Fertility and Reproductive Medicine Center

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REQUEST FOR IN VITRO FERTILIZATION AND EMBRYO TRANSFER

I, _____, (DOB), a patient of Dr Ratts and my partner, _____, (DOB), request that The Infertility and Reproductive Medicine Center at Washington University and Barnes-Jewish Hospital and its designated physicians, perform the procedure of IN VITRO FERTILIZATION (IVF) AND EMBRYO TRANSFER (ET). This technique involves the stimulation of my ovaries with medications (controlled ovarian hyperstimulation) followed by the retrieval of egg(s) that have developed as a result of the stimulation. Egg(s) are then combined with sperm in the laboratory. A predetermined number of resultant embryos may then be transferred into my uterus (womb).

Controlled Ovarian Hyperstimulation involves:

1. Using a gonadotropin releasing hormone agonist or antagonist to suppress the pituitary gland. This prevents the brain from stimulating the ovary. Gonadotropins are administered to stimulate the ovaries and to increase the chance of collecting multiple eggs. Finally, human chorionic gonadotropin (HCG) is given to induce the final maturation of the eggs before retrieval. I/we have access to information on the potential side effects of gonadotropins and understand the potential risks associated with the process, including ovarian hyperstimulation syndrome, multiple gestation, ovarian torsion (twisting of the ovary), miscarriage, ectopic (tubal) pregnancy, and ovarian cancer (see the American Society of Reproductive Medicine - Fact Sheet - Side Effects of Gonadotropins).

2. Using an antibiotic to assist in prevention of bacterial infection, which may potentially affect cycle outcome.

3. Using a steroid (methylpredisolone) when embryos require micromanipulation procedures (ICSI, assisted hatching, embryo biopsy). This may assist in prevention of an autoimmune destruction of the embryo(s). Potential rare side effects include infection and/or aseptic necrosis of the femoral head (hip bone).

4. Measuring hormones such as estradiol (estrogen) with serial blood tests to monitor the hormone production from the developing follicle(s) (a structure that may contain an egg) within the ovary. Approximately 1-2 tablespoons of blood is removed each time to run these blood tests.

5. Ultrasound examinations using a vaginal probe are performed a number of times during the stimulation process to evaluate follicle growth and to determine when the follicles are ready for the injection of hCG, which will induce egg maturation.

Surgical retrieval of eggs involves:

Imaging the ovaries with ultrasound to guide a needle through the vagina and into the follicles. Intravenous medications are used for heavy sedation (asleep, but not usually general anesthesia).

Insemination of eggs involves:

1. The culture of eggs in the laboratory before combining them with sperm. Two methods are used to achieve fertilization. With conventional insemination the eggs are incubated (inseminated) with sperm and checked for fertilization the next day. In many cases, (e.g. significantly decreased sperm count, motility or morphology, history of previously failed fertilization, or unexplained infertility) the sperm is directly injected into the egg (Intra Cytoplasmic Sperm Injection, "ICSI"). I/we understand that prior to any manipulation, eggs are treated with hyaluronidase, an enzyme that removes cumulus cells (cells attached outside the zona pellucida) surrounding the egg. This process allows direct visualization of the egg to determine if it is mature enough for ICSI. Not all captured eggs achieve adequate maturity for sperm injection. In many cases, the eggs are divided and inseminated with both techniques. This is commonly done in cases of unexplained infertility.

I/we understand that ICSI is now a routine procedure in most IVF laboratories and studies show that the pregnancy rates approach or are as high as those reported using conventional insemination. However, ICSI has been associated with an increase in certain fetal abnormalities related to some types of male infertility. I/we understand that I/we may request another meeting with our physician to discuss this and obtain more information to determine if our offspring may be at a higher risk for certain problems after birth.

I/we understand that it is standard procedure for the embryology laboratory to inseminate or inject all of our eggs on the day of collection unless they have been found to be degenerate (not alive). If I/we do not want all of our eggs inseminated or injected, I/we understand that I/we must inform our physician, who will discuss this with us and notify the embryology lab of our decision.

2. Incubating fertilized eggs in a culture medium that supports cell growth and division.

3. Transferring selected embryos into the uterus with a small catheter. This is generally performed without the need for anesthesia. The transfer of too many embryos may result in an increased risk of multiple gestations without appreciable increase in the chances for conception.

4. Assisted hatching is a procedure by which the zona pellucida (shell that surrounds the embryo) is thinned and perforated in the laboratory prior to embryo transfer. This procedure is used for but not limited to: women over 37 years of age, patients who have failed to achieve a pregnancy in previous IVF cycles or with embryos that have been frozen. The process assists the embryo to "hatch" from the zona pellucida in preparation for implantation.

I/we understand that the ability of the manipulated embryos that are hatched to establish pregnancy after transfer in the human has not been fully determined. It is unknown if manipulation of the embryos will increase the risk of obstetric complications or fetal abnormalities.

Cryopreservation involves:

1. Freezing embryos that are not transferred.

2. Storing cryopreserved embryos in the laboratory facilities at the IVF Program. The program makes no promises, inducements or guarantees as to the length of time these embryos will be preserved and such decisions shall be made in accordance with The IVF Program's policies relating to disposition of biological material and in consultation with us. I/we understand that a storage fee will be billed after the first year of storage and that this fee may change at any time. The IVF Program will not store embryos if the storage fee is not paid.

I/we understand that it is our responsibility to notify the IVF Program if our mailing address changes. If the IVF Program cannot locate us, I/we understand and consent to the discarding of stored embryos by the IVF Program. Below is the mailing information that should be kept on record to be used by the IVF Program unless I/we submit in writing an alternate address:

_____

Name(s)

_____

Address

3. The program discards any embryos that are not transferred or cryopreserved.

4. I/we understand that after embryos are cryopreserved, I/we authorize the IVF Program to discuss any medical treatment, future storage and disposition pertaining to the cryopreserved embryos with both partners.

Center Policy for Unused Specimens:

It is the Center's policy that unused specimens (discard materials) may be used by the laboratory for training personnel, testing equipment or evaluating new techniques. I/we understand that all specimens are discarded (thrown away) after they are used. Examples of discard materials include excess sperm not used for insemination; eggs that failed to mature and/or did not fertilize, eggs that fertilized abnormally so they could not be used for transfer, embryos that stopped developing before the day of transfer, embryos that are not cryopreserved, and discarded culture media.

I/we understand that if we do not agree with this program policy, I/we are to notify our physician who will discuss this issue with us and notify the laboratory of our wishes.

After the Egg Retrieval:

Patients are given luteal support (the time after egg retrieval) in the form of natural progesterone starting on the day of egg retrieval. This is generally given as an intramuscular injection, although

oral and vaginal preparations are also available. Common side effects with progesterone agents include breast tenderness and bloating.

Risks and discomforts associated with the procedures include:

1. Injection of medications or blood drawing may cause mild discomfort, including bruising, bleeding, infection, or scarring at the needle site. Nerve injury is uncommon but may also occur.

2. Specific risks associated with medications used in controlled ovarian hyperstimulation (see side effects of gonadotropins fact sheet - enclosed).

3. Lack of follicle development, excessive follicle development, or ovulation before egg retrieval. Inability to produce sperm or sperm of inadequate quality.

4. Potentially unknown adverse effects of tissue culture media, its protein or antibiotic supplements or the use of blood products in the preparation of culture media. Also, unknown adverse effects of culture conditions.

5. Although The Center does its best to ensure that all blood products are safe and of the highest standard and purity, some lots of blood products may conceivably contain viruses or other yet unknown contaminants. Since current scientific procedures are unable to detect, screen for or remove these substances, a potential risk of adverse effect remains. An example of such risk is Creutzfeld Jakob Disease. It is a rare progressive disease that causes degenerative changes of the nervous system and can have incubation times as long as 30 years or more. The cause of CJD has not been conclusively determined and there is no practical diagnostic test for the disease. To date, no case of CJD in humans has been traced to the injection of blood or its derivatives (i.e. protein used for media supplementation).

6. Failure to obtain eggs due to adhesions, technical failures, or unavailability of an adequate surgical facility (natural disasters).

7. Inability of sperm to fertilize the eggs.

8. Degeneration (breakdown) of eggs and/or embryos before transfer.

9. It is possible that sperm of subfertile males may enhance the risk of genetic anomalies in the offspring, may increase the chance of infertility in the offspring or may increase the chance of abortion.

10. Intraoperative risks such as bleeding, infection, or injury to abdominal organs. Treatment could involve transfusion, antibiotics, or immediate major surgery.

11. Anesthesia may cause drowsiness, nausea and vomiting or rare drug reactions that could result in death.

12. Post-operative discomforts such as fatigue, soreness, cramping, and bleeding.

13. Improper development or function, or degeneration (breakdown) of embryos prior to cryopreservation.

14. Unsuccessful cryopreservation or cryopreservation of defective embryos.

15. Laboratory accidents, natural disasters and/or equipment failure resulting in loss or damage to sperm, eggs, embryos or cryopreserved embryos. In the event of a natural disaster, it may be necessary to move your sperm, eggs, embryos or cryopreserved embryos to another location.

16. Psychological stress resulting in diverse symptoms such as increased anxiety, sleeplessness, appetite changes, sexual difficulties and mood changes in either partner.

In addition to the risks listed above, there may be others that are unforeseeable.

Consent and Release:

I/we have read and understand the above information concerning IVF procedures. Our physician has verbally informed us about the procedures, and I/we have had a chance to ask questions and have voluntarily decided to participate in The Center and consent to the procedures as described. I/we acknowledge and agree that I/we have been informed of all known or potential risks, discomforts, side effects and hazards associated with this procedure. I/we have had the opportunity to obtain answers to all of our questions concerning the nature of the procedure, alternatives, if any, and potential risks, discomforts, side effects and hazards of the procedure.

I/we understand that there is no guarantee that pregnancy will occur, nor that if it does it will be carried to term or will be normal. I/we also understand that there is a risk of multiple gestation or tubal pregnancy. I/we assume all of the risks of this procedure and hereby release and discharge Washington University, Barnes-Jewish Hospital, its employees and agents, The Infertility and Reproductive Medicine Center at Washington University and Barnes-Jewish, our physicians and such assistants as s/he may utilize from any and all causes, damages or injuries associated with or arising in connection with this procedure. I/we further agree that Washington University, Barnes-Jewish Hospital, its employees and agents, The Infertility and Reproductive Medicine Center at Washington University and Barnes-Jewish Hospital, our physicians and such assistants as s/he may utilize shall have no legal or financial obligations or responsibilities of any type for any child or children conceived or born as a result of these procedures or for the physical or mental characteristics of any such child or children.

I/we understand that The Center is required to submit IVF data to a federal agency and there is a small chance that we will be contacted by the federal agency for follow up. Otherwise, I/we understand that our records will be maintained confidentially as are any other medical records. I/we understand that coverage from medical insurance carriers vary for different parts of the procedure. I/we have been made aware of the costs and understand and agree that we are financially responsible for any medical costs incurred by us that are not covered by medical insurance carriers.

In the event of death of a partner, the surviving partner in accordance with The Center's medical policies and practice will make decisions regarding the utilization or disposition of eggs, sperm or embryos. In the event of death of both partners, The Center will dispose of sperm, egg or embryos, unless other directives are made available in advance.

In the event of separation or dissolution, the Center will use or dispose of eggs, sperm or embryos according to the terms of an agreement signed by both partners (to the extent the agreement is consistent with existing law), or according to the terms of an order of court. Pending the determination of use or disposition, in the event of separation or dissolution, both parties understand and agree to remain fully responsible for costs associated with storage of eggs, sperm or embryos.

- **I/we agree to ICSI (inject mature eggs with sperm) if recommended by our physician.**
  Yes ☐ **No** ☐ **Initials: Patient** **Partner**

- **I/we agree to assisted hatching if recommended by our physician.**
  Yes ☐ **No** ☐ **Initials: Patient** **Partner**

- **I/we agree to cryopreserve those embryos that are in excess of the number appropriate for transfer to my uterus at this time.**
  Yes ☐ **No** ☐ **Initials: Patient** **Partner**

_____ _____

Patient, Date Patient's Husband/Partner (if applicable), Date

_____

Witness, Date