BRAVERMAN
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Answers for Recurrent Pregnancy Loss

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Consent to Assisted Reproductive Procedures: In Vitro Fertilization Using Anonymously DonatedSperm and Embryo Transfer

It has been determined through diagnostic testing and/or previous infertility treatments that I / we are candidates for assisted reproductive procedures. I / We understand that assisted reproductive procedures are not always successful and that alternative therapies may be available to me /us. I / We have considered the available options and elect to pursue this treatment.

Medical Procedures:

1. Diagnostic tests, such as semen analysis, blood tests to determine baseline hormone levels and infectious disease screening, PAP test, vaginal cultures and ultrasound examination of the ovary to determine baseline follicle count and "mock" embryo transfer may be performed prior to initiating treatment. Ultrasonography is a diagnostic procedure that uses sound waves to provide a picture of the ovaries.

2. An anonymous donor will be selected from an accredited sperm bank bythepatient. Two vials of frozen IUI-readvsperm will be purchased bythepatient and shipped to Braverman Reproductive Immunology P.C. at the patient's expense. The sperm will be stored at Braverman Reproductive Immunology P.C. in a frozen state until they are thawed for use in a treatment cycle. Usually, one vial of frozen sperm is thawed per IVF insemination. The second vial would be thawed and used only if the first vial does not contain enough viable sperm to achieve a pregnancy. If the second vial is not needed, it will be stored in a frozen state at Braverman Reproductive Immunology P.C. for a period of six (6) months or until the patient instructs otherwise. After six (6) months, the patient must arrange to have the frozen sperm transferred to a long-term storage facility.

3. Oral contraceptive pills containing estrogen will taken in the menstrual cycle immediately prior to the IVF treatment cycle to provide a baseline state for the ovaries. A synthetic hormone will be taken by subcutaneous injection to temporarily suppress the pituitary gland from stimulating the ovaries. Medications containing ovarian stimulating hormones (FSH, LH, hCG) will be taken by subcutaneous injection to stimulate the growth of several ovarian follicles containing eggs.

4. Periodic blood tests will be performed to monitor the changes in hormone levels related to the growth of the ovarian follicles that contain the egg(s). Blood samples are kept for approximately one week and then discarded.

5. Ultrasound examinations will be used to monitor the growth of the ovarian follicles and to determine when the follicles reach maturity. Upon reaching maturity, a medication containing the hormone hCG will be taken by subcutaneous injection to induce the final maturation of the majority of the eggs.

6. The eggs will be retrieved from the ovary, under anesthesia, 34-37 hours after the hCG injection (before ovulation). Eggs are retrieved using an ultrasound-guided needle through the back wall of the vagina into the ovarian follicles. The fluid contents of the follicles will be aspirated and the fluids will be examined to identify and retrieve the eggs. Not all follicles may yield an egg.

7. All of the retrieved eggs will be placed together with the sperm of the anonymous donor in a sterile plastic dish containing a specially formulated culture medium to facilitate fertilization. Excess thawed sperm are discarded at this time.

8. In certain patients, a procedure called Intracytoplasmic Sperm Injection (ICSI) may be utilized to facilitate the fertilization of the eggs. This is a procedure whereby a single sperm cell is manually injected into each mature egg. The ICSI procedure is employed in cases when there is a risk that conventional methods of insemination will fail to fertilize the eggs. The Physicians and Embryologists at Braverman Reproductive Immunology P.C. will evaluate this risk and determine if ICSI is necessary, unless instructed otherwise by the patient.

   Intracytoplasmic sperm injection (ICSI) is a laboratory procedure developed to help infertile couples undergoing in vitro fertilization (IVF) due to male factor infertility. ICSI, a form of micromanipulation, involves the injection of a single sperm directly into the cytoplasm of a mature egg (oocyte) using a glass needle (pipette). This process increases the likelihood of fertilization when there are abnormalities in the number, quality, or function of the sperm. ICSI is generally unsuccessful when used to treat fertilization failures that are primarily due to poor egg quality.

   A variety of abnormalities can cause male infertility. Sperm can be completely absent from the ejaculate (azoospermia) or present in low concentrations (oligospermia). Sperm may have poor motility (asthenospermia) or have an increased percentage of abnormal shapes (teratospermia). There may also be functional abnormalities which prevent the sperm from binding to and/or fertilizing the egg.

Indications for Intracytoplasmic Sperm Injection

- Very low numbers of motile sperm.
- Unexplained infertility
- Severe teratospermia.
- Problems with sperm binding to and penetrating the egg,
- Antisperm antibodies thought to be the cause of infertility.
- Prior or repeated fertilization failure with standard IVF methods.
- Frozen sperm limited in number and quality.
- Obstruction of the male reproductive tract not amenable to repair. Sperm may then be obtained from the epididymis by a procedure called microsurgical epididymal sperm aspiration (MESA), or from the testes by testicular sperm aspiration (TESA).

  Fertilization occurs in 50% to 80% of injected eggs. The ICSI process may damage a small percentage of eggs. The fertilized egg may fail to divide, or the embryo may arrest at an early stage of development. Approximately 30% of all ICSI cycles performed in the United States in 1998 resulted in a live birth, which is comparable to rates seen with traditional IVF. Younger patients may achieve even more favorable results. Factors such as poor egg quality and advanced maternal age may

result in lower rates of success.

ICSI does not increase the incidence of multiple gestation as compared to standard IVF. Because ICSI is a relatively new technique, first performed in 1992, long-term data concerning future health and fertility of children conceived with ICSI is not available. Some studies report that the incidence of a congenital malformation called hypospadias (urethra opening on underside of penis) is increased in babies conceived through ICSI. This is an area of ongoing investigation. Because some causes of male infertility are familial and are related to genetic problems, male offspring might have reproductive problems as adults. Despite these concerns, ICSI is a major advance in the treatment of severe infertility.

9. The resulting embryos will be grown in an incubator in the laboratory under strictly controlled conditions. Unfertilized and abnormally fertilized eggs are discarded in an ethical manner on the day following the egg retrieval.

10. The egg and developing embryo is contained within a protein coat called the zona pellucida. At the blastocyst stage, the embryo must "hatch" out of this protein coat in order to make direct cell-to-cell contact with the lining of the uterus to facilitate implantation. Embryos developed in vitro can experience difficulty "hatching" out of this protein coat. Accordingly, a procedure known as Assisted Zona Hatching may be performed prior to embryo transfer. Assisted hatching is a micromanipulation technique that involves making a small hole in the protein coat of the developing embryo to facilitate the hatching process. This procedure has been in clinical use for more than 10 years and there have been no reports indicating that this procedure can increase the incidence of miscarriage or birth defects.

11. Developing embryos are transferred to the uterus. The number of embryos to be transferred will be decided prior to transfer by the patient in conjunction with the doctor and the embryologist. The embryo(s) are deposited at the top of the uterus using a small, flexible plastic tube (catheter). The embryo(s) must initiate attachment to the uterine wall and continue the implantation process in order for a successful pregnancy to occur. Extra embryo(s) of good developmental potential may be cryopreserved (frozen) for transfer in a subsequent cycle. The risks and benefits of embryo cryopreservation are explained in a separate consent form that must be signed prior to cryopreservation of embryos. If the patient and partner do not elect to cryopreserve the extra embryo(s), the extra embryos will be discarded, in an ethical manner immediately following embryo transfer. Any embryos that have stopped growing or are deemed to have poor developmental potential are discarded in an ethical manner immediately after the embryo transfer.

12. Progesterone supplements will be used in the early stages of pregnancy to maintain and promote the continuation of the pregnancy.

13. A blood sample will be taken approximately 11 days (9 days for blastocyst) after transfer to determine whether pregnancy has occurred and is proceeding normally.

14. If a pregnancy is initiated, blood tests and ultrasound examinations will be performed to monitor the ongoing pregnancy.

Potential Risks:
The potential risk or discomforts of in vitro fertilization and related procedures include, but are not limited to the following:

1. Blood Sampling - Frequent blood sampling can cause discomfort and bruising at the site of venipuncture.

2. Ultrasound Examination - There are currently no known risks associated with ultrasound examination of the uterus.

3. Semen Analysis - There are currently no known risks associated with producing a semen specimen by masturbation.

4. PAP Test - There is a slight risk of temporary vaginal bleeding associated with the sampling the surface of the cervix.

5. Vaginal Cultures - There is a slight risk of temporary vaginal bleeding associated with the sampling the surface of the cervix.

6. Mock Embryo Transfer - In preparation of the actual embryo transfer performed following in vitro fertilization of the eggs and subsequent embryonic development, a "mock" or "trial" embryo transfer may be performed in a preceding cycle to determine the depth of the uterine cavity and the curvature of the cervical canal. The "mock" or "trial" embryo transfer is a non-surgical procedure that is usually painless or causes only minimal discomfort. The "mock" embryo transfer carries a slight risk of infection. The procedure usually takes approximately ten minutes to complete.

7. Medications - Several medications are used during ovarian stimulation, embryo transfer and to maintain an ongoing pregnancy. Each of the medications has potential side effects as follows:

   Oral Contraceptive Pills (Desogen, etc.)
   This medication is a low dose estrogen/progesterone pill taken during menstrual cycle prior to initiating ovarian stimulation in order to induce a quiescent, baseline hormonal state and to prevent the development of ovarian cysts. The potential risks associated with long term exposure to oral contraceptive pills include, but are not limited to, the following: development of blood clots, heart attack, stroke, gall bladder disease and very rarely, liver tumors. Since exposure to this medication will be brief (21 days), the potential risks are very low. Side effects may include vaginal bleeding, fluid retention, spotty darkening of the skin, nausea and vomiting, change in appetite, headache, nervousness, depression, dizziness, loss of scalp hair, rash and vaginal infections.

   Leuprolide Acetate (Lupron for subcutaneous injection)
   This medication is a synthetic hormone that temporarily stops the body from producing other hormones that stimulate the ovaries. When the medication is stopped, hormone levels will return to normal. This medication may cause side effects that include, but are not limited to: nausea, vomiting, hot flashes, night sweats, bone pain, swelling of feet and ankles, headache or difficulty urinating. These symptoms usually disappear as the body adjusts to the medication.

   Menotropins (Pergonal, Gonal F, Follistim, Repronex, etc., for subcutaneous injection)
   These medications (follicle stimulating hormone and luteinizing hormone) are used to stimulate the

growth of ovarian follicles and induce ovulation. These medications may cause side effects that include, but are not limited to: fever, breathing trouble, bloating, stomach pain or upset, enlarged ovaries, irritation at the site of injection and/or skin rash. These symptoms usually regress without treatment in two to three weeks after egg retrieval. Ovarian Hyperstimulation Syndrome (OHSS) is distinct from enlarged ovaries and is characterized by an increase in vascular permeability that results in the rapid accumulation of fluid in the peritoneal cavity, thorax and potentially, the pericardium. Early symptoms of OHSS include severe pelvic pain, severe bloating, nausea, vomiting and rapid weight gain. OHSS occurs in 0.4- 1.3% of women taking menotropins. Any patient experiencing symptoms of OHSS should immediately contact the clinical staff at 516-584-8710.

Chorionic Gonadotropins (hCG, Profasi, Pregnyl, Ovidrel, etc. for subcutaneous injection)
This medication (hormone) is used to induce the final maturation of the eggs and ovulation. This medication may cause side effects that include, but are not limited to: headache, stomach pain, irritability, restlessness, mood changes, fatigue, acne and pain or irritation at the injection site.

Estrogen (Estradiol Transdermal Patches or pills)
This medication (estrogen hormone) is used to maintain the appropriate hormonal balance after the egg retrieval to maximize the possibility of implantation and continued pregnancy. This medication can cause side effects including, but not limited to, the following: dizziness, headache, lightheadedness, stomach upset, bloating and nausea. These symptoms usually disappear as the body adjusts to the medication.

Progesterone (for intramuscular injection or suppository)
This medication (progesterone hormone) is used to maintain the appropriate hormonal balance after the egg retrieval to maximize the possibility of implantation and continued pregnancy. This medication can cause side effects including, but not limited to, the following: nausea, headache, depression, itching, increased hair growth, increased sensitivity to sunlight, changes in menstrual flow, increased vaginal secretions, breast tenderness, fluid retention and pain or irritation at the injection site.

Antibiotics (Doxycycline Capsules)
This medication is used to prevent infection following egg retrieval. This medication can cause side effects including, but not limited to, the following: stomach upset, diarrhea, nausea, headache, vomiting and increased sensitivity to sunlight.

Corticosteroids (Medrol Tablets)
This medication is used to slightly suppress the immune system and thereby enhance embryo implantation. This medication can cause side effects including, but not limited to, the following: dizziness, nausea, indigestion, increased appetite, and weight gain, weakness or sleep disturbances. These effects usually disappear as the body adjusts to the medication.

8. Anesthesia - Certain complications may result from the use of any anesthetic agent including, but not limited to, respiratory problems, adverse reaction to the medication, paralysis, brain damage or even death.

9. Egg Retrieval - Egg retrieval is a minor surgical procedure that carries a small risk of bowel or bladder perforation, internal bleeding or infection. These complications, although rare, may require hospitalization, surgical correction and/or blood transfusion. Complications may also result in organ damage or impairment of future fertility. The procedure, performed under anesthesia, usually takes 15

to 20 minutes to complete. Upon awaking from anesthesia, some patients experience slight to moderate pelvic pain, Vaginal bleeding after the egg retrieval is common. Any discomfort usually disappears within 24 hours.

10. Embryo Transfer - An embryo transfer is a procedure not requiring anesthesia that carries the slight risk of infection. The embryo transfer procedure is usually painless or only causes minimal discomfort. The procedure usually takes approximately ten minutes to complete.

11. Multiple Gestations - Multiple gestations (twins, triplets or more) may result. This may increase the risk of premature delivery and other maternal complications and increase financial and emotional cost. Pre-term delivery may also result in complications to the offspring including long-term disabilities or death. Multi-fetal reduction (termination of one or more embryos) is an available alternative, with its own attendant risks and benefits.

12. Pregnancy - If pregnancy is successfully established, there is still a possibility of miscarriage, ectopic (tubal) pregnancy, stillbirth and/or congenital abnormalities (birth defects). At this time, the risk of the development of an abnormal fetus is not believed to be greater than in a naturally conceived pregnancy. In the event that any serious abnormality is discovered, the various alternative courses of action, including elective termination of pregnancy, will be outlined and discussed, with the final decision on the course of action residing with the patient. The program's statistical experience in achieving pregnancies has been explained. There is no guarantee that this procedure will result in a successful pregnancy.

13. Psychological Stress - Infertility treatment is emotionally difficult to go through. The relative uncertainty of the outcome can cause considerable anxiety to the individuals involved. Counseling is available for those couples who feel they would benefit from talking with a professional trained in the specific issues associated with infertility treatment.

Consent

1. I / We understand that certain diagnostic tests such as semen analysis, blood tests, relevant genetic tests, ultrasound examination of the ovaries and mock embryo transfer may be performed in preparation for an attempt at Donor Egg In Vitro Fertilization and Embryo Transfer at Braverman Reproductive Immunology P.C. and that these tests carry associated risks. I / We certify these risks have been explained to me/us and I / We hereby consent to participate in these diagnostic tests.

2. I / We understand that there are risks associated with taking fertility enhancing medications, and although at the present time no conclusive evidence exists that these medications increase the risks of breast, ovarian, or other cancers, I/we do understand that future studies may modify the above statement. I / We acknowledge the risks have been explained to me/us and I / We hereby consent to use these medications.

3. I / We understand that certain therapeutic procedures such as egg retrieval, semen preparation, in vitro fertilization and embryo transfer will be performed in conjunction with my treatment at Braverman Reproductive Immunology P.C. and that these procedures carry associated risks. I certify that these risks have been explained to me and I / We hereby consent to participate in these procedures.

4. I / We understand that egg(s) will be taken from the ovaries of a donor and sperm from my partner (or sperm donor) will be mixed in the laboratory to achieve fertilization. If the eggs fertilize, and if the embryos develop appropriately, two or more embryos will be transferred into my uterus. The embryos will be transferred to the uterus using a small plastic tube inserted through the cervix. I / We hereby certify that the risks associated with these procedures have been explained to me/us and that I / We hereby consent to participate in these procedures as part my/our treatment at Braverman Reproductive Immunology P.C.

5. I / We understand that the reasonably known risks and consequences associated with the transfer of the embryo(s) to my uterus include a slight chance of infection. After the embryo transfer, blood tests will be required to monitor hormone levels and to determine if pregnancy has occurred. In addition, if pregnancy does result, additional blood tests and ultrasound examinations will be required to monitor the ongoing pregnancy. I / We understand that as with any pregnancy, there is a risk of complication during the pregnancy and childbirth. These include, but are not limited to the following:
    a. tubal pregnancy
    b. multiple gestation
    c. infection
    d. hemorrhage
    e. cesarean section
    f. all the risks and inconveniences associated with carrying a child and giving birth.

6. I / We understand that if pregnancy occurs that it is important to obtain appropriate prenatal medical care and I / We agree to do so. I / We understand that my/our failure to obtain such care may adversely affect the pregnancy and / or the fetus and agree to seek appropriate prenatal care.

7. I / We understand that that there is no guarantee that I will become pregnant as a result of the In Vitro Fertilization and Embryo Transfer procedures at Braverman Reproductive Immunology P.C.. Any of the following conditions may occur which would prevent the establishment of pregnancy:
    a. The response to the follicle stimulation medications may be sub-optimal, thus the egg retrieval of the donor may be cancelled.
    b. The time of ovulation may be misjudged, thus the egg retrieval may be canceled.
    c. The attempt to obtain the egg(s) may be unsuccessful.
    d. The egg(s) may not be mature or of sufficient quality to fertilize.
    e. Fertilization may not occur.
    f. The embryo(s) may not develop normally.
    g. The embryos exhibit poor developmental potential, thus the embryo transfer is cancelled
    h. Implantation of the embryo(s) into the wall of the uterus may not occur.

8. I / We understand that I / We am/are free to discontinue participation in the In Vitro Fertilization / Embryo Transfer Program at Braverman Reproductive Immunology P.C. at any time, by informing the staff either verbally or in writing. I / We understand that my/our decision to discontinue participation will in no way prejudice other treatment that I / We may receive from the staff at Braverman Reproductive Immunology P.C..

9. I / We understand that, in accordance with the Fertility Clinic Success Rate Act of 1993, all fertility clinics are required by federal law to report annually birth outcomes for the purpose of delivery validation and as a tool to measure and assess any potential long term affects of assisted reproductive techniques on patients and their offspring. I / We will be asked to provide this program

with information regarding my / our pregnancy, labor and delivery, and birth outcome. The data that I / we and / or your obstetrician provide will be collected and reported anonymously with the highest regard for preserving my / our confidentiality. Data from my / our 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 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 me / us, 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 me / us will not be disclosed to anyone else without my/our consent.

10. I / We understand that should the results of my treatment or any aspect of it be published in medical or scientific journals, all possible precautions will be taken to protect my/our anonymity. I / We grant permission to Braverman Reproductive Immunology P.C. to publish information relating to my case in professional journals, providing that my name is not used.

11. I / We confirm that the exact nature of In Vitro Fertilization / Embryo Transfer and associated procedures, including the risks, benefits and alternatives have been explained to me/us by our treating physician. I/We understand the explanation that has been given and have had the opportunity to ask any questions and to have these questions answered. Any future questions we have may be addressed to the staff of Braverman Reproductive Immunology P.C.. I / We acknowledge that these procedures are being performed at our request and with our consent.

Recipient of Donated Eggs Name	Signature	Date
Partner's Name	Signature	Date
Clinic Witness's Name	Signature	Date