PATIENT _____DATE _____ OD OS

INFORMED CONSENT FOR INTRAVITREAL INJECTION OF TRIAMCINOLONE ACETONIDE

INDICATIONS AND POSSIBLE BENEFITS

Your eye doctor (ophthalmologist) has diagnosed you with and eye condition that causes swelling (edema or inflammation), leakage from the blood vessels in the eye, and/or abnormal growth of blood vessels. Triamcinolone acetonide is a steroid injected into the jelly or vitreous portion of the eye; we will refer to this type of injection of this drug as IVTA. IVTA reduces the swelling, leakage, and abnormal blood vessel growth, and may improve how well you see.

"OFF-LABEL" STATUS

Triamcinolone acetonide is approved by the Food and Drug Administration (FDA) to treat the swelling caused by many medical conditions. It can be injected into a muscle, the skin, or a joint. Once a medication is approved by the FDA, physicians may use it "off-label" for other purposes if it will benefit their patient. Before doing so, they are expected to know the medication well and have sound medical evidence for its use. Although the FDA did not approve this drug to treat eye conditions, ophthalmologists have been injecting this medication in and around the eye for over 30 years, since studies have shown that it helps treat eye conditions like yours. There are serious risks from this type of injection and from the medication itself. The FDA asked the manufacturer to warn physicians about these risks, and to recommend that they not inject them into and around the eye. Despite these known risks and the manufacturer's warning, the FDA has stated that physicians may continue to inject it for eye conditions. Your ophthalmologist feels that this medication is the right one for your condition at this time. Injecting it in you eye instead of giving a pill or drops helps to **minimize** the side effects and **maximize** the benefits.

POSSIBLE LIMITATIONS AND ADMINISTRATION

The goal of treatment is to prevent further loss of vision. Although some patients have regained vision, the medication may not restore vision that has already been lost, and may not ultimately prevent further loss of vision caused by your disease. After the pupil is dilated and the eye is numbed with anesthesia, the medication is injected into the vitreous, the jelly-like substance in the back part of the eye. IVTA is administered by an injections into your eye as needed; your ophthalmologist will tell you how often you will receive the injection, and for how long.

ALTERNATIVES

You do not have to receive IVTA treatment for your condition, although without treatment, diseases like yours can lead to further vision loss and blindness, sometimes very quickly. Your ophthalmologist will let you know if other medications are available for your condition, whether laser or other types of surgery are the only alternatives, and whether these treatments have already been tried but have not helped your condition.

COMPLICATIONS FROM THE MEDICATION AND INJECTION

Your condition may not get better or it may become worse. Any or all of these complications discussed below may cause you to lose vision or cause blindness. Additional medications or procedures, including surgery, may be needed to treat these complications. During the follow up visits or phone calls, you will be checked for possible side effects and the results will be discussed with you.

Possible complications and side effects of IVTA include but are not limited to retinal detachment, cataract formation (clouding of the lens of the eye), glaucoma (increased pressure into the eye), hypotony (reduced pressure in the eye), damage to the retina or cornea (structures of the eye), and bleeding. There is also the possibility of an eye infection (endophthalmitis). You will receive eye drops with instructions on when to use them to reduce the possibility of this occurring. Any of these rare complications may lead to severe, permanent loss of vision.

Patients receiving IVTA may experience less severe side effects related to the pre-injection preparation procedure (eyelid speculum, anesthetic drops, dilating drops, antibiotic drops, povidone-iodine drops and the injection of the anesthetic). These side effects may include eye pain, subconjunctival hemorrhage (bloodshot eye), vitreous floaters, irregular or swelling of the cornea, inflammation of the eye, and visual disturbances.

PATIENT CONSENT

The above explanation has been read by/to me. The nature of my eye condition has been explained to me and the proposed treatment has been described. The risks, benefits, alternatives, and limitations of the treatment have been discussed with me. All of my questions have been answered.

I understand that triamcinolone acetonide was approved by the FDA for injections into muscles, the skin, and joints and that it has not been approved for injection in or around the eye to treat eye conditions. Nevertheless, I wish to be treated with triamcinolone acetonide, and I am willing to accept the potential risks that my physician has discussed with me.

Patient initials _____

I will take all prescribed medications exactly as ordered and will immediately contact my ophthalmologist if any of the following signs of infection or other complications develop; pain, blurry or decreased vision, sensitivity to light, redness to the eye (compared to immediately after the injection), or discharge from the eye. I have been instructed NOT to rub my eyes or swim for three days after each injection. I will keep all post-injection appointments or scheduled telephone calls so my doctor can check for complications.

Patient initials _____

I hereby authorize Dr. _____ to administer the intravitreal injection of triamcinolone acetonide in my _____ (state “right” or “left”) eye at regular intervals as needed. This consent will be valid unless I revoke it by refusing an injection or my condition changes to the point that the risks and benefits of this medication for me are significantly different.

_____ _____

Patient’s Signature Date

_____ _____

Witness’s Signature Date

_____ _____

Physician’s Signature Date