# **Consent for Laser Surgery to Treat ROP (Retinopathy of Prematurity)**

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** 3/9/2023

**What is ROP and how is it treated?**

Retinopathy of prematurity (ROP) is a condition of the retina (the layer of nerve tissue in the back of the eye that enables us to see). When a baby is born prematurely (too early), the retina has not had time to finish forming. After the premature birth, the blood vessels at the back of the eye stop growing. Soon the eye starts to make a chemical called vascular endothelial growth factor (VEGF). This chemical makes the blood vessels start growing again. However, these are not normal blood vessels. These abnormal blood vessels can bleed. They can also pull (detach) the retina away from its normal position. This is called a retinal detachment (RD), and it can cause blindness.

**How is ROP treated?**

There are two ways ophthalmologists treat ROP. One method is laser surgery. The laser stops the eye from making more of the VEGF chemical in order to stop the abnormal vessels from growing and keep the retina attached. Another method is injecting a drug called anti-VEGF medication into the eye to stop the VEGF chemical from causing the abnormal blood vessel growth. In some instances, the ophthalmologist may use both laser and anti-VEGF injection to treat ROP.

**Your Ophthalmologist Is Recommending Laser Surgery.**

Ophthalmologists have been treating ROP with laser surgery for many years. This type of laser surgery is called PRP (pan-retinal photocoagulation). The laser stops the eye from making more of the VEGF chemical. When successful, the abnormal blood vessels stop growing, the retina stays attached, and the central vision is preserved. Laser surgery works for most babies.

**Laser surgery is recommended for one of two reasons in ROP.**

1. Type I ROP (acute, high-risk ROP): This is the stage of ROP where prompt treatment is required to prevent blindness.
2. Persistent Avascular Retina (PAR): This is the type of ROP when mild ROP is present or the blood vessels fail to grow to the front of the eye after a previous successful anti-VEGF injection. Although the ROP is not acute (Type 1) in these cases, laser surgery is recommended to prevent any reactivation of ROP or worsening of mild ROP to severe ROP.

The goal of the laser is to keep the retina attached and save the baby’s vision. Some babies still lose vision or go blind even if they have laser. In some instances, the baby may need another laser surgery to stop the growth of the abnormal blood vessels.

If abnormal blood vessels continue to grow they can pull the retina off the eye and cause a retinal detachment (RD). If a RD develops, the baby will need surgery to treat the RD.
An ophthalmologist will need to keep examining the baby’s eyes after laser to make sure the ROP is gone. You will need to continue to take the baby to the ophthalmologist’s office for eye exams after the baby goes home.

The baby could have very poor vision or go blind if the ROP is not treated. The baby cannot choose whether to have treatment. You have the legal right to choose if the baby will get treatment for ROP.

Your ophthalmologist has a legal duty to treat the baby. If you decide not to treat the ROP, your ophthalmologist must talk to other doctors and child protective services about your choice.

**Summary of risks of laser treatment**

* The baby will need to have anesthesia during the laser surgery. The exact type of anesthesia will be decided by the neonatologist together with the ophthalmologist, and will depend on various factors. The surgery may be performed in the operating room, or in the NICU. The anesthesia may consist of medications delivered through the veins, or through a breathing tube, or both. Risks of any anesthesia include problems with heart rate, blood pressure, and breathing, any of which may require additional treatment. Severe problems from anesthesia may result in heart failure, stroke, or death. Your doctors will discuss specific risks with you in more detail, as the risks will be different depending on the overall health of your baby and which type of anesthesia is used.

* The laser surgery might not stop the ROP.
* The ROP can come back. The baby may need another laser surgery to treat the ROP.
* The baby could lose vision or go blind.
* The laser surgery could cause other eye problems:
	+ Loss of side (peripheral) vision
	+ Damage to the retina: RD, fold in the retina, or scarring of the macula (center of the retina)
	+ Bleeding in the eye (vitreous hemorrhage)
	+ High eye pressure (glaucoma)
	+ Low eye pressure (hypotony)
	+ Burns to the cornea (clear covering of the front of the eye)
	+ Clouding or scarring of the cornea
	+ Damage to the iris (colored part of the eye)
	+ Eyes that look in different directions (strabismus)
	+ Need for very thick glasses
	+ Bigger eye (enlargement)
	+ Smaller eye (shrinkage)
	+ Eye irritation, inflammation, and lots of tears

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

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

**Who will perform the surgery?**

I understand that my surgery will be performed by the ophthalmologist. Nurses/nurse practitioners, physician assistants, and doctors in training may be present during the surgery and may participate in the surgery under the direct supervision of the ophthalmologist for all critical portions of the surgery. Some aspects of the pre- and post-operative care may be provided by the ophthalmologist or his/her associates and other medical professionals in the NICU, or the baby’s primary eye care provider.

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

* The surgeon has discussed with you the information in this consent form.
* The ophthalmologist or staff offered you a copy of this form.
* You are aware that the baby may lose vision or go blind after surgery.
* You are aware that the baby may need another surgery.
* The ophthalmologist or staff answered your questions about laser surgery for ROP.
* The risks and benefits of laser treatment and alternatives, including no treatment, have been explained to you.
* Your right to refuse this treatment for the baby has been explained. You also understand that if you do refuse the treatment, the ophthalmologist must ask other doctors or child protective services to talk to you about your decision.

**I want the [Ophthalmologist’s Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_] to treat the baby with laser surgery for \_\_\_\_\_\_\_\_\_ (state acute Type 1 ROP or Persistent Avascular Retina (PAR) here) on:**

* **\_\_\_\_\_\_\_ the right eye**
* **\_\_\_\_\_\_\_ the left eye**
* **\_\_\_\_\_\_\_ both eyes.**

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Patient’s Name Date of Birth

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Parent’s Name Relationship to child if other than parent

(or person authorized to sign for patient)

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Signature Date