BRAVERMAN
IVF & Reproductive Immunology, P.C.
Answers for Recurrent Pregnancy Loss

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Consent to Assisted Reproductive Procedures: Controlled Ovarian Stimulation, Use of Donated Sperm, Intrauterine Insemination (IUI)

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.

Procedures:

1. Diagnostic tests, such as semen analysis, blood tests to determine baseline hormone levels, PAP test, vaginal cultures and ultrasound examination of the ovary to determine baseline follicle count may be performed prior to initiating treatment.
2. Braverman IVF & Reproductive Immunology P.C. routinely tests female patients for Cystic Fibrosis. Cystic Fibrosis (CF) occurs at increased frequency in Caucasians and individuals of Ashkenazi Jewish descent, but can occur in any ethnic group. It is a disorder of mucus production, primarily affecting the pulmonary, gastrointestinal and reproductive systems. Although there is some variability of clinical expression, most individuals with CF require lifelong medical care and experience reduced life expectancy. positive test result is an indication that the individual may be predisposed to or have Cystic Fibrosis and may wish to consider further independent testing, consult their physician and / or pursue genetic counseling.
3. Oral contraceptive pills containing estrogen and progesterone will be taken in the menstrual cycle immediately prior to the intrauterine insemination (IUI) treatment cycle to induce a baseline state for the ovaries. A synthetic hormone medication called Lupron 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 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 will be sent to a reference laboratory for analysis.
5. Ultrasound examinations will be used to monitor the growth of the ovarian follicles and to determine when the follicles reach maturity. Ultrasonography is a diagnostic procedure that uses sound wave to provide a picture of the ovaries. Upon reaching maturity, a medication containing the hormone hCG
will be taken by subcutaneous injection to induce the final maturation and ovulation of the eggs.
6. Licensed semen banks are required to test semen donors for HIV (the AIDS virus) and other sexually transmitted diseases, (including, but not limited to, gonorrhea, syphilis, herpes, hepatitis B and C, cytomegalovirus, and chlamydia). These banks are also required to freeze donor semen specimens and maintain then in a frozen state for at least six months prior to use so that the donor may be retested

higher than normal risk of transmitting a genetic condition is eliminated. All donors are DNA tested to exclude cystic fibrosis carriers. Sickle cell carrier testing is performed on donors with African-American/African ancestry. Carrier status is tested on donors with Jewish or French Canadian ancestry for Tay-Sachs disease.

7. Braverman IVF & Reproductive Immunology P.C. may only use sperm from donors who have been screened and tested by FDA registered and New York State Licensed Sperm Banks. Any Sperm Bank that Braverman IVF & Reproductive Immunology P.C. uses provides current and valid proof of documentation. I /we will have to use sperm from Sperm Banks that are appropriately licensed and compliant with state and federal regulations. Braverman IVF & Reproductive Immunology P.C. will provide a list of recommended Sperm Banks for my / our use if I / we so choose.

8. I/we will be the given the opportunity to make selections of anonymous donor specimens from one or more lists, which the semen bank will provide. The donor(s) will not be identified and my identity will not be revealed to the donor(s). Two vials of frozen IUI-ready sperm will be purchased by me / us and shipped to Braverman IVF & Reproductive Immunology P.C. at the patient's expense. The sperm will be stored at Braverman IVF & 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 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 via is not needed, it will be stored in a frozen state at Braverman IVF & 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.

9. New York State law requires the outcome of the artificial insemination to be reported to the licensed semen bank.

10. The thawed sperm will be drawn up into a small plastic tube (catheter). The catheter will be pass through the cervix into the uterus and the sperm will be deposited in the uterine cavity.

11. Progesterone supplements, in the form of vaginal suppositories, may be used in the early stages of pregnancy to maintain and promote the continuation of the pregnancy.

12. A blood sample will be taken approximately 7 days after the insemination to assess the progesterone level and make sure it is adequate to support a pregnancy. A blood sample will be taken approximately 14 days after insemination to determine whether pregnancy has occurred and is proceeding normally.

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

Risks:

The potential risk or discomforts of intrauterine insemination 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 ovaries.

3. Use of Sperm from an Anonymous Donor - If the sperm is purchased from an accredited sperm bank (American Association of Tissue Banks) that is also FDA registered and New York State Licensed, the donor was screened for known hereditary and infectious diseases including hepatitis and HIV. At the present time, there does not appear to be any specific risks associated with the use of sperm from an anonymous donor. These banks are also required to freeze donor semen specimens and maintain then in a frozen state for at least six months prior to use so that the donor may be retested for HiV and other sexually transmitted diseases. This significantly reduces the risk of AIDS and other disease transmission, but does not guarantee that the donor has not been infected; that is, the risk remains that the AIDS virus or other sexually transmitted diseases can be transmitted to the patient through the donor's sperm. I also understand that unavoidable infections, some of which are contagious, are risks of the artificial insemination procedure. In addition, both my partner and I will be tested for sexually transmitted diseases as deemed appropriate by your physician.

4. Medications - Several medications are used before and during the ovarian stimulation and to maintain an ongoing pregnancy. Any medication can cause side effects and the medications associated with infertility treatment are no exception. However, major side effects are very rare.

   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 (OHHS) 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 OHHS include severe pelvic pain, severe bloating, nausea, vomiting and rapid weight gain. OHHS occurs in 0.4 - 1.3% of women taking menotropins. Any patient experiencing symptoms of OHHS should immediately contact Jeffrey Braverman, MD\ at 516-584-8710.

Chorionic Gonadotropins (hCG, Profasi, Pregnyl, 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.

Progesterone (vaginal suppositories)
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.

5. Intrauterine insemination - The intrauterine insemination is a non-surgical procedure that carries the slight risk of infection. The intrauterine insemination procedure is usually painless or only causes minimal discomfort. The procedure usually takes approximately ten minutes to complete. Risks include infection with possible tuba! damage, pain, bleeding, and rare anaphylactic reactions (loss of consciousness and shock which may be fatal).

6. Multiple Gestations - Because multiple eggs are ovulated and more than one egg may fertilize following intrauterine insemination, 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. Selective Fetal Reduction (the termination of growth of one or more fetuses) is an available alternative, with its own attendant risks and benefits.

7. 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.

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

Consent

1. I / We understand that certain diagnostic tests such as semen analysis, blood tests, relevant genetic tests, and ultrasound examination of the ovaries may be performed in preparation for an intrauterine insemination procedure at Braverman IVF & 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. We consent to testing for Cystic Fibrosis and understand that if there are any additional genetic tests that are recommended, we will be consented separately for those tests. We understand that we have the right to seek genetic counseling prior to the signing of this consent. We also understand that no tests other than the tests authorized will be performed on the biological sample provided and that the sample shall be destroyed at the end of the testing process or not sixty days after the sample was taken.

3. 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.

4. I / We understand that certain therapeutic procedures such as intrauterine insemination with donated sperm will be performed in conjunction with my treatment at Braverman IVF & Reproductive Immunology P.C. and that these procedures carry associated risks. I certify that these risks have been explained to me / us and I / we hereby consent to participate in these procedures.

5. I / We understand that multiple eggs will be ovulated and sperm from an anonymous donor will be introduced into the uterus to achieve fertilization. If multiple eggs fertilize, and if the embryos develop appropriately, more than one embryo may implant in my uterus. I / We understand that there is a significant risk of high order multiple gestation (triplets, quadruplets and more) associated with intrauterine insemination. 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 IVF & Reproductive Immunology P.C..

6. I / We understand that the reasonably known risks and consequences associated with intrauterine insemination include a slight chance of infection. After the insemination, 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. ectopic (tubal) pregnancy
    b. multiple gestation
    c. infection
    d. hemorrhage
    e. cesarean section
    f. all of the customary risks associated with carrying a child and giving birth

7. I / We understand that there is an unavoidable risk of multiple gestations associated with ovarian stimulation and intrauterine insemination.

8. It has been explained to me that studies have shown the quality of frozen sperm to be inferior to that of fresh sperm. Using frozen sperm may necessitate the performance of multiple insemination procedures before a pregnancy results. I /we understand, however, that pregnancy may never occur, regardless of whether fresh or frozen sperm is utilized. I / We understand that if a pregnancy occurs, 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.

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 that there is no guarantee that I will become pregnant as a result of the intrauterine insemination procedure at Braverman IVF & Reproductive Immunology P.C. Any of the following conditions may occur which would prevent the establishment of pregnancy:
    a. The response to the ovary stimulating medications may be poor and the insemination may be cancelled
    b. The egg(s) may not be mature or of sufficient quality to fertilize.
    c. In some cases, the partner may be unable to supply a semen specimen.
    d. Fertilization may not occur.
    e. The embryo(s) may not develop normally.
    f. Implantation of the embryo(s) into the wall of the uterus may not occur,

11. I / We understand that I / we am / are free to discontinue participation in the intrauterine insemination program at Braverman IVF & 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 IVF & Reproductive Immunology P.C..

12. 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 IVF & Reproductive Immunology P.C. to publish information relating to my case in professional journals, providing that my name is not used.

13. I / We understand that Braverman IVF & Reproductive Immunology P.C. has the right to refuse to use

14. I / We understand and acknowledge that the staff at Braverman IVF & Reproductive Immunology P.C. has not undertaken hereby, or in any other document or oral communication, to advise me of my legal rights, now existing or hereafter arising, and specifically disclaim any responsibility to do so. I understand that Braverman IVF & Reproductive Immunology P.C. recommends that I consult legal counsel so as to be fully informed of my legal rights and obligations, but if I elect not to do so, such election is hereby acknowledged to have been determined without reliance upon statements, oral or written of Braverman IVF & Reproductive Immunology P.C..

15. I / We confirm that the exact nature of intrauterine insemination and associated procedures, together with the known risks of these procedures, have been explained to me/us by my/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 IVF & Reproductive Immunology P.C. I/ We acknowledge that these procedures are being performed at our request and with our consent.

Signature of Patient	Signature of Partner
Print Name Date	Print Name Date

Signature of Witness

Print Name and Title Date