INFORMED CONSENT FOR EXCIMER LASER PHOTOREFRACTIVE KERATECTOMY

I, _____, agree to have my surgeon, _____ M.D., perform the U.S. Food and Drug Administration (FDA) approved laser procedure called PHOTOREFRACTIVE KERATECTOMY (PRK). The excimer laser will be used to reshape the front of the cornea (the clear front part of the eye) to reduce or eliminate the need for glasses or contact lenses. I understand that this procedure is permanent and irreversible. I also understand that this is an elective procedure.

PROCEDURE (RIGHT – LEFT – BOTH):
My eye(s) being treated will receive topical anesthetic drops to reduce or eliminate discomfort associated with the procedure. I will be lying on my back under the laser and will be asked to look up into the operative microscope at a flashing red light. The laser will remove a calculated amount of tissue from the cornea in an attempt to reshape the cornea to reduce my dependence on glasses or contact lenses.

During the laser procedure a popping or cracking sound will be heard. After the procedure a bandage soft contact lens will be placed on my eye(s) along with antibiotic and anti-inflammatory drops. I realize that I may experience discomfort or pain in the hours following treatment as well as light sensitivity, tearing, irritation, and redness. Additional drops and instructions will be provided.

RISKS:
_____(Initials) 1. I understand that, as with all surgical procedures, the results cannot be guaranteed. There is also no guarantee that I will eliminate my reliance on glasses or contact lenses. It is possible that the treatment could result in under-correction (residual nearsightedness or myopia), over-correction (farsightedness or hyperopia), or astigmatism, any of which may require glasses or contact lenses. It is also possible that this treatment may increase my dependence on reading glasses, or that I may require reading glasses at an earlier age. I understand that further treatment may be necessary, including the use of eyedrops, the wearing of glasses or contact lenses, or an additional laser treatment.

_____(Initials) 2. I understand that if I currently wear reading glasses, I will likely still need them after this treatment. I also understand that if I currently do not need reading glasses, I will most likely need them at some point in time.

_____(Initials) 3. (Female only). I am not pregnant or nursing. If it is possible that I am pregnant, I will obtain a pregnancy test to ascertain that I am not pregnant since pregnancy could adversely affect the treatment results. Also, I will notify my doctor immediately if I become pregnant within the six months following treatment. I understand that the use of oral contraceptive agents may increase certain risks associated with the procedure.

_____(Initials) 4. I understand that I should make the doctor aware of any vascular or autoimmune disease I may have, or of any drug therapy that may suppress the immune system.

_____(Initials) 5. I understand that the FDA has not specifically approved the use of a bandage soft contact lens immediately after the procedure. The contact lens is used to reduce postoperative pain or discomfort that can be severe. The contact lens however can increase the risk of corneal infection or inflammation. I will inform my doctor if I do not want a contact lens used after the procedure.

_____(Initials) 6. I have been informed that complications can occur which, although usually temporary, may be permanent, and include:

a. *Decrease in best-corrected visual acuity.* A decrease in best-corrected visual acuity (vision with eyeglasses or contact lenses) may occur.

b. *Glare and halos.* Glare from bright lights or halos around lights may be experienced especially at night. The glare may be severe enough to cause difficulty driving at night or under low-light conditions.

c. *Decrease in contrast sensitivity.* A decrease in the *quality* of vision may occur even with excellent visual acuity as measured on a standard eye chart.

d. *Corneal scarring.* A scar dense enough to affect vision may occur after the procedure.

e. *Elevated intraocular pressure.* High pressure in the eye, which may reduce vision, may occur while taking eye drops after the procedure. This condition is treated with additional drops, or rarely, surgery.

f. *Delayed healing.* Delayed healing of the skin on the surface of the cornea may extend the discomfort.

_____(Initials) 7. Other complications which have been reported include: cataract, corneal ulceration, infection, inflammation in the eye, corneal inflammation, double vision, drooping eyelid, shadow images, ghost images, and allergic reactions to the prescribed medications. Since it is impossible to state every complication of PRK, it is understandable that the above list is not complete or exhaustive. Fortunately, most complications are rare, temporary, or mild. Since each person is unique and responds differently to surgery and the healing process that follows, there can be no guarantee made to me regarding the results of PRK on my eye.

Notes:

BENEFITS AND ALTERNATIVES TO TREATMENT:
The benefit of the procedure is to reduce my dependence on glasses or contact lenses and to reduce my blurriness when not wearing glasses or contact lenses (uncorrected visual acuity).

Non-surgical alternatives to treatment include continued wear of glasses or contact lenses. Surgical alternatives to PRK include radial keratotomy (RK), automated lamellar keratectomy (ALK), laser in-situ keratomileusis (LASIK), and others. RK uses a special knife to make incisions in the cornea and ALK uses a motorized blade to remove a small amount of tissue from the center of the cornea. LASIK combines the use of a motorized blade and a laser to reshape the cornea.

Notes:

AGREEMENT:
My signature indicates that I have read and understand the information provided and have discussed the risks, benefits, and alternatives of the procedure with an eye care provider. I have had an opportunity to ask my physician questions and would like to proceed with treatment. I have received and read the FDA-mandated patient information booklet entitled "Facts You Need to Know About Photorefractive Keratectomy (PRK) Surgery." I agree that I will follow postoperative instructions and go to the required follow-up evaluations.

_____	_____	
(Patient)	(Patient Signature)	(Date)
_____	_____	
(Physician)	(Physician Signature)	(Date)
_____	_____	
(Witness)	(Witness Signature)	(Date)