CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Sponsor / Study Title:	**Medennium, Inc. "An Evaluation of the Efficacy and Safety of the Phakic Refractive Lens (PRL™) when Implanted for the Treatment of Myopia"**
Protocol No.:	**PRL-98-005**
Principal Investigator:	**I. Howard Fine, MD / Richard S. Hoffman, MD / Mark Packer, MD**
Address:	**1550 Oak Street, Suite #5 Eugene, OR 97401 (541) 687-2110**

Please read this consent form carefully. Take time to ask as many questions as you want. If there are any words or information you do not clearly understand, study personnel will be happy to explain them to you. Before agreeing to participate in this research study, it is important that you read the explanation of the procedures and the potential risks and benefits.

INTRODUCTION

You are being asked to participate in this research study because you have myopia (nearsightedness). If you agree to take part in this study, you will be one of about 430 subjects enrolled at up to 20 different locations. Your participation would last 3 years and involve about 12 visits to the study doctor.

Your participation is this study is voluntary.

NATURE AND PURPOSE OF THE STUDY

For many years, people with myopia have used different methods to treat their myopia. Medennium, Inc. (the study sponsor) has developed a lens to be inserted into the eye without taking out the eye's natural lens. The lens, designed to reduce nearsightedness, is called the Phakic Refractive Lens, or PRL.

The purpose of this research study is to learn about the safety of the PRL when inserted into your eye and about how well it improves your vision and reduces the need for the use of corrective lenses (glasses or contact lenses). The PRL is an investigational device, which means it is a device that has not been approved by the Food and Drug Administration (FDA) for commercial use but may be used in research studies.

The PRL has been studied for several years in Russia (300 subjects), Italy (72 subjects), and in Mexico (132 subjects). In the United States, there have been two small studies in which 23 subjects with legally blind eyes (20/200 or worse) received the lens and a larger study in which 100 subjects with nearsightedness were treated with the lens.

If you decide to participate, one of your eyes will be implanted with the device and one of your eyes will not be implanted. The study doctor will decide which eye is the "implanted eye" and which eye is the non-implanted "fellow eye." This informed consent form only applies to the first implanted eye. In the future, it may be possible that the fellow eye may be treated if the FDA approves fellow eye implants. There would be a minimum of 3 months after implant surgery in the first eye before the fellow eye could be implanted.

STUDY PROCEDURES

If the study doctor feels you may qualify to participate in this study, he/she will describe the implant, how it is used, and what you need to do if you volunteer to be in the study group. If you are interested, you will be given this consent form which you must read and sign before any study-specific procedures are performed during your screening visit. Your role in this study will last for about three years. There are at least twelve study visits. There may be up to three (3) screening visits, an iridotomy day, a surgery day, and nine follow-up visits. The 3 year follow-up visits pertaining to the PRL are provided to the patient at no additional fee.

If you wear contact lenses, you must stop wearing them before the screening exam specific to this study. This is very important to help the study doctor choose the correct lens for your eye. If you wear soft lenses, you should stop wearing them for at least 14 days before the screening exam. If you wear hard (PMMA), gas permeable, or toric lenses, you should stop wearing them for at least 3 weeks before the screening exam.

Study Visit 1: Screening

During the first study visit, you will be given a questionnaire to complete. You will be asked questions about your medical history and your eye problems. If you are not completely truthful with the study doctor regarding your health history, you may harm yourself by taking part in this study.

You will receive a complete eye exam. Your vision will be tested, your eye will be dilated (which opens your pupil), and the study doctor will look inside your eye using a slit lamp.

If you are a contact lens wearer, the screening may require up to 3 visits.

You should not participate if:

- ? You are unable or unwilling to wear glasses after surgery. (You may still need to wear glasses after surgery and you may not wear contact lenses on the study eye during the three-year study).
- ? You are pregnant, planning to become pregnant during the first three months after surgery, or currently nursing an infant. (The medications used in this study, during and after the implant procedure, are all approved marketed medications. However, these medications may involve risk to an embryo, fetus, or nursing infant).

Study Visit 2: Iridotomy

The iridotomy is a procedure to prevent one type of glaucoma caused if the implant blocks fluid in the iris of the eye. If your study doctor requires it, you may be asked to sign a separate consent form for the iridotomy and for the lens implant surgical procedures.

For the iridotomy procedure:

- ? Several drops of an eye solution will be placed in your eye to numb it.
- ? Two small holes will be made, by laser, in the iris (the colored part of the eye). These small holes will let fluid flow freely through the eye after the lens is inserted.
- ? The study doctor may choose to do an iridectomy on the day of surgery during the implant procedure instead of this laser procedure.

Study Visit 3: Surgery

For the PRL implant procedure:

- ? About 30 minutes before the surgery, you will be given sedation by mouth or through a vein in your arm to make you drowsy and relaxed during surgery.
- ? Several drops of an eye solution will be placed in your eye to numb it and additional numbing will be added by injecting anesthetic behind your eye.
- ? During the surgery, a small incision will be made on the surface of your eye. The implant will be inserted through this small incision and will unfold over the top of your natural lens.
- ? After the lens is inserted and is properly placed, some subjects may need to have a small stitch placed in the eye to close the incision.
- ? The surgical procedure should take 10 to 20 minutes.
- ? Antibiotic and anti-inflammatory eye drops may be put into your eye to prevent infection and help the eye to heal. Your eye may be taped shut to protect it from being bumped or touched by accident until the study visit on next day.
- ? The implant procedure may be video and/or audio taped for teaching and evaluation purposes although your identity will not be revealed.

For the iridectomy procedure:

- ? A small hole will be made by incision in the iris (the colored part of the eye). This small hole will let fluid flow freely through the eye after the lens is inserted.

The study doctor will send you home when he/she thinks it is safe for you to leave the clinic. You must have someone available to drive you home since you will not be allowed to drive until the effects of the medication given during the surgery wear off. Before you leave the clinic, you will be given instructions for taking pain medication, antibiotic eye drops, and anti-inflammatory eye drops.

It is important that you do not rub the eye after surgery until your study doctor says it is acceptable to do so.

Study Visit 4 - 12: Follow-up

There are nine follow-up visits scheduled at: 1 day (study visit 4), 3 days (study visit 5), 1 week (study visit 6), and then 1, 3, 6, 12, 24, and 36 months after the surgery (study visits 7, 8, 9, 10, 11, and 12). You may need to make additional visits to the clinic if you have any problem with your eye after the surgery. At each visit, the pressure inside your eye will be measured, your eye will be examined, and your vision will be checked. Many of the tests that were done before your eye surgery will be repeated during some or all of the follow-up visits. It is important that you keep all of your study visit appointments. These visits are crucial to monitor the safety of your eye.

RISKS AND DISCOMFORTS

Possible risks from the iridotomy include:

- ? The hole in the colored part of the eye may close completely and would need to be reopened.
- ? The pressure in the eye may increase and may need to be treated with medication or another iridotomy.
- ? There may be swelling in the colored part of the eye.
- ? There may be damage to the clear front portion of your eye.
- ? There may be bleeding inside the eye.
- ? The natural lens in the eye may become cloudy. Surgery to remove the cataract may be needed.

? There may be laser burn inside your eye.

Possible risks from the implant or surgical procedure include:

? The natural lens in the eye may become cloudy. Surgery to remove the cataract may be needed.
? The implant may move off-center. Surgery to re-center or remove the implant may be needed.
? The pressure in the eye may increase and may need to be treated with medication or additional surgery.
? The colored part of the eye may not respond as well to light as it normally does, resulting in a larger pupil.
? There may be swelling or redness.
? There may be infection of varying types or severity.
? There may be some pain, discomfort, or a feeling like something is in your eye.
? There may be some other damage to the colored part of your eye or the clear front portion of your eye.

Any of these could have temporary or permanent effects on your vision or require additional treatment.

The PRL is made of silicone, which is widely used to make other devices used or placed in the eye. The PRL, like any implant in the body, is a foreign body and there is always a chance that it could be rejected. If there is any sign that the implant is being rejected, surgery would be required to remove the implant.

The study doctor could also decide not to insert the PRL if there is an unexpected problem during surgery. If this happens, you will be advised to continue using glasses or contact lenses to correct your refractive error.

During the study, if you experience any medical problems related to your eye surgery (itching, pain, discomfort, etc.), please contact the study doctor.

Possible side effects from the iridotomy, the surgical procedure, or the implant include:

? It is possible that the implant will not correct all of your refractive error.
? The current study is not designed to treat astigmatism. Your astigmatism that is present before surgery may possibly worsen after surgery. This could require the use of glasses after the surgery.
? You may experience glare or a "halo" effect around lights at night. Your vision may not seem as sharp in a dimly lit room, in fog, or at night. You may have problems in bright light.
? There may be a "balance" problem between your two eyes after the implant has been inserted in one eye, but not the other.
? The natural lens or PRL may be damaged or displaced if the eye is injured.
? You may experience some double vision.

Since the PRL is investigational, there may be other risks or side effects associated with its use, or with the surgical procedure, which are not known at this time.

ALTERNATIVE TREATMENTS

The alternative to corrective eye surgery is corrective lenses (glasses or contact lenses). Other corrective eye surgery procedures include:

- ? Radial keratotomy (RK)
- ? Automated lamellar keratoplasty (ALK)
- ? Photorefractive keratectomy (PRK)
- ? Laser thermal keratoplasty (LTK)
- ? Laser in situ keratomileusis (LASIK)
- ? Corneal rings
- ? Other phakic intraocular lenses (IOLs)
- ? Lensectomy with IOL replacement.

These procedures, as well as their potential limitations and risks, can be further explained by the study doctor.

POTENTIAL BENEFITS

There is no guarantee that you will receive any medical benefit as a result of participation in this study. It is possible that your symptoms of myopia will improve. It is also possible that your condition will remain the same or worsen. However, your participation in the study may provide information that will benefit other people. Your participation will help the study sponsor in the development of this implant. Information about the condition of your eyes will be shared with you.

REIMBURSEMENT FOR STUDY PARTICIPATION

There is no monetary compensation available to you for your participation in this study.

Cost to Subject:

The implant device will be provided to you at no charge. However, since the PRL requires a refractive surgery procedure, you may be responsible for paying the study doctor's usual and customary refractive surgery fee. You should discuss with the study doctor the amount of the total cost to you before agreeing to participate in this study.

It is suggested that you contact your insurance carrier to determine its policy on payment of cost of participation in this research study. Your insurance carrier may not cover the costs associated with your participation (including any hospitalization, administration of study device, and treatment of side effects caused by the study device) in this study. Payment of such costs could be very expensive and would be your responsibility.

COMPENSATION FOR STUDY-RELATED INJURY

If you are injured because of your study participation, you should seek medical help immediately.

If a physical injury occurs as a direct result of the implant, the surgical procedure, or any study procedures, the medical care required to treat the injury will be provided at no cost to you, if that cost is not reimbursable through your own health insurance. If a research-related injury occurs, you must contact the study doctor immediately.

By signing this consent form, however, you do not give up your right to pursue a claim through the legal system.

CONFIDENTIALITY

Your medical records and medical information gathered from this study will be submitted to Medennium, Inc., their representatives, and the Food and Drug Administration (FDA) under the regulations issued by the federal agency, and/or other regulatory agencies. Information from your participation in this study may be submitted to government agencies in other countries where the study device may be considered for approval. **Oregon Eye Surgery Center Institutional Review Board** (an independent ethics committee that reviews this study) may also review medical records and any study data generated to assure compliance with federal regulations.

Because of the need to release information to these and other parties, absolute confidentiality cannot be guaranteed. The collection and submission of the data will be accomplished with strict adherence to professional standards of confidentiality.

Information from this study may be published in a medical journal, but your confidentiality will be respected and no names will be used in any report. Photos, or videos of your eye, and any audiotapes, which have no identification, may be used; however, if you are identifiable, separate, specific written permission will be requested.

NEW FINDINGS

During the course of the study, the study doctor will tell you of any new significant findings that may affect your willingness to continue to participate.

RESEARCH QUESTIONS AND CONTACTS

You may freely ask questions about this informed consent form or the study now or at any time during the study. If you experience an adverse reaction, have questions about the research, a research related injury, or compensation, during this study you may contact Drs. Fine, Hoffman, or Packer at telephone number 541-687-2110.

If you have questions about your rights as a research subject, you may call collect or write to: Cheri VanBebber, RN, IRB Chairperson, Oregon Eye Surgery Center, 1550 Oak Street, Eugene, OR 97401, phone: 541-683-8771.

VOLUNTARY PARTICIPATION

Your participation in this study is voluntary. You may refuse to participate or may quit at any time during the study. All you have to do is tell the study doctor. Withdrawal will occur without penalty or loss of benefits to which you are otherwise entitled. If you withdraw from the study, no prejudice will be shown toward you for medical care or participation in future research studies. However, it is important that you report any problems that might have occurred during your participation in the study.

In addition, the study doctor or the sponsor may terminate your participation, without regard to your consent, if you have had an unexpected reaction, if you do not follow the study plan, if you experience a study-related injury or for administrative reasons. Any time your participation is terminated you should go through the study termination procedures or any other procedures the study doctor considers necessary for your own safety.

CONSENT STATEMENT

I have read this consent form and its contents were explained. My questions have been answered. I consent voluntarily to participate in this research study and I will receive a signed and dated copy of this consent form for my records.

By signing this consent form, I am not giving up any of my legal rights. I also understand that nothing in this consent form is intended to change any applicable federal, state, or local laws regarding informed consent.

_____ ____/____/____
Signature of Research Subject Date

_____ Study Eye: ☐ Right ☐ Left
Printed Name of Research Subject

_____ ____/____/____
Signature of Person Explaining Consent Date

_____
Printed Name of Person Explaining Consent

INVESTIGATOR'S STATEMENT

The subject signing this consent form has had the study fully and carefully explained and the subject has been given an opportunity to ask any questions regarding the nature, risks, and benefits of his/her participation in this research study.

_____ ____/____/____
Investigator or Designee Signature Date

_____
Printed Name of Investigator or Designee