CONSENTS FOR IUI (Clomid or Injectable Fertility Drugs)

CONSENT FOR OVARIAN STIMULATION AND/OR SUPEROVULATION

You are about to undergo a cycle of ovarian stimulation in which you will be given fertility drugs for the purposes of producing multiple eggs (ovulation & superovulation). The benefit of this therapy is to either make you ovulate if you did not do so in the past or to make you ovulate with more than one egg (to increase the likelihood of a sperm interacting with an egg), in an effort to increase your likelihood of conception

All drugs which stimulate the ovaries may result in a condition known as **"ovarian hyperstimulation syndrome"**. In these instances, the ovaries over-respond to the medication, are cystic and grow to a very large size. There is an associated accumulation of fluid throughout the body, particularly noticeable in the abdomen, and lungs. In some patients this may be severe enough to require hospitalization for intravenous fluid support and observation. Rarely, blood clots may occur and effect the lungs, heart, kidneys and brain (causing transient or permanent damage). The risk of ovarian hyperstimulation severe enough to require hospitalization is less than 1%. Deaths have occurred from the most severe forms of ovarian hyperstimulation syndrome.

The medications which you will be using are mostly hormones designed to stimulate the ovaries to produce multiple eggs. Since they are hormones, there may be associated emotional responses following the use of these medications. Responses vary from individual to individual, but includes depression, euphoria, restlessness, nervousness, irritability, and sleeplessness.

In February of 1993 an article published in the American Journal of Epidimiology inferred that fertility drugs may increase the chance of ovarian cancer. These findings were preliminary and the conclusions of this report have been widely challenged. A similar article in the New England Journal of Medicine (September 1994) associated the use of clomiphene with ovarian cancer. Since then there have been studies supporting and refuting the effect of fertility drugs on the risk of developing ovarian cancer. Therefore, the potentially cancer-causing long term side effects of these medications remains unknown.

If pregnancy is achieved, the majority of gestations are singletons. Approximately 1/3 of all initial implantations are lost as miscarriages. One half of these are so-called preclinical or biochemical pregnancies. In these cases, the pregnancy test is positive, but no gestation is seen by ultrasound and the pregnancy disappears spontaneously. The other half of miscarriages are clinical. This means that the pregnancy test is positive and the ultrasound shows evidence of a pregnancy inside the uterus. However, the pregnancy does not develop normally and fails to progress. In these cases, the miscarriage may be associated with heavy vaginal bleeding and require a dilatation and curettage (D&C; which is a minor surgical procedure) in order to empty the uterus and stop the bleeding. In a small percentage of pregnancies, the embryo implants in the fallopian tube (tubal / Ectopic pregnancy). In these cases, surgery or medical treatment is required to remove the pregnancy. These pregnancies are nonviable and can cause abdominal pain, vaginal bleeding, and can also rupture and require emergency surgery to stop the bleeding. If surgery is required the tube and or the ovary can either be saved or will need to be removed depending on the clinical situation. With any surgery there is also the risk of injury to bowel, bladder, blood vessels, other organs, and death. With any bleeding there is always a risk of blood transfusions. You need to realize that there is some degree of control over avoiding unpleasant outcomes, yet even when everything is done within the standard of care, a few patients may experience complications of the treatment. Note all patient need to have medical insurance or accept full financial responsibility for any complications that may arise as a result of their treatment. The Center for Reproductive Health and gynecology is not responsible for your Transportation fees to a medical facility Emergency room care, hospitalization costs, medical and diagnostic fees and any loss of income immediate or in the future you might experience as a result of your treatment with us.

Occasionally it may be necessary to cancel a cycle following its initiation. This results from either a poor response to the medication or an overly vigorous response. In the event of a cycle cancellation, the patient is still responsible for expenses incurred in the attempt. Multiple gestation occurs frequently (15-30%) following the use of fertility drugs. The Center For Reproductive Health & Gynecology (physician) maintain discretionary power over the decision to cancel a cycle to protect the health of the patient being treated.

- **_____ _____ Your Initials Here and signature at the end of this document indicates that you have read the preceding consent about the risk of taking oral or injectable fertility drugs, that you have had the opportunity to ask questions, and that all your questions have been answered to your satisfaction**.

INITIALS_____ _____

INFORMED CONSENT FOR INTRAUTERINE INSEMINATION

BACKGROUND: A semen specimen is obtained from 1) Your Husband, 2) a sperm bank, 3) a designated donor, or 4) your partner. The actual sperm cells are separated from the bodily fluids secreted at the time of ejaculation by mixing with a sterile solution and spinning the entire volume in a centrifuge. The sperm, being heavier than water, form a pellet at the bottom of the test tube. The sperm is collected in a syringe with a soft plastic catheter tube. A speculum is placed into your vagina so that the cervix is visualized. The cervix has an opening (so) that leads to the uterus (womb) which in turn is open to the fallopian tubes where the egg (oocyte) is picked up and where fertilization occurs. The cervix is wiped free of excess discharge and the catheter is passed through the cervix up to the top of the uterus. The sperm are then pushed through the tubing into the uterus from which they should swim into the fallopian tubes.

RATIONALE: This procedure is recommended for women requiring donor sperm, for partners of men with abnormal sperm counts or function. Additionally, it is often utilized when an ovulation induction medication such as clomiphene citrate (Serophene, Clomid) or human menopausal gonadotropin (Pergonal, Metrodin, Fertinex, Humegon, Repronex, Fertinex, Gonal-F, etc.) is being taken.

RISK: (include but are not limited to)
1) Cramping or discomfort during the placement of the catheter and, rarely, later during the day. Pain noted after the procedure is usually related to the actual ovulation and not the insemination. It is okay to take Tylenol, Tylenol Extra-strength, or aspirin for this. Do not take ibuprofen or similar drugs.
Because the tube passes through your vagina or because the semen itself may have bacteria in it, a bacterial infection may occur in the uterus and/or fallopian tubes. If you have a fever, foul discharge, or abdominal pain, contact the office immediately. You need antibiotics and in the most extreme case may need hospitalization. This is very rare but can have serious consequences including scarring and closure of the fallopian tubes leading to infertility requiring surgery or in-vitro fertilization.

2) If your fallopian tubes are already scared, you can get pregnant in the fallopian tube (Ectopic pregnancy) meaning that the embryo implants not in the uterus, but in the fallopian tubes. This is potentially life threatening and can require an operation and/or chemotherapy. The risk of an Ectopic pregnancy is no greater than if you conceived from intercourse and can occur in the absence of tubal damage.

3) AIDS (HIV), hepatitis, syphilis, and several other infections may be contracted through intrauterine insemination and, of course, intercourse. The chances are almost certainly higher with the former. The State of California requires that all women and their partners be screened for these diseases prior to insemination. Infection may still occur if either of you is exposed to these organisms just prior to or after the blood is analyzed. Semen donors are screened for more diseases and at more frequent interval.

- **_____ _____ I have read the above consent and have had my questions answered. I understand the indications for and accept the risks from intrauterine insemination of sperm. I agree not to hold Dr. Najmabadi, Dr. Thornton, CRH&G or whomever they may designate to inseminate me responsible for the above stated risks. I hereby request to be inseminated with sperm obtained from _____.**

- **The male partner (_____) understands that, according to California Law (Civil Code Section 7005), if he is married to the female partner, and if under the supervision of a licensed physician a female partner is inseminated artificially with semen or products thereof donated by a man who is not her male partner, the male partner is treated in law as if he were the natural father of a child thereby conceived.**

INITIALS_____ _____

RISK OF MULTIPLE GESTATION

You have elected a prescribed course of treatment which utilizes fertility drugs known to put you at risk for multiple gestation (twins, triplets, quadruplets, etc.). These are inherently difficult pregnancies, which may be further complicated by underlying health problems or age (when > 35 years). Conditions associated with multiple gestations include: premature labor, premature birth, stillbirth (death of one or more of the fetuses), incompetent cervix (opening of the cervix and loss of the pregnancy prior to estimated date of delivery), diabetes, placenta previa (placenta blocking the exit from the uterus), and thrombophlebitis (blood clots). Cesarean section is commonly required to deliver these babies safely, and at a much higher incidence than what is normally seen for singletons (one baby).

Any of these problems may require you to be emergently hospitalized, and the care needed may be prolonged (weeks or months). Occasionally babies will be born so premature that they cannot survive. In other cases the problems of prematurity are very severe leaving the child permanently and severely disabled. The total expense of health care for you and your babies may be high. This may be further compounded by loss of wages from time off work.

If appropriate and indicated you will be referred to a high risk Maternal Fetal Medicine Doctor, or a qualified specialist to perform a procedure to reduce multiple pregnancies down to two or three intrauterine pregnancies (Selective Reduction). You will be asked to consult the specialist and based on the information given to you, decide on the best possible course of action for you. The doctor performing the procedure will provide you with the proper consents.

The Center For Reproductive Health & Gynecology can neither predict nor prevent a patient from experiencing any of these events once that pregnancy has been established. The only way to minimize risk is to limit the number of embryos entering the uterus (for IVF/Gift/ Zift/TET). Even then, there is a slight chance for multiple gestation (i.e. identical twins from when an embryos divides in two spontaneously prior to implantation). Treatment with fertility medication and intrauterine insemination or Assisted Reproductive Techniques may lead to multiple gestation since we can not predict the number of fertilized eggs that will finally implant.

- _____ _____ **Your Initials Here and signature at the end of this document indicates that you understand and accept the risks of multiple gestation, that you have considered the alternatives, that you have read the preceding consent, that you have had the opportunity to ask questions, and that all your questions have been answered to your satisfaction**.

_____ _____

Patient's Signature **Date**

_____ _____

Husband's Signature **Date**

_____ _____

Witness **Date**

_____

Names of Couple (Please Print)

_____

Street Address

_____

City **State** **Zip Code**

_____

Home Phone **Business Phone**

PLEASE MAKE SURE THAT YOU HAVE SIGNED AND INITIALED ALL DESIGNATED AREAS MARKED FOR SIGNITURE OR INITIALS IN THIS ENTIRE DOCUMENT.

INITIALS_____ _____

CENTER FOR REPRODUCTIVE HEALTH & GYNECOLOGY
PHYSICIAN-PATIENT ARBITRATION AGREEMENT

Article 1: Agreement to Arbitrate: It is understood that any dispute as to medical malpractice, that is as to whether any medical services rendered under this contract were unnecessary or unauthorized or were improperly, negligently or incompetently rendered, will be determined by submission to arbitration as provided by California law, and not by a lawsuit or resort to court process except as California law provides for judicial review or arbitration proceedings. Both parties to this contract, by entering into it, are giving up their constitutional right to have any such dispute decided in a court of law before a jury, and instead are accepting the use of arbitration.

Article 2: All Claims Must be Arbitrated: It is the intention of the parties that this agreement bind all parties whose claims may arise out of or relate to treatment or services provided by the physician including any spouse or heirs of the patient and any children, whether born or unborn, at the time of the occurrence giving the rise to any claim. In the case of any pregnant mother, the term "patient" herein shall mean both the mother and the mother's expected child or children.

All claims for monetary damages exceeding the jurisdictional limit of the small claims court against the physician, and the physician's partners, associates, association, corporation or partnership, and the employee, agents and estates of any of them, must be arbitrated including, without limitation, claims for loss of consortium, wrongful death, emotional distress or punitive damages. Filing of any action in any court by the physician to collect any fee from the patient shall not waive the right to compel arbitration of any malpractice claim. However, following the assertion of any claim against the physician, any fee dispute, whether or not the subject of any existing court action, shall also be resolved by arbitration.

Article 3: Procedures and Applicable Law: A demand for arbitration must be communicated in writing to all parties. Each party shall select an arbitrator (party arbitrator) within thirty days and a third arbitrator (neutral arbitrator) shall be selected by the arbitrators appointed by the parties within thirty days thereafter. Each party to the arbitration shall pay such party's pro rata share of the expenses and fees of the neutral arbitrator, together with other expenses of the arbitration incurred or approved by the neutral arbitrator, not including counsel fees or witness fees, or other expenses incurred by a party for such party's own benefit.

Either party shall have the absolute right to arbitrate separately the issues of liability and damages upon written request to the neutral arbitrator.

The parties consent to the intervention and joinder in this arbitration of any person or entity which would otherwise be a proper additional party in a court action, and upon such intervention and joinder any existing court action against such additional person or entity shall be stayed pending arbitration.

The parties agree that provisions of California law applicable to health care providers shall apply to disputes within this arbitration agreement, including, but not limited to, Code of Civil Procedure Sections 340.5 and 667.7 and Civil Code Sections 3333.1 and 3333.2. Any party may bring before the arbitrators a motion for summary judgement or summary adjudication in accordance with the Code of Civil Procedure.

INITIALS_____ _____

Article 4: General Provisions: All claims based upon the same incident, transaction or related circumstances shall be arbitrated in one proceeding. A claim shall be waived and forever barred if (1) on the date notice thereof is received, the claim, if asserted in a civil action, would be barred by the applicable California statute of limitations, or (2) the claimant fails to pursue the arbitration claim in

accordance with the procedures prescribed herein with reasonable diligence. With respect to any matter not herein expressly provided for, the arbitration shall be governed by the California Code of Civil Procedure provisions relating to arbitration.

Article 5: Revocation**:** This agreement may be revoked by written notice delivered to the physician within 30 days of signature and if not revoked will govern all medical services received by the patient.

Article 6: Retroactive Effect: If patient intends this agreement to cover services rendered before the date it is signed (including, but not limited to, emergency treatment) patient should initial below:

Effective as of the date of first medical services. _____
Patient's or Patient's Representative's Initial

If any provision of this arbitration agreement is held invalid or unenforceable, the remaining provisions shall remain in full force and shall not be affected by the invalidity of any other provision.

I understand that I have the right to receive a copy of this arbitration agreement. By my signature below, I acknowledge that I have received a copy.

NOTICE: BY SIGNING THIS CONTRACT YOU ARE AGREEING TO HAVE ANY ISSUE OF MEDICAL MALPRACTICE DECIDED BY NEUTRAL ARBITRATION AND YOU ARE GIVING UP YOUR RIGHT TO A JURY OR COURT TRIAL. SEE ARTICLE 1 OF THIS CONTRACT.

By: **By:**

_____ _____
Physician's or Duly (Date) **Patient's Signature (Date)**
Authorized Representative's Signature

_____
Center for reproductive Health & Gynecology **Print Patient's Name**

_____
Print or Stamp Name of Physician,
Medical Group or Association Name **By:**

_____
Patient's Representative's Signature (Date)

By:

_____
Signature of Translator (if applicable) (Date)

_____
Print Name and Relationship to Patient

_____
Print Name of Translator

A signed copy of this document is to be given to the Patient. Original is to be filed in Patient's medical records.

PLEASE MAKE SURE THAT YOU HAVE SIGNED AND INITIALED ALL DESIGNATED AREAS MARKED FOR SIGNITURE OR INITIALS IN THIS ENTIRE DOCUMENT.

INITIALS_____ _____