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**ROP Safety Net Toolkit**

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**OMIC policyholders who provide care must comply with the ROP Safety Net.**

OMIC’s ROP Safety Net is based on our claims experience. It is designed to address the causes of ROP lawsuits in order to protect the infant and the ophthalmologist. The ROP Safety Net Toolkit contains sample protocols, which may need to be customized, and refers to ROP clinical care guidelines. These protocols and guidelines are recommendations and do not constitute the standard of care. Ophthalmologists should use their professional judgment in determining the applicability of a given recommendation to their particular patients and practice situation.

The Toolkit does not provide legal advice. Consult an attorney if legal advice is desired or needed. Information contained here is not intended to be a modification of the terms and conditions of the OMIC professional and limited office premises liability insurance policy. Please refer to the OMIC policy for these terms and conditions.

**Version 8/10/18**

# **Procedure 3a. Treat ROP at hospital**

**Treat ROP at hospital principles**

1. The hospital has a treating ophthalmologist available to provide ROP treatment within 72 hours of notice that it is needed.
2. The hospital either allows infants discharged from the NICU to be readmitted for ROP treatment or has a transfer agreement in place with a hospital that does allow discharged infants to be admitted for ROP treatment within 72 hours of notice that it is needed.
3. The hospital is able to provide anti-VEGF drugs at the appropriate compounded dose and supplies for intravitreal injections.
4. The hospital has an ROP coordinator (H-ROPC) who is familiar with and understands the ROP Screening Policy Statement (PS)[[1]](#footnote-1) and the Tables in the ROP toolkit that are based upon it, and is able to use the Tables to review and clarify the appropriateness of follow-up and treatment intervals, and coordinate discharge or transfer.
5. The ophthalmologist:
   1. Has sufficient knowledge and experience to identify accurately the location and sequential retinal changes of ROP after pupillary dilation using binocular indirect ophthalmoscopy (BIO) with a lid speculum and scleral depression if needed, per the PS.
   2. Uses the International Classification of Retinopathy of Prematurity ([ICROP](#_ICROP._Synopsis_of)) Revisitedto classify, diagram, and record the retinal findings.
   3. Knows and understands treatment criteria [[Table 4. When to treat](#_Table_4._)].

**Treatment process**

**Use the hyperlinks to see tables and forms. To go back to where you were in the document on a PC, press Alt+left arrow.**

1. The screening ophthalmologist determines that treatment might be needed [[Table 4. When to treat](#_Table_4._)], documents the findings using ICROP, and notifies the neonatologist and ROPCs.
2. The screening ophthalmologist conducts and documents a transfer-of-care discussion with the treating ophthalmologist if another ophthalmologist will provide the treatment.
3. The treating ophthalmologist obtains informed consent for the treatment [[Consent for laser](#_Consent_for_laser), [Spanish consent for laser](#_Consentimiento_para_cirugía), [Consent for injection](#_Consent_for_injection_1), [Spanish consent for injection](#_Consentimiento_para_aplicación)].
4. The H-ROPC schedules the procedure, and confirms that treatment will be provided within 72 hours.
5. The treating ophthalmologist performs and documents the procedure, and informs the parents of the results and when the follow-up exam will take place.
6. The treating ophthalmologist informs the ROPCs of the date and type of treatment and when the next exam is needed, giving both the interval and approximate date of the exam [[Table 3. Follow-up exams](#_Table_3.__1)]. Current guidelines suggest that the ophthalmologist should examine the eye 3 to 7 days after treatment.
7. The treating ophthalmologist reexamines the eye to determine if more treatment is needed.
   1. The H-ROPC contacts the O-ROPC of the screening ophthalmologist if the treating ophthalmologist does not perform the follow-up exams.
   2. The treating ophthalmologist contacts the screening ophthalmologist and conducts and documents the transfer-of-care discussion.
8. The ophthalmologist notifies the ROPCs when treatment is complete, and instructs both to update the Hospital ROP Tracking List.
9. The ophthalmologist continues to examine, treat, and track the infant until **one** of these criteria to end screening/treatment has been met and documented:
   1. ***Per the Policy Statement, one exam is sufficient only if it unequivocally shows the retina to be fully vascularized in both eyes.***
   2. A treating ophthalmologist has confirmed that all treatment and follow-up examinations are complete
   3. Both eyes have met the conclusion-of-acute-screening criteria based upon a BIO exam [[Table 5. When to stop](#_Table_5._)].
   4. The current ophthalmologist conducts and documents a transfer-of-care discussion with the ophthalmologist who will take over care.
10. The ophthalmologist informs the neonatologist and ROPCs of the need for an outpatient screening exam for eye conditions associated with prematurity if ROP screening is complete.

# [**Table 1. Which infants need an ROP screening examination**](#Table_1)

Infants meeting any of the following criteria need an exam:

* Birth weight of ≤ 1500 g (3 lbs., 4 oz.)
* Gestational age of 30 weeks or less (as defined by the attending neonatologist)
* Selected infants with a birth weight between 1500 and 2000 g (from 3 lbs., 4 oz. to 4lbs, 6 oz.) or gestational age of more than 30 weeks with an unstable clinical course, including those requiring cardiorespiratory support and who are believed by their attending pediatrician or neonatologist to be at high risk for ROP.

**REFERENCE: ROP Screening Policy Statement # 3**. Based on Recchia, Franco and Capone, Antonio, Contemporary Understanding and Management of Retinopathy of Prematurity, *Retina* 2004; 24:283-92.

# **[Table 2. When to start ROP screening](#Table_2)**

The onset of serious ROP correlates better with postmenstrual age (gestational age at birth plus chronological age) than with postnatal age. This protocol bases the initial eye examination on postmenstrual age and chronological age. The initial eye examination should be conducted:

* By 31 weeks postmenstrual age if gestational age < 27 weeks
* At 4 weeks chronological age if gestational age ≥ 27 weeks

**Age in weeks at initial exam**

|  |  |  |
| --- | --- | --- |
| **Gestational age at birth** | **Postmenstrual age** | **Chronologic age** |
| 22a\* | 31 | 9 |
| 23a\* | 31 | 8 |
| 24\* | 31 | 7 |
| 25\* | 31 | 6 |
| 26 | 31 | 5 |
| 27 | 31 | 4 |
| 28 | 32 | 4 |
| 29 | 33 | 4 |
| 30 or more | 34 | 4 |
|  |  |  |

a This guideline should be considered tentative rather than evidence-based for 22-to-23-week infants owing to the small number of survivors in these gestational age categories.

**\*** Infants born before 25 weeks’ gestational age should be considered for earlier screening on the basis of severity of comorbidities (6 weeks’ chronological age, even if before 31 weeks’ postmenstrual age, to enable earlier identification and treatment of aggressive posterior ROP [a severe form of ROP that is characterized by rapid progression to advanced states in posterior ROP] that is more likely to occur in this extremely high-risk population).

**REFERENCE:** **ROP Screening Policy Statement #3.** Based upon Reynolds JD, Dobson V, Quinn GE, et al. CRYO-ROP and LIGHT-ROP Cooperative Groups. Evidence-Based Screening Criteria for Retinopathy of Prematurity: Natural History Data from the CRYO-ROP and LIGHT-ROP Studies. *Arch Ophthalmol.* 2002; 120: 1470-1476.

# **[Table 3. Follow-up schedule for ROP exams](#Table_3)**

The examining ophthalmologist should use retinal findings as classified by [ICROP](https://jamanetwork.com/journals/jamaophthalmology/fullarticle/417157) to determine the timing of the follow-up examinations.

* 1-week or less
  + Immature vascularization in zone 1—no ROP
  + Immature retina extends into posterior zone II, near the boundary of zone I
  + Stage 1 or 2 ROP in zone I
  + Stage 3 ROP in zone II
  + The presence or suspected presence of aggressive posterior ROP
  + Infants treated solely with anti-VEGF medications such as bevacizumab
* 3 to 7 days
  + After treatment to ensure that there is no need for additional treatment in areas where ablative treatment was not complete.
* 1 to 2 weeks
  + Immature vascularization in posterior zone II
  + Stage 2 ROP in zone II
  + Unequivocally regressing ROP in zone I
* 2 weeks
  + Stage 1 ROP in zone II
  + Immature vascularization in zone II—no ROP
  + Unequivocally regressing ROP in zone II
* 2 to 3 weeks
  + Stage 1 or 2 ROP in zone III
  + Regressing ROP in zone III

**REFERENCE**: **ROP Screening Policy Statement #4**. Based on Reynolds JD, Dobson V, Quinn GE, et al. CRYO-ROP and LIGHT-ROP Cooperative Groups. Evidence-Based Screening Criteria for Retinopathy of Prematurity: Natural History Data from the CRYO-ROP and LIGHT-ROP Studies. *Arch Ophthalmol.* 2002; 120: 1470-1476.

# **Table 4. When to treat ROP**

* Treatment should be initiated for the following retinal findings:
  + Zone I ROP: any stage with plus disease
  + Zone I ROP: stage 3—no plus disease
  + Zone II ROP: stage 2 or 3 with plus disease
* The presence of plus disease in zones I or II suggests that peripheral ablation, rather than observation, is appropriate.\*
  + Plus disease is defined as abnormal dilatation and tortuosity of the posterior retinal blood vessels in 2 or more quadrants of the retina meeting or exceeding the degree of abnormality represented in reference photographs
* Consideration may be given to treatment of infants with zone I stage 3+ ROP with intravitreal injection of bevacizumab.#
  + Bevacizumab is not approved by the US Food and Drug Administration for the treatment of ROP.
  + Treatment should only be administered after obtaining detailed informed consent, because there remain unanswered questions involving dosage, timing, safety, visual outcomes, and other long-term effects.
  + Infants treated with bevacizumab should be monitored weekly until retinal vascularization is complete.
  + Longer follow-up is required because recurrence occurs considerably later (16 ± 4.6 weeks vs 6.2 ± 5.7 weeks) than after laser therapy.
* Special care must be used in determining the zone of disease.
  + See page 992 of [ICROP](https://jamanetwork.com/journals/jamaophthalmology/fullarticle/417157) for specific examples of how to identify zone I and II disease by using a 28-diopter lens with binocular indirect ophthalmoscopy.
* The presence of plus disease rather than the number of clock hours of disease may be the determining factor in recommending ablative treatment.
* Treatment should generally be accomplished, when possible, within 72 hours of determination of treatable disease to minimize the risk of retinal detachment.
* Follow up is recommended in 3 to 7 days after treatment to ensure that there is no need for additional treatment in areas where ablative treatment was not complete.

**REFERENCE: ROP Screening Policy Statement #7 and #9 based upon:**

\* Early Treatment for Retinopathy of Prematurity Cooperative Group. Revised Indications for the Treatment of Retinopathy of Prematurity. Results of the Early Treatment for Retinopathy of Prematurity Randomized Trial. *Arch Ophthalmol.* 2003; 121:1684-1694.

* # Mintz-Hittner HA, Kennedy KA, Chuang AZ; BEAT-ROP Cooperative Group. Efficacy of intravitreal bevacizumab for stage 3+ retinopathy of prematurity. *N Engl J Med*. 2011; 364(7):603–615.

# **Table 5. When to stop ROP screening**

**Per the Policy Statement, one exam is sufficient only if it unequivocally shows the retina to be fully vascularized in both eyes.**

The conclusion of acute-retinal-screening examinations should be based on age and retinal ophthalmoscopic findings. Findings that suggest that examinations can be terminated include:

* Zone III retinal vascularization attained without previous zone I or II ROP
  + If there is examiner doubt about the zone or if the PMA (postmenstrual age) is less than 35 weeks, confirmatory examinations may be warranted.
* Full retinal vascularization in close proximity to the ora serrata for 360°--that is, the normal distance found in mature retina between the end of vascularization and the ora serrata.
  + **Per the Policy Statement, this criterion should be used when ROP is treated solely with anti-VEGF medication.**
* Postmenstrual age of 50 weeks and no prethreshold disease or worse ROP is present
  + Prethreshold disease defined as:
    - Stage 3 ROP in zone II
    - Any ROP in zone I
* Regression of ROP (see [ICROP](#_Appendix_B._))
  + Care must be taken to be sure that there is no abnormal vascular tissue present that is capable of reactivation and progression in zone II or III.

**REFERENCE: ROP Screening Policy Statement # 5.** Based upon Reynolds JD, Dobson V, Quinn GE, et al. CRYO-ROP and LIGHT-ROP Cooperative Groups. Evidence-Based Screening

# **ROP Tracking List**

NOTE: To use as an Excel document, click on the list, choose “Worksheet Object” and then “Open.”



# **Consent for laser surgery 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.

The goal of laser surgery is to keep the retina attached and save the baby’s vision.Central vision may be good, but the baby will lose some side vision. The laser surgery does not work on every baby. Some babies need more than one laser surgery. Some babies lose vision or go blind even if they have the laser surgery. Sometimes, the abnormal vessels keep growing after laser surgery. These abnormal blood vessels pull the retina out of its normal position and cause an RD. The baby will need other types of surgery to treat the RD.

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.

**This laser surgery has risks and can cause problems.**

There are risks with every surgery. These risks can cause vision loss or blindness. Here are some common or serious ones:

* The laser surgery might not stop the ROP.
* The ROP can come back again. The baby may need another laser surgery to treat the ROP.
* Your baby could lose vision or go blind.
* Anesthesia can cause heart or breathing problems, or death
* The laser surgery could cause other eye problems:
  + Loss of side (peripheral) vision
  + Damage to the retina: RD, fold in the retina, dragging 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)

**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 ophthalmologist 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 surgery.
* The ophthalmologist or staff answered your questions about laser surgery for ROP.
* You understand that it is your right to refuse 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 laser surgery.

**I want the ophthalmologist to treat my baby with laser surgery on:**

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

Patient (or person authorized to sign for patient) Date

# **Consentimiento para cirugía láser para el tratamiento de la ROP (retinopatía de la prematurez)**

Su bebé tiene una condición de la retina (la parte posterior del ojo) conocida como ROP. Cuando nace un bebé prematuro (antes de tiempo), la retina no ha tenido tiempo de acabar de formarse. Después de un nacimiento prematuro, los vasos sanguíneos en la parte posterior del ojo dejan de crecer. Muy pronto el ojo comienza a producir una sustancia química conocida como VEGF (factor de crecimiento de la vasculatura endotelial). Esta sustancia química hace que los vasos sanguíneos comiencen a crecer de nuevo.

Sin embargo, estos no son vasos sanguíneos normales. Son vasos sanguíneos anormales que pueden sangrar. También pueden halar (desprender) la retina de su posición normal. Esto se conoce como DR (desprendimiento de retina) y puede producir ceguera. Este documento ofrece información acerca de los tipos de tratamiento. Explica también lo que ocurre si no se trata al bebé para la ROP.

**Los oftalmólogos (cirujanos de los ojos) pueden tratar la ROP.**

Los oftalmólogos han venido tratando la ROP con cirugía láser desde hace muchos años. Este tipo de cirugía láser se llama PRP (fotocoagulación panretiniana, por su abreviatura en inglés). El láser detiene la producción de la sustancia química VEGF en el ojo. En la mayoría de los casos, los vasos sanguíneos anormales dejan de crecer, la retina permanece adherida y la visión central es buena. El láser es un buen tratamiento para la mayoría de los bebés.

Pero algunos bebés están demasiado enfermos para ser tratados con cirugía o para recibir anestesia. En otros bebés, los vasos sanguíneos anormales están demasiado atrás en el ojo para poder utilizar el láser con seguridad. Es posible que otras partes del ojo o la sangre que puede haber en el ojo bloqueen el paso del láser para alcanzar los vasos sanguíneos anormales. Los oftalmólogos pueden inyectar un medicamento en el ojo del bebé para tratar la ROP.Esta técnica se conoce como inyección intravítrea. El medicamento impide que el ojo siga produciendo la sustancia VEGF y se conoce como medicamento anti-VEGF.

El objetivo de la inyección es mantener la retina adherida y salvar la visión del bebé.La visión central puede ser buena pero el bebé puede perder parte de la visión lateral. La cirugía láser no da resultado en todos los bebés. Algunos requieren más de una cirugía láser. Algunos bebés pierden visión o quedan ciegos aún si se les ha practicado cirugía láser. A veces, los vasos anormales siguen creciendo después de la cirugía, estos vasos sanguíneos anormales halan la retina levantándola de su posición normal y producen lo que se conoce como DR. El bebé requerirá otros tipos de cirugía para tratar el DR.

Su bebé podría terminar con una visión muy baja o quedar totalmente ciego si la ROP no se trata a tiempo. Su bebé no está en capacidad de decidir si quiere o no el tratamiento. Será usted quien decida si su bebé recibe o no el tratamiento para la ROP. Tiene el derecho legal de elegir a nombre de su bebé. Debido a que usted es una persona adulta, puede negarse (puede decir que no) al tratamiento para salvar su propia visión o su propia vida.

Su oftalmólogo tiene el deber legal de tratar al bebé. Si usted decide no tratar la ROP del bebé, su oftalmólogo deberá hablar con otros médicos y con los servicios de protección del menor, acerca de su decisión.

**La cirugía láser puede causar los siguientes problemas.**

Hay riesgos con todas las inyecciones y con todos los medicamentos. Estos riesgos pueden producir pérdida de visión o ceguera. Los siguientes son algunos de los problemas más comunes o más graves:

* La cirugía láser podría no detener el desarrollo de la ROP.
* La ROP puede reiniciarse más adelante. Es posible que el bebé requiera otra cirugía con láser para tratar la ROP.
* Su bebé podría perder visión o quedar ciego.
* La anestesia puede producir problemas cardiacos o respiratorios o la muerte
* La cirugía láser podría causar otros problemas oculares:
  + Pérdida de visión lateral (periférica)
  + Daño a la retina: DR, un pliegue en la retina, arrastre o cicatrización de la mácula (centro de la retina)
  + Sangrado dentro del ojo (hemorragia vítrea)
  + Alta presión dentro del ojo (glaucoma)
  + Baja presión dentro del ojo (hipotonía)
  + Quemaduras en la córnea (la parte transparente que cubre el frente del ojo)
  + Opacificación o cicatrización de la córnea
  + Daño al iris (la parte de color del ojo)
  + Ojos que miran en direcciones distintas (estrabismo)
  + Necesidad de usar anteojos con lentes muy gruesos
  + Ojos más grandes (agrandamiento)
  + Ojos más pequeños (ojos de menor tamaño)

**Consentimiento**. Al firmar al final de este documento, usted da su consentimiento (acepta) y declara que:

* Ha leído este formulario de consentimiento informado, o que alguien que se lo ha leído a usted.
* Entiende la información de este formulario.
* El cirujano o el personal del hospital le han entregado una copia de este formulario.
* Se da cuenta de que su bebé puede perder visión o quedar ciego.
* Se da cuenta de que su bebé puede requerir otra cirugía.
* El cirujano de los ojos o el personal del hospital ha respondido a sus preguntas relacionadas con la inyección para la ROP.
* Entiende que tiene derecho a negarse a aceptar (a decir que no a) este tratamiento para su bebé. Además, entiende que si se niega a aceptar el tratamiento, el oftalmólogo deberá pedir a otros médicos o a personas que trabajen con los servicios de protección del menor que hablen con usted acerca de su decisión.
* Acepta la cirugía láser.

**Deseo que el oftalmólogo le realice a mi bebé una cirugía láser para la ROP en:**

* **\_\_\_\_\_\_\_ el ojo derecho**
* **\_\_\_\_\_\_\_ el ojo izquierdo**
* **\_\_\_\_\_\_\_ ambos ojos.**

Paciente (o persona autorizada para firmar por el paciente) Fecha

# **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 cause 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

# **Consentimiento para aplicación de la inyección como tratamiento de la ROP (retinopatía de la prematurez)**

Su bebé tiene una condición de la retina (la parte posterior del ojo) conocida como ROP.Cuando nace un bebé prematuro (antes de tiempo), la retina no ha tenido tiempo de acabar de formarse. Después de un nacimiento prematuro, los vasos sanguíneos en la parte posterior del ojo dejan de crecer. Muy pronto, el ojo comienza a producir una sustancia química conocida como VEGF (factor de crecimiento de la vasculatura endotelial). Esta sustancia química hace que los vasos sanguíneos comiencen a crecer de nuevo.

Sin embargo, estos no son vasos sanguíneos normales. Son vasos sanguíneos anormales que pueden sangrar. También pueden halar (desprender) la retina de su posición normal. Esto se conoce como DR (desprendimiento de retina) y puede producir ceguera. Este documento ofrece información acerca de los tipos de tratamiento. Explica también lo que ocurre si el (la) bebé no recibe tratamiento para la ROP.

**Los oftalmólogos (cirujanos de los ojos) pueden tratar la ROP.**

Los oftalmólogos han venido utilizando cirugía con láser para tratar la ROP desde hace muchos años. Este tipo de cirugía con láser se llama PRP (fotocoagulación panretiniana, por su abreviatura en inglés). El láser detiene la producción de la sustancia química VEGF en el ojo. En la mayoría de los casos, los vasos sanguíneos anormales dejan de crecer, la retina permanece adherida y la visión central es buena. El láser es un buen tratamiento para la mayoría de los bebés.

Pero algunos bebés están demasiado enfermos para ser tratados con cirugía o para recibir anestesia. En otros bebés, los vasos sanguíneos anormales están demasiado atrás en el ojo para poder utilizar el láser con seguridad. Es posible que otras partes del ojo o la sangre que puede haber en el ojo bloqueen el paso del láser para alcanzar los vasos sanguíneos anormales.

Los oftalmólogos pueden inyectar un medicamento en el ojo de su bebé para tratar la ROP.Esta técnica se conoce como inyección intravítrea. El medicamento impide que el ojo siga produciendo la sustancia VEGF y se conoce como medicamento anti-VEGF. Hay tres medicamentos anti-VEGF. Se llaman Avastin, Eylea y Lucentis. Los oftalmólogos le explicarán cuál de estos medicamentos se inyectará.

**Su bebé puede necesitar más tratamiento.**

El objetivo de la inyección es mantener la retina adherida y salvar la visión de su bebé. Algunos bebés pierden visión o quedan ciegos aún si reciben la inyección. A veces, los vasos anormales siguen creciendo después de la inyección. El (la) bebé puede requerir otra inyección o una cirugía con láser para detener el desarrollo de los vasos sanguíneos anormales. Estos vasos sanguíneos anormales pueden halar de la retina y separarla del ojo ocasionando lo que se conoce como un DR. El (la) bebé requerirá otros tipos de cirugía para tratar el DR. Un oftalmólogo tendrá que examinar constantemente los ojos de su bebé durante al menos seis meses después de la aplicación de la inyección para asegurarse de que ya no haya ROP. Tendrá que llevar a su bebé al consultorio del oftalmólogo para estos exámenes después de que el (la) bebé haya salido del hospital para su casa.

Su bebé podría terminar con una visión muy baja o quedar totalmente ciego(a) si la ROP no se trata a tiempo. Su bebé no está en capacidad de decidir si quiere o no el tratamiento. Será usted quien decida si su bebé recibe o no el tratamiento para la ROP. Tiene el derecho legal de elegir a nombre de su bebé. Debido a que usted es una persona adulta, puede negarse (puede decir que no) al tratamiento para salvar su propia visión o su propia vida.

Su oftalmólogo tiene el deber legal de tratar a su bebé. Si usted decide no tratar la ROP de su bebé, su oftalmólogo deberá hablar con otros médicos y con los servicios de protección del menor, acerca de su decisión.

**Los medicamentos anti-VEGF no han sido aprobados por la FDA para ser utilizados en el tratamiento de los niños. Esto es lo que se conoce como un “uso no incluido en la etiqueta”.**

La sustancia química del VEGF produce enfermedades oculares en los bebés prematuros y en los adultos. Algunos medicamentos anti-VEGF han sido aprobados por la FDA (Administración de Alimentos y Drogas) para tratar afecciones oculares en adultos. Los oftalmólogos han administrado inyecciones anti-VEGF a adultos durante muchos años. Los oftalmólogos comenzaron a tratar la ROP con medicamento anti-VEGF en el 2006. Los oftalmólogos siguen estudiando qué tan bueno es el resultado del medicamento para tratar la ROP y qué cantidad de medicamento debe administrarse a los bebés.

**Los médicos no saben si el medicamento anti-VEGF inyectado en el ojo pueda dañar otras partes del organismo de su bebé.**

La medicina sale del ojo y entra a la circulación sanguínea de su bebé. Llega al cerebro, a los pulmones y a los riñones. El cerebro, los pulmones y los riñones necesitan la sustancia química del VEGF para crecer. El medicamento puede dañar el cerebro, los pulmones y los riñones.

* Los oftalmólogos y los neonatólogos (doctores de los bebés) están estudiando a los bebés que reciben este medicamento para ver si presentan problemas con el desarrollo de su cerebro, sus pulmones y sus riñones.
* Con frecuencia, los bebés prematuros tienen problemas con su cerebro, sus pulmones y sus riñones que son producidos por el nacimiento prematuro. Pueden estar muy enfermos. Los bebés enfermos pueden tener más problemas después de las inyecciones.
* También es difícil saber si los problemas que puedan presentarse sean causados por ser prematuros o por recibir el medicamento.
* EL oftalmólogo hablará con el neonatólogo para saber si es seguro administrar este medicamento a su bebé.

**Esta inyección tiene riesgos y puede ocasionar problemas.**

Hay riesgos con todas las inyecciones y con todos los medicamentos. Estos riesgos pueden producir pérdida de visión o ceguera. Los siguientes son algunos de los problemas más comunes o más graves:

* La inyección podría no detener el desarrollo de la ROP.
* La ROP puede reaparecer más adelante. Es posible que el (la) bebé requiera otra inyección o una cirugía con láser para tratar la ROP.
* Su bebé podría perder visión o quedar ciego(a).
* Cuando se practica cirugía con láser para tratar la ROP, el oftalmólogo sabrá en unas pocas semanas si la ROP puede reactivarse o no. El oftalmólogo tendrá que seguir controlando y examinando periódicamente los ojos de su bebé para detectar la ROP durante mucho tiempo después de la inyección. El (la) bebé podría necesitar cirugía con láser si la retina no crece completamente después de la inyección.
* La inyección puede producir otros problemas oculares:
  + Una infección ocular que puede causar ceguera
  + Un RD (desprendimiento de retina)
  + Cataratas (opacidad del cristalino)
  + Glaucoma (alta presión dentro del ojo)
  + Hipotonía (baja presión dentro del ojo)
  + Daño a la retina
  + Daño en la córnea (la superficie transparente que cubre el frente del ojo)
  + Sangrado dentro del ojo
  + Enrojecimiento intenso en la parte blanca del ojo
  + Irritación ocular y abundante lagrimación
* Los pacientes adultos que han recibido estas inyecciones anti-VEGF han presentado infartos cardiacos, accidentes cerebrovasculares o muerte. La FDA no sabe si el medicamento ha sido la causa de estos problemas.

**Consentimiento**. Al firmar en la parte inferior de esta página, usted da su consentimiento y confirma que:

* Ha leído este formulario de consentimiento informado, o que alguien que se lo ha leído a usted.
* Entiende la información de este formulario.
* El cirujano o el personal del hospital le han entregado una copia de este formulario.
* Se da cuenta de que el (la) bebé puede perder visión o quedar ciego(a).
* Se da cuenta de que el (la) bebé puede requerir otra inyección o una cirugía.
* Se da cuenta de que la FDA no aprobó este medicamento para la ROP.
* El cirujano de los ojos o el personal del hospital han respondido a sus preguntas relacionadas con la inyección para la ROP.
* Entiende que tiene derecho a negarse a aceptar (a decir que no a) este tratamiento para su bebé. Además, entiende que si se niega a aceptar el tratamiento, el oftalmólogo deberá pedir a otros médicos o a personas que trabajen con los servicios de protección del menor que hablen con usted acerca de su decisión.
* Acepta la inyección.

**Deseo que el oftalmólogo le administre a mi bebé una inyección para la ROP en:**

* **\_\_\_\_\_\_\_ el ojo derecho**
* **\_\_\_\_\_\_\_ el ojo izquierdo**
* **\_\_\_\_\_\_\_ ambos ojos.**

Paciente (o persona autorizada para firmar por el paciente) Fecha

# **ICROP. Synopsis of International Classification of Retinopathy of Prematurity Revisited (ICROP 2005)[[2]](#footnote-2)**

* UNIFYING PRINCIPLES UNDERLYING CLASSIFICATION
  + The more posterior the disease and the greater the amount of avascular retinal tissue, the more serious the disease
* REVISIONS incorporated into the 2005 recommendations
  + Concept of a more virulent retinopathy usually observed in the lowest-birth-weight infants—aggressive posterior ROP (AP-ROP).
  + Description of an intermediate level of vascular dilatation and tortuosity (pre-plus disease) between normal-appearing posterior pole vasculature and frank plus disease that has marked dilation and tortuosity of the posterior pole vessels
  + Clarification of the extent of zone I.
* LOCATION (3 zones)
  + Each zone is centered on the optic disc rather than the macula, in contrast to standard retinal drawings.
  + Zone I (posterior pole or innermost zone) consists of a circle, the radius of which extends from the center of the optic disc to twice the distance from the center of the optic disc to the center of the macula.
  + Zone II extends centrifugally from the edge of zone I to the nasal ora serrata (at the 3 o’clock position in the right eye, and the 9 o’clock position in the left eye).
  + Zone III is the residual crescent of retina anterior to zone II.
    - By convention, zones II and III are considered to be mutually exclusive.
    - ROP should be considered to be in zone II until it can be determined with confidence that the nasal-most 2 clock hours are vascularized to the ora serrata.
* EXTENT OF DISEASE (clock hours)
  + This is specified as hours of the clock or as 30° sectors. As the observer looks at each eye, the 3 o’clock position is to the right and nasal in the right eye, and temporal in the left eye, and the 9 o’clock position is to the left and temporal in the right eye, and nasal in the left eye.
  + The boundaries between sectors lie on the clock hour positions; that is, the 12-o’clock sector extends from 12 o’clock to 1 o’clock.
* STAGING OF THE DISEASE: 5 stages
  + Describes the abnormal vascular response at the junction of the vascularized and avascular retina.
    - Because more than one ROP stage may be present in the same eye, staging for the eye as a whole is determined by the most severe manifestation present. For purposes of recording the complete examination, each stage is defined and the extent of each stage by clock hours or sector is recorded.
  + Stage 1: Demarcation Line
    - This line is a thin but definite structure that separates the avascular retina anteriorly from the vascularized retina posteriorly.
    - There is abnormal branching or arcading of vessels leading up to the demarcation line that is relatively flat, white, and lies within the plane of the retina.
    - Vascular changes can be apparent prior to the development of the demarcation line, such as dilatation rather than tapering of the peripheral retinal vessels, but these changes are insufficient for the diagnosis of ROP.
  + Stage 2: Ridge
    - The ridge is the hallmark of stage 2 ROP. It arises in the region of the demarcation, has height and width, and extends above the plane of the retina. The ridge may change from white to pink and vessels may leave the plane of the retina posterior to the ridge to enter it.
    - Small isolated tufts of neovascular tissue lying on the surface of the retina, commonly called “popcorn,” may be seen posterior to this ridge structure. Such lesions do not constitute the fibrovascular growth that is a necessary condition for stage 3.
  + Stage 3: Extraretinal Fibrovascular Proliferation
    - Extraretinal fibrovascular proliferation or neovascularization extends from the ridge into the vitreous. This extraretinal proliferating tissue is continuous with the posterior aspect of the ridge, causing a ragged appearance as the proliferation becomes more extensive.
    - The severity of a stage 3 lesion can be subdivided into mild, moderate, or severe depending upon the extent of extraretinal fibrovascular tissue infiltrating the vitreous.
  + Stage 4: Partial Retinal Detachment
    - Stage 4 is divided into extrafoveal (stage 4A) and foveal (stage 4B) partial retinal detachments. Stage 4 retinal detachments are generally concave and most are circumferentially oriented.
    - The extent of retinal detachment depends upon the number of clock hours of fibrovascular traction and their degree of contraction.
    - Typically, retinal detachments begin at the point of fibrovascular attachment to the vascularized retina. In progressive cases, the fibrous tissue continues to contract and the tractional retinal detachment increases in height, extending both anteriorly and posteriorly.
    - Radial detachments and more complex configurations are less common.
  + Stage 5: Total Retinal Detachment
    - Retinal detachments are generally tractional and may occasionally be exudative.
    - They are usually funnel shaped. The configuration of the funnel itself permits a subdivision of this stage. The funnel is divided into anterior and posterior parts.
      * When open both anteriorly and posteriorly, the detachment generally has a concave configuration and extends to the optic disc.
      * The funnel can be narrow in both its anterior and posterior aspects with the detached retina located just behind the lens.
      * The funnel can be open anteriorly but narrowed posteriorly (less common).
      * The funnel can be narrow anteriorly and open posteriorly (least common).
* PLUS DISEASE
  + The above stages focus on the changes at the leading edge of the abnormally developing retinal vasculature.
  + Additional signs indicating the severity of active ROP have been referred to as “plus” disease. These include:
    - Increased venous dilatation and arteriolar tortuosity of the posterior retinal vessels
    - Iris vascular engorgement
    - Poor pupillary dilatation (rigid pupil)
    - Vitreous haze.
  + The definition of plus disease has been refined to define the minimum amount of vascular dilatation and tortuosity using “standard” photographs and the number of quadrants involved.
  + A + symbol is added to the ROP stage number to designate the presence of plus disease.
    - Stage 2 ROP combined with posterior vascular dilatation and tortuosity would be written “stage 2+ ROP.”
* PRE-PLUS DISEASE
  + ROP activity indicated by abnormal dilatation and tortuosity of the posterior pole vessels. Plus disease is the severe form of this vascular abnormality.
  + Pre-plus disease is defined as vascular abnormalities of the posterior pole that are insufficient for the diagnosis of plus disease but that demonstrate more arterial tortuosity and more venous dilatation than normal.
  + Over time, the vessel abnormalities of pre-plus may progress to frank plus disease as the vessels dilate and become more tortuous.
  + Note pre-plus after the stage: “stage 2 with pre-plus disease.”
* AGGRESSIVE POSTERIOR ROP
  + This is an uncommon, rapidly progressing form designated AP-ROP. **If untreated, it usually progresses to stage 5 ROP.**
  + It is characterized by:
    - Posterior location
    - Prominence of plus disease
    - Ill-defined nature of the retinopathy.
  + Most common in zone I, but may occur in posterior zone II
  + Development and distinguishing features
    - Early on, posterior pole vessels show increased dilation and tortuosity in all 4 quadrants that is out of proportion to the peripheral retinopathy
    - The vascular changes progress rapidly
    - Shunting occurs from vessel to vessel within the retina and not solely at the junction between vascular and avascular retina
    - Often difficult to distinguish between arterioles and venules because both have significant dilation and tortuosity
    - May be hemorrhages between vascularized and avascular retina
    - Does not progress through the classic stages 1 to 3
    - May appear as only a flat network of neovascularization at the deceptively featureless junction between vascularized and nonvascularized retina and may be easily overlooked
    - Typically extends circumferentially and is often accompanied by a circumferential vessel
    - Performing indirect ophthalmoscopy with a 20-D condensing lens instead of a 25- or 28-D lens may help to distinguish the deceptively featureless neovascularization
  + Previously referred to as “type II ROP” and “Rush disease.” Aggressive, posterior ROP more accurate.Diagnosis can be made on a single visit, does not require evaluation over time.
* REGRESSION OF ROP
  + Most ROP regresses spontaneously by a process of involution or evolution from a vascoproliferative phase to a fibrotic phase
  + One of the first signs of stabilization of the acute phase of ROP is the failure of the retinopathy to progress to the next stage.
  + Morphological signs of regression
    - Occurs largely at the junction of vascular and avascular retina as retinal vascularization advances peripherally
    - On serial examinations, the anteroposterior location of retinopathy may change from zone I to zone II or from zone II to zone III.
    - The ridge may change in color from salmon pink to white.
  + Involutional sequelae of ROP
    - Peripheral changes
      * Vascular
        + Failure of peripheral, retinal vascularization
        + Abnormal, nondichotomous branching of the retinal vessels
        + Vascular arcades with circumferential interconnection
        + Telangiectatic vessels
      * Retinal
        + Pigmentary changes
        + Vitreoretinal interface changes
        + Thin retina
        + Peripheral folds
        + Vitreous membranes with or without attachment to retina
        + Lattice-like degeneration
        + Retinal breaks
        + Traction-rhegmatogenous retinal detachment
    - Posterior changes
      * Vascular
        + Vascular tortuosity
        + Straightening of blood vessels in temporal arcade
        + Decrease in angle of insertion of major temporal arcade
      * Retinal
        + Pigmentary changes
        + Distortion and ectopia of macula
        + Stretching and folding of retina in macular region leading to periphery
        + Vitreoretinal interface changes
        + Vitreous membranes
        + Dragging of retina over optic disc
        + Traction-rhegmatogenous retinal detachment
      * The more severe the acute phase of the retinopathy, the more likely involutional changes will be severe as the disease enters what was formerly called the “cicatricial phase.”

1. “Screening Examination of Premature Infants for Retinopathy of Prematurity.” Policy Statement issued by the American Academy of Pediatrics (AAP) Section on Ophthalmology, the American Association of Pediatric Ophthalmology and Strabismus (AAPOS), and the American Academy of Ophthalmology (AAO). Originally issued in 1997 and updated in 2001, 2005, and 2006; current version published in *Pediatrics* (Volume 131, Number 1, 2013, at <http://pediatrics.aappublications.org/content/131/1/189>. [↑](#footnote-ref-1)
2. The International Classification of Retinopathy of Prematurity Revisited. International Committee for the Classification of Retinopathy of Prematurity. *Arch Ophthalmol* 2005. 123: 991-999. Available at Available at <https://jamanetwork.com/journals/jamaophthalmology/fullarticle/417157>. [↑](#footnote-ref-2)