Ovulation and Insemination Treatment
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Introduction

The aim of treatment for infertility is to help achieve a healthy pregnancy. In general, evaluation and treatment for infertility is considered when a woman/couple has been attempting pregnancy on her/their own unsuccessfully for one year, or less, if the woman is over 35. However, there are exceptions to this generalization, e.g. the woman has a previously identified ovulation problem because she has absent, infrequent or irregular menstrual cycles, or the man has had a previous vasectomy. In some cases, specific reason(s) for infertility can be identified after complete evaluation, in which case the appropriate treatment can be prescribed. However, in many cases, the reason(s) for infertility are not readily identified and empiric treatment (i.e. treatment based on clinical experience) is attempted.

There are several methods for treating infertility. This handbook describes some of the simpler methods such as intrauterine insemination (IUI) and ovulation induction with hormonal medications. Which procedure is desirable or preferable for a particular woman/couple depends on your individual medical circumstances, including the identified reason(s), if any, for infertility. You will choose your treatment from the various options available to you based on the information concerning risks, benefits and alternatives provided by your physician, together with your understanding of the various treatment options. In some cases, your choice of treatment may be influenced by your social situation and personal preferences as discussed during the discussions with our clinical team.

The purpose of this handbook is to give you an overview of infertility treatment with IUI and ovulation induction. The information is part of the process of understanding your individual medical circumstances. When you meet with your physician and the clinical personnel at Shady Grove Fertility, you will receive additional information about how your particular situation relates to the general information contained in this handbook. You will make certain decisions from the choices available. You should sign the "Consent to Ovulation Induction, Monitoring and/or Insemination Treatment" form only after you have read this Booklet, consulted with your physician and weighed the risks and benefits of the recommended treatment plan. Unless treatment decisions change, the signed consent form will be considered valid for one (1) year.

EngagedMD

EngagedMD is a web based educational and informed consent program developed to inform and educate patients about the Ovulation Induction and Insemination process. The online educational modules outline all aspects of this treatment process to help you make informed decisions about your treatment.

The program enables you to learn about Ovulation Induction and Inseminations at your own pace and in the comfort of home. Your medical team will assign you the video educational modules to complete. Each module includes a quiz to test for understanding of the material in the module. After the modules are completed, your medical team can review a completion report and discuss any areas where there are questions or need for further information.
Intrauterine Insemination (IUI)

IUI is one of the simpler treatments for infertility and is performed very frequently. When the male partner has a low sperm count or motility, or when the woman’s cervical mucus is inadequate, IUI is used to increase the chances of sperm coming in contact with the egg(s) so that fertilization and pregnancy are more likely to occur. IUI is also used for donor sperm insemination. IUI is usually utilized after consideration of your infertility situation and after it has been demonstrated that at least one fallopian tube is open. A hysterosalpingogram (HSG) is a diagnostic test where your uterus and fallopian tubes are visualized by X-ray after a special dye is injected into the uterus. This is a common test ordered during the prescreening stage and is generally performed at Shady Grove Fertility. In some programs, tubal patency may sometimes be determined by a special ultrasound examination, the hysterosonogram, which is performed in the office.

For IUI, semen is processed to concentrate the motile sperm that are then injected into your uterus via a narrow tube (catheter). The IUI is timed to coincide as closely as possible with ovulation. The procedure is usually not painful although some women may feel minimal cramping as the catheter is inserted. Rarely, excessive curvature of the pathway through the cervix into the uterus makes insertion of the catheter difficult, but a full bladder will often straighten the curvature. In rare circumstances, an instrument (tenaculum) may be required to straighten the pathway or ultrasound guidance may be used. Any pain or cramps caused by use of the tenaculum may be minimized with a local anesthetic (topical or injected) into the cervix.

IUI or the treatment cycle may be canceled for any of the following reasons: (a) ovulation on the side of a blocked tube; (b) spontaneous premature ovulation; (c) poor ovarian response to stimulation resulting in inadequate/insufficient follicle development or hormone production; (d) presence of too many follicles, thereby increasing risk of multiple pregnancy and ovarian hyperstimulation syndrome.

Potential Complications and/or Side Effects

(a) Pelvic infection due to bacteria introduced with the sperm or by the insertion of the catheter through the cervix can occur. This is extremely rare, but could result in the blockage of the fallopian tubes.

(b) Occasionally, your cervix may need to be dilated in order to insert the catheter. This is unusual; however, if it is necessary, there is a risk of perforating the uterus. Such perforation rarely requires surgical repair, but may warrant hospitalization for observation.

IUI may be performed during a natural cycle, or during a cycle where ovulation-inducing medications are used (stimulated cycle).
Oocyte (Egg) Development

Natural Cycle

Most women with regular menstrual periods have normal development and release of an egg every month. If a woman is less than 40 years of age and her menses occur every 26 to 32 days, it is likely that an egg is produced each cycle and that her ovarian hormone levels are normal. However, in some cases, even though a woman has regular menstrual cycles, there is a possibility that the hormones of ovulation are not being produced normally so that the egg produced is unlikely to result in a successful pregnancy.

For a planned IUI in a natural cycle, you will be instructed on how to predict the day of ovulation using a urinary ovulation prediction kit. The IUI will ordinarily be performed on the day after your positive result. Very rarely, the urinary ovulation prediction kits do not work very well. In these cases, the day of ovulation may be predicted by doing serial blood hormone tests and ultrasound scans of the ovaries. Such testing will require several visits. All ultrasound scans are done vaginally. You do not need a full bladder at the time of ultrasound. All blood work and ultrasound appointments must be scheduled. Your primary nurse can assist you in making these appointments.

Stimulated Cycle

If testing of your natural cycle results in identification of hormonal or endometrial deficiency, a Stimulated Cycle may be recommended. There are several different types of medications that may be used for a stimulated cycle.

Ovulation Induction with Clomiphene Citrate (Serophene, Clomid®)

Clomiphene Citrate is one type of ovulation induction medication that may be used. It is used primarily to treat women who have ovulation disorders as reflected by infrequent or irregular menstrual cycles. It is sometimes used in women who ovulate normally but in whom release of more than one egg each month is desired. For example, in women with unexplained infertility or mild endometriosis and in women with only one open fallopian tube, clomiphene can be used to try to induce release of at least one egg from each ovary. However, gonadotropins (Follistim® or Gonal-F® discussed on page 5) are more commonly used for this purpose.

Clomiphene works at the level of the brain and pituitary gland, facilitates the release of more of the gonadotropins, *follicle stimulating hormone* (FSH) and *Luteinizing hormone* (LH), from the pituitary. FSH and LH in turn stimulate the ovaries to produce eggs and the ovarian hormones *estradiol* (E₂) and *progesterone* (P₄).

Clomiphene is a tablet that is taken by mouth for five days, typically beginning on cycle day 3 of the menstrual cycle, after we have confirmed that you are not pregnant with a negative pregnancy test, baseline ultrasound and hormone tests. The initial dosage is 50 to 100 mg (one or two tablets) daily at
bedtime, or as prescribed by your physician. Monitoring of egg development is usually done with serial urinary LH hormone or blood hormone tests and ultrasound scans of the ovaries to determine when the egg(s) is/are mature. Ultrasound scans are done vaginally. You do not need a full bladder at the time of ultrasound. These ultrasound scans can be done when you are menstruating. Bleeding does not interfere with the ultrasound images. All blood work and ultrasound appointments must be scheduled.

An injection of Ovidrel® may be given to trigger release of your egg(s). If this option is chosen, the IUI is usually scheduled to be done 36-40 hours after this trigger injection. Often supplemental progesterone tablets are prescribed vaginally to assist implantation.

Stimulated Cycle: Ovulation Induction with Gonadotropins

(Menopur®, Follistim®, Gonal-F®)

Gonadotropins are used in women who have failed to ovulate and/or achieve successful pregnancy with clomiphene or in whom release of more than one egg each month is desired (see page 4). It is also used to treat couples with unexplained infertility. Gonadotropins may only be used in women whose ovaries are capable of responding to stimulation with FSH. Menopur® consists of a combination of both gonadotropins, follicle stimulating hormone (FSH) and luteinizing hormone (LH), which stimulate ovarian production of eggs and the hormones, estradiol (E₂) and progesterone (P₄). Follistim® and Gonal-F® consist of pure FSH with no LH.

Menopur®, Follistim®, and Gonal-F® are given by subcutaneous injections. When absence of pregnancy is confirmed with a negative pregnancy test result, treatment is begun after onset of menstrual bleeding, usually starting on cycle day 3 with 75-150 IU daily. However, starting day and/or dosage may be modified according to your characteristics (e.g. age, weight, etc.) and previous response to treatment. If one treatment cycle is to immediately follow a previous one, a blood pregnancy test will be performed. A baseline ultrasound scan of the ovaries may be done to rule out ovarian cyst(s) persisting from the previous treatment cycle. All ultrasound scans are done vaginally. You do not need a full bladder at the time of ultrasound. These ultrasound scans can be done when you are menstruating, bleeding does not interfere with the ultrasound images. All blood work and ultrasound appointments must be scheduled.

Treatment with gonadotropins requires close monitoring of egg development with blood E₂ and LH tests and ultrasound scans of the ovaries to determine when the eggs are mature and to adjust the dosage of gonadotropins when necessary. When the eggs are believed to be mature based on follicle size and blood E₂ and LH levels, Ovidrel® is given to trigger the release of the egg(s). IUI, if indicated, is scheduled for 36-40 hours after the Ovidrel injection. You will start vaginal progesterone supplements for luteal phase support the day after your IUI.

If your period does not start, a blood pregnancy test is done 15 to 18 days after IUI. If the first pregnancy test is positive, subsequent blood tests will be done to confirm appropriate rise in the blood levels of the pregnancy hormone. A pelvic ultrasound scan is done approximately five weeks after IUI to determine location and number of pregnancy sacs and fetal heartbeats.
Stimulated Cycle: Ovulation Induction in women with Chronic Anovulation

Polycystic Ovary Syndrome

Women with Chronic Anovulation (a condition commonly referred to as Polycystic Ovary Syndrome or PCOS) often have high blood levels of LH. Therefore, when inducing ovulation in women with Chronic Anovulation, a purified preparation of FSH such as Follistim® or Gonal-F® may be used instead of Menopur®, because the latter product contains equal amounts of FSH and LH.

Follistim®, and Gonal-F® are given by subcutaneous injections. Treatment is started after onset of menstrual bleeding, usually starting on cycle day 3. However, women with PCOS often do not have spontaneous menses so that menstrual bleeding often needs to be induced with oral progesterone (medroxyprogesterone acetate (Provera®) tablets). The ovaries of women with PCOS are often extremely sensitive to stimulation with FSH so the initial dose of FSH is usually low at 37.5 - 75 IU daily, compared to 75-150 IU daily for women without PCOS. The initial dose may be adjusted according to previous response to treatment. Dosage increases are usually made in smaller increments than in women without PCOS, i.e. increments of 37.5 IU if necessary.

If one treatment cycle is to immediately follow another one, a precycle blood pregnancy test will be performed. A baseline ultrasound scan of the ovaries will be done to rule out ovarian cyst(s) persisting from the previous cycle. All ultrasound scans are done vaginally. You do not need a full bladder at the time of ultrasound. These ultrasound scans can be done when you are menstruating, bleeding does not interfere with the ultrasound images. All blood work and ultrasound appointments must be scheduled.

Monitoring of egg development with blood estradiol (E2) and LH tests and ultrasound scans determine when the eggs are mature, at which time Ovidrel® is given to trigger ovulation. IUI, if indicated, is scheduled for 36–40 hours after the Ovidrel injection. Following IUI, vaginal progesterone support will be provided. A pregnancy test is done 15 to 18 days after IUI. If the first pregnancy test is positive, subsequent blood tests will be done to confirm appropriate rise in the blood levels of the pregnancy hormone. A pelvic ultrasound scan is done approximately five weeks after IUI to determine the location and number of pregnancy sacs and fetal heartbeats present.
Potential Complications and/or Side Effects from Use of Ovulation Induction Medications

Monitoring of ovarian stimulation involves blood tests and ultrasound examination. The taking of blood samples may cause discomfort and/or bruising, infection and/or scarring at the needle site. Rarely it may also be associated with nerve damage.

Vaginal ultrasound examinations are used to visualize the ovaries and the uterus and to help predict the timing of ovulation. Occasionally there may be some discomfort; however, generally ultrasounds are considered harmless and painless. The effects of repeated ultrasound examinations on developing eggs are not known. There are no other known risks associated with ultrasound.

Multiple Pregnancy

The risk of multiple pregnancy is increased with the use of clomiphene. There is an approximately 8% risk of twins and less than 1% risk of triplets or more. The most frequent adverse reaction to clomiphene includes ovarian enlargement, transient hot flashes (which may be unpleasant but are not dangerous), mood swings, and abdominal discomfort. Women who do not ovulate normally on their own may notice symptoms usually associated with ovulation, e.g. midcycle ovulation pain, premenstrual symptoms (abdominal discomfort, breast tenderness, etc.) and menstrual cramps. If you experience pelvic pain, you should report it to your physician. Other side effects, occurring in a very small percentage of women, include nausea, vomiting, nervousness, insomnia, blurred vision and other visual symptoms, headache, dizziness and light-headedness. You should report any of these side effects to your clinical team.

Gonadotropin use often results in release of several eggs from the ovaries that may result in multiple pregnancy (e.g. twins, triplets, etc). If a woman conceives after gonadotropin use, the risk of multiple pregnancy is significantly increased. Multiple pregnancy may occur in up to 20% of pregnancies resulting from gonadotropin use. The risk of multiple pregnancy may be minimized by careful monitoring and adjustment of gonadotropin dosage, or cancellation of a cycle if too many mature follicles develop. Multiple pregnancies are associated with higher risks of premature births and pregnancy related complications. Your attitude regarding fetal reduction, a procedure that may be employed in early pregnancy to reduce a pregnancy from quadruplets or triplets to twins, must be considered. If you and your partner have serious emotional, ethical or religious reservations regarding the procedure, you should carefully evaluate the use of gonadotropins, because their use is associated with a high risk of multiple pregnancy. Most of the side effects of these drugs are minor, involving discomfort, but not usually requiring continuing or unusual medical intervention.

Serious complications of these medications, with the exception of multiple births [See Pregnancy and Birth Following Infertility Treatments] are rare. The manufacturers advise that serious pulmonary conditions and thromboembolic (blood clot) events have been reported in conjunction with the use of ovarian stimulation medication and some patients might have a hypersensitivity to such drugs. Symptoms of generalized rash, swelling or difficulty breathing should be reported to your doctor. These drugs may occasionally cause the development of ovarian cysts (non-cancerous, fluid-filled structures in the ovaries); in rare instances these may need to be removed surgically, in which case hospitalization may be required. The removal of an ovarian cyst can result in the loss of an ovary, though such a loss is
extremely rare. It is also possible for an ovarian cyst to rupture, causing a brief episode of pain. Under rare circumstances, the rupture of an ovarian cyst may be associated with sudden bleeding and require surgery and/or blood transfusion(s). Such acute bleeding is very rare. Any of these medications should not be used during pregnancy. It is sometimes difficult to rule out the possibility of a pregnancy even when it seems that normal menstruation has occurred. For this reason, you will be asked to have a pregnancy test prior to commencing a cycle. Additionally, you may be asked to refrain from intercourse, or use barrier protection at certain times of your cycle.

A published study in the past addressed a potential risk of ovarian cancer associated with the use of certain medications for ovarian stimulation. Since that time, the consensus of medical opinion on the issue, as voiced by the Society of Assisted Reproductive Technology (SART) and the American Society for Reproductive Medicine (ASRM), is that there is no conclusive evidence of risk. As part of your patient counseling, you should discuss this issue with your physician.

Genetic Abnormalities Associated with the Age of the Father/Sperm Donor

While it is well known that an increasing age of the woman’s eggs at conception increases the risk of many genetic disorders (generally referred to as ‘aneuploidy’) like Down’s Syndrome, recent research (Nature, 2012) suggests that the age of the father at the time of conception, in addition to the mother’s age, may be an important risk factor for childhood disorders. As with all of the studies looking at the risk of birth defects after fertility treatment, the studies are controversial and the effects are small. Some studies have suggested that as the father ages (40 or greater), especially beyond the age of 50, the risk for childhood diseases or birth defects increases slightly. For example, if the risk at a paternal age of 35 is 2-3%, it may increase to 3-4% at age 50.

Controlled Ovarian Hyperstimulation and Ovarian Hyperstimulation Syndrome

Ovulation induction drugs are also occasionally associated with a risk of ovarian hyperstimulation syndrome (painful enlargement of the ovaries). The process of Controlled Ovarian Hyperstimulation for IUI, involves the intentional control over stimulation of the ovaries in order to obtain an optimal number of mature eggs. It is possible that this may result in a dramatic increase in the size of the ovaries, causing a number of symptoms referred to as Ovarian Hyperstimulation Syndrome (OHSS). Symptoms of OHSS, if they occur, are related to the significant enlargement of the ovaries and fluid accumulation in the abdomen that usually follows 5 to 7 days after ovulation. Severe hyperstimulation can be worse with pregnancy, therefore another option is to cancel the cycle. OHSS is usually managed by bed rest at home but may require removal of the abdominal fluid by aspiration, a procedure performed in our Ambulatory Surgery Center. In rare instances, hospitalization may be required. Severe hyperstimulation may result in major complications such a stroke and kidney failure. However, fluid aspiration is highly successful in improving symptoms and shortening the course of the situation.

Risks include, but are not limited to:

- Twisting or rupture of the ovary, which may require surgery, and/or surgical removal of ovary including transfusion
- Blood clots, embolism, fluid overload in lungs
• Fluid accumulation in the abdomen that may require transvaginal and/or abdominal aspiration of fluid including placement of a temporary drainage tube

• Kidney and/or other organ dysfunction and even death have been reported from severe ovarian hyperstimulation syndrome

The hormones of pregnancy may prolong and/or make ovarian hyperstimulation more severe, especially in the presence of multiple gestations.

The risks of Ovarian Hyperstimulation Syndrome may be minimized by:

• Terminating the cycle
• Not performing intrauterine insemination or having intercourse
• Terminating a pregnancy once established

In most cases of cycle cancellation, it is possible to attempt another cycle with adjusted levels of medications.

Warning signs include, but are not limited to, the following:

• Nausea and vomiting
• Severe pelvic pain
• Severe abdominal bloating
• Weight gain of 2 or more pounds/day for 2 days or more
• Difficulty breathing
• Decreased urination despite usual or increased fluid intake.

*If you experience any one or a combination of these symptoms, please contact your physician or nurse.*
Pregnancy and Birth Following Infertility Treatments

The likelihood that infertility treatments will result in a clinical pregnancy or live birth depends on many individual factors, primarily, the age of the woman, the quality of the sperm, the response of the woman's ovaries to stimulation with clomiphene or gonadotropins, the cause of infertility, and the condition of the uterus. Whatever the course of treatment, the response of any individual patient cannot be predicted with certainty. It is important to discuss your particular circumstances and history with your physician in order to arrive at a reasonable understanding of your chances of pregnancy or birth following one or more treatment cycles. There are no guarantees of successful outcome, however, no matter how favorable the rate that may be projected for a given couple.

After pregnancy is achieved, the following complications may occur:

- The fetus may not develop normally and spontaneous miscarriage may occur.
- Ectopic pregnancies (where the embryo implants and begins to develop outside the uterus) occur more frequently in couples receiving treatment for infertility than in couples conceiving spontaneously after sexual intercourse. This increased frequency may be the result of the fact that tubal disease is a contributing factor in many infertile couples. Most ectopic pregnancies are tubal pregnancies. Tubal ectopic pregnancies may be treated surgically or medically. Surgery may result in damage to or the loss of a fallopian tube and further impair fertility. In rare instances, a tubal pregnancy may present as a medical emergency in which the patient may go into shock as a result of blood loss and require blood transfusions and other treatment.
- The discovery of abnormalities in the fetus through prenatal diagnostic procedures (e.g. triple screen blood testing, chorionic villus sampling, amniocentesis, or ultrasound) may lead the woman/couple to decide to terminate the pregnancy.

Even an apparently normal ongoing pregnancy presents risks to both the mother and the baby, and does not guarantee a normal delivery at term of a normal infant. In pregnancies occurring after infertility treatments, as in pregnancies resulting from intercourse, serious unforeseen obstetrical complications occur. Such complications may result in miscarriage, the loss of the child in advanced pregnancy (stillbirth) or delivery of a baby too premature to survive. A prematurely born infant may experience serious or life threatening complications or permanent medical disability.

The use of medications for ovulation induction involves an increased risk of multiple pregnancy. Additionally, the rate of all types of complications greatly increases when there is a multiple pregnancy. Other obstetrical complications seem to occur following infertility treatments at the same rate that they occur in pregnancies following intercourse.

The rate of major birth defects in children born to mothers in the general population is about 3-4%. The risk that a child will be born with a major birth defect increases as its parents’ ages increase. There is no evidence that genetic problems, which are responsible for half of birth defects, are increased by infertility treatments, but amniocentesis and/or chorionic villus sampling, each of which can aid the recognition of many of these defects early in pregnancy, should be discussed with your obstetrician.
Some defects can be detected by ultrasound screening. However, not all defects will necessarily be detected by ultrasound or other examinations. It is generally recommended that women who will be age 35 years or older by the date of expected delivery should consider prenatal diagnostic testing. This should be discussed with your obstetrician.

In rare instances, pregnancy may result in serious harm or even death to the mother due to occurrences such as pulmonary embolism (blood clot to the lung), stroke or hemorrhage after delivery. There is no known increased risk for these complications in pregnancies following infertility treatments.

The physicians of Shady Grove Fertility do not function as obstetricians, but will work cooperatively with your obstetrician in early pregnancy. Generally, the diagnosis and early care of pregnancy are provided at Shady Grove Fertility. You will return to your obstetrician for routine care after a healthy pregnancy has been established, usually between the 7-9th weeks. Details of your infertility treatment, the pregnancy hormonal testing and pregnancy ultrasound scans will be released to your designated obstetrician and to your referring physician, unless specifically requested otherwise by you.
Financial Responsibility & Insurance Coverage

Financial responsibility for all services and medical treatments given by and for Shady Grove Fertility, physician and staff services, laboratory services and hospital costs associated with medical care, is the sole responsibility of you and your partner receiving these treatments. Financial responsibility for any pregnancy, any pregnancy complications, and any child(ren) resulting from treatment with Shady Grove Fertility, is the sole responsibility of you and your partner receiving these treatments.

The staff of Shady Grove Fertility makes every effort to accurately predict the cost of services before they are rendered, but the costs may vary depending on unforeseen circumstances and/or complications of the treatment. Shady Grove Fertility reserves the right to change its charges and fees with appropriate notice. The financial staff of Shady Grove Fertility will work with you to determine likely insurance reimbursement for care rendered, but the ultimate responsibility for payment rests with you, not your insurance company.

Embryo Options

Shady Grove Fertility has partnered with Embryo Options, a secure web based company, to provide an online payment process for cryopreservation as well as education on options for disposition of cryopreserved eggs, embryos, and sperm.

Enrollment into Embryo Options is free. You will not be charged cryopreservation fees until you have cryopreserved eggs, embryos, or sperm, and in accordance with your financial program (i.e. commercial insurance). You will pre-enroll in Embryo Options through the Embryo Options website where you will gain access to the Embryo Options educational website as well as the pre-enrollment form. Enrollment instructions are attached to the consent to cryopreserve sperm or the consent for the use of donor sperm. If using cryopreserved sperm or donor sperm in your treatment cycle, it will be mandatory that you enroll in Embryo Options. Contact your financial coordinator or primary clinical team for more information on Embryo Options.
Protecting Confidentiality: Communications with Physicians

In keeping with established medical ethics and general medical procedures, details of the medical care you receive through Shady Grove Fertility are confidential, except when release is legally authorized or required. **Our Notice of Privacy Practices provided to you on your first visit describes how we will protect your privacy rights, as well as how you can request restrictions on release of information.**

*It is our policy, in compliance with HIPAA, to disclose information or copies of the medical record only as allowed for treatment, payment or healthcare operations. Otherwise no information is released without written authorization of the person receiving treatment.* In the case of HIV results, a separate written authorization of the person tested needs to be given prior to release of results.

In the normal course of medical practice, communications, either verbal or written are made from time to time with the physician(s) who referred you for care. If you do not wish this, Shady Grove Fertility must be notified in writing. Upon establishment of a pregnancy, it is our policy to send basic information to your designated obstetrician. This letter or verbal communication may include the type of therapy, including ovum or sperm donation used, and the current status of the pregnancy monitoring and instructions for any medications that need to be continued during the pregnancy.

It is the practice of Shady Grove Fertility to report clinical treatment and results in scientific/medical meetings and journals without identifying specific couples involved in the treatment.
HIV (Human Immunodeficiency Virus) Antibody Test and other Infectious Disease Testing

Tests for previous exposure to the HIV virus are performed on blood samples obtained from both partners. HIV is the virus that causes AIDS. A positive test indicates that you have been infected with the HIV virus and are able to infect others.

It has been the policy of Shady Grove Fertility to insist that couples be tested for the presence of HIV. The purpose of this testing is to prevent the transmission of HIV in a possible offspring. Women who harbor the virus, but have no symptoms of AIDS, may pass the serious disease to their offspring. Treating the pregnant woman may reduce the rate of transmission to the fetus. Men and women, whether or not they are symptomatic, may pass the virus to their sexual partners. Needle sharing with infected persons and blood products used medically are the other means of transmission of the AIDS virus.

Infected people may harbor the virus for many years (at least ten years in some cases) without manifesting any symptoms of AIDS. The fact that a person harbors the virus and is potentially contagious may be determined by a blood test. The blood test may not be accurate in the first weeks or even months after contracting the viral infection, since the test measures the individual’s immune (antibody) response to the virus, and this response takes time to fully develop. It is not clear whether all persons with HIV will ultimately develop AIDS, but careful medical follow-up is required.

Each state regulates the performance of the test; most states mandate that individuals being tested be counseled about AIDS and about the implications of positive and negative test results. It is the policy of Shady Grove Fertility to limit the number of clinical staff who has access to HIV test results in order to assist in the protection of confidentiality. Copies of HIV test results are not sent out without the express written permission of the individuals.

In signing the Consent to Ovulation Induction, Monitoring And/Or Treatment form, patients at Shady Grove Fertility are consenting to be tested for HIV (the virus that causes AIDS) and to the release of the results to her/their physician at Shady Grove Fertility. Each member of the couple is also asked to agree to inform the other partner about the results of the test.

In addition to HIV testing, you and your partner will be tested for Hepatitis B Surface antigen, Hepatitis C Core Antibody, and syphilis before being allowed to start your treatment cycle.
Donor Sperm Insemination

Use of donor sperm may be indicated when there is absence of sperm or sperm that is unlikely to fertilize eggs. The success of insemination with thawed frozen donor sperm appears to be lower than the chance of conceiving with fresh sperm.

Shady Grove Fertility maintains working relationships with several national sperm banks that recruit and screen donors according to standards established by the American Society for Reproductive Medicine and the American Association of Tissue Banks. The genetic and medical histories of each donor, as reported by the donor, are reviewed and traced back two generations. The donor and his sperm are screened for some, but not all genetic diseases such as sickle cell anemia, Tay-Sachs disease, thalassemia, and for various sexually transmitted diseases, including but not limited to hepatitis, human immunodeficiency virus (HIV), cytomegalovirus, gonorrhea, chlamydia, trichomonas, monilia, gardnerella and syphilis. These standards have been established to reduce the risk of transmission of genetic and infectious diseases. However, in spite of these precautions, it is possible for donated sperm to harbor unidentified genetic abnormalities or undetected infections which may be passed on to the resulting child(ren). Infected sperm may also pass on a disease to the woman attempting pregnancy.

The risk of major birth defects following use of donor sperm appears to be the same as in the general population. Similarly, there is no apparent increase in the risk of pregnancy complications following donor sperm insemination.

Before starting a treatment cycle, you will be provided with information on how to contact a sperm bank and information on how to order donor sperm. **It is your responsibility to contact the sperm bank, select and order the donor sperm of your choice, and ensure its timely delivery to the facilities of Shady Grove Fertility for use in your treatment cycle.**

When use of donor sperm is indicated, it is required that the couple participates in at least one counseling session with one of Shady Grove Fertility’s, or other recommended, mental health professionals. This may be waived if you have already had counseling with a licensed therapist who specializes in infertility counseling. To use sperm from a known donor, it is required that the designated donor also participates in counseling sessions, both separately and together with the recipient woman/couple. If the designated donor is married or in a significant relationship, his partner must also be involved. The designated donor must be tested according to the standards established by the American Society for Reproductive Medicine and the American Association of Tissue Banks**. His genetic and medical history must be reviewed; he and his sperm must be screened for any relevant genetic diseases as well as for sexually transmissible diseases. These services will be provided and facilitated by the sperm bank. The sperm of the designated donor will only be used for insemination after six months of quarantine if the designated donor again tests negative for the standard panel of sexually transmissible diseases at that time.

By initialing the option for donor sperm and in signing the "Consent to Ovulation Induction, Monitoring And/Or Treatment form, you are authorizing Shady Grove Fertility to use donor sperm from a single donor as the sole source of sperm in any one treatment cycle and that, from the moment of insemination, you accept any child(ren) resulting from the procedure of donor sperm insemination as your own. The child(ren) produced as a result of donor sperm insemination is/are considered, in all respects, your child(ren). Financial responsibility for the pregnancy, any pregnancy complications and the child(ren) resulting from donor sperm insemination with Shady Grove Fertility, is your responsibility.

**HIV III, HTLVIII, hepatitis B surface antigen, hepatitis C core antibody, syphilis, gonorrhea and Chlamydia cultures, CMV IgG and IgM.