# AGREEMENT AND CONSENT FOR THE RECEIPT OF HUMAN EGGS IN CONNECTION WITH IN VITRO FERTILIZATION

(Anonymous Donor)

The Vincent Reproductive Medicine and IVF Program is signing this Agreement. If I am entering the IVF process with a man that I consider to be my life partner ("Partner"), and I intend to have my Partner's sperm be used in this process to fertilize the donated eggs, my Partner's agreement and consent to participate in this process are also required. My Partner's signature on this document signifies that he has read and understands this form and that he fully and freely agrees to participate in the IVF Program in accordance with the terms set forth below.

# **Purpose**

I understand that the purpose of my participation in the process described in this form is to seek to achieve a pregnancy by combining eggs collected from the Donor with sperm from my Partner or a sperm donor (with my, and if applicable, my Partner's authorization), and to have the resulting embryos transferred to my uterus. The purpose of this form is to document that I understand the treatment process, its benefits, and the material risks associated with the process, and that I freely and voluntarily agree to participate in the process as a recipient of Donor eggs.

## **The Screening Process**

I have been informed that, before I can be accepted as a candidate to receive donated eggs, I must undergo a thorough medical screening and evaluation. I understand that the screening process is intended to minimize the risks associated with in vitro fertilization for me and 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 passed on to a child borne by 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 also 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 sign a separate consent form for the HIV test.)

I will also be screened to determine my blood type and to evaluate other medical issues if deemed appropriate by the IVF team.

I understand that the screening process is of critical importance to the IVF team and to any offspring which may result from this process, and that my medical history and status will have a direct effect on 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 any exposure I have to an infectious or communicable disease. I also agree that, during the time that I am involved in 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 an appropriate candidate for IVF/embryo transfer of the Donor's eggs. I understand that the IVF team may determine that I cannot continue with the process. If I am eligible to continue, I agree to follow the procedures set forth below.

# **Uterine Preparation**

I understand that I will have to take medication on a specified schedule in order to prepare my uterus to receive any embryos which result from the fertilization of the Donor's eggs.

I further understand that, at some time before I am able to have embryos transferred to my uterus, it will be necessary for me to undergo a practice IVF treatment cycle (called a "mock cycle"). During that cycle, my response to medications will be monitored closely through pelvic ultrasound exams (a kind of x-ray, but using sound waves instead of radiation), and one or more endometrial biopsies (the removal and laboratory examination of my uterine tissue) to evaluate the effects of treatment.

I understand that, even though I may have a normal menstrual cycle, it will be necessary for me to take medications that will temporarily change my normal cycle. I have been informed that I may need to self-administer a medication daily that will put me into a reversible menopausal state. The medication is called Leuprolide Acetate and it is associated with occasional hot flushes and mood swings. I understand that I will also need to take a skin patch form of estrogen to help develop the uterine lining. If the lining does not appear to be developing appropriately, I have been told that I may have to take additionalestrogen by

injection, orally, or by vaginal suppository. I understand that I will also have to self-administer progesterone once the uterine lining is developed. I will take the progesterone by injection and vaginally based on the results of my mock cycle and the opinion of the IVF team.

During the cycle, my response will be monitored with blood hormone levels and ultrasound exams of my pelvis. I understand that, even if I take the medications according to instructions, my body may not respond in a way that is likely to support a pregnancy. In these circumstances, my treatment cycle will be cancelled and an embryo transfer will not be performed. My physician may then recommend that I try different preparatory steps to stimulate my uterine lining.

I have been told that, even if my treatment cycle is cancelled due to failure of my uterus to develop, the Donor may, following consultation with me, be allowed to continue the egg donor process, with the option of freezing any fertilized eggs (embryos) for future use when my uterine lining can be more appropriately developed.

I also understand that, if the IVF team believes that additional attempts to prepare me to receive an embryo are unlikely to succeed, my participation in the IVF Program as an egg recipient may be terminated.

## **Egg Donor Participation**

I understand that, as part of the egg donation process, the Donor will take medicines which are designed to make several of her eggs mature so that those eggs can be removed from her uterus (through a process called egg retrieval), donated, fertilized with sperm from my Partner (or a sperm donor, if applicable), and transferred to my uterus. I also understand that only if one or more eggs is/are fertilized successfully and develop(s)/matures satisfactorily can it/they be transferred to my uterus.

## **Embryo Transfer**

I have been informed that, generally, the procedure referred to as embryo transfer (the procedure by which the embryo(s) resulting from the Donor's eggs is/are transferred to my uterus) is performed 2 to 5 days after the date of egg retrieval from the Donor, and that usually no anesthetic is required for this procedure. It has been explained that, once I am in the transfer room, I will be positioned on a stretcher in a similar position to the one used to obtain a Pap smear. A speculum (a vaginal instrument used to expose the cervix) is then placed in my vagina and, after washing the cervix, the physician will transfer the embryos with a type of tube (called a "catheter") into my uterus. I understand that, once the embryos have been transferred, the IVF lab will examine the catheter to confirm that any embryos contained in the catheter have been discharged into my uterus. It has been suggested that I reduce my activity for the 24-48 hours following my embryo transfer.

I am aware that the chance of a successful pregnancy increases with the number of embryos transferred. I also understand that transferring multiple embryos will increase the possibility that I will experience a multiple pregnancy (<u>i.e.</u>, twins, triplets, etc.). I have been told that embryos which the IVF team determines have resulted from abnormal fertilization or failed

to develop properly will not be transferred, and that they will be disposed of. I have also been told that embryos that are not transferred, but which are of suitable quality for transfer ("extra" embryos), can be frozen, stored, and transferred at a later date. Alternatively, these extra embryos can be disposed of. I have been asked to make a decision regarding what I wish to do with any extra embryos produced for me from the Donor's eggs. My decision regarding the disposition of extra embryos is discussed in a separate consent form.

## **Following Embryo Transfer**

I have been told that the time period which follows my embryo transfer and precedes the receipt of the results of my pregnancy test may prove to be the most difficult and challenging time of this process. I have been encouraged to contact the IVF Program for support and to discuss any concerns I may have during this trying time.

It has been explained that, no earlier than 10 days following the embryo transfer, I will be asked to have a blood pregnancy test. If this test is found to be positive, a repeat pregnancy test will likely be done 2 days later. I have been informed that, if the test results continue to be encouraging, I will be asked to have a vaginal ultrasound examination approximately 3 to 4 weeks after the embryo transfer to determine the status of my pregnancy.

I have been informed that, if I do not get pregnant, I should make an appointment with my primary physician to discuss my IVF cycle results and that, at that time, the specific results of my cycle will be reviewed with me, along with my options for the future.

# Ownership Rights for Embryos and Resulting Offspring from Egg Donation

I understand that the Donor has signed an agreement/consent form that states that, once the donated eggs are removed from her body, she has no further responsibility or obligation in relation to the eggs, or in relation to any resulting embryos, or in relation to any resulting offspring from the embryos. I also understand that the agreement/consent form signed by the Donor states that she has agreed that she has no rights or claims regarding any of her donated eggs or any of the resulting embryos or offspring. I have been told that the donor agreement/consent form signed by the Donor states that, once the Donor has given up her eggs for donation, her participation in the egg donor process is completed.

I understand and agree, and my Partner (if, applicable) agrees, that any offspring from the egg donation and IVF process are my children and, if applicable, the children of my Partner. I further understand and agree that I and, if applicable, my Partner, am/are fully responsible for any and all offspring of the donated eggs, regardless of the outcome of the pregnancy.

## **Donor Information**

I have been informed that the Donor has agreed, as part of her agreement/consent to participate as an egg donor, to relinquish, irrevocably and unconditionally, any claim, right or cause of action against any recipient to whom embryos resulting from her donated eggs may be transferred, and any such recipient's former, current or future partner relating to any donated eggs or any offspring born or resulting from the use of such donated eggs, and any claim or right in or to such offspring.

I agree that I and my Partner (if applicable) each do hereby relinquish, irrevocably and unconditionally, any claim, right or cause of action against the Donor relating to any donated eggs or any offspring born or resulting from the use of the donated eggs, unless it is determined that any information or representation provided or made by the Donor is false and said falsity results in harm to me or any offspring resulting from this process.

# **Confidentiality**

I understand that my identity will not be revealed to the Donor and that the Donor's identity will not be revealed to me.

I understand that I will not receive any information about the Donor, and that all reasonable efforts will be made to maintain the confidentiality of any information obtained by the IVF Program concerning any individual involved in this process (me, the Donor, the Donor's partner (if applicable), my partner), and that that information will only be disclosed with the written consent of the relevant individual. I understand that the IVF Program cannot guarantee that an inadvertent disclosure of information might not occur and compromise the confidentiality of the participants.

# I hereby agree that I:

- a) will make no attempt, at any time, to disclose any information regarding embryos resulting from the donated eggs;
- b) will make no attempt, at any time, to identify, find or contact, or to disclose (if known to me) the identity or location of the Donor (or former, current or future partner of any Donor) of the eggs donated by me;
- c) have relinquished, irrevocably and unconditionally, any claim, right or cause of action against any Donor to whom embryos resulting from my donated eggs may be transferred, and any such Donor'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 Donor of my eggs will be required to sign an agreement/consent which includes a statement that:

- a) neither she, nor her partner (if applicable), will make any attempt, at any time, to identify, find or contact, or to disclose (if known to her/them) my (her/their egg recipient's) identity or location; and
- b) the Donor and her partner (if applicable) have relinquished, irrevocably and unconditionally, any claim, right or cause of action against me (her/their egg recipient) relating to any donated eggs or any offspring born or resulting from the use of the donated eggs.

# **Financial Compensation**

I understand and agree that I and, if applicable, my Partner, may compensate the Donor for her participation in this process, as reimbursement for any inconvenience and time spent by her. I understand that my insurance company may not cover this expense.

#### **Financial Responsibility**

I understand and agree that I and, if applicable, my Partner am/are responsible for all charges incurred as part of the egg donation and embryo transfer process. This includes, but is not limited to, physician, laboratory and any hospital charges, as well as charges incurred by the IVF team, and includes additional testing or screening of the Donor requested by me or my Partner (if applicable), and all other expenses and costs incurred subsequent to the embryo transfer process by or for me or any offspring that results from this process.

I further understand and agree that the IVF Program shall have the right, in its sole discretion, to require that I and/or my Partner (if applicable) pay in advance, in whole or in part, the costs and expenses for ovarian stimulation and egg retrieval of/from the Donor; it being understood and agreed that any such costs and expenses not paid in advance shall be payable by me and/or my Partner (if applicable) upon the demand of the IVF Program.

I understand that my insurance may or may not cover all of these charges, but that the egg donor will not be responsible for any unpaid sums.

I agree to purchase a Blanket Special Risk Insurance Policy for the donor to cover any unexpected medical costs incurred by the donor, should a medical complication occur related to her participation in the IVF process.

I and my Partner (if applicable) each hereby acknowledge(s) that we are responsible, individually, and together, for the care and support, financially and otherwise, of any offspring born as a result of the procedures described in this document and that neither of us shall make any claim against the IVF Program for any contribution of any kind to the care or support, financial or otherwise, of any such offspring.

#### **Risk Factors and Treatment Outcomes**

I understand that the processes for egg donation, egg retrieval, and embryo transfer, particularly when donated eggs are involved, carry some measure of risk. It has been explained to me that the primary risks associated with these processes are as follows:

# I. Risk Factors Associated with Receiving Donated Eggs

I understand that, if my treatment cycle is cancelled, or if the Donor fails to produce healthy eggs, or if the eggs produced by the Donor do not result in the successful implantation of embryos in my uterus, I may have to wait before attempting another treatment cycle. I also understand that, if the Donor is willing to donate a second time, several months will likely be

required before the Donor can participate in this process again. If the Donor is not willing to attempt another cycle, I understand that another Donor will have to be found before I can attempt another cycle and that that process may take months or even years. I also understand that the Donor is free to revoke her consent to participate in this process at any time before egg retrieval. This, too, could result in my having to wait a long period of time before I can find another donor.

I understand that there are other risks associated with receiving a donated egg. I understand that measures will be taken to prevent these risks, including obtaining certain medical and related information from the Donor and performing certain tests on the Donor, but that it cannot be guaranteed that the risks will be eliminated. The risks from a donated egg include, but are not limited to the following:

- a) I understand that, although the Donor will be tested for the presence of various infections and communicable diseases, there is a small risk that her eggs will carry or be infected by such a disease which could be passed on to me or any offspring of the Donor's eggs. These infections could include hepatitis or HIV, which may be fatal. The Federal Drug Administration (FDA) requires that all egg donors be retested for these diseases within 7 days of their egg retrieval. If the egg donor fails to have these done, all embryos will be cryopreserved until these tests are completed. This may prevent you from completing your cycle.
- b) I understand that, although the Donor will be screened for certain diseases which can be inherited (based on her history and ethnic background), not all congenital defects or heritable diseases can be predicted by genetic testing and that, therefore, a disease or defect could be passed on to me or the offspring created by this process.
- I understand that if my blood type is Rh-negative and the offspring which results from the Donor's eggs is Rh-positive, I might produce antibodies which can attack and destroy the offspring's red blood cells. I understand that there is effective treatment which is routinely used in these circumstances and that it frequently prevents this problem. I understand that the treatment for this problem is a medication that I can take by injection during pregnancy, and that this medication is called RhoD Immune Globulin (which sometimes carries the name RhoGAM or WinRho-SDF).
- d) I understand that the Donor may not provide accurate or complete information about her medical history and that this could have an effect on the IVF Program's ability to perform effective screening of the Donor for participation as an egg donor, which, in turn, could have an effect on my health, the health of my Partner (if applicable), and/or the health of any offspring of this process.

# II. Risk Factors Associated with Donor's Ovulation Stimulation, Insemination and Egg Retrieval Procedures.

I understand that the Donor's reproductive system may not respond in the desired way to the medicines taken by her during the ovulation stimulation process and that the process to stimulate the production of the Donor's eggs may be stopped before eggs are produced.

I also understand that even if the medicine appears to have worked successfully, and a procedure to remove the Donor's eggs is performed, it is possible that the procedure will be unsuccessful, or that fewer eggs will be produced than expected, or that no healthy eggs will be produced and removed from the Donor.

Even if healthy eggs are produced and removed from the Donor, I understand that they may not successfully fertilize and that, if they successfully fertilize, they may not develop normally.

And I understand that, even if one or more healthy eggs is/are removed from the Donor and successfully fertilized, and even if the successfully fertilized eggs or embryos develop normally, they may not be transferred successfully to my uterus or may not successfully implant in my uterus to establish a pregnancy.

Finally, I understand that laboratory handling may inadvertently harm the eggs, sperm or embryos.

#### III. Risk Factors Associated with Medications

The estrogen and progesterone used during mock cycles causes few side effects during the mock and treatment cycles. These compounds are similar to the body's natural hormones.

I understand that Leuprolide Acetate, or Lupron, will put me into a temporary, reversible menopausal state. For this reason, I have been told that I may experience hot flashes after using the medication for about a week. Additionally, although most patients tolerate Lupron quite well, I have been told that some women report headaches or temporary bloating of the abdomen. I am aware that Lupron may also temporarily 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 Lupron.

It has been explained to me that it is advisable to refrain from any extensive sun exposure for up to 2 weeks following my taking Doxycycline, since this medication can cause the development of an extensive skin rash following exposure to the sun. I have been told that I should be sure to eat prior to taking Doxycycline, since it can upset an empty stomach.

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 avoid 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.

## IV. Risk Factors Associated with Monitoring

The primary monitoring tools utilized during the course of the treatment 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.

#### V. Other Risk Factors

**Pregnancy-** I understand that, if pregnancy does result from these procedures, there is a possibility that ectopic pregnancy, miscarriage, stillbirth or birth defects, complications of childbirth or delivery, multiple births, undesirable hereditary characteristics or tendencies of my offspring or other adverse consequences could occur.

**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 have been informed that the medications I have been prescribed as an egg recipient have not been associated with ovarian cancer.

**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, and that the period of time between embryo transfer and the receipt of the results of my pregnancy test may be particularly stressful. For these reasons, I have been encouraged to meet with a counselor before, during and after my treatment cycle.

## Further Acknowledgments, Agreements and Consents

I acknowledge that I am voluntarily agreeing to receive human eggs donated by another woman in an effort to assist me to achieve a pregnancy through IVF.

I acknowledge that I have read and fully understand this agreement/consent form, as well as the IVF Patient Handbook provided to me by the IVF team (I also viewed the IVF Program Video), and that all of my questions concerning the above-described treatments have been fully answered to my satisfaction.

By participating as a recipient of donated eggs, 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 and my Partner (if applicable) understand that medical information concerning me/us and this treatment process may be analyzed and could be used in a publication which would not contain any identifying information, and I authorize such analysis and publication.

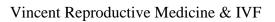
I and my Partner (if applicable) each hereby acknowledges that, if offspring results from the procedures described in this document, there is a possibility that such offspring could be mentally or physically abnormal, or have undesirable hereditary tendencies, conditions or characteristics, and/or that such offspring or I and/or my Partner (if applicable) may contract sexually transmitted or other infectious or communicable diseases or conditions as a result of the procedures.

I and my Partner (if applicable) will consider disclosing to any offspring resulting from this process that the offspring is or may be related to any present or future child produced from the Donor's eggs. I and my Partner (if applicable) 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 and my Partner (if applicable) each hereby acknowledges that the IVF Program has made no representation, express or implied, with respect to the nature of the legal relationship of any offspring born as a result of these procedures to either me, my Partner (if applicable) or the Donor.

I and my Partner (if applicable) each hereby irrevocably and unconditionally relinquishes, releases and gives up forever any claim, right or cause of action of any kind whatsoever which now exists or may arise in the future against the IVF Program, the Donor, her then husband or partner, if any, her 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.

	Patient's Name	Patient's S.S. # and D.O.B.
	Patient's Signature	Patient's Initials
Agreed to:		
rigiced to:	Partner's Name	Partner's Signature
	Date	
	VINCENT REPRODUCTIVE	
	MEDICINE & IVF, MASACHUSETTS	
	GENERAL HOSPITAL	
	By:	
	[Name, Title: Print]	[Signature]
	Date:	



Massachusetts General Hospital