

## CONSENT FORM FOR IN VITRO FERTILIZATION USING FROZEN EGGS

### INSTRUCTIONS:

This consent form provides a description of the treatment that you are undertaking.

- Read the consent completely. If you have any questions please speak with your doctor.
- Do not make any additions or deletions to the consent.
- Treatment **cannot** be started until all consents are signed.
- Consents must be signed in front of your nurse or physician.

### INTRODUCTION

Eggs (also called oocytes) that have been previously frozen can be thawed, fertilized in the laboratory and transferred into a woman's uterus in an attempt to achieve a pregnancy. This document explains the technique and describes the major and foreseeable risks, and the responsibilities of those who participate in this treatment.

This consent is valid for one year after it has been signed. Please make a copy for your records. It is recommended that you review the consent prior to each treatment cycle. If you have any questions about your treatment then it is your responsibility to speak with your physician.

#### *Pre-treatment Recommendations*

During treatment a woman should avoid any activity, behavior and medications that could reduce her chance of conceiving and having a healthy baby. In addition, the recommendations listed below should be followed.

1. A prenatal vitamin should be taken on a daily basis before the treatment is begun, optimally for at least one month prior to conception. This will reduce the chance that a baby will be born with a neural tube defect (e.g. spina bifida), which is a birth defect that affects the development of the spine.
2. Smoking must be avoided before and during treatment. It is also contraindicated during pregnancy.
3. Recreational drugs are absolutely contraindicated.
4. Ingestion of aspirin or aspirin-like products (e.g. Motrin<sup>®</sup>, Advil<sup>®</sup>, Anaprox<sup>®</sup>, Naprosyn<sup>®</sup>, Aleve<sup>®</sup>, etc.) should be avoided during treatment. However, in certain circumstances your doctor may prescribe low dose aspirin (baby aspirin, 81 mg). Tylenol<sup>®</sup> is safe to take before and during pregnancy.
5. The use of alcohol should be avoided during treatment and after pregnancy is established.
6. The use of all prescription and over-the-counter medications (including herbal remedies) should be discussed with a physician before starting a treatment cycle. We do not recommend the use of any herbal remedies and/or medications that are not FDA-regulated.
7. HIV (human immunodeficiency virus) screening is strongly recommended for all couples undergoing infertility treatment. HIV is the virus that causes acquired immunodeficiency syndrome (AIDS). A woman infected with HIV can pass the virus to her unborn child. Please talk to your physician about having this test performed.

8. Ingestion of some fish, which contain higher amounts of mercury, can affect the development of the nervous system of a fetus. During the treatment and after pregnancy is established you should avoid eating these fish shark, swordfish, king mackerel, tilefish and tuna. You should limit the intake of all other fish to 12 oz. per week.

## **DESCRIPTION OF TREATMENT**

This treatment involves several steps, as outlined below. Patients are not guaranteed success at any or all of these steps. If optimal results are not achieved at any step, it may be recommended that the treatment should be stopped and the cycle cancelled.

### **I. Maturation of the Uterine Lining**

There are several medications that are used to prepare the lining of the uterus (called endometrium) for implantation. Your doctor will use some or all of the medications below.

#### **Estrogen and Progesterone**

Estrogen is administered orally (Estrace<sup>®</sup>) or in combination with a patch (Vivelle<sup>®</sup>). The estrogen is started with the beginning of the menstrual period. The estrogen medication is important to make sure the lining of the uterus is of the appropriately developed. After the estrogen has been administered for approximately two weeks, another medication called progesterone is started. The progesterone is given either vaginally or intramuscularly and causes the final maturation of the uterine lining. The embryos are typically replaced after a few days of progesterone.

#### **Lupron<sup>®</sup>/Estrogen**

Lupron<sup>®</sup> is an injectable medication that initially stimulates the pituitary gland to release FSH and LH, which are the hormones that regulate ovulation. With continued administration of Lupron<sup>®</sup>, the pituitary gland is temporarily depleted of FSH and LH, which prevents the ovaries from ovulating unexpectedly during the treatment cycle. After the Lupron<sup>®</sup> has had this desired effect, estrogen and progesterone are administered as described above.

Lupron<sup>®</sup>, estrogen and progesterone are not FDA-approved for this purpose. These medications have been approved for other indications; Lupron<sup>®</sup> has been approved for the treatment of endometriosis and uterine fibroids. Estrogen and progesterone medications have been approved for hormonal replacement for menopausal women.

### **Monitoring**

During this phase of the treatment, ovarian ultrasound examination of the uterine lining and hormone blood tests may be performed to help determine the best timing of the embryo transfer. The need for monitoring requires that you be in the vicinity of a Boston IVF monitoring site during the treatment.

### **Side Effects**

The use of these medications (Lupron<sup>®</sup>, estrogen, and progesterone) can cause side effects such as nausea, vomiting, hot flashes, headaches, mood swings, joint pains and visual symptoms. Some women may have an allergic reaction to the drugs. A rare risk of estrogen administration is the formation of blood clots, which can compromise the blood supply to vital organs, causing serious problems. These problems may include a stroke or heart attack. Any of these conditions may cause death or serious long-term disability. Most studies of low-dose estrogen usage by women do not show an increased risk for these complications.

### **II. Thawing of the Frozen Eggs**

On the appropriate day, the frozen eggs will be removed from the storage tank and thawed. After the thawing is completed, the eggs are examined to determine their viability. On average, 60-70% of frozen eggs will survive the thawing. However, it is possible that none of the eggs will survive the thawing.

### **III. Insemination of Eggs**

On the day of the thawing of the frozen eggs, a sperm sample must be available. Under some circumstances, sperm can be frozen prior to the day of the anticipated insemination. Reasons to consider sperm freezing would be if the male partner cannot be available on the day that the eggs are thawed or there has been difficulty in the past with the production of a semen sample. You are responsible for making arrangements to freeze sperm prior to the start of treatment if this applies to you. In some situations a couple or patient may choose to use donor sperm. The biologist processes the sperm sample and then the eggs are inseminated. Egg freezing results in egg shell 'hardening' and sperm insemination with intracytoplasmic sperm injection (ICSI) is required (described below).

#### ***Intracytoplasmic sperm injection (ICSI) -***

The ICSI procedure is a process, whereby, with the aid of a microscope and fine instruments, a single sperm is injected directly into each egg. ICSI is required in all cases of eggs that were frozen and thawed due to poor fertilization results with regular IVF insemination. Is it believed that the freezing and thawing process makes it difficult for sperm to penetrate the egg shell.

Reports on the risk of birth defects associated with ICSI (compared to those associated with conventional fertilization in IVF cycles) have yielded conflicting results. The most comprehensive study conducted thus far, based on data from five-year-old children, has suggested that ICSI is associated with an increased risk of certain major congenital anomalies. However, whether the association is due to the ICSI procedure itself, or to inherent sperm defects, could not be determined because the study did not distinguish between male factor conditions and other causes of infertility. Note that even if there is an increased risk of congenital malformations in children conceived with ICSI, the risk is relatively low (4.2% versus ~3% of those conceived naturally). The impact of ICSI on the intellectual and motor development of children conceived via ICSI also has been controversial. An early report suggested that development in such children lagged significantly behind that of children resulting from conventional IVF or those conceived naturally. However, more recent studies from larger groups, using standardized criteria for evaluation, have not detected any differences in the development or the abilities of children born after ICSI, conventional IVF, or natural conception. In standard IVF using ICSI, the ICSI technique is typically used when there is a sperm problem to begin with. With egg freezing, the sperm is typically normal and thus adverse outcomes reported with ICSI used to treat sperm problems may not apply to ICSI used for insemination of thawed eggs.

On average, 60-70% of eggs will fertilize following the standard insemination or the ICSI procedure but in some cases none of the eggs fertilize. If fertilization is confirmed, plans are then made for the embryo transfer. In some cases of documented fertilization the embryos stop their development and the embryo transfer is cancelled.

### **IV. Embryo Transfer**

After fertilization has been confirmed, the development of the embryos is monitored in the laboratory. If the embryos continue their development then plans are made for the embryo transfer. The embryo transfer is performed 3 to 6 days following the egg retrieval. Embryos transferred 3 days after the egg retrieval are generally at the 4 to 8 cell stage. Embryos transferred on day 5 or 6 are at a more advanced stage and may have developed into a blastocyst, which is made up of over 50 cells. Your physician will discuss with you the optimal time of the transfer. In the event that the embryos stop their development, the embryo transfer is not performed.

At the time of the embryo transfer, a physician will review the fertilization results and the development of the embryos. You will discuss with a physician the optimal number of embryos to be transferred. Increasing the number of embryos transferred will increase the chances of pregnancy, but will also increase the risk of a multiple pregnancy (e.g., twins, triplets, etc). Remaining embryos that are not transferred will be examined and, if they are of suitable quality, may be frozen, stored and transferred at a later date. Alternatively, these "extra" embryos can be discarded.

Embryos which result from abnormal fertilization (i.e., polyspermy -when more than one sperm fertilizes an egg) will be discarded because they have no chance of developing normally. In addition, embryos that fail to develop properly (e.g.,

fail to divide, demonstrate other significant abnormalities of development) will also be discarded. Eggs and/or embryos, which have failed to develop (not viable), will not be transferred and will be discarded.

In order to perform the embryo transfer the woman is placed in the same position for a pelvic exam. A speculum is placed into the vagina and the cervix is visualized. The vagina and cervix are rinsed with a solution. An abdominal ultrasound is often performed to help visualize the passage of the catheter. The biologist loads the embryos into a catheter, which the physician inserts through the cervical canal and into the uterine cavity. After placement of the catheter the embryos are injected into the uterine cavity. You will be sent home shortly after the embryo transfer. Generally, no anesthesia is required for an embryo transfer.

Very rarely, a uterine infection may occur after embryo transfer. The most common symptoms associated with infection are pain and fever. If fever, vomiting, abdominal pain or any other symptoms develop following embryo transfer, you should contact your physician.

### **Assisted Embryo Hatching**

Your physician may recommend that assisted hatching be performed on the embryos just prior to the transfer. The zona pellucida is the outer protective membrane (the 'egg shell') that surrounds the egg. After the sperm has penetrated the egg and fertilization has occurred, the embryo develops within the confines of the zona pellucida for a period of 5-7 days. Thereafter, an area of the zona pellucida thins out and the embryo "hatches" or is expelled out of the confines of the zona pellucida. It is only then that the embryo has the opportunity to implant into the uterine wall for the establishment of a pregnancy. It is possible that some embryos do not undergo this "hatching" process normally. A laboratory technique has been developed to facilitate the embryo with this "hatching" process and is referred to as *assisted hatching*. There is controversy as to whether the performance of assisted hatching increases the chance of a successful pregnancy following IVF treatment. *Your doctor may or may not recommend assisted hatching if you are undergoing a day three embryo transfer.*

***The assisted embryo hatching procedure-*** The assisted hatching procedure is performed on the day of the embryo transfer. With the aid of a microscope and fine instruments and often using a microscopic laser, the zona pellucida is made thinner. The embryos are then transferred back into the incubator until the embryo transfer is performed. Your physician may prescribe an antibiotic and a corticosteroid (methylprednisolone), which will be started on the day of the egg retrieval and continued for a period of four days.

The following risks are associated with the assisted hatching procedure.

1. The embryos may be destroyed or injured precluding their ability to implant.
2. There is an increased chance that an embryo splits and leads to a set of identical twins. This type of a multiple pregnancy is referred to as monozygotic twinning (MZT). The risks associated with MZT are described later in the consent under Treatment Outcomes.
3. The procedure may yield presently unknown risks to the baby and/or mother.
4. Assisted hatching may not improve your chances of establishing a pregnancy.
5. There are risks associated with medications that may be prescribed to help prevent an inflammatory response or infection following assisted hatching.
  - a. Methylprednisolone- This medication has an anti-inflammatory action and modifies the immune response. The following side effects may occur but are more common when this drug is administered for a longer duration or at higher doses: mood swings, insomnia, depression, psychotic manifestations, muscle weakness, permanent hip replacement, impaired wound healing, increase sweating, headaches, vertigo, allergic reaction, loss of muscle mass, osteoporosis and abdominal distention. Other side effects include an increase in blood pressure, salt and water retention, increase excretion of potassium and calcium may occur. The use of methylprednisolone may mask the signs of an infection, make one susceptible to a new infection, and make it difficult to localize the source of an infection.
  - b. The use of antibiotics may result in the following side effects which are dose-related: nausea, vomiting, diarrhea, loss of appetite, rashes, sensitivity to the sun, rare hypersensitivity reaction which may cause

shock, blood diseases including reduced platelets or fractured blood cells which could result in anemia and/or bleeding.

**V. Embryo Cryopreservation of viable, high quality embryos (if any) not transferred:**

I/We understand that to date, there are no known effects from long-term storage of cryopreserved (frozen) embryos. Although there are theoretical risks of congenital malformations, I/we understand that the best available research suggests that the rate of birth defects in children born following the cryopreservation of embryos is the same as the rate observed in an age-matched group of pregnant women who conceived without assisted reproduction:

Choose one option:

1. \_\_\_\_\_ **Patient initials**    \_\_\_\_\_ **Partner initials**    I/We **AGREE** to embryo cryopreservation  
(if applicable)

**OR**

2. \_\_\_\_\_ **Patient initials**    \_\_\_\_\_ **Partner initials**    I/We **DO NOT AGREE** to embryo cryopreservation  
(if applicable)

**Disposition of Cryopreserved Embryos:**

Any disposition of embryos requires the written authorization of both partners. If your embryos were formed using eggs/sperm from a third party donor, your instructions to donate these embryos must be in accordance with prior agreements with the egg/sperm donor or applicable law. Your instructions to donate the embryos may require separate consent from the egg/sperm donor.

**I/We understand and agree that in the event of death or incapacitation of one partner, the embryo(s) will become the sole and exclusive property of the surviving partner, unless otherwise directed by law, a court order or as designated in my/our will. If the surviving partner, friends or family members wish to conceive with these embryos after your death, a legal document indicating this intent will be required.**

I/We understand that the cryopreserved embryos will incur a charge according to the Fees for Embryo Cryopreservation and Storage policy of Boston IVF. Cryopreserved embryos will be maintained until specific directives and authorization for those directives are provided by me/us. Options for disposition are discussed in the Consent for Treatment Guideline and consent forms are required at the time of disposition. Boston IVF reserves the right at its sole discretion to make decisions regarding the final disposition of cryopreserved embryos if fee obligations are not met. In the event of divorce or dissolution of the relationship between patient and partner, embryos cannot be used, donated or discarded without the expressed, written consent of both parties or as directed by a court order, even if donor eggs/sperm were used.

**VI. Luteal Phase Support following Embryo Transfer**

Progesterone, a hormone produced by the ovary, prepares the lining of the uterus for implantation during the normal menstrual cycle. For this reason, supplemental progesterone is administered to help assist implantation. Natural progesterone is available and can be administered vaginally (Endometrin®, Crinone®, Prochieve®, Prometrium®, or pharmacist-compounded suppositories) or by intramuscular injection. If pregnancy occurs, the progesterone may be continued for a period of time. Studies have confirmed that there is no increased risk of birth defects or health risks to women who take natural progesterone supplements during pregnancy. Some women may receive alternate forms of luteal phase support in lieu or in addition to progesterone. These include oral estradiol and human chorionic gonadotropin injections. Side effects of progesterone include depression, sleepiness, allergic reactions and, if given by intra-muscular injection, additional risks include infection or pain at the application site. Estradiol, if prescribed, can

be administered by oral, trans-dermal, intramuscular, or vaginal administration. Side effects of estradiol include nausea, irritation at the injection site if given by the trans-dermal route and the risk of blood clots or stroke.

Eleven days after embryo transfer, a blood pregnancy test will be done. If this test is found to be positive, a repeat pregnancy test may be done 2-3 days later. If the pregnancy test results are within expected values then a vaginal ultrasound will be done approximately five weeks after the embryo transfer to determine the status of the pregnancy. Because of the potential for complications following the embryo transfer, access to medical care is important up to the time of the pregnancy test and beyond if pregnancy is established. If travel is absolutely necessary, it should be discussed with a physician.

## **VII. Risks to the Woman**

### **1. Ovarian Hyperstimulation Syndrome**

To increase the number of eggs that develop, a series of hormone shots are given. The hormones used in this regimen are known to have, or suspected of having a variety of side effects, some minor and some potentially major. The most serious side effect of ovarian stimulation is ovarian hyperstimulation syndrome (OHSS). Its symptoms can include increased ovarian size, nausea and vomiting, accumulation of fluid in the abdomen, breathing difficulties, an increased concentration of red blood cells, kidney and liver problems, and in the most severe cases, blood clots, kidney failure, or death. The severe cases affect only a very small percentage of women who undergo in vitro fertilization—0.2 percent or less of all treatment cycles—and the very severe are an even smaller percentage. Only about 1.4 in 100,000 cycles has lead to kidney failure, for example. OHSS occurs at two stages: early, 1 to 5 days after egg retrieval (as a result of the hCG trigger); and late, 10 to 15 days after retrieval (as a result of the hCG *hormone* if pregnancy occurs). The risk of severe complications is about 4 to 12 times higher if pregnancy occurs which is why sometimes no embryo transfer is performed to reduce the possibility of this occurring.

### **2. Cancer**

Many have worried that the use of fertility drugs could lead to an increased risk of cancer—in particular, breast, ovarian, and uterine (including endometrial) cancers. One must be careful in interpreting epidemiological studies of women taking fertility drugs, because all of these cancers are more common in women with infertility, so merely comparing women taking fertility drugs with women in the general population inevitably shows an increased incidence of cancer. When the analysis takes into account the increased cancer risk due to infertility per se, the evidence does not support a relationship between fertility drugs and an increased prevalence of breast or ovarian cancer. More research is required to examine what the long-term impact of fertility drugs may be on breast and ovarian cancer prevalence rates. For uterine cancer, the numbers are too small to achieve statistical significance, but it is at least possible that use of fertility drugs may indeed cause some increased risk of uterine cancer.

### **3. Risks of Pregnancy**

Pregnancies that occur with IVF are associated with increased risks of certain conditions including pre-eclampsia, placenta previa, placental abruption, gestational diabetes and cesarean section. Some of these risks stem from the higher average age of women pregnant by IVF and the fact that the underlying cause of infertility may be the cause of the increased risk of pregnancy complications. There may be additional risks related to the IVF procedure per se, but it is difficult to assign the relative contributions.

Currently more than 30% of IVF pregnancies are twins or higher-order multiple gestations (triplets or greater). Identical twinning occurs in 1.5% to 4.5% of IVF pregnancies. IVF twins deliver on average three weeks earlier and weigh 1,000 gm (2.2 pounds) less than IVF singletons. Of note, IVF twins do as well as spontaneously conceived twins. Triplet (and greater) pregnancies deliver before 32 weeks (7 months) in almost half of cases.

Additionally, while embryos are transferred directly into the uterus with IVF, ectopic (tubal, cervical and abdominal) pregnancies as well as abnormal intra-uterine pregnancies have occurred either alone or concurrently with a normal intra-uterine pregnancy. These abnormal pregnancies often times require medical treatments with methotrexate (a weak chemotherapy drug) or surgery to treat the abnormal pregnancy. Side effects of methotrexate include nausea or vomiting, diarrhea, cramping, mouth ulcers, headache, skin rash, sensitivity to the sun and temporary abnormalities in

liver function tests. Risks of surgery include the risks of anesthesia, scar tissue formation inside the uterus, infection, bleeding and injury to any internal organs.

A miscarriage is a failed intrauterine pregnancy. The risk of miscarriage in the general population is 15-20%. The risk of miscarriage increases with advancing maternal age. For women over 40 years of age, the risk may exceed 40%. Studies have shown that there is either no increase or a slight increase in the risk of miscarriage in women who conceive with IVF. Most miscarriages are associated with lower abdominal cramping and bleeding, but do not necessarily require surgical treatment. In some cases, removal of the pregnancy tissue must be accomplished by a surgical procedure called a dilatation and curettage (D&C).

## **VIII.Risks to Offspring**

### **1. Overall risks:**

Initially egg freezing was viewed by the American Society for Reproductive Medicine (ASRM) as experimental but in October 2012 the Practice Committee of the ASRM reviewed the available published data and concluded that this technique should no longer be considered experimental (Fertil Steril, 2012). They also reported that there are no increases in chromosomal abnormalities, birth defects, or developmental deficits in the children born from cryopreserved oocytes (eggs). However egg freezing is a new technology and there could be unforeseen risks realized in the future.

There is always the possibility that eggs will not survive thawing or will not fertilize, and, as a result, no viable embryos will be available for embryo transfer. Therefore, Boston IVF cannot guarantee the successful live birth of a baby from frozen eggs.

Since the first birth of an IVF baby in 1978, more than 3 million children have been born worldwide following IVF treatments. Numerous studies have been conducted to assess the overall health of IVF children and the majority of studies on the safety of IVF have been reassuring. As more time has passed and the dataset has enlarged, some studies have raised doubts about the equivalence of risks for IVF babies as compared to naturally conceived babies. A major problem in interpreting the data arises from the fact that comparing a group of infertile couples to a group of normally fertile couples is not the proper comparison to make if one wants to assess the risk that IVF technology engenders. Infertile couples, by definition, do not have normal reproductive function and might be expected to have babies with more abnormalities than a group of normally fertile couples. This said, even if the studies suggesting an increased risk to babies born after IVF prove to be true, the absolute risk of any abnormal outcome appears to be small. Singletons conceived with IVF tend to be born slightly earlier than naturally conceived babies (39.1 weeks as compared to 39.5 weeks). IVF twins are not born earlier or later than naturally conceived twins. The risk of a singleton IVF conceived baby being born with a birth weight under 5 pounds nine ounces (2500 grams) is 12.5% vs. 7% in naturally conceived singletons.

### **2. Birth Defect:**

The risk of birth defects in the normal population is 2-3 %. In IVF babies the birth defect rate may be 2.6-3.9%. Studies to date have not been large enough to prove a link between IVF treatment and specific types of birth defects.

### **3. Imprinting Disorders:**

These are rare disorders having to do with whether a maternal or paternal gene is inappropriately expressed. Since the incidence of this syndrome in the general population is 1/15,000, even if there is a 2 to 5-fold increase to 2-5/15,000, this absolute risk is very low.

**4. Childhood cancers:** Most studies have not reported an increased risk with the exception of retinoblastoma:

**5. Infant Development:** In general, studies of long-term developmental outcomes have been reassuring so far; most children are doing well.

**6. Risks of a Multiple Pregnancy:** The most important maternal complications associated with multiple gestation are preterm labor and delivery, pre-eclampsia and gestational diabetes (see prior section on Risks to Woman). Others include gall bladder problems, skin problems, excess weight gain, anemia, excessive nausea and vomiting, and exacerbation of pregnancy-associated gastrointestinal symptoms including reflux and constipation. Chronic back pain, intermittent heartburn, postpartum laxity of the abdominal wall, and umbilical hernias also can occur. Triplets and above increase the risk to the mother of more significant complications including post-partum hemorrhage and transfusion. Prematurity accounts for most of the excess perinatal morbidity and mortality associated with multiple gestations. Moreover, IVF pregnancies are associated with an increased risk of prematurity, independent of maternal age and fetal numbers. Fetal growth problems and discordant growth among the fetuses also result in perinatal morbidity and mortality. Multifetal pregnancy reduction (where one or more fetuses are selectively terminated) reduces, but does not eliminate, the risk of these complications.

Fetal death rates for singleton, twin, and triplet pregnancies are 4.3 per 1,000, 15.5 per 1,000, and 21 per 1,000, respectively. The death of one or more fetuses in a multiple gestation (vanishing twin) is more common in the first trimester and may be observed in up to 25% of pregnancies after IVF. Loss of a fetus in the first trimester is unlikely to adversely affect the surviving fetus or mother. No excess perinatal (mature fetus or newborn) or maternal morbidity has been described resulting from a “vanishing” embryo.

Demise of a single fetus in a twin pregnancy after the first trimester is more common when they share a placenta, ranging in incidence from 0.5% to 6.8%, and may cause harm to the remaining fetus.

Monozygotic twinning (MZT) is a multiple pregnancy that results from the splitting of a single embryo, which will lead to a set of identical twins. The incidence of MZT is increased in pregnancies conceived following IVF and may occur between 1.5-5% of IVF pregnancies. In addition to the above stated complications associated with a multiple pregnancy with MZT there is a greater chance of twin-to-twin transfusion, which can affect the growth of the fetuses and increase the chance of other complications. Twins sharing the same placenta have a higher frequency of birth defects compared to pregnancies having two placentas. MZT occurs more frequently after blastocyst transfer.

Placenta previa and vasa previa are more common complications in multiple gestations. Abruption placenta also is more common and postpartum hemorrhage may complicate 12% of multifetal deliveries. Consequences of multiple gestations include the major sequelae of prematurity (cerebral palsy, retinopathy of prematurity, and chronic lung disease) as well as those of fetal growth restriction (polycythemia, hypoglycemia, necrotizing enterocolitis). It is unclear to what extent multiple gestations themselves affect neuro-behavioral development in the absence of these complications. Rearing of twins and high-order multiples may generate physical, emotional, and financial stresses, and the incidence of maternal depression and anxiety is increased in women raising multiples. At mid-childhood, prematurely born offspring from multiple gestations have lower IQ scores, and multiple birth children have an increase in behavioral problems compared with singletons. It is not clear to what extent these risks are affected by IVF per se.

A multiple pregnancy may pose increased emotional and financial hardship for a couple. The risk of a multiple pregnancy can be reduced by decreasing the number of embryos that are transferred but this also reduces the overall chance of success. You are encouraged to have a discussion with your physician about the optimal number of embryos to transfer.

***The Option of Selective Reduction:*** Pregnancies that have more than 2 fetuses are considered an adverse outcome of infertility treatment. The greater the number of fetuses within the uterus, the greater is the risk for adverse perinatal and maternal outcomes. Patients with more than twins are faced with the options of continuing the pregnancy with all the risks previously described, terminating the entire pregnancy, or reducing the number of fetuses in an effort to decrease the risk of maternal and perinatal morbidity and mortality. Multifetal pregnancy reduction (MFPR) decreases risks associated with preterm delivery, but often creates profound ethical dilemmas. Pregnancy loss is the main risk of MFPR. However, current data suggest that such complications have decreased as experience with the procedure has grown. The risk of loss of the entire pregnancy after MFPR is approximately 1%.



In general, the risk of loss after MFPR increases if the number of fetuses at the beginning of the procedure is more than three. While there is little difference between the loss rates observed when the final number of viable fetuses is two or one, the loss rate is higher in pregnancies reduced to triplets. Pregnancies that are reduced to twins appear to do as well as spontaneously conceived twin gestations, although an increased risk of having a small for gestational age fetus is increased when the starting number is over four. The benefit of MFPR can be documented in triplet and higher-order gestations because reduction prolongs the length of gestation of the surviving fetuses. (This has been demonstrated for triplets; triplets have a 30-35% risk of birth under 32 weeks compared to twins which is 7 to 10%.)

### **IX. Ethical and Religious Considerations in Infertility Treatment**

Infertility treatment can raise concerns and questions of an ethical or religious nature for some patients. The technique of in vitro fertilization (IVF) involves the creation of human embryos outside the body, and can involve the production of excess embryos and/or 'high-order' multiple pregnancy (triplets or more). We encourage patients and their spouses or partners who so desire to consult with trusted members of their religious or ethics community for guidance on their infertility treatment.

### **X. Psychosocial Effects of Infertility Treatment**

IVF can be psychologically stressful. Anxiety and disappointment may occur at any of the phases described above. Significant commitment of time and finances may be required. Patients are encouraged to consider meeting with a counselor. If you are interested in meeting with a social worker or psychologist, please speak to your physician.

### **XI. Legal Considerations and Legal Counsel**

The law regarding embryo cryopreservation, subsequent thaw and use, and parent-child status of any resulting child(ren) is, or may be, unsettled in the state in which either the patient, spouse, partner, or any donor currently or in the future lives, or the state in which the ART Program is located. We acknowledge that the ART Program has not given us legal advice, that we are not relying on the ART Program to give us any legal advice, and that we have been informed that we may wish to consult a lawyer who is experienced in the areas of reproductive law and embryo cryopreservation and disposition if we have any questions or concerns about the present or future status of our embryos, our individual or joint access to them, our individual or joint parental status as to any resulting child, or about any other aspect of this consent and agreement.

### **XII. Alternatives to IVF**

Pursuing adoption, egg donation or not undergoing treatment are options.

### **XIII. Reporting Outcomes**

The 1992 Fertility Clinic Success Rate and Certification Act requires the Centers for Disease Control and Prevention (CDC) to collect cycle-specific data as well as pregnancy outcome on all assisted reproductive technology cycles performed in the United States each year and requires them to report success rates using these data. Consequently, data from my/our IVF procedure will be provided to the CDC, and to the Society of Assisted Reproductive Technologies (SART) of the American Society of Reproductive Medicine (ASRM) (if my/our clinic is a member of this organization). The CDC may request additional information from the treatment center or contact me/us directly for additional follow-up. Additionally, my/our information may be used and disclosed in accordance with HIPAA guidelines in order to perform research or quality control. All information used for research will be de-identified prior to publication. De-identification is a process intended to prevent the data associated with my/our treatment being used to identify me/us as individuals.

There are many complex and sometimes unknown factors, which may prevent the establishment of pregnancy. Known factors, which may prevent the establishment of pregnancy, include, but are not limited to, the following:

1. The eggs may not survive the thawing.
2. The male partner may be unable to produce a semen sample or the semen sample may be of insufficient quantity or quality.
3. Fertilization of the eggs and sperm to form embryos may not occur.
4. Cell division of the embryos may not occur.

5. The embryos may not develop normally.
6. Embryo transfer into the uterus may be technically difficult or impossible.
7. If the transfer is performed, implantation may not result.
8. If implantation occurs, the embryo(s) may not grow or develop normally

Equipment failure, infection, technical problems, human error and/or unforeseen factors may result in loss or damage to the eggs, semen sample and/or embryos. The foregoing general information is based upon the experience and knowledge of the Boston IVF physicians. It is based, in part, upon a review of the literature pertaining to Reproductive Medicine. This information is generally accurate and comprehensive, however, medicine is a dynamic discipline and reproductive medicine in particular is constantly evolving. Estimates of risks factors and the relative benefits of alternative treatment that have been discussed with you represent the best professional judgment of the physicians and caregivers of Boston IVF taking into account your specific needs and circumstances.

### ***PRIVACY***

*Data from your 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 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.*

## **ACKNOWLEDGEMENT OF INFORMED CONSENT AND AUTHORIZATION**

I (We) acknowledge that I (we), the undersigned, am (are) voluntarily seeking treatment with Egg Thawing and **In Vitro Fertilization (IVF)** in order to conceive a child. I (we) will acknowledge our natural parentage of any child or children born through this treatment.

I (we) have discussed this treatment in detail with a Boston IVF physician and caregivers in language that I (we) understand. I (we) understand the purpose, risks and benefit of the treatment. **I (we) acknowledge that I (we) have read all pages of this consent form and all of my (our) questions concerning the treatment have been fully answered to my (our) satisfaction.**

I (we) am (are) aware that there are other centers in the area that offer this treatment and I (we) have freely chosen to have the treatment at Boston IVF.

**By consenting to treatment at Boston IVF I (we) accept the responsibilities, conditions and risks involved as set out in this document and as explained by the staff of Boston IVF. In addition, I (we) consent to the techniques and procedures used to accomplish this treatment described in this document and as explained by the physicians and staff of Boston IVF.**

I (we) understand and acknowledge that medicine is not an exact science and that in cases of doubt Boston IVF physicians and caregivers will exercise their best professional judgment.

I (we) acknowledge and agree that acceptance into treatment and our continued participation is within the sole discretion of Boston IVF. I (we) understand that should this cycle be unsuccessful; it may be determined that further treatment may not be indicated.

I (we) acknowledge that it is my (our) responsibility to notify Boston IVF in writing if I (we) become aware of any information that Boston IVF should have in order to discharge its obligations under this agreement.

I (we) agree to notify BIVF immediately in writing of any change in our marital status including separation or divorce.

I (we) understand that I (we) am (are) financially responsible for any medical expenses that are not covered by our insurance policy.

In order to obtain required cycle outcome data I (we) give Boston IVF consent to contact any physicians who provided care during and after a pregnancy.

By signing this document, I (we) acknowledge that I (we) have had a thorough discussion with my (our) Boston IVF physician and caregivers. This discussion included information on the risks, benefits, side effects and complications of the treatment. Furthermore, I (we) acknowledge that the discussion with my (our) Boston IVF physician provided sufficient information to allow me (us) to make an informed decision whether or not to proceed with treatment. The discussion with the Boston IVF physician included alternatives including the option of having no treatment.

**By signing this document, I (we) acknowledge that my (our) Boston IVF physician and caregivers have obtained from me (us) informed consent to proceed with In Vitro Fertilization (IVF).**

**It is required that you have this document witnessed at Boston IVF, if unable because of distance the default is to have this document officially notarized.**



**Witness of Consent Form (if this form is completed no need to complete notarization form)**

\_\_\_\_\_  
**Patient Name (print)**                      **Patient Signature**                          /    /      
**Date of Birth (MM/DD/YYYY)**

    /    /      
**Today's Date (MM/DD/YYYY)**

**PATIENT- TYPE OF PICTURE IDENTIFICATION:**      Driver's License    Passport    Other: \_\_\_\_\_

ID NUMBER: \_\_\_\_\_                      State/Country: \_\_\_\_\_                      Expiration Date:     /    /      
(MM/DD/YYYY)

\_\_\_\_\_  
**Witness Name and Title (print)**                      **Witness Signature**                          /    /      
**Today's Date (MM/DD/YYYY)**

\_\_\_\_\_  
**Partner Name (if applicable, print)**                      **Partner Signature**                          /    /      
**Date of Birth (MM/DD/YYYY)**

    /    /      
**Today's Date (MM/DD/YYYY)**

**PARTNER - TYPE OF PICTURE IDENTIFICATION:**      Driver's License    Passport    Other: \_\_\_\_\_

ID NUMBER: \_\_\_\_\_                      State/Country: \_\_\_\_\_                      Expiration Date:     /    /      
Date (MM/DD/YYYY)

\_\_\_\_\_  
**Witness Name and Title (print)**                      **Witness Signature**                          /    /      
**Today's Date (MM/DD/YYYY)**

**Physician Attestation**

The above mentioned patient and partner (if applicable) have been informed and counseled by me and other team members regarding the risks and benefits of the relevant treatment options, including non-treatment. The patient and partner (if applicable) expressed understanding of the information presented during the discussion.

\_\_\_\_\_  
**Physician Name (print)**    **Physician signature**

    /    /      
**Today's Date (MM/DD/YYYY)**



**Notarization Form** (This form is only needed if not able to have witnessed at Boston IVF)

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
**Patient name (print)** Date of Birth (MM/DD/YYYY)

State of: \_\_\_\_\_ County of: \_\_\_\_\_

On this \_\_\_\_\_ day of \_\_\_\_\_ 20\_\_\_\_, before me, the undersigned notary public, personally appeared \_\_\_\_\_, proved to me through satisfactory evidence of identification, which were \_\_\_\_\_, to be the person whose name is signed on the proceeding or attached document in my presence.

ID NUMBER: \_\_\_\_\_ Expiration Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
(MM/DD/YYYY)

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
Today's Date (MM/DD/YYYY)

\_\_\_\_\_  
Notary Signature

\_\_\_\_\_  
Title

My appointment expires: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
(MM/DD/YYYY)

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
**Patient name (print)** Date of Birth (MM/DD/YYYY)

State of: \_\_\_\_\_ County of: \_\_\_\_\_

On this \_\_\_\_\_ day of \_\_\_\_\_ 20\_\_\_\_, before me, the undersigned notary public, personally appeared \_\_\_\_\_, proved to me through satisfactory evidence of identification, which were \_\_\_\_\_, to be the person whose name is signed on the proceeding or attached document in my presence.

ID NUMBER: \_\_\_\_\_ Expiration Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
(MM/DD/YYYY)

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
Today's Date (MM/DD/YYYY)

\_\_\_\_\_  
Notary Signature

\_\_\_\_\_  
Title

My appointment expires: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
(MM/DD/YYYY)