This form is intended as a sample. It does not constitute the standard of care nor does it provide legal advice. It contains the information OMIC recommends the surgeon personally discuss with the patient.

**How to use this sample**

* Please modify it to fit your actual practice.
* **Remove this instruction box.**
* Add your letterhead to the first page of the consent form.
* Change font size if necessary.

**After the patient signs the form**

* Give the patient a copy of the signed form.
* Send a copy to the hospital or surgery center as verification that you have obtained informed consent.
* Keep the original in the patient’s medical record.

**Version** 07/01/2015

**There are four parts to the plain-language cataract consent forms:**

* Use the main cataract consent form for all patients having cataract surgery [www.omic.com/cataract-plain-language-consent-forms/](http://www.omic.com/cataract-plain-language-consent-forms/)
* Add an addendum if needed:
  + Astigmatism correction: use for toric IOL and relaxing incisions [www.omic.com/astigmatism-correction/](http://www.omic.com/astigmatism-correction/)
  + Presbyopia correction: use for presbyopia-correcting IOLs and monovision [www.omic.com/presbyopia-correction/](http://www.omic.com/presbyopia-correction/)
  + Laser-assisted cataract surgery: use for laser-assisted cataract surgery or laser relaxing incisions [www.omic.com/laser-assisted-cataract-surgery/](http://www.omic.com/laser-assisted-cataract-surgery/)
    - Remove the paragraph about relaxing incisions if you are using the laser without creating one (e.g., implantation of a premium IOL without a relaxing incision)
* You may want to create forms for astigmatism, presbyopia, or laser-assisted surgery that contain both the main consent form and the appropriate addendum.

**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.

**These cataract consent forms are written using “plain language” principles.**

The goal is to make the document easy for your patients to understand. Patients facing cataract surgery are asked to make a number of decisions, including whether to have a premium IOL, how to correct astigmatism and presbyopia, and if they want laser-assisted cataract surgery. Many patients are not suitable candidates for these options, or do not have the resources to pay the additional fees for them. We did not want patients to feel confused or overwhelmed by information about procedures they may not have. For that reason, we limited the information in our basic cataract consent form. It is for patients who will have a monofocal IOL and wear glasses to correct astigmatism or presbyopia. We developed “plain language” additions to address other options.

**This document does not contain all the information patients needs to know about cataract surgery options.** Instead, it contains brief, basic information about key aspects of cataract surgery. For example, the presbyopia addendum explains presbyopia and lists monovision and premium IOLs as the two options to treat it. It does not describe the difference between the types of presbyopia-correcting IOLs. The astigmatism consent offers a toric IOL or a relaxing incision, but does not distinguish between manual limbal relaxing incisions or arcuate incisions created with the femtosecond laser. You and your staff will, therefore, need to educate your patients before asking them to sign the consent. Provide enough information so that they can make decisions about the various options you offer. Consider providing educational materials, such as the AAO’s pamphlets, as well as brochures from the manufacturer of the premium IOL. Document your educational efforts.

**Decide what is best for your patient population.** We field tested these forms. Most patients found them easier to understand than our prior sample cataract forms, and felt less confused about the many options. A few patients preferred detailed forms with more technical information. You know your patients best, and can decide which type of form works best for your practice. You may decide to keep using your current cataract consent form.

**Ophthalmologists in Florida** **should continue to use the cataract consent form approved by the Florida state board of medicine**. Use of the Florida form helps defend eye surgeons from allegations of lack of informed consent. Just as importantly, no report to the Medical Board is required if the patient experiences complications listed in this state-specific form. <http://www.omic.com/cataract-consent-form-fl-specific/>.

**Laser-Assisted Cataract Surgery**

**The femtosecond laser** **(FS laser)** is a medical tool the eye surgeon may use to perform some of the steps of cataract surgery. The eye surgeon uses the laser instead of a surgical blade and other tools. The laser makes a cut in the cornea (the front window of the eye). It is also used to make a circular opening in the outer layer of the cataract. It can help break up the cataract.

**The FS laser can also treat astigmatism during the cataract surgery.** Astigmatism causes blurry vision. Normally, eyes are round (like a baseball). With astigmatism, the eye is long (like a football). Glasses can treat this. Or eye surgeons can treat astigmatism during cataract surgery by making a cut in the cornea to change its shape. This cut is called a **relaxing incision.**

You have to pay extra for a relaxing incision.Medicare and private insurance do not pay for this.

**There may be more risk if the FS laser is used after refractive surgery.** Refractive surgery is a procedure that makes you see better (improves your refraction) by changing the shape of the cornea, the clear front of the eye.The FS laser uses suction. If you have had a type of refractive surgery called LASIK, the suction could open up or move the flap. If you have had other refractive surgeries called AK or RK, the suction could open up the old wound. If the flap or the wound is opened up or moved, this could cause leaking, astigmatism, or scarring.

**The use of the FS laser on patients who have had refractive surgery is considered “off-label.”** This means that the U.S. Food and Drug Administration (FDA) approved the laser for cataract surgery on the eyes of patients who have not already had refractive surgery. When eye surgeons use the laser during cataract surgery on patients who have had refractive eye surgery, its use is considered “off-label”. Your visual outcome after surgery may not be as good if these problems happen.

**Risks.** As with all surgery and medical procedures, problems can happen. In addition to all the risks for cataract surgery, here are some common or serious risks for the FS laser.

* The cornea could be scratched. You could have an infection, bleeding, damage to your eye, fluid leakage from the eye, or increased eye pressure.
* More time may be needed to perform the surgery. You may need to be taken to two different locations or two different rooms to perform the surgery.
* The cuts into the cornea and the cataract might be off-center, incomplete, or broken up. If this happens, the FS laser can be used again or the eye surgeon could use a blade to cut the cornea.
* The sack containing the cataract might tear, allowing pieces of the cataract to move into the back of the eye. If this happens, you may need another surgery called a vitrectomy to remove the cataract pieces.

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

* You read this informed consent form or someone read it to you.
* You understand the information in this consent form.
* The eye surgeon or staff offered you a copy of this form.
* The eye surgeon or staff answered your questions about the FS laser.

**I consent to:**

**☐ Use of the FS laser for some of the steps of the cataract surgery operation** on my \_\_\_\_\_\_\_\_\_\_ (state “right” or “left”) eye.

.

**☐ Use of the FS laser to create a relaxing incision** in my \_\_\_\_\_\_\_\_\_\_ (state “right” or “left”) eye.

Patient (or person authorized to sign for patient) Date