Specialists In Reproductive Medicine & Surgery, P.A.

www.DreamABaby.com • Fertility@DreamABaby.com

Excellence, Experience & Ethics

Patient Consent for Therapy
Assisted Reproductive Technologies

This is to certify that we, _____ & _____ hereby agree to a form of treatment commonly known as the Assisted Reproductive Technologies (ART).

We have medical problems, which are unresolved by conventional therapy. We understand that the ART procedures provide a means by which some previously infertile couples may conceive and deliver children. After a detailed and complete discussion with the medical staff of Specialists in Reproductive Medicine & Surgery, P.A., (SRMS), we hereby request this therapy understanding that there are potential risks and benefits of the procedures.

General Steps:

The following is a general outline of the steps that may be required to perform the ART procedures realizing the list is not inclusive of all possibilities, but includes the most common concerns.

Medications:

The use of "fertility drugs" such as Aromatase Inhibitors (Letrozole), Human Menopausal Gonadotropins (Repronex, Menopur, Bravelle, Follistim & Gonal-F), Gonadotropin antagonists (Ganirelix), Human Chorionic Gonadotropin, HCG (Ovidrel, Profasi, Pregnyl), Leuprolide (Lupron) and Progesterone may be administered. Most of these hormones are the same as, or very similar to, the natural hormones which are released during a normal menstrual cycle. The medications are usually administered orally or by injection. Specific information about each drug will be provided. The frequency of administration varies, but some medications may be given twice each day.

Depending on results of a semen culture done in the one to two months prior to the ART cycle, antibiotics may be administered orally to the male partner during the month of the female partner's egg retrieval.

In addition, the female will also receive intravenous (lV) antibiotics during the egg retrieval procedure. Other medications will be provided during the egg retrieval procedure by direct or IV injection which will relax the patient, minimize discomfort, help to prevent nausea and may

include, but are not to be limited to Diazepam (Valium), Midazolam (Versed), Lidocaine (Xylocaine), Fentanyl (Sublimaze), Meperidine (Demerol), and Promethazine (Phenergan). None of these medications have conclusively been shown to cause fetal abnormalities when used near the time of conception and are some of the same medications a woman may receive during labor/delivery.

Blood/Urine/Semen Specimens:

Blood specimens are frequently needed every few days and occasionally every day. When transferring frozen embryos, urine specimens may be required up to twice each day. Semen specimens are required for testing and occasionally for cryopreservation. Sperm cryopreservation is done to ensure the availability of enough sperm for insemination of the retrieved eggs. Annual storage fees will be assessed for all specimens kept beyond the original IVF cycle. Details regarding the fees are available from the front office. Please understand that due to limited storage capability, the practice cannot routinely store specimens for an indefinite period of time.

Egg Retrieval:

The vaginal ultrasound is used to guide a slender needle, which enters the vaginal space and then the ovary itself. This procedure is accomplished usually using IV medications.

Egg/Sperm:

A wide variety of procedures may be performed in the combining of the egg and the sperm (husband's sperm unless a donor has been previously arranged) and then placing the embryos into the woman's uterus:

IVF (In Vitro Fertilization)

The eggs and sperm are placed together in a culture dish to accomplish fertilization. Some of the fertilized embryos are then later transferred into the uterine cavity through the use of slender catheters.

The above procedures may be combined in order to maximize our chances for pregnancy. We understand that all retrieved eggs will be exposed to sperm unless special requests are made.

Micromanipulation:

A variety of assisted technologies have developed including micromanipulating eggs, sperm and embryos to enhance fertilization and improve on rates of implantation. The following are some examples:

ICSI (Intra Cytoplasmic Sperm Injection)

A single sperm is directly injected into the human egg to achieve fertilization. This procedure is commonly performed where there are significant male-factor concerns, timing of fertilization must be precise or if conventional insemination procedures may yield uncertain success.

Initials:	Date:

AH (Assisted Hatching)
The outer covering of the embryos is dissolved in a specific region to allow the cell mass to "hatch" and implant on the uterine wall.

PGD (Preimplantation Genetic Diagnosis)
One of the early embryonic cells is removed on Day 3 of growth and is analyzed for genetic problems such as Down's syndrome, inherited genetic diseases and gender. Normal embryos are then usually transferred on Day 5 or 6 of growth.

The above procedures may be combined in order to maximize the chances for a healthy pregnancy.

Embryos:

The embryos will be graded on structural criteria based on current scientific knowledge. Eggs and/or embryos that appear structurally abnormal will not be transferred to the uterus nor preserved by cryopreservation techniques. Abnormal eggs or embryos have a high frequency of genetic abnormalities and if placed in the uterine cavity, will frequently be miscarried or result in the formation of an abnormal offspring. The abnormal eggs and/or embryos may be examined in an attempt to understand the reasons for their abnormal development.

We, therefore, consent to the disposal of egg(s), sperm or embryo(s) that are not capable of surviving. In addition, we consent to the disposal or utilization of other cells, body tissues or fluids that may be obtained during the ART procedures.

Embryo Cryopreservation:

When possible and desired, the embryos will be cryopreserved wherein the embryos are frozen in liquid nitrogen for future use. The cryopreservation consent explains this procedure in greater detail.

Those patients that undergo ART here at SRMS understand that SRMS will no longer simply destroy excess cryopreserved embryos. Numerous options will be available to couples who no longer desire their cryopreserved embryos but outright destruction of them will no longer be an option. The staff here at SRMS has dedicated their lives to the creation of families and believes that the embryos deserve a greater level of respect than outright destruction.

Potential Complications:

Blood Work:
Bruising at the needle site may occur.

Ovarian Hyperstimulation:
These concerns are specifically addressed in "Ovarian Hyperstimulation Precautions." If hyperstimulation develops, complications can include low blood pressure, abnormal blood clotting, abdominal pain with fluid retention, swelling and very rarely death.

Egg Retrieval:

Initials:	Date:

Neither removing the eggs via a slender needle placed through the vaginal walls under ultrasound guidance nor the transfer of the actual eggs/sperm/embryos are high-risk procedures. Pelvic discomfort and slight vaginal bleeding may be experienced. Infrequent and rare surgical complications include, but are not necessarily limited to, infection, blood loss, the incision of vital organs and anesthetic risks. At SRMS, the surgical complication rate with the egg retrieval procedure is less than 1%. Additional concerns are detailed in the SRMS Operative Consent form.

Embryo Transfer:
The process of placing embryos into the uterus is a low-risk procedure. Pelvic discomfort and cervical/uterine bleeding may infrequently occur.

Micromanipulation Techniques:
While certainly not intended, the micromanipulation techniques can occasionally result in partial or complete destruction of the eggs, sperm and embryos.

Multiple Gestations:
Twins, triplets or more may occur when ART is used to achieve a pregnancy. The generally accepted risk is up to 50%. We understand that all multiple gestation pregnancies are high-risk for such complications as, but not necessarily limited to, premature labor/birth, bed rest, hospitalization, nausea/emesis, anemia, hypertension, pre-eclampsia, gestational diabetes and a surgical delivery. Options such as fetal reduction may allow one, two or three of the infants to survive. We understand that we may need to leave the state to find individuals skilled in this procedure.

Pregnancy Complications:
Patients who undergo ART seem to have a higher risk of pre-eclampsia and placental abruption (placenta pulls away form the uterine wall) and placenta previa (placenta blocks the cervix), fetal loss after 24 weeks gestational age and an increase in the cesarean delivery rate. Many of these issues are probably due to maternal problems and not the ART process itself. Infertile women are known to have more pregnancy complications compared to normal controls.

Pregnancy Loss:
Any pregnancy may result in a spontaneous miscarriage and ART is no exception. A stillbirth is also possible but does not seem to occur more frequently when ART is used when compared to the general population. Young women loose only 10% of their pregnancies while older women may loose up to 60% of their established pregnancies.

Ectopic Pregnancy:
The general incidence for an ectopic pregnancy, usually located in the fallopian tube, in patients using ART is 3%. Once pregnant, there is a 1:100-200 risk for having a concomitant intra-uterine and ectopic gestation called a **heteroectopic** pregnancy. If this occurs, surgery is usually needed to remove the ectopic pregnancy while trying to conserve the intra-uterine pregnancy.

Initials:	Date:

Abnormal Gestations:

Over 1,000,000 children have been born using ART worldwide and no consistent patterns of abnormal gestations have been found. Major congenital malformations, neurological dysfunction, developmental delay or childhood cancers have **not** consistently been found to occur more often in ART offspring. That stated, there may be insufficient information at this time as to whether the occurrence of these events are increased or perhaps even decreased by ART.

There have been some studies which indicate the average ART pregnancy will deliver somewhat earlier with a smaller-for-gestational-age baby (i.e., lower birth weight) compared to those conceived through natural means. Some of these children will require intensive care admission. These problems may be due to the fact that the patients are simply at higher risk for problems because of the issues that made them subfertile in the first place. We do not see the same complications when the embryos are placed in a surrogate uterus, so it seems unlikely that the issues are with the embryos or the way in which they were created, but rather, are caused by underlying medical issues present in the women seeking ART therapy.

There is a greater incidence of being delivered by Cesarean section for pregnancies conceived via ART.

While still very, very rare, there is an increase in the incidence of fetal or infant death. The cause is uncertain and may be due to maternal reasons.

Additional data has been published that indicates some male-factor problems may be passed on to the children. This seems to occur at a very low rate, but can occur. The overall outcome is usually similar to that of the father (i.e., reproductive issues). Fertility and other medical issues may occur to the male child or the female offspring may carry a genetic problem that could eventually affect her children. Once again, the medical outcomes are usually no different than the male partner who originally provided the sperm.

In genomic imprinting, certain genes from the father are regulated differently than the same genes from the mother, giving each parent a distinct contribution to the embryo. Imprinted genes commonly influence growth, development and/or placental function. These issues seem to be very important in reproductive cloning, but it remains uncertain if ART increases the incidences of these very rare diseases which are estimated to occur in 1/10,000 to 1/15,000 births. Even if the ART patients are at twice the risk, the incidence will be 1/5,000 to 1/7,500 births, still an amazingly rare event.

It is becoming clear that screening the embryos for genetic disease through Preimplantation Genetic Diagnosis (PGD) vastly reduces the incidence of genetically and physically impaired offspring. There is a growing body of data that suggests that PGD reduces the number of miscarriages and the birth of Down syndrome gestations. In this case, ART has clearly reduced the incidence of catastrophic genetic problems.

Initials:	Date:

Unexpected Events:

We understand that, despite reasonable precautions, any of the following may occur which would prevent the establishment of a pregnancy:

- Realizing this is an elective procedure, the clinician reserves the right to cancel the cycle at anytime if he/she feels my health is at risk or the chances of success are minimal.
- The time of ovulation may be miscalculated thus making it impossible to obtain the already ovulated egg(s).
- Even with ideal timing, some follicles do not contain eggs.
- The male partner may be unable to obtain a sperm specimen upon request necessitating the use of the previously preserved frozen semen. If no sperm is frozen, there may be no sperm available for fertilization.
- The eggs may not be normal or they may not fertilize.
- Even if fertilization occurs, cell growth and division may not occur.
- Even if cell growth and division occurs, the embryo may not develop normally.
- If the embryo transfer is delayed, it will not be possible to maintain the life of the embryo.
- Loss or damage to the eggs/sperm/embryos may occur during the actual transfer process.
- Even if the embryos develop and are placed back into the uterine cavity, actual implantation of the embryos on the walls of the uterus may not occur.
- While the most extremes of precautions are taken, a laboratory accident may result in the loss or damage of the sperm, eggs or embryo.
- The medical staff of SRMS will not be held accountable for acts of God, which do not allow for any of the outlined procedure(s) to take place.

Psychological Concerns:

We are aware that the preparation for and the ART themselves may have serious psychological consequences with respect to, but not limited to, the mother-child, the father-child, the mother-father as well as other family relationships. The decision of what to do with excess cryopreserved embryos is often a difficult one for the ART patient. Psychological counseling is always available upon request.

Legal Concerns:

We shall indemnify SRMS for any attorney's fees, court costs, damages, judgments, or any other losses or expenses incurred by SRMS, or for which SRMS, may be responsible with respect to any 'third party" claim, legal action or defense thereto, arising out of The ART procedures herein contemplated, including, but not limited to any claim or legal action brought by the child or children resulting from the ART procedures.

Education, Publication and Confidentiality Concerns:

It is possible that our participation in this program may aid in the development of techniques that will assist other couples and that new and useful information may be obtained from our procedures. Therefore, realizing that our identity will **not** be disclosed, we agree to the taking and publication of photographs, slides or videotapes and/or the active/passive participation of medical/laboratory guests here at SRMS. We realize that specific medical details

Initials:	Date:

maybe included in medical discussions or publications without our consent as long as reasonable efforts are made to conceal our identity. Only with prior consent will our identity be purposefully disclosed. These photographs may be used for general documentation of the medical records or for educational purposes, i.e., publications and/or lectures at a national, state or local level.

The confidentiality of the medical records will be maintained in accordance with Florida law. SRMS is mandated by Federal statutes to obtain confirmation of all delivery data on the ART pregnancies. We agree to forward any needed information to fulfill the Federal statutes including, but not necessarily limited to, a copy of the birth certificate & a copy of the birth announcement, the newborn sex, newborn weight and any information regarding pregnancy, delivery and newborn complications. We agree that our records may be reviewed by outside agencies including, but not necessarily limited to, the Federal Food and Drug Administration (FDA) or the Society of Assisted Reproductive Technologies (SART). Upon occasion, we understand that these same agencies may contact us to confirm the pregnancy outcome.

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

Alternatives:

We understand that there may be other alternatives in obtaining a child rather than ART such as, but not limited to, adoption. In spite of the other alternatives, we request that ART be used.

General Concerns:

We understand that the practice of medicine is not an exact science and while our physician has recommended ART for our condition, **there is no guarantee that the procedures will result in a successful pregnancy and delivery.**

We understand that we may elect not to continue with the ART procedures at any time and that this decision will not affect present or future medical care at SRMS. Likewise, we acknowledge that our acceptance and continued participation in the program is at the sole discretion of the ART team.

We have read the above materials and understand the possible complications of the proposed procedures. We have had the opportunity to ask questions and to inquire about the risks and benefits of the ART program. Our questions have been answered to our satisfaction and we understand the information given to us.

We understand that this Consent for ART Therapy is to be considered valid for **all** future ART procedures, unless specifically revoked by us.

Initials:	Date:

All of the blanks in this consent have been filled prior to the signing of the signatures below:

Cycle#1

_____	_____	___/___/___
Patient's Signature	Patient's Name (print)	Date
_____	_____	___/___/___
Partner's Signature	Partner's Name (print)	Date
_____	_____	___/___/___
Nurse Coordinator Signature	Nurse's Name (print)	Date
_____	_____	___/___/___
Practitioner's Signature	Practitioner's Name (print)	Date

Cycle#2

_____	_____	___/___/___
Patient's Signature	Patient's Name (print)	Date
_____	_____	___/___/___
Partner's Signature	Partner's Name (print)	Date
_____	_____	___/___/___
Nurse Coordinator Signature	Nurse's Name (print)	Date
_____	_____	___/___/___
Practitioner's Signature	Practitioner's Name (print)	Date

Cycle#3

_____	_____	___/___/___
Patient's Signature	Patient's Name (print)	Date
_____	_____	___/___/___
Partner's Signature	Partner's Name (print)	Date
_____	_____	___/___/___
Nurse Coordinator Signature	Nurse's Name (print)	Date
_____	_____	___/___/___
Practitioner's Signature	Practitioner's Name (print)	Date

Revised 04/12/2016
K\docs\forms\Patient Consent for Therapy Assisted Reproductive Technologies.doc

Initials:	Date: