INFORMED CONSENT FOR INTRAVITREAL KENALOG™ (TRIAMCINOLONE) INJECTION (IVKI)

INDICATIONS AND POSSIBLE BENEFITS
You have been diagnosed with an eye condition that causes swelling, inflammation, leakage from the blood vessels in the eye, and/or the abnormal growth of blood vessels. Triamcinolone acetonide (Kenalog™) is a steroid which can be injected into the jelly or vitreous portion of the eye. IVKI reduces the swelling, leakage, and abnormal blood vessel growth, and may improve how well you see.

"OFF-LABEL" STATUS INFORMATION
Kenalog,™ is approved to treat the swelling caused by many medical conditions, but is not approved for use in the eye. Triesence™ and Trivaris™ are forms of triamcinolone that are approved by the Food and Drug Administration (FDA) for certain eye conditions such as sympathetic ophthalmia, temporal arteritis, uveitis, and when the inflammation caused by other eye conditions does not improve with steroid eye drops. Retina specialists use triamcinolone in its various forms to treat many other eye conditions. The use of a medication for an "off-label" purpose is a legal and necessary part of the practice of medicine. The FDA has confirmed that once it approves a medication, physicians may use it "off-label" for other purposes if that use will benefit their patient. "Off-label use of a medication is appropriate when there is sound medical evidence for its use.

POSSIBLE LIMITATIONS
The goal of treatment with IVKI 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.

ADMINISTRATION
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. IVKI is administered into your eye as needed.

ALTERNATIVES
You do not have to receive IVKI treatment for your condition, although without treatment, diseases like yours can lead to further vision loss and blindness, sometimes very quickly.

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, 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 in 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). Any of these rare complications may lead to severe, permanent loss of vision.

Patient Initials_____

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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, irregularity 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 Kenalog™ 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 Kenalog™, and I am willing to accept the potential risks that my physician has discussed with me.

- 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 of 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.

- I hereby authorize Dr. Claron D. Alldredge to administer the intravitreal injection of TA 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 Date