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**ROP Safety Net Hospital Toolkit**

**Reviewed by**

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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 04/01/2022**

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

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# **Procedure 1.Tracking ROP care of hospitalized infants**

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

**Tracking principles for hospitalized infants**

1. The ophthalmologist is personally involved in the tracking.
2. The hospital has an ROP coordinator (H-ROPC) who:
   1. Is familiar with and understands the ROP Screening Policy Statement (PS)[[1]](#endnote-1),[[2]](#endnote-2) and the Tables in this 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.
3. Hospitalized infants are tracked by at least two ROP team members:
   1. The hospital ROP coordinator (H-ROPC) **AND**
   2. The office ROP coordinator (O-ROPC) for each ophthalmologist or practice currently providing care.
4. There is only one Master Hospital [ROP Tracking List](#_Table_1._Which) of hospitalized infants who need ROP care, and it is kept by the H-ROPC, who sends a copy to the O-ROPC **at least once a week.**
   1. The Hospital ROP Tracking List contains the following information for each ROP exam and treatment:
      1. Birth information: Infant’s name, date of birth, gestational age at birth, birth weight, and medical record number.
      2. Exam information: Postmenstrual age (gestational age + chronological age), date of exam or treatment, ROP status, next exam (given as both an interval and an approximate date), discharge/transfer date, and date when the infant met the conclusion of acute-phase-screening criteria.
5. The H-ROPC and O-ROPC compare the updated Master Hospital ROP Tracking List with the prior week’s list **at least once a week**, and contact the neonatologist and ophthalmologist about any missed, cancelled, or rescheduled ROP exams.
6. Each infant who meets the criteria for ROP screening is tracked until he meets the end-of-acute screening criteria [[Table 5. When to stop](#_Table_5.__1)].

**Tracking process**

1. The neonatologist identifies new infants who meet screening criteria [[Table 1. Who to screen](#_Table_1._Which_1)] and indicates when the initial ROP exam should take place [[Table 2. When to start](#_Table_2._When)].
2. The neonatologist instructs the hospital ROP coordinator (H-ROPC) to add the infant’s name and date of initial exam to the Master Hospital [ROP Tracking List](#_Table_1._Which).
3. The H-ROPC contacts the office ROPC (O-ROPC) to schedule the initial exam.
4. The O-ROPC adds the infant to the Hospital ROP Tracking List and begins tracking when the H-ROPC requests:
   1. The initial ROP exam with a screening ophthalmologist or
   2. A consultation with a treating ophthalmologist to determine if treatment is needed [[Table 4. When to treat](#_Table_4._)].
5. The H-ROPC and O-ROPC update the current Hospital ROP Tracking List:
   1. After each exam:
      1. The screening ophthalmologist informs both the ROPCs of the results of the ROP exam and the interval **and** approximate date of the next exam (e.g., next ROP exam in two weeks on approximately 9/25/22).
      2. The ROPCs compare the scheduled follow-up interval to that recommended in the ROP Screening Policy Statement (PS) [[Table 3. Follow-up exams](#_Table_3.__1)] and contact the ophthalmologist if the interval is longer than the one indicated by the PS and/or longer than 3 weeks since the last exam.
   2. When treatment is needed:
      1. The screening ophthalmologist informs both the ROPCs that treatment might be needed, and contacts the treating ophthalmologist to conduct the transfer-of-care discussion.
      2. The H-ROPC contacts the O-ROPC for the treating ophthalmologist and schedules an exam to determine if treatment is needed.
   3. After treatment:
      1. The treating ophthalmologist informs both ROPCs of the type of treatment and the interval **and** approximate date of the next exam.
         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 to conduct the transfer-of-care discussion.
      2. The ROPCs compare the scheduled follow-up interval to that recommended in the PS and contact the ophthalmologist if the interval indicated is longer than the one indicated.
   4. When care of the infant is transferred to/from:
      1. Screening and treating ophthalmologist
      2. Hospital-based and outpatient ophthalmologist
      3. Ophthalmologist in one hospital and ophthalmologist in another hospital.
   5. When ROP screening and treatment are complete.
      1. ***Per the Policy Statement*, *one exam is sufficient only if it unequivocally reveals the retina to be fully vascularized in both eyes.***
      2. The ROPCs continue to track until one of the following conditions has been met and documented:
         1. A treating ophthalmologist has verified that the treatment and follow-up examinations are complete.
         2. Both eyes have met the conclusion-of-acute-screening criteria based upon a binocular indirect ophthalmoscopy exam [[Table 5. When to stop](#_Table_5.__1)].
         3. The current ophthalmologist conducts and documents a transfer-of-care discussion with the ophthalmologist who will take over care.

# **Procedure 2. ROP exam**

**Hospital ROP exam principles**

1. The hospital has a treating ophthalmologist with staff privileges who can provide ROP treatment within 72 hours.
2. The hospital admits infants from the outpatient setting who need ROP treatment, or has a transfer agreement in place with a hospital that does admit infants and can provide ROP treatment within 72 hours.
3. The ophthalmologist:
   1. Has an O-ROPC who works with the H-ROPC to track infants needing ROP care.
   2. Has sufficient knowledge and experience to accurately identify the location and sequential retinal changes of ROP after pupillary dilation using binocular indirect ophthalmoscopy with a lid speculum and scleral depression (as needed) (PS #2).
   3. Uses the International Classification of Retinopathy of Prematurity (ICROP), Third Edition[[3]](#endnote-3) to classify, diagram, and record the retinal findings (PS #2).
   4. Knows and understands treatment criteria [[Table 4. When to treat](#_Table_4._)].

**Hospital ROP exam procedure**

1. The H-ROPC contacts the O-ROPC of the screening ophthalmologist to schedule the initial ROP exam and begin tracking.
2. The H-ROPC or NICU nurse assists the ophthalmologist with the exam and:
   1. Reviews the list of infants to be examined that day, along with their medical records.
   2. Consults with the neonatologist to determine if any contraindications to the examination exist and:
      1. Notifies the O-ROPC of any infant who cannot undergo the scheduled eye exam.
      2. Reschedules the exam within the time interval indicated by the infant’s most recent eye exam.
      3. Contacts the neonatologist and ophthalmologist to determine the best course of action, and documents the discussion, if the infant cannot be examined within the indicated interval.
      4. Documents the notification and reason for not having the exam in the infant’s medical record.
      5. Notifies the parent of the delay and documents the discussion.
   3. Provides the following supplies:
      1. Sterile NICU eye tray with lid speculum and depressor
      2. Anesthetic eye drops
      3. Indirect ophthalmoscope (if ophthalmologist does not bring one)
      4. 20 and 28 diopter lenses
      5. Dilating eye drops
      6. Gloves
   4. Dilates the infants’ eyes at the time ordered by the ophthalmologist per the dilating protocol.
   5. Ensures that participants in the eye exam have washed their hands, and, if indicated, wear gloves to prevent eye irritation and infection.
   6. Secures the infant in a blanket, holds the infant during the exam, and provides a pacifier and/or oral sucrose for comfort.
   7. Monitors the infant for side effects associated with the dilating eye drops and exam.
   8. Documents the dilation, exam, and the infant’s condition during the exam.
   9. Cleans and sterilizes the equipment according to the manufacturer’s specifications to prevent eye irritation and infection.
3. The ophthalmologist performs a binocular indirect ophthalmoscopy (BIO) exam after pupillary dilation and documents the findings using ICROP.
4. The ophthalmologist determines the timing of the next examination [[Table 3. Follow-up exams](#_Table_3.__1)].
   1. Current guidelines indicate a range of 1 to 3 weeks between examinations, depending upon the findings.
   2. Infants at high risk for ROP may need more frequent examinations.
   3. Infants treated with an anti-VEGF medication (i.e., Avastin or Lucentis) need to be monitored until at least 65 weeks postmenstrual age (PMA).
5. The ophthalmologist writes an order for the next exam indicating the interval **and** approximate date (e.g., next eye exam in two weeks around 9/25/22) and:
   1. Notifies the ROPCs of the next exam interval and approximate date, and instructs them to update the Hospital ROP Tracking List.
6. The ophthalmologist screens for ROP until one of the following conditions has been met and documented:
   1. ***Per the Policy Statement, one exam is sufficient only if it unequivocally reveals the retina to be fully vascularized in both eyes.***
   2. A treating ophthalmologist has verified that the 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.__1)].
   4. The current ophthalmologist conducts and documents a transfer-of-care discussion with the ophthalmologist who will take over care.

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

**Treat ROP at hospital principles**

1. The hospital is able to provide anti-VEGF drugs at the appropriate compounded dose and supplies for intravitreal injections.

**Treatment process**

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 surgery](#_Consent_for_laser),  or [Consent for injection](#_ICROP._Synopsis_of)].
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 ROP](#_Table_5.__1)].
   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.

# **Procedure 4. Discharge**

**Discharge principles**

1. 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.
2. No hospital may discharge an infant who needs ROP care unless it first:
   1. Obtains the agreement of the hospital-based ophthalmologist **AND**
   2. Schedules ophthalmic care in the outpatient setting with an ophthalmologist who agrees to screen the ROP patient **AND**
   3. Sends the ophthalmologist appropriate records and current contact information for the parent.
3. The hospital has a written discharge agreement with outpatient ophthalmologists who do not provide ROP care at the hospital. The agreement addresses ROP tracking, follow-up, and treatment.

**Discharge process**

1. The neonatologist notifies the ophthalmologist and hospital ROP coordinator (H-ROPC) that a discharge is planned.
2. The ophthalmologist determines if the infant needs another ROP exam or additional treatment prior to discharge and writes a final ophthalmic consult note that summarizes the infant’s current ROP status and screening/treatment recommendations (a new note may not be needed if the ophthalmologist has evaluated or treated the infant very recently).
3. The ophthalmologist tells the H-ROPC (hospital ROPC) and O-ROPC (office ROPC):
   1. The interval and approximate date of the next ROP exam if screening is not complete (e.g., follow-up exam in 2 weeks around 9/25/22) [[Table 3. Follow-up exams](#_Table_3.__1)].
   2. If ROP screening is complete [[Table 5. When to stop](#_Table_5.__1)].
4. The ophthalmologist instructs the ROPCs to update the Hospital [ROP Tracking List](#_Table_1._Which) to show that the infant was discharged.
5. The ophthalmologist completes and signs the [Discharge letter](#_Letter_to_parent:) or [Spanish Discharge letter](#_ICROP._Synopsis_of_1), and writes an order for the hospital ROPC or NICU nurse to:
   1. Review the letter with the parent, and obtain the parent’s signature.
   2. Give a copy of the signed document to the parent.
   3. Place a copy of the signed document in the infant’s medical record.
6. The neonatologist explicitly addresses eye care in the discharge summary based upon the most recent ophthalmology note:
   1. States the interval and approximate date of the next exam (e.g., ROP exam needed in two weeks around 9/25/22) if ROP screening is not complete **OR**
   2. Directs the pediatrician to refer the infant to an ophthalmologist to screen for conditions common in premature infants, such as amblyopia, strabismus, etc.
7. The H-ROPC coordinates the discharge:
   1. Confirms that the ophthalmologist has been notified of the discharge and has agreed to it.
   2. Contacts the O-ROPC of the ophthalmologist who will provide outpatient ROP care and:
      1. Confirms that an ophthalmologist has agreed to take over the ROP care,
      2. Indicates the interval and approximate date of the first outpatient exam,
      3. Schedules the initial ROP exam with the ophthalmologist, and
      4. Sends all pertinent medical records and current contact information for the parent.
   3. Informs the parent:
      1. Of the name of the outpatient ophthalmologist,
      2. The date and location of the next ROP exam, and
      3. That Child Protective Services may be contacted if the parent does not keep outpatient appointments exactly as scheduled.

# **Procedure 5. Transfer for other care**

**Transfer for other care principles**

1. The hospital may only transfer an infant who needs ROP care if it first:

* 1. Obtains the agreement of the transferring, hospital-based ophthalmologist **AND**
  2. Schedules ophthalmic care at the receiving hospital with an ophthalmologist who agrees to screen for ROP **AND**
  3. Verifies that the receiving hospital has designated someone who is familiar with and understands the ROP Screening Policy Statement to track the ROP care until the infant meets the end-of-acute screening criteria [[Table 5. When to stop](#_Table_5.__1)] **AND**
  4. Confirms that the hospital will schedule the first outpatient ROP appointment if the infant is discharged before ROP screening is complete **AND**
  5. Sends the hospital appropriate records and current contact information for the parent.

**Transfer process**

1. The neonatologist notifies the ophthalmologist and hospital ROP coordinator (H-ROPC) that a transfer for non-ROP care is planned, and clarifies whether the infant will be transferred back after the non-ROP care.
2. The ophthalmologist determines if the infant needs another ROP exam or additional treatment prior to transfer and writes a final ophthalmic consult note that summarizes the infant’s current ROP status and screening/treatment recommendations (a new note may not be needed if the ophthalmologist has evaluated or treated the infant very recently).
3. The ophthalmologist tells the H-ROPC and office ROPC:
   1. The interval and approximate date of the next ROP exam if screening is not complete (e.g., follow-up exam in 2 weeks around 9/25/22) [[Table 3. Follow-up exams](#_Table_3.__1)].
   2. If ROP screening is complete [[Table 5. When to stop](#_Table_5.__1)].
4. The ophthalmologist instructs the ROPCs to update the Hospital [ROP Tracking List](#_Table_1._Which) to show that the infant was transferred for non-ROP care.
5. The ophthalmologist completes and signs the [Transfer for other care letter](#_Transfer_for_other) or [Spanish Transfer for other care letter](#_Carta_de_remisión), and writes an order for the H-ROPC or NICU nurse to:
   1. Review the letter with the parent, and obtain the parent’s signature.
   2. Give a copy of the signed document to the parent.
   3. Place a copy of the signed document in the infant’s medical record.
6. The neonatologist explicitly addresses eye care in the neonatology discharge summary based upon the most recent ophthalmology note:
   1. States the interval and approximate date of the next exam (e.g., ROP exam needed in two weeks around 9/25/22) if ROP screening is not complete **OR**
   2. Directs the pediatrician to refer the infant to an ophthalmologist to screen for conditions common in premature infants, such as amblyopia, strabismus, etc.
7. The H-ROPC coordinates the transfer:
   1. Confirms that the ophthalmologist has been notified of the transfer and has agreed to it.
   2. Contacts the Admitting Nurse at the receiving hospital and:
      1. Confirms that an ophthalmologist has agreed to take over the ROP care if it is still needed,
      2. Verifies that the receiving hospital has designated someone who is familiar with and understands the ROP Screening Policy Statement to track the ROP care until the infant meets the end-of-acute screening criteria [[Table 5. When to stop](#_Table_5.__1)]
      3. Confirms that the hospital will schedule the first outpatient ROP appointment if the infant is discharged before ROP screening is complete
      4. Indicates the interval and approximate date of the first ROP exam at the receiving hospital,
      5. Schedules the initial ROP exam with an ophthalmologist, and
      6. Sends all pertinent medical records and current contact information for the parents.
   3. Informs the parent of the name of the ophthalmologist at the receiving hospital.
8. The H-ROPC coordinates the transfer back to the original hospital if the infant will return there:
   1. Speaks to the nurse at the other hospital to obtain the ophthalmic records, and learns the infant’s ROP status, and the interval and approximate date of the next ROP exam.
9. The H-ROPC informs the O-ROPC and the ophthalmologist who will take over when the infant is coming back, provides the other hospital’s ROP records, and schedules the next exam. The ROPCs resume tracking.

# **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)**

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.

**Version** 04/04/2022

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.

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.

**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.

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 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 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.

**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. 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)
  + Eye irritation, inflammation and lots of tears

**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 after surgery.
* 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.**

Parent (or person authorized to sign for patient) Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Relationship to child if other than parent

# **Please contact OMIC risk management regarding Spanish translation of consent for laser surgery.**

**Informed consent for injection to treat ROP (retinopathy of prematurity)**

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**Version** 04/04/2022

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**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

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

Relationship to child if other than parent

# **Please contact OMIC risk management department regarding Spanish translation of consent for injection to treat.**

# **Discharge letter**

Ophthalmologist: Place on your letterhead

Dear \_\_\_\_\_\_\_\_\_

I am an ophthalmologist (eye physician and surgeon). Your baby’s doctor asked me to examine the baby’s eyes. This letter will explain why I did the exam. It will also explain when an ophthalmologist needs to examine the baby’s eyes again.

**Your baby may have a condition of the retina (the back of the eye) called ROP (retinopathy of prematurity).** After a premature birth, the blood vessels at the back of the eye may stop growing. The baby’s body responds by making a chemical called VEGF (vascular endothelial growth factor) that causes new blood vessels to grow. These blood vessels are not normal: they can bleed and can also pull (detach) the retina away from its normal position. If the retina becomes detached, it can cause blindness.

ROP needs to be treated with 72 hours if it reaches a certain stage. Your baby could go blind without treatment.

**The next few months are very important.** We need your help to keep your baby from going blind. An ophthalmologist will need to examine the baby’s eyes many times. The ophthalmologist is checking for abnormal blood vessels. The exams must continue until the blood vessels heal.

You must bring the baby in to the office or clinic for every appointment. The ophthalmologist will contact you if you missan appointment. If the ophthalmologist cannot reach you, the ophthalmologist may need to contact Child Protective Services to help bring the baby in for an eye exam.

**Here is what I found today when I examined your baby**

* \_\_\_\_Your baby’s blood vessels are abnormal and the baby may need treatment soon. An ophthalmologist will examine the baby each week to see if treatment is needed. The next ROP exam should take place by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (date) in \_\_\_\_\_ weeks.
* \_\_\_\_Your baby’s blood vessels are abnormal but the baby does not need treatment right now. An ophthalmologist will examine the baby again to see if treatment is needed. The next ROP exam should take place by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (date) in \_\_\_\_\_ weeks.
* \_\_\_\_\_Your baby’s blood vessels are almost normal. The baby will not need treatment for ROP, but does need a different type of eye exam to check for crossed eyes, lazy eye, or nearsightedness. Your baby should be checked by \_\_\_\_\_\_\_\_\_\_\_ (date). Ask the baby’s doctor (pediatrician) for a referral to an ophthalmologist then call the ophthalmologist and make the appointment. It is very important that the baby is examined by the date shown above.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of ophthalmologist Date

# **Please contact OMIC risk management for Spanish translation of discharge letter.**

# **Transfer for other care letter**

Ophthalmologist: Place on your letterhead. Revise the letter as needed if the infant will not return to the original hospital after treatment.

Dear \_\_\_\_\_\_\_\_\_

I am an ophthalmologist (eye physician and surgeon). Your baby’s doctor asked me to examine the baby’s eyes. This letter will explain why I needed to do the exam, and why the baby will need more eye exams.

**Your baby may have a condition of the retina (the back of the eye) called ROP (retinopathy of prematurity).** After a premature birth, the blood vessels at the back of the eye may stop growing. The baby’s body responds by making a chemical called VEGF (vascular endothelial growth factor) that causes new blood vessels to grow. These blood vessels are not normal: they can bleed and can also pull (detach) the retina away from its normal position. If the retina becomes detached, it can cause blindness.

ROP needs to be treated with 72 hours if it reaches a certain stage. Your baby could go blind without treatment.

**The next few months are very important.** We need your help to keep your baby from going blind. An ophthalmologist will need to examine the baby’s eyes many times. The ophthalmologist is checking for abnormal blood vessels. The exams must continue until the blood vessels heal. An ophthalmologist at the next hospital will examine the baby’s eyes there. I will examine the baby’s eyes again at this hospital if your baby comes back here. Additional exams may be needed after you take the baby home.

When your baby is allowed to go home, the hospital will make an ROP appointment with an ophthalmologist. You must bring the baby in to the office or clinic for every appointment. The ophthalmologist will contact you if you missan appointment. If the ophthalmologist cannot reach you, the ophthalmologist may need to contact Child Protective Services to help bring the baby in for an eye exam.

**Here is what I found today when I examined your baby**

* \_\_\_\_Your baby’s blood vessels are abnormal and the baby may need treatment soon. An ophthalmologist will examine the baby each week to see if treatment is needed. The next ROP exam should take place by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (date) in \_\_\_\_\_ weeks.
* \_\_\_\_Your baby’s blood vessels are abnormal but the baby does not need treatment right now. An ophthalmologist will examine the baby again to see if treatment is needed. The next ROP exam should take place by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (date) in \_\_\_\_\_ weeks.
* \_\_\_\_\_Your baby’s blood vessels are almost normal. The baby will not need treatment for ROP, but does need a different type of eye exam to check for crossed eyes, lazy eye, or nearsightedness. Your baby should be checked by \_\_\_\_\_\_\_\_\_\_\_ (date). Ask the baby’s doctor (pediatrician) for a referral to an ophthalmologist then call the ophthalmologist and make the appointment. It is very important that the baby is examined by the date shown above.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of ophthalmologist Date

# **Please contact risk management for Spanish translation of transfer for other care letter.**

# **[Table 1. Which infants need an ROP screening examination](#Table_1)[[4]](#endnote-4)**

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 g and 2000 g (from 3 lbs., 4 oz. to 4 lbs., 6 oz.) or gestational age of more than 30 weeks who are believed by their attending pediatrician or neonatologist to be at risk for ROP (such as infants with hypotension requiring inotropic support, infants who received oxygen supplementation for more than a few days, or infants who received oxygen without saturation monitoring).

# **[Table 2. When to start ROP screening](#Table_2)[[5]](#endnote-5)**

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** |
| 22[[6]](#footnote-1)[[7]](#footnote-2) | 31 | 9 |
| 23\*† | 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 |
|  |  |  |

# **[Table 3. Follow-up schedule for ROP exams](#Table_3)[[8]](#endnote-6)**

The examining ophthalmologist should use retinal findings as classified by ICROP3 to determine the timing of the follow-up examinations.

* 1 week or less
  + Zone I: Immature vascularization, no ROP
  + Zone I: Stage 1 or 2 ROP
    - **NOTE IN PS:** Zone I, Stage 3 requires treatment, not observation
  + Immature retina extends into posterior zone I, near the boundary of zone I –zone II.
  + Suspected presence of aggressive ROP
  + After laser photocoagulation or anti-VEGF injection to ensure that there is no need for additional laser treatment in areas where ablative treatment was not complete or additional anti-VEGF injection.
* 1 to 2 weeks
  + Posterior zone II: Immature vascularization
  + Zone II, Stage 2 ROP
  + Zone I: Unequivocally regressing ROP
* 2 weeks
  + Zone II: Stage 1 ROP
  + Zone II: no ROP, immature vascularization
  + Zone II: Unequivocally regressing ROP
* 2 to 3 weeks
  + Zone III: Stage 1 or 2 ROP
  + Zone III: Regressing ROP

# **Table 4. When to treat ROP[[9]](#endnote-7)**

* The presence of plus disease in zones I or II suggests that peripheral ablation, rather than observation, is appropriate.
  + Plus, and preplus disease“is defined by the appearance of dilation and tortuosity of retinal vessels, and preplus disease is defined by abnormal vascular dilation, tortuosity insufficient for plus disease or both.”
  + “These changes should be assessed by vessels within zone 1, rather than from only vessels within the field of narrow-angle photographs and rather than from the number of quadrants of abnormality.”
* Treatment should be initiated for the following retinal findings that characterize Type 1 ROP:
  + 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
* Treatment should generally be accomplished, when possible, within 72 hours of determination of treatable disease to minimize the risk of retinal detachment.
* Consideration may be given to treatment of infants with zone I stage 3+ ROP with intravitreal injection of bevacizumab.
  + Bevacizumab and other anti-VEGF substances are 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, and visual and systemic outcomes. Studies have yielded contrary findings on the increased incidence of neurodevelopmental problems, including severe cerebral palsy, hearing loss, and bilateral blindness.
  + Infants treated with bevacizumab should be monitored closelyuntil at least 65 weeks postmenstrual age
  + Longer follow-up is required because recurrence occurs considerably later (16 ± 4.6 weeks vs 6.2 ± 5.7 weeks) than after laser therapy. There are reports of recurrence requiring retreatment as late as 65 to 70 weeks postmenstrual age.
  + The timeframe of highest disease reactivation is between 45 and 55 weeks.
* Follow up is recommended in 3 to 7 days after laser photocoagulation or anti-VEGF injection to ensure that there is no need for additional laser treatment in areas where ablative treatment was not complete or for additional anti-VEGF injection.

# **Table 5. When to stop ROP screening[[10]](#endnote-8)**

**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:

* Full retinal vascularization in close proximity to the ora serrata for 360° i.e., the normal distance found in mature retina between the end of vascularization and the ora serrata.
* Zone III retinal vascularization attained without previous zone I or II ROP
  + If there is examiner doubt about the zone or if the postmenstrual age is less than 35 weeks, confirmatory examinations may be warranted.
* Postmenstrual age of 45 weeks: No type 1 ROP or worse is present, and no anti-VEGF treatment
  + Type 1 ROP disease (previously called “pretheshold”) defined as:
    - Stage 3 ROP in zone II
    - Any ROP in zone I
* Postmenstrual age of 65 weeks: Infants treated with anti-VEGF
  + Follow closely until at least 65 weeks postmenstrual age
  + Particularly close follow-up is needed during the time of highest risk for disease reactivation (45 to 55 weeks PMA)
  + 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
  + Full retinal vascularization should be the criterion for all infants treated solely with anti-VEGF medication.
  + Full retinal vascularization is not always achieved in infants treated with anti-VEGF alone.
  + If there is not full retinal vascularization at 65 weeks PMA, rely upon prolonged observation, clinical judgment, and evolving criteria for termination of exams or a need for further treatment.
* Regression of ROP (ICROP3)
  + 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.
  + “Regression can be complete or incomplete. Location and extent of peripheral avascular retina (PAR) should be documented.”

**References**

1. Fierson WM, American Academy of Pediatrics (AAP) Section on Ophthalmology, American Academy of Ophthalmology, American Association for Pediatric Ophthalmology and Strabismus, American Association of Certified Orthoptists. Screening Examination of Premature Infants for Retinopathy of Prematurity. [Policy Statement.] *Pediatrics*. 2018;142(6):e20183061. Available at: <http://pediatrics.aappublications.org/content/142/6/e20183061> (Accessed: 3/16/22) [↑](#endnote-ref-1)
2. The clinical tables in this OMIC toolkit refer to numbered recommendations from the ROP Position Statement. [↑](#endnote-ref-2)
3. Chang MF, Quinn GE, Fielder AR, Wu WC, Zhao P, Zin A, *et al*. International Classification of Retinopathy of Prematurity, Third Edition. *Ophthalmology*. 2021;128(10):E51-E68. Available at: <https://doi.org/10.1016/j.ophtha.2021.05.031> (Accessed: 3/10/22) [↑](#endnote-ref-3)
4. Source: ROP Policy Statement, Recommendation #1. [↑](#endnote-ref-4)
5. Source: ROP Policy Statement, Recommendation #2. [↑](#endnote-ref-5)
6. 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. [↑](#footnote-ref-1)
7. Some practitioners have advocated for earlier screening on the basis of speculation that treatable aggressive ROP (A-ROP) 2 could occur before 31 weeks postmenstrual age. A-ROP is a severe form of ROP that is characterized by rapid progression in whichever retinal location it is found. [↑](#footnote-ref-2)
8. Source: ROP Policy Statement, Recommendation #4. [↑](#endnote-ref-6)
9. Source: ROP Policy Statement, Treatment Section. [↑](#endnote-ref-7)
10. Source: ROP Policy Statement, Recommendation #4. [↑](#endnote-ref-8)