PLACE LETTERHEAD HERE AND REMOVE NOTE

Note: This form is intended as a sample form of the information that you as the surgeon should personally discuss with the patient. Please review and modify to fit your actual practice. Give the patient a copy and send this form to the hospital or surgery center as verification that you have obtained informed consent.

NOTE TO PHYSICIANS: REMOVE THIS SECTION FROM CONSENT FORM

- Patient selection: to determine if patients are eligible for Macugen™, they should be evaluated for lesion type, location, and size, and have at least an initial fluorescein angiogram.
- To prevent complications associated with intravitreal injections such as endophthalmitis, retinal detachment, and increased intraocular pressure, review the latest guidelines on care before, during, and after injections. One source is the article by Flynn, Harry W., Scott, Ingrid U., Evolving Guidelines for Intravitreous Injections. *Retina* 24:S3-S19, 2004.
- Macugen injections are given every six weeks for up to a year or longer. In general, informed consent may be considered to have continuing force and effect until the patient revokes the consent or until circumstances (e.g., the patient's medical or ocular condition) change so as to materially affect the nature of the procedure or the risk/benefit ratio. Prior to subsequent injections, the continued need, effectiveness, and safety of the medication should be evaluated and documented. If the patient's medical or ocular condition changes to the point that the risk/benefit ratio is affected, it would be prudent to either discontinue treatment or obtain and document informed consent again.
- The FDA approval states that only one eye at a time should be injected. The FDA also notes that the safety and efficacy of Macugen after two years has not been demonstrated, and that Macugen was noted to be less effective the second year. Further studies should provide guidance in the use of Macugen for greater than two years.

CONSENT FOR MACUGEN™ INTRAVITREAL INJECTION

Patient:_____ **Record #:**_____

INDICATIONS

You have an eye condition called age-related macular degeneration (AMD). AMD is the leading cause of blindness in people over 50 years of age. It is caused by the breakdown of the central portion of the retina (the nerve layer part of your eye that works like the film in a camera to pick up the picture) called the macula. The macula is responsible for the fine central vision in the eye that is needed for driving a car, reading fine print, recognizing faces, etc. There are two types of macular degeneration: dry and wet. In the "wet" form of AMD, abnormal blood vessels grow in the back of the eye. Sometimes these vessels leak blood or fluid that causes blurred or distorted vision. Vision loss may be quick and severe.

ADMINISTRATION AND BENEFITS

Macugen™ works by stopping the growth of new blood vessels that damage the macula. The goal is to slow down the vision loss. Although a number of patients have regained some vision, the medication may not restore vision that has already been lost. After the pupil is dilated and the eye is numbed with anesthesia, the medication is injected into the vitreous, or jelly-like substance in the back chamber of the eye. Macugen™ is administered by an injection into your eye every six weeks for up to one year or longer.

ALTERNATIVES

You do not have to receive treatment for your condition, although without treatment, the disease can lead to further vision loss and blindness. Other forms of treatment may be available, such as focal laser photocoagulation or photodynamic therapy. Your doctor will discuss with you the benefits and risks associated with other choices of treatment.

COMPLICATIONS FROM THE MEDICATION AND INJECTION

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. During the follow up visits or phone calls, you will be checked for possible side effects and the results will be discussed with you.

Macugen™ may cause allergic reactions in a small number of people. Symptoms of an allergic reaction can include a rash, hives, itching, shortness of breath, and rarely death. In general, allergic reactions to medicines are more likely to occur in people who have allergies to other drugs, foods, or things in the environment, such as dust or grass. If you have allergies to other medicines, foods, or other things in the environment, or if you have asthma, you should let your doctor know.

Possible complications and side effects of the procedure and administration of Macugen™ 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). You may receive eye drops with instructions on when to use them to reduce the possibility of this occurring.

Patients receiving an injection of Macugen™ may experience some 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, cataract, and visual disturbances.

The most frequently reported adverse events in patients treated with Macugen™ are anterior chamber inflammation (inflammation inside the eye), blurred vision, cataract, conjunctival or subconjunctival hemorrhage, corneal edema, eye discharge, eye irritation, eye pain, increased intraocular pressure (IOP), ocular discomfort, punctate keratitis (irritation of the cornea), reduced visual acuity, visual disturbance, vitreous floaters, and vitreous opacities.

PATIENT RESPONSIBILITIES

I will contact my ophthalmologist immediately 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.

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 hereby authorize Dr. _____ to administer the intravitreal injection of Macugen™ in my _____ Right eye _____ Left eye eye every six weeks. 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 Signature (or Person Authorized to Sign for Patient) Date