AGREEMENT AND CONSENT FOR THE TRANSFER OF HUMAN EMBRYOS IN CONNECTION WITH IN VITRO FERTILIZATION (Gestational Carrier)

This document sets forth the terms pursuant to which I, _____, request, agree and consent to act as a gestational carrier in connection with infertility treatment provided to _____ (the "Intended Mother") and, if applicable, _____ (the "Intended Father"), who shall be referred to in this form as the "Intended Parents". My role as gestational carrier will involve having human embryos created through assisted reproductive technology and provided by the Intended Parents transferred into my uterus with the intent that I will become pregnant and be able to carry the pregnancy to term in an effort to assist the Intended Parents to achieve a pregnancy through the process called in vitro fertilization ("IVF"). The gestational carrier and IVF process will be undertaken through the Vincent Reproductive Medicine and IVF Program, Massachusetts General Hospital (MGH). This program, including respective employees, agents and assigns, will be referred to in this document as the "IVF Program".

Purpose

I understand that the purpose of my participation in the process described in this form is to assist the Intended Parents to achieve a pregnancy by having human embryos created through the combination of eggs and sperm collected from the Intended Parents and/or third party donors transferred to my uterus. I understand that I will not be genetically related to the embryo transferred into 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 gestational carrier. I represent that I have entered into a separate contractual agreement with the Intended Parents that governs my rights and responsibilities with respect to my role as gestational carrier and that the IVF Program is not a party to that arrangement nor has it reviewed or provided input to the terms of the agreement.

The Screening Process

I have been informed that, before I can be accepted as a candidate to act as a gestational carrier, 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 that might result from this process. I also understand that MGH will use all reasonable efforts to protect the confidentiality of the results of the screening process in accordance with the Partners Privacy Notice (which I have separately received), hospital policies, and applicable law, 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) I will be asked to undergo a psychological evaluation, which might include testing and/or consultation or an interview with a mental health professional;

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

d) I and my partner, if applicable, 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), and we understand that we will be notified of the results of these tests. (I understand that I/we 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. I understand that there may be information learned from my screening process which would be relevant to the Intended Parents in which case I may be asked to authorize disclosure of my screening results to them.

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 to act as a gestational carrier for the Intended Parents. 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 the Intended Parents' embryos.

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 will be performed.

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 additional estrogen 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 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 gestational carrier may be terminated.

Procedures Applicable to the Intended Parents

I understand that, assuming the Intended Mother's eggs will be used to create the embryos transferred to my uterus, the Intended Mother will take medicines which are designed to make several of her eggs mature so that those eggs can be removed from her ovaries (through a process called egg retrieval), fertilized with sperm from the Intended Father (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)/mature(s) satisfactorily can it/they be transferred to my uterus. It is also possible that the Intended Parents have already had embryos created at a prior date, which are now in frozen storage; under such circumstances the frozen embryos will need to be thawed and evaluated before being transferred to my uterus. Alternatively, it is possible that the Intended Parents may use (or have used) an egg donor for purposes of creating the embryo(s), which egg donor will undergo the egg retrieval process. If the Intended Mother will have her eggs retrieved under the care of the IVF Program, she will be given a separate form to review and sign and will have the risks and benefits of the procedures she will undergo explained to her separately.

Embryo Transfer

I have been informed that the procedure referred to as embryo transfer (the procedure by which the Intended Parents' embryo(s) is/are transferred to my uterus) is generally performed 2 to 5 days after the date of egg retrieval from the Intended Mother or a third party egg donor, assuming that fresh (not frozen) embryos are used, and that usually no anesthetic is required for this procedure. If frozen embryos are used, the transfer could happen on the day the embryos are thawed or up to 5 days post-thaw. 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 (i.e., twins, triplets, etc.). I am aware that multiple pregnancies carry a higher risk of certain negative outcomes for the baby such as: fetal loss or death, fetal growth restriction, premature births, low birth weight, physical and/or mental abnormalities in the resulting children; as well as in increase in certain risk factors to me during the pregnancy itself such as: high blood pressure, preeclampsia, pre-term labor, diabetes, placental abruption (tearing), placenta previa (incorrect placement), and cesarean or other operative delivery. I understand that the IVF team will follow its standard protocols and guidelines in deciding on the appropriate number of embryos to transfer to my uterus, and that this decision will be made in consultation with both me and the Intended Parents.

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.

Ownership Rights for Embryos and Resulting Offspring

I understand that the Intended Parents have signed an agreement/consent form that states that they agree they have absolute responsibility and obligation in relation to their embryos and to any resulting offspring from the embryos.

I understand and agree, and my Partner (if applicable) agrees, that any embryos used in and any offspring resulting from the IVF process described in this form in which I will participate as a gestational carrier are the children of the Intended Parents and neither I nor my Partner (if applicable) have any legal claim to or responsibility for these embryos or resulting offspring.

Financial Responsibility

The Intended Parents are responsible for the ordinary costs of my treatment as a Gestational Carrier at the IVF Program, including but not limited to any medical and psychological evaluations, tests, medications, and surgical procedures. I understand, however, that complications may arise resulting in additional medical and hospital expenses, and I certify that I have insurance coverage for such expenses, as well as for all necessary obstetrical care. I further understand that I am responsible to the IVF Program and MGH for any such medical or hospital costs not covered by my insurance although I am free to make separate arrangements with the Intended Parents for payment or reimbursement of such expenses.

Risk Factors and Treatment Outcomes

I understand that the processes for having embryos transferred into my uterus [and carrying a pregnancy to term?]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 Embryo Transfer

I may suffer mild discomfort from the embryo transfer. There is also a minimal risk of developing an infection, which in some cases may require hospitalization and intravenous antibiotic treatment. I understand that it is possible I may have an allergic reaction to the antibiotic(s), which in rare cases may be severe.

I understand that there are risks of contracting infectious diseases associated with receiving embryos that were created from third parties' reproductive tissues (eggs and sperm). I understand that measures will be taken to prevent these risks, including obtaining certain medical and related information from and performing certain tests on the tissue donors to the extent possible (which may be the Intended Parents or may be other donors from whom the Intended Parents received donated eggs and sperm to create their embryos), but that it cannot be guaranteed that the risks will be eliminated. These risks include, but are not limited to the following:

a) I understand that, although the individuals who provided the tissues to create the embryos will, to the extent possible, be tested for the presence of various infections and communicable diseases, there is a small risk that the embryos will carry or be infected by such a disease which could be passed on to me or any resulting offspring. These infections could include hepatitis or HIV, which may be fatal. I understand that the donors of the sperm and eggs used to create the embryos transferred to my uterus may not provide accurate or complete information about their medical histories and that this could have an effect on the IVF Program's ability to perform effective screening of the source of the embryos, whether the Intended Parents or other third party donors, which, in turn, could have an effect on my health and the health of my partner (if applicable).

b) I understand that if my blood type is Rh-negative and the offspring which results from the Intended Parents' embryo(s) 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).

II. Risk Factors Associated with Medications

The estrogen and progesterone used during mock cycles cause few side effects. 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, blood clots, high blood pressure, gallstones, liver disease and visual symptoms. There is also the possibility that they increase the risk of endometrial or breast cancer. 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.

III. 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.

IV. 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. There is also a risk that pregnancy may not occur. I understand that I will be given additional information about my labor and delivery by my obstetrician and will be asked to sign a separate consent form.

Psychological Risks – It has been explained to me that acting as a gestational carrier can be psychologically stressful. The ability to transfer an embryo into the uterus of an unrelated woman is relatively new in human experience and there is little information about the psychological effects of treatment on the individuals involved in this arrangement. In particular, I understand that the psychological and emotional risks of carrying a child for another woman are currently unknown, especially if the Intended Parents and the gestational carrier continue to have a social relationship after the child is born. For these reasons, I have been encouraged to meet with a counselor before, during and after my participation.

Further Acknowledgments, Agreements and Consents

I acknowledge that I am voluntarily agreeing to act as a gestational carrier and receive human embryos that are not created from my own genetic material into my uterus in an effort to assist the Intended Parents 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 gestational carrier, 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 must and I agree to refrain from unprotected sexual intercourse during the month prior to embryo transfer, and until receipt of the results of my pregnancy tests following the embryo transfer. If I do engage in sexual intercourse during this time, I understand that I must use a barrier method of contraception.

I and my partner (if applicable) each hereby acknowledge that the IVF Program has played no role in locating me or introducing me to the Intended Parents or otherwise recruiting me to act as a gestational carrier. Neither the IVF Program or any agent, affiliate or representative thereof is a party to or has participated in any arrangement or agreement that I may have with the Intended Parents.

I and my partner (if applicable) have consulted with an attorney prior to signing this agreement/consent form, and I have had a full and complete opportunity to seek information and advice regarding the legal aspect of my decision to serve as a gestational carrier. The IVF Program has made no representations to me concerning any law or legal matters with respect to my acting as a gestational carrier, and I am not relying on any such representations in giving this consent.

My acceptance into and continued treatment as a gestational carrier at the IVF Program are within the sole discretion of the IVF Program. At all times, the IVF Program retains the right to discontinue this treatment.

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 Partners HealthCare System, Inc., Massachusetts General Hospital, the IVF Program, and their trustees, officers, employees, servants, agents, medical staff, affiliates and representatives (collectively, "Liabilities") arising from or in connection with my service as a gestational carrier for the Intended Parents, including but not limited to any Liabilities relating to any legal claim I may have with respect to a child that I carry and/or deliver as a gestational carrier, to the extent such Liabilities are not attributable to the negligence or willful misconduct of the IVF Program; however, this relinquishment and release shall not include Liabilities based on injuries to myself that are attributable to the negligence or willful misconduct of the IVF Program. .

I have had the opportunity to ask questions regarding my treatment and realize that my physicians are available to answer any questions that arise during the course of my treatment. [I understand that Massachusetts General Hospital is a teaching hospital and as such, fellows, residents, interns and medical and nursing students may participate in and/or observe my care and surgical procedures under the supervision of a senior physician or nurse.] I understand that bodily tissues or fluids remaining from my procedures may be photographed during surgery and/or be preserved for diagnostic, scientific, and teaching purposes.

My signature(s) below constitute my acknowledgement of the following:

1. That I have read, understood, and agreed to the forgoing;

2. That the proposed procedures have been satisfactorily explained to me and that I have all the information that I desire;

3. That I will be given a copy of the consents that I sign;

4. That I request to serve as a gestational carrier on behalf of the Intended Parents and hereby give my express authorization and consent to all procedures necessary to serve in this capacity.

	_____	_____
	Patient's Name	Patient's S.S. # and D.O.B.
	_____	_____
	Patient's Signature	Patient's Initials
Agreed to:	_____	_____
	Partner's Name	Partner's Signature

_____

Date

VINCENT REPRODUCTIVE MEDICINE & IVF, MASACHUSETTS GENERAL HOSPITAL

Date: _____

_____

By: _____ [Signature]

[Name, Title]