Purpose of risk management recommendations
OMIC regularly analyzes its claims experience to determine loss prevention measures that our insured ophthalmologists can take to reduce the likelihood of professional liability lawsuits. OMIC policyholders are not required to implement these risk management recommendations. Rather, physicians should use their professional judgment in determining the applicability of a given recommendation to their particular patients and practice situation. These loss prevention documents may refer to clinical care guidelines such as the American Academy of Ophthalmology's *Preferred Practice Patterns*, peer-reviewed articles, or to federal or state laws and regulations. However, our risk management recommendations do not constitute the standard of care nor do they 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 08/08/2023

Protocol and Recommendations for Telemedicine for Evaluation of Retinopathy of Prematurity (ROP)

The protocol listed in these materials is based upon the Policy Statement "Screening Examination of Premature Infants for Retinopathy of Prematurity,"[1] and the Joint Technical Report "Telemedicine for Evaluation of ROP."[2] The protocol incorporates both required conditions of coverage for Dr. xxxxxx's malpractice policy with OMIC as well as risk management recommendations which individual physicians may adapt to their own system and institutional policies and procedures (see box regarding risk management recommendations).

Section 1. Hospital Written Protocol

A. The NICU will have a written protocol for the use of telemedicine (TM) to evaluate retinopathy of prematurity (ROP) screening based on the Policy Statement[1] (PS) and Joint Technical Report[2] (JTR) that addresses the following:
   1. Which infants require an ROP screening exam [Table 1a]
   2. Which infants need an in-person Binocular Indirect Ophthalmoscopy (BIO) exam instead of an imaging session [Table 1b]
   3. The ROP imaging and interpretation workflow (JTR page e249)
   4. The protocol that the ophthalmologist will follow to arrange for:
      a. An urgent in-person BIO exam if the photos show referral-warranted ROP [Table 1b]
      b. An in-person BIO exam to determine if the infant has met conclusion-of-acute-screening criteria [Table 5]
      c. An in-person BIO exam either prior to discharge or in the outpatient setting within 72

hours of discharge.

5. Management of non-ROP ocular findings (JTR page e248)
6. Equipment cleaning and maintenance
7. Imaging personnel and training (JTR page e245)
8. Image capture, transmission, and storage (JTR pages e246-7)
9. Continuous quality monitoring of remote digital fundus imaging telemedicine (RFDI-TM) care (JTR page e249)
10. Compliance with HIPAA, privacy, and Digital Imaging and Communication in Medicine Standards (DICOM) (JTR pages e244 and e247)

Section 2. Hospital and Personnel Qualifications and Duties

A. **Ophthalmologist qualifications.** As the person who interprets, conducts screening exams, and provides treatments, the ophthalmologist must agree to:

1. Possess and maintain sufficient knowledge and experience to identify accurately the presence of ROP, and the location, severity, and temporal profile/sequential retinal changes of ROP after pupillary dilation using binocular indirect ophthalmoscopy
2. Use the International Classification of Retinopathy of Prematurity (ICROP) Revisited to classify, diagram, and record the retinal findings [ICROP].
3. Maintain an outpatient ROP coordinator (O-ROPC) who works with the hospital ROP coordinator (H- ROPC) to track infants.

B. **Hospital agreement with the ophthalmologist.** The hospital where the images are taken has granted staff privileges to and has a signed written active agreement with the ophthalmologist to:

1. Interpret images and send reports per the written protocol.
2. Perform a live examination if/when the infant has met criteria to end ROP screening.
3. Treat Type 1 ROP within 72 hours, A-ROP within 48 hours.

C. **Hospital ROP coordinator (H-ROPC).** The hospital where the images are taken employs or contracts with a H-ROP who:

1. Is familiar with and understands the Policy Statement[1] and the JTR[2] and the Tables in the ROP toolkit that are based upon them. They are able to use the Tables to review and clarify the appropriateness of follow-up and treatment intervals, along with coordinate discharge or transfer.
2. Keeps the Master Tracking List of hospitalized infants who need ROP imaging sessions [**See tracking procedure for more details about the tracking process]**.
3. Reviews the Master Tracking List with the ophthalmologist and/or his/her O-ROPC at **least once a week.** The ROPCs, together with the ophthalmologist, compare the current list with the list from the prior week. The H-ROPC notifies the Neonatologist of all missed, cancelled, or rescheduled ROP exams.

D. **Imagers.** The imagers performing remote imaging:

1. Have been trained in RDFI-TM techniques by a certified ophthalmic photographer or someone else familiar with fundus photography in general and with the particular camera/information system to be used. Prior successful participation in a clinical trial using telemedicine for ROP qualifies an imager as appropriately trained and able to train others.

2. Have demonstrated to the ophthalmologist who performs the BIO exam that a sufficient number of images for each infant are adequate and readable for the ophthalmologist to make appropriate determination of the disposition for the baby.
3. Have ongoing systematic evaluation and oversight from an ophthalmologist.
4. Obtain the standard images of each eye using the standard image sequence based upon (JTR e245-6).
5. Obtain additional images if needed to capture all 12 clock-hours of the peripheral fundus (JTR e246).

Section 3. Tracking of ROP Imaging Sessions

A. Tracking Principles
   a. The ophthalmologist must be personally involved in the tracking.
   2. Hospitalized infants are tracked by at least two ROP team members:
      a. The H-ROPC **and**
      b. **The ophthalmologist AND**
      c. The O-ROPC (if the remote imaging is in a different practice or health system—in some places the H-ROPC and the O-ROPC may be in the same system with access to the same tracking data)
   3. There is only one Master Tracking List of hospitalized infants who need ROP imaging sessions.
      a. The H-ROPC keeps the Master Tracking List through ROPCHECK software (systems could vary but must contain the elements pursuant to the ROP Safety Net).
      b. The Master Tracking List contains the following information for each ROP session:
         i. Infant's name, date of birth, gestational age at birth, current post menstrual age, birthweight and current weight, medical record number.
         ii. Date of imaging session, ROP status, and appropriate follow-up session:
            - Next date for remote imaging (given as both an interval and an approximate date),
            - date of BIO exam to end imaging, discharge/transfer date, OR
            - date when the infant met the conclusion of acute-phase-screening criteria
   4. The H-ROPC sends the O-ROPC an updated copy of the Master Tracking List **at least once a week.** The O-ROPC uses the updated copy of the Master Tracking List to update the Office Tracking List.
   5. The H-ROPC and O-ROPC compare the updated Master 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 imaging sessions.
   6. Each infant who meets the criteria for ROP screening is tracked until they meet the end-of-acute screening criteria.

B. Tracking Process
   1. The neonatologist identifies new infants who meet screening criteria [Table 1a] and indicates when the initial ROP imaging session should take place.
   2. The neonatologist instructs the H-ROPC to add the infant's name and date of initial imaging session to the Hospital ROP Master Tracking List.
   3. The H-RPOP contacts the O-ROPC to schedule the initial imaging session, or if appropriate, schedules the imaging session with the imagers directly. [Table 2]. (The imager may already be an inpatient

hospital staff member)

4. The O-ROPC adds the infant to the Office Tracking List of hospitalized infants who need imaging sessions and begins tracking when the H-ROPC requests the initial imaging session.
5. The H-ROPC updates the current Master Tracking List:
   a. After each imaging session
      i. The ophthalmologist will inform the H-ROPC and O-ROPC of the results of the ROP imaging session and the interval **and** approximate date of the next imaging session (e.g., next imaging session in two weeks on approximately 9/25/22).
      ii. The H-ROPC and O-ROPC compare the scheduled follow-up interval to that recommended in the ROP Screening Policy Statement (PS)[3] [Table 3] and contact the ophthalmologist if the interval indicated is longer than the one indicated by the PS and/or longer than 3 weeks since the last imaging session.
   b. When a BIO exam is needed
      i. The ophthalmologist informs the H-ROPC of the need for a BIO exam.
      ii. If another Ophthalmologist is arranged to see the child for a BIO exam, the ophthalmologist practicing telemedicine will ensure that proper transfer of ophthalmic care is arranged prior to transfer. The child will be tracked by the H-ROPC and/or O-ROPC until BIO exam has been completed by outside ophthalmologist, at which point transfer of care will deemed complete.
   c. When treatment is needed
      i. The ophthalmologist informs the H-ROPC of the need for likely ROP treatment [Table 4].
      ii. The ophthalmologist schedules a BIO exam (per Section 3, Item B5b) to determine if treatment is needed. The decision for treatment requires a BIO exam to confirm findings prior to treatment. The BIO exam can be performed on the day of treatment. **This may occur in the hospital where the imaging is performed, or, in a facility or hospital where the infant is transferred for treatment.**
   d. After treatment
      i. The treating ophthalmologist informs both the H-ROPC and O-ROPC of the results of the ROP treatment and the interval and approximate date of the next exam.
      ii. The H-ROPC and O-ROPC compare the scheduled follow-up interval to that recommended in the PS [Table 3] and contact the ophthalmologist if the interval indicated is longer than the one indicated by the PS.
   e. When care of the infant is transferred from:
      i. the ophthalmologist practicing telemedicine to/from another screening or treating ophthalmologist,
      ii. Hospital-based ophthalmologist to/from a different outpatient ophthalmologist, or
      iii. Ophthalmologist in one hospital to ophthalmologist in another hospital.
   f. ROP imaging, screening, and treatment are complete [Table 5]

6. The H-ROPC and O-ROPC, continue to track until one of the following conditions has been met and documented:
   a. A treating ophthalmologist has verified that the treatment and follow-up examinations are

complete.

b. Both eyes have met the conclusion-of-acute-screening criteria based upon a BIO exam [Table 5]. Of note:
   i. ***Per the PS, one exam is sufficient only if it unequivocally shows the retina to be fully vascularized in both eyes.***
   ii. ***Per the JTR, each infant needs a BIO exam to determine if the infant has met the conclusion-of-acute-screening criteria.***

c. The ophthalmologist conducts and documents a transfer-of-care discussion with another ophthalmologist who will take over care.

Section 4. Imaging Session Process

A. The neonatologist (or designee, may be NNP, etc.) identifies new infants who meet ROP screening criteria [Table 1a] and indicates the approximate date of the initial ROP imaging session [Table 2].

B. The neonatologist or designate instructs the H-ROPC to add the infant's name and date of the initial session to the Master Tracking List of hospitalized infants who need ROP imagingsessions.

C. The neonatologist or designate obtains the parent's informed consent for remote digital fundus imaging telemedicine (RDFI-TM) [Consent for ROP Imaging] at the time the child is added to the Master Tracking List (imagers may be able to get consent themselves if they are **privileged** NNP, PA, etc.)

D. The H-ROPC schedules the initial imaging session with the photographer.

E. The H-ROPC notifies the appropriate person (O-ROPC of the ophthalmologist practicing telemedicine, H-ROPC in the hospital of the ophthalmologist practicing telemedicine) of the date of the initial imaging session and provides the him or her with:
   1. A copy of the infant's face sheet that includes demographics, contact information, and insurance.
   2. A copy of the signed Consent for ROP Imaging

F. The H-ROPC or designated NICU nurse assists the photographer with the imaging session as follows:
   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 imaging session exist.
      a. Notifies the O-ROPC and photographer of any infant who cannot undergo the scheduled imaging session.
      b. Reschedules the imaging session within the time interval indicated by the infant's most recent eye exam.
      c. Contacts the neonatologist and the ophthalmologist to determine the best course of action, and documents the discussion, if the infant cannot be imaged within the indicated interval.
      d. Documents the notification and reason for not having the imaging session in the infant's medical record.
      e. Notifies the parents of the delay and documents the discussion with the parents.
   3. Provides the supplies needed for imaging session.
   4. Dilates the infants' eyes at the time ordered by neonatologist.

5. Ensures that participants in the imaging session have washed their hands with an agent safe for the cornea, and, 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 the exam.
8. Documents the dilation, imaging session, and the infant's response to the exam.
9. Cleans and sterilizes the equipment according to the manufacturer's specifications to prevent eye irritation and infection.

G. The photographer obtains the standard images of each eye using the standard image sequence based upon (JTR e245-6). e photographer obtains additional images if needed to capture all 12 clock-hours of the peripheral fundus (JTR e246).

Section 5. Transmission of Images and Reports

A. The H-ROPC transfers the images to the medical record directly and/or the reading physician via secure methods.
B. The H-ROPC notifies the ophthalmologist that the images have been transferred.
C. The ophthalmologist confirms receipt of the images as soon as possible.
D. The ophthalmologist performs a preliminary review of the images as soon as possible (but less than 24 hours) to determine if hospital-based care or additional images are needed. If additional images are needed the ophthalmologist notifies the H ROPC
E. The ophthalmologist contacts the H-ROPC as soon as possible (but less than 24 hours) if an emergent BIO exam or possible treatment is required [Table 1b].
    1. The H-ROPC schedules an exam with ophthalmologist practicing telemedicine or another outside ophthalmologist. If necessary, the infant may need to be transferred for the BIO exam.
F. The ophthalmologist prepares and securely sends a definitive report within 24 hours or receipt last images sent [RDFI-TM report].
G. The H-ROPC acknowledges receipt of the ophthalmologist's report and places it in the infant's medical record.
H. The H-ROPC contacts the O-ROPC and the ophthalmologist if the report is not received within 24 hours.
I. the ophthalmologist notifies the H ROPC and O-ROPC of the next imaging session in his report, indicating the interval and approximate date (e.g., next eye exam in two weeks around 9/25/22) [Table 3]
J. The H-ROPC updates the Master Tracking List and provides this to the O-ROPC, who will confirm the accuracy of the updated list with the ophthalmologists' most recent imaging report.
K. The ophthalmologist continues to review RDFI photos until one of the following criteria is met:
    1. He or she determines that imaging sessions are complete and notifies the H-ROPC and O-ROPC.
    2. notifies the O-ROPC that the infant will be discharged or transferred, at which point the ophthalmologist evaluates when any additional imaging is necessary taking into account the date and results of the most recent imaging study;
    3. the ophthalmologist conducts and documents a transfer of care when another outside ophthalmologist has agreed to take over the care.

Section 6. Scheduling an Outpatient BIO Exam and Discharge Home

A. The ophthalmologist contacts the H-ROPC to request a BIO exam when the infant:
   1. Is not a candidate for imaging
   2. Has referral-warranted ROP [Table 1b].
   3. May have met the conclusion of acute-screening criteria [Table 5].
      a. Each infant who is evaluated for ROP using telemedicine must have a BIO exam to determine if the infant has met the end-of-screening criteria.
      b. The BIO exam to confirm end of screening criteria must take place either:
         I. Prior to discharge from the NICU or
         II. In the outpatient setting within 72 hours of discharge from the hospital if the most recent imaging is interpreted as no ROP with persistent avascular retina
         III. In the outpatient setting within 1 week of discharge from the hospital if the most recent imaging is felt to demonstrate complete retinal vascularization

B. The H-ROPC will contact the O-ROPC to schedule an outpatient BIO exam appointment when the infant is ready to be discharged from the hospital if a BIO exam confirming the conclusion of acute-screening criteria [Table 5] has not already been performed.

C. The neonatologist confirms that the infant is ready for discharge, and explicitly addresses eye care in the discharge summary based upon the most recent ophthalmology note.
   1. ROP screenings not yet complete:
      a. States that a BIO exam is needed within 72 hours of discharge from the hospital, and gives the interval and approximate date (e.g., ROP exam needed in two days around 9/25/22).
   2. ROP screenings complete:
      a. This requires that a BIO exam has already been performed in the hospital, confirming the acute-screening criteria [Table 5] has previously been met.
      b. Directs the pediatrician to refer the infant to an ophthalmologist to screen for conditions common in premature infants, such as amblyopia, strabismus, etc. The timing of this exam will be dictated by the recommendations in the last BIO exam report.

D. The H-ROPC coordinates the discharge and:
   1. Confirms that the ophthalmologist has been notified of the discharge.
   2. Schedules the initial BIO exam with the outpatient ophthalmologist and ensures this appointment is documented in the neonatology discharged summary, and
   3. Contacts the ophthalmologist's O-ROPC to:
      a. Confirm that either the ophthalmologist practicing telemedicine or another ophthalmologist has agreed to take over the outpatient ROP care and documents this in the patient's chart,
      b. Indicate the interval and approximate date of the first outpatient BIO exam, and
      c. end all pertinent medical records, including the neonatology discharge summary, and current accurate contact information for the parents to the ophthalmologist's O-ROPC.
   4. Reminds the parents of the previously signed Consent for ROP Imaging
   5. Has the parents sign the ROP Discharge Agreement and informs the parents:
      a. Of the name of the outpatient ophthalmologist who will manage their child's ROP,

b. The date and location of the next ROP exam, and
c. That Child Protective Services may be contacted if the parents do not keep outpatient appointments exactly as scheduled.

F. The H-ROPC will provide the O-ROPC with a copy of the ROP Discharge Agreement along with current patient information including demographics, contact information, and insurance. In order to assure appropriate patient follow-up, the H-ROPC and O-ROPC will maintain communication as needed after discharge regarding patient contact information, missed/rescheduled appointments, readmission to hospital, etc.

Section 7. Transfer to Another Hospital for a BIO Exam

A. When a BIO exam is needed but the infant is not ready to be discharged home, the H-ROPC will coordinate a transfer to another hospital if the ophthalmologist practicing telemedicine is unavailable.

B. The Neonatologist will discuss the need for transfer and a BIO exam with the parents, and explicitly addresses the need for a BIO exam and/or treatment within 72 hours of discharge in the neonatology discharge summary.

C. The H-ROPC coordinates the transfer and will:
1. Contact the Admissions Nurse at the receiving hospital to:
   a. Confirm that an ophthalmologist has agreed to perform a BIO exam and treat if needed within 72 hours of transfer.
   b. Send all pertinent medical records and current parental contact information to the receiving hospital.
2. Inform the parents of the name of the ophthalmologist who will be managing the child's ROP at the receiving hospital.

D. If an Ophthalmologist besides the telemedicine ophthalmologist performs the BIO exam at the receiving hospital, the transferring H-ROPC will be responsible to coordinate with the receiving hospital's H-ROPC the timing of the BIO exam.
1. The BIO exam should be completed within 72 hours of transfer.
2. The transferring H-ROPC will send the telemedicine ophthalmologist's O-ROPC the date and results of the BIO exam performed at the receiving hospital.

The telemedicine ophthalmologist's O-ROPC will document these results in the clinic chart and have the doctor sign off on this documentation.

E. The H-ROPC will update the Master Tracking List and will provide this to the O-ROPC for review and documentation at the ophthalmologist's office.

Section 8. Tables

Table 1a. Who needs ROP screening exam

Infants who meet any of the following criteria need an ROP screening 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: Policy Statement # 3. Based on Recchia, Franco and Capone, Antonio, Contemporary Understanding and Management of Retinopathy of Prematurity, *Retina* 2004; 24:283-92.

Table 1b. Who needs BIO exam to screen for ROP

Infants in a telemedicine ROP protocol need a BIO (binocular indirect ophthalmoscopy) exam when any of the following conditions is present:

- Referral-warranted ROP:
  - Any ROP in zone I
  - Presence of stage 3 ROP at any time during the infant's hospital course
  - Presence of pre-plus or plus disease
- Ready for discharge or transfer from hospital
- Non-readable images for any reason (poor dilation, unclear media, inadequate image quality, etc.)
- Infants felt to meet end of acute screening criteria based on results of their most recent imaging study

Infant is suitable for RDFI-FM (remote dilated fundus imaging-telemedicine) exam:

- Meets criteria and age for ROP screening
- Eyes able to be photographed with readable images obtained by imager

REFERENCE: Based on "Telemedicine for Evaluation of Retinopathy of Prematurity," the Joint Technical Report issued by the AAP Section on Ophthalmology, the AAO, and the American Association of Certified Orthoptists (AACO) Published in Pediatrics (Volume 135, Number 1, 2015, http://pediatrics.aappublications.org/content/135/1/e238

Table 2. When to start ROP screening

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:

- Gestational age < 27 weeks: by 31 weeks' postmenstrual age.
- Gestational age ≥ 27 weeks: at 4 weeks' chronological age.

	Age at Initial Examination (weeks)	
Gestational Age at Birth (weeks)	**Postmenstrual**	**Chronologic**
22[a*]	31	9
23[a*]	31	8
24*	31	7
25*	31	6
26	31	5
27	31	4
28	32	4
29	33	4
30	34	4
Older gestational age, high risk factors[b]		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.

[b] Consider timing based on severity of comorbidities.

* 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 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: 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.

Follow-up examinations should be recommended by the examining ophthalmologist on the basis of retinal findings classified according to the revised international classification.

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

REFERENCE: 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. Treatment for ROP

- Treatment should be considered 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
  - 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/posterior Zone 2, stage 3+ ROP, aggressive ROP (A-ROP), patients with inability to tolerate prolonged anesthesia, visibility impaired by blood or structures, or failed laser treatment for treatment of ROP with intravitreal injection of Anti-VEGF agents[1,**]
  - Bevacizumab is not approved by the US Food and Drug Administration for the treatment of ROP, and is used off label for this condition. Aflibercept is the only FDA approved medication for the treatment of ROP. Biosimilars should not be used for treatment of ROP in any case unless part of a clinical trial or investigative study.
  - 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.[1]
  - Infants treated with bevacizumab or alfibercept should be monitored weekly until retinal vascularization
    is complete/near-complete or until laser treatment for persistent avascular retina (PAR) laser has been performed.[1]
- Special care must be used in determining the zone of disease.

  The International Classification of Retinopathy of Prematurity Revisited classification gives specific examples of how to identify zone I and II disease by using a 28-diopter lens with binocular indirect ophthalmoscopy
    - See page 992 of the article, accessed 6/25/18 and available at https://jamanetwork.com/journals/jamaophthalmology/ full article/417157
- Treatment should generally be accomplished, within 72 hours of determination of treatable disease to minimize the risk of retinal detachment, and 48 hours for A-ROP.
- Follow up is recommended within one week after treatment to ensure that there is no need for additional treatment in areas where ablative treatment was not complete.

REFERENCE: 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 BIO exam is sufficient only if it unequivocally shows the retina to be fully vascularized in both eyes (PS #1).

Per the Joint Technical Report, RDFI-TM cannot be used to determine if the infant meets the criteria to end acute-retinal-screening examinations. The infant must have at least one BIO exam either prior to discharge from the NICU; within 72 hours of the last RDFI-TM examination if the most recent image demonstrates peripheral avascular retina; or within one week of the most recent imaging if that imaging demonstrated full retinal vascularization; or if photos are inadequate to confirm presence or absence of ROP.

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 after PMA 38 weeks
- 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.
- 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

REFERENCES:

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.

Joint Technical Report e248.

Section 9. Appendix

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 practice.
- **Delete 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.

[Your Letterhead]

Consent to Use Photos to Check for Retinopathy of Prematurity (ROP)

Dr. xxxxxx is an ophthalmologist (eye surgeon). Your baby's NICU doctor has asked him/her to check photos of your baby's eyes. This letter will explain why. It will also explain when an ophthalmologist needs to examine the baby's eyes.

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 fully develop. After the premature birth, the blood vessels at the back of the eye stop growing. Then the eye starts to make a chemical called vascular endothelial growth factor (VEGF). This chemical makes the blood vessels in the eye to start growing again, but these are not normal blood vessels. These abnormal blood vessels can bleed and pull (detach) the retina away from its normal position. This is called a retinal detachment (RD) and can result in blindness. There are treatments for ROP to reduce the chance of an RD and associated blindness. Without treatment, a baby has a much higher chance of going blind. Unfortunately, even with proper treatment, some babies still go blind.

An ophthalmologist needs to check for ROP to see if the baby's eyes need to be treated. In some hospitals, an ophthalmologist comes to the hospital and examines every baby who might have ROP. The ophthalmologist examines the baby's eyes two or more times a month. In other hospitals, photos of the baby's eyes are taken to decide when an in-person exam is needed. A person with training to take digital images of babies' eyes (for example, a nurse, nurse practitioner, PA, photographer) takes photos of the blood vessels in the baby's eyes with a special camera. The hospital then sends the photos electronically to the ophthalmologist for review. The ophthalmologist checks the photos to decide if and when an in-person exam is needed. The ophthalmologist then sends a report back to the imager and the hospital neonatologist, guiding them on when the next photos need to be taken or when an in-person

exam is needed. Some babies only require one in-person exam. The baby will have fewer in-person exams by the ophthalmologist if photos are taken.

The ophthalmologist who checks the photos is not in the hospital with the baby. The ophthalmologist might even be in another state. The ophthalmologist and the hospital use computers, email, and telephones (technology) to check the baby. When an ophthalmologist in one place uses technology to check a patient in another place, this is called **telemedicine**. The hospital and the ophthalmologist keep the photos and reports private. They are protected since they are considered medical records.

Things you need to know about the use of telemedicine for premature baby eye exams:

1. The ophthalmologist may not check the photos or send the report immediately, but will do so within 24 hours.
2. There may be some problems with checking photos for ROP:
   a. The photos may not be good enough. If that happens, the ophthalmologist will ask the nurse to take the photos again.
   b. The baby's eye condition makes it impossible to take a clear photograph. An ophthalmologist would then go to the hospital to examine the baby. Alternatively, the baby may need to be transferred to another hospital where the eye exam can be performed in-person by an ophthalmologist.
3. The ophthalmologist may determine that the ROP is getting worse. The ophthalmologist will go to the hospital to examine the baby or request the baby be transferred to another hospital to be examined in-person. This exam might show that treatment is needed.
4. The ophthalmologist may determine that the baby's retinas are getting better, but it needs to be confirmed by an in-person exam. A confirmatory examination will require the baby's family to take the child to the ophthalmologist's office, which may require considerable travel. The exam might show that the baby does not need more eye photos or exams. Alternatively, the exam may show that the baby requires additional exams at the ophthalmologist's office.

Consent. By signing below, you agree that:

- You have read this informed consent form, or someone has read it to you.
- You understand the information in this form.
- The hospital staff offered you a copy of this form.
- The hospital staff answered your questions about using photos to check for ROP.
- Telemedicine may be used for your baby's eye examinations.
- You will bring your baby to the ophthalmologist's office at the time recommended after discharge to have an in-person eye examination. Failure to do so may result in Child Protective Services or similar agency being contacted to assist in having your baby's eyes properly examined in-person by the ophthalmologist.
- You have been offered a copy of this document.

I agree that photos can be used to check my baby's eyes for ROP and agree to bring my baby to Dr. xxxxxx's office as directed after discharge for an in-person eye examination.

Patient's Name	**Date of Birth**
Parent/Other Legally Responsible Person Signature	**Date/Time**
Printed Name	**Relationship**
Witness Signature	**Date/Time**
Translator Signature (if needed)	**Date/Time**

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 practice.
- **Delete 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.

[Your Letterhead]

Retinopathy of Prematurity (ROP) Discharge Agreement

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 sometimes has not had time to finish forming. After the premature birth, the blood vessels at the back of the eye stop growing. Then the eye starts to make a chemical called vascular endothelial growth factor (VEGF). This chemical makes the blood vessels in the eye to start growing again, but these are not normal blood vessels. These abnormal blood vessels can bleed and pull (detach) the retina away from its normal position. This is called a retinal detachment (RD) and can result in blindness. There are treatments for ROP to reduce the chance of an RD and associated blindness. Without treatment, a baby has a much higher chance of going blind. Unfortunately, even with proper treatment, some babies still go blind.

While in the hospital, your baby's retinas have been monitored with photos. The photos do not show the whole eye. Now that your baby is going home, the next exam will take place at the ophthalmologist's office. This exam must be done by (DATE) _____. The hospital will schedule an appointment for you, but you are responsible to take your baby to this appointment.

You must bring the baby to the ophthalmologist's office for the appointment. ROP can cause blindness if not treated in time. The ophthalmologist needs to make sure that your baby's eyes are not at risk for blindness. If you do not bring the baby for the appointment on the scheduled day, the ophthalmologist may need to contact Child Protective Services or similar agency.

Consent. By signing below, you consent (agree) that:

- You read this form, or someone read it to you.
- You understand the information in this form.
- The neonatologist or nursery staff offered you a copy of this form.

- The baby will need at least one in-person eye exam to check on the ROP status.
- You will bring the baby to the ophthalmologist's office for an eye exam on the scheduled day. The hospital will make the appointment for you.
- You have been offered a copy of this document.

Patient's Name	**Date of Birth**
Patient/Other Legally Responsible Person Signature	**Date/Time**
Print Name	**Relationship**
Witness Signature	**Date/Time**
Translator Signature (if needed)	**Date/Time**

RDFI-TM Report

Based on "Telemedicine for Evaluation of Retinopathy of Prematurity," the Joint Technical Report issued by the AAP Section on Ophthalmology, the AAO, and the American Association of Certified Orthoptists (AACO). The recommendations on the report format and content are on pages e247-248 in the electronic version of the document; hereafter designated as JTR; numbers refer to pages in the electronic version of the document. Published in *Pediatrics* (Volume 135, Number 1, 2015, http://pediatrics.aappublications.org/content/135/1/e238).

- General information
    - Patient name
    - Medical record number
    - Date of examination
    - Date/time images were received, interpreted, and the report transmitted
    - Date of birth
    - Birth weight
    - Gestational age at birth
    - PMA (postmenstrual age) at examination
    - Weight at examination
    - Medical history/active problem list
    - Institution originating the photos and its location
- Interpretation
    - The eye(s) for which images are provided
    - The number of images provided per eye
    - Interpretation of the anterior segment image regarding:
        - Image quality
        - Dilation adequate for imaging
        - Corneal clarity
        - Presence/absence of iris vasculature
    - Interpretation of fundus images regarding:
        - Image quality
        - Media clarity
        - Optic nerve status
        - Fovea/foveal reflex
        - Presence/absence of pre-plus or plus disease
        - Zone of imaged/visualized retina
        - Zone of vascularized retina
        - Stage and extent of ROP, if present
        - Other findings (e.g., hemorrhage, double demarcation line, masses)
        - Interval changes since last photos based upon review of serial images
- Impressions
    - Summary content regarding image number, quality, and adequacy for interpretation
    - Summary of ROP findings in the traditional lowest zone/highest stage format
    - Status compared with previous examinations
    - The presence of any non-ROP pathology
- Recommendations
    - Whether reimaging is necessary if image quality was poor or inadequate
    - The timing—**given as both an interval and an approximate date**—of follow-up imaging per current AAO/AAPOS/AAO guidelines found in the PS
    - Whether bedside examination is needed
    - Appropriate follow-up for any non-ROP ocular pathology

Master Tracking List

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

Name	Birth info: DOB, GA, weight	Initial exam due: Date, age	ROP status: Date, age	Next exam due: interval & date	ROP status: Date, age	Next exam due: interval & date	ROP status: Date, age	Next exam due: interval & date	ROP status: Date, age	Next exam due: interval & date
Birth info: DOB = date of birth, GA = gestational age, weight in grams. Add other information as needed (e.g., multiple births)										
Initial exam: Date when screening should begin, based on Table 2										
ROP status: Based on ICROP revised: stage, zone, clock hours, presence of plus disease, etc., date of exam, postmenstrual age at exam (GA plus chronological age)										
Follow-up exam: Determined at time of exam, given as interval and date (e.g., 2 weeks on 7/24/22)										
Treatment date and type: Laser, anti-VEGF, vitrectomy										
Discharge or transfer date: Date infant leaves hospital of birth or care is transferred to another MD										
Screening end date: when infant meets end-of-acute-phase ROP screening criteria [Table 5]										

ICROP. Synopsis of International Classification of Retinopathy of Prematurity Revisited (ICROP 2021)[4]

- 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 ROP (A-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 <u>not</u> constitute the fibrovascular growth that is a necessary condition for stage 3.
    - <u>Stage 3: Extraretinal Fibrovascular Proliferation</u>
        - 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.
    - <u>Stage 4: Partial Retinal Detachment</u>
        - 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.
    - <u>Stage 5: Total Retinal Detachment</u>
        - 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 ROP
    - This is an uncommon, rapidly progressing form designated A-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 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
      - Telangiectasia 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, 2006, and 2018; current version published in *Pediatrics*. 2018;142(6):e20183061. Available at: http://pediatrics.aappublications.org/content/142/6/e20183061 (Accessed: 1/10/2023).

This document refers to recommendations based upon the numbers assigned to them in the PS.

[2] "Telemedicine for Evaluation of ROP". Joint Technical Report issued by Fierson WM, Capone A, American Academy of Pediatrics Section on Ophthalmology, American Academy of Ophthalmology, and American Association of Certified Orthoptists. *Pediatrics* Volume 135, Number 1, January 2015, pages e238-e254. Specific recommendations referred to with electronic page numbers (e.g., JTR e239).

[3] "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, 2006, and 2018; current version published in *Pediatrics. 2018;142(6):e20183061.* Available at: http://pediatrics.aappublications.org/content/142/6/e20183061 *(Accessed: 1/10/2023).* This document refers to recommendations based upon the numbers assigned to them in the PS.

4 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: 1/10/2023)