INFORMED CONSENT FOR INTRAVITREAL AVASTIN™ (BEVACIZUMAB) INJECTION

INDICATIONS AND POSSIBLE BENEFITS

You have been diagnosed with an eye condition that causes leakage from the blood vessels in the eye, and/or the abnormal growth of blood vessels. Avastin™ works by blocking a substance known as vascular endothelial growth factor or VEGF. This growth factor causes existing blood vessels to leak which leads to swelling and causes new blood vessels to grow. The new blood vessels can cause damage inside the eye. Blocking or inhibiting VEGF helps prevent further growth of the blood vessels and reduce blood vessel leakage and swelling. Avastin is commonly used by retina specialists to treat a variety of conditions including, but not limited to, age related macular degeneration, histoplasmosis, angioid streaks, trauma, diabetic retinopathy, retinal vein occlusions, and neovascular glaucoma. Avastin frequently reduces the swelling, leakage, and abnormal blood vessel growth, and may improve how well you see.

"OFF-LABEL" STATUS INFORMATION

Avastin™ was approved by the Food and Drug Administration (FDA) for the treatment of metastatic colorectal cancer, but is not approved for use in the eye. Macugen™ and Lucentis™ are other medications that block VEGF and are approved by the Food and Drug Administration (FDA) for certain eye conditions such age related macular degeneration. Retina specialists use Avastin™ to treat many 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 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 the disease.

ADMINISTRATION

Avastin™ is administered by an injection into your eye. After the pupil is dilated and the eye is numbed with anesthesia and sterilized with antiseptic, the medication is injected into the vitreous, a jelly-like substance in the back chamber of the eye.

ALTERNATIVES

You do not have to receive treatment for your condition, although without treatment, these diseases can lead to further vision loss and blindness, sometimes very quickly. Other forms of treatment are available. At present, there are three FDA-approved treatments for neovascular age-related macular degeneration. Many other conditions are treated with these medications "off-label." The first two are photodynamic therapy with a drug called Visudyne™ and injection into the eye of a drug called Macugen™. Although both of these treatments have been proven to slow down the rate of visual loss, most people do not get back better vision. The third medication, Lucentis™ is similar to Avastin™**.** In addition to the FDA-approved medications intravitreal Kenalog™—a long-acting cortisone-like drug—"off-label" to treat eye conditions like yours.

COMPLICATIONS FROM THE MEDICATION AND INJECTION

Complications when Avastin™ is given to patients with cancer

When Avastin™ is given to patients with metastatic colorectal cancer, some patients experienced serious and sometimes life-threatening complications, such as gastrointestinal perforations or wound healing complications, hemorrhage, arterial thromboembolic events (such as stroke or heart attack), hypertension, proteinuria, and congestive heart failure.

Patients who experienced these complications not only had metastatic colon cancer, but were also given 400 times the dose you will be given, at more frequent intervals, and in a way (through an intravenous infusion) that spread the drug throughout their bodies.

Patient Initials_____

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Risk when Avastin™ is given to treat patients with eye conditions
Ophthalmologists believe that the risk of these complications for patients with eye conditions is very low. Patients receiving Avastin™ for eye conditions are healthier than the cancer patients, and receive a much smaller dose, delivered only to the cavity of their eye. While there are no FDA-approved studies about the use of Avastin™ in the eye that prove it is safe and effective, Lucentis™, a similar drug, was recently approved for AMD. One study of patients who received Avastin™ through an intravenous infusion reported only a mild elevation in blood pressure. Another study of patients treated like you will be with intravitreal Avastin™ did not have these elevations in blood pressure or the other serious problems seen in the patients with cancer.

The benefits and risks of intravitreal Avastin™ for eye conditions are not yet fully known. In addition, whenever a medication is used in a large number of patients, a small number of coincidental life-threatening problems may occur that have no relationship to the treatment. For example, patients with diabetes are already at increased risk for heart attacks and strokes. If one of these patients being treated with Avastin™ suffers a heart attack or stroke, it may be caused by the diabetes and not the Avastin™ treatment.

Known risks of intravitreal eye injections
Your condition may not get better or may become worse. Any or all of these complications may cause decreased vision and/or have a possibility of causing blindness. Additional procedures may be needed to treat these complications.

Possible complications and side effects of the procedure and administration of Avastin™ 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.

Patients receiving an injection of Avastin™ 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 my questions have been answered.

- I understand that Avastin™ was approved by the FDA for the treatment of metastatic colorectal cancer, and has not been approved for the treatment of eye conditions. Nevertheless, I wish to be treated with Avastin™, and I am willing to accept the potential risks that my physician has discussed with me.

- I hereby authorize Dr. Alldredge to administer the intravitreal injection of Avastin™ as needed. This consent will be valid until I revoke it 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