BOSTON IVF

CONSENT FORM FOR AN EGG DONOR

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 physician.
- Do not make any additions or deletions to the consent.
- Treatment **cannot** be started until all consents are signed.

INTRODUCTION

In Vitro Fertilization (IVF) is a treatment that helps an infertile patient achieve a pregnancy. The technique involves four main steps: 1) the development of eggs in a patient's ovaries; 2) the removal of eggs from their ovaries; 3) the placement of the eggs and sperm together in the laboratory to allow fertilization to occur, and; 4) the transfer of fertilized eggs (embryos) into a patient's uterus for the establishment of pregnancy.

The reproductive potential of some patients is compromised because they do not produce eggs, produce poor quality eggs and/or embryos, or are carriers of a genetic condition. An option for these patients is to undergo egg donation. Treatment with egg donation involves a donor with ovaries who serves as an egg donor and a patient who serves as the egg recipient. It is a process where the egg donor has eggs removed from their ovaries and donated to an egg recipient. The eggs are then fertilized with sperm in the laboratory. The fertilized eggs (embryos) are then transferred into the uterine cavity of the egg recipient (or gestational carrier if applicable) for implantation and the establishment of pregnancy. Following the delivery, the intention is that the egg recipient will be the parent of the offspring.

This consent explains egg donation and describes the major risks. In addition, the responsibilities of those who participate in this treatment are discussed. This consent is valid for a period of one calendar 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:
Egg donors should avoid any activity, behavior, or medications that might interfere with the treatment, or pose a risk to the egg recipient or the unborn child. Below are recommendations for patients participating in this treatment.

1. Smoking must be avoided before and during treatment.
2. Recreational drugs are absolutely contraindicated.
3. Ingestion of aspirin or aspirin-like products (e.g. Motrin®, Advil®, Anaprox®, Naprosyn®, Aleve®, etc.) should be avoided during treatment.
4. The use of alcohol should be avoided during treatment.
5. The use of all prescription and over-the-counter medications (including herbal remedies) should be discussed with a Boston IVF physician before starting a treatment cycle.

DESCRIPTION OF EGG DONATION TREATMENT

Egg donation treatment is done in conjunction with IVF, which involves several steps. Success cannot be guaranteed at any or all of these steps. If optimal results are not appreciated at any step, it may be recommended that the treatment be stopped and the treatment cycle cancelled. The steps of the treatment are discussed below.

I. **Ovulation Induction:** The egg donor will take medications to stimulate the development of multiple ovarian follicles (the fluid-filled cysts in the ovary that contain eggs).

II. **Egg Retrieval:** The egg donor will have the eggs removed from their ovaries.

III. **Preparation of the Endometrium:** The uterine cavity of the egg recipient (or gestational carrier if applicable) has to be hormonally prepared prior to the embryo transfer to allow implantation to occur.

IV. **Insemination of the Eggs:** The eggs and sperm will be placed together in the laboratory and incubated in an effort to achieve possible fertilization and growth of the embryos.

V. **Embryo Transfer:** One or more embryos will be transferred into the uterus of the egg recipient (or gestational carrier if applicable).

VI. **Embryo Freezing:** Following the embryo transfer, any remaining embryos of suitable quality may be frozen (cryopreserved) and stored for future embryo transfer(s). These frozen embryos will be owned and controlled by the egg recipient (or couple).

The egg donor will undergo steps I-II. The recipient (or gestational carrier if applicable) will undergo steps III- V that are described below.

Treatment with IVF 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 be stopped and the cycle cancelled.

I. Ovulation Induction

The eggs are present in the ovaries within fluid-filled cysts called follicles. During a menstrual cycle, usually one mature follicle develops, which results in the ovulation of a single egg. Several hormones including follicle stimulating hormone (FSH) and luteinizing hormone (LH) influence the growth of the ovarian follicle. These hormones are produced by the pituitary gland, which is located at the base of the brain. FSH is the main hormone that stimulates the growth of the follicle, which produces an estrogen hormone called *estradiol*. When the follicle is mature, a large amount of LH is released by the pituitary gland. This surge of LH helps to mature the egg and leads to ovulation 36-40 hours after its initiation.

The success of IVF is dependent on the number of eggs that are removed from the ovaries. Medications are administered to increase the number of follicles that develop, which will increase the number of eggs that are obtained at the egg retrieval, which will increase the number of embryos that will be available for transfer. By increasing the number of embryos that can be transferred, the chance of pregnancy increases. There are several medications that can be used for this phase of treatment.

1. *Gonadotropins* - these are injectable medications commonly prescribed to stimulate the ovaries of patients undergoing IVF treatment. Two types of gonadotropins can be prescribed and are discussed below.

    a. FSH (Gonal-F®, Follistim®, Bravelle®) - These medications contain only FSH and are administered on a daily basis by injection.

    b. Human Menopausal Gonadotropins (Menopur®) - These medications contain equal amounts of FSH and LH, and are administered on a daily basis by injection.

2. *GnRH Agonist (Lupron®)* – This medication is taken by injection. There are two forms of the medication: a short acting medication requiring daily injections. The primary role of the short acting form is to prevent a premature LH surge, which could result in the release of eggs before they are ready to be retrieved. Since GnRH-agonists initially cause a release of FSH and LH from the pituitary, they can also be used to start the growth of the follicles or initiate the final stages of egg maturation. The second form is a onetime injection to trigger ovulation 36 hours before the egg retrieval. The two forms are never used together in a medication protocol, it will be one or the other. Though leuprolide acetate *(Lupron®)* is an FDA (Federal Drug Administration) approved medication, it has not been approved for use in IVF, although it has routinely been used in this way for more than 20 years. Potential side effects usually experienced with long-term use include but are not limited to hot flashes, vaginal dryness, bone loss, nausea, vomiting, skin reactions at the injection site, fluid retention, muscle aches, headaches, and depression. No long term or serious side effects are known. Since GnRH-a are often times administered after ovulation, it is possible that they will be taken early in pregnancy. The safest course of action is to use a barrier method of contraception (condoms) the month you will be starting the GnRH-a. GnRH-a have not been associated with any fetal malformations however you should discontinue use of the GnRH-a as soon as pregnancy is confirmed.

3. *GnRH Antagonist (Cetrotide®, Ganirelix®)* - GnRH antagonists are medications that reversibly bind to GnRH receptors in the pituitary gland and prevent release of FSH and LH. GnRH antagonists are administered in combination with gonadotropins. The major benefit of a GnRH antagonist is that it suppresses a LH surge thereby preventing ovulation.

4. *Human Chorionic Gonadotropin [hCG] (Ovidrel®, Pregnyl®, Novarel®)* - This medication contains the pregnancy hormone, hCG, which functions similarly to LH. There are two forms of the medication: the first is a short

acting medication requiring daily injections and the second form is a onetime injection to trigger ovulation 36 hours before the egg retrieval. The two forms are never used together in a medication protocol, it will be one or the other.

5. *Oral contraceptive pills*- Many treatment protocols include oral contraceptive pills to be taken for 2 to 4 weeks before gonadotropin injections are started in order to suppress hormone production or to schedule a cycle. Side effects include unscheduled bleeding, headache, breast tenderness, nausea, swelling and the risk of blood clots or stroke.

Note: Many of the medications that are used are administered by an injection. The egg donor or another support person can be instructed to give these injections.

Side Effects

As with all injectable medications, bruising, redness, swelling, or discomfort can occur at the injection site. Rarely, there can be an allergic reaction to these drugs. The use of the above listed medications can cause side effects such as nausea, vomiting, hot flashes, headaches, mood swings, visual symptoms, memory difficulties, joint problems, weight gain and weight loss, all of which are temporary. The intent of giving these medications is to mature multiple follicles, and many women experience some bloating and minor discomfort as the follicles grow and the ovaries become temporarily enlarged. Other possible side effects include the following:

- *Ovarian Hyperstimulation* - After the egg retrieval is performed, the ovarian follicles, which have been aspirated, can fill up with fluid and form cysts. The formation of cysts will result in ovarian enlargement and can lead to lower abdominal discomfort, bloating and distention. These symptoms generally occur within two weeks after the egg retrieval. The symptoms usually resolve within 1-2 weeks without intervention. If ovarian hyperstimulation occurs your physician may recommend a period of reduced activity and bed rest. Pregnancy can worsen the symptoms of ovarian hyperstimulation. Severe ovarian hyperstimulation is characterized by the development of large ovarian cysts and fluid in the abdominal and, sometimes, chest cavities. Symptoms of severe ovarian hyperstimulation include abdominal distention and bloating along with weight gain, shortness of breath, nausea, vomiting and decreased urine output. Approximately 2% of women will develop severe ovarian hyperstimulation and may need to be admitted to the hospital for observation and treatment. To help alleviate the symptoms of severe ovarian hyperstimulation an ultrasound-guided paracentesis can be performed which results in the removal of fluid from of the abdominal cavity. Rare, but serious consequences of severe ovarian hyperstimulation include formation of blood clots that can lead to a stroke, kidney damage and possibly death. Every woman who takes these medications can develop ovarian hyperstimulation. In some cases when there is concern that a woman is at significant risk for ovarian hyperstimulation, the cycle may be cancelled or the eggs will be retrieved and any embryos that result may be frozen.

- *Ovarian Torsion (Twisting*) - In less than 1% of cases, a fluid filled cyst(s) in the ovary can cause the ovary to twist on itself. This can decrease the blood supply to the ovary and result in significant lower abdominal pain. Surgery may be required to untwist or possibly remove the ovary.

- *Ovarian Cancer*- Some research suggested that the risk of ovarian tumors may increase in patients who take any fertility drugs over a long period of time. These studies had significant flaws which limited the strength of the conclusions. More recent studies have not confirmed this risk. A major risk factor for ovarian cancer is infertility per se, suggesting that early reports may have falsely attributed the risk resulting from infertility to the use of medications to overcome it. In these studies, conception lowered the risk of ovarian tumors to that of fertile patients.

- *Breast and Uterine 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.

Monitoring

During the ovulation induction phase of treatment, monitoring of follicular development is performed with periodic blood hormone tests and/or vaginal ultrasound exams. Monitoring helps the physician to determine the appropriate dose of the medications and the timing of the egg retrieval. Vaginal ultrasound examinations are usually painless and generally considered to be safe. However, the possibility of harm cannot be excluded. Blood drawing may be associated with mild discomfort and, possibly, bruising, bleeding, infection or scar at the needle sites. The need for repeated ultrasound examinations and/or blood drawing on a frequent basis requires the egg donor's presence in the vicinity of a Boston IVF monitoring site.

II. Egg Retrieval

Oocyte retrieval is the removal of eggs from the ovary. A transvaginal ultrasound probe is used to visualize the ovaries and the egg-containing follicles within the ovaries. A long needle, which can be seen on ultrasound, can be guided into each follicle and the contents aspirated. The aspirated material includes follicular fluid, oocytes (eggs) and granulosa (egg-supporting) cells. Specimens normally discarded from this procedure may be used for future research purposes. If this is done all specimens will be anonymized and your name or medical information will not used. Rarely the ovaries are not accessible by the transvaginal route and laparoscopy or transabdominal retrieval is necessary. These procedures and risks will be discussed with you by your doctor if applicable. Anesthesia is generally used to reduce if not eliminate discomfort. Risks of egg retrieval include:

Infection*:* Bacteria normally present in the vagina may be inadvertently transferred into the abdominal cavity by the needle. These bacteria may cause an infection of the uterus, fallopian tubes, ovaries or other intra-abdominal organs. The estimated incidence of infection after egg retrieval is less than 0.5%. Treatment of infections could require the use of oral or intravenous antibiotics. Severe infections occasionally require surgery to remove infected tissue. Infections can have a negative impact on future fertility. Prophylactic antibiotics are sometimes used before the egg retrieval procedure to reduce the risk of pelvic or abdominal infection in patients at higher risk of this complication. Despite the use of antibiotics, there is no way to eliminate this risk completely.

Bleeding*:* The needle passes through the vaginal wall and into the ovary to obtain the eggs. Both of these structures contain blood vessels. In addition, there are other blood vessels nearby. Small amounts of blood loss are common during egg retrievals. The incidence of major bleeding problems has been estimated to be less than 0.1%. Major bleeding will frequently require surgical repair and possibly loss of the ovary. The need for blood transfusion is rare. (Although very rare, review of the world experience with IVF indicates that unrecognized bleeding has led to death.)

Trauma: Despite the use of ultrasound guidance, it is possible to damage other intra-abdominal organs during the egg retrieval. Previous reports in the medical literature have noted damage to the bowel, appendix, bladder, ureters, and ovary. Damage to internal organs may result in the need for additional treatment such as surgery for repair or removal of the damaged organ. However, the risk of such trauma is low.

Failure**:** It is possible that the aspiration will fail to obtain any eggs or the eggs may be abnormal or of poor quality and otherwise fail to produce a viable pregnancy.

Anesthesia - For the egg retrieval, medications usually are administered by an anesthesiologist. The patient will have a consultation with the anesthesiologist before the procedure to review the risks and benefits of the anesthesia. In some cases the use of anesthesia on a specific patient may be associated with an increased risk. In such cases the physician may offer local anesthesia without the assistance of an anesthesiologist. It is mandatory that there is no oral intake after midnight prior to the egg retrieval. After the procedure is completed, the patient will be discharged home usually within

one hour. **Because of the anesthetic medications that are used a patient must be accompanied home by a responsible adult.** Each patient is responsible for bringing a responsible adult with them on the day of the egg retrieval. Following the egg retrieval, vaginal spotting and lower abdominal cramping are normal. During the remainder of the day following the surgery, activities should be limited. If significant bleeding, vomiting, abdominal pain or any other symptoms develop, you should contact a Boston IVF physician. If you should have any difficulty in contacting a Boston IVF physician the patient or their caretaker should proceed to the emergency department of the nearest hospital.

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 ovaries may not respond adequately to the medications.
2. Technical problems including inadequate visualization or the position of the ovaries may prevent the retrieval of the eggs.
3. There may be failure to recover an egg because ovulation has occurred prior to the time of the egg retrieval.
4. Eggs may not be recovered.
5. The eggs may not be normal.
6. 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.

RIGHTS OF THE DONOR AND RECIPIENT

The intentions of the egg donor and recipient are clear and unambiguous from the outset. When the egg donor signs their consent form they explicitly agree that once the eggs leave their body, they waive any right and relinquishes any claim to the donated eggs as well as any embryos or offspring that might result from their use. The recipient in turn, releases the egg donor from any and all liability for any problem occurring during pregnancy and for any mental or physical disabilities, financial support, care, custody or living expenses, education, health and welfare of the child(ren) born as a result of egg donation. The egg recipient will assume all costs related to the egg donor's medical screening, stimulation (including medications) and egg retrieval. The egg recipient will purchase Accident Medical Expense insurance coverage for the egg donor which will cover all medical expenses for the egg donor in the event there is a medical complication directly related to ovarian stimulation or egg retrieval only. The recipient also accepts complete financial responsibility for the care and storage of any eggs/embryos frozen for them during treatment. The recipient has the right to determine the fate of all eggs/embryos frozen for them including but not limited to discarding them, donating them to another recipient person or couple or donating them for research. Non-identified egg donors also expect the right to privacy following egg donation. The egg recipient clearly and unambiguously agrees not to seek the identity of the donor now or in the future unless otherwise agreed between the recipient person or couple and the egg donor not through or involving Boston IVF. It is understood that Boston IVF has no control over the actions of the egg recipient. Donor names and addresses will be kept on file at Boston IVF for 10 years.

UNANTICIPATED CHANGES IN THE LAW

State or Federal laws may change in the future that permit the egg donor and/or egg recipient to locate one another. There is no way to predict when or if such a change will ever occur. We recommend that you speak with a lawyer about the implications of this possibility.

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 am voluntarily participating in the Donor Egg Program at Boston IVF. Participation means that oocytes (eggs) retrieved from my ovaries will be donated to result in a pregnancy in egg recipient. I understand that my egg(s) may be fertilized with sperm for the designated recipient(s). I understand that my egg(s) may be frozen for possible future fertilization. I understand that the egg(s) may be used to simply donate the substance (cytoplasm and other cellular components) to the egg(s) of egg recipient. If fertilization takes place, the embryo(s) may be transferred to the uterus or fallopian tube(s) of the recipient(s) (or gestational carrier if applicable) in the hopes that a pregnancy will occur.

I have discussed this treatment in detail with the Boston IVF staff in language that I understand. I understand the purpose, risks and benefit of egg donation. **I acknowledge that I have read all pages of this consent form and all of my questions concerning the treatment have been fully answered to my satisfaction.**

Contractual agreements separate from this consent form between egg donors and egg recipients are mandatory. We strongly encourage egg donors to learn about their legal rights and responsibilities from their assigned reproductive lawyer prior to starting treatment.

I have been given the opportunity to undergo medical, psychological and legal counseling, which have been met to my satisfaction.

I assert that I have answered all questions asked of me truthfully. I assert that I have not provided misleading information for the purpose of becoming an egg donor. I assert that I have not intentionally modified, omitted or altered in a misleading manner information that I have provided to Boston IVF, a third party agency, health professionals involved in the screening process or the egg recipient. I believe that I am a low risk candidate for sexually transmitted diseases (STDs) such as hepatitis, genital herpes, Chlamydia, HIV (Human Immunodeficiency Virus), etc. I agree to be screened for STDs including HIV and understand that I will be informed of positive results. I am fully aware that I cannot contract these diseases by being an egg donor. I agree to inform Boston IVF if I engage or have engaged in any activities that put me at risk for STDs (i.e. new or multiple partners or sharing needles). I agree to be screened for genetic diseases and I agree to report to the program any newly diagnosed or discovered genetic disorders that affect me or any family members, which were not identified or discussed during the initial screening process.

I understand that the information non-identified egg donors provide to Boston IVF on the Donor Questionnaire and Consultation Form (absent their name, date of birth, address, and telephone number) along with infectious and genetic disease testing will be provided to the egg recipient. If I am a non-identified egg donor, I consent to the release of this information to the egg recipient(s). I understand that my identity will be kept confidential unless disclosure is agreed to by prior arrangement or is required by law. I understand that Boston IVF has no control over the egg recipients actions if they attempt to seek my identity.

When the oocyte(s) are retrieved, they are accompanied by fluid from the ovary and other ovarian cells. I agree to allow these materials obtained from my body which would ordinarily be discarded, to be studied for research purposes. These

studies may lead to advancements in medical knowledge and our understanding of human reproduction. I understand that my anonymity will be protected and that no publication resulting from these scientific studies will contain my name or other information that would allow me to be identified.

I understand that medical information concerning my treatment may be analyzed and could be used in a publication. In accordance with federal law, non-identifying information and information concerning my treatment will be submitted to a national data registry that publishes statistics on treatment outcomes.
I agree that once the egg(s) leave my body, I waive any right and relinquish any claim to the donated egg(s) as well as any embryo(s) or offspring that might result from their use. I understand that the egg recipient(s) of my egg(s) may regard the donated egg(s) and any embryo(s) as her own and any offspring from the embryo(s) shall be regarded as the child(ren) of the egg recipient(s) and not my child(ren). I understand that the egg recipient(s) of the donated egg(s) has released me from liability for any problem occurring during pregnancy and for any mental or physical disabilities, financial support, care, custody or living expenses, education, health and welfare of the child(ren) born as a result of my egg donation.

By consenting to treatment at Boston IVF I 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 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 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 acknowledge and agree that acceptance into treatment and my continued participation is within the sole discretion of Boston IVF. I understand that should this cycle be unsuccessful, it may be determined that further treatment may not be indicated.

In the unlikely event that I become ill or am injured as a direct result of my participation in the egg donor program, I understand that I must notify my egg donation team at Boston IVF immediately.

By signing this document I acknowledge that I have had a thorough discussion with the Boston IVF staff. This discussion included information on the risks, benefits, side effects and complications of egg donation. Furthermore, I acknowledge that the discussion with the Boston IVF staff provided sufficient information to allow me to make an informed decision whether or not to proceed with treatment. The discussion with the Boston IVF staff included the alternative of not proceeding with egg donation.

By signing this document I acknowledge that Boston IVF has obtained from me informed consent to proceed with egg donation.

BOSTON IVF

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

_____ _____ _____

Patient Name (print) **Patient Signature** **Today's Date** (MM/DD/YYYY)

_____

Date of Birth (MM/DD/YYYY)

PATIENT- 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 has 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 has expressed understanding of the information presented during the discussion.

_____ _____

Physician Name (print) **Physician Signature**

_____

Today's Date (MM/DD/YYYY)

BOSTON IVF

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

Patient Name (print)	Patient Signature	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)