# **Consent for injection to treat ROP (retinopathy of prematurity)**

Your baby has a condition of the retina (the back of the eye) called ROP.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 VEGF (vascular endothelial growth factor). This chemical makes the blood vessels start growing again.

But 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 an RD (retinal detachment), and it can cause blindness. This document gives information about the types of treatment. It also explains what happens if the baby does not get treatment for ROP.

**Ophthalmologists (eye surgeons) can treat ROP.**

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. The abnormal blood vessels usually stop growing, the retina stays attached, and the central vision is good. Laser works for most babies.

But some babies are too sick to have surgery or anesthesia. In other babies, the abnormal blood vessels are too far back in the eye to use the laser safely. Other parts of the eye or blood in the eye may block the path to the abnormal blood vessels.

Ophthalmologists can inject a medicine in the baby’s eye to treat ROP.This is called an intravitreal injection. The medicine stops the eye from making the VEGF chemical. It is called an anti-VEGF medicine. There are three anti-VEGF medicines. They are called Avastin, Eylea, and Lucentis. The ophthalmologist will talk to you about which medicine will be injected.

**The baby may need more treatment.**

The goal of the injection is to keep the retina attached and save the baby’s vision. Some babies 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 abnormal blood vessels. These abnormal blood vessels can pull the retina off the eye and cause an RD. The baby will need other types of surgery to treat the RD. An ophthalmologist will need to keep examining the baby’s eyes for at least six 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.

Your baby could have very poor vision or go blind if the ROP is not treated. Your baby cannot choose whether to have treatment. You need to decide if your baby will get treatment for ROP. You have the legal right to choose for your baby. Because you are an adult, you can refuse (say no) to treatment to save your own vision or your own life.

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.

**Anti-VEGF medicines have not been approved by the FDA to treat children. This is called off-label use.**

The VEGF chemical causes eye diseases in premature babies and adults. Some anti-VEGF medicines have been approved by the FDA (Food and Drug Administration) to treat eye conditions in adults. Ophthalmologists have given anti-VEGF injections to adults for many years. Ophthalmologists started to treat ROP with anti-VEGF medicine in 2006. Ophthalmologists are still studying how well the medicine works to treat ROP and how much medicine to give babies.

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

The medicine gets out of the eye and into the baby’s bloodstream. It reaches the brain, lungs, and kidneys. The brain, lungs, and kidneys need the VEGF chemical to grow. The medicine may harm the brain, lungs, and kidneys.

* Ophthalmologists and neonatologists (baby doctors) are studying babies who get this medicine to see if they have problems with the development of their brain, lungs, and kidneys.
* Premature babies often have problems with their brains, lungs, and kidneys that are caused by being born too soon. They can be very sick. Sick babies may have more problems after injections.
* It is also hard to know if problems that do show up are caused by being premature or from getting the medicine.
* The ophthalmologist will talk to the neonatologist about whether it is safe for your baby to have this medicine.

**This injection has risks and can cause problems.**

There are risks with all injections and with all medicines. These risks can cause vision loss or blindness. Here are some common or serious ones:

* The injection might not stop the ROP.
* The ROP can come back again. The baby may need another injection or laser surgery to treat the ROP.
* Your 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 come back. The ophthalmologist may not know for months or years if the ROP will come back after an injection. The ophthalmologist will have to keep checking the eyes for ROP for a very long time after the injection. The baby may need laser surgery if the retina does not grow completely after the injection
* The injection can cause other eye problems:
  + An eye infection that could lead to blindness
  + RD (detached retina)
  + Cataracts (clouding of the eye’s lens)
  + Glaucoma (high eye pressure)
  + Hypotony (low eye pressure)
  + Damage to the retina
  + Damage to the cornea (clear covering of the front of the eye)
  + Bleeding in the eye
  + Bright redness in the white part of the eye
  + Eye irritation and lots of tears
* Adult patients who had these anti-VEGF injections have had heart attack, stroke, or death. The FDA does not know if the medicine caused these problems.

**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 form.
* The eye surgeon or staff offered you a copy of this form.
* You are aware that the baby may lose vision or go blind.
* You are aware that the baby may need another injection or surgery.
* You are aware that the FDA did not approve this medicine for ROP.
* The eye surgeon or staff answered your questions about the injection for ROP.
* You understand that it is your right to refuse (say no) this treatment for your baby. 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.
* You agree to the injection.

**I want the ophthalmologist to give my baby an injection for ROP in:**

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

Patient (or person authorized to sign for patient) Date