IVF Consent Form For In Vitro Fertilization--Embryo Transfer

1. Both (patient)_____

and (partner) _____

wish to conceive a child by methods of In Vitro Fertilization and embryo transfer.

2. This is an established treatment but there is no guarantee that a successful pregnancy will result.

3. The ripening of an egg or several eggs is stimulated by the injections of hormones. The side effects of these drugs have been reviewed for us and are listed in the fact sheet from the American Society for Reproductive Medicine. Possible risks and complications of these medications include: bruising, discomfort, or infection as a result of subcutaneous or intramuscular injection; ovarian hyperstimulation; pain, infection, bleeding, or injury to pelvic organs at the time of egg retrieval; untoward reaction to anesthesia; infection or bleeding from the pelvic organs as a result of embryo transfer into the womb. Ovarian tumors have been linked with the prolonged use of fertility drugs in some studies. Several laboratory procedures need to be performed prior to egg retrieval from the ovary. These include frequent hormone measurements in 10 cc blood samples obtained by puncture of a vein in the forearm and ultrasound measurements of both ovaries.

4. The husband/partner will be asked to provide a semen sample by masturbation on the day of the egg recovery. Since there is always a risk that there will be no fresh sperm available on the day of retrieval, due to inability to collect, no sperm in the sample, weather, family issues etc., we have been given the opportunity to freeze a sample prior to the cycle.

_____ We have or plan to freeze a sample
_____ We have elected not to freeze a sample and understand the risk of not having sperm available for fertilization.

5. Couples may elect to have some or all of their oocytes treated with intracytoplasmic sperm injection (ICSI). This is often recommended if there has been previous fertilization failure in IVF, or in cases in which it is expected that fertilization would be poor or non-existent, i.e. very abnormal semen analyses, or a long history of failed intrauterine inseminations and unexplained infertility. In this procedure, a single sperm is injected into an oocyte. While this does not guarantee fertilization, it can significantly increase the likelihood of fertilization, thereby increasing the number of embryos available for transfer and/or freezing. While this does not guarantee pregnancy, there is a statistical relationship between the number of embryos transferred and the chances of pregnancy. This procedure carries with it a risk of oocyte damage occurring at a rate of about 7%. Damaged oocytes are not suitable for transfer. Initial studies have shown no adverse

effect on the children born as a result of this procedure, however, because the first successful pregnancy occurred in 1992, there is no long term follow-up information available.

6. Couples, whose cases involve any of the following, will be candidates for Assisted Hatching (AHA).
a. A female partner who is 36 years old or older.
b. Couples with one prior unsuccessful cycle of IVF.
c. Embryos of poor quality (significant fragmentation).
d. A female partner with elevated FSH levels.
e. Females who require high doses of gonadotropins to get to retrieval.
f. Noticeably thick zonas (the protein coating surrounding the egg).

In this procedure a solution is used to open a small hole in the protein coat surrounding the embryo, thereby assisting the ability of the embryo to extrude from the protein so that it comes in contact with the lining of the uterus. This is an important step in implantation. There is a small risk of damage to some of the embryos with this procedure, and the IVF laboratory will make the determination of embryo viability after hatching. Information regarding the long-term effects of hatching is not available, as it is a relatively new procedure. However, there is no evidence that there is an increase in the miscarriage rate or the rate of birth defects seen in children resulting from this procedure.

7. The procedure of egg retrieval from the ovaries is performed by transvaginal ultrasound-guided retrieval, which is considered a surgical procedure. Local anesthesia with sedation is used. After culturing the eggs, the viable eggs are inseminated with the husband's sperm. After a period of observation, some of the embryos are transferred into the womb by means of a small tube, which is inserted through the vagina and the mouth of the womb. The number of embryos to be transferred will be decided upon on the day of transfer.

8. In the event that more than 4-6 oocytes are recovered, the option of freezing extra embryos is available. If we choose not to freeze, and do not wish to discard extra embryos, a maximum of 3-6 oocytes will be inseminated, and any resulting embryos transferred. If we do wish to freeze, all of the apparently normal oocytes will be inseminated, some of the embryos may be frozen, and some of the embryos will be transferred. Embryos may be frozen at the one-cell (pro-nuclear) stage and/or at the blastocyst stage, depending on individual circumstances, and at the discretion of the embryology laboratory staff. In general, any embryos not selected for transfer or cryopreserved will be cultured until the sixth day after retrieval. Embryos that continue development to the blastocyst stage may be frozen at that time. All embryos that do not continue to develop to the blastocyst stage will be discarded on the sixth day after retrieval. If we do not wish to freeze, but do wish to have all oocytes inseminated, any embryos remaining after the embryo transfer are to be discarded.

9. Equipment malfunction or technical error may occur and result in egg or embryo loss.

10. We understand that the sequence of events described above is to some extent unpredictable and might have to be varied or terminated without warning at any stage in any particular cycle. This could require repeating some or all of the steps in the process including all of the time, discomfort, and expense involved in repeating the treatments.

11. We understand that failure to achieve pregnancy may occur as a result of technical difficulties with any of the steps described above. Some examples of specific difficulties are:

a. Sub-optimal follicular development may cause the cycle to be cancelled.
b. The ovaries may not be accessible for egg retrieval.
c. The retrieved egg(s) may be abnormal.
d. Fertilization may not occur.
e. Fertilization may be abnormal.
f. Embryo development may not occur.
g. Implantation of the embryo in the womb may not occur.
h. Loss or damage of the egg(s), semen, or pre-embryo(s) may occur.
i. Natural disaster may make key personnel unavailable.

12. If pregnancy is established, it may result in miscarriage, stillbirth, birth defects, or tubal pregnancy. After fertilization of several eggs, there is a significant possibility that the transfer of multiple embryos may lead to multiple pregnancy such as a twin pregnancy or greater number of fetuses. Such pregnancies are at increased risk for many different complications, in particular premature labor. Furthermore, the use of ovulation induction drugs and probably IVF itself appear to increase the risk of identical twinning, which carries with it additional obstetrical risks. It may be that this risk is further increased with specific interventions such as day five embryo transfer and assisted hatching.

13. The possibility of polyspermic fertilization and the policy of not transferring polyspermic eggs have been explained to us.

14. We acknowledge that we have had the opportunity to ask questions which have been answered to our satisfaction.

15. Data from your ART procedure will also be provided to the Centers for Disease Control and Prevention (CDC). The 1992 Fertility Clinic Success Rate and Certification Act requires that the CDC collect data on all assisted reproductive technology cycles performed in the United States annually and report success rates using these data. Because sensitive information will be collected on you, CDC applied for and received an "assurance of confidentiality" for this project under the provisions of the Public Health Service Act, Section 308(d). This means that any information that CDC has that identifies you will not be disclosed to anyone else without your consent

Patient _____

Partner_________________________________

Physician______________________________

Date _____________