collection will be done two weeks after embryo transfer to determine if pregnancy has occurred and is proceeding normally.
- 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.

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Conventional IVF

1. For conventional IVF a semen specimen must be collected on the day of egg retrieval for insemination of the eggs. *All of the oocytes that are obtained during egg retrieval will be inseminated unless we specify differently (see below).*
2. If sperm parameters are not optimal on the day of insemination then our conventional IVF cycle will automatically be converted to ICSI unless we specify differently (see below).
3. Low fertilization or fertilization failure can occur with an IVF cycle.
4. Normal fertilized eggs will be placed into culture media for embryonic growth.
5. If the embryos are developing normally, transfer of some the embryo(s) into the uterus will be done by means of a small tube inserted through the cervix.

I/we acknowledge that conventional IVF has been recommended for our cycle. We accept and understand the information above and agree to have this procedure performed. Initials ____ / ____

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

Intracytoplasmic Sperm Injection (ICSI)

1. For ICSI a fresh semen specimen or frozen sperm (partner or donor) may be used for ICSI insemination. *All of the mature oocytes that are collected during egg retrieval will be injected by ICSI unless we specify differently (see below).*
2. Low fertilization or fertilization failure can occur with an ICSI cycle.
3. Normal fertilized eggs will be placed into culture media for embryonic growth.
4. If the embryos are developing normally, transfer of some the embryo(s) into the uterus will be done by means of a small tube inserted through the cervix.

I/we acknowledge that ICSI has been recommended for our cycle. We accept and understand the information above and agree to have this procedure performed. Initials ____ / ____

Restriction on the Number of Eggs to be Inseminated

I/we do not want all of our eggs to be inseminated. Therefore, I/we request that only ____ eggs be inseminated (or injected by ICSI). I/we understand that this may result in lower a fertilization rate and fewer embryos for selection and transfer. Initials ____ / ____

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Additional Risks

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 and cannot fertilize or develop into embryos.
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).
12. If pregnancy is successfully established, miscarriage, ectopic pregnancy, multiple births, stillbirth and/or congenital abnormalities (birth defects) may occur.

I/we understand that any of the above may occur which could prevent the establishment of a pregnancy.

Initials ____ / ____

Multiple Pregnancy and Selective Reduction

I/we understand that there is a risk of multiple pregnancy and that selective reduction of multiple pregnancies is an option that may reduce the risks associated with it. I/we understand that this procedure is at additional cost and carries a 1%-3% risk of losing one or all of the remaining fetuses.

I/we **are** open to selective reduction

Initials ____ / ____

I/we **are not** open to selective reduction

Initials ____ / ____

General

All of our questions have been answered, and we know that any future questions concerning our care will be answered by our physician. I/we have reviewed the costs of treatment and acknowledge that we will be personally responsible for all expenses that are not covered by insurance.

Initials ____ / ____

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Our participation in the IVF program 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 through 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.

| | | |
|----------------------------------|-------------------|-------------|
| _____ | _____ | _____ |
| Signature, female partner | Print Name | Date |
| _____ | _____ | _____ |
| Signature, medical staff witness | Date | |
| _____ | _____ | _____ |
| Signature, male partner | Print Name | Date |
| _____ | _____ | _____ |
| Signature, medical staff witness | Date | |

Note: This consent form must be signed by patient and partner (if applicable) in the witness of an Oregon Health & Science University employee. If it is signed off-site then signatures must be notarized (see next page).

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Notarized Signatures (for off-site signatures)

We have read this form and consent voluntarily to participate in the Oregon Health & Science University's IVF program. We acknowledge that we have had the benefits and risks of this procedure explained to us by and had our questions answered to our full satisfaction. I/we hereby agree to all of the terms and conditions in this consent form.

Signature, female partner Date Signature, male partner Date

Witness by Notary Public

State of _____, County of _____
I certify that I know or have satisfactory evidence that

_____ and _____
are the persons who appeared before me, and said persons acknowledged that they signed this instrument and acknowledged it to be their free and voluntary act for the uses and purposes mentioned in the instrument.

Date _____

(Signature of Notary Public)

(Title)

My appointment expires: _____ Residing in: _____