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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 1b. Tracking outpatient ROP care**

**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.**

**Outpatient tracking principles**

1. A hospital with a treating ophthalmologist has agreed to admit infants from the outpatient setting who need ROP treatment, and can provide treatment within 72 hours.
2. The ophthalmologist is personally involved in the tracking.
3. The practice has a written protocol for contacting Child Protective Services.
4. The office ROP coordinator (O-ROPC):
	1. Is familiar with and understands the PS 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.
	2. Works with the Hospital ROPC (H-ROPC) when an infant is discharged to schedule the initial outpatient visit.
	3. Educates the parent about ROP on an ongoing basis.
	4. Coordinates care provided during ROP exams.
	5. Coordinates transfers of care from one ophthalmologist to another.
5. The office ROP coordinator (O-ROPC) keeps the Outpatient [ROP Tracking List](#_ROP_Tracking_List) of infants who are examined in the office.
	1. The Outpatient 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.
	2. NOTE: The Outpatient ROP Tracking List may be a continuation of the Hospital ROP Tracking List, or a separate list.
6. The O-ROPC tracks outpatient ROP appointments in two ways:
	1. Reviews outpatient appointments **daily** and
	2. Reviews the Outpatient Tracking List **at least once a week**
7. The O-ROPC notifies the ophthalmologist of all missed, cancelled, and rescheduled ROP appointments, and follows up as instructed by the ophthalmologist.
8. The O-ROPC tracks each infant until the infant meets end-of-acute-screening criteria [[Table 5. When to stop](#_Table_5._)].

**Tracking 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 hospital ROPC (H-ROPC) contacts the O-ROPC when an infant needs 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 outpatient ROP exam, and
	4. Sends the O-ROPC all pertinent medical records and current contact information for the parent.
2. Staff members who answer phones use the [ROP exam request form](#_ROP_exam_request) to determine if ROP care is needed when a parent, physician, or hospital where the ophthalmologist does not provide ROP care requests an appointment for an infant.
3. The O-ROPC adds the infant to the Outpatient [ROP Tracking List](#_Tracking_list) and begins outpatient tracking.
4. The O-ROPC updates the Outpatient ROP Tracking List at each of the following stages in care:
	1. After each exam:
		1. The ophthalmologist informs the O-ROPC of the results of the ROP exam and the interval and approximate date of the next exam (e.g., next exam in two weeks on approximately 9/25/18).
		2. The O-ROPC compares the requested follow-up interval to that recommended in the ROP Screening Policy Statement (PS)[[1]](#footnote-1) [[Table 3. Follow-up exams](#_Table_3.__1)] and contacts 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 might be needed:
		1. The screening ophthalmologist informs the O-ROPC that an infant might need treatment [[Table 4. When to treat](#_Table_4._)], and contacts the treating ophthalmologist to conduct the transfer-of-care discussion.
		2. The O-ROPC contacts the Admitting Nurse for the Ambulatory Surgery Center at the hospital where the infant will be treated.
		3. The Admitting Nurse contacts the treating ophthalmologist to schedule the consultation to determine if treatment is needed.
	3. After treatment:
		1. The treating ophthalmologist informs the O-ROPC of the treatment given, and the interval and approximate date of the follow-up exam.
			1. The O-ROPC of the treating ophthalmologist contacts the O-ROPC of the screening ophthalmologist if the treating ophthalmologist does not perform the follow-up exams.
			2. The treating ophthalmologist conducts and documents the transfer-of-care discussion with the screening ophthalmologist.
		2. The O-ROPC compares the scheduled follow-up interval to that recommended in the PS and contacts the ophthalmologist if the interval is longer than the one indicated by the PS.
	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 to 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 shows the retina to be fully vascularized in both eyes.***
		2. The infant is tracked by the O-ROPC 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._)].
			3. The current ophthalmologist conducts and documents a transfer-of-care discussion with the ophthalmologist who will take over care.
5. The O-ROPC follows up on all missed, cancelled, or rescheduled ROP appointments, including no-shows and cancelled or rescheduled appointments and:
	1. Reschedules the exam as directed by the ophthalmologist.
	2. Sends the [Missed appointment letter](#_Missed_appointment_letter) if unable to reach the parents and schedule the exam.
	3. Contacts Child Protective Services if requested by the ophthalmologist.

# [**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 Criteria for Retinopathy of Prematurity: Natural History Data From the CRYO-ROP and LIGHT-ROP.

# **ROP Tracking List**

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



# **ROP exam request form**

**Date** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PARENT/GUARDIAN NAME:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Home & Cell Phone Numbers \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Alternate contact and contact information \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**REFERRING HOSPITAL/PHYSICIAN**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contact person \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone/Fax/Email \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reason for referral \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**BABY NAME:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Premature? Yes/No If so, how premature? \_\_\_\_\_\_\_\_ (weeks/months)

Birth date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Current age \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Birth weight \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Current weight \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Eye exam in the hospital? Yes/No Date of last eye exam \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Ophthalmologist who did last eye exam \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**APPOINTMENT SCHEDULING (Date and initial)**

* Scheduled appointment for \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.
* Educated about risks
	+ Advised to call the office right away if the baby cannot come for the appointment.
	+ Reminded family that baby could go blind from ROP if not treated on time.
	+ Informed that practice may contact Child Protective Services.
* Gave contact form to office ROP coordinator, who will add baby to the ROP tracking list.

# **Missed appointment letter**

This sample letter is provided as a guideline only and should be modified according to the situation. ***If the baby’s condition warrants a certified letter, send it both certified and through the regular mail.*** Place the letter and the signed return receipt (if sent certified) in the baby’s chart.

**PRACTICE NAME AND ADDRESS**

[CERTIFIED MAIL-RETURN RECEIPT REQUESTED]

(Date)

Dear (person caring for baby):

You missed the eye exam appointment for your premature baby on \_\_\_\_\_\_\_\_ (date). We were unable to reach you by telephone.

Your baby is being screened or treated for an eye condition known as retinopathy of prematurity or ROP.

**Without proper care, your baby may suffer permanent damage, such as a retinal detachment, and lose vision or even develop blindness in both eyes.**

**If you do not call our office by** [insert date] **at the number listed above, I may need to contact Child Protective Services to help make sure that your infant gets the care he or she needs.**

I am not trying to alarm you or get you in trouble. I am trying to give your baby the care needed to prevent blindness.

Please contact our office as soon as possible to reschedule.

With best regards,

(Physician’s Signature & Name)

# **Carta de incumplimiento de cita médica**

Esta es una carta de muestra y solo debe modificarse según la situación. ***Si el estado del (de la) bebé requiere el uso de una carta certificada, envíela tanto certificada como por vía regular.*** Incluya la carta y el comprobante de recibo firmado (si se ha enviado una carta certificada) en la historia clínica del (de la) bebé.

**NOMBRE Y DIRECCIÓN DEL CENTRO MÉDICO**

[SE REQUIERE CARTA CERTIFICADA]

(Fecha)

Apreciado(a) (persona responsable por el cuidado del (de la) bebé):

Usted no trajo a su bebé prematuro(a) a la cita que tenía programada el \_\_\_\_\_\_\_\_ (fecha). No pudimos comunicarnos por teléfono con usted.

Su bebé está siendo examinado(a) o tratado(a) para una afección ocular que se conoce como retinopatía de la prematurez o ROP.

**A menos que reciba atención adecuada, su bebé puede sufrir daño ocular permanente como un desprendimiento de retina y pérdida de la visión o inclusive puede sufrir pérdida de la visión en ambos ojos.**

**A menos que llame al consultorio antes de** [fecha] **al número que aparece arriba, estaré obligado(a) a comunicarme con los Servicios de Protección del Menor para poder estar seguro(a) de que su bebé obtenga el cuidado médico que requiere.**

No es mi intención alarmarlo(a) ni causarle problemas. Lo que pretendo es que su bebé reciba la atención que requiere para evitar que quede ciego(a).

Por favor comuníquese con nuestro consultorio a la mayor brevedad para programar otra cita.

Atentamente,

(Firma y nombre del médico)

1. “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 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>. This document refers to recommendations based upon the numbers assigned to them in the PS. [↑](#footnote-ref-1)