**Remove the section in red.**

**Add your letterhead to the first page of the consent form.**

**Keep each section together on the same page: move it as needed.**

**Change font size for large print.**

**Version 3/13/20**

**There are two Lucentis forms**

* Use this form for all adult patients receiving Lucentis
* Ask women of child-bearing age to sign a second document about the possible risk to the fetus.
	+ We developed the second document in response to the safety warning issued by the FDA in June, 2015. The FDA changed the safety labeling for intravenous Avastin, adding a section on embryo-fetal toxicity. In that warning, the FDA instructs physicians to “advise females of reproductive potential to use effective contraception during treatment with and for 6 months after the last dose of Avastin.” It is not clear whether intravenous Avastin causes harm to the human fetus. The FDA warning did not address intravitreal Avastin, as this use is off-label. It also did not address intravitreal Lucentis. To reduce the potential liability for ophthalmologists using anti-VEGF drugs, we feel it is prudent to address this potential risk with pre-menopausal women. Ask them to sign the “possible risk to the fetus” form [www.omic.com/lucentis-risk-to-fetus/](http://www.omic.com/lucentis-risk-to-fetus/).

**This is a sample consent form.** OMIC policyholders are not required to use it. Be sure to review it and modify it to suit your actual practice.

**Document your informed consent discussion.** Documentation about the discussion and use of a procedure-specific consent form help defend you against allegations of lack of informed consent.

**Offer the patient a copy** **of your consent form**. Encourage the patient to read it again at home with his or her family, and to call with any questions.

**This version of the Lucentis consent form is written using “plain language” principles.**

The goal is to make the document easy for your patients to understand. Here are some of the changes we made. Ophthalmologists use a number of anti-VEGF drugs. We included the names of these drugs in our prior sample consent forms. When we field tested the new form, patients found the names very distracting, so we removed them and stated in the Alternatives section that there are other drugs available to treat their eye problem. Patients also had a difficult time reading the document when it defined the various diseases that Lucentis is used to treat, such as age-related macular edema and diabetic retinopathy. We, therefore, removed disease names from the form. Instead, the form now explains that Lucentis is used to treat the growth of blood vessels in the eye and swelling in the back of the eye. You know your patients and can decide which type of form works best for your practice. You may decide to keep using your current consent form.

**Review our risk management recommendations on the use of anti-VEGF drugs in adults.**

This loss prevention document addresses on- and off-label use, preventing endophthalmitis, informed consent issues, and documentation. It incorporates key guidelines on intravitreal injection published by a panel of experts. It also addresses the FDA warning about Avastin in more detail. Here is a link to the risk management recommendations [www.omic.com/anti-VEGF-drugs-in-adults/](http://www.omic.com/anti-VEGF-drugs-in-adults/).

**Informed consent for Lucentis™ (ranibizumab)**

Ophthalmologists (eye surgeons) treat some types of eye problems with a medication called Lucentis. Lucentis can help decrease vision loss due to 2 types of eye problems:

1. The growth of harmful blood vessels in your eyes
2. Swelling in the back of the eye (macular edema).

**Lucentis is given by an injection (shot) into the back of your eye.** The ophthalmologist may put eye drops to enlarge the pupil (black circle) in the center of your eye to see the back of your eye clearly. Next, the ophthalmologist will numb your eye as much as possible so that you do not feel pain. Then the ophthalmologist injects Lucentis into the back part of your eye. Most patients need Lucentis injections about every 4 weeks because its effect wears off over time. Your ophthalmologist will tell you how often you will need Lucentis injections.

**You may have some minor problems right after the injection.**

* Your vision might be blurry right after the injection. Do not drive or use machines until your vision gets better.
* Your eye may be irritated and make a lot of tears for a few hours.
* The white part of your eye might turn bright red. This is from a small amount of bleeding on the surface of your eye. It will not change how well you see. This will clear up in a few days or a week.
* You might see small specks called floaters. Many people already have floaters. These new floaters may go away in a few days, or you may stop noticing them. Some floaters are drops of the oil that lubricates the syringe. These will not go away.

**Tell the ophthalmologist right away if you notice any other problems after the injection such as:**

* Eye pain, blurry or decreased vision, extra sensitivity to light, eye redness, and pus or other discharge coming from the eye.
* New or large floaters that do not go away.
* Flashing lights or decreased side vision with the floaters.

You can help prevent or reduce these problems. Do not rub your eyes or go swimming for 3 days after each injection. Call your ophthalmologist right away if you notice any of these problems. Keep all appointments with your ophthalmologist.

**Benefits (how this medication can help).** The goal of using Lucentis for eye problems is to prevent more vision loss. But Lucentis may not bring back vision loss that happened before treatment.

**Alternatives (choices and options).** Lucentis is not the only option. Your other treatment choices may include:

* No treatment. If you decide not to have treatment, then your eye problems can quickly get worse. You could have more vision loss or even blindness.
* Other medications approved by the Food and Drug Administration (FDA) for treating your type of eye problem.
* Other medications approved by the FDA for a different condition. Ophthalmologists use these medications “off-label” because they can help slow the growth of harmful eye blood vessels and lessen swelling that decreases vision.
* Your ophthalmologist will tell you how the risks and benefits of these medications.

**Risks (problems this medication may cause).** As with all medications, there are risks from getting Lucentis injections in the eye. These risks can cause vision loss or blindness. Your ophthalmologist cannot tell you about every risk. Here are some common or serious ones:

* Lucentis might not improve your vision. Your vision may get worse.
* Lucentis injections can cause other eye problems such as:
	+ An eye infection
	+ Detached retina (the light-sensitive part of the back of your eye might get pulled off)
	+ Cataracts (clouding of the eye’s lens)
	+ Glaucoma (increased eye pressure)
	+ Hypotony (reduced eye pressure)
	+ Retina or cornea damage
	+ Bleeding within the eye
	+ Inflammation inside the eye that can cause vision loss, pain, or redness
* Some patients taking this medication have had heart attack, stroke, or death. The FDA does not know if the medicine caused these problems. Patients with diabetes may have these problems more often. Tell your ophthalmologist if you have had a heart attack or stroke.
* Eye problems from Lucentis can appear days, weeks, months, or even years after your injection. The costs to treat these are not included in the fee you pay for the Lucentis injection.

**By signing below, you consent (agree) that:**

* You read this informed consent form or had it read to you.
* You were told you have harmful blood vessels or swelling in the back of your eye.
* Your questions about using Lucentis to treat your eye problem have been answered.
* You consent to have the ophthalmologist inject Lucentis into your \_\_\_\_\_\_\_\_\_\_\_ (“right,” “left”, or “both”) eye(s).
* You consent to keep having Lucentis injections unless you tell your ophthalmologist that you no longer want the medication or your eye problems change so much that there are new risks and benefits to discuss with the ophthalmologist.

Patient (or person authorized to sign for patient) Date