INFORMED CONSENT FOR LASER ASSISTED SUBEPITHELIAL KERATOMILEUSIS (LASEK)/PHOTO-REFRACTIVE KERATECTOMY (PRK)

Please read the following consent form very carefully. Please initial each page where indicated. Do not sign this form unless you have read and understand each page.

PATIENT'S NAME: _____ **PROCEDURE DATE:** ___/___/____

SURGEON'S NAME: ***Michael A. McMann, MD, FAAO***

TREATMENT EYE (CIRCLE): **RIGHT** Eye **LEFT** Eye **BOTH** Eyes Patient Initials ____

MONOVISION (CIRCLE): **YES** **NO** **SLIGHT** Which Eye? _____

COMMENTS: _____

INTRODUCTION:

This information is to help you make an informed decision about having Laser Assisted Subepithelial Keratomileusis (LASEK)/Photo-Refractive Keratectomy (PRK) surgery to treat nearsightedness, farsightedness, and/or astigmatism. Take as much time as you wish to make a decision before signing this form. You are encouraged to ask questions and have them answered to your satisfaction before you give your permission for surgery. Every surgery has risks as well as benefits and each person must evaluate this risk/benefit ratio for himself/herself in light of the information presented.

LASEK/PRK involves the use of a device known as an excimer laser. LASEK/PRK is one of a number of alternatives for correcting nearsightedness, farsightedness and astigmatism. In LASEK/PRK, a mechanical brush (PRK) or alcohol (LASEK) are used to remove the thin skin layer on the surface of the cornea known as the corneal epithelium to expose the underlying corneal stroma. Next, the excimer laser is used to remove layers of tissue from the corneal stroma to reshape it to reduce your refractive error. Next, in LASEK the corneal epithelium is repositioned over the treated cornea. However, this corneal epithelium is damaged from the alcohol and in the majority of LASEK cases it naturally falls off in the first 24 hours. Finally, in both LASEK and PRK a bandage contact lens is placed on the eye. This bandage contact lens is kept in place for a period of 3-6 days.

LASEK/PRK is an elective procedure. There is no emergency condition or other reason that requires or demands that you have it performed. You could continue wearing contact lenses or glasses and have the same visual acuity you now have. LASEK/PRK, at best, can only match your best corrected visual acuity that you have with contact lenses or glasses. This procedure, like all surgery, presents some risks, many of which are listed below. You should also understand that there may be other risks not known, which may become known later. Despite the best of care, complications and side effects may occur. Should this happen in your case, the result might be affected even to the extent of making your vision worse or requiring more extensive surgery.

You shall understand that LASEK/PRK surgery will not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, retinal degeneration or detachment.

During pregnancy, your degree of myopia or hyperopia can fluctuate, which could influence your results. If you know you are pregnant, plan to, or become pregnant within the next six months, it is important that you notify Dr. McMann immediately. You also should advise Dr. McMann of any drug therapy you are on or any vascular or auto-immune diseases you may have.

ALTERNATIVES TO LASEK/PRK

If you decide not to have LASEK/PRK, there are other methods of correcting your nearsightedness, farsightedness or astigmatism. These alternatives include, among others, eyeglasses, contact lenses and other refractive surgical procedures.

PATIENT CONSENT

In giving my permission for LASEK/PRK, I understand the following: The long-term risks and effects of LASEK/PRK are unknown. I have received no guarantee as to the success of my particular case. I understand that the following risks are associated with the procedure:

VISION THREATENING COMPLICATIONS

1. I understand that the excimer laser could malfunction, requiring the procedure to be stopped before completion. Depending on the type of malfunction, this may or may not be accompanied by visual loss.

2. I understand that irregular healing could result in a distorted cornea. This would mean that glasses or contact lenses may not correct my vision to the level possible before undergoing LASEK/PRK. If this distortion in vision is severe, a partial or complete corneal transplant might be necessary to repair the cornea.

3. I understand that it is common for LASEK/PRK patients to develop some degree of corneal haze/scarring, which in some cases may not go away completely. If the haze/scarring is severe, re-treatment may be necessary. Corneal haze/scarring could cause loss of best-corrected vision and in rare cases the need for a partial or full thickness corneal transplant using a donor cornea.

4. I understand that topical corticosteroid drops also may be required for months to reduce the possible development of haze/scarring. However, if steroids are used for a number of months in multiple doses per day, some individuals may develop a condition called glaucoma, which could permanently damage the optic nerve. Cataracts also can be the result of using topical steroids for too long.

5. I understand that mild or severe infection is possible. Mild infection can usually be treated with antibiotics and usually does not lead to permanent visual loss. Severe infection, even if successfully treated with antibiotics, could lead to permanent scarring and loss of vision that may require corrective laser surgery or, if very severe, corneal transplantation or even loss of the eye.

6. I understand that other very rare complications threatening vision include, but are not limited to, corneal swelling, corneal thinning (ectasia), appearance of "floaters" and retinal detachment, hemorrhage, venous and arterial blockage, cataract formation, total blindness, and even loss of my eye.

7. I understand keratoconus is a degenerative non-inflammatory progressive corneal thinning disease affecting vision that occurs in approximately 1/2000 in the general population. While there are several tests that suggest which patients might be at risk, this condition or an indistinguishable condition called post-refractive surgery ectasia can develop in patients who have no known pre-operative risk factors. Since keratoconus/post-refractive surgery ectasia may occur on its own, there is no absolute test that will ensure a patient will not develop keratoconus/post-refractive surgery ectasia following laser vision correction. Keratoconus/post-refractive surgery ectasia is usually treated with rigid or hard contact lenses, but in severe cases may require a cornea transplant.

NON-VISION THREATENING SIDE EFFECTS

1. **I understand that I may experience significant pain following LASEK/PRK that may last for up to 6 days. I understand that this pain may be disabling and can prevent me from working.**

Patient Initials____

2. I understand that there may be increased sensitivity to light, glare, and fluctuations in the sharpness of vision. I understand these conditions usually occur during the normal stabilization period of from one to three months, but they may also be permanent.

3. **I understand that there is an increased risk of eye irritation related to drying of the corneal surface following the LASEK/PRK procedure. These symptoms may be temporary or, on some occasions, permanent, and may require frequent application of artificial tears and/or closure of the tear duct openings in the eyelid.**

Patient Initials____

4. I understand that an overcorrection or undercorrection could occur, causing me to become farsighted or nearsighted or increase my astigmatism and that this could be either permanent or treatable. I understand that an enhancement or contact lenses or glasses may be needed to correct a possible overcorrection or undercorrection. I understand an overcorrection or undercorrection is more

likely in people over the age of 40 years and may require the use of glasses for reading or for distance vision some or all of the time.

5. **I understand that after refractive surgery, a certain number of patients experience glare, a "starbursting" or halo effect around lights, or other low-light vision problems that may interfere with the ability to drive at night or see well in dim light. Although there are several possible causes for these difficulties, the risk may be increased in patients with large pupils or high degrees of correction. For most patients, this is a temporary condition that diminishes with time or is correctable by wearing glasses at night or taking eye drops. For some patients, however, these visual problems are permanent. I understand that my vision may not seem as sharp at night as during the day and that I may need to wear glasses at night or take eye drops. I understand that it is not possible to predict whether I will experience these night vision or low light problems, and that I may permanently lose the ability to drive at night or function in dim light because of them. I understand that I should not drive unless my vision is adequate. These risks in relation to my particular pupil size and amount of correction have been discussed with me.**

Patient Initials____

6. I understand that there may be a "balance" problem between my two eyes after LASEK/PRK has been performed on one eye, but not the other. This phenomenon is called anisometropia. I understand this would cause eyestrain and make judging distance or depth perception more difficult. I understand that my first eye may take longer to heal than is usual; prolonging the time I could experience anisometropia.

7. I understand that, after LASEK/PRK, the eye may be more fragile to trauma from impact. I understand that the treated eye, therefore, is somewhat more vulnerable to all varieties of injuries.

8. I understand it would be advisable for me to wear protective eyewear when engaging in sports or other activities in which the possibility of a ball, projectile, elbow, fist, or other traumatizing object contacting the eye may be high.

9. I understand that there is a natural tendency of the eyelids to droop with age and that eye surgery may hasten this process.

10. I understand that temporary glasses either for distance or reading may be necessary while healing occurs and that more than one pair of glasses may be needed.

11. I understand that the long-term effects of LASEK/PRK are unknown and that unforeseen complications or side effects could possibly occur.

12. I understand that the visual acuity I initially gain from LASEK/PRK could regress, and that my vision may go partially back to a level that may require glasses or contact lens use to see clearly.

13. I understand that the correction that I can expect to gain from LASEK/PRK may not be perfect. I understand that it is not realistic to expect that this procedure will result in perfect vision, at all times, under all circumstances, for the rest of my life. I understand I may need glasses to refine my vision for some purposes requiring fine detailed vision after some point in my life, and that this might occur soon after surgery or years later.

14. I understand that I may be given medication in conjunction with the procedure and that my eye may be patched afterward and I will therefore need a driver.

15. I understand that presbyopia is a condition that affects the lens inside the eye and occurs in all individuals as they age into their 40's. With presbyopia, the lens inside the eye loses its ability to change focus planes, thus leaving the eye with one fixed focal plane. When this occurs, most individuals notice that they need bifocals or reading glasses in order to read up close. LASEK/PRK reshapes the surface of the eye (cornea) and does not correct presbyopia. I understand that if I currently need reading glasses, I will still likely need reading glasses after this treatment. It is possible that dependence on reading glasses may increase or that reading glasses may be required at an earlier age if I have this surgery.

16. I understand that even 90% clarity of vision is still slightly blurry. Enhancement surgeries can be performed when vision is stable UNLESS it is unwise or unsafe. In order to perform an enhancement surgery, there must be adequate tissue remaining. If there is inadequate tissue, it may not be possible to perform an enhancement. An assessment and consultation will be held with Dr. McMann at which time the benefits and risks of an enhancement surgery will be discussed.

17. I understand that, as with all types of surgery, there is a possibility of complications due to anesthesia, drug reactions, or other factors that may involve other parts of my body. I understand that, since it is impossible to state every complication that may occur as a result of any surgery, the list of complications in this form may not be complete.

18. I understand that having any form of refractive surgery may potentially disqualify me from some professions including the military and certain law enforcement agencies. I accept full responsibility for any current or future professional disqualifications I may incur as a result of having refractive surgery.

FOR PRESBYOPIC PATIENTS: I certify that the option of monovision has been discussed with my optometrist and/or ophthalmologist.

PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING

I certify that the details of the procedure known as LASEK/PRK have been presented to me in detail in this document and explained to me by Dr. McMann. Dr. McMann has answered all my questions to my satisfaction. I therefore consent to LASEK/PRK surgery on my (please check which eye(s) surgery is to be performed on):

_____ **Right** eye _____ **Left** eye _____ **Both** eyes

To assure that you understand the information presented, please WRITE the following statements in your own handwriting, "*I understand the information presented and I have had all of my questions answered to my satisfaction. I am making an informed decision in giving my permission to have LASEK/PRK surgery performed on my (please write in your own handwriting which eye(s) are to be performed).*"

I give permission for Dr. McMann to record on video or photographic equipment my procedure, for purposes of education, research, or training of other health care professionals. I also give my permission for Dr. McMann to use data about my procedure and subsequent treatment to further understand LASEK/PRK. I understand that my name will remain confidential, unless I give subsequent written permission for it to be disclosed outside Dr. McMann's office or the center where my LASEK/PRK procedure will be performed.

_____ _____

Patient Signature Date Witness Signature Date

_____

Michael A. McMann, MD Date

I have been offered a copy of this consent form (please initial). _____

Addendum: Consent for Bilateral Simultaneous LASEK/PRK

LASEK/PRK has become a common procedure for many refractive surgery patients. While many patients choose to have both eyes treated at the same surgical setting, there may be risks associated with simultaneous treatment that are not present when the eyes are treated on different days**. If you elect to have surgery performed on both eyes at the same time, you should understand both the possible advantages and disadvantages of your decision**.

Safety: The risks of infection, severe inflammation, delayed clouding of the cornea, corneal scarring and internal bleeding or retinal damage are very rare but potentially devastating. If these complications occur in one eye, they may also occur in the other. Should any of these complications happen, you could experience significant loss of vision or even temporary or permanent legal blindness. By choosing to have LASEK/PRK performed on separate days, you avoid the risk of having one or more of these complications in both eyes at the same time.

Accuracy: If there is an over-correction or under-correction in one eye, chances are it may happen in both eyes. If a retreatment is required in one eye, it is quite possible that your fellow eye may also require a retreatment. By having surgery on separate days, the doctor can monitor the healing process and visual recovery in the first eye and may be able to make appropriate modifications to the treatment plan for the second eye. In some patients, this might improve the accuracy of the result in the second eye. By correcting both eyes simultaneously, there is no opportunity to learn from the healing patterns of the first eye before treating the second eye.

Visual Recovery: Most LASEK/PRK patients experience visual recovery over a period of 1-2 weeks. During this time, some patients may experience symptoms such as blurred vision, night glare or ghost images that can result in prolonged recovery of normal vision. Blurred vision may rarely continue for more than several weeks, which could make driving difficult or dangerous and could interfere with your ability to work if it occurs in both eyes. There is no way of predicting how long your eyes will take to heal. If the eyes are operated separately, you can generally function with the fellow eye while the first eye fully recovers. However, there may be a period of imbalance in vision between your two eyes, producing a form of double vision. If you are able to wear a contact lens in your unoperated eye, the corrective lens could minimize this imbalance. The balance in vision between your two eyes will usually be restored more rapidly if they are operated on the same day.

Satisfaction: Both eyes tend to experience similar side effects. If you experience undesirable side effects such as **PAIN,** glare, ghost images, increased light sensitivity, or corneal haze in one eye, you will likely experience them in both eyes. These side effects may cause a decrease in vision or other negative effects, and some patients have elected to not have their second eye treated. By having each eye treated on separate dates, you will have the opportunity to determine whether the LASEK/PRK procedure has produced satisfactory visual results without loss of vision or other uncommon

undesirable side effects. However, if you experience significant **PAIN** from the surgery and recovery, this will likely occur again when the second eye is treated.

Convenience: It may be inconvenient for you to have each eye treated at separate visits because it would necessitate two periods of recovery from the laser surgery and might require additional time away from work.

Cost: Professional and facility fees may be greater if the eyes are operated on different days, and the additional time off work that may also be needed can be costly.

Consent Statement:

I have read and understand the above risks and benefits of bilateral simultaneous LASEK/PRK, and I understand that this summary does not include every possible risk, benefit and complication that can result from bilateral simultaneous LASEK/PRK. Dr. McMann has answered all of my questions to my satisfaction about the LASEK/PRK procedure. I wish to have both of my eyes treated during the same treatment session if Dr. McMann determines that the treatment in the first eye appeared to be technically satisfactory.

The reason(s) I wish to have both eyes treated at the same time are:

☐ Greater convenience
☐ Possible faster recovery
☐ Less time away from work
☐ Contact lens intolerance and/or difficulty wearing contacts
☐ Elimination of possible vision imbalance between treated and untreated eyes

☐ Other:_____

_____ _____
Patient Signature Date

_____ _____
Witness Signature Date

_____ _____
Michael A. McMann, MD Date