**AGREEMENT AND INFORMED CONSENT FOR DONATION OF HUMAN EGGS ("OOCYTES") FOR IN VITRO FERTILIZATION ("IVF")**
**(Known Donor)**

This document sets forth the terms pursuant to which I,_____, have agreed voluntarily to donate some of the eggs (called "oocytes") which I will produce during my menstrual cycle to _____ ("Recipient"), who has been unable to have children and who wishes to attempt to have children through the treatment process referred to as in vitro fertilization ("IVF"). The egg donation process will be undertaken through the Vincent Reproductive Medicine & IVF Program, Massachusetts General Hospital. Said program, including respective employees, agents and assigns shall be referred to in this document as the "IVF Program".

I understand that the eggs donated by me will be mixed with sperm produced by the Recipient's partner or a sperm donor in the hope that the eggs will become fertilized, creating embryos that will be transferred to the Recipient in the hope that the recipient can achieve a healthy pregnancy.

**Purpose**

I understand that the purpose of my participation in the process described in this form is to assist Recipient to achieve a pregnancy with eggs donated by me and later combined with sperm from the Recipient's partner or a sperm donor. The purpose of this form is to document that I understand the process, its benefits, and the material risks, and that I freely and voluntarily agree to participate in the process as an egg donor.

**The Screening Process**

I have been informed that, before my eggs can be used for IVF, I must undergo a thorough medical screening and evaluation. I understand that the screening process is intended to minimize the risks associated with egg donation for me and the Recipient, as well as for any offspring which might result from this process. I also understand that the results of the screening process will be kept confidential, except to the extent that I agree otherwise in this document or elsewhere.

I have been informed that the screening process will involve at least the following:

a) I will be asked to provide a detailed health history, including a history of my habits, use of alcohol and other substances, and sexual relationships;

b) Based on my history and ethnic background, I will be tested to determine whether I have or may be carrying certain diseases that might be inherited from me;

c) I will be asked to undergo a psychological evaluation, which might include testing and/or consultation or an interview with a mental health professional;

d) I will be asked to undergo a physical examination, including a pelvic examination, pelvic ultrasound, and a Pap smear;

e) I will be tested for infectious and other communicable diseases, including gonorrhea, chlamydia, hepatitis, syphilis, and human immunodeficiency virus or "HIV" (the virus that causes AIDS). (I understand that I will be asked to execute a separate consent form for the HIV test.)

I will also be screened to determine my blood type (Rh factor) and to evaluate other medical issues as deemed appropriate by the IVF team.

I understand that the screening process is of critical importance to the IVF team, the Recipient and her partner, and any offspring which may result from my egg donation, and that my medical history and status will have a direct effect on the Recipient and any offspring. I agree to answer all requests for medical and family history truthfully and to the best of my knowledge.

Prior to and during the time of my participation in the IVF Program, I agree to immediately inform the IVF team, in writing, of any material change in my lifestyle, habits or health status which could reasonably impact my health, including any illnesses I contract or exposure I have to an infectious or communicable disease. I also agree that, during the time that I am involved with the IVF Program, I will not smoke cigarettes, marijuana, or other substances, drink alcoholic beverages or use any illegal drugs or nonprescription medications without the approval of one of the IVF Program physicians.

I understand that, at the conclusion of the screening process, the IVF team will determine whether I am eligible to participate as an egg donor. If I am considered eligible, I will proceed with ovulation induction (described below) once the Recipient has been properly prepared to receive my eggs.

## I. Ovulation Induction

I understand that the IVF process involves four phases, only two of which, ovulation induction and egg retrieval, involve my direct participation. I also understand that it cannot be guaranteed that a successful result will be achieved in either of these phases; and that it cannot be guaranteed that the IVF process will result in a pregnancy for the Recipient. I am aware that, if good results are not obtained in either phase, it may be recommended that my participation in the IVF process be terminated and that the IVF cycle be cancelled.

It has been explained to me that the ovulation induction phase of the IVF process is intended to control the timing of the release of my eggs and to increase the chance that more than one egg will be produced during the IVF cycle. I have been told that this is accomplished through the use of medications which will first suppress my ovaries and, later, stimulate my ovaries.

I have been informed that I will begin taking the medication called Leuprolide Acetate (also called Lupron) starting in the second half of my menstrual cycle to suppress my ovaries. Once Leuprolide Acetate is started, I will be taking this medication as a daily injection for at least two weeks. An ultrasound (a kind of x-ray which uses sound waves instead of radiation) will be taken of my reproductive organs and a blood test will be performed after I have been on

Leuprolide Acetate two weeks to make sure that the Leuprolide Acetate has adequately suppressed my ovaries.

If the results of the ultrasound and blood test indicate that my ovaries are suppressed, I will be told when to start to take certain active medications which will stimulate the ovaries. These medications include Bravelle, Gonal-F, Follistim, and Repronex. During the stimulation phase, I understand that I will usually be taking one injection each evening of the active medications, along with a single morning injection of Leuprolide Acetate. Occasionally, instead of Leuprolide Acetate, I may be asked to take a medication to help prevent my follicles (the structures which contain my eggs) from releasing an egg before egg retrieval. The medicine, called Antagon or Cetrotide, is started on approximately the fourth to seventh day of my treatment cycle.

Additional ultrasound and blood work monitoring will start a few days after the start of the active medications to monitor the development of my follicles, to monitor my hormone levels, and, with this information, to make appropriate adjustments of my medications and calculate the timing of egg release and retrieval. When my eggs are mature, I understand that I will be given instructions to take a medication called human chorionic gonadotropin or "hCG" (also called Profasi, Pregnyl, Ovidrel or Novarel) to trigger ovulation.

I have been told that I will be instructed how to give myself (or have someone give me) the injections which are required during the ovulation induction phase.

**Egg Retrieval**

I understand that the procedure to retrieve my eggs will take place approximately 36 hours after my single injection with hCG. I understand that egg retrieval is an outpatient procedure. I have been told that, during the procedure, I will be placed in the same position as if I were having a pelvic exam. After the vagina is cleaned with a saline solution, a vaginal ultrasound probe will be placed in the vagina allowing the physician to visualize my follicles. With ultrasound guidance, a needle is inserted through the vaginal wall and, separately, into each follicle in both of my ovaries. Fluid is removed from each follicle and examined by the lab to determine whether an egg is present. I have been told that the egg retrieval procedure is usually completed within approximately 30 minutes.

I understand that, occasionally, because of the position of my ovaries, it may be necessary to perform a procedure called a laparoscopy in order to retrieve my eggs. This involves the placement of a surgical telescope through a small cut or incision in my skin below the belly button. This procedure allows the physician to view my ovaries and to remove fluid from the follicles under direct visualization. I am aware that the performance of a laparoscopy requires general anesthesia.

Alternatively, I understand that, depending on the location of the ovaries, the eggs may be retrieved through the abdominal wall with ultrasound guidance. If this approach is used to retrieve my eggs, I have been informed that an anesthesiologist will give me intravenous medication to help make me feel comfortable during the procedure. I have been told that my lower abdomen will be cleaned and a needle will be guided, with ultrasound guidance, through

my bladder and into the ovary. It has been explained that, as noted above with the vaginal procedure, fluid is then removed from each follicle and examined by the lab to determine whether an egg is present.

I have been informed that an adult should accompany me home after the egg retrieval procedure and stay with me for the 24 hours following my departure from the hospital after egg retrieval.

I understand that, with the use of fertility drugs, more than one egg is frequently collected during the egg retrieval procedure. Prior to the egg retrieval procedure, an ultrasound will determine the approximate number of follicles present on each of my ovaries. This should provide a guide, but by no means an exact determination, as to how many eggs I can expect to have retrieved during the retrieval process. In some instances, no eggs are retrieved; in others, up to 20 eggs may be obtained. I understand that not every follicle contains an egg, and that some eggs are not healthy or will not fertilize. I also understand that some eggs may be released by the ovaries and lost prior to the egg retrieval process and that some eggs may not develop properly.

I understand that all of the eggs retrieved from me during this process will be donated for use by the Recipient; and that, following retrieval, my healthy donated eggs will be mixed with sperm in the hope of producing healthy fertilized eggs ("embryos"), and that some or all of the healthy embryos will be transferred to the Recipient in the hope that one or more pregnancies will result. Additionally, healthy appearing embryos may be frozen (cryopreserved) for future use by the Recipient.

**Ownership Rights for Embryos and/or Offspring Resulting from Egg Donation**

I understand and agree that, as of the time that my eggs are removed from me during the egg retrieval process, my eggs will be deemed donated to the IVF Program for the benefit of the Recipient and that: (a) I will no longer have any rights or responsibilities with respect to the eggs, (b) I will no longer have any rights or responsibilities with respect to any embryos or offspring that result from the eggs, and (c) I will no longer have any rights or responsibilities in relation to the ultimate disposition of any remaining eggs whether or not they are fertilized. I also understand that once I have given up my eggs for donation at the time of egg retrieval, my participation in the egg donor process is completed.

I understand that any offspring which result from my egg donation and IVF are not my children. I, freely and willingly, waive all rights with respect to any offspring born as a result of this procedure.

I also understand that, as egg donor, I have no claims for any rights or other claims against the Recipient, even if I and the Recipient are related, or against any offspring of the IVF procedure.

I understand that the Recipient is fully responsible, financially and otherwise, for any and all offspring, regardless of the outcome of the pregnancy, and that the Recipient has executed an agreement/consent whereby she has assumed such responsibility.

I hereby agree that I have relinquished, irrevocably and unconditionally, any claim, right or cause of action against the Recipient, and the Recipient's former, current or future partner relating to any donated eggs or any offspring born or resulting form the use of my donated eggs, and any claim or right in or to such offspring.

I understand that the Recipient will be required to sign an agreement/consent which includes a statement that she and her partner have relinquished, irrevocably and unconditionally, any claim, right or cause of action against me (her egg donor) relating to any donated eggs or any offspring born or resulting from the use of the donated eggs.

**Financial Compensation**

I hereby affirm that I am donating my eggs voluntarily and without coercion.

I understand that I will not receive financial compensation from the IVF Program for my participation in the program, and that any financial arrangements between me and the Recipient in connection with my participation in the IVF Program or the donation process, other than as expressly set forth herein, are private arrangements between me and the Recipient.

**Financial Responsibility**

I understand that the Recipient is responsible for all charges incurred as part of the egg donation process. This includes, but is not limited to, physician, laboratory and hospital charges as well as charges incurred by the IVF team.

The Recipient's insurance may or may not cover all of these charges, but I, as the egg donor, will not be responsible for any unpaid monies.

The Recipient will be required to purchase a Blanket Special Risk Insurance Policy in addition to any insurance I may have, to cover any unanticipated medical expenses I might incur due to complications related to the IVF process.

**Risk Factors and Treatment Outcomes**

I understand that the egg donation process requires that I take a variety of medications, undergo monitoring through a variety of means, and undergo a number of procedures. I also understand that all of these carry some measure of risk. It has been explained to me that the primary risks associated with the egg donation process are as follows:

**I. Risk Factors Associated with Medications**

I understand that Leuprolide Acetate, or Lupron, will put me into a temporary menopausal state. For this reason, I have been told that I may begin to experience hot flashes after using the medication for about a week. Additionally, although most patients tolerate Leuprolide Acetate quite well, I have been told that some women report headaches or temporary bloating of the abdomen. I am aware that Leuprolide Acetate may also change the nature of my menstrual cycle. I have been told that my period may come earlier or later than I expect; the

flow may also be heavier or lighter than usual. There have been no documented long-term side effects of Leuprolide Acetate.

It has been explained to me that many women actually have a decrease in side effects once they start their active medications (Bravelle, Gonal-F, Follistim, and Repronex) and that this is related to the increased estrogen in the blood stream during the stimulation phase, which decreases the side effects associated with Leuprolide Acetate. Although side effects can occur (see discussion of ovarian hyperstimulation, below), I have been informed that most women tolerate these medications quite well. Antagon and Cetrotide have not been associated with significant side effects, although on occasion, these medications may not prevent the release of the egg(s) from the ovaries prior to egg retrieval.

I understand that, except for ovarian hyperstimulation (which will be described below), which can occasionally be caused by hCG (Profasi, Pregnyl, Ovidrel or Novarel), there are almost no known side effects associated with injections of hCG, and that most women tolerate this medication quite well.

In addition to the above, I am aware that the use of the above medications can also cause side effects such as nausea, vomiting, hot flashes, headaches, mood swings and visual symptoms. Allergic reactions are also possible, but rare. I have been told that I may take Tylenol or Extra Strength Tylenol as needed for pain control. I have been warned to <u>avoid</u> taking Advil or any other brand of Ibuprofen, however. Should I feel the need to take any other form of medication, I have been asked to please contact the IVF Program first.

### II. Risk Factors Associated with Monitoring

The primary monitoring tools utilized during the course of the IVF cycle are ultrasound examinations and blood testing. I have been informed that ultrasound examinations are usually painless and generally considered to be safe. Blood drawing may be associated with mild discomfort and, occasionally, bruising, bleeding, infection or scarring at the needle sites.

### III. Risk Factors Associated with Egg Retrieval

It has been explained to me that complications from the egg retrieval process occur at a rate of less than 1–2% and may include infection within the pelvis, bladder infection, injury to the intestines or injury to blood vessels resulting in hemorrhage. I understand that any of these complications, and others, could require hospitalization and, possibly, additional medical or surgical treatments that could impair or prevent the chances of my achieving pregnancy in the future, although this is rare. Also in extremely rare instances, it may be necessary to remove one or both of my ovaries, or to perform a hysterectomy. In rare instances, a blood transfusion may be required. An antibiotic is administered prior to the performance of the egg retrieval procedure to reduce the chances of an infection. A side effect of this medication could be an allergic reaction.

I am informed that, if it is necessary to perform a laparoscopy in connection with egg retrieval, the complication rate is also less than 1-2%. Performance of a laparoscopy requires general anesthesia. I am aware that some of the risks of laparoscopy include injury to the bowel,

bladder, uterus and blood vessels that may require surgery, including emergency surgery, but that this is rare.

I have been told that the risks associated with egg retrieval through the abdominal wall are similar to those associated with retrieval through the vagina, although with retrievals through the abdominal wall, I have been told that blood may appear in my urine which may make it difficult for me to urinate. In this situation, it has been explained that a catheter may be placed in my bladder until the blood has disappeared, usually 1 to 3 days.

As part of the egg retrieval procedure, medications are administered by an anesthesiologist. I have been informed that I will have a consultation with the anesthesiologist before the procedure to review the risks and benefits of the anesthesia. I have also been told that it is critical that I not eat or drink anything after midnight of the evening before my egg retrieval procedure.

## IV. Other Risk Factors Associated with the Egg Donor Process

**Ovarian Hyperstimulation –** I have been told that, after egg retrieval, my follicles can fill up with fluid and form cysts. This, in turn, can cause enlargement of my ovaries and, in some cases, lead to discomfort and bloating in my lower abdomen. I am told that these symptoms generally occur 5-10 days after the egg retrieval, and that, if they occur, they usually resolve within 1-2 weeks on their own. I am also aware that approximately 1-2% of all patients who take fertility medications develop severe ovarian hyperstimulation. This condition is characterized by 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. I have been informed that women with severe ovarian hyperstimulation may need to be admitted to the hospital for observation and treatment, and that rare, but serious consequences of severe ovarian hyperstimulation include formation of blood clots that can lead to stroke, kidney damage and possibly death. I know that every woman who is administered fertility medications can develop ovarian hyperstimulation, but the chance is higher in a woman with a high level of estrogen in her blood and a large number of ovarian follicles. For this reason, in cases when the estrogen level is significantly elevated, the cycle may be cancelled or the eggs will be retrieved and all embryos that result will be frozen.

**Ovarian Torsion (Twisting)** – I have been informed that, 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 –** I have also been informed that, in the general population, any woman has a 1 in 70 chance of developing ovarian cancer during her lifetime. Studies have shown that infertile women have a higher chance of developing ovarian cancer than fertile women. I am also aware that controversial data exists that associates the use of ovulation inducing drugs with an increased risk of ovarian cancer. I have been informed, however, that, presently, a cause and effect relationship has not been clearly established.

**Pregnancy** – I have been told that some of my eggs may be released into my reproductive system around the time of egg retrieval. Therefore, it is possible that I could become pregnant during my participation in this process. I am advised that if I wish to seek to avoid pregnancy during the process, I should seek advice about the use of contraceptive methods or abstain from intercourse during the process.

**Psychological Risks –** It has been explained to me that undergoing IVF treatment is psychologically stressful. I have also been told that anxiety and disappointment may occur at any of the phases described above. I understand that a significant commitment of time may be required for this process. It has been explained to me that the psychological impact of being an egg donor is unknown, but that it could be significant. For these reasons, I have been encouraged to meet with a counselor before, during and after a treatment cycle.

**ACKNOWLEDGEMENT OF INFORMED CONSENT AND AUTHORIZATION**

I acknowledge that I, the undersigned, am voluntarily participating as an egg donor with the expectation that my eggs will be utilized by the Recipient to conceive a child, and that I will have no further rights, following donation of the eggs, with respect to those eggs, with respect to the disposition by the IVF Program or Recipient of any embryos resulting from those eggs, or with respect to any child which may be born as a result of the donation.

I acknowledge that I have read and fully understand this consent form and that all of my questions concerning the treatment have been fully answered to my satisfaction.

By participating as an egg donor, I accept the responsibilities, conditions and risks involved as set out in this document and as explained to me by the IVF team. In addition, I consent to the techniques and procedures described in this document and explained by the IVF team.

I acknowledge and agree that my acceptance as an egg donor and my continued participation is within the sole discretion of the IVF team.

I understand that medical information concerning this treatment process may be analyzed and could be used in a publication, which would not include any identifying information, and I authorize such analysis and publication.

I agree to consider disclosing to any child born to me that he may be related to a child produced from my eggs. I acknowledge and agree that neither the IVF Program, nor any individual or entity associated with the Program, has an obligation or duty to make any of these disclosures.

I hereby acknowledge that the IVF Program has not made any representation, express or implied, with respect to the nature of the legal relationship of any offspring born as a result of the egg donation process to me or the Recipient.

I hereby irrevocably and unconditionally relinquish, release and give up forever any claim, right or cause of action of any kind whatsoever which now exists or may arise in the future against MGH the IVF Program, their staffs, the Recipient, her partner, if applicable,

her/their heirs, executors and administrators, arising out of or relating to the procedures described in this document, any pregnancy, injury or complication resulting therefrom, and any offspring born from such procedures.

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| _____ | _____ |
| Donor's Name | Donor's S.S. # and D.O.B. |
| _____ | _____ |
| Donor's Signature | Donor's Initials |

Agreed to:

VINCENT REPRODUCTIVE
MEDICINE & IVF PROGRAM,
MASSACHUSETTS GENERAL
HOSPITAL

By: _____
[Name, Title]