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**ROP Safety Net: Hospital Toolkit**

OMIC ROP Task Force

OMIC has devoted considerable time and effort to improving patient safety and reducing the liability of ROP (retinopathy of prematurity) care, and is grateful to the ophthalmologists and staff on our ROP Task Force for their expertise and input: Anne M. Menke, RN, PhD; Jeremiah Brown, MD; Denise Chamblee, MD; Robert S. Gold, MD (Task Force Chair); Betsy Kelley, MBA, Gaurav Shah, MD; Trexler M. Topping, MD; Robert Wiggins, Jr., MD; and George Williams, MD. Hans Bruhn, MHA, also provided valuable feedback.

**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 generally not required to implement risk management recommendations. Rather, physicians use their professional judgment in determining the applicability of a given recommendation to their particular patients and practice situation. Some of the risk management recommendations about ROP, however, have become underwriting requirements; these are detailed in the ROP Questionnaire that OMIC policyholders who provide ROP care are asked to complete. Please contact your underwriting representative for more information.

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. If legal advice is desired or needed, an attorney should be consulted. 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.

**10/31/17**

Screening and treating premature infants for retinopathy of prematurity (ROP) is an important aspect of ophthalmic care that provides a valuable service to not only the individual baby but also to society as a whole. Although claims for mismanagement of ROP are relatively infrequent, indemnity payments for these claims can be high due to the young age of the plaintiffs and the significant loss of vision that can result even with treatment (see “ROP Safety Net: Risk Analysis” at <http://www.omic.com/rop-creating-a-safety-net/>). Concerned about their liability exposure, numerous screening and treating ophthalmologists have called OMIC to request sample protocols to help standardize care at their hospitals. We provide this guidance in the hospital and office toolkits. Much of the material in the two toolkits is the same, including the procedures, forms, and clinical guidelines. The office version also includes a procedure for staff to schedule the initial outpatient appointment, identify infants who need ROP care, and follow up on missed appointments.

**Every team member needs to be prepared to keep infants safe every day**

The ROP healthcare team at each hospital and office changes from time to time. The whole team, however, needs to be able to create safety from day one. To ensure continuity of care and guide new and back-up team members, the ROP Safety Net Toolkit provides very detailed information, including step-by-step protocols and procedures for ROP tracking, exams, treatment, and discharge/transfer. This toolkit should be kept at the point of care, available on a daily basis to all involved in this care.

Redundancy, role clarification, and standardization are key components of the Safety Net. Some of the information is presented more than once, and some tasks are assigned to more than one person. This is intentional. For example, multiple members of the ROP team educate the parents, and three people track hospitalized infants. The sample protocols and procedures assign each task in the ROP care process, both in the hospital (or other healthcare facility) and during outpatient care, so that there is no confusion about who is responsible for any given step. The peer-reviewed clinical guidelines support decision making at the bedside. Critical information from these guidelines, such as when to provide treatment, is provided in tables. The appropriate guideline or table is given in brackets with the step (e.g., [Table 1]).

Adults who are responsible for the baby also have a vital role to play in the ROP care process. Sometimes this is the infant’s parents, sometimes another family member, sometimes a legally appointed guardian or foster parent. By “parent” we mean whoever has current custody of the baby and is responsible for making medical decisions on the baby’s behalf.

**I. PURPOSE OF HOSPITAL ROP TOOLKIT**

* The goal of implementing these protocols and procedures is to minimize the risk of blindness in premature infants.

**II. CONTENT OF HOSPITAL ROP TOOLKIT**

* Protocol 1. Clinical Guidelines
* Protocol 2. ROP Care Team Members, Qualifications, and Duties
* Procedure 1. Tracking ROP exams and treatment
* Procedure 2. ROP exam
* Procedure 3. ROP treatment
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* Table 1. Which infants to screen for ROP
* Table 2. When to start screening
* Table 3. Follow-up interval
* Table 4. When to treat
* Table 5. When to stop screening
* Form 1. Tracking list
* Form 2. ROP exam form
* Form 3. “Dear Parent” letter
* Form 4. Laser Treatment for ROP consent form
* Form 5. Anti-VEGF Injection for ROP consent form
* Appendix A. “Screening Examination of Premature Infants for Retinopathy of Prematurity,” the Policy Statement issued by the American Academy of Pediatrics (AAP) Section on Ophthalmology, the American Association for Pediatric Ophthalmology and Strabismus (AAPOS), and the American Academy of Ophthalmology (AAO). Originally issued in 1997 and updated in 2001, 2005, 2006, and 2013, the Policy Statement is published in *Pediatrics* (Volume 131, Number 1, 2013, at <http://pediatrics.aappublications.org/content/131/1/189>. NOTE: for copyright reasons, you must download your own copy of this article to include in the protocols.
* Appendix B. Synopsis of The International Classification of Retinopathy of Prematurity Revisited. International Committee for the Classification of Retinopathy of Prematurity. *Arch Ophthalmol* 2005: 123: 991-999.

**Protocol 1. Clinical Guidelines**

1. Screening and treatment of ROP are based upon the 2013 AAP/AAO/AAPOS Policy Statement (PS) [Appendix A]. Protocols and procedures that differ from PS guidelines are based upon peer-reviewed articles, which are kept in a file.
2. The International Classification of Retinopathy of Prematurity Revised (ICROP) is used to classify, diagram, and record the retinal findings at the time of the examination or treatment [Appendix B].

**Protocol 2. ROP Care Team Members, Qualifications, and Duties**

Neonatologist/Nurse Practitioner (NP)

1. Identifies new infants who meet screening criteria [Table 1].
	1. Notifies the hospital ROP coordinator (ROPC).
		1. Orders the ROPC to add the infant’s name to the ROP tracking list and contact the ophthalmologist involved in that child’s care and that ophthalmologist’s office ROPC to add the infant to their tracking list.
	2. Determines when an infant needs the initial eye exam and notifies the hospital ROPC [Table 2].
2. Educates parents on an ongoing basis.
	1. Informs the parents of the need for an eye exam.
	2. Explains the ROP disease process and the risk of blindness.
	3. Informs the parents of the results of screening exams and treatment.
	4. Indicates when the next exam or treatment will take place.
	5. Documents the educational efforts.
3. Informs the ophthalmologist of any contraindications to exams or treatment.
4. Notifies the ophthalmologist when an infant is ready to be discharged or transferred.
5. Explicitly addresses eye care in the neonatology discharge summary based upon the most recent ophthalmology note.
	1. ROP screenings not yet complete: Gives the interval and approximate date of the next ROP exam (e.g., eye exam needed in two weeks around 9/25/17).
	2. ROP screenings complete: Directs the pediatrician to refer the infant to an ophthalmologist to screen for conditions common in premature infants, such as amblyopia, strabismus, etc.

Screening ophthalmologist

*Qualifications*

* The screening ophthalmologist should have sufficient knowledge and experience to identify accurately the location and sequential retinal changes of ROP after pupillary dilation using binocular indirect ophthalmoscopy with a lid speculum and scleral depression (as needed).

*Duties*

1. Tracks each infant who meets the criteria for ROP screening.
	1. Adds infant to the tracking list and begins tracking when notified by the hospital ROPC that an infant meets ROP screening criteria [Table 1].
	2. Continues examining and tracking until one of the following conditions has been met and documented:
		1. Both eyes have met the conclusion-of-acute-screening criteria based upon a BIO exam [Table 5].
		2. A treating ophthalmologist has verified that the treatment and follow-up examinations are complete.
		3. The ophthalmologist conducts and documents a transfer-of-care discussion with the ophthalmologist who will take over care.
		4. ***One exam is sufficient only if it unequivocally shows the retina to be fully vascularized in each eye.***
2. Performs and documents a binocular indirect ophthalmoscopy exam after pupillary dilation.
	1. Documents the examination findings using ICROP Revised.
	2. Determines the timing of the follow-up examination based upon PS [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 need more frequent examinations.
		3. Infants treated with an anti-VEGF medication (i.e., Avastin or Lucentis) need to be monitored for a much longer period of time.
	3. Writes an order for the next exam indicating the interval and approximate date (e.g., next eye exam in two weeks around 9/25/16).
	4. Completes and signs the “Dear Parent” letter.
		1. Writes an order for the hospital ROPC or NICU nurse to:
			1. Review the “Dear Parent” letter with the parent,
			2. Ask the parent to sign the “Dear Parent” letter,
			3. Give a copy of the signed document to the parent, and
			4. Place a copy of the signed document in the infant’s medical record.
	5. Notifies the hospital and office ROPCs of the next exam interval and approximate date.
	6. Instructs all to update the tracking lists.
3. Determines when treatment is needed.
	1. Contacts the treating ophthalmologist and conducts and documents a transfer-of-care discussion (if the screening ophthalmologist does not provide treatment).
	2. Notifies the neonatologist and hospital and office ROPCs.
	3. Completes and signs the “Dear Parent” letter. Writes an order for the hospital ROPC or NICU nurse to give it to the parent.
4. Determines if the infant needs another exam or additional treatment prior to discharge/transfer.
	1. Writes a final ophthalmic consult note that summarizes the infant’s current ROP status and screening/treatment recommendations (a new note may not be needed if the ophthalmologist has evaluated or treated the infant very recently).
	2. Tells the hospital and office ROPCs the interval and approximate date of the next exam.
	3. Completes the final “Dear Parent” letter and write an order for the hospital ROPC or NICU nurse to give it to the parent.
	4. Instructs all to update the ROP tracking list to show that the infant was discharged/transferred.
5. Notifies the hospital and office ROPCs when screening is complete. Instructs all to update their tracking list.

Treating ophthalmologist

*Qualifications*

* The treating ophthalmologist should have sufficient knowledge and experience to identify accurately the location and sequential retinal changes of ROP after pupillary dilation using binocular indirect ophthalmoscopy with a lid speculum and scleral depression (as needed).

*Duties*

1. Tracks each infant who meets the criteria for ROP screening.
	1. Adds infant to the tracking list and begins tracking when the infant meets treatment criteria [Table 1].
	2. Tracking continues until one of the following conditions has been met and documented:
		1. Both eyes have met the conclusion-of-acute-screening criteria based upon a BIO exam [Table 5].
		2. A treating ophthalmologist has verified that the treatment and follow-up examinations are complete.
		3. The ophthalmologist conducts and documents a transfer-of-care discussion with the ophthalmologist who will take over care.
		4. ***One exam is sufficient only if it unequivocally shows the retina to be fully vascularized in each eye.***
2. Confirms that treatment is needed.
	1. Documents the exam and treatment recommendations.
	2. Notifies the neonatologist, hospital ROPC, and office ROPC that treatment is needed. Instructs all to update their tracking list.
	3. Completes and signs the “Dear Parent” letter.
		1. Writes an order for the hospital ROPC or NICU nurse to:
			1. Review the “Dear Parent” letter with the parent,
			2. Ask the parent to sign the “Dear Parent” letter,
			3. Give a copy of the signed document to the parent, and
			4. Place a copy of the signed document in the infant’s medical record.
	4. Notifies the parents that treatment needs to be provided within the next 72 hours.
	5. Obtains and documents informed consent for the treatment [Form 4 or 5].
3. Performs and documents the treatment.
	1. Informs the hospital and office ROPCs of the date and type of treatment as well as the follow-up exam, giving both the interval and approximate date of the follow-up exam (e.g., eye exam in 2 weeks around 9/25/16) [Table 3].
		1. Current guidelines suggest that this confirmatory exam take place 3 to 7 days after treatment.
	2. Instructs all to update the tracking list.
	3. Informs the parents of the results of the treatment and the timing of the follow-up exam.
4. Performs an eye exam to determine if additional treatment is needed.
5. Determines if the infant needs another exam or additional treatment prior to discharge/transfer.
	1. Writes a final ophthalmic consult note that summarizes the infant’s current ROP status and screening/treatment recommendations (a new note may not be needed if the ophthalmologist has evaluated or treated the infant very recently).
	2. Tells the hospital and office ROPC the interval and approximate date of the next exam.
	3. Completes the final “Dear Parent” letter and write an order for the hospital ROPC or NICU nurse to give it to the parent.
	4. Notifies the office ROPC of the discharge/transfer.
	5. Instructs all to update the ROP tracking list to show that the infant was discharged/transferred.
6. Notifies the hospital and office ROPCs when screening and treatment is complete. Instructs all to update their tracking list.

Hospital ROP coordinator (H-ROPC)

*Qualifications*

* Is familiar with and understands the 2013 AAP/AAO/AAPOS Policy Statement (and the Tables in the hospital ROP toolkit that are based upon it).
* Is able to use the PS to review and clarify the appropriateness of follow-up and treatment intervals, and coordinate discharge or transfer.
* Has identified and trained someone with equivalent qualifications to serve as back-up H-ROPC.

*Duties*

1. Maintains the official ROP tracking list for hospitalized infants.
2. Tracks all infants who meet the screening criteria for ROP during ROP screening.
3. Sends the ophthalmologist and office ROPC an updated ROP list **at least once a week.** Reviews the list with them and works with the ophthalmologist and office ROPC to resolve any differences.
4. Educates parents on an ongoing basis.
	1. Informs the parents of the need for an eye exam.
	2. Explains the ROP disease process and the risk of blindness.
	3. Informs the parents of the results of screening exams and treatment.
	4. Indicates when the next exam or treatment will take place.
	5. Documents the educational efforts.
5. Coordinates nursing care provided during ROP exams.
6. Coordinates treatment at hospital.
7. TRANSFER: Coordinates transfer to another hospital if needed for treatment or other care
	1. Sends all pertinent medical records and current contact information for the parents.
	2. TREATMENT.
		1. Confirms that the hospital has a treating ophthalmologist.
		2. Confirms that the hospital and the treating ophthalmologist there can provide treatment within 72 hours **OR**
		3. Contacts the screening ophthalmologist and the neonatologist if the receiving hospital cannot provide treatment within 72 hours.
	3. TRANSFER FOR OTHER CARE.
		1. Confirms that the hospital has a screening ophthalmologist.
		2. Contact the Admissions Nurse at the second hospital to:
			1. Confirm that an ophthalmologist has agreed to take over the ROP care,
			2. Indicate the interval and approximate date of the first eye exam at the new hospital.
8. DISCHARGE: Coordinates discharge by scheduling the initial outpatient eye exam at an ophthalmologist’s office.
	1. Confirms that the ophthalmologist has been notified of the discharge and has agreed to it.
	2. Contacts the office ROPC to:
		1. Confirm that an ophthalmologist has agreed to take over the ROP care,
		2. Indicate the interval and approximate date of the first outpatient exam,
		3. Schedule the initial ROP exam with the ophthalmologist, and
		4. Send all pertinent medical records and current contact information for the parents.
	3. Informs the parent:
		1. Of the name of the ophthalmologist,
		2. The date and location of the next ROP exam, and
		3. That Child Protective Services may be contacted if the parents do not keep outpatient appointments exactly as scheduled.

Office ROP coordinator (O-ROPC)

*Qualifications*

* Is familiar with and understands the 2013 AAP/AAO/AAPOS Policy Statement (and the Tables in the hospital ROP toolkit that are based upon it).
* Is able to use the PS to review and clarify the appropriateness of follow-up and treatment intervals, and coordinate discharge or transfer.
* Has identified and trained someone with equivalent qualifications to serve as back-up O-ROPC.

*Duties*

1. Maintains the office ROP tracking list.
2. Tracks all infants who meet the screening criteria for ROP during ROP screening and treatment.
3. Reviews the official list of hospitalized infants who need ROP screening sent by the hospital ROPC **at least once a week** and works with the ophthalmologist and hospital ROPC to resolve any differences.
4. Reviews the list of infants in the outpatient setting who need ROP screening **at least once a week** with the ophthalmologist to ensure that all outpatient appointments are kept.
5. Educates parents on an ongoing basis.
6. Works with the hospital ROPC to schedule the initial outpatient visit.
7. Trains office staff on how to identify infants who need ROP screening, assist with exams, and follow up on missed appointments.

**Procedure 1. Tracking ROP exams and treatment**

Tracking principles

1. There is only one official list at the hospital.
2. The hospital ROPC keeps the official hospital list.
3. The hospital ROPC sends the ophthalmologist and office ROPC an updated ROP list **at least once a week.**
4. Each tracker reviews the list **at least once a week**, and works with the hospital ROPC to resolve any differences.
5. Each infant who meets the criteria for ROP screening is tracked through the whole process of care.
6. Hospitalized infants are tracked by three ROP team members:
	1. Each ophthalmologist providing care (screening and treating ophthalmologists),
	2. The office ROPC for each ophthalmologist, and
	3. The hospital ROPC.
7. The tracking list contains the following information for each ROP exam and treatment:
	1. Infant’s name, date of birth, gestational age at birth, weight, medical record number.
	2. Date of exam or treatment, ROP status, follow-up 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.

Tracking process

1. The neonatologist or pediatric nurse practitioner (NP) identifies new infants who meet screening criteria [Table 1].
2. The neonatologist or NP instructs the hospital ROPC to add the infant’s name to the ROP tracking list.
3. The hospital ROP contacts the screening ophthalmologist and office ROPC.
4. The ophthalmologist and office ROPC add the infant to the tracking list and begin tracking.
	1. Screening ophthalmologists and their office ROPC start tracking when they are notified that an infant has met screening criteria.
	2. Treating ophthalmologists and their office ROPC start tracking when they are notified that an infant may need treatment.
5. Ophthalmologists and all ROPCs update the tracking list when:
	1. New infants reach the appropriate age to start screening exams.
		1. The hospital ROPC contacts the screening ophthalmologist and office ROP to request the initial exam.
	2. After each exam.
		1. The screening ophthalmologist informs both the hospital and office 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 9/25/16).
		2. The hospital and office ROPCs 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 and/or longer than 3 weeks since the last exam.
	3. After treatment
		1. The treating ophthalmologist informs both the hospital and office ROPC of the results of the ROP exam and the interval and approximate date of the next exam.
		2. The hospital and office ROPCs 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.
	4. When care of the infant is transferred from:
		1. Screening to treating ophthalmologist,
		2. Hospital-based to outpatient ophthalmologist, or
		3. Ophthalmologist in one hospital to ophthalmologist in another hospital.
	5. When ROP screening is complete.
		1. The infant is tracked by ophthalmologists and all ROPCs until one of the following conditions has been met and documented:
			1. Both eyes have met the conclusion-of-acute-screening criteria based upon a BIO exam [Table 5].
			2. A treating ophthalmologist has verified that the treatment and follow-up examinations are complete.
			3. The ophthalmologist conducts and documents a transfer-of-care discussion with the ophthalmologist who will take over care.
			4. ***One exam is sufficient only if it unequivocally shows the retina to be fully vascularized in each eye.***

**Procedure 2. ROP Exam**

1. Schedule the initial ROP exam with the ophthalmologist [Hospital ROPC, Table 2].
2. Provide nursing care during the ROP exam [Hospital ROPC or NICU nurse].
	1. Review the list of infants to be examined that day, along with their medical records.
	2. Consult with the neonatologist to determine if any contraindications to the examination exist.
		1. Notify the ophthalmologist and office ROPC of any infant who cannot undergo the scheduled eye exam.
		2. Reschedule the exam within the time interval indicated by the infant’s most recent eye exam.
		3. Contact the neonatologist and ophthalmologist to determine the best course of action, and document the discussion, if the infant cannot be examined within the indicated interval.
		4. Document the notification and reason for not having the exam in the infant’s medical record.
		5. Notify the parents of the delay and document the discussion.
	3. Provide the necessary 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. Dilate the infants’ eyes at the time ordered by the ophthalmologist per the dilating protocol.
	5. Ensure that participants in the eye exam have washed their hands with an agent safe for the cornea, and, if indicated, wear gloves to prevent eye irritation and infection.
	6. Secure the infant in a blanket, hold the infant during the exam, and provide a pacifier and/or oral sucrose for comfort.
	7. Monitor the infant for side effects associated with the dilating eye drops and exam.
	8. Document the dilation, exam, and the infant’s response to the exam.
	9. Clean and sterilize the equipment according to the manufacturer’s specifications to prevent eye irritation and infection.
3. Perform a binocular indirect ophthalmoscopy exam after pupillary dilation [Ophthalmologist].
	1. Document the examination findings using ICROP Revised.
	2. Determine the timing of the follow-up examination based upon PS [Table 3].
		1. Current guidelines indicate a range of 1 to 3 weeks between examinations, depending upon the findings. Infants at high risk for ROP need more frequent examinations. Infants treated with an anti-VEGF medication (i.e., Avastin or Lucentis) need to be monitored for a longer period of time.
	3. Write an order for the next exam indicating the interval and approximate date (e.g., next eye exam in two weeks around 9/25/16).
	4. Complete and sign the “Dear Parent” letter.
		1. Write an order for the hospital ROPC or NICU nurse to:
			1. Review the “Dear Parent” letter with the parent.
			2. Ask the parent to sign the “Dear Parent” letter.
			3. Give a copy of the signed document to the parent.
			4. Place a copy of the signed document in the infant’s medical record.
	5. Notify the hospital and office ROPCs of the next exam interval and approximate date.
	6. Instruct all to update their tracking list.
4. Screen for ROP until one of the following conditions has been met and documented [ophthalmologist]:
	1. Both eyes have met the conclusion-of-acute-screening criteria based upon a BIO exam [Table 5]
	2. A treating ophthalmologist has verified that the treatment and follow-up examinations are complete
	3. The ophthalmologist conducts and documents a transfer-of-care discussion with the ophthalmologist who will take over care
	4. ***One exam is sufficient only if it unequivocally shows the retina to be fully vascularized in each eye.***

**Procedure 3. ROP Treatment Process**

Treatment principles

1. The hospital must have a treating ophthalmologist available to provide ROP treatment within 72 hours of notice that it is needed OR have a transfer agreement in place with a hospital that can accept the transfer and provide the treatment within 72 hours.
2. The hospital must either allow discharged infants to be readmitted for treatment or have a transfer agreement in place with a hospital that does allow discharged infants to be admitted for treatment.

Treatment process

1. Determine when treatment is needed [Screening ophthalmologist, Table 4]
	1. Contact the treating ophthalmologist and conduct and document a transfer-of-care discussion.
	2. Notify the neonatologist, hospital ROPC, and office ROPC.
	3. Complete and sign the “Dear Parent” letter.
		1. Write an order for the hospital ROPC or NICU nurse to:
			1. Review the “Dear Parent” letter with the parent.
			2. Ask the parent to sign the “Dear Parent” letter.
			3. Give a copy of the signed document to the parent.
			4. Place a copy of the signed document in the infant’s medical record.
2. Confirm that treatment is needed [Treating ophthalmologist, Table 4].
	1. Document the exam and treatment recommendations.
	2. Notify the neonatologist, hospital ROPC, and office ROPC that treatment is needed. All update their tracking list.
	3. Complete and sign the “Dear Parent” letter.
		1. Write an order for the hospital ROPC or NICU nurse to:
			1. Review the “Dear Parent” letter with the parent.
			2. Ask the parent to sign the “Dear Parent” letter.
			3. Give a copy of the signed document to the parent.
			4. Place a copy of the signed document in the infant’s medical record.
	4. Notify the parents that treatment needs to be provided within the next 72 hours.
	5. Obtain and document informed consent for the treatment [Form 4 or 5].
3. Confirm that treatment will be provided within 72 hours [Hospital ROPC]
	1. Confirm the treatment time with the treating ophthalmologist and schedule the procedure **OR**
	2. Coordinate transfer to a hospital that has a treating ophthalmologist, and follow the transfer procedure [Procedure 4].
		1. Confirm that the receiving hospital and the treating ophthalmologist there can provide treatment within 72 hours.
		2. Contact the screening ophthalmologist and the neonatologist if the receiving hospital cannot provide treatment within 72 hours
4. Perform and document the procedure [Treating ophthalmologist].
	1. Inform the hospital and office ROPCs of the date and type of treatment as well as the follow-up exam, giving both the interval and approximate date of the follow-up exam [Table 3]. All update the tracking list.
		1. Current guidelines suggest that the ophthalmologist should examine the eye 3 to 7 days after treatment.
	2. Inform the parents of the results of the treatment and the timing of the follow-up exam.
5. Examine the eye to determine if more treatment is needed [treating ophthalmologist].
6. Continue to examine, treat, and track the infant until **one** of these criteria to end screening/treatment has been met and documented [treating ophthalmologist]:
	1. Both eyes have met the conclusion-of-acute-screening criteria based upon a BIO exam [Table 5], or
	2. All treatment and follow-up examinations are complete, or
	3. The ophthalmologist conducts and documents a transfer-of-care discussion with the ophthalmologist who will take over care.
7. Notify the hospital and office ROPCs when screening or treatment is complete, and instruct all to update their tracking list [Treating ophthalmologist].

**Procedure 4. Discharge/transfer process**

Discharge/transfer principles

1. No hospital may discharge or transfer an infant who meets screening criteria for ROP without first:
	1. Obtaining the agreement of the hospital-based screening/treating ophthalmologist AND
	2. Scheduling ophthalmic care at the next hospital or the outpatient setting with an ophthalmologist who agrees to treat the ROP patient AND
	3. Sending appropriate records and current caregiver contact information.

Transfer process

1. Coordinates transfer to another hospital or treatment or other care [H-ROPC]
	1. Send all pertinent medical records and current contact information for the parents.
	2. TREATMENT
		1. Confirm that the hospital has a treating ophthalmologist.
		2. Confirm that the hospital and the treating ophthalmologist there can provide treatment within 72 hours **OR**
		3. Contact the screening ophthalmologist and the neonatologist if the receiving hospital cannot provide treatment within 72 hours.
	3. TRANSFER FOR OTHER CARE
		1. Confirm that the hospital has a screening ophthalmologist.
		2. Contact the Admissions Nurse at the second hospital to:
			1. Confirm that an ophthalmologist has agreed to take over the ROP care.
			2. Indicate the interval and approximate date of the first eye exam at the new hospital.
2. Explicitly address ROP care in the neonatology discharge summary based upon the most recent ophthalmology note [Neonatologist or NP].
	1. Clarify that treatment needs to take place within 72 hours (give date and time).
	2. ROP screenings not yet complete: Gives the interval and approximate date of the next ROP exam (e.g., eye exam needed in two weeks around 9/25/17).
	3. ROP screenings complete: Directs the pediatrician to refer the infant in 3 to 6 months, per the ophthalmologist’s instructions, to an ophthalmologist to screen for conditions common in premature infants, such as amblyopia, strabismus, etc.

Discharge process

1. Notify the ophthalmologist and office ROPC that a transfer is planned [Neonatologist or NP].
2. Determine if the infant needs another eye exam or additional treatment prior to discharge [Ophthalmologist].
	1. Write a final ophthalmic consult note that summarizes the infant’s current ROP status and screening/treatment recommendations (a new note may not be needed if the ophthalmologist has evaluated or treated the infant very recently).
	2. Tell the hospital ROPC the interval and approximate date of the next exam.
	3. Complete the final “Dear Parent” letter and write an order for the hospital ROPC or NICU nurse to give it to the parent.
	4. Notify the office ROPC of the discharge/transfer.
	5. Instruct all to update the tracking list to show that the infant was discharged/transferred.
3. Explicitly address ROP care in the neonatology discharge summary based upon the most recent ophthalmology note [Neonatologist or NP].
	1. ROP screenings not yet complete: Gives the interval and approximate date of the next ROP exam (e.g., eye exam needed in two weeks around 9/25/17).
	2. ROP screenings complete: Directs the pediatrician to refer the infant in 3 to 6 months, based upon the ophthalmologist’s advice, to an ophthalmologist to screen for conditions common in premature infants, such as amblyopia, strabismus, etc.
4. Coordinate discharge by scheduling the initial outpatient eye exam at an ophthalmologist’s office [Hospital ROPC].
5. Confirm that the ophthalmologist has been notified of the discharge and has agreed to it.
6. Contact the office ROPC to:
	* 1. Confirm that an ophthalmologist has agreed to take over the ROP care,
		2. Indicate the interval and approximate date of the first outpatient exam,
		3. Schedule the initial ROP exam with the ophthalmologist, and
		4. Send all pertinent medical records and current contact information for the parents.
7. Inform the parent:
	* 1. Of the name of the ophthalmologist,
		2. The date and location of the next ROP exam, and
		3. That Child Protective Services may be contacted if the parents do not keep outpatient appointments exactly as scheduled.

**Table 1. Which infants need an ROP screening examination (US Criteria)**

* 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 #1, based upon 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**

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)** | **Age at Initial Examination (weeks)** |
| **Gestational Age at Birth (weeks)** | **Postmenstrual**  | **Chronologic** |
| 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 | 34 | 4 |
| 31 b | 35 | 4 |
| 32 b | 36 | 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 If necessary.

**\*** 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:** 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**

Follow-up examinations should be recommended by the examining ophthalmologist on the basis of retinal findings classified according to the revised international classification [PS # 4, Appendix B].

* 1-week or less follow-up
	+ Immature vascularization: zone 1—no ROP
	+ Immature retina extends into posterior zone II, near the boundary of zone !
	+ Stage 1 or 2 ROP: zone I
	+ Stage 3 ROP: zone II
	+ The presence or suspected presence of aggressive posterior ROP
	+ Infants treated solely with anti-VEGF medicastions such as bevacizumab#
* 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.

# “Screening Examination of Premature Infants for Retinopathy of Prematurity,” the Policy Statement issued by the American Academy of Pediatrics (AAP) Section on Ophthalmology, the American Association of Pediatric Ophthalmology and Strabismus (AAPOS), and the American Academy of Ophthalmology (AAO). Originally issued in 1997 and updated in 2001, 2005, and 2006, the Policy Statement is published in *Pediatrics* (Volume 131, Number 1, 2013, at <http://pediatrics.aappublications.org/content/131/1/189>.

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

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 2013 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:
		- Stage 3 ROP in zone II
		- Any ROP in zone I
* Regression of ROP (see 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:** 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.

**Form 3. Dear Parent letter (English)**

Ophthalmologist: Place on your letterhead

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

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

**Your baby may have a condition of the retina (the back of the eye) called ROP (retinopathy of prematurity).** After a premature birth, the blood vessels at the back of the eye may stop growing. The baby’s body responds by making a chemical called VEGF (vascular endothelial growth factor). This chemical makes new blood vessels start growing.

But these are not normal blood vessels. These abnormal blood vessels can bleed. They can also pull (detach) the retina away from its normal position. This is called an RD (retinal detachment), and it can cause blindness. ROP needs to be treated with 72 hours. Your baby could go blind without treatment.

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

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

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

\_\_\_\_Your baby’s blood vessels are abnormal. The baby may need treatment soon. I will examine the baby each week to see if treatment is needed. The next ROP exam is on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (date) in \_\_\_\_\_ weeks.

\_\_\_\_Your baby’s blood vessels are abnormal. But the baby does not need treatment right now. I will examine the baby again to see if treatment is needed. The next ROP exam is on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (date) in \_\_\_\_\_ weeks.

\_\_\_\_\_Your baby’s blood vessels are almost normal. The baby will not need treatment for ROP. But the baby needs a different type of eye exam. This exam will include a check for crossed eyes, lazy eye, or nearsightedness. Babies who were very small when they were born will be checked in three months. Bigger babies will be checked in six months. Your baby needs to be checked on about \_\_\_\_\_\_\_\_\_\_\_ (date). Ask the baby’s doctor (pediatrician) for a referral to an ophthalmologist. Then call the ophthalmologist and make the appointment.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Name of ophthalmologist \_\_\_\_\_ Date

# Form 3. “Dear Parent” letter (SPANISH)

# Estimado(a) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Por petición del neonatólogo(a) quien atiende a su bebé, he realizado un examen de los ojos de su bebé. Soy parte de un grupo de oftalmólogos (Médicos de ojos) quienes ayudan al hospital en el cuidado de bebés prematuros. Esta información le explica porqué fué necesario que se le realizara este examen y porqué es necesario que su bebé vuelva a ser examinado.

**¿Que es Retinopatía de prematuridad** **(ROP)?**

El ojo es muy parecido a una cámara en su función. La parte anterior del ojo contiene las estructuras que enfocan la imagen y regularizan la cantidad de luz que entra en el ojo, así como el lente y el obturador de una cámara. La retina en la parte posterior del ojo funciona como la película en la cámara. Sin película, una cámara no puede tomar una fotografía, y sin una retina que funciona, el ojo no puede ver.

ROP es una enfermedad que potencialmente ciega y afecta a varios miles de bebés prematuros cada año en los Estados Unidos. En general afecta a los bebés más jóvenes, y más enfermos. Cuando un bebé nace prematuro, la retina se ha formado sólo parcialmente. Los vasos sanguíneos crecen en la retina en la parte más posterior del ojo, pero no en el resto de la retina. La primera etapa de ROP sucede cuando los vasos sanguíneos paran de crecer y forman una línea que separa la parte normal de la parte prematura de la retina. En la segunda etapa, la línea de separación asume sustancia tal como si fuera una cresta elevada de tejido. Mientras la ROP avanza a la tercera etapa, nuevos vasos anormales y frágiles crecen hacia el centro del ojo. En este momento, el ojo aún es capaz de repararse a sí mismo. Si la tercera etapa avanza aún más, los vasos normales se dilatan, indicando que la ROP no se desaparecerá por si sola. A esta etapa se le llama "enfermedad plus". Si suficiente retina tiene tercera etapa y "enfermedad plus", entonces es necesario que se administre tratamiento. Sin tratamiento, la ROP puede causar que la retina se arranque de la parte posterior del ojo (desprendimiento de la retina), lo cual puede llegar a ceguera.

Cuando la ROP se desarrolla, una de tres situaciones puede suceder:

1. En la mayoría de los bebés prematuros quienes desarrollan ROP, los vasos sanguíneos anormales sanan completamente por sí solos, por lo general durante el primer año de vida.
2. En algunos bebés, los vasos sanguíneos anormales sanan solo parcialmente. En estos infantes comunmente se les desarrolla: miopía (corto de vista), ambliopía (ojo perezoso), o estrabismo (bizquera). Anteojos o gafas se pueden requerir desde una edad temprana. En algunos casos, puede quedar una cicatriz en la retina, lo cual puede resultar en problemas visuales que no se pueden corregir con anteojos o gafas.
3. En los casos más severos, que ocurren en los infantes más jovencitos, más pequeños y enfermos, los vasos sanguíneos anormales forman un tejido cicatricial, el cual jala la retina fuera de su posición normal en la parte posterior del ojo. Este problema resulta en una pérdida severa de la vista. Afortunadamente, hay un tratamiento que ayuda a mitigar la perdida severa de visión. En uno de cada cuatro bebés, a pesar de todo tratamiento, esta condición puede llegar a la ceguera.

**¿Y Qué Sobre los Ojos de su Bebé? (Lea el párrafo marcado abajo.)**

* Los ojos de su bebé tienen vasos sanguíneos maduros y tienen un riezgo bajo a desarrollar ROP. Un oftalmólogo debe realizarle otro examen de ojos a su bebé **en seis meses** o en \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**(approximate date).** Otras enfermedades de los ojos, como bizquera, ojo perezoso, y myopía severa (corto de la vista), ocurren más frequentemente en bebés prematuros y pueden llegar a ser visibles sólo hasta entre los 8 y 12 meses de edad.

**Es su responsabilidad el hacer arreglos para este examen de los ojos de su bebé. Favor de pedir a su pediatra que le refiera a un doctor.**

* Su bebé no tiene ROP pero podría desarrollar problemas más adelante porque los vasos sanguíneos no han madurado enteramente . Su bebé debe ser sometido a otro examen de ROP en **\_\_\_\_ dias o \_\_\_\_\_\_ semanas en \_\_\_\_\_\_\_\_\_\_\_\_(date).**
* Su bebé tiene ROP temprana. La ROP no es severa y de momento, no requiere de tratamiento. Para vigilar el posible desarrollo serio de ROP, su bebé debe ser sometido a otro examen de ROP en **\_\_\_\_ (dias) o \_\_\_\_\_\_ (semanas) en \_\_\_\_\_\_\_\_\_\_\_\_\_(date)**
* Su bebé tiene ROP activa y se le está supervisando de cerca, de menos una vez por semana, para ver si el tratamiento es necesario. Si el tratamiento es necesario, debe proveerse entre 48 a 72 horas. Se le debe administrar otro examen de ROP a su bebé en \_\_\_\_\_\_\_\_\_\_\_**días** o \_\_\_\_\_\_\_\_\_\_\_ **semanas en** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. **(Date)**

Firma del Oftalmólogo Fecha

Nombre del Oftalmólogo

**COMO PUEDEN AYUDAR QUIENES CUIDAN DE UN BEBE PREMATURO**

ROP puede desarrollarse muy rápidamente, por lo que esta cita no se debe cambiar o reprogramar. **Favor de llamar a nuestra oficina inmediatamente si no puede guardar la cita (por ejemplo, si su bebé se encuentra enfermo). El perder esta cita puede resultar en ceguera de su bebé. Si su bebé está a riesgo, podriamos ser obligados a llamar a Servicios de Protección Infantil. Si usted decide no llevar a su bebé a recibir la atención medica que el oftalmólogo cree necesaria para prevenir daño a su bebe, el doctor está obligado a informar a otros médicos y al departamento de servicios de protección infantil sobre su decisión.**

He leído y comprendo la información en este formulario:

Firma del Padre, Madre o Guardián Fecha

Nombre del Padre, Madre o Guardián

**Padre/Madre/Guardián: Esta es su copia para guardar.**

**FORM 4E. Laser treatment of ROP**

NOTE TO OPHTHALMOLOGIST: THIS FORM IS INTENDED AS A SAMPLE. PLEASE REVIEW AND MODIFY AS NEEDED, AND PLACE ON YOUR LETTERHEAD.

Version 9/6/16

**Laser surgery to treat ROP (retinopathy of prematurity)**

Your baby has a condition of the retina (the back of the eye) called ROP. When a baby is born prematurely (too early), the retina has not had time to finish forming. After the premature birth, the blood vessels at the back of the eye stop growing. Soon the eye starts again to make a chemical called VEGF (vascular endothelial growth factor). This chemical makes the blood vessels start growing again.

But these are not normal blood vessels. These abnormal blood vessels can bleed. They can also pull (detach) the retina away from its normal position. This is called an RD (retinal detachment), and it can cause blindness. This document gives information about the types of treatment. It also explains what happens if the baby does not get treatment for ROP.

**Ophthalmologists (eye surgeons) can treat ROP.**

Ophthalmologists have been treating ROP with laser surgery for many years. This type of laser surgery is called PRP (pan-retinal photocoagulation). The laser stops the eye from making more of the VEGF chemical. The abnormal blood vessels usually stop growing, the retina stays attached, and the central vision is good. Laser works for most babies.

But some babies are too sick to have surgery or anesthesia. In other babies, the abnormal blood vessels are too far back in the eye to use the laser safely. Other parts of the eye or blood in the eye may block the path to the abnormal blood vessels. Ophthalmologists can inject a medicine in the baby’s eye to treat ROP.This is called an intravitreal injection. The medicine stops the eye from making the VEGF chemical. It is called an anti-VEGF medicine.

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

Your baby could have very poor vision or go blind if the ROP is not treated. Your baby cannot choose whether to have treatment. You need to decide if your baby will get treatment for ROP. You have the legal right to choose for your baby. Because you are an adult, you can refuse (say no) to treatment to save your own vision or your own life.

Your ophthalmologist has a legal duty to treat the baby. If you decide not to treat the ROP, your ophthalmologist must talk to other doctors and child protective services about your choice.

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

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

* The laser surgery might not stop the ROP.
* The ROP can come back again. The baby may need another laser surgery to treat the ROP.
* Your baby could lose vision or go blind.
* Anesthesia can cause heart or breathing problems, or death
* The laser surgery could cause other eye problems:
	+ Loss of side (peripheral) vision
	+ Damage to the retina: RD, fold in the retina, dragging or scarring of the macula (center of the retina)
	+ Bleeding in the eye (vitreous hemorrhage)
	+ High eye pressure (glaucoma)
	+ Low eye pressure (hypotony)
	+ Burns to the cornea (clear covering of the front of the eye)
	+ Clouding or scarring of the cornea
	+ Damage to the iris (colored part of the eye)
	+ Eyes that look in different directions (strabismus)
	+ Need for very thick glasses
	+ Bigger eye (enlargement)
	+ Smaller eye (shrinkage)

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

* You read this informed consent form, or someone read it to you.
* You understand the information in this form.
* The ophthalmologist or staff offered you a copy of this form.
* You are aware that the baby may lose vision or go blind.
* You are aware that the baby may need another surgery.
* The ophthalmologist or staff answered your questions about laser surgery for ROP.
* You understand that it is your right to refuse this treatment for your baby. You also understand that if you do refuse the treatment, the ophthalmologist must ask other doctors or child protective services to talk to you about your decision.
* You agree to the laser surgery.

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

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

Patient (or person authorized to sign for patient) Date

**Form 4S. Consent for laser treatment of ROP (Spanish)**

NOTE TO OPHTHALMOLOGIST: THIS FORM IS INTENDED AS A SAMPLE. PLEASE REVIEW AND MODIFY AS NEEDED, AND PLACE ON YOUR LETTERHEAD.

**Spanish version: 6/25/13**

**CONSENTIMIENTO INFORMADO PARA LA CIRUGIA LASER, FOTOCOAGULACION PAN-RETINIANA, PARA EL TRATAMIENTO DE RETINOPATIA DE PREMATURIDAD**

**Nombre del Paciente \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Fecha \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

El propósito de este documento es informarle para que usted pueda decidir si su bebé debe tener el tipo de cirugía láser llamada fotocoagulación panretiniana o PRP. Usted tiene el derecho de hacer cualquier pregunta sobre la operación antes de aceptar que el oftalmólogo (a) o cirujano (a) del ojo, lleve a cabo la cirugía de su bebe. Aunque el oftalmólogo(a) no desea apresurar su decisión, es importante que usted sepa que **una vez que el bebé se diagnostica con Retinopatía de prematuridad o ROP, el tratamiento debe administrarse dentro de 72 horas, o 3 dias.**

**INDICACIONES DE LA CIRUGIA LASER PRP PARA LA ROP**

El ojo funciona de manera muy similar a una cámara. La parte anterior del ojo contiene las estructuras que enfocan la imagen y regulan la cantidad de luz que entra en el ojo, similar al lente y obturador de la cámara. La retina, en la parte posterior del ojo, funciona como la película en la cámara. Sin la película, una cámara no puede tomar una fogografía, y sin que la retina funcione, el ojo no puede ver.

Su bebé tiene una condición de la retina llamada retinopatía de prematuridad (ROP). ROP es potencialmente una enfermedad causante de ceguera que afecta a varios miles de bebés prematuros cada año en los EEUU, usualmente a los infantes más pequeños, jóvenes y enfermos. Cuando un bebé nace prematuro, la retina se forma sólo parcialmente. Los vasos sanguíneos crecen hasta la retina en la parte más posterior del ojo, pero no hacia el resto de la retina. La primera etapa de ROP se manifiesta cuando los vasos sanguíneos dejan de crecer y forman una línea que separa la parte normal de la parte prematura de la retina. En la segunda etapa, la línea de separación toma cuerpo como una cresta de tejido elevada. En el avance hacia la tercera etapa de ROP, nuevos vasos sanguíneos anormales y frágiles crecen hacia el centro del ojo. En este punto, el ojo es todavía capaz de repararse a sí mismo. Si esta tercera etapa avanza aún más, los vasos normales se dilatan, indicando la posibilidad de que la ROP no se desaparesca por si sola. A esto se le llama "enfermedad plus". Si suficiente retina tiene ROP de la tercera etapa y "enfermedad plus", el tratamiento es necesario. Sin tratamiento, ROP puede causar que la retina se desprenda de la parte posterior del ojo (desprendimiento de la retina), lo cual puede causar ceguera.

**BENEFICIOS POSIBLES DE CIRUGIA LASER PRP PARA LA ROP**

Fotocoagulación panretiniana o PRP emplea un láser para tratar la retina periférica para que deje de soltar los químicos que empeoran la ROP en el ojo. Libre de estas sustancias dañinas, la retina puede permanecer adjunta, y la ceguera puede ser impedida. Para realizar este precedimiento, el bebé es sedado, y la pupila del bebé se hace más grande (se dilata) con gotas de los ojos. Un instrumento llamado el espéculo del párpado se usa para mantener el ojo del bebé abierto durante el procedimiento. El laser se apunta a un lado de la retina (la retina periférica) a través de la pupila del bebé. Puesto que el láser trata la retina periférica, el bebé pierde un poco de visión periférica o visión lateral, y esto puede causar reducción de vista nocturna. Usualmente, esto no presenta problemas para el niño/niña a través de su crecimiento. En casos favorables del ROP, el tratamiento con láser resulta en la desaparición de los vasos anormales y potencialmente con buena visión. En algunos casos, el ROP sigue progresando y la retina se desprende. La eliminación del tejido vítreo que llena el ojo puede aliviar la tracción que jala la retina y la desprende de la pared del ojo. Si la retina se desprende, entonces podría ser necesaria la eliminación del vitreo (vitrectomía) y lente. En ocaciones raras, puede ser necesaria la aplicación de una banda de silicona alreredor del ojo (cirugía escleral de pandeo). Sin tratamiento, la retina puede desprenderse enteramente. En esos casos, los ojos resultan con visión muy mala.

**ALTERNATIVAS A LA CIRUGIA LASER PRP PARA LA ROP**

Su bebé no tiene que recibir tratamiento para la ROP. Pero sin tratamiento la enfermedad puede resultar en el desprendimiento de la retina y pérdida severa de la vista o ceguera total. También se ha utilizado la crioterapia para tratar la ROP. Crioterapia utiliza un probador puesto contra la parte exterior del ojo del bebé para tratar la retina periférica congelándola. Ahora la mayoría de oftalmólogos tratan la retina periférica con un láser en lugar de crioterapia. La cirugía láser PRP no funciona en el caso de todo bebé, y no se les puede hacer la cirugia láser a todos los bebés. Algunos bebés están demasiado enfermos para tolerar la anestesia necesaria durante la cirugía; en el caso de algotros bebés, los vasos anormales se encuentran en un área que el láser no puede alcanzar sin peligro, o sangre o estructuras del ojo le impiden al cirujano poder ver donde poner los puntos láser. En estas situaciones, y en algunos casos de ROP severa en la parte más posterior de la retina (zona 1 y zona posterior 2), oftalmólogos pueden realizarle una inyección con un medicamento que detiene los químicos que dañan al ojo, y hace que los vasos anormales desaparescan. Este procedimiento se llama "inyección intra-vítrea de medicamento anti-VEGF (IVAV)"

**RIESGOS Y COMPLICACIONES DE LA CIRUGIA LASER PRP PARA TRATAMIENTO DE LA ROP**

Al decidir si deba o no someterse a la cirugía, el paciente (o la persona responsable por el cuidado del niño (a)) debe analizar y comparar los riesgos posibles de la cirugía y los beneficios anticipados de la cirugía. Como toda cirugía, la cirugía laser para la ROP tiene riesgos. Al realizarse la cirugía, las estructuras del ojo pueden dañarse y causar complicaciones los cuales pueden resultar en la pérdida de la vista. Cirugía o medicamentos pueden ser necesarios para tratar esas complicaciones.

En la mayoría de bebés con ROP y cuyos ojos fueron tratados con cirugía laser PRP, la retina permaneció adjunta y el bebé no se cegó. Aunque el objetivo de la cirugía is el prevenir el desprendimiento de la retina y la ceguera, aun con tratamiento adecuado, no todos los ojos de bebé responden. Hasta uno de cada cuatro bebés (25%) puede desarrollar pérdida severa de la vista, incluyendo ceguera, aun con tratamiento. En algunos casos, la cirugía puede tener que repetirse para poder tratar la ROP. Si la ROP empeora con el tratamiento laser, procedimientos adicionales, tales como la vitrectomía o el procedimiento de cirugía escleral de pandeo pueda ser necesario. Al crecer, los bebés con ROP pueden desarrollar otros problemas de los ojos tal como ojo perezoso y bizquera a tal grado que requieren cuidado de un oftalmólogo por el resto de sus vidas.

**Riesgos de la cirugía laser para tratar la ROP incluyen, pero no se limitan a:**

* Fracaso de lograr el objetivo de la cirugía: aún con tratamiento, uno a cuatro bebés (25%) desarrollan pérdida severa de visión, incluyendo ceguera.
* Daño a la retina (desprendimiento de la retina, pliegue retiniano, cicatrización en la mácula)
* Sangrado en el ojo (hemorragea vítrea)
* Presión del ojo elevada (glaucoma)
* Presión del ojo baja (hipotonía)
* Quemaduras corneales (la parte transparente que cubre lo anterior del ojo)
* Daño al iris del ojo (la parte de color del ojo)
* Daño al lente (catarata)
* Pérdida de la visión o pérdida de ojo
* Pérdida de la vista lateral
* Necesidad del uso de anteojos muy gruesos
* Opacidad o cicatrización de la córnea
* Disminución o pérdida de la vista causada por la pérdida de circulación a los tejidos vitales en el ojo
* Desalineación de los ojos (estrabismo)
* Agrandamiento del ojo
* Encogimiento del ojo
* Complicaciones asociadas con la anestesia, incluyendo la necesidad de ser conectado a un ventilador, colapso cardiaco o respiratorio, y muerte.

**¿MI BEBÉ TIENE QUE RECIBIR EL TRATAMIENTO PARA LA ROP?**

Sin tratamiento, su bebé puede resultar con muy poca vista o con ceguera total en los dos ojos. Como adulto, usted tiene el derecho legal de rechazar tratamiento para sí mismo y salvar su propia vista o su propia vida. Es evidente que los bebés no pueden hacer esas decisiones por sí mismos. Mientras que usted tiene el derecho legal a tomar decisiones para su bebé, el doctor tiene un deber legal de proveerle cuidado médico al bebé. Si usted rechaza el tratamiento que el doctor juzga necesario para evitar daño a su bebé, el doctor está obligado a pedir a otros médicos y al departamento de servicio de protección infantil que hablen con usted sobre su desición.

**CONSENTIMIENTO PARA LA CIRUGIA LASER PARA LA ROP**

El oftalmólogo(a) me ha explicado el problema de los ojos de mi bebé, los riesgos, beneficios, y alternativas a la cirugía láser PRP para tratar la ROP. Aunque es imposible que el doctor (a) me informe sobre toda complicación que sea posible ocurrir, el doctor(a) ha respondido satisfactoriamente a todas mis preguntas. Comprendo que no se puede garantizar que la cirugía prevenga la ceguera de mi hijo(a), y que es posible que la cirugía tenga que repetirse para tratar efectivamente al bebé.

Al firmar este consentimiento informado para la cirugía láser para tratar la ROP a favor de mi hijo(a), declaro que se me ha ofrecido una copia, comprendo enteramente los riesgos posibles, beneficios, y complicaciones de la cirugía láser y:

* He leido este consentimiento informado \_\_\_\_\_\_\_\_\_ **(iniciales de la persona responsable)**
* El formulario de consentimiento se me leyó por\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (**nombre).**

**Deseo que el Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ realize la cirugía laser fotocuagulación pan-retiniana en mi hijo(a).**

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

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

He leído y comprendo la información en este formulario:

Firma del Padre, Madre o Guardián Fecha

Nombre del Padre, Madre o Guardián

**Padre/Madre/Guardián: Esta es su copia para guardar.**

**FORM 5. Anti-VEGF injection for ROP (English)**

NOTE TO OPHTHALMOLOGIST: THIS FORM IS INTENDED AS A SAMPLE. PLEASE REVIEW AND MODIFY AS NEEDED, AND PLACE ON YOUR LETTERHEAD

Revised 9/6/16

Injection to treat ROP (retinopathy of prematurity)

Your baby has a condition of the retina (the back of the eye) called ROP.When a baby is born prematurely (too early), the retina has not had time to finish forming. After the premature birth, the blood vessels at the back of the eye stop growing. Soon the eye starts again to make a chemical called VEGF (vascular endothelial growth factor). This chemical makes the blood vessels start growing again.

But these are not normal blood vessels. These abnormal blood vessels can bleed. They can also pull (detach) the retina away from its normal position. This is called an RD (retinal detachment), and it can cause blindness. This document gives information about the types of treatment. It also explains what happens if the baby does not get treatment for ROP.

**Ophthalmologists (eye surgeons) can treat ROP.**

 Ophthalmologists have been treating ROP with laser surgery for many years. This type of laser surgery is called PRP (pan-retinal photocoagulation). The laser stops the eye from making more of the VEGF chemical. The abnormal blood vessels usually stop growing, the retina stays attached, and the central vision is good. Laser works for most babies.

But some babies are too sick to have surgery or anesthesia. In other babies, the abnormal blood vessels are too far back in the eye to use the laser safely. Other parts of the eye or blood in the eye may block the path to the abnormal blood vessels.

 Ophthalmologists can inject a medicine in the baby’s eye to treat ROP.This is called an intravitreal injection. The medicine stops the eye from making the VEGF chemical. It is called an anti-VEGF medicine. There are three anti-VEGF medicines. They are called Avastin, Eylea, and Lucentis. The ophthalmologist will talk to you about which medicine will be injected.

The goal of the injection is to keep the retina attached and save the baby’s vision.

Some babies lose vision or go blind even if they have the injection. Sometimes, the abnormal vessels keep growing after the injection. The baby may need another injection or laser surgery to stop the abnormal blood vessels. These abnormal blood vessels can pull the retina off the eye and cause an RD. The baby will need other types of surgery to treat the RD.

The VEGF chemical causes eye diseases in premature babies and adults. Some anti-VEGF medicines have been approved by the FDA (Food and Drug Administration) to treat eye conditions in adults. Ophthalmologists have given anti-VEGF injections to adults for many years. Ophthalmologists started to treat ROP with anti-VEGF medicine in 2006. Anti-VEGF medicines have not been approved by the FDA to treat children, so this use is called off-label. Ophthalmologists are still studying how well the medicine works to treat ROP and how much medicine to give babies.

Your baby could have very poor vision or go blind if the ROP is not treated. Your baby cannot choose whether to have treatment. You need to decide if your baby will get treatment for ROP. You have the legal right to choose for your baby. Because you are an adult, you can refuse (say no) to treatment to save your own vision or your own life.

Your ophthalmologist has a legal duty to treat the baby. If you decide not to treat the ROP, your ophthalmologist must talk to other doctors and child protective services about your choice.

**This injection has risks and can cause problems.**

There are risks with all injections and with all medicines. These risks can cause vision loss or blindness. Here are some common or serious ones:

* The injection might not stop the ROP.
* The ROP can come back again. The baby may need another injection or laser surgery to treat the ROP.
* Your baby could lose vision or go blind.
* When ROP is treated with laser surgery, the ophthalmologist knows in a few weeks if the ROP will come back. The ophthalmologist may not know for months or years if the ROP will come back after an injection. The ophthalmologist will have to keep checking the eyes for ROP for a very long time after the injection. The baby may need laser surgery if the retina does not grow completely after the injection
* The injection can cause other eye problems:
	+ An eye infection
	+ RD (detached retina)
	+ Cataracts (clouding of the eye’s lens)
	+ Glaucoma (high eye pressure)
	+ Hypotony (low eye pressure)
	+ Damage to the retina
	+ Damage to the cornea (clear covering of the front of the eye)
	+ Bleeding in the eye
	+ Bright redness in the white part of the eye
	+ Eye irritation and lots of tears
* Adult patients who had these anti-VEGF injections have had heart attack, stroke, or death. The FDA does not know if the medicine caused these problems.

**Doctors do not know if the anti-VEGF medicine injected in the eye harms other parts of the baby’s body.**

The medicine gets out of the eye and into the baby’s bloodstream. It reaches the brain, lungs, and kidneys. The brain, lungs, and kidneys need the VEGF chemical to grow. The medicine may harm the brain, lungs, and kidneys.

* Ophthalmologists and neonatologists (baby doctors) are studying babies who get this medicine to see if they have problems with the development of their brain, lungs, and kidneys.
* Premature babies often have problems with their brains, lungs, and kidneys that are caused by being born too soon. They can be very sick. Sick babies may have more problems after injections.
* It is also hard to know if problems that do show up are caused by being premature or from getting the medicine.
* The ophthalmologist will talk to the neonatologist about whether it is safe for your baby to have this medicine.

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

* You read this informed consent form, or someone read it to you.
* You understand the information in this form.
* The eye surgeon or staff offered you a copy of this form.
* You are aware that the baby may lose vision or go blind.
* You are aware that the baby may need another injection or surgery.
* You are aware that the FDA did not approve this medicine for ROP.
* The eye surgeon or staff answered your questions about the injection for ROP.
* You understand that it is your right to refuse (say no) this treatment for your baby. You also understand that if you do refuse the treatment, the ophthalmologist must ask other doctors or child protective services to talk to you about your decision.
* You agree to the injection.

**I want the ophthalmologist to give my baby an injection for ROP in:**

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

Patient (or person authorized to sign for patient) Date

**Form 5. Intravitreal anti-VEGF injection (Spanish)**

NOTE TO OPHTHALMOLOGIST: THIS FORM IS INTENDED AS A SAMPLE. PLEASE REVIEW AND MODIFY AS NEEDED, AND PLACE ON YOUR LETTERHEAD

Spanish version: 6/25/13

INYECCION DE ANTI-VEGF INTRAVITREA PARA EL TRATAMIENTO DE LA RETINOPATIA DE LA PREMATURIDAD

**¿Que es la retinopatía de la prematuridad (ROP)?**

Un Doctor de los ojos (Oftalmólogo) ha determinado que su bebé tiene una enfermedad en la parte posterior del ojo o de la retina. La retina tiene un tejido de células nerviosas que cubre la pared posterior del ojo, la cual funciona como la pelicula de una cámara. Sin la pelicula, la cámara no puede tomar la foto, y sin la función de la retina, el ojo no puede ver. Cuando un bebé nace prematuro, la retina se ha formado solo en parte. Normalmente, a las 16 semanas de embarazo, vasos saguíneos crecen en la retina para proveer oxígeno desde la parte posterior del ojo. El crecimiento no se completa hasta el fin del embarazo. Por haber nacido temprano, los vaso saguíneos de su bebé se han desarrollado hacia dentro de la retina en la parte más posterior del ojo pero no hacia el resto de la retina. Cuando el crecimiento para, un producto químico que se llama VEGF se suelta, el cual causa el crecimiento de vasos saguíneos anormales, lo que resulta en una condición llamada **retinopatía de la prematuridad o ROP**. ROP es una enfermedad que puede resultar en ceguera total y afecta a miles de bebés cada año en los Estados Unidos, generalmente los más pequeños y los más enfermos.

La ROP tiene varias etapas. En la primera etapa, los vasos sanguíneos dejan de crecer y forman una línea que separa la retina normal con sus vasos sanguíneos de la retina prematura sin vasos sanguíneos. En la segunda etapa, la línea de separación forma una cresta de tejido levantada. Mientras la ROP avanza a la tercera etapa, vasos sanguíneos anormales crecen fuera de la superficie de la retina hacia el centro del ojo. Si la ROP avanza aún más, los vasos pueden crecer más amplios o dilatarse. A esta etapa se le llama "enfermedad plus". Estas etapas pueden ocurrir en el periodo más temprano del desarrollo cuando los vasos sanguíneos todavía se encuentran en la parte posterior de la retina (zona 1) o más tarde en el embarazo cuando los vasos sanguíneos han crecido más cerca de la parte anterior de la retina (zona 3). Cuando la enfermedad alcanza una cierta etapa, aumenta la probabilidad de que la ROP empeore. Cuando se alcanza esta etapa, tratamiento es necesario para reducir la probabilidad de la pérdida de vista y ceguera. Es necesario dar el tratamiento dentro de tres días o 72 horas.

**¿COMO SE TRATA LA ROP?**

Generalmente, Oftalmólogos tratan la ROP con **cirugía láser** llamada **fotocoagulación pan retiniana o PRP**, siempre que puedan ver la retina claramente. PRP funciona al hacer que la retina deje de soltar el producto químoco VEGF en el ojo, el cual causa el crecimiento de los vasos sanguíneos anormales. Mientras se mantenga libre de sustancias dañinas, la ROP suele no empeorar, la retina puede permanecer adjunta, y la ceguera se puede evitar. En la mayoría de bebés con ROP, cuyos ojos han sido tratados con cirugía láser PRP, la retina permaneció adjunta y el bebé no quedó ciego.

La cirugía láser PRP no funciona en todo bebé, y no a todo bebé se le puede hacer la cirugía Láser. Algunos bebés se encuentran demasiado enfermos y no pueden tolerar la anestésia necesaria durante la cirugía; en otros, los vasos anormales están en áreas que el láser no puede alcanzar sin peligro, o sangre u otras estructuras del ojo impiden que el cirujano pueda ver donde poner los puntos de láser. En estas situaciones, y en casos de ROP severa en la parte posterior de la retina (zona 1 y zona posterior 2), el oftalmólogo puede realizar **una inyección con un medicamento** que impide que los productos químicos dañen el ojo, y hace qe los vasos anormales desaparescan. Este procedimiento se llama **"Inyección intravítrea de un medicamento anti-VEGF (IVAV)"**. Se le aplican gotas al ojo para dilatarlo y entumecerlo. Después el oftalmólogo inyecta el medicamento en el centro de la gelatina vítrea que llena el ojo.

**¿COMO AFECTARA IVAV LA VISTA DE MI BEBE?**

El objetivo de IVAV es parar el crecimiento de los vasos sanguíneos anormales e impedir que la retina se desprenda de la parte posterior del ojo. Puede ser necesario que se repita el tratamiento. Es posible que IVAV no haga desaparecer los vasos anormales, o pueden desaparecer y volver a aparecer más tarde, en algunos casos, después de varios meses. En algunos casos es necesario administrar los dos tratamientos, PRP e IVAV, en algotros casos se administra uno de los dos. En algunos casos es necesario que se administre uno o los dos tratamientos a la misma vez, dependiendo como responde el ojo del bebé. En algunos casos, la ROP continua empeorando aún con cirugía láser y/o con inyección intravitrea anti-VEGF. Cuando esto sucede, la retina se desprende y el ojo entra la etapa 4 de ROP y más cirugía es necesaria para tratar la ROP. En la **Cirugía de Vitrectomía** se hacen cortes diminutos en el ojo para sacar la gelatina vítrea y aliviar la tira de la retina. A veces también debe quitarse el lente natural del ojo. Raramente, es necesario colocar una banda de silicona alrededor del ojo (**cirugía escleral de pandeo**) para ayudar a la retina a mantenerse conectada. Los bebés que tienen ROP desarrollan otros problemas de los ojos a lo largo de su crecimiento, como ambliopía (ojo perezoso) y estrabismo (bizquera), más amenudo que bebés que no nacieron prematuros. Bebés quienes han tenido ROP deben consultar con un oftalmólogo para el cuidado de la vista por toda la vida.

**¿HA SIDO APROBADO EL TRATAMIENTO IVAV POR LA ADMINISTRACION DE DROGAS Y ALIMENTACION?**

Sí. Sin embargo, la Administración De Drogas y Alimantación no aprovó ningúna de estas drogas para tratamiento de infantes prematuros. Oftalmólogos han usado medicamentos anti-VEGF desde hace muchos años para tratar condiciones de los ojos en adultos que son causadas por VEGF, el mismo producto químico que causa ROP. AvastinTM (bevacizumab) fué desarrollado y aprobado para parar el crecimiento de vasos sanguineos anormales que crecen cuando el cancer colorecto se propaga en todas las partes del cuerpo. Varios medicamentos que paran el VEGF han sido aprobados para inyecciones antivitreas en los ojos de adultos; en estos se incluyen Lucentis**TM** (ranibizumab), Macugen**TM** (pegaptanib), y Eylea**TM** (aflibercept). Otros se usan "fuera de etiqueta" para ese propósito. Cuando un medicamento es aprobado por la ADA para un propósito, doctores pueden usarlo "fuera de etiqueta" para otros propósitos si están bien informados sobre el medicamento, basan su uso en un método científico firme y un buen informe médico, y mantienen registros de su uso y efectos. Oftalmólogos han utilizado Avastin**TM** (bevacizumab) en bebés prematuros por unos cuantos años.

**¿CUALES SON LOS RIESGOS PRINCIPALES DE IVAV?**

**Riesgos de cualquier procedimiento, cirugía, o anestesia**

El cirujano de ojos opina que IVAV es de beneficio para el bebé. Sin embargo, es importante recordar que todos los medicamentos, procedimientos y cirugías tienen ambos beneficios y riesgos. La condición del bebé puede empeorar en vez de mejorarse. Cualquier o todas las complicaciones descritas en este documento pueden empeorar la visión y/o tener la posibilidad de causar ceguera total.

**Riesgos conocidos de inyecciones intravitreas**

Complicaciones posibles y efectos secundarios del procedimiento para administrar el medicamento incluyen y no se limitan a desprendimiento de la retina, desarrollo de cataratas (opacidad del cristalino del ojo), glaucoma (presión alta del ojo), hipotonía (presión baja del ojo), daño de la retina o córnea (estructuras del ojo), y sangrado. También hay la posibilidad de infección en el ojo (endoftalmitis). El bebé puede recibir gotas de los ojos para reducir la posibilidad de que esto ocurra. Cualquiera de estas complicaciones raras pueden causar pérdida de la vista severa o permanente en uno o los dos ojos.

Pacientes pueden experimentar efectos secundarios menos severos de los pasos necesarios para preparar el ojo para la inyección (poner el espéculo de párpado, gotas anestéticas, gotas de dilatación, gotas antibióticas, gotas de povidona yodada y la inyección del anestético). Estos efectos secundarios pueden incluir dolor del ojo, hemorragia subconjuntival (ojo inyectado en sangre), flotadores vítreos, irregularidad o hinchazón de la cornea, inflamación del ojo, y disturbios visuales.

**Riesgos cuando se administran fármacos anti-VEGF**

El primer fármaco aprobado para tratar condiciones de VEGF en el ojo fué Macugen**TM** (pegaptanib). Sin embargo, la experiencia mayor hasta hoy ha sido con un fármaco inicialmente desarrollado para tratar cancer llamado Avastin**TM** (bevacizumab). Cuando se les administró a pacientes cuyo cáncer del colon se deseminó a otras partes del cuerpo, algunos pacientes experimentaron graves complicaciones potencialmente mortales, tales como perforaciones gastrointestinales o complicaciones de cicatrización de heridas, hemorragia, eventos tromboembólicos arteriales (ATE) tal como derrame cerebral o ataque al corazón, insuficiencia cardíaca congestiva, hipertensión y proteinuria. Pacientes quienes experimentaron estas complicaciones no solo tenían cancer en varias partes del cuerpo, pero también se les administró dosis 400 veces más alta que la que se administra para tratar condiciones del ojo, a intervalos más frecuentes, y de una manera (a través de una infusión intravenosa) que propaga la droga en todas partes de sus cuerpos.

**Riesgos cuando IVAV se utiliza para tratar pacientes adultos con condiciones de los ojos**

Aún cuando no hay estudios aprobados por la ADA sobre el uso de Avastin**TM** (bevacizumab) en el ojo que prueban que es seguro y eficaz, tres fármacos anti-VEGF— Macugen**TM** (pegaptanib), Lucentis**TM** (ranibizumab), and Eylea**TM** (aflibercept)—han sido aprobados para condiciones de los ojos de adultos. Investigación de estos fármacos ha demostrado que el riesgo de eventos ATE tal como ataque al corazón o derrame cerebral en pacientes adultos con condiciones del ojo es bajo. Pacientes adultos que reciben IVAV para enfermedades oculares son más saludables que los enfermos de cancer, y reciben una dosis significativamente menor, administrada solo en el ojo. Estos medicamentos se han administrado cientos de miles de veces a pacientes adultos con enfermedades del ojo sin los otros problemas serios vistos en enfermos de cancer. Aunque hubo un índice bajo de eventos ATE tales como ataque al corazón o derrame cerebral, este es un riesgo potencial en pacientes adultos. Pacientes con diabetes pueden tener un índice más alto de muerte después de IVAV, pero hasta el presente, la investigación no puede decir si la muerte fue causada por el diabetes o el fármaco.

**Riesgos cuando IVAV se utiliza para tratar bebés prematuros**

Oftalmólogos deciden tratar ROP con IVAV basado en investigaciónes que comenzaron en 2006, la cual sigue en curso. Los resultados hasta hoy son basados en el uso de AvastinTM (bevacizumab), y demuestran que IVAV para el crecimiento de vasos sanguíneos anormales con un riesgo bajo de complicaciones. Pero hay algunos riesgos. Si AvastinTM (bevacizumab) se administra, el bebé mantiene en riesgo de que la ROP vuelva por un tiempo más largo. Como resultado, será necesario que el bebé se mantenga bajo el cuidado del oftalmólogo por un periodo de tiempo más largo para segurar que el riesgo de ROP ha pasado. Oftalmólogos también han aprendido que el desprendimiento de la retina puede ocurrir aún cuando IVAV se ha utilizado. El cirujano de ojo puede decidir utilizar LucentisTM (ranibizumab) en vez de AvastinTM (bevacizumab). Todos los fármacos anti-VEGF funcionan muy similarmente, y bajo algunas circumstancias el cirujano de ojo puede preferir uno de estos de entre los demás para tratar ROP en su bebé.

Las investigaciones que condujeron a los oftalmólogos a utilizar AvastinTM (bevacizumab) para tratar ROP sigue en curso. Oftalmólogos siguen investigando lo bién que funciona IVAV para tratar ROP y qué tan seguro es, así también como la mejor cantidad que se debe administrar, con qué frecuencia, y qué tipos de ROP responden mejor. Bebés prematuros necesitan VEGF para el desarrollo de sus pulmones, cerebros, y riñones. Una cantidad pequeña del medicamento inyectado en el ojo sale del ojo y entra al flujo sanguíneo del bebé. Aún no se sabe si esta cantidad en el flujo sanguíneo del bebé puede impedir el desarrollo completo de los pulmones, cerebro y riñones del bebé o si puede causar daño. Los resultados hasta hoy indican de lo contrario. Es demasiado pronto para saber si hay efectos secundarios de largo tiempo de IVAV en bebés prematuros que puedan causar problemas en el ojo u otras partes del cuerpo.

También es difícil saber si problemas que aparecen son resultado de IVAV. Bebés prematuros pueden tener otras condiciones causadas por haber nacido demasiado temprano. Estas otras condiciones también pueden causar daños por sí solos y hacer que sea más probable que ocurran daños o complicaciones en el tratamiento para ROP o que sean más dificiles de tratar. El oftalmólogo hablará con el doctor del bebé cuando decida si administrarle IVAV.

**¿SE LE TIENE QUE ADMINISTRAR EL TRATAMIENTO PARA ROP A MI BEBE?**

Sin uno o más de estos tratamientos, su bebé puede terminar con vista muy baja o ceguera total en los dos ojos. Como adulto, usted tiene el derecho legal de rechazar tratamiento para salvar su propia vista o su propia vida. Por supuesto que los bebés no pueden hacer estas decisiones. Mientras que usted tiene el derecho legal de hacer decisiones para su bebé, el doctor tiene un deber legal de proveer cuidado médico a su bebé. Si usted rechaza tratamiento que un doctor opina ser necesario para impedir daño a su bebé, se requiere que su doctor hable con y pida que otros doctores y el departamento de servicios de protección infantil hablen con usted sobre su decisión.

**LA ACEPTACION DE RIESGOS POR EL GUARDIAN**

Yo entiendo que es imposible que el doctor me informe de toda complicación posible que pueda ocurrir. Al firmar abajo, yo estoy de acuerdo que el doctor ha respondido todas mis preguntas, que se me ha ofrecido una copia de este formulario de consentimiento, y que yo entiendo y acepto los riesgos, beneficios, y alternativas de la **Inyección intravítrea de un medicamento anti-VEGF llamado:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (state name of drug)** en **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (state "el ojo derecho," "el ojo izquierdo" o "los dos ojos").** Entiendo que tengo derecho a rechazar este tratamiento para mi bebé. También entiendo que si rechazo el tratamiento, el doctor debe pedir que otros doctores o el departamento de protección infantil hablen conmigo sobre mi decisión.

Persona autorizada para firmar por el bebé Fecha