Watchful Eye®

Together WE can prevent blindness from ROP

A hospital-based program for timely screening and follow-up of Retinopathy of Prematurity

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TABLE OF CONTENTS

Below is the list of the documents contained in the manual. These documents are provided as "samples" that you may use to help you implement the Watchful Eye® program at your hospital.

Please download from American Academy of Pediatrics website:
Screening Examination of Premature Infants for Retinopathy of Prematurity
Pediatrics 2006;117;572-576 at www.pediatrics.org/cgi/doi/10.1542/peds.2005-2749

HOW TO USE THIS MANUAL

Disclaimer

Recommendations presented here should not be considered inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtain the same results. The ultimate judgment regarding the propriety of any specific procedure or treatment must be made by the physician/healthcare provider in light of the individual circumstances presented by the patient. This information is intended solely to provide risk management recommendations. It is not intended to constitute legal advice and should not be relied upon as a source for legal advice. If legal advice is desired or needed, an attorney should be consulted.

Overview

The Watchful Eye Implementation Manual is based upon the St. Luke's Hospital & Health Network (St. Luke's) Watchful Eye (WE) Program. St. Luke's has two NICUs: one 23 bed Level IIIB NICU located in Bethlehem, Pennsylvania and the other a 7 bed Level IIB NICU located in Allentown, Pennsylvania. All ROP laser treatment is provided at Hershey Medical Center, in Harrisburg, Pennsylvania.

St. Luke's WE program has been in place for approximately 3 years. The *conceptual model* that has been developed and refined over this time period is applicable to *all* NICUs that examine and treat ROP; however, the specific protocols and sample documents will need to be tailored to each hospital. How a hospital and providers implement the WE program will depend upon many possible variables including:

a. the size of the hospital or hospital system
b. whether the NICU is part of a teaching hospital or non-teaching hospital
c. the size of the NICU (or NICUs in a system with multiple hospitals)
d. whether the hospital has EMR, paper charts or some combination of both
e. whether the examining ophthalmologist is the same as the treating ophthalmologist (pediatric ophthalmologist, retina specialist or general ophthalmologist)
f. whether there is more than one examining/treating ophthalmologist examining babies in the NICU
g. whether the babies receive laser treatment in the NICU or must be transferred for treatment
h. whether the ophthalmologist seeing the baby at the 6 month follow-u p appointment is the same as the examining ophthalmologist in the NICU.

Although the list of possible variations among NICUs is vast, the one essential component that can be controlled across all hospital systems is the overall management of ROP care by the Retinopathy of Prematurity Coordinator (ROPC). With this person (or persons depending on the size of the NICU) in place, it is believed that the St. Luke's Watchful Eye model of hospital centered care can be scaled up or down as needed by the hospital.

Policy & Procedure

The first document is the sample NICU "Policy & Procedure". This document will be used to establish the program within the hospital. It is assumed that the NICU policy and procedure for care of retinopathy of prematurity (ROP) is part of the overall NICU Policy & Procedure Manual of the hospital or hospital network. This document gives an overview of the NICU's team effort to screen babies at risk of ROP. The document sets forth the necessary inpatient and outpatient phases for coordination of care. It provides the references that support the NICU ROP policy and procedure. This document also provides important guidance to others who are reviewing the NICU for patient safety, quality of care, and accreditation.

ROPC Job Description

The NICU ROP job description sets forth the duties of the clinical registered NICU nurse, who is the ROP Coordinator. The coordination of the entire patient care team, including neonatologist, ophthalmologist, other NICU staff, and parent/caregivers, hinges on the ROP coordinator. This clinical nurse not only addresses inpatient care but also tracks the baby when discharged or transferred. This is *the* pivotal position in the Watchful Eye program.

ROP Protocols and Tracking System

The next documents are the protocols specific to each healthcare provider ensuring successful assessment, treatment and tracking.

The initial protocols relate to when the baby is first identified by the neonatologist as needing an ROP exam. This triggers the responsibilities of ROPC and the ophthalmologist duties in the WE program. This is the first "double check" in the WE system as the ROPC also checks all new admissions to the NICU to see if they meet screening criteria as set forth in AAP Policy Statement.

The manual provides a "sample order" for eye examination. This will need to be amended as needed by each hospital.

The "three ring binder" shown in the manual is simply an example of organizing all the relevant information (this implementation manual), phone numbers, and specific steps regarding the Watchful Eye program unique to your hospital/NICU.

The "mailbox" shown in the manual is a method of communicating with the ROPC when s/he is not working on the unit, e.g., weekends, holidays, etc. Each hospital/NICU will have to address back-up if there is only one ROPC for the NICU.

The discharge tracking and transfer protocols primarily address the responsibilities of the ROPC. Most high risk appointment times are associated with transfer and discharge and this is the time that the function of the ROPC is most crucial in maintaining continuity of care.

The sample “physician transfer/discharge summary” is provided to show that the ROP care is part of the overall discharge planning for the baby.

The sample “discharge instructions” is signed by the parent/caregiver prior to the baby leaving the unit. It should be noted that this is only one of the steps taken in the process of educating the parents to the importance of keeping follow-up appointments. One copy is for the NICU chart, one for the parent, and one copy for the ROP Tracking System.

Ophthalmologist and ROPC outpatient follow-up protocols set forth specific duties of each provider. These documents are unique in that the ROPC actually continues to monitor the follow-up of the baby after discharge. So many tragic cases of parents not bringing their child to follow-up appointments or confusion in making appointments occur at this juncture of care. The WE program finally addresses this issue head on by ensuring that the same level of ROP care provided in the NICU is provided upon discharge. No longer are babies lost to follow-up when discharged because of a lack of coordination among caregivers and providers.

As the St. Luke’s WE program has demonstrated, ROP parent education decreases noncompliance. However, there are situations where the ROPC is made aware of missed appointments and specific measured steps are set forth to deal with contacting the parents. A sample “noncompliance letter to parent” is provided. The letter to the noncompliant patient is written on the hospital letterhead but is signed by the ophthalmologist. This is another example of the overall responsibility of the hospital ROPC in tracking care.

Logbook and Filing System

As noted above, each NICU will have its own specific method of setting up an ROP tracking system. That being said, the St. Luke’s logbook and filing system sets forth the basic essential components of carefully tracking and monitoring the baby’s ROP care. The “sample ROP logbook” is in a column format for the number of babies on the unit. The columns are a useful outline of the tasks that need to be accomplished and documented as the ROP examinations and treatments are carried out.

The logbook is used in conjunction with the sample “color coded ROP filing system”. Colored hanging files are set up for a two-month period of time. They are added to (refreshed) every week. Individual patient manila folders are placed in the colored hanging files according to the next exam due date. Dates are marked on the tabs of the inpatient and outpatient files which correspond to the dates of the ophthalmologist’s examinations. After the examination, patient folders are placed in the colored hanging files according to the next exam due date or based upon the ophthalmologist’s recommendation.

The WE manual provides an overview of how the ROP filing system might be updated over a four week period of time.

POLICY AND PROCEDURE

Title: **Retinopathy of Prematurity**

Scope: **Hospital**

Manual: **NICU Policy & Procedure Manual**

Origination Date:

Revision Dates:

Review Dates:

Purpose:

American Academy of Pediatrics policy (reference 1 below) states that infants with a birth weight of less than 1500 grams or a gestational age of 30 weeks or less, as well as those at high risk for development of Retinopathy of Prematurity (ROP) as determined by the attending physician or NNP, should be screened for ROP. Examinations should be performed by binocular indirect ophthalmoscopy after pupillary dilation. Follow-up examinations should be performed until full bilateral retinal vascularization is achieved or as determined by the ophthalmologist. The first examination should be performed at four weeks postnatally or at the discretion of the attending neonatologist or NNP.

Definitions:

N/A

Procedure:

A. The first screening examination should be performed after discharge only if circumstances prevent examination in the hospital. All infants meeting the criteria and not examined should have appointments prior to discharge.

1. The ophthalmologist's office will be notified by the ROP Clinical Nurse Coordinator when the above mentioned infants are admitted to the NICU/ITN and an appointment will be made for a four-week inpatient exam and recorded in the ROP logbook.
2. The ROP Clinical Nurse Coordinator will electronically document that the exam has been completed. The nurse will notify the ophthalmologist and neonatologist if the eye exam does not occur as scheduled and/or ordered.

3. If the infant is discharged prior to the scheduled eye exam, the ROP Clinical Nurse Coordinator notifies the ophthalmologist's office and reschedules the appointment as an outpatient.
4. Parents should be educated about their baby's eye exam and ROP and be given a copy of the *Parents' Guide to Their Premature Baby's Eyes* prior to the first eye exam.
5. The ROP Clinical Nurse Coordinator is responsible to follow any/all ROP patient requiring exams after discharge up to the time determined by the ophthalmologist.
6. Refer to attachments for protocols.

B. Procedure:

1. Eye examinations are done by ophthalmology consultation.
2. All infants who are to have eye examinations or eye surgery will have their eyes dilated per physician order:
3. Document medication appropriately on electronic medical record.
4. The nurse should position the infant for examination securely and assist the ophthalmologist with the exam.

Attachments:

Discharge Instructions: About Your Premature Baby's Eyes

A Parents' Guide to their Premature Baby's Eyes

Physician's Orders for Eye Exam - NICU

References:

1. American Academy of Pediatrics Section on Ophthalmology, American Academy of Ophthalmology, & American Association for Pediatric Ophthalmology and Strabismus. (2006). Screening Examination of Premature Infants for Retinopathy of Prematurity [Policy statement]. *Pediatrics,* 117*,* 572–576; DOI:10.1542/peds.2005-2749.
2. Association of Women's Health, Obstetric, and Neonatal Nurses; National Association of Neonatal Nurses; American Association of Critical Care Nurses; Verklan, T.; & Walden, M. (2004). *Core Curriculum for Neonatal Intensive Care Nursing* (3rd ed.). Philadelphia: Elsevier.
3. Chow, L., Wright, K., Sola, A., & CSMC Oxygen Administration Study Group. (2003). Can Changes in Clinical Practice Decrease the Incidence of Severe Retinopathy of Prematurity in Very Low Birth Weight Infants? *Pediatrics, 111,* 339–345.
4. Fanaroff, A., & Martin, R. (2002). Development and Disorders of Organ Systems: The Eye. In *Neonatal Perinatal Medicine* (pp. 1595–1599). St. Louis: Mosby.
5. Kenner, C., & Lott, J. W. (2003). Physiologic Adaptation of the Neonate. In *Comprehensive Neonatal Nursing: A Physiologic Perspective* (pp.746–749). St. Louis: Saunders.
6. Merenstein, G. B., & Gardner, S. L. (2002). *Handbook of Neonatal Intensive Care* (pp. 525–531). St. Louis: Mosby.

7. Phelps, D. L. (1995). Retinopathy of Prematurity. *Pediatrics in Review, 16*(2), 50–56.
8. Repka, M. X., Tung, B., Good, W. V., Shapiro, M., Capone, A., Baker, J. D., et al. (2006). Outcome of Eyes Developing Retinal Detachment During the Early Treatment for Retinopathy of Prematurity Study (ETROP). *Archives of Ophthalmology, 124*(1), 24–30.
9. Taeusch, H. W., & Ballard, R. A. (1998). *Avery's Diseases of the Newborn* (pp. 1329–1342).

Policy Responsibility:

		Development/Review/Revision
		Development/Review/Revision

Disclaimer Statement:

This policy and procedure is intended to provide a description of a course of action to comply with legal requirements and/or operational standards. There may be specific circumstances not contemplated by this policy and procedure that may make compliance either unclear or inappropriate. For advice in these circumstances, consult with your Chain of Command, Administrator on Call, Clinical Risk Management, Legal Services, Accreditation and Standards, or Compliance Officer, as appropriate.

Approval:

NICU ROPC JOB DESCRIPTION

Hospital Name here:

Job Title: Registered Nurse Retinopathy of Prematurity Coordinator

Department: Neonatal Intensive Care Unit

Reports: Patient Care manager

Job Summary:

Using a "double check" system, the Registered Nurse Retinopathy of Prematurity Coordinator (ROPC), in collaboration with the Neonatologist and Ophthalmologist, is responsible for coordinating and tracking the retinal screening of the preterm infants while inpatient and as outpatient up to the time the infant's retinas reach vascular maturity. The ROPC must have sufficient understanding of Retinopathy of Prematurity (ROP) to assume responsibility for tracking infants until they meet end of screening/treating criteria as set forth in the Policy Statement[1].

The intent of this job description is to provide a summary of the major duties and responsibilities of this position and shall not be considered as a detailed description of all the work requirements that may be inherent in the position.

Work Performed

Job Duties and Responsibilities

While patient is an inpatient:

1. Review each new admission to the NICU checking birth weight and gestational age that falls within the Policy Statement screening criteria for ROP. (Double check system)
2. Review neonatologist orders for preterm babies eligible for screening and compare with Policy Statement screening criteria. (Double check system).
3. Add infant's name and other demographic data to ROP tracking system
   a. The ROP tracking system (chart and logbook) must be updated after each ROP examination/treatment. Close attention must be paid to timing of next examination/treatment date until both eyes have met the conclusion of acute screening criteria.
4. Notify ophthalmologist and his/her staff of infants to be screened. (Double check system.)
   a. With assistance of ophthalmologist, orient staff in each ophthalmology office to ensure that staff understands the importance of each scheduled ROP screening/treatment date.

5. Be sufficiently familiar with ROP screening and treatment techniques thus offering appropriate support and education to the parents.
    a. Ensure appropriate education and parent information is provided prior to each eye screening and after each exam.
    b. Give support and understanding to parents with emphasis on educating them to the importance of the screening process
    c. Ensure parents are informed of the examination results and when the next the exam is schedule.
6. Assist ophthalmologist and observe baby during the screening process.
    a. Following the appropriate order from the ophthalmologist, ensure administration of eye medication prior to exam.
    b. Ensure all supplies (sterile eye lid retractor and obturator kits, indirect ophthalmic light, lenses, gloves, and sterile 2x2s) are stored inside the drawers of the ROP exam cart.
7. Review the ophthalmologist's order and ROP exam note for date of next exam or treatment and compare with compliance with Policy Statement criteria. (Double check system)
8. Coordinate communication between Ophthalmologist and Neonatologist ensuring each understands patient's ROP status. (Double check system)
9. Promote accurate record keeping in the NICU chart and the ROP tracking system.
10. Communicate between neonatal units to ensure that screening and treatment is appropriately maintained in babies who are transferred.
11. Schedule outpatient appointments. These appointments should be scheduled only with an ophthalmologist who has agreed to accept the ROP patient.
12. Continue tracking of infant until both eyes have met the conclusion of acute screening criteria.
13. Monitor and audit the eye screening protocol and discuss methods to ensure compliance with Policy Statement criteria.

While patient is an out-patient:

1. Through collaboration with the ophthalmologist's office, continues to follow and track
   out-patient retinal screenings up to vascular maturity as deemed by the ophthalmologist in accordance with the Policy Statement. (Double check system)
2. Maintains appropriate documentation in the ROP tracking system and sends completed ROP tracking records to the hospital medical records point person so documents can be added to the patient permanent medical records
3. Takes necessary action when parents are noncompliant with follow up screening visits. This may include sending out certified letters and, at times, contacting Child Protective Services.

Essential Functions:

1. Maintains confidentiality of all materials handled within the hospital system as well as the proper release of information ensuring HIPPA compliance.

2. Complies with hospital and departmental policies regarding issues of employee, patient and environmental safety and follows appropriate reporting requirements.
3. Demonstrates/models the Hospital's Service Excellence Standards of Performance in interactions with all customers (internal and external).
4. Demonstrates Performance Improvement in the following areas as appropriate: Clinical Care/Outcomes, Customer/Service Improvement, Operational System/Process, and Safety.
5. Demonstrates financial responsibility and accountability through the effective and efficient use of resources in daily procedures, processes and practices.
6. Complies with hospital and departmental policies regarding attendance and dress code.
7. Demonstrates competency in the assessment, range of treatment, knowledge of growth and development and communication appropriate to the age of the patient treated.

Other Functions:

Other related duties as assigned.

Physical and Sensory Requirements:

Sit up to 2 hours per day; 1 hour at a time. Stand for up to 10 hours per day; 8 hours at a time. Walk 6 hours per day; 1 hour at a time. Consistently lift, carry and push objects up to 10 lbs. Occasionally lift, carry and push objects up to 75 lbs. Transport patients weighing up to 300 lbs. via wheelchair, bed and/or stretcher. Frequently stoop and bend. Frequently reach above shoulder level. Must be able to perceive attributes of an object through touch. Must be able to hear as it relates to normal conversation, and high and low frequencies. Must be able to see as it relates to general, near, far, color and peripheral vision.

Potential On-The-Job Risks: (If any)

Specific Protective Equipment Available: Follow MSDS and OSHA precautions for exposure to biological and chemical hazards.

Most Complex Duty: Ability to maintain excellent record keeping and have strong teaching skills as well as neonatal intensive care nursing experience. Ensures continuity of care throughout retinal maturation.

Supervision (Received by and/or Given To): By the neonatologist, ophthalmologist and patient care manager.

Communications: Must have excellent communication skills.

Additional Requirements: must have knowledge of retinopathy of prematurity and have the ability to educate the parents.

Minimum Qualifications

Education: Neonatal registered nurse.

Training and Experience: Neonatal nursing minimal 2 years experience.

Work Schedule: Works days and evenings flexible schedule to fit with Ophthalmologist screening schedule minimum of 16 hours per week.

Revised: (_ date _)

Resources

American Academy of Pediatrics Section on Ophthalmology, American Academy of Ophthalmology, & American Association for Pediatric Ophthalmology and Strabismus. (2006). Screening Examination of Premature Infants for Retinopathy of Prematurity [Policy statement]. *Pediatrics,* 117, 572–576.

NEONATOLOGIST AND OPHTHALMOLOGIST

INITIAL ROP PROTOCOLS

The Attending Neonatologist is Responsible:

1. For identifying all eligible infants for ROP screening examinations and ordering appropriate timing of all consultations, as coordinated with the Retinopathy of Prematurity Coordinator (ROPC);
2. For informing the ophthalmologist should any medical contraindication for dilation or ophthalmoscopic examination develop, as coordinated with the ROPC;
3. If high risk pre-threshold or threshold ROP develops prior to discharge for informing the patient's parents or legal guardians, and discussing with them the need to transfer the patient to an appropriate facility for treatment;
4. If any ROP other than high risk pre-threshold or threshold ROP develops prior to discharge, for informing the patient's parents or legal guardians, and discussing with them the need for regular follow-up appointments upon discharge, as coordinated with the ROPC; and
5. If patient has mature retina and is not at risk for ROP at time of discharge or transfer to another facility, for discussing with the patient's parents or legal guardians the need for a follow-up appointment in six months, as coordinated with the ROPC.

The Ophthalmologist is Responsible:

1. For ROP examinations for all eligible infants when requested by the neonatologist, as coordinated with the ROPC;
2. For continuing to screen for ROP while the patient is in the NICU, at medically appropriate intervals, as coordinated with the ROPC;
3. **For using ICROP to classify, diagram, and record retinal findings;**
4. **For noting follow-up period both as an interval and a date;**
5. For dictating a report immediately following each examination;
6. For causing such report to be transcribed and sent via secure Email to the ROPC, the report shall include an assessment and a treatment plan; and
7. For following the guidelines described in the follow up ROP protocols following the patient's discharge from the NICU.

RETINOPATHY OF PREMATURITY COORDINATOR

INITIAL PROTOCOLS

The Retinopathy of Prematurity Coordinator (ROPC) is responsible for:

Tracking:

1. Reviewing NICU admissions and confirming with the neonatologist's list of patients who require screenings according to AAP policy statement—(Double check system);
2. After the initial examination, verifying with the ophthalmologist the list of names for follow-up examinations—(Double check system);

Examination:

1. To inform parents or legal guardians of the date and time of examinations;
2. To obtain dilation orders from the ophthalmologist and administer the medications as ordered by the ophthalmologist in preparation for the eye examination;
3. To gather eye charts and prepare consultation sheets and previous eye exam records;
4. To confer with NICU nurse, determine stability or special needs of infant pre-exam;
5. To recruit assigned NICU nurse to monitor vital signs and adjust oxygen as necessary during exam, notify ROPC if necessary to interrupt exam
6. ***To ensure that there is one sterile NICU eye tray with lid speculums and depressors for each patient and 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 irritations and infection***
7. To set up equipment and assist ophthalmologist to position and secure infant during exam;
8. To administer eye drops
9. ***To have equipment cleaned and sterilized to prevent eye irritation and infection after each patient use.***
10. To secure respiratory devices such as ETT, NTT, or CPAP prongs and maintain head stability during exam
11. To review findings and any special concerns with ophthalmologist;
12. To report exam results to assigned NICU nurse and record on bedside chart, as well as date of next exam

Communication:

1. Frequently checking the designated communication tool (e.g., secure Email) for any schedule changes or other communication with the ophthalmologist;

2. Communicating with the neonatologist prior to the examination and verifying that infant is stable enough to tolerate the ophthalmic examination – (Double check system);
3. Providing the team members (neonatologist, nursing staff, and parents or legal guardians) current ROP results. This is communicated in the following ways:
    a. The neonatologist-
    The ROPC places the examination report on the chart; it is dictated by the ophthalmologist and sent via secure Email. The neonatologist reviews the report during daily rounds of the infant. The ROPC also notifies the neonatologist of any concerns of ophthalmologist, such as likelihood of surgery. — (Double check system);
    b. The nursing staff-
    The ROPC documents the exam findings and date of next exam on the bedside communication tool. The nursing staff utilizes this tool when giving bedside SBAR report—(Double check system);
    c. The parents or legal guardians-
    The ROPC contacts them either in person or by phone after each examination, tells them when the next exam is, and reviews the latest report— (Double check system);

Education:

1. Meeting with the parents or legal guardians about two weeks prior to the first examination;
2. The initial meeting lasts approximately 15 minutes. It consists of:
    a. The ROPC introduction and role to facilitate communication and continuity of care for a high risk area of the neonatal population;
    b. Giving parents or legal guardians the ROPARD "A Parents' Guide to their Premature Baby's Eyes" brochure;
    c. A PowerPoint presentation about ROP, the depth of information taught is dependent upon the risk level of the infant, and the education and understanding level of the parents or legal guardians;
    d. Answers questions or concerns of parents, legal guardians with initial exam and continued exams;
3. Acting as a patient advocate and arranging a meeting, if requested, between the parents or legal guardians, and neonatologist, and /or ophthalmologist.

Recording:

1. Maintaining each patient's ROP chart or folder, which is stored in the file cabinet according to the next exam date.
2. Documenting, per hospital policy, the date and infant's tolerance of the eye examination in the hospital record and the ROP log book.

PHYSICIAN'S ORDERS FOR EYE EXAM - NICU

ALLERGIES

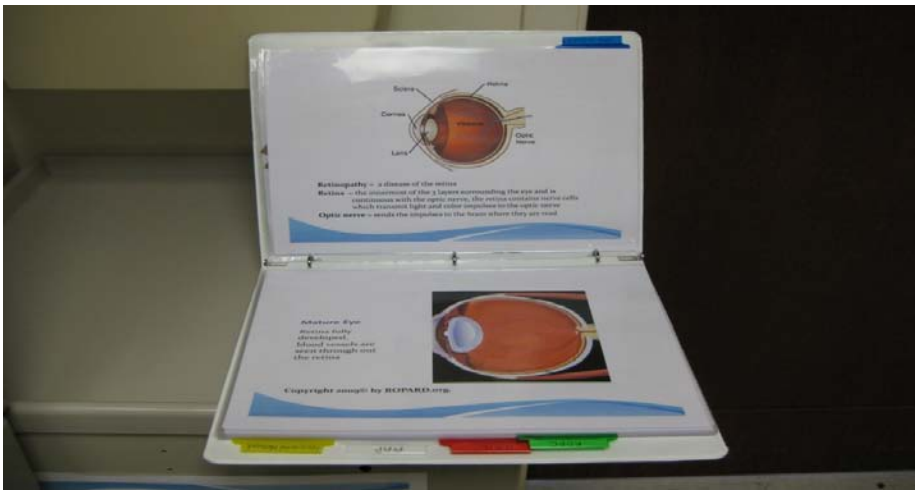
DATE	TIME	PLEASE! USE **BLACK** BALL POINT PEN ONLY **NO ADDENDUM ORDERS AFTER PHARMACY COPY REMOVED**
		CHECK ALL ITEMS THAT DO APPLY
		Telephone Order
		o Dr._____
		o Dr._____
		o Dr._____
		o Cyclopentolate 0.2% / phenylephrine 1% (Cyclomydril®)
		Instill one drop every 5 minutes X 3 doses
		o Each eye o Left eye o Right eye
		Start (date) _____ @ _____ Time
		o Tetracaine hydrochloride ophthalmic solution 0.5%
		Instill one drop immediately prior to placing pediatric eyelid speculum for examination
		o Each eye o Left eye o Right eye
		Start (date) _____ @ _____ Time
		_____ Physician's Signature / Date / Time

PHYSICIAN'S ORDERS ---- EYE EXAM - NICU

Revised July 2010

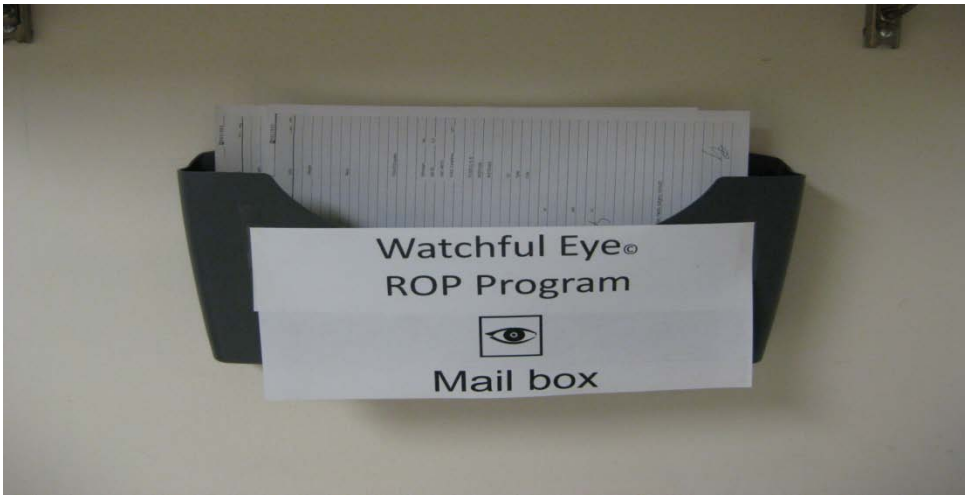
THREE RING BINDER

The St. Luke's Hospital maintains a three ring binder that not only has the teaching material for the parents but also the contact information for the key people in the care of ROP patients. This includes the screening/treating ophthalmologist(s), the backup ophthalmologists, the pediatric ophthalmologists for 6 month follow-up appointment, Child Protective Services, ROPARD, transfer hospital(s) for treatment, treating ophthalmologists at transfer hospital.



ROP MAILBOX

St. Luke's maintains a ROP Program Mailbox. If a patient is discharged when the ROP Coordinator is not working the discharge instruction sheet is put in the mailbox. The document that goes to the screening ophthalmologist is also put in this box.



RETINOPATHY OF PREMATURITY COORDINATOR

DISCHARGE TRACKING PROTOCOL

The Retinopathy of Prematurity Coordinator (ROPC) is responsible for:

Mature retinas:

1. Notifying the ophthalmologist of infants discharged who require ROP exams and sending one copy of signed "discharge instructions";
2. Verifying the complete address and at least two phone numbers where parents or legal guardians can be reached;
3. Scheduling a six-month follow up appointment with a pediatric ophthalmologist who participates with the insurance, and verifying the date with the parents or legal guardians;
4. Teaching parents or legal guardians the importance of the six-month examination in order to prevent or treat non-ROP premature eye disorders. Information only needs to be reviewed at this point because education started before the initial exam.

Immature retinas:

1. Surveying those infants requiring ROP exams who are nearing discharge status;
2. Scheduling an appointment with an insurance participating ophthalmologist based on the recommendation of the last retinal exam. This prevents a missed appointment due to an unexpected early discharge—(Double check system);
3. Maintaining contact with parents or legal guardians during the infant's NICU stay and educate them regarding the importance of keeping scheduled retinal exam appointments. This helps prepare the parents or legal guardians with the transfer of care and an understanding of their responsibility. Parents or legal guardians are educated on the decreased risk of severe vision loss or blindness by simply keeping ALL retinal appointments;
4. Informing parents or legal guardians upon discharge that if the infant does not present for an ROP appointment, the ophthalmologist is obligated to contact Child Protective Services. Parents or legal guardians sign a discharge instruction form which states they are aware of this, a copy stays on the chart, parents receive a copy, and the ophthalmologist receives a copy of this signed document. Refer to 'Discharge Instructions: About Your Premature Baby's Eyes';
5. Involving and educating parents or legal guardians while their infant is in the NICU decreases the need to involve Child Protective Services for missed ROP appointments after discharge.

DISCHARGE INSTRUCTIONS: ABOUT YOUR PREMATURE BABY'S EYES

This information explains the need for follow up care.

WHAT IS RETINOPATHY OF PREMATURITY? The retina is the inner lining of the eye that receives light and turns it into messages that are sent to the brain. If one thinks of the eye as being like a camera, the retina functions as the film. Blood vessels that supply the retina are one of the last structures of the eye to mature; they have barely completed growing when a full-term baby is born. This means that a premature infant's retina is not yet completely developed. For reasons not yet fully understood, the blood vessels in the immature part of the retina may develop abnormally in some premature infants. This is called retinopathy of prematurity (abbreviated ROP). When ROP develops, one of three different things can happen:

(1) In most babies who develop ROP, the abnormal blood vessels will heal themselves completely, usually during the first year of life.

(2) In some babies the abnormal blood vessels heal only partially. In these infants, nearsightedness, lazy eye or a wandering eye commonly develops. Glasses may be required early in life. In some cases a scar may be left in the retina, resulting in vision problems that are not entirely correctable with glasses.

(3) In the most severe cases, the abnormal blood vessels form scar tissues which pull the retina out of its normal position in the back of the eye. This problem results in a severe loss of vision. Fortunately, there is treatment that may minimize severe vision loss. Occasionally, despite all treatment, this condition can lead to blindness.

WHAT ABOUT YOUR BABY'S EYES?

The Neonatologist taking care of your infant can give you more information and will arrange a meeting with the Ophthalmologist for additional details if you wish.

Based on the eye exam performed on your infant, (only the checked information applies to your infant):

A._____ Your infant's eyes have mature blood vessels and have no risk for developing ROP. He/she should have another eye exam by an Ophthalmologist in six months. Other eye diseases, such as crossed eyes, lazy eye and extreme nearsightedness, occur more frequently in premature infants and may not become apparent until the infant is older. It is your responsibility to arrange this follow-up exam for your baby. An appointment has been made for _____(DATE)_____.

B._____ Your baby does not have ROP but could develop problems later because the retinal blood vessels are still not fully mature. Your baby has been scheduled for an ROP exam again on___(DATE)_____.

C_____ Your baby has early ROP. The ROP is not severe and does not require treatment at this time. To watch for possible serious developments, your baby has been scheduled for an ROP exam again on ___(DATE)_____.

PARENTS: If B or C are checked, an outpatient Ophthalmology appointment is scheduled. The appointment will be with _____(NAME OF PHYSICIAN)_____ on the date noted above.

This return appointment is extremely important for the health of your baby's eyes. Missing this appointment may result in your baby's blindness. If you fail to keep this appointment, the Ophthalmologist and/or_____ may contact the appropriate legal authorities, as required by law, in an effort to locate your baby and provide treatment.

I have read and understand the information on this sheet and have a copy of the Parent's Guide.

_____ _____

Signature of the parent/ surrogate decision maker Date/Time

_____ _____

Relationship to the Patient Witness

PHYSICIAN TRANSFER /
DISCHARGE SUMMARY

Date of Birth: _____ Birth Weight: _____

Admission Date: _____ Gestational Age on Admission _____wk

Discharge Date: _____ Gestational Age on Discharge _____ wk

NICU Length of Stay _____

Reason for Transfer:

_____

_____

Prenatal/PerinatalHistory:_____

_____

_____

_____

Maternal Labs:

Blood Type: _____ Serology: _____

Rh: _____ HBsag: _____

Rubella:_____ Group B Strep: _____

HIV:_____

Maternal Medications:

_____

_____

_____

Maternal History:

_____

_____

_____

_____

Delivery Room
History:_____

_____

_____

_____

_____

RESPIRATORY

RDS:_____

Apnea of Prematurity:

Other:_____

CARDIAC:

PDA:_____

Other:

FLUIDS, ELECTROLYTES, NUTRITION:

Feeding Difficulty:

Electrolyte Disturbance:

Renal:

Other:

HEME

Hyperbilirubinemia:

Anemia:

Thrombocytopenia:

NEURO:

Seizures:

Intracranial Hemorrhage:

SOCIAL:

Drug Withdrawal:

INFECTIOUS DISEASE:

Sepsis:

Other:

Metabolic Screening PKU:

PHYSICIAN TRANSFER /
DISCHARGE SUMMARY

OPHTHALMIC

ROP

Date of Last Eye Exam: _____

Findings:

_____
_____
_____

Recommendations:_____
_____
_____
_____

Other:_____
_____
_____

Physical Exam:

_____
_____
_____
_____

Medications:

☐ MAR Printed

☐ Medication Reconciliation Completed

Other:

_____
_____
_____
_____

DISCHARGE ASSESSMENT

Weight at Discharge: _____

Length at Discharge: _____

Head Circumference: _____

_____
Physician / NNP Signature Date / Time

RETINOPATHY OF PREMATURITY COORDINATOR

TRANSFER TRACKING PROTOCOL

The Retinopathy of Prematurity Coordinator (ROPC) is responsible for:

1. Notifying the ophthalmologist of infants transferred to another facility who require ROP exams;
2. Confirming the "sending physician" documented the last findings and next exam date on the copy of the physician transfer summary/discharge record kept in the NICU—(Double check system);
3. Calling the receiving hospital to confirm the infant is scheduled for an ROP exam on the date recommended by the ophthalmologist—(Double check system);
4. Calling the receiving hospital on the scheduled exam date to verify the exam was done, obtaining the results, and date of next scheduled exam. This information is documented in the patient's chart and tracking log—(Double check system).

More Double Checks:

1. Neonatologist documents on the physician / transfer summary sheet the last ROP findings and date of next exam. The receiving physician is informed through written doctor-to-doctor report—(Double check system).
2. Nurses utilize the bedside communication tool for current ROP status and next exam date. This information is relayed to the receiving nurse during nurse-to-nurse verbal report and documented in the transfer summary.—(Double check system).

NEONATOLOGIST, OPHTHALMOLOGIST and ROPC

TRANSFER FOR ROP TREATMENT PROTOCOLS

The Screening Ophthalmologist is Responsible for:

1. Determining if treatment is needed and when patient needs to be transferred
2. Notifying the ROPC, neonatologist, and treating ophthalmologist of the need for treatment
3. Coordinating care with the treating ophthalmologist
4. Documenting the treatment recommendation

The Neonatologist is Responsible for:

1. Contacting the receiving hospital neonatologist and arranging for transfer of the patient

The ROPC is Responsible for:

1. Confirming with the screening ophthalmologist and verifying treating ophthalmologist has accepted transfer of patient
2. Confirming with sending neonatologist that receiving neonatologist has accepted transfer of patient
3. Confirming nursing staff is aware of transfer
4. Confirming parents (caregivers) are aware of transfer
5. Verifying that all team members are aware of the same information
6. Updating hospital ROP tracking log

The ROPC following transfer is responsible for:

1. Calling the treating hospital for updates on patient until infant is transferred back or until ophthalmologist has determined retinal maturity.
2. Continuing to track the infant in the hospital tracking system until ophthalmologist has determined retinal maturity.

OPHTHALMOLOGIST and ROPC

OUTPATIENT FOLLOW-UP ROP PROTOCOLS

For infants who are diagnosed with ROP other than high risk pre-threshold or threshold ROP, the ophthalmologist shall provide the follow-up ROP Services, as follows:

1. The ophthalmologist will schedule and provide the follow-up examinations, at medically appropriate intervals, in his office.
2. The ophthalmologist will dictate a report immediately following each examination.
3. The ophthalmologist will cause the report to be transcribed and sent via secure Email to the ROPC.
4. The ROPC will place a copy of such report in the patient's ROP tracking system medical chart. (Since patient is discharged, the NICU chart will have been sent to medical records already.)
5. Each report dictated by the ophthalmologist will include an assessment and a treatment plan.
6. Upon conclusion of the follow-up services, when the infant reaches vascular maturity, the ophthalmologist will schedule an appropriate follow-up visit, as coordinated with the ROPC, at the office of a pediatric ophthalmologist.
7. If high risk pre-threshold or threshold ROP develops during the provision of the follow-up ROP services, the ophthalmologist will inform the patient's parents or legal guardians and discuss with them the need for treatment at an appropriate facility.
8. When the infant reaches retinal vascular maturity per ophthalmologist exam, the ROP chart is sent to the medical records department.

If the patient fails to present for examination, the ophthalmologist shall follow these guidelines or protocols:

1. If the patient does not present for examination, that same day, the ophthalmologist will call the parent to reschedule an appointment within 24 hours.
2. If the parents or legal guardians of the infant cannot be reached within 24 hours of the missed appointment, the ophthalmologist contacts the ROPC.
3. The ROPC attempts one call to the parents or legal guardians. If no contact is made, the ophthalmologist will send the parents or legal guardians a "non-compliant" letter via Federal Express for overnight delivery, as coordinated with the ROPC.
4. If there is no reply from the parents or legal guardians within 24 hours of receipt of the non-compliant letter, the ophthalmologist will contact Child Protective Services, as coordinated with the ROPC, and report the case as child neglect because of potential preventable blindness.

The ophthalmologist will arrange for appropriate coverage for those infants that require examination in his or her absence.

OPHTHALMOLOGIST and ROPC

NONCOMPLIANT OUTPATIENT TRACKING PROTOCOLS

1. In cases of noncompliance, the ROPC is made aware of the missed appointment on DAY 1 after the missed appointment. ROPC makes one call to each of the verified phone numbers provided by the parents or legal guardians.
    a. If contact is made the appointment is rescheduled as per recommendation of the ophthalmologist.
    b. If contact is unsuccessful, the ROPC prepares the noncompliant letter (see documents section), and obtains the signature of the ophthalmologist.
    c. The letter is sent to the parents or legal guardians via Federal Express, overnight delivery, signature required.
    d. The tracking number is recorded and used to verify the date the letter was delivered and person who accepted delivery

2. The ROPC contacts the ophthalmologist on DAY 2 after the missed appointment - (Double check system).
    a. If the appointment is scheduled and the parent complied, the ROPC calls the parents to give positive reinforcement for making the appointment, and reiterates the importance of keeping eye appointments - (Double check system).
    b. If the appointment has not been made, the ROPC contacts the social worker for the NICU to notify them of the noncompliant case.

3. The ROPC contacts the ophthalmologist on DAY 3 after the missed appointment to learn if the appointment has been scheduled. (Double check system.)
    a. If the appointment is scheduled, the ROPC calls the parents to give positive reinforcement for making the appointment, and reiterates the importance of keeping ALL eye appointments - (Double check system).
    b. If the appointment has not been made by the afternoon of DAY 3 after the missed appointment, the ROPC, in conjunction with the NICU social worker, contacts Child Protective Services and reports the incident as child neglect. This is done because undiagnosed, untreated ROP can cause blindness - (Double check system).

HOSPITAL LETTERHEAD

DATE
NAME OF OPHTHALMOLOGIST
ADDRESS OF OPHTHALMOLOGIST
PHONE NUMBER OF OPHTHALMOLOGIST

Re: NAME OF INFANT

Dear NAME OF PARENTS OR LEGAL GUARDIANS,

Your baby failed to appear at a follow up **retinopathy of prematurity (ROP) /Aggressive Posterior ROP examination** originally scheduled _____DATE___. My office called you to reschedule the appointment, but we were unable to reach you.

FAILURE TO CONTINUE ROP EXAMINATIONS / AGGRESSIVE POSTERTIOR ROP EXAMINATIONS FOR YOUR BABY MAY RESULT IN SERIOUS VISION LOSS OR BLINDNESS. IF YOU DO NOT CALL MY OFFICE BY DATE AT THE NUMBER LISTED ABOVE, I WILL CONTACT (NAME OF HOSPITAL) AND REQUEST THAT CHILD PROTECTIVE SERVICES BE CONTACTED.

Sincerely,

SIGNATURE OF OPHTHALMOLOGIST

Copy: ROPC

ROP LOG BOOK COMPONENTS

The log book is used by the ROPC to document specific dates, times, and other important information key to accurately tracking continuity of care and compliance.

1st column: (*Paste identification label*) Baby's first and last name; birth weight; gestational age; date of birth; medical record number; mother's name; father's name; home address; phone numbers; insurance information; pediatrician

2nd column: Date information sent to contact person in ophthalmologist's office

3rd column: Date and name of parent or caregiver given ROP handout brochure; date and name of parent or caregiver given ROP education

4th column: Date of discharge or date of transfer, location, and reason for transfer

5th column: Confirm contact information of parents/caregivers: names; current address; current phone numbers

6th column: Exam dates; gestational age; ROP findings; O_2 method; O_2 percentage

7th column: Follow up exam dates; gestational age; ROP findings; O_2 method & O_2 concentration

8th column: Dates of noncompliance; phone calls; Federal Express; agency contact

9th column: Follow-up after discharge; name of ophthalmologist; date and time of appointment

10th column: Date discharge; date the 'pink copy' (ophthalmologist's formal record, with parent or legal guardian signature, of acknowledgement of risk of potential blindness if an eye appointment is missed) was sent to ophthalmologist - (Double check)

11th column: Date ROP chart sent to medical records and case closed; retinal maturity reached

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	Column 7	Column 8	Column 9	Column 10	Column 11
Baby's name, BW, GA, DOB, Medical Record #, Mothers' Name, Father's Name, Home Address, Phone numbers, Insurance information, Pediatrician	Date patient information sent to ophthalmologist contact person	Date & person taught, Date ROP handout given	Date of discharge or transfer- location & reason	Confirm contact, names, addresses, phone numbers	Exam dates, GA, ROP finds, O_2 method, O_2%	Follow up exam dates, GA, ROP findings, O_2 method, O_2%	Dates of non-compliance, Phone calls, Fed Ex letter, Agency contact	Follow up after discharge, Date & Time of appointment, Name of Ophthalmologist	Date discharge, Record sent to Ophthalmologist	Date chart sent to medical records and case closed maturity reached
#1 Paste identification label from chart here or enter data										
#2 Paste identification label from chart here or enter data										
#3 Paste identification label from chart here or enter data										
#4 Paste identification label from chart here or enter data										
#5 Paste identification label from chart here or enter data										
#6 Paste identification label from chart here or enter data										
#7 Paste identification label from chart here or enter data										
#8 Paste identification label from chart here or enter data										
#9 Paste identification label from chart here or enter data										
#10 Paste identification label from chart here or enter data										

COLOR CODED FILING SYSTEM COMPONENTS

Colored hanging files are set up for a 2 month period of time. They are added to (refreshed) every week.

Individual patient manila folders are placed in the colored hanging files according to the next exam due date.

Dates are marked on the tabs of the inpatient and outpatient files which correspond to the dates of the ophthalmologist's examinations.

After the examination, patient folders are relocated into the next due exam dated hanging file, according to the ophthalmologist's recommendation.

Color coding for folders:

1. Red is for non compliance
2. Red is also for issues which need ROPC attention
3. Green for inpatient
4. Yellow for outpatient
5. Orange for inpatient at another facility
6. Blue for babies with mature retinas who are still inpatients, these babies have a six month follow up appointment scheduled with a pediatric ophthalmologist
7. Blue also for babies with mature retinas who have been discharged, their eye chart is waiting to be sent to medical records department
8. Purple (ROP forms) doctors medication orders, consultation forms, discharge sheets, progress notes

So when the drawer of the file cabinet is opened, at a glance, the ROPC can tell if there is an exam due for:

1. an inpatient,
2. an outpatient,
3. an inpatient at another facility,
4. a non compliant patient,
5. an issue that needs attention,
6. if there are any inpatients with mature retinas,
   or
7. if any eye charts need to be sent to the medical records department.

Updating – Week of April 16, 2010

4/16/10 Baby 1 (recheck 2 weeks, move to green 4/30/10) and Baby 4 (recheck 2 weeks, move to green 4/30/10)
4/16/10 Baby 2 (recheck 2 wks, move to yellow 5/7/10)
4/16/10 inpatient at another facility Baby 3 (recheck 2 wks, transfer back move to green 4/30/10)
4/23/10 Baby 5
4/23/10
4/30/10 **(Baby 1, Baby 3, and Baby 4 moved from 4/16/10 folders)** Baby 6
4/30/10
5/7/10 inpatient
5/7/10 outpatient **(Baby 2 moved from 4/16/10 folder)**
5/14/10 inpatient
5/14/10 outpatient

Actions for week of 4/16/10: There two inpatients (Baby 1 and Baby 4) and one outpatient (Baby 2) and one inpatient at another facility (Baby 3) that need examinations. After examinations Babies 1, 3, & 4 move two weeks ahead to 4/30/10. Baby 3 is transferred back to inpatient (green folder). Baby 2 moves three weeks ahead to outpatient.

Updating ROP Filing System – Week of April 2, 2010

4/2/10 Inpatient Baby 1 (recheck 2 weeks, move to 4/16/10 green folder)
4/2/10 outpatient Baby 2 (recheck 2 weeks, move to 4/16/10 yellow folder)
4/9/10 inpatient
4/9/10 outpatient
4/9/10 inpatient at another facility Baby 3 (new admit and transfer)
4/16/10 Baby 4 (new admit) **(BABY 1 moved from 4/2/10)**
4/16/10 **(BABY 2 moved from 4/2/10)**
4/23/10 Baby 5 (new admit)
4/23/10
4/30/10 Baby 6 (new admit)
4/30/10
Mature still inpatient Baby 7

Actions for week of 4/2/10: There is one inpatient, Baby 1, and one outpatient, Baby 2, scheduled for exams this week. Based upon exam findings the ophthalmologist determines that each baby needs a two week recheck per AAP ROP policy guidelines. Therefore, Baby 1 will be moved from inpatient 4/2/10 to inpatient exam 4/16/10 and Baby 2 will be moved from outpatient exam 4/2/10 to outpatient exam 4/16/10.

Based on gestational age and birth weight the neonatologist has scheduled initial exam dates for new admits (green inpatients): Baby 4 on 4/16/10; Baby 5 on 4/23/10 and Baby 6 on 4/30/10.

Baby 3 was a new admit but had to be transferred to another facility (inpatient at another facility). This baby is scheduled for exam on 4/9/10.

Updating – Week of April 23, 2010

4/23/10 Baby 5 (mature)
4/23/10
4/30/10 Baby 1, Baby 3, Baby 4 and Baby 6
4/30/10
5/7/10 inpatient
5/7/10 outpatient Baby 2
5/14/10 inpatient
5/14/10 outpatient
5/21/10 Baby 8 (new admit)
5/21/10
Mature still inpatient **(Baby 5 moved from 4/23/10 because mature retinas)**

Actions for week of 4/23/10: One inpatient (Baby 5) exam. After exam, ophthalmologist determines that Baby 5 has fully vascularized retinas, so move file to folder mature retina still inpatient.

Based on gestational age and birth weight, the neonatologist has scheduled initial exam dates for new admits (green inpatients) Baby 8 on 5/21/10 (5/21/10 folder not shown in photo).

Updating – Week of April 9, 2010

Attention Copy of ROP discharge record, Baby 7 sent to ophthalmologist
4/9/10 inpatient
4/9/10 outpatient
4/9/10 inpatient at another facility Baby 3 (recheck 1 wk, move to 4/16/10 folder)
4/16/10 Baby 1 and Baby 4
4/16/10 Baby 2
4/16/10 inpatient at another facility **(Baby 3 moved from 4/9/10 folder)**
4/23/10 Baby 5
4/23/10
4/30/10 Baby 6
4/30/10
5/7/10 inpatient
5/7/10 outpatient
Mature still inpatient Baby 7 (discharged, move to medical records)
Medical Records **(Baby 7's chart moved to medical records)**

Actions for week of 4/9/10: There is one inpatient at another facility (Baby 3) that needs an examination. The ophthalmologist at the other facility determines the exam findings indicate a one week recheck per ROP policy guidelines. The ROPC is aware because Watchful Eye policy dictates a call is made to the other facility to verify an exam was done, the results, and date of next exam are recorded.

Baby 7 is discharged and the chart moves to the medical records folder.

NEONATOLOGIST, OPHTHALMOLOGIST(S) and ROPC

INPATIENT ROP TREATIMENT PROTOCOLS

For infants who are diagnosed with ROP and needing treatment, the neonatologist, ophthalmologist ("**screening**" and "**treating**") and ROPC shall provide the following services.

1. The **screening** ophthalmologist will
    a. Determine if treatment is needed
    b. Notify the caregiver of the need for treatment within the next 48 to 72 hours
    c. Document the treatment recommendation and discussions
    d. Provide treatment within 48 to 72 hours **OR**
    e. If the **screening** ophthalmologist is not the **treating** ophthalmologist, ask the neonatologist/NICU to
        i. Contact the hospital's **treating** ophthalmologist to provide treatment within 48 to 72 hours if a **treating** ophthalmologist is on staff and available **OR**
        ii. Transfer care to a hospital that can provide care within 48 to 72 hours

2. The neonatologist will
    a. Order a consultation with a **treating** ophthalmologist to take place within the next 48 to 72 hours **OR**
    b. Order a transfer to a hospital that can accept the infant and provide ROP treatment within 48 to 72 hours (if no **treating** ophthalmologist is available in the hospital)

3. The ROPC will
    a. Review the ophthalmologist's treatment decision and contact the OR to schedule the procedure (if the **screening** ophthalmologist <u>will</u> be providing treatment) **OR**
    b. Review the neonatologist's order for consultation with a **treating** ophthalmologist and confirm that the **treating** ophthalmologist and Operating Room can provide the treatment within 48 to 72 hours (if the **screening** ophthalmologist will <u>not</u> be providing treatment but the hospital has a **treating** ophthalmologist) **OR**
    c. Contact the hospital where the ROP treatment will be provided and confirm that the treatment can be provided within 48 to 72 hours (if the hospital does not have a **treating** ophthalmologist who can provide the treatment within 48 to 72 hours)
        i. Contact the ophthalmologist and the neonatologist if the receiving hospital cannot schedule the procedure within 48 to 72 hours
    d. Update the Hospital Tracking List with the date of the treatment, the name of the **treating** ophthalmologist and, if necessary, the hospital where treatment will take place

4. The **treating** ophthalmologist will
    a. Confirm his/her availability to examine and treat the infant within 48 to 72 hours, and indicate the date and time of the treatment
    b. Perform a binocular indirect ophthalmoscopy exam after pupillary dilation to confirm the need for treatment

c. Document the examination findings and treatment recommendation.
d. Obtain and document informed consent for treatment from the caregivers (see **Consent for Laser Treatment of ROP**)
e. Perform and document the procedure
f. Inform the ROPC and caregiver of the results of the treatment
g. Determine the follow-up interval and write an order for the interval and approximate date of the follow-up exam (e.g., eye exam in 2 weeks around 9/25/10)
h. Continue to examine, treat, and track the infant until **one** of these conditions has been met and documented
    i. Both eyes have met the conclusion-of-acute-screening criteria
    ii. All treatment and follow-up examinations are complete
    iii. Care of the infant has been transferred to another ophthalmologist

CONSENT FOR 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.

INFORMED CONSENT FOR PAN-RETINAL PHOTOCOAGULATION LASER SURGERY TO TREAT RETINOPATHY OF PREMATURITY

Patient's name _____Date _____

This document is intended to provide you with information so that you can decide whether your baby should have a type of laser surgery called pan-retinal photocoagulation or PRP. You have the right to ask any questions you might have about the operation before agreeing to have the ophthalmologist, or eye surgeon, perform it on your baby. While the ophthalmologist does not wish to rush you into a decision, it is important to know that **once the baby is diagnosed with ROP, treatment must be given within 72 hours, or 3 days.**

INDICATIONS FOR PRP LASER SURGERY FOR ROP

The eye functions much like a camera. The front of the eye contains the structures which focus the image and regulate the amount of light that enters the eye, similar to the lens and shutter of a camera. The retina in the back of the eye, functions like the film in the camera. Without film, a camera cannot take a picture, and without a functioning retina, the eye cannot see.

Your baby has a condition of the retina called retinopathy of prematurity (ROP). ROP is a potentially blinding disease that affects several thousand premature babies each year in the United States, usually the smallest, youngest, and sickest infants. When a baby is born prematurely, the retina is only partially formed. The blood vessels have grown into the retina at the very back of the eye but not into the rest of the retina. The first stage of ROP is when the blood vessels stop growing and form a line that separates normal from premature retina. In the second stage, the line of separation takes on substance as an elevated ridge of tissue. As the ROP advances into the third stage, fragile new abnormal blood vessels grow toward the center of the eye. At this point, the eye is still capable of repairing itself. If this third stage advances even more, the normal vessels dilate, indicating that the ROP may not go away on its own. This is known as "plus disease." If enough retina has third stage ROP and "plus disease," then treatment is needed. If untreated, ROP can cause the retina to pull away from the back of the eye (a retinal detachment), which can lead to blindness.

POSSIBLE BENEFITS OF PRP LASER SURGERY FOR ROP

Pan-retinal photocoagulation or PRP uses a laser to treat the peripheral retina so that it will stop releasing the chemicals in the eye that make the ROP worse. Free from these harmful substances, the retina may remain attached, and blindness may be prevented. To perform the procedure, the baby is sedated, and the pupil of the baby's eye is made bigger (dilated) with eye drops. An instrument called a lid speculum is used to hold the baby's eye open during the

procedure. The laser is aimed at the side of the retina (the peripheral retina) through the baby's pupil. Since the laser treats the peripheral retina, the baby will lose some peripheral or side vision, and this may cause reduced night vision. This usually does not present a problem for the child as he or she grows older. In favorable cases of ROP, laser treatment results in disappearance of the abnormal vessels with potentially good vision. In some cases, the ROP continues to progress and the retina detaches. Removal of the vitreous tissue that fills the eye can relieve the traction which pulls the retina away from the wall of the eye. If the retina detaches, removal of the vitreous (vitrectomy) and lens may be needed. Rarely, a band of silicone may need to be placed around the eye (a scleral buckling operation). Left untreated, the retina can become totally detached. These eyes have very poor visual outcomes.

ALTERNATIVES TO PRP LASER SURGERY FOR ROP

Your baby does not have to receive treatment for ROP. Without treatment, however, the disease may lead to a retinal detachment and severe visual loss or blindness. Cryotherapy has also been used to treat ROP. Cryotherapy uses a probe placed against the outside of the baby's eye to treat the peripheral retina by freezing it. Most ophthalmologists now treat the peripheral retina with a laser instead of cryotherapy.

RISKS AND COMPLICATIONS OF PRP LASER SURGERY FOR ROP

When deciding whether or not to have surgery, the patient (or caregivers of the child) must weigh the possible risks of the surgery against the benefits the surgery is expected to produce. Like all surgery, laser surgery for ROP has risks. While performing the surgery, structures of the eye can be damaged and cause complications, which may lead to loss of vision. Surgery or medications may be needed to treat these complications.

In the majority of babies with ROP whose eyes have been treated with PRP laser surgery, the retina remained attached and the baby did not go blind. While the goal of the surgery is prevent a retinal detachment and blindness, even with proper treatment, not all babies' eyes respond. Up to one out of every four babies (25%) may still develop severe visual loss, including blindness, even with treatment. For some babies, the laser surgery may have to be repeated in order to treat the ROP. If the ROP gets worse even with laser treatment, additional procedures, such as a vitrectomy or a scleral buckle procedure, may be needed. As babies with ROP get older, they develop other eye problems such as lazy eye and crossed eyes, and so require lifelong care from an ophthalmologist.

Risks for laser surgery for ROP include, but are not limited to:

- Failure to achieve the goal of surgery: even with treatment, one out of 4 babies (25%) develop severe visual loss, including blindness
- Damage to the retina (retinal detachment, retinal fold, or macular dragging or scarring)
- Bleeding in the eye (vitreous hemorrhage)
- Elevated eye pressure (glaucoma)
- Decreased eye pressure (hypotony)
- Corneal burns (clear covering of the front of the eye)
- Damage to the iris (colored portion of the eye)

- Damage to the lens (cataract)
- Loss of vision or loss of the eye
- Loss of side (peripheral) vision
- Need for very thick glasses
- Corneal clouding or scarring
- Decrease or loss of vision caused by loss of circulation to the vital tissues in the eye
- Eye misalignment (strabismus)
- Eye enlargement
- Eye shrinkage
- Complications associated with the anesthesia, including the need to be on a ventilator, heart or breathing collapse, and death

CONSENT FOR LASER SURGERY FOR ROP

The ophthalmologist has explained to me the problem with my baby's eyes, and the risks, benefits, and alternatives to PRP laser surgery for ROP. Although it is impossible for the doctor to inform me of every possible complication that may occur, the doctor has answered all my questions to my satisfaction. I understand that there is no guarantee that the surgery will prevent blindness in my child, and that the surgery may need to be repeated to effectively treat the baby.

In signing this informed consent for laser surgery for ROP on behalf of my child, I am stating that I have been offered a copy, I fully understand the possible risks, benefits, and complications of the laser surgery and:

- I have read this informed consent _____ **(caregiver's initials)**
- The consent form was read to me by _____ (**name).**

I wish to have Dr. _____ perform pan-retinal photocoagulation laser surgery on my child.

_____ _____

Patient (or person authorized to sign for patient) Date

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.

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

Nombre del Paciente _____**Fecha** _____

El propósito de este documento es informarlo para que usted pueda decidir si su bebé debe tener el tipo de cirugía laser llamada fotocoagulación panretiniana o FPR. 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 la prematurez o RDP, el tratamiento debe administrarse dentro de 72 horas, o 3 dias.**

INDICACIONES DE LA CIRUGIA LASER FPR PARA LA RDP

El ojo funciona de manera muy similar a una cámara. La parte frontal 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 fogografia, y sin que la retina funcione, el ojo no puede ver.

Su bebé tiene una condición de la retina llamada retinopatía de la prematurez (RDP). RDP es potencialmente una enfermedad causante de ceguera que afecta a varios miles de bebés prematuros cada año en los EEUU, usualmente a los infantes mas 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 RDP 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 RDP, 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 RDP no se desaparesca por si sola. A esto se le llama "enfermedad plus". Si suficiente retina tiene RDP del tercer grado y "enfermedad plus", el tratamiento es necesario. Sin tratamiento, RDP puede causar que la retina se desprenda de la parte posterior del ojo (desprendimiento de la retina), lo que puede causare ceguera.

BENEFICIOS POSIBLES DE CIRUGIA LASER FPR PARA LA RDP

Fotocoagulación panretiniana o FPR emplea un laser para tratar la retina periférica para que deje de soltar los químicos que empeoran la RDP en el ojo. Libre de estas

sustancias dañinas, la retina puede permanecer conectada, y la ceguera puede ser prevenida. 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 laser 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 RDP, el tratamiento con laser resulta en la desaparición de los vasos anormales y potencialmente con buena visión. En algunos casos, el RDP 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 alrededor del ojo (explante escleral). Sin tratamiento, la retina puede desprenderse enteramente. En esos casos, los ojos resultan con visión muy mala.

ALTERNATIVAS A LA CIRUGIA LASER FPR PARA LA RDP

Su bebé no tiene que recibir tratamiento para la RDP. 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 RDP. 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 laser en lugar de crioterapia.

RIESGOS Y COMPLICACIONES DE LA CIRUGIA LASER FPR PARA TRATAMIENTO DE LA RDP

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 RDP 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 RDP y cuyos ojos fueron tratados con cirugía laser FPR, 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 RDP. Si la RDP empeora con el tratamiento laser, procedimientos adicionales, tales como la vitrectomía o el procedimiento de explante escleral pueda ser necesario. Al crecer, los bebés con RDP pueden desarrollar otros problemas de los ojos tal

como ojo perezoso y ojos bizcos a tal grado que requieren cuidado de un oftalmólogo por el resto de sus vidas.

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

- Fracaso de lograr el objetivo de la cirugía: aun 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

CONSENTIMIENTO PARA LA CIRUGIA LASER PARA LA RDP

El oftalmólogo(a) me ha explicado el problema de los ojos de mi bebé, los riesgos, beneficios, y alternativas a la cirugía laser FPR para tratar la RDP. 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 laser para tratar la RDP 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 laser 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

"DEAR CAREGIVER" LETTER IN SPANISH

Note to Ophthalmologist: Place on Letterhead

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 por Prematurez (RDP)?

El ojo es muy parecido 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 la lente y el obturador de una cámara. La retina en la parte posterior del ojo funciona como la cinta en la cámara. Sin cinta, una cámara no puede tomar una fotografía, y sin una retina que funciona, el ojo no puede ver.

RDP 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 mas jóvenes, y mas enfermos. Cuando un bebé nace prematuro, la retina se formado sólo parcialmente. Los vasos sanguineos crecen en la retina el la parte más posterior del ojo, pero no en el resto de la retina. El primer grado de RDP sucede cuando los vasos sanguineos paran de crecer y forman una linea que separa la parte normal de la parte prematura de la retina. En el segundo grado, la linea de separación asume sustancia tal como si fuera una cresta elevada de tejido. Mientras la RDP avanza al tercer grado, nuevos vasos anormales y frágiles creen hacia el centro del ojo. En este momento, el ojo aún es capaz de repararse a sí mismo. Si el tercer grado avanza aún más, los vasos normales se dilatan, indicando que la RDP no se desaparecerá por si sola. A esta etapa se le llama "enfermedad plus". Si suficiente retina tiene tercer grado y "enfermedad plus", entonces es necesarion que se administre tratamiento. Sin tratamiento, la RDP puede causar que la retina se arranque de la parte posterior del ojo (desprendimiento de la retina), lo cual puede llevar a ceguera.

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

1. En la mayoría de los bebés prematuros quienes desarrollan RDP, los vasos sanguineos anormales sanan completamente por sí solos, por lo general durante el primer año de vida.
2. En algunos bebés, los vasos sanguineos 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 mas severos, que ocurren en los infantes más jovencitos, más pequeños y enfermos, los vasos sanguíneos anormales forman un tejido cicatricial, el cual hala 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 la pérdida severa de visión. En uno de cada cuatro bebés, a pesar de todo tratamiento, esta condición puede llevar 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 de desarrollar ROP. Un oftalmólogo debe realizar otro examen de los 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 mas 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 exámen 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 mas adelante porque los vasos sanguíneos no hann 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 ves 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 exámen de ROP a su bebé en **_____días** o **_____ semanas en _____**. **(Date)**

Firma del Oftalmólogo Fecha

_____

Nombre del Oftalmólogo

COMO PUEDEN ALLUDAR 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 riezgo, podriamos ser obligados a llamar a Servicios de Protección de Menores.**

He leído y comprendo la información en este formulario:

_____

Firma del Padre, Madre o Tutor(a) Fecha

_____

Nombre del Padre, Madre o Tutor(a)

Padre/Madre/Tutor: Esta es su copia para guardar.