**[Your Letterhead]**

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 practice.
* **Delete 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** 05/05/23

**Informed Consent for RxSight’s Light Adjustable Lens**

**What is a cataract and how is it treated?**

You have consented to cataract surgery because the lens in your eye has become cloudy, causing blurred vision, dulled vision, sensitivity to light and glare, and/or ghost images. Your ophthalmologist will replace your cloudy lens with an intraocular lens (IOL). Your ophthalmologist is recommending the RxSight Light Adjustable Lens (RxLAL™).

**What is the RXSight Light Adjustable Lens and how will this IOL affect my vision?**

The RxSight Light Adjustable Lens (RxLAL™) is similar to other intraocular lenses (IOLs) that can be implanted in your eye to replace the natural lens that is removed during cataract surgery. While all IOLs are intended to improve vision after cataract surgery, most patients will require glasses (or contact lenses) to improve their vision to the level required for driving or reading. The RxLAL™ may reduce the need for glasses or contact lenses because the focusing power of the IOL can be adjusted after your cataract surgery to meet your particular needs. These adjustments are made beginning 2-4 weeks after your cataract surgery by applying specific patterns of ultraviolet (UV) light to the IOL to change its shape, which results in changes to the refractive correction of your vision. The UV light is delivered with the RxSight Light Delivery Device (LDD), either by your surgeon or by an optometrist

The number of light adjustment treatments vary from patient to patient. The adjustments will be completed when your refraction is stable. When you and you and your doctor agree that the final criteria have been met, a final LDD treatment will lock in the RxLAL™ and make the refraction permanent.

* ***From immediately after surgery until 24 hours after the completion of the lock-in treatment 2-4 weeks after surgery, you will need to protect the RxLAL™ from UV light by wearing protective eyewear during ALL waking hours.***

**How will the RXSight Light Adjustable Lens (RxLAL™) affect my vision and/or condition?**

The goal of implanting any intraocular lens is to correct the decreased vision that was caused by the cataract.Your ophthalmologist obtains measurements of the eye before surgery to try to calculate the best power lens for your eye and minimize your need for glasses after surgery.

While all IOLs improve vision after cataract surgery, the focus power of the lens is often not exactly on target. Because of this, most patients will require glasses (or contact lenses) to improve their vision to the level needed for either driving or reading, or both. The focus power of the RxLAL™ can be adjusted after your cataract surgery, which may reduce the need for glasses or contact lenses.

Careful follow-up is required after surgery. After your eye heals, you will still need regular eye exams to monitor the health of your eyes.

**What alternative types of IOLs are available?**

Your ophthalmologist will help you decide on the type of IOL that will replace your cloudy lens. There are IOLs available to treat nearsightedness (myopia), farsightedness (hyperopia), and astigmatism. IOLs usually provide either near or distance vision; these single focus lenses are called monofocal IOLs. Some newer IOLs can provide for near, intermediate, and distance vision; these multiple focus lenses are called multifocal IOLs. IOLs that treat astigmatism are called toric IOLs. You can also have one eye corrected for near vision, and the other for distance vision, a choice called monovision. The RxLAL™ is a monofocal IOL that can be set for distance vision, near vision, or monovision. The difference between the RxLAL™ and other monofocal IOLs is the fact that it can be adjusted after surgery.

**What are the main risks of the RXSight Light Adjustable Lens (RxLAL™)?**

It is impossible to list all risks and complications that may occur. The main risks and complications of implanting the RxLAL™ include:

* There is no guarantee that the IOL will improve your vision. Sometimes it doesn’t work.
* As with all surgery, there are risks. Sometimes it can make the problem worse, cause an injury, or create a new problem; if it does, this is called a complication.
* Complications can happen right away or not until days, weeks, months, or years later.
* You may need more treatment or surgery to treat the complication.
* Before the RxLAL™ is locked in, you can experience a decrease in vision if you are exposed to daylight or any other UV light source when you are not wearing protective eyewear. If this happens, the RxLAL™ may need to be removed and replaced with a new intraocular lens to improve vision. This can lead to other complications from the additional surgery.
* Therefore, immediately after surgery, when your patch is removed, ***you must wear the special UV protective eyewear provided to you until 24 hours after the final treatment, which may be up to 4 weeks***. The protective eyewear will protect the RxLAL™ from UV light from the sun and other UV sources that are common both indoors and outside. Three pairs of UV protective glasses will be provided to you: a *clear pair, a clear pair with readers,* and a *dark tinted pair*, to be worn as follows:
	+ When indoors, the clear pair must be worn at all times as it is not always possible to know which light sources may affect the lens.
	+ Before moving outside, the clear glasses ***must*** be changed to the dark-tinted glasses as sunlight carries a greater risk of changing the shape of the lens in an uncontrolled manner.
	+ You do not have to wear the dark tinted glasses outside at night, as there is no sunlight.
	+ The clear glasses may be worn at night to protect the RxLAL™ from other UV light sources, or as recommended by your surgeon.

* ***Patients unwilling to comply with the postoperative regimen for adjustment and lock-in treatment, including wearing the UV-protective eyewear, should not choose the* RxLAL™** ***for their cataract surgery.***

**Risks associated with postoperative RxSight Light Delivery Device (LDD) Treatments:**

It is impossible to list all risks and complications that may occur. The main risks and complications of the LDD treatments include:

* Your pupil may not dilate sufficiently to perform the light adjustments. If it is not possible to enlarge the pupil enough so that the entire lens can be seen to perform the adjustments, additional eye drops or surgery may be needed to further enlarge the pupil. If the pupil cannot be sufficiently enlarged after these types of treatments, the lens may need to be removed
* The desired results of the surgery and/or light treatment may not be obtained or may not last.
* UV light can cause a reactivation of previous herpes virus infection in the eye, which is why it is important to tell your doctor about any previous eye infections or problems. Notify your doctor if you suspect previous herpes eye disease.
	+ A reactivation of herpes virus may lead to scarring of the cornea, blurred vision, eye pain, extreme light sensitivity, permanent loss of vision, and possible need for corneal transplant. It should be noted that the risk of herpes virus reactivation is not unique to UV light. Herpes can reactivate with any ocular surgery due to the stress of surgery and the use of topical steroids.
* LDD light treatment can lead to a temporary or longer-term pink to red tinge to the vision or color vision deficiency.
* Some medications and supplements can potentially increase your eye’s sensitivity to UV light: tetracycline, doxycycline, psoralens, amiodarone, phenothiazines, chloroquine, hydroxychloroquine, hydrochlorothiazide, hypercin, ketoprofen, piroxicam, lomefloxacin, and methoxyarene.
* It is important that you discuss your medications with your doctor and notify your doctor if you are on any of the listed mediations prior to pursuing a LAL.
* **A patient taking a systemic medication that is considered toxic to the retina such as tamoxifen (e.g., Nolvadex®) may be at increased risk of retinal damage during LDD treatment.**

**How will complications during surgery be handled?**

I understand that If a complication happens during surgery, the ophthalmologist may need to perform another surgery right away to treat it. The ophthalmologist may discover a new condition or problem for the first time during the surgery. The ophthalmologist may need to change the plan for surgery to treat this condition or problem right away.

I authorize such procedures to be performed.

**Who will perform my surgery?**

I understand that my surgery will be performed by my ophthalmologist. Another ophthalmologist may be present at my surgery and may participate in the surgery under the direct supervision of my ophthalmologist for all critical portions of the surgery.

Some aspects of my post-operative care may be provided by my optometrist.

**Patient’s Acceptance of Risks**

Your signature on this document means:

* Your ophthalmologist has discussed the information in the form, including the risks, benefits, and alternatives of the procedure, as well as the consequences of refusing treatment.
* Your doctor has answered your questions to your satisfaction.
* I acknowledge that no guarantees or promises have been made to me concerning the results of any procedure or treatment.
* You have been offered a copy of this document.

You consent to implanting the RXSight Light Adjustable Lens (RxLAL™) in your:

**\_\_\_Left** eye **\_\_\_Right** eye **\_\_\_Both** eyes

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Patient Name Date of Birth

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Patient Signature Date

*If patient is unable to consent:*

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Signature of person authorized to consent for patient Date

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Relationship to patient