# **Informed Consent for Injection 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?**

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 injecting a drug called anti-VEGF medication into the eye to stop the VEGF chemical from causing the abnormal blood vessel growth and keep the retina attached. Another 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. In some instances, the ophthalmologist may use both anti-VEGF injection and laser to treat ROP.

**Your Ophthalmologist Is Recommending Injection.**

Some babies are too sick to have surgery or the anesthesia that is required for laser surgery. In other babies, the abnormal blood vessels are too far back in the eye to perform laser surgery safely. Other parts of the eye or blood in the eye may block the view to the abnormal blood vessels, making it impossible to perform the laser surgery.

As an alternative to laser surgery, ophthalmologists can inject anti-VEGF medication into the baby’s eye to treat ROP.This is called an intravitreal injection. There are many anti-VEGF medications but the ones which are used to treat ROP include Avastin (bevacizumab), Eylea (aflibercept), and Lucentis (ranibizumab). The ophthalmologist will talk to you about which medication will be injected.

**How will the treatment affect the baby’s vision and ROP?**

The goal of the injection is to keep the retina attached and save the baby’s vision. Some babies still lose vision or go blind even if they have the injection. Sometimes, the abnormal vessels keep growing after the injection. The baby may need another injection or laser surgery to stop the growth of the abnormal blood vessels. In many instances, healthy/normal blood vessels fail to grow to the front of the eye after successful anti-VEGF injection. This is called persistent avascular retina (PAR) and can occur weeks or even months after anti-VEGF injection. Laser may be needed to treat PAR.

If abnormal blood vessels continue to grow they can pull the retina off the eye and cause an RD. If an RD develops, the baby will need surgery to treat the RD. An ophthalmologist will need to keep examining the baby’s eyes for at least 6 months after the injection to make sure the ROP is gone. You will need to take the baby to the ophthalmologist’s office for these 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.

**Only one anti-VEGF injection for ROP has been approved by the Food and Drug Administration (FDA) to treat children. The others that are used are “off-label.”**

Some anti-VEGF medications have been approved by the FDA to treat eye conditions in adults. When drugs are used for a purpose that the FDA did not specifically approve, it is called using the drug “off-label.” In 2006, ophthalmologists started using anti-VEGF medications off-label to treat babies with ROP. Ophthalmologists continue to study how well anti-VEGF works to treat ROP and how much medication to give for the best results.
Three drugs are currently used for ROP. Bevacizumab (trade name Avastin) is the most widely used but is off-label. Ranibizumab (trade name Lucentis) is also off-label. Aflibercept (trade name Eylea) received FDA approval in 2023. Biosimilars are still not recommended for any of these drugs to treat ROP. Your doctor will discuss the best choice of drug with you.

**Doctors do not know if anti-VEGF medication injected into the eye harms other parts of the baby’s body.**

Anti-VEGF medication injected in the eye reaches the brain, lungs, and kidneys. These organs need the VEGF chemical to grow. The anti-VEGF medication may harm the brain, lungs, and kidneys.

* Ophthalmologists and neonatologists (doctors who care for newborns) continue to study babies who get anti-VEGF injections to see if they affect the development of their brain, lungs, and kidneys after injections.
* Premature babies often have problems with their brains, lungs, and kidneys and can be very sick. Sick babies may experience other health issues after injections.
* It is not known if problems that may show up later in life are caused by being born prematurely or from getting the anti-VEGF medication.
* The ophthalmologist will talk to the neonatologist about whether it is safe for your baby to have anti-VEGF medication.

**Anti-VEGF Biosimilar drugs**

Biosimilar drugs are medications chemically changed to closely resemble an original drug. None of the anti-VEGF biosimilar drugs available are FDA-approved for the treatment of ROP and there is very little knowledge and experience on their safety and effectiveness in a baby’s eye. The use of off-label bevacizumab biosimilars for the treatment of ROP is prohibited until further clinical data becomes available. Ask your ophthalmologist if you have any questions about biosimilar drugs.

**Summary of risks of injection**

* The injection might not stop the ROP.
* The ROP can come back. The baby may need another injection or laser surgery to treat the ROP.
* The baby could lose vision or go blind.
* When ROP is treated with laser surgery, the ophthalmologist knows in a few weeks if the ROP will return. The ophthalmologist may not know for months or years if the ROP will come back after an injection. The ophthalmologist must keep checking the eyes for ROP for at least 6 months after the injection. The baby may need laser surgery if the ROP gets worse or the retina does not grow normal vessels after the injection.
* The injection can cause other eye problems:
	+ An eye infection that could lead to blindness and/or require surgery or removal of the eye
	+ Damage to the retina: retinal detachment (RD)
	+ Clouding of the eye’s lens (cataracts)
	+ High eye pressure (glaucoma)
	+ Low eye pressure (hypotony)
	+ Damage to the cornea (clear covering of the front of the eye)
	+ Bleeding in the eye (vitreous hemorrhage)
	+ Bright redness in the white part of the eye
	+ Eye irritation, inflammation, and lots of tears
* The baby will need to have anesthesia during the injection. The exact type of anesthesia will be decided by the neonatologist together with the ophthalmologist, and will depend on various factors. The injection is generally performed in the NICU, but in some cases may be done in the operating room. 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.
* Other unknown risks. Some adult patients who have had anti-VEGF injections have had heart attack, stroke, or death. The FDA does not know if the anti-VEGF medication caused these problems.

**How will complications during the injection be handled?**

If a complication happens during the injection, 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 injection. The ophthalmologist may need to change the plan to treat this problem or condition right away.

**Who will perform the injection?**

The injection will be performed by the ophthalmologist. Nurses/nurse practitioners, physician assistants, and doctors in training may be present during the injection and may participate under the direct supervision of the ophthalmologist for all critical portions of the procedure. 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 by the baby’s primary eye care provider.

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

* The ophthalmologist has discussed the information in this consent form with you.
* The ophthalmologist or staff has answered your questions about the injection for ROP.
* You are aware that the baby may lose vision or go blind from ROP even with treatment.
* You are aware that the baby may lose vision or go blind after the injection.
* You are aware that the baby may need another injection or laser or other surgery.
* You have been told whether the FDA has approved the medicine for treating ROP, or whether it is being used off-label.
* The risks and benefits of treatment by injection and alternatives, including no treatment, have been explained to you.
* Your right to refuse this treatment for the baby has been explained and you 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.
* You authorize the performance of additional procedures or changes to the treatment plan that need to happen right away due to complications or unforeseen conditions.
* You acknowledge that no guarantees or promises have been made to you concerning the results of any procedure or treatment.
* The ophthalmologist or staff offered you a copy of this form.

**I want [Ophthalmologist’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_] to give the baby an injection of \_\_\_\_\_\_\_\_\_\_\_ (insert medication name- here) for ROP in:**

**\_\_\_\_\_\_\_ 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