# **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 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.

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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.

**Treatment with Medication**

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 medication in the baby’s eye to treat ROP.This is called an intravitreal injection. The medication, called anti-VEGF, stops the eye from making the VEGF chemical. There are three anti-VEGF medications: Avastin, Eylea, and Lucentis. The ophthalmologist will talk to you about which medication will be injected.

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 growth of the abnormal blood vessels. If the 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.

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 have the legal right to choose if your 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.

**Anti-VEGF injection for ROP has not been approved by the FDA (Food and Drug Administration) to treat children. This is called off-label use.**

Some anti-VEGF medications have been approved by the FDA to treat eye conditions in adults. Ophthalmologists started to treat ROP with anti-VEGF medication in 2006. Ophthalmologists continue to study how well anti-VEGF works to treat ROP and how much medication to give babies.

**Doctors do not know if anti-VEGF medication injected in 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) are studying babies who get anti-VEGF to see if they develop other health issues with 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 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.

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

There are risks with all injections and with all medications. 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. 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 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 retina does not grow completely after the injection.
* In rare instances anesthesia can cause heart or breathing problems, or even death.
* 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, inflammation and lots of tears
* 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.

**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 from the ROP even with treatment.
* You are aware that the baby may need another injection or laser surgery.
* You are aware that the FDA has not approved this medicine for treatment of 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 to) 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 of \_\_\_\_\_\_\_\_\_\_\_(insert medication name- Avastin, Eylea or Lucentis) for ROP in:**

**\_\_\_\_\_\_\_ the right eye**

**\_\_\_\_\_\_\_ the left eye**

**\_\_\_\_\_\_\_ both eyes.**

Parent (or person authorized to sign for patient) Date

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Relationship to child if other than parent