INFORMED CONSENT FOR
AVASTIN TM (BEVACIZUMAB) INTRAVITREAL INJECTION

INDICATIONS:
Abnormal growth of new blood vessels beneath the macula (area of fine central vision in the retina) can occur in conditions such as Age-related macular degeneration (AMD), myopia, histoplasmosis, angioid streaks, and eye injury. Sometimes there is no known reason for the abnormal blood vessels. These abnormal blood vessels leak fluid, blood and protein beneath the retina resulting in vision loss that may become severe and permanent without treatment.

Swelling of the central retina (macular edema) can occur in many conditions such as diabetic retinopathy, retinal vein occlusion etc., The swelling can result in vision loss that can progress and become permanent without treatment.

POSSIBLE BENEFITS AND “OFF-LABEL” STATUS:
Avastin™ was not initially developed to treat your eye condition but for treatment of metastatic colorectal cancer. Avastin has been extensively used as an “off-label” drug in ophthalmology. “Off-label" in regards to usage of avastin in your eye means that avastin was not developed for use in the eye. But based on existing sound medical evidence, your ophthalmologist considers that usage of avastin will benefit your eye condition and hence suggests it as an option for treating your eye.

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 the 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 chamber of the eye. Avastin™ is administered by an injection into your eye as needed at regular intervals (about every four to six weeks);
your ophthalmologist will tell you how often you will receive the injection, and for how long.

**ALTERNATIVES:**
You do not have to receive treatment for your condition, although without treatment, these diseases can lead to further vision loss and blindness.

The approved options as of now for treating your eye condition are Lucentis and Accentrix (Novartis), Eyelea (Bayer), Razumab (Intas). Some patients with macular edema may also benefit from Ozurdex (Allergan) a steroid implant.

**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.

**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 low. Patients receiving Avastin® for eye conditions are healthier than the cancer patients, and receive a significantly small dose, delivered only to the cavity of their eye. Two large trials and a large compilation of data comparing Avastin to other similar drug have found Avastin to be as safe as the other FDA approved drug.

**Known risks of intravitreal eye injections:**
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 a serious eye infection (endophthalmitis). Any of these rare complications may lead to severe, permanent loss of
vision, particularly endophthalmitis, which may rarely result in loss of the eye as well. 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 RESPONSIBILITIES:
I 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 so my doctor can check for complications.

____________ Patient initials

Although the likelihood of serious complications affecting other organs of my body is low, I will immediately contact my primary care physician or go to the Emergency Room if I experience abdominal pain associated with constipation and vomiting, abnormal bleeding, chest pain, severe headache, slurred speech, or weakness on one side of the body. As soon as possible, I will also notify my ophthalmologist of these problems.

__________ Patient initials

I will inform my ophthalmologist if I need to have any surgery, and I will inform any other surgeon, including dentists, that I am on a medication that needs to be stopped before I can have surgery.

_________ Patient initials

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.

Patient initials

I hereby authorize Dr. __________ to administer the intravitreal injection of Avastin™ in my ________ (state “right” or “left”) eye at regular intervals 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.

CONSENT OBTAINED AFTER EXPLAINING TO THE PATIENT IN __________________ LANGUAGE

EXPLAINED BY ____________________________

WITNESS NAME AND SIGNATURE ____________________________

__________________________  ____________________________
Patient’s Signature  Date

__________________________  ____________________________
Witness’s Signature  Date