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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.

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# **Procedure 2a. ROP exam in hospital**

**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.**

**ROP exam in hospital principles**

1. The hospital has a treating ophthalmologist with staff privileges, or has a transfer agreement in place with a hospital that can accept the transfer and 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 hospital has an ROP coordinator (H-ROPC) who:
   1. 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.
   2. Keeps the Master Hospital [ROP Tracking List](#_ROP_Tracking_List_1) of hospitalized infants who need ROP care, and sends the office ROPC (O-ROPC) a copy of it.
   3. Reviews the Hospital ROP Tracking List with the O-ROPC **at least once a week.** The ROPCs compare the current list with the list from the prior week. The H-ROPC notifies the ophthalmologist and neonatologist of all missed, cancelled, or rescheduled ROP exams.
4. 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) Revisited[[2]](#footnote-2)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**

**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.**

1. The neonatologist identifies new infants who meet screening criteria [[Table 1. Who to screen](#_Table_1._Which_1)] and indicates the approximate date of the initial ROP exam [[Table 2. When to start](#_Table_2._When)].
2. The neonatologist instructs the H-ROPC to add the infant’s name and date of the initial ROP exam to the Hospital [ROP Tracking List](#_ROP_Tracking_List_1).
3. The H-ROPC contacts the O-ROPC of the screening ophthalmologist to schedule the initial ROP exam and begin tracking.
4. 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.
5. The ophthalmologist performs a binocular indirect ophthalmoscopy (BIO) exam after pupillary dilation and documents the findings using ICROP.
6. The ophthalmologist determines the timing of the next examination [[Table 3. Follow-up exams](#_Table_3._)].
   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).
7. The ophthalmologist writes an order for the next exam indicating the interval **and** approximate date (e.g., next eye exam in two weeks around 9/25/19) and:
   1. Notifies the ROPCs of the next exam interval and approximate date, and instructs them to update the Hospital ROP Tracking List.
8. 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._)].
   4. The current ophthalmologist conducts and documents a transfer-of-care discussion with the ophthalmologist who will take over care.

**[Table 1. Which infants need an ROP screening examination](#Table_1)[[3]](#footnote-3)**

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 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).

**REFERENCE: ROP Screening Policy Statement # 1**. 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.

**\***Some practitioners have advocated for earlier screening on the basis of speculation that treatable aggressive posterior ROP (AP-ROP) could occur before 31 weeks postmenstrual age. AP-ROP is a severe form of ROP that is characterized by rapid progression to advanced states in posterior ROP.

**REFERENCE:ROP Screening Policy Statement #2.** 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 (11): 1470-1476.

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

The examining ophthalmologist should use retinal findings as classified by ICROP[[4]](#footnote-4) 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 –zone II.
  + Suspected presence of AP-ROP (aggressive posterior 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

**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 (11): 1470-1476.

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

* 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
  + The presence of plus disease rather than the number of clock hours of disease, is the better determining factor in recommending ablative treatment.
* 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.

**REFERENCE:ROP Screening Policy Statement #4 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:

* 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.
* 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 (see ICROP)
  + 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 # 4.** 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.*Arch Ophthalmol.* 2002; 120 (11): 1470-1476.

# **ROP Tracking List**

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



1. Fierson WM. “Screening Examination of Premature Infants for Retinopathy of Prematurity.” Policy Statement (PS) issued by the American Academy of Pediatrics (AAP) Section on Ophthalmology, the American Association of Pediatric Ophthalmology and Strabismus (AAPOS), and the American Association of Certified Orthoptists. Originally issued in 1997 and updated in 2001, 2005, 2006, and 2018; current version published in *Pediatrics* (Volume 142, Number 6, 2018, at <http://pediatrics.aappublications.org/content/early/2018/11/21/peds.20183061>. This document refers to recommendations based upon the numbers assigned to them in the PS. [↑](#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 <https://jamanetwork.com/journals/jamaophthalmology/fullarticle/417157>. [↑](#footnote-ref-2)
3. Clinical tables based upon Fierson WM. “Screening Examination of Premature Infants for Retinopathy of Prematurity.” Policy Statement (PS) issued by the American Academy of Pediatrics (AAP) Section on Ophthalmology, the American Association of Pediatric Ophthalmology and Strabismus (AAPOS), and the American Association of Certified Orthoptists. Originally issued in 1997 and updated in 2001, 2005, 2006, and 2018; current version published in *Pediatrics* (Volume 142, Number 6, 2018, at <http://pediatrics.aappublications.org/content/early/2018/11/21/peds.20183061>. This document refers to recommendations based upon the numbers assigned to them in the PS. [↑](#footnote-ref-3)
4. 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 <https://jamanetwork.com/journals/jamaophthalmology/fullarticle/417157>. [↑](#footnote-ref-4)