

Name _____ DOB _____

INFORMED CONSENT FOR EYLEA™ (aflibercept) INTRAVITREAL INJECTION

INDICATIONS

EYLEA™ is approved by the Food and Drug Administration (FDA) to treat an eye condition called age-related macular degeneration (AMD), which is the leading cause of blindness in people over 50 years of age. 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. Without treatment, vision loss may be quick and severe.

POSSIBLE BENEFITS, LIMITATIONS, AND ADMINISTRATION

EYLEA™ works by inhibiting the growth of the abnormal blood vessels that cause AMD; it also decreases swelling of the macula. 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. The eye is numbed with anesthesia, the medication is injected into the vitreous, or jelly-like substance in the back chamber of the eye. **EYLEA™** is administered by an injection into your eye initially as needed, and then at regular intervals (about every eight 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, AMD and macular edema can lead to further vision loss and blindness, sometimes very quickly. Other forms of treatment are available. At present, there are other FDA-approved treatments for neovascular AMD: photodynamic therapy with a drug called Visudyne™, and injection into the eye of a drug called Macugen™ or Lucentis™. Although these treatments have been proven to slow down the rate of visual loss, most people do not get back better vision. In addition to the FDA-approved medications, some ophthalmologists use Avastin™ which is a similar drug, used off-label, for the treatment of AMD or macular edema.

COMPLICATIONS FROM THE MEDICATION AND INJECTION

Complications of EYLEA™

Your condition may not get better or may become worse. Any or all of the following 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.

Although not common, some patients have had eye and non eye related blood clots (heart attacks, strokes, and death). If you have had a stroke or heart attack, you should discuss this issue with your physician. 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.

